PULSED SHORT WAVE THERAPY: ITS CLINICAL USE AND PHYSIOLOGICAL EFFECTS IN HEALTHY SUBJECTS AND OSTEOARTHRITIC PATIENTS

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To my beloved mother

ACKNOWLEDGMENTS

I wish to acknowledge the people who supported and helped me accomplish this achievement

My deepest gratitude goes to my family and friends in Kuwait who tolerated my mood swings, anger, frustration and were always there for me and provided me with support and encouragement.

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ABSTRACT

Pulsed Short Wave Therapy (PSWT): its clinical use and physiological effects in healthy subjects and osteoarthritic (OA) patients

PSWT is a commonly used electrotherapy modality and surveys have shown it to be one of the most widely used modalities among physiotherapists in the UK. Nevertheless, the literature supporting its therapeutic effects and explaining its mechanism of actions remain scant, of poor methodological quality and of minimal clinical value.

This research program was set to examine both the nature of use and the efficacy of PSWT. The nature of PSWT use was examined in outpatient clinics using an audit and a nationwide survey. The efficacy of PSWT was examined in two randomised placebo controlled trials; one conducted in a laboratory setting on healthy subjects and the other was a clinical trial on patients with osteoarthritis. Following the same methodology and protocol, the effects of low and high dose of PSWT on skin temperature (SkT), blood volume (BVol), and nerve conduction velocity (NCV) were evaluated against a placebo and a control condition.

The findings have revealed the poor documentary skills of physiotherapists, and a state of confusion in the clinical decision-making with regard to PSWT dosage. Based on experimentation, it was established that patients react differently from healthy subjects when similar levels of energies are applied. Whilst low dose resulted in non-significant changes in SkT and NCV in healthy subjects, the same dose significantly altered BVol, SkT, and NCV in patients. Placebo effects were found to account for 39% of the patients' response to PSWT treatments.

The findings have revealed a discrepancy between evidence and practice that necessitates a reconsideration of the treatment approaches adopted by physiotherapists when using PSWT. The study has also demonstrated the physiological and therapeutic efficacy of PSWT on patients with osteoarthritis, and showed that treatment outcomes are dependent on the amount of exogenous energy applied and the type of tissue treated.

The thesis also highlights areas for future research based on the literature reviewed and the experimentation conducted.

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LIST OF ABBREVIATIONS

%: Percentage
↓: Decrease
↑: Increase
°: Degrees
<: Less than
>: More than
α: Significance level
λ: Wave length
ΔT: Net increase in temperature
μA: Microampere
μsec: Microsecond
A: Ampere
ADL: Activities of daily living
ANOVA: Analysis of variance
AP: Action potential
BD: Body density
BEI: Bioelectric impedance
BMI: Body mass index
bpm: Beat per minute
BVol: Blood volume
Ca^{++}: Calcium
cm: Centimater
CorT: Core temperature
CSP: Chartered Society of Physiotherapy
CSWD: Continuous short wave diathermy
CUS: Continuous ultrasound
D.C.: Direct current
E: Electric field
EIB: Electric interference band
ELF: Extremely low frequency
EM: Electromagnetic
EMF: Electromagnetic field
EMG: Electromyography
EMR: Electromagnetic radiation
ESR: Erthrocyte sedimentation rate
Ex: Exercise
F: Frequency
FFT: Fast Furrier Transformation
FIS: Functional incapacity score
G: Gauss
H: Magnetic field
Hz: Hertz (pulses per second)
ICC: Interclass correlation coefficient
ICD: International classification of disease

ICIDH: International classification of impairment, disabilities, and handicap
IF: Infrared
IFC: Interferential current
In vivo: in the living
In Vitro: in the test tube
K^+: Potassium
Kg: Kilogram
Km: Kilometre
LDF: Laser Doppler flowmetry
LF: low frequency
m/s: Meter per second
m: Meter
mA: Milliampers
MMT: Manual muscle testing
min: minutes
MP: Mean power
MRI: Magnetic resonance imaging
MW: Microwave diathermy
Na^+: Sodium
NCV: Nerve conduction velocity
NRPB: National Radiological Protection Board
OA: Osteoarthritis
p: Significance level
PD: pulse duration
PEME: Pulsed electromagnetic energy
PEMET: Pulsed electromagnet energy treatment
PEMT: Pulsed electromagnetic therapy
PP: Peak power
PP+: Phyaction Performa +
PPG: Photoplethysmography
pps: Pulses per second
PRR: Pulse repetition rate
PSW: Pulsed short wave
PSWD: Pulsed short wave diathermy
PSWT: Pulsed short wave therapy
PulsR: Pulse rate
PUS: Pulsed ultrasound
RA: Rheumatoid arthritis
RBC: Red blood cells
RCT: Randomised controlled trials
RF: Radiofrequency
ROM: Range of motion
SAE: Self addressed envelope
SAR: Specific absorption rate
SD: Standard deviation
sec: Second
SFM: Skin fold measurements
SkT: Skin temperature
SRS: Stratified random sampling
SW: Short wave

SWD: Short wave diathermy
T: Tesla
TENS: Transcutaneous nerve stimulation
TMJ: Temporomandibular joint
US: Ultrasound
UV: Ultraviolet
VAS: Visual analogue scale
VOP: Venous occlusion plethysmography
W: Watt

CHAPTER 1

INTRODUCTION AND CURRENT RESEARCH ISSUES WITH PULSED SHORT WAVE THERAPY (PSWT)

1.0 DEVELOPMENT OF PSWT GENERATORS

Early experiences with high frequency current started around the 1880's when a French physiologist named d'Arsonval passed a current of 1 ampere (despite the belief that a current of such strength could be deadly) through his body and the body of his assistant and they only experienced gentle warmth (Scott, 2002).

Based on that work, the first attempts at PSWT production started in 1930 by an American physicist Arthur Milinowski and his colleague Dr Ebraham Ginsberg. Their experimentation had focused on eliminating the heating effect associated with the application of continuous short wave diathermy (CSWD) and reducing the adverse outcomes associated with the application of CSWD for sprains (Low and Reed, 2000; Lightwood, 1989). They introduced pauses in the electromagnetic field (EMF) output of the CSWD, which was thought at the time to allow for dissipation of heat and the prevention of thermal build up (Arghiropol et al, 1992). Their attempts culminated in the production of an ultra short wave apparatus in 1936. They followed their efforts by experimenting on animals; however their task was terminated by World War II. In 1953 experiments were resumed and the first Diapulse apparatus was produced and marketed.

The revolution of Diapulse was followed by the production of Curapuls in 1970, a machine that was capable of providing both continuous and pulsed EMF, and this was followed by the production of Megapulse in 1981, which was also capable of producing continuous and pulsed output (Hayne, 1984).

Introduction of PSWT to the UK however, was not until 1968 when Miss Parclay observed its therapeutic effects on the speed of recovery with the American team in Mexico Olympics. She later co-operated with a local physician to look into its efficacy

with different conditions. Since then PSWT has been increasingly employed in various UK hospitals (Foley-Nolan, 1990).

1.1 TERMINOLOGY WITH PSWT

PSWT can be operated in both thermal and athermal modes, as such it has been classified as being one of the diathermy family. Diathermy machines are those devices that emit high frequency EMF and are capable of producing heat in the tissues (Prentice and Draper, 2001). This group includes pulsed ultrasound (PUS), continuous ultra sound (CUS), CSWD, and microwave (MW) (Figure 1.1).

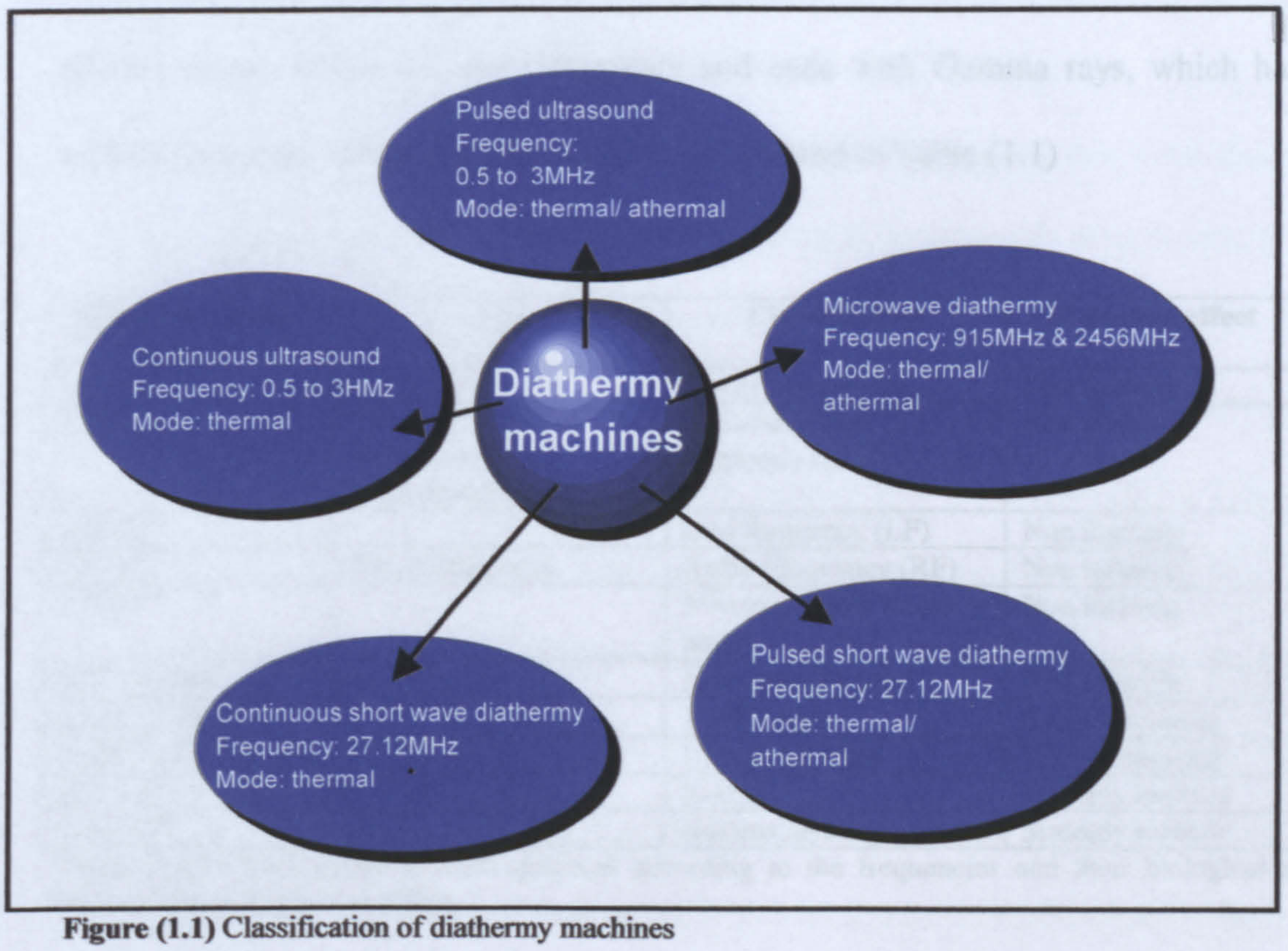


Figure (1.1) Classification of diathermy machines

Unlike other electrotherapy modalities, PSWT has fallen victim to numerous diverse interpretations resulting in the use of several terminologies (Prentice and

Draper, 2001). It has been referred to as pulsed electromagnet energy treatment (PEMET), pulsed electromagnetic therapy (PEMT), and magnetotherapy. Adding to this confusion is the reporting in some of the electrotherapy literature referring to PSWT by its make or manufacturer's name as such it has been a common practice to refer to PSWT as Megapulse or Diapulse.

Two more terms that have been used repeatedly in the literature are pulsed short wave diathermy (PSWD), and pulsed electromagnetic energy (PEME). Using the term PEME or the terms mentioned above to describe the pulsed mode of SW is confusing. The electromagnetic (EM) spectrum encompasses frequencies ranging from zero to 10^{20}Hz (Foley-Nolan, 1990; Delpizzo and Joyner, 1987). The spectrum starts with direct current, which has zero frequency and ends with Gamma rays, which has the highest frequency range. Further explanation is found in Table (1.1)

Frequency range (Hz)	Use	Classification	Biological effect
0		Direct current (D.C.)	Non ionising
0-300	Domestic EMF equipments Bone healing devices	Extremely low frequency (ELF)	Non ionising
300-10^4		Low frequency (LF)	Non ionising
10^4-10^9	SW, Ultrasound	Radio Frequency (RF)	Non ionising
10^9-10^{12}		Microwave and Radar bands	Non ionising
$10^{12} - 4x10^{14}$		Infra-red (IF) band	Non ionising
$4x10^{14} - 7x10^{14}$		Visible light	Weakly ionising
$7x10^{14} - 10^{18}$		Ultraviolet band	Weakly ionising
$10^{18} - 10^{20}$		X-rays	Strongly ionising
Over 10^{20}		Gamma rays	Strongly ionising

Table (1.1) Classification of EM spectrum according to the frequencies and their biological effects (adapted from Rubik et al,1992)

Another classification by Markov and Colbert (2000) divide EMF frequencies according to their therapeutic use. The classification includes magnetic (H) field, Low frequency sine wave (mostly 50 or 60 Hz), pulsed EM (Low frequency fields with

specific shapes and amplitude), pulsed RF (13.56 MHz, 27.12 MHz, 40.68 MHz), transcranial magnetic stimulation (uses short and intense magnetic fields) and millimetre waves (those with high frequency ranging from 30-100 GHz) and each of these categories can be taken to mean PEME if delivered in a pulsed mode. With both classifications the term PEME does not necessarily describe PSWT as PEME could employ a wide range of frequencies other than the 27.12 MHz RF assigned for the therapeutic SW. Additionally, the wide range of equipment utilising EMF employs currents with different amplitude, shapes, engineering, physical and biological effects (Markov and Colbert, 2000) making them even more different than the frequency of 27.12 MHz. Other classifications can be found in the literature, but the above two classifications are used as an example.

In the term PSWD, the confusion comes from assigning the word diathermy (heat through) to the name implying a heating modality. Although several reports have demonstrated the thermal effects associated with its use (Murray and Kitcken, 2000; Bricknell and Watson, 1995), the word diathermy negates the possibility of using this modality in the non-thermal mode as such could be confusing. Although the term PSWD represents the best terminology among the others discussed above, throughout this work the pulsed mode of SW will be referred to as PSWT (pulsed short wave Therapy) as this term was seen to better cover the thermal and the non-thermal modes of pulsed short wave. The term SW however, will be used wherever the reported literature does not make the distinction of whether SW was on a pulsed or a continuous mode.

1.2 THE NEED FOR RESEARCH IN PSWT EFFICACY

PSWT is one of the electro-physical modalities that have been used for many years to treat a variety of soft tissue lesions (Kahn, 2000). It is used to alleviate pain, aid the resolution of haematoma, bruising, inflammation, and oedema, and increase the rate of healing in soft tissue lesions (Kitchen and Partridge, 1996). It is argued that PSWT has undergone a fluctuating pattern of use throughout the years and is experiencing a decline in its use (Prentice and Draper, 2001). Several reasons have been proposed in the literature as being responsible for the move away from PSWT use. For example, the presence of a considerable number of portable modalities that are capable of tackling pain with minimal difficulty to both therapist and patient, and the long list of precautions and contraindications associated with PSWT use (Behrens and Michlovitz, 1996; Nieda et al, 1996). Other reasons that could be responsible for PSWT being superseded by other electrotherapy modalities or other physiotherapy interventions could be the unresolved issues on its harmful effects on the operator (Shields, 2003; Kitchen, 2002), its cost and its interference with other electro-physical modalities found in the vicinity (Wadsworth and Chanmugam, 1983).

Kitchen (1995b) debates this view, stating that PSWT is a widely used modality and is being employed clinically more than CSWD. Kitchen adds that therapists are increasingly moving towards applying lower levels of energy and preferring athermal on thermal modes of treatments. This move is caused by the belief that lower levels of energy are safer to use and are expected to achieve the desired physiological responses with minimal side effects (Low and Reed, 2000).

Further validation to the wide clinical use of PSWT was reflected by the surveys conducted throughout the years in England.

A survey undertaken by Pope et al in 1995 confirmed PSWT to be one of the top three modalities used in physiotherapy after ultrasound (US) and interferential current (IFC), with the majority of their sample opting to use it twice daily. Kitchen and Partridge in 1996, also showed PSWT to be a very common treatment modality in England being accessible to 98% of the respondents (response rate 89%, 98 therapists from 14 outpatient departments) and that 72% of those respondents used it more than once a week.

In agreement with the above findings were the results of the survey conducted by Foster et al (1999). They demonstrated on a sample of 813 physiotherapists across England and Ireland (response rate of 58.3%) that PSWT is one of the top three modalities being used by 64.3% of their sample. The survey has also demonstrated that PSWT is more popular than CSWD, with 11.2% of the sample choosing it as their first option among other electrotherapy modalities compared to 5.2% choosing CSWD as a first treatment option. Similar findings were reported by Shields (2003) in a survey conducted in Ireland. PSWT was owned and used by 53.8% of the hospital-based therapist surveyed and again PSWT was more popular among therapists than CSWD (Shields, 2003).

Despite this wide use, the majority of therapists whether privately-based or NHS-based were reluctant to buy new SW machines due to its unproven therapeutic effects (Pope et al, 1995), lack of space, cost and safety issues related to its use (Shields, 2003).

Moreover, a lot of discrepancy surrounds PSWT as still little is known with regards to why or how to best use it (Robertson and Spurritt, 1998), specific information on dosage parameters, and defined biophysical mechanisms (Markov and Colbert, 2000). All of these factors may indicate a possible under-explored therapeutic effect

(Pope et al, 1995). Moreover, with the increasing attention paid to electro-physical agents, PSWT remains to be the one with the least attention (Kitchen, 1995a).

The claims that this modality can operate in the athermal mode and still result in therapeutic effects was and still is an area for debate (Cleary, 1996; Martin et al, 1990; Foster and Palastanga, 1985). Failure to provide evidence for such claims have lead some to attribute the effects of PSWT to placebo (Wall, 1992). With the literature being nowhere conclusive (Ide, 1990) a lot of therapists have relied on their personal experience, anecdotal evidence and repeated observations to guide them through their practice (Bork, 1993). Such behaviour was validated by the work of Turner & Whitfield (1999) where they demonstrated that 90% of the sample surveyed in both UK and Australia listed their prior experience as the main source for the choice of a treatment technique in many areas of practice including electrotherapy.

With the pressure mounting on policy makers to best utilise the financial resources, hit and miss policies of treatment, and treatment based on opinions and preferences can be considered a waste of time and money (Hicks, 1999). Therapists need to have a clear understanding of the molecular, and cellular mechanism underpinning the electro-physical agents they employ in their practice (Dyson, 1990) in order to obtain the most of their equipment, and to better market their practice for users, purchasers of service and policy makers.

A major problem that faces therapists trying to extrapolate research findings to the clinical setting is the absence of full reporting of dosage. Specifying dosimetry becomes even more difficult with the response being dose-specific. Rubik et al (1992) concurs that the relation between biological response and the energy applied is not linear. As such higher amounts of energy are not necessarily associated with better outcomes. It is only the proper frequency at the proper site that could result in clinically

useful outcomes (Rubik et al, 1992). In order to plan an optimal treatment regime, the practitioner has to choose the appropriate setting among a variety of parameters, which include pulse duration (PD), pulse repetition rate (PRR), and power output. However, literature offers little direction for clinicians in terms of dose-response relationship. To further complicate the situation there has been a paucity of studies looking into the effectiveness of certain dosage parameters on particular dysfunctions (Green, 1991). All of this creates a state of uncertainty when it comes to a clinical decision-making process. This confusion was reflected in the work by Kitchen (1995b), when in an interview, therapists were asked to specify their dosage parameters with given conditions. They were able to do so with regard to Laser and US but not PSWT or CSWD, conveying the lack of knowledge in that area. Respondents also expressed their lack of confidence with these two modalities.

The literature is confusing in terms of the information given. Wadsworth and Chanmugam (1983) argue that best results with PSWT are obtained when the power is set to the highest level possible, this is excluding acute conditions when the power needs to be reduced. Cameron et al (1999) recommended the combination of high peak power (PP) with the highest PRR. Low and Reed (2000) on the other hand, consider PRR the determining factor for best treatment outcomes and recommend using high PRR to obtain the best results. All these recommendations are merely suggestions and have no experimental support.

Given the above, the need for more trials that explore PSWT mechanism of action, and the area of dosimetry are urgently needed (Kitchen and Partridge, 1996; Beckermann et al, 1992; Holmes and Rudland, 1991). Both laboratory and clinical trials are needed to provide evidence on PSWT efficacy, and to justify its continued clinical use. Such demand highlights the importance of the current work.

Interestingly, reviewing the literature that has discussed PSWT use and mechanism of action, it could be found that most of it was laboratory based employing normal subjects, and there has been very little work directed to studying a physiological response in a patient population. Experimentation needs to be directed to uncover mechanisms of action and reactions to EMF with both healthy subjects and patient population. It is suggested that injured tissues may be more sensitive to the energy delivered hence unlike healthy tissues they may react to lower doses of energy (Bricknell and Watson, 1995). As a result, experimental findings from healthy subjects should not be directly extrapolated to the patient population (Kitchen and Partridge, 1996).

All the above justify and highlight the importance of both clinical and laboratory studies. It is anticipated that the findings of this study when incorporated with other work done in the field will help develop theoretical basis that may support (or not) the use of some modes of PSWT and explain part of its mechanism of action.

Compared with other electrotherapy modalities, PSWT requires minimal attention once set up, and as such has the advantage of leaving therapists with time to concurrently attend to other clients (Comorosan et al, 1993). PSWT is also capable of stimulating tissues up to a depth of 3 cm (Prentice and Draper, 2001), or as claimed by some up to 5 cm (Behrens and Michlovitz, 1996). PSWT can deliver heat more effectively than many modalities such as IF or hot pack (Draper et al, 2002; Draper et al, 1999) and has achieved better results with pain compared with CSWD (Wagstaff et al, 1986, Wilson, 1974). This is because at similar power outputs, the pulsed field has higher amplitude and a greater probability of overcoming the intensity threshold of the tissues, thus eliciting a biological response (Tenforde, 1996). Additionally, unlike other electrotherapy modalities, PSWT has been shown to have remote effects; that is by

applying it to the abdomen a desirable change in the circulatory system can be observed at the extremities and as such can be used in cases where direct application of an electrotherapy modality to a painful area is not possible (Wessman and Kottke, 1967; Morrissey, 1966; Erdmann, 1960). It could be added that PSWT can retain therapeutic effects more than other modalities such as US. In a study by Draper et al (1995) that was later validated by Garret et al (2000) it was shown that after 20 minutes of treatment, PSWT recoded the highest temperature increase compared to US, and while US took 14.88±4.7 minutes to revert to baseline temperature PSWT took 38.50±6.61 minutes. This means that PSWT could provide longer time for physiotherapists to exercise or manipulate the treated area (Rose et al, 1996; Draper et al, 1995). All of this makes PSWT a versatile modality to work with and being able to provide evidence on its efficacy could be of significant clinical benefit.

The early chapters of this thesis review the literature and experimentation conducted to-date on PSWT in order to summarise the experimental work, highlight areas for future research and provide justification for undertaking the current work. No attempts however, were made to include CSWD in the review, the reasons are three fold. Firstly: although these two modalities are expected to function on the same principle it is not agreed that both affect various tissues similarly unless both were set on the thermal mode, and as such they should be treated as two distinct modalities. Secondly: there exists a considerable amount of literature on CSWD, its use and mechanism of action unlike PSWT, which has received minimal attention throughout the years (Kitchen, 1995a). Thirdly: separating the two modalities could be of more benefit clinically as this will reduce the state of confusion in the literature and allow clinicians to better judge the efficacy of these modalities based on individualised body of knowledge.

1.3 THE SCOPE OF THE CURRENT STUDY

The current study was based on incorporating both the qualitative and the quantitative approaches to research in order to enrich the study findings. Phase 1 which was the qualitative work was accomplished in two stages. The initial stage was an audit in eight randomly chosen hospitals (Chapter 5). The work was undertaken to evaluate the documentary skills of physiotherapists in the area of electrotherapy with particular reference to PSWT, and to gather preliminary data on the current clinical use of PSWT in outpatient clinics in England. This information was used in construction of a questionnaire, which was utilised in the second stage of the project (Chapter 6). Stage 2 was a nationwide postal survey, which was conducted across England on a sample of 360 physiotherapists. The survey covered physiotherapists from all clinical grades working in outpatient clinics and using PSWT in their routine treatment of patients.

Phase two of the project was a quantitative laboratory based study. The experimental work was undertaken in three stages; stage 1 (Chapter 8) was the pilot experimental work, which aimed to validate the acquisition system and establish the feasibility of the experimental protocol. This was followed by a small pilot laboratory work on 10 healthy subjects to test the experimental protocol and to examine its practicality, reliability and validity. Essential alterations were made to the methodology of the experiment before the laboratory trial on healthy subjects was undertaken. Normative data were derived from a single blinded placebo controlled laboratory-based trial (stage 2-Chapter 9). In this trial, 31 healthy students and staff were recruited. Comparison was made to the physiological effects of applying two modes of treatments dose (high dose of 24W and a low dose of 3W) to the knee joint and measuring its effects on skin temperature (SkT), blood volume (BVol), and nerve conduction velocity (NCV).

Response to the treatment was compared with those of a placebo group and a control group.

In order to bridge the gap between laboratory experimentation and the real world and in order to identify a clearer and wider perspective on the physiological changes accompanying the administration of PSWT, a clinical trial was conducted (stage 3-Chapter 10). Based on the same methodology and using the same outcome measures as the laboratory trial, a single blinded placebo controlled trial that compared twenty six osteoarthritic (OA) patients reactions to the same doses of treatment was undertaken. This section aimed to compare the changes seen in a healthy tissue and a diseased tissue to the administration of PSWT.

The last chapter (Chapter 11) of this thesis is a general discussion that summarises the experimentations conducted in this research programme and discusses the main findings in terms of the overall research question. The chapter also identifies the strengths and limitations of this work and discusses areas for future research.

1.4 OVERALL STUDY AIMS

- To evaluate the quality of therapists' documentation in the field of electrotherapy with specific reference to PSWT treatments.
- To explore the nature of clinical practice with PSWT in outpatient clinics in England.
- To subject clinical practice to validation for efficacy via laboratory and clinical experimentation.

These aims cover the general concept underpinning the implementation of the current research, more specific aims and hypothesis will be discussed in each experimental chapter relative to the work conducted.

CHAPTER 2

PSWT BACKGROUND, MECHANISM OF ACTION AND SAFETY

2.0 EM SPECTRUM

The EM spectrum encompasses a range of radiation waves with frequencies ranging between 3.10^5 - 3.10^{23} Hz with wavelengths ranging between 10^3 m to several Km. These EM waves are electric fields (E) and magnetic fields (H) fields travelling in space at a speed of $3x10^8$ ms^{-1}. The E field can be found wherever electric charges are in motion. Charges exert forces on one another in a direction along the lines of force between them. Charges with the same sign repel and charges with opposite signs attract. The magnitude of the force exerted on one charge by another charge is proportional to the square distance between the two charges (Durney and Christensen, 2000). The H field on the other hand, is produced by the moving electrical current. Both fields travel in straight lines with the E component perpendicular to the H component (Rubik et al, 1992). The EM spectrum includes waves such as radio waves (RF), microwaves, X-rays and more. Further clarification is found in Figure (2.1).

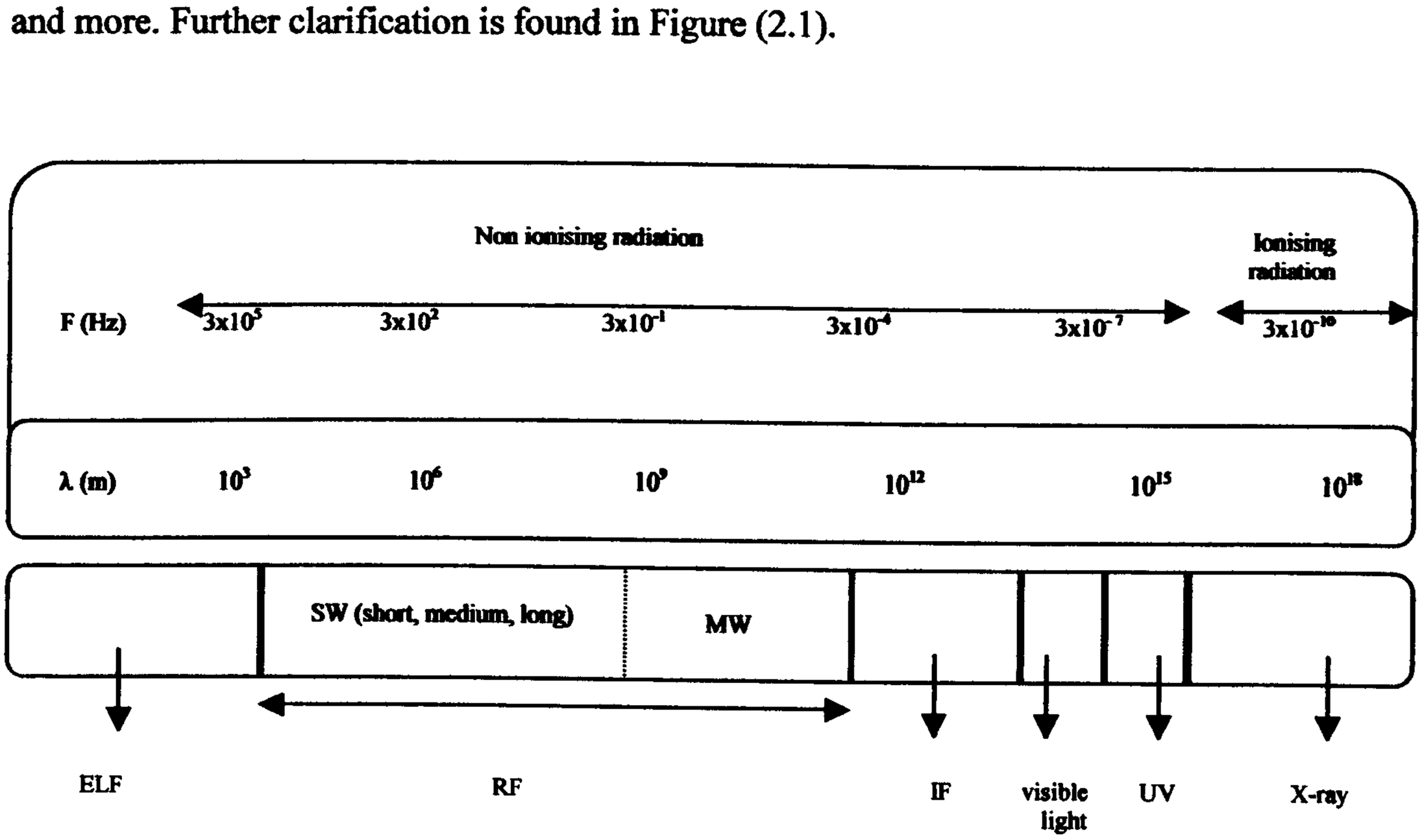


Figure (2.1) EM spectrum (from Durney and Christensen, 2000)

These frequencies can be classified according to their biological effects into ionising or non-ionising frequencies. The term non-ionising radiation refers to all forms of radiation that have energies less than 30 electron-volt and contrary to ionising radiation have insufficient energy to alter the basic constitutions (atoms & molecules) of matter and break down chemical bonds (Rubik et al, 1992), and as such are expected to cause less health hazards.

The frequency range of 10-100 MHz named RF contains short, medium, and long waves. The short wave range of this band has been employed medically in the production of the physiotherapy modalities PSWT and CSWD.

2.1 SW GENERATORS

Therapeutic SW equipment is one of the many medical devices that utilises high frequency EMF. In an attempt to regulate the use of high frequency currents in different disciplines, the Federal Communication Commission in 1947 assigned three frequencies at the short end of the RF band for the medical use of SW (Foley-Nolan, 1990). They are the frequency of 40.68 MHz (±20 KHz) and a wave length of 7.5 m, the frequency of 13.56 MHz (±6.25 KHz) and a wave length of 22m, and the frequency of 27.12 MHz (±160 KHz) and a wave length of 11m (Prentice and Draper, 2001). It is believed that these frequencies could resonate better with the human body resulting in maximum energy transfer and absorption (Martin et al, 1991). The frequency of 27.12 MHz is the most commonly used among the above mentioned frequencies as it has the largest error margin and the biggest band amplitude allowing the frequency to drift with minimal interference to other equipments (Low and Reed, 2000).

SW can be applied to the tissues in either a continuous or a pulsed mode. The alternating high frequency current in both modes is produced in a similar manner. Two

circuits are incorporated to produce high frequency EMF (Figure 2.2), the machine and the patient circuits. The machine (or the oscillator) circuit is composed of a high frequency generator, amplifier (to raise the output to therapeutic levels), and a power supply. The second circuit is the patient (or the resonator circuit) composed of a variable capacitor (to account for the changing capacity of the resonator circuit due to the type of tissue treated), and a method of transferring energy to the tissues and this is achieved by either capacitive or inductive electrodes (Figure 2.2).

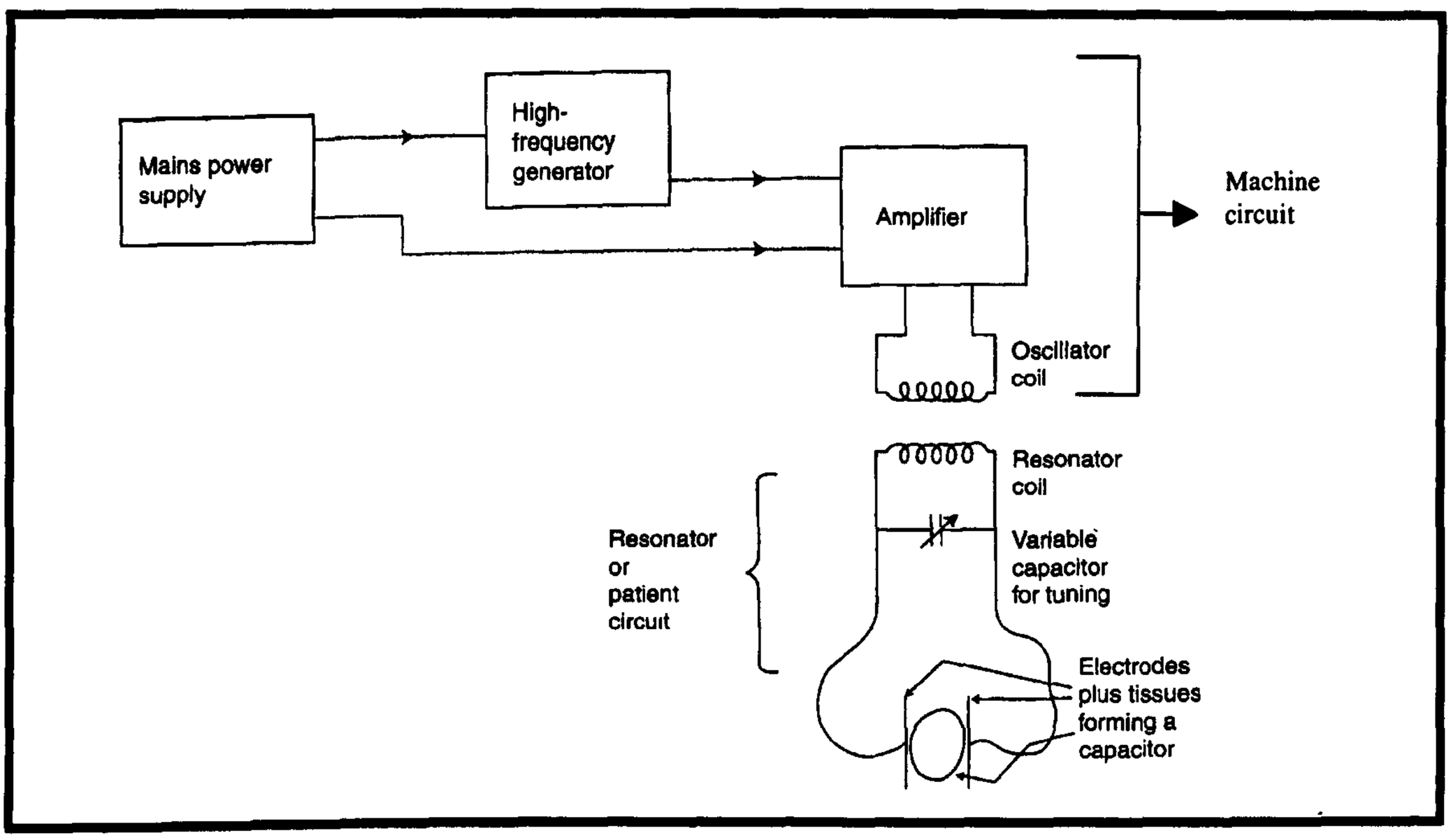


Figure (2.2) Electrical circuits with SW generators, with capacitive electrodes coupled to patient tissues (adapted from Kitchen, 2002).

As identified previously, the output of a SW machine can be delivered to the tissues in either a continuous or a pulsed mode. The difference between the two is that with CSWD the energy is delivered to the patient the whole time of the treatment as such it is always associated with thermal effects. With PSWT, the output is delivered to the tissues in a train of pulses of varying durations and repetition rate as such allowing

high amplitude of energy to be delivered to the tissues with either thermal or non-thermal effects (Wadsworth and Chanmugam, 1983). These pulses vary in frequency between 15-800 Hz, though the range of pulses may be different between various PSWT units. The duration of these pulses is controlled by the operator and may range between 20-400 μs (Prentice and Draper, 2001). Most PSWT machines have peak power (PP) output ranging from 50W (Medilink-EMS) – up to 1000 W (Curapuls-Enraf-Nonius).

Pulsing the output of PSWT means that the therapist can control the mean power (MP) delivered to the tissues. This is achieved by altering variables such pulse repetition rate (PRR), pulse duration (PD) and PP. Changing these variables however is dependent on the manufacturing properties of the PSWT machines as some equipment has fixed PP output (such as Megapulse), while others may have fixed PD (such as Diapulse).

Although a PSWT unit produces both E and H fields in the tissue, this ratio could differ according to the type of electrode in use, the carrying frequency, and manufacturing characteristics. Equipment with a carrying frequency of 13.56 MHz for example, tends to have a higher ratio of H fields when compared to the machines using a frequency of 27.12 MHz (Markov and Colbert, 2000; Hand, 1990).

2.2 METHODS OF COUPLING SW TO THE TISSUES

There are two methods of transferring energy to the tissues when using PSWT: the capacitance and the inductance methods. Each application affects different target structures and each has its own mechanism of producing heat in the tissues. The interaction between the tissues and the field produced by SW generators is governed by the dielectric constant of the tissues, which is dependent on the depolarisation

characteristics and the amount of water content. The interaction is also affected by the specific absorption rate (SAR), which is a function of a tissue's electrical properties, and the ease by which energy is absorbed by the tissues (Scott, 2002; Hand, 1990). This interaction is explained further in Section (2.4).

2.2.1 Capacitive method

Capacitor electrodes produce a higher proportion of E than H field in the tissues with the field being stronger in the centre of the treated area (Prentice and Draper, 2001). The strength of the field is governed by the electrode placement in relation to the tissue (stronger field when the electrodes are situated closer to the skin), the size of the electrodes (small, medium and large; small electrodes have less penetration than large electrodes. Uniform field in the tissues is achieved by using electrodes that are slightly larger than the treated area) and spacing (Hand, 1990).

The heat produced using the capacitive method is the resultant of the movement of three components: charged molecules, dipolar molecules and non-polar molecule. Heat can be produced as a result of the oscillation of charged molecules such as protein and ions about a mean position along the lines of the E forces that are created by the EMF. The oscillation and friction converts the molecule kinetic energy to heat.

Molecules such as water, some proteins, and hormones possess permanent electric dipoles. Normally, these dipoles are randomly arranged. Under the influence of an E field, these dipolar molecules undergo polarisation and align themselves to the opposite charged pole of the E field. The alternating nature of the field causes the dipoles to rotate and collide, and the friction between these dipoles generates heat. The extent of this alignment is determined by the strength of the field (Hand, 1990). Additionally, each of these polar molecules possess a weak field of its own, extending from the

positive to the negative pole, and when the substance is under the influence of E field, the net result of these fields governs the electric properties of the matter. Dipolar molecules produce a mixture of real and displacement currents. Real current refers to the current that develops in the tissues and determines the electrical properties and heat production in a matter (Ward, 1980) unlike the displacement current which does not play a great role in the electrical properties of a matter (Scott, 2002).

The third type of molecules is the non-charged molecules. E field affects non-charged molecules by polarising and distorting their electron cloud fields. Movement of the non-charged molecules in response to the E field results in displacement currents and as such contributes the least to heat production in the tissues, unlike the movement of charged molecules, which could result in real current. This is because the induced dipoles are not as strong as natural dipoles and tends to lose their properties as soon as the E field is removed (Ward, 1980).

As mentioned earlier the heat produced using the capacitive method is governed by the strength of the E field and conductivity of the tissues (more heat is produced in tissues with high conductivity). Capacitive application is expected to concentrate the field in the superficial tissues such as the skin and fat layers rather the deep tissues such as muscles (Van der Esch and Hoogland, 1991). This is mainly caused by the reduction of field intensity as it propagates in the tissues. The refraction of the lines of force as they cross the muscle fat layer causes the loss of part of the applied field strength and termination of some field lines (Ward, 1980).

As the heating pattern with these electrode is mostly in the skin, and subcutaneous fat layer, this method is best suited for treating ribs, spine, and areas of low subcutaneous fat such as hands and feet (Prentice and Draper, 2001).

Two types of electrodes are used with the capacitive method: air space plates and pad electrodes (Wadsworth and Chanmugam, 1983).

2.2.1.1 Air space plates

Air space plates are composed of two metal plates (ranging in diameter from 7.5 to 17.5 cm) enclosed in plastic or sometimes a glass plate guard. Two electrodes are needed for this application and the patient is part of the electrical circuit acting as a dielectric. The distance between the skin and the electrodes can be adjusted not only by changing the skin/electrode distance but also by adjusting the metal plates within the electrode housing. No consensus exists in the literature on the ideal skin electrode distance, with some suggesting 2.5 cm (Wadsworth and Chanmugam, 1983) and others recommending 2-4 cm (Scott, 2002; Low and Reed, 2000). However, no justification was given to the choice of these values.

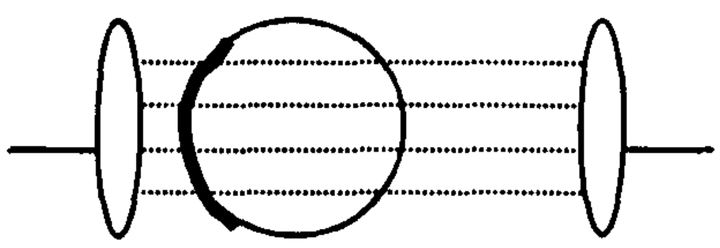
2.2.1.2 Pad (rubber) electrodes

These types of electrodes are composed of a metal plate encased in rubber. They are placed on the treated part with the electrode in uniform and even contact with the skin. Two electrodes are used and the area treated is part of the circuit. Spacing between the skin and the electrodes is ensured by layers of towelling or felt spacers. The amount of heating generated in the tissue is dependent on the spacing between skin and electrodes (more distance between the pads is thought to provide deeper penetration) (Prentice and Draper, 2001).

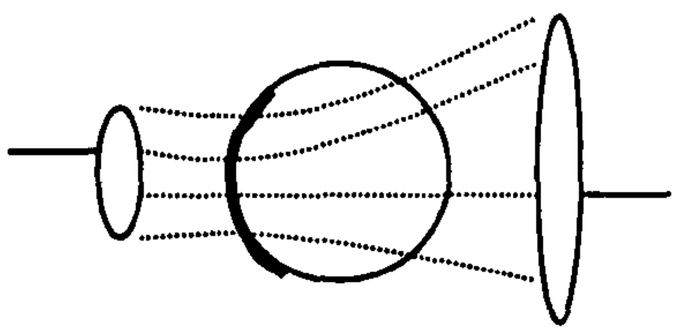
2.2.2 Electrode arrangement

With conductive techniques, electrodes can be positioned in a contra-planar, coplanar, longitudinal, or crossfire arrangement. In contra-planar the electrodes are

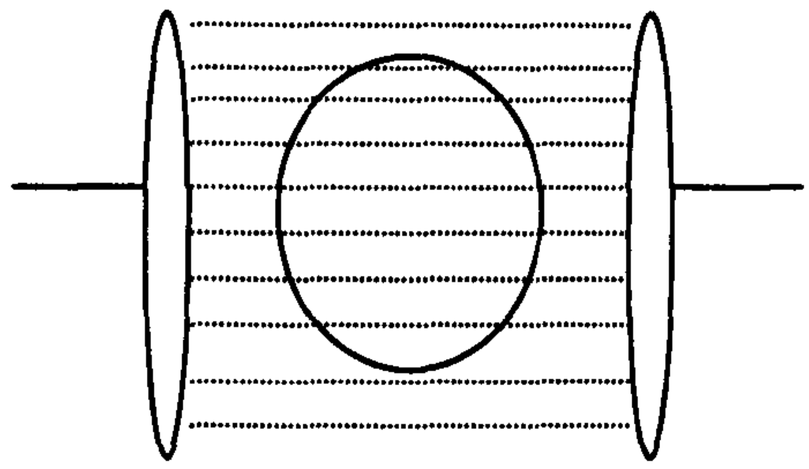
placed opposite to each other on either side of the treated area. The distance between the skin and the electrodes (Figure 2.3) can either be symmetrical if an even field is desirable or they can be positioned with uneven distances if the aim is to concentrate the field on one side of the treated area (Wadsworth and Chanmugam, 1983).



Uneven spacing concentrates the field on the side where the electrode is the closet to the part treated



Using different sized electrodes concentrates the field on the side closet to the small electrode, and alters the uniformity of the field



Using even spacing and equal sized electrodes lead to a uniform field in the tissues

Figure (2.3) Spacing of electrodes, and its effect on field distribution

Electrodes can also be positioned in a co-planar arrangement where both electrodes are placed on the same aspect of the treated area. For safety reasons the distance between the two electrodes needs to be more than the sum of skin electrode distance in order to result in better field distribution. Although this technique produces superficial field, the depth of the field can be increased by increasing the distance between the two electrodes (Martin et al, 1991).

Other electrode arrangements include the longitudinal application where the electrodes are placed at either ends of a limb parallel to the alignment of the tissues. In the

crossfire technique, the electrodes are placed diagonally over the treated tissue for half the time and are then changed to the other diagonal for the rest of the time. This technique is best used with cavities containing air such as the sinus and the uterus (Forster and Palastanga, 1985).

2.2.3 Electrodes size

The size of the applicators is another important factor in determining the strength of the field in the tissues (Figure 2.3). Using two electrodes of similar size results in uniform distribution of the field in the tissues. Using electrodes of different sizes however, leads to the accumulation of the field on the side of the smaller electrode (Tzima and Martin, 1994). Hand (1990) adds that applicators act as antennas for coupling the power to the tissues. When small applicators are used (small in relation to the other electrode or in relation to the size of the treated area) they act as poor radiators decreasing the intensity of the field as the distance increases. This is believed to cause excessive heating at the superficial layers and reduction in the depth of penetration (Hand, 1990).

2.2.4 Inductive method

The inductive method produces mainly H field via a cable that is either wrapped around the extremity or coiled inside an electrode housing. Unlike the conductive technique, the patient is not part of the circuit, and the electrodes are placed perpendicular to the part treated (circuplode) or wrapped around it (cable) (Hand, 1990). When the alternating high frequency current is generated in the cable, the E field is passed in the tissues, generating an H field that is set up at right angles to the direction of current flow (Scott, 2002). The amount of E field emitted by the electrodes can be decreased with some electrodes like the monode by using Faradic screen. The

magnitude of the H field is proportional to the strength of the E field. The strength of the H field is determined by the rate at which the current alternates, and the number of coils of the conducting wire contained within a conductor (Hand, 1990).

The generated H field induces a secondary current in the tissues known as the eddy current (which is small circular E fields). Heat is generated as a result of the friction between eddy currents and intermolecular vibration of the tissue contents. It is believed that the effect of the H field produced by the inductive technique acts as a carrier for the eddy current which acts as the main element responsible for the physiological effect gained during the application (Scott, 2002). This form of heating is not associated with strong sensory stimulation and as such, the heat may not be as obvious to the patient as in the capacitive application (Prentice and Draper, 2001).

The inductive application is believed to result in selective heating with tissues having high electrolyte content and low impedance such as muscle and blood. The most superficial layers such as skin and fat are minimally affected (Lehmann and DeLateur, 1990). Ward (1980) argues that with an inductive application, there will be both superficial and deep heating. Structures such as blood and muscles will be heated as they have high dielectric content, however the superficial fat layer will also be heated because fat is an inhomogeneous structure and usually incorporates areas of high conductivity found in the tiny blood and lymphatic vessels. These tissues lack an efficient way of dissipating heat, and as such tend to absorb heat and concentrate it in the tiny blood vessels. Hand (1990) adds that when the separation between the electrode and tissue is less than 3 cm, high intensities of the power are absorbed by the fat layer. However, by increasing this distance the field is expected to penetrate up to a depth of 4 cm. Although this reference is one of the few that discussed the exact distance between inductive electrode and the tissues it was not clearly mentioned

whether these findings were based on experimentation or were based on a theoretical model. Draper et al (1999) were able to demonstrate up to 4°C increase in intramuscular temperature using inductive electrodes (skin temp was not measured). Although the distance between the electrode and the treated area was not mentioned, it could be deduced from the pictures that it was less than 1 cm.

Inductive PSWT can be applied to the tissues by means of either a drum or a cable electrode (Prentice and Draper, 2001).

2.2.4.1 Drum electrode

The drum is composed of one or more monoplanar coils encased inside a plastic housing Figure (2.4). A main disadvantage with this technique is not being able to fit the skin contour, and its size means if a large area is to be treated more than one electrode may be needed (Wadsworth and Chanmugam, 1983). Maximum penetration with this technique is believed to be 3-4 cm given that the subcutaneous fat layer does not exceed 2 cm. This is believed to be caused by the distortion of the field when it passes the fat layer and crosses the fat/muscle interface which is expected to lead to unwanted increase in temperature in the fat layer (Prentice and Draper, 2001; Low and Reed, 2000; Ward, 1980). Examining seven types of applicators Lehmann et al (1983) demonstrated using human tissue substitute substances that the SAR ratio of muscle to fat heating with inductive electrodes could vary between 0.39-2.67:1 times. Measurements were taken using thermographic scanning with power 420 W (it was not mentioned whether this was the mean or the peak output). However, heating pattern vary between applicators due to differences in electrostatic shielding (Lehmann et al, 1983).

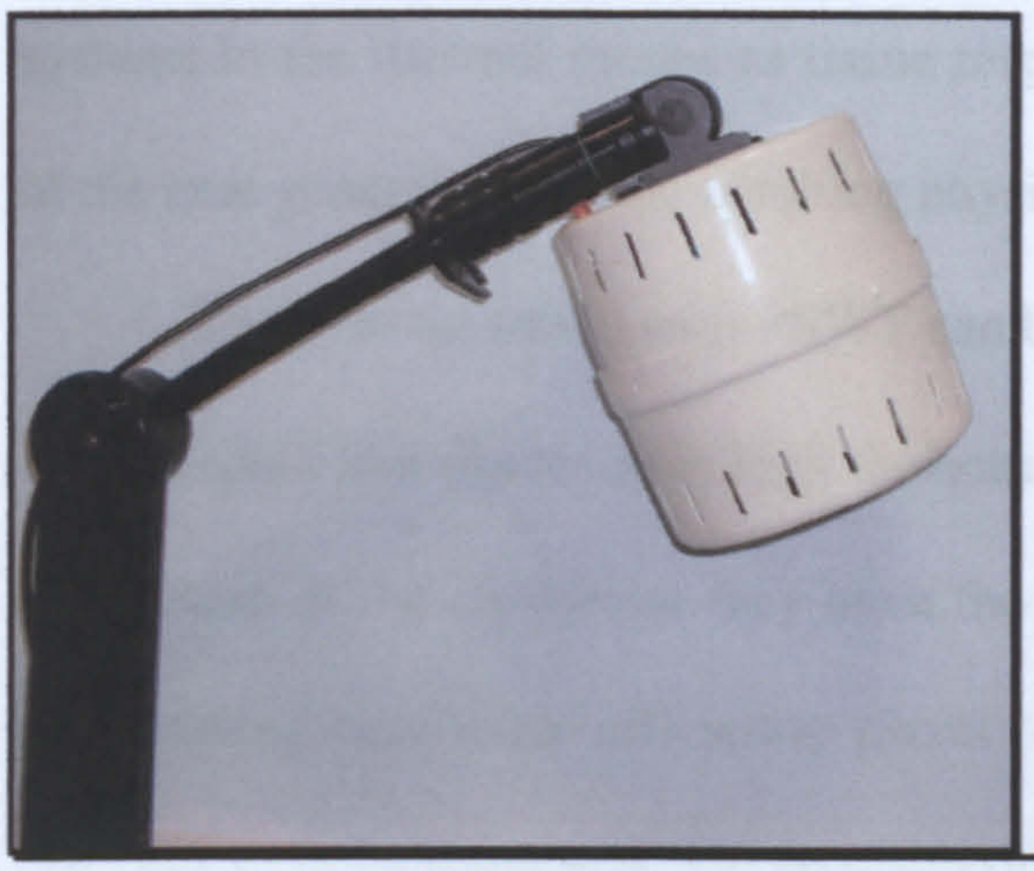


Figure (2.4) Drum electrode

2.2.4.2 Cable electrode

The cable is a thick insulated wire with plugs on either end. The cable can be wrapped in a pancake arrangement and placed over the treated area or it can be wrapped around the extremity. It has the advantage of fitting the contour of the body unlike air space or drum electrodes. A distance of at least 1 cm should be kept between the skin and the electrode, and a distance of about 5 cm should be kept between the turns of the cable to prevent overheating (Prentice and Draper, 2001).

It is of interest to mention that most of the theories explaining the field distribution under the various types of electrodes, their depth of penetration, and the possible approaches for arrangements remain to be theoretical with little supportive research evidence. Whilst these beliefs are widely accepted, further research is warranted.

2.3 HEAT PRODUCTION WITH PSWT

It is believed that PSWT can work in either thermal or non-thermal modes. Considerable understanding exists about the interaction between EMF and biological

systems in the thermal modes as tissue responses to the field can be measured in terms of the heat generated and the resulting physiological reactions (Tenforde, 1996).

The thermal mode with PSWT can be achieved by using long PD and high PRR. It is accepted that tissues with high dielectric content such as muscle and blood are good conductors of the current as they have the ability to absorb more energy and dissipate the resulting heat more efficiently (Scott, 2002). Fatty tissues on the other hand have low dielectric constant and low conductivity (Ward, 1980) and as such tend to heat up. Some have explained this by poor vascularity and the lack of thermoregulatory mechanism in the fatty layer (Wadsworth and Chanmugam, 1983) whilst others suggested that it is the tiny blood vessels spread throughout the fatty layer, which are responsible for retaining heat and the build up of temperatures (Ward, 1980). These views remain to be theories with little supportive evidence.

The athermal effects of PSWT have been an area of dispute (Cleary, 1996; Adey, 1988). It is accepted that athermal mode results when short pulses are interposed by long inter pulse periods. Such application is believed to cause no net increase in temperature (ΔT) as all the heat gained during the "on phase" is dissipated by the circulating blood during the inter pulse period (Scott, 2002). However, this could be taken to be true when the duration of the treatment is short. It is expected that long treatment durations are able to facilitate the accumulation of heat and a change of the application from being athermal to thermal. Heat generated in the tissues is the product of tissue resistance and current density as explained in Equation (2.1).

Equation (2.1) Heating= Current density^2 x Resistance (Prentice and Draper, 2001)

Hitherto, it is anticipated that longer treatment durations are expected to result in more energy delivered to the tissues; higher current densities and a possibility of heat build up compared to applications with short durations.

Wadsworth and Chanmugam (1983) argue that the determining factor in the production of heat is the PRR and that reducing it will reduce the amount of heat experienced by the patient however, no rationale or experimental evidence was given for such claims. Other work on the thermal sensation and heat production with PSWT (Murray and Kitchen, 2000) has confirmed Wadsworth and Chanmugam views. The authors have shown that definite thermal sensation can be experienced by the subjects if the MP was increased to 21.19 ± 8.27W using PRR. However, it could be debated that other variables such as PD, PP can also contribute to the net amount of energy delivered during a treatment, which were not comprehensively investigated in the literature. Two other unpublished studies have examined the relation between detectable and definite thermal sensation (**www.electrotherapy.org**). McMahon and Watson examined the effect of applying 400 μsec, 400 pps, MP of 10.82W on the time it takes subjects to report thermal sensation. In a sample of 40 subjects, they found that it took 104±65 sec to reach possible thermal sensation and a 179±107 sec to reach definite perception.

Another unpublished study by Watson and Evans, examined the time it takes 20 non-injured subjects to report possible and definite thermal sensation using two parameter combination and same MP. The dose used was 400 μsec, 800 pps, MP 12W, and 100 μsec, 800 pps, MP 12W. Only eight out of 20 subjects reported thermal heat. SkT results with the two modes were not significant. These findings are in agreement with the above studies as a MP of 12 W is not enough to lead to thermal sensation. The studies also imply that it is the MP rather than the combination of the parameters such as PD and PRR that are responsible for the thermal sensation with PSWT. Further validation to this notion was provided by the laboratory work conducted by Hill et al (2001) where they were able to demonstrate that changing parameters (PD, PRR) while keeping MP the same did not alter the outcome.

Controversies arise as to whether PSWT can really be considered an athermal modality (Cleary, 1996; Barker et al, 1985; Ward, 1980). It was postulated that the amount of energy delivered to the tissues is one of the determining factors governing whether the application is associated with a thermal effect or not (Murray and Kitchen, 2000; Bricknell and Watson, 1995; Oliver, 1984). With PSWT, the term athermal could be taken to have two meanings, external and internal athermal effects. External athermal effects refer to the thermal sensation experienced by the patients. That is to say, athermal mode is where the patient reports no perceptible thermal sensation (Scott, 2002). This thermal sensation experienced by the patient could vary depending on the subject sensory threshold and sensitivity of skin thermoreceptors (Kingsley, 1996).

Internal athermal effects denote the change in the state of the cell in response to PSWT when ΔT is zero and no measurable change in the state of the cell is detected.

As such, athermal could be viewed to have different meanings, and several thresholds, which necessitate clear definition in the literature. Nevertheless, this aspect is rarely explained and usually both athermal types are confused.

Adey (1988) argues that EMF absorbed by the tissues will always result in internal thermal energy regardless of the mode of application. The energy delivered to the tissues increases the kinetic energy of the molecules resulting in random ionic movement. Atoms become excited, and move into higher levels of energy, releasing photons of EMF, which may be transferred to other atoms or changed into heat (Scott, 2002; Low and Reed, 2000). Tissues contain ions, polar molecules and non-charged molecules. The energy delivered to the tissues has the effect of orienting dipoles according the applied current, polarizing atoms and molecules and displacing the electric cloud of non-charged molecules. The friction and the collision resulting from dipoles when orienting to the applied field or molecules vibrating in their place, and

polarisation of non-charged molecules is transferred into heat (Durney and Christensen, 2000; Delpizzo and Joyner, 1987). The resultant current flow in the tissues is given by the sum of drift, friction, and oscillation for each component in the treated tissues. Although no ΔT is detected externally, non-uniform heating occurs and microthermal effects are still occurring at the cellular level. These effects however are believed to be caused by E rather than H fields (Durney and Christensen, 2000).

Contrary to the work of Cleary, Ward (1980) argues that energy could still be applied to the tissues and result in no heat internally as this is dependent on the nature of tissues treated. Tissues could be irradiated with PSWT, collision and friction of molecules could still be occurring, however, the proportion of E current converted into heat could be very slight, and no real current is initiated in the tissues. In this case, the molecule movement results in thermal agitation (Foster, 1996) and their movement could be no more than random movement or electrical noise (Stenger, 1999), which lasts for the time of the pulse on period (Michaelson and Elson, 1996; Tenforde, 1996). It could be added that even with tissues containing high dielectric molecules, under the influence of E field it is the extent of dipolar alignment to E field that determines the amount of heat produced and this is dependant on the strength of the applied current, and amount of E field absorbed by these molecules (Hand, 1990). Ward (1980) adds that it is the proportion of displacement to real current that determines whether a given application is thermal or not. Hence it could be argued that since almost all thermal effects are related to E field, and since the E field is reduced to the minimum with the monode (drum electrode) when using a faradic screen, it could be speculated that other mechanisms, probably non-thermal, could be responsible for the therapeutic effects obtained especially if the low dose levels PSWT is used (Ward, 1980).

Given the above, PSWT application can be thermal and athermal, internal and external depending on the conductivity of the tissues stimulated (Behrens and Michlovitz, 1996; Delpizzo and Joyner, 1987), the method of application, the dosage used (Lehmann et al, 1983) and the time of exposure (Behrens and Michlovitz, 1996).

2.4 MECHANISMS OF ACTION OF PSWT

The effects of irradiating tissues with PSWT will be divided for ease of explanations into two levels, the micro level and the macro level. The micro level deals with changes that occur in and around the cell in terms of ion transport, membrane permeability and others. In the macro effects section, body reactions to the applied EMF are discussed and the way in which the changes at the cell level influence the overall response to reduce symptoms are explained.

2.4.1 Micro effects of EMF

It is believed that the response of biological systems to EMF could be the result of either thermal or athermal effects. In the thermal mode, it has been hypothesised that a temperature increase of more than 1°C is useful for mild inflammation, and an increase between 2-3°C is helpful in reducing pain and muscle spasm whereas an increase of 3-4°C is necessary to cause tissue extensibility (Prentice and Draper, 2001).

With thermal application that produces temperature increase above 1°C in the tissues, the body temperature increases and then stabilises. This is accompanied by an increase in BVol, increase in heart rate, increase in blood pressure, and changes in the neuroendocrine functions in an attempt to regulate the rate of heat dissipation and prevent heat from building up and the possibility of irreversible damage occurring in the

tissues. For applications that result in less than 1°C temperature rise, the changes in cell behaviour was found to be reversible on termination of application (Michaelson and Elson, 1996; Tenforde, 1996).

The effects of athermal or microthermal exposures on human tissues remain uncertain (Tenforde, 1996). The work conducted on EMF at both ELF and the high frequency of 27.12 MHz has shed some light on this area. However, despite the actual underpinning mechanism not being fully understood (Rubik et al, 1992), several theories have been postulated.

Inside the cell, it is theorised that the nucleus and the microtubules are some of the structures that may respond to exogenous EMF. The nucleus is postulated to be one of the sites for interaction. It is not known how this interaction occurs, but it is expected to be mediated by the presence of ions such as Ca^{++} (Low and Reed, 2000). Another site that is thought to change cell function under the influence of EMF is the mitochondria, which could alter the rate of cell metabolism (Cleary, 1996).

The work conducted by Pope et al (1989) on rats have shown that the interior of the cell reacts to the applied current by decreasing mitochondria size and increasing plasmic reticulum size. There was a decrease in cell lipid size, a migration of these lipid cells to cell poles and an increase in activity of ATP-ase. The size of the response was seen to correlate with the amount of energy delivered to the cell. Reaction was higher with PD 400 μs, PRR 400 pps intensity 1, for 10 minutes, compared to PD 400 μsec, PRR 80 pps intensity 4, 10 minutes (treatments were delivered using Diapulse).

Microtubules are another structure found within the cell, and because they are dipoles (Charman, 1990) they are expected to respond to the alternating E field by rotating and colliding producing heat (Low and Reed, 2000), which may alter cell function. There may be other structures inside the cell that could react to the exogenous

EMF but the above identified are the most frequently discussed. However, issues discussed above are assumptions that need to be clarified and further researched.

One of the main sites for interaction between EMF and the biological tissues outside the cell is thought to be the cell membrane. It is at this site that amplification to the exogenous signals is occurring (Cleary, 1996; Adey, 1988).

It is believed that the E field could change membrane selectivity to ions hence altering ion transport across the membrane (Hand, 1990). EMF is suggested to change the rate of opening, formation of ion channels across the protein bilayer found in cell membrane (Cleary, 1996). This changes the charged ion build up at the surface and the way new molecules are bound to the surface (Polk and Postow, 1996). Cations such as Na^+ and K^+ were found to leak from inside the cell to extra cellular fluids under the influence of EMF (Cleary, 1996) altering the intracellular and the extracellular environment (Adey, 1988). It is also expected that such changes may restore ions, oxygen and nutrients concentrations to a more balanced state (Markov and Colbert, 2000). By doing that the function of the bioelectric closed circuit normally found in lymphatic and micro vascular systems is restored to normal (Rubik et al, 1992; Herbst et al, 1988; Nordenstrom, 1983).

EMF absorption was found to be non-uniform with maximum absorption occurring at the poles of the cell where the E component of the field is perpendicular to the cell. This absorption was found to be related to the carrying frequency of the current and the angle of EMF incident. Optimal absorption was found to be when angle of incident is either 0° or 180° (Cleary, 1996). Mcleod et al (1992) have argued that the efficacy of a treatment is dependant on providing selective pathways through the channels across the cell membrane and this is a frequency dependant process. They proposed that the helical radius of various ions in the field is modulated differently

under the influence of EMF to facilitate the passage of the ions through the channels easily. The cross sectional area of the channels found in the cell membrane plays a big role in the ionic transport across the membrane. Moreover, both the ionic pathway and the channel need to be in resonance and the sharpness of this resonance is determined by the parameters of the applied field. Interestingly, the above authors only found one intensity window for biological effects and there was a cut point beyond which there were no interaction between the field and the cell. They also reported that best results were obtained when there was maximum disturbance to the cell environment whether this was its internal environment (wound healing situation) or external environment (applied current, or change in temperature). These factors are considered to activate selective transient ion channels in an attempt to establish equilibrium (McLeod et al, 1992). Although such an explanation is plausible, it was based on a computerised model that was not substantiated with in vivo or in vitro experimentation.

Homeostatic equilibrium and communication between cells and their environment is normally maintained through a series of signal biochemical processes which include neural messages, growth regulatory factors, internal currents of muscle and nerve. These signals are responsible for regulating all cell activities such as cell differentiation, gene expression, and enzyme activity. These signals however, are thought to alter in response to exogenous EMF consequently altering cell function (Luben, 1996).

All the above changes are expected to revert the diseased cell potential to normal status, correct the endogenous abnormalities and restore cell polarity (Nordenstorm, 1983). However, it is argued that the exogenous field needs to be of sufficient strength to couple with and overcome the internal electrical noise found in the targeted tissue (Barnes, 1996) and it needs to be applied at sufficient durations for the biological

system to respond before it could be of any use therapeutically (Foster, 1996). For example, cell enzymes are structures that contain protein and are heat sensitive. Enzyme activity may cease and structural damage may occur at temperatures above 45° C (Kiang et al, 1990; Vidair et al, 1990). As such appropriate levels of energy need to delivered to the tissues to avoid unwanted adverse reactions.

Cell response was found to be temperature specific with some of the reactions occurring at certain temperature ranges (17.7-25°C) and with SAR above 100W/kg, other work has showed the cell to be even more sensitive responding to SAR as low as 4W/Kg (Luben, 1996).

There is no consensus however, on the latent effect of EMF application. Cleary (1996) argues that the alteration in cell state could last up to 4 days with SAR of 5- 25 W/Kg, suggesting accumulative effects of EMF. Tenforde (1996) disagrees stating that with athermal exposure or when the increase in tissue temperature does not exceed 1°C, the effects were found to be reversible upon termination of the exposure. However, Tenforde did not specify the dosage, or the SAR for the exposure that lead to such findings, as such these results should be viewed with caution.

Experimental work has shown that different carrying frequencies affect different target tissues (windows of frequency) (Trock, 2000). For example, Ca^{++} binding to cells was observed to occur with low carrying frequencies in cardiac cells, and cat brain but the same applications were not found to have any effect with skeletal muscle and rat brain cells (Postow and Swicord, 1996). Hill et al (2001) have demonstrated that human fibroblasts were selective in that they showed the highest level of proliferation when MP was 12W, the proliferation was found to be less with values outside this range. Human chondrocytes were found to proliferate at constant dosages of 6W when treatment time was 5 minutes and to decline when the treatment time was changed to 10

minutes (Hill et al, 2001). Although a lot of work needs to be done in this area, the above-mentioned observations must be taken into consideration when extrapolating research findings between different frequencies of EMF and among different species. It also suggests the existence of MP and time window that need to be explored further due to its influential effects on treatment outcome.

2.4.2 Macro effects of EMF

EMF coupling to endogenous fields is believed to alter physiological processes (Ward, 1980). Though not experimentally supported, it is thought that such reactions could promote endothelial cell proliferation (O'Connor et al, 1990), and repair the vascular network in the injured area (Markov and Colbert, 2000; Rubik et al, 1992; Herbst et al, 1988). Moreover, by increasing nutrients and oxygen supply to the tissue, growth and healing are expected to occur. It is not clear though which of these changes is purely the result of thermal effect and which is expected to be mediated by the microthermal effects, thus they will be discussed in conjunction.

The macro effects of EMF are (Scott, 2002; Low and Reed, 2000; Wadsworth and Chanmugam, 1983):

- Speeding the recovery of soft tissue injuries by increasing the activity of fibroblast and the stimulation of ATP and protein synthesis (Cameron et al, 1999), which may increase in the rate of collagen deposition (Low and Reed, 2000). Interestingly, EMF can work in two directions. It could accelerate cell growth as in tissue healing and it could inhibit abnormal high cell proliferation like in neoplastic growth (Markov and Colbert, 2000). For example, by exposing human lymphocytes for 2 hours to a 27 MHz field and a SAR ranging between 0.5 to 200W/Kg, it was found that cell proliferation increased when SAR was up

to 25W/Kg, however, it was suppressed when the exposure exceeded 50W/Kg (Cleary, 1996). The latter observations were further supported by the suppression of melatonin levels in the body as a result of EMF irradiation, a process that is known to be involved in strengthening body defence against caner growth.

- Tendon extensibility: using PSWT in the thermal mode could lead to elongation of collegneous structures and mobilise scars provided that the application of heat is associated with stretching (Kitchen, 2002).
- Muscle performance: muscle performance can be enhanced by using the thermal mode of PSWT. Heat can improve flexibility, isometric strength and increase range of motion (ROM) if the application was accompanied by stretching (Draper et al, 2002; Peres, 2002).
- In cases of oedema and haematomas: PSWT is expected to aid the resolution of haematomas and oedema by increasing the rate of interstitial fluid drainage (Goat, 1989), and increasing venous return (Wadsworth and Chanmugam, 1983; Golden et al, 1981). As such helping to reduce the removal of the excess fluid from the injured tissues back to the circulation. Heat however, is contraindicated in the early stages of oedema or haematoma as it may increase capillary hydrostatic pressure and lead to the production of bradykinin or histamine which are chemical mediators that could aid in increasing vessels permeability consequently increasing oedema (Kitchen, 2002).
- In cases of inflammation, PSWT is believed to aid the resolution of inflammation by increasing phagocytosis (Cameron et al, 1999), increasing the number of white blood cells and antibodies that help reinforce body defence mechanism, removal of noxious toxins and improve oxygenation (Wadsworth

and Chanmugam, 1983). Evidence to the above claims was provided by Hill et al (2001) who demonstrated that there was a significant increase in fibroblast number after 10 minutes PSWT with MP of 48W applied twice daily. Hill et al have also demonstrated that cell proliferation is time and energy dependent. This means that research findings on certain parameters cannot be simply extrapolated to other settings. All of which warrants further investigations in order to establish the appropriate treatment parameters to use clinically.

- PSWT is expected to reduce joint stiffness by reducing synovial fluid viscosity (Scott, 2002; Yung et al, 1986).
- The vasodilatation observed with PSWT is thought to occur as a result of several mechanisms. It is theorised that the accumulation of waste products, or the direct stimulation of smooth muscles of the vessels in response to heat are ways by which blood vessel dilatation is triggered (Ward, 1980). Blood vessels are thought to dilate in response to the stimulation of sensory nerve endings at the skin surface, which in turn are stimulated by the heat, initiating an axon reflex (Kitchen, 2002). With vasodilatation, there may be a decrease in blood viscosity to ease the flow of blood (Low and Reed, 2000).
- The increase in temperature associated with PSWT use is claimed to increase metabolism and speed up chemical reactions (Ward, 1980). It is expected that for each 1°C increase in tissue temperature, there will be 13% increase in the rate of metabolic reaction (Kitchen, 2002). These claims were only validated in animal studies (Vanharanta et al, 1982) and no human studies are available.
- Though still anecdotal, it has been accepted widely that PSWT can cause pain reduction as a result of the inhibition to the sensory impulses transmission, which may lead to a sedative effect in the treated area. Inflammatory pain is

expected to reduce as a result of the vasodilatation and absorption of the exudates accumulating in the tissues (Ward, 1980). The pain resulting from muscle spasm could decrease as a consequence of vasodilatation and the removal of excess lactic acid and other metabolic products in the muscle that cause muscle soreness (Kitchen, 2002).

- PSWT is expected to aid nerve regeneration particularly small diameter fibres (Wilson and Jagadeesh, 1976). The effect of PSWT on nerves is an under researched area and the increase in the rate of nerve regeneration was only demonstrated in animal studies (Zienowicz et al, 1991; Raji and Bowden 1983; Wilson and Jagadeesh, 1976) and human studies are still lacking.

The majority if not all of the above-mentioned physiological responses are proposed and lack experimental evidence however, as theories they can be expected to be reactions that are dependent on the rate of temperature increase, the electrical characteristics and SAR of the targeted tissue. The lack of a clear understanding of PSWT mechanism of action makes it very hard to reach a clinical decision about the actual therapeutic effect of PSWT.

2.5 GENERAL CONTRA-INDICATIONS AND PRECAUTIONS WITH PSWT

For years, the use of PSWT was associated with few contra-indications compared to CSWD. This was due to the belief that PSWT is a completely athermal modality and as such there was no need to warn the patient during the treatment or perform a sensory test (Forster and Palastanga, 1985). However, the increasing amount of evidence suggesting the ability of PSWT to heat the tissues when enough energy has been applied (Murray and Kitchen, 2000; Bricknell and Watson, 1995) necessitate a

change in the way PSWT is perceived being athermal modality and indeed a change to its list of contra-indications. It is worth noting that the list of contra-indications discussed below is drawn mainly from electrotherapy textbooks. Most of these contra-indications are speculation and deduction lacking experimental evidence.

2.5.1 Metal implanted in the treated area

Despite the lack of studies examining the effect of PSWT on a metal implant, it has been widely accepted that metal is a highly conductive substance, and its presence near a treated area creates an alternative pathway of low resistance, disturbing the EMF field and concentrating the line of force in the metal away from the treated area (Wadsworth and Chanmugam, 1983). The high field density created in the tissues could cause high thermal load and consequently a burn (Scott, 2002). These findings however, have only been validated with CSWD (Stott and Wallbank, 1993; Heick et al, 1991) and the support with regard to PSWT use is still lacking.

The dispute on using PSWT with metal implants (Scott, 2002; Low and Reed, 2000) is due to its mixed mode of action (thermal and athermal). The application of PSWT at low doses is expected to result in no perceivable thermal sensation hence it was thought to be safe practice. The literature however, lacks a definition of what is meant by low dose and when would the athermal mode becomes a thermal mode especially with the experimental evidence giving different power levels 10.8W (Bricknell and Watson, 1995), 21.5W (Murray and Kitchen, 2000), and 25W (Wadsworth and Chanmugam, 1983). Such conflicts suggest that PSWT use with patients bearing any metal implant in any part of their body should be avoided until further decisive evidence have been presented.

2.5.2 Cardiac pacemaker and hearing aid

It has been accepted that PSWT treatment to patients wearing pacemakers is an absolute contra-indication. This is because of the possibility that EMF emitted from PSWT machines could interfere with the function of some of these pacemakers resulting in a change in their rhythm. The use of PSWT on the extremities however, was suggested by some to be safe (Prentice and Draper, 2001; Delpizzo and Joyner, 1987). The use of low energy pulsed SWD (equipment was manufactured by the authors and was worn as a collar for 8 hours) was associated with arm parasthesia (Foley-Nolan et al, 1990). Although recent advances in technology are expected to improve the shielding of the new generations of pacemakers, making them more immune to interference from PSWT, safe practice however, necessitates that even the application of low dose of PSWT to any part of the body should be avoided due to the possibility of the pacemakers having metal part in them and the devastating risk it may have on patient health when it malfunction as a result of being in EMF.

PSWT is also expected to interfere with the function of some hearing aids (Low and Reed, 2000). Experimentation has shown that absorption of pulsed RF in the brain causes a rise in the temperature leading to air expansion which eventually launches pressure waves inside the skull. These waves can turn into acoustic waves, which reach the cochlea and disturb the function of the hearing aid aside from causing patient pain and discomfort (Bassen, 1998; Roschmann, 1991).

2.5.3 Circularity disorder

The thermal application of PSWT is associated with an increase in blood flow to the treated area (Draper et al, 1999). It is speculated that patients with venous thrombosis or phlebitis may be in danger of dislodging the blood clot as a result of the

dilation of the blood vessels. Some however, have argued the safe application of PSWT with these conditions once the vessel has fibrosed (Low and Reed, 2000).

Patients with arterial diseases may also experience tissue destruction due to the inability of the blood vessels to function effectively in dissipating the heat resulting from the treatment. In all the above conditions, it is expected that the impaired circulation could be responsible for a decrease in the amount of oxygen supplied to the treated area and a possibility of a gangrene developing (Low and Reed, 2000).

PSWT should also be avoided on areas of recent injury or tissues that have the tendency to bleed as with vasodilatation the blood is expected to decrease in viscosity (Scott, 2002) inducing more haemorrhage (Forster and Palastanga, 1985)

It is likely that patients with diseased heart muscle may lack the ability to respond to the increased demands in the blood that are needed as a result of the vasodilatation occurring in the treated area. It is deduced that the heart may not be able to increase its output endangering the patient of undue physical stress (Wadsworth and Chanmugam, 1983). It is not clear whether these changes are proportional to the severity of the condition, that is the more serious the condition the worse the outcomes of using PSWT. Findings are mainly deductive due to the obvious ethical issues associated with conducting such studies.

2.5.4 Inflammation

Applying PSWT in a thermal mode could exacerbate the inflammatory process and as such need to be avoided. The use of this modality in the athermal mode is considered appropriate and is expected to aid its resolution (Low and Reed, 2000).

The use of PSWT should be avoided at the "flare up" stage of OA and rheumatoid arthritis (RA). Heat is believed to increase the activity of collagenase (a cartilage

destroying enzyme), leading to more destruction in the joint (Van Den Bouwhuijsen et al, 1990).

The application of PSWT to tuberculosis should also be avoided as the increase in circulation may spread the infection to other parts of the body (Low and Reed, 2000; Van Den Bouwhuijsen et al, 1990).

2.5.5 Diabetes

Diabetic patients are predisposed to peripheral neuropathy (Mendell et al, 2001). This could result in the loss of sensation and as such, high field intensities may endanger patients of being burned (Kahn, 2000).

2.5.6 Pelvic area

It is contra-indicated to irradiate the pelvis during pregnancy as this may induce haemorrhage or miscarriage.

Applying PSWT to female pelvis during menstruation is expected to increase haemorrhage (Wadsworth and Chanmugam, 1983) and possibly disturb the menstrual cycle (Van Der Esch and Hoogland, 1991).

Evidence with regard to male gonads has demonstrated adverse reactions in both animal and human studies. Male fertility was shown to decrease when the heat is applied on their reproductive organs (Dada et al, 2003; Hjollund et al, 2002; Lue et al, 2002), as such the use of PSWT should be avoided.

2.5.7 Malignancy

Applying PSWT in a thermal mode could promote the growth of metastasis (Scott, 2002; Prentice and Draper, 2001). Tumours are known to respond adversely to a mild increase in temperature meaning that malignant cells undergo a more rapid increase in temperature than normal cells especially if the area has been previously treated with radiotherapy (Delpizzo and Joyner, 1987).

Outside the realm of physiotherapy, heat is used widely in treating cancer and limiting its growth (Vargas et al, 2003; Bachar et al, 2003). This practice cannot be applied to the heat produced from PSWT generators because despite the attempts to calculate PSWT dosimetry it remains difficult to quantify (Behrens and Michlovitz, 1996). PSWT incorporate power meters that only indicate the amount of power emitted by the machine and not that delivered to the patient and as such, it becomes very hard to measure the amount of energy delivered to the tissues (Delpizzo and Joyner, 1987).

Hand (1990) discusses that the frequency of 27.12 MHz has been used to treat tumours and states that two electrodes of different sizes should be placed within a distance of 3-5 cm from the tumour. However, this was the only reference located that discussed the use of SW for tumour management. Nevertheless, for safe practice, it is considered best to avoid using PSWT with malignant conditions.

2.6 ELECTRO-POLLUTION

Electro-pollution is a term that refers to the health hazards associated with the exposure to exogenous EMF (Rubik et al, 1992). EMF pollution could be caused by either residential (e.g. electric blankets, home heating, heated waterbeds, mobile phones, television, and radio), occupational (e.g. power lines, radio transmitters, medical devices, video display units, electric power transmitters, and long range military

communication systems) or exposure to natural fields from the atmosphere (e.g. solar activity, thunderstorms, lighting) (Markov and Colbert, 2001).

The work on low and extremely low frequencies of EMF has associated exposure with detrimental effects on health (Shaw and Croen, 1993; Hand, 1990). Animal studies have shown an association between a decrease in foetus weight, increase in anomalies, increase in mortality (Martin et al, 1991; Peterson, 1983), and reduced fertility (Brown-Woodman et al, 1989) with increased EMF exposure. Structural damage to the cell was found to be greatest 4 hours after exposure to LF compared to immediately after exposure (Lai and Singh, 1995).

Observations on humans have also shown an association between the risk of spontaneous abortion (Ouellet-Hellstrom and Stewart, 1993; Taskinen et al, 1990; Goldhaber et al, 1988), foetus malformation (Nordstrom et al, 1983), low birth babies (Wertheimer and Leeper, 1989), birth defect (Kallen et al, 1992), headache (Dowson et al, 1988), adult cancer (Pollan et al, 1999; Wartenberg, 1996), childhood cancer (Feychting and Ahlbom, 1993; Savitz et al, 1990), Alzheimer disease (Sobel et al, 1996) and the exposure to low frequencies of EMF.

Although the mechanism underpinning these observations is not completely known (Berman, 1990), some theories have been put forward to explain these incidents. It is plausible that weak EMF could disturb cell to cell communication, a crucial process for good health. The process of cell communication is maintained via a series of chemical reactions and ionic transport system. Exposure to EMF could disturb this system leading to unregulated cell proliferation, activation of tumour promoting agents such as Ornithine decarboxylase (Luben, 1996) resulting in cell damage. Body immunity to tumours may also be suppressed as a consequence of the depressed

production of some hormones such as thyroxin, thyrotropin, steroid, plasma corticosterone (Michaelson and Lin, 1978; Yang et al, 1983).

Another type of cell damage could also occur from the disturbance of Ca^{++} binding to cell membrane and enhanced DNA synthesis (Adey, 1990; Blackman et al, 1985; Liboff et al, 1984), increase in the intracellular level of growth enzyme (Litovitz et al, 1993) the breakdown of neuro-endocrine-immune system interaction (Tendorde, 1996), and chromosomal stickiness and breakdown (Hand, 1990) all of which could disturb the environment around the foetus resulting in the adverse reactions.

Conversely, it has been argued that hyperthermia is the mechanism by which all these adverse effects occur (Taskinen et al, 1990). Animal studies have shown that increase of maternal temperature by 4°C is enough to disturb the environment around the foetus and lead to malformations and increased mortality (Lary et al, 1986). Excessive heat could cause enzyme breakdown, change the cell membrane to a more fluid state, stimulate mediators such as histamine and brakykinin to alter capillary hydrostatic pressure and increase capillary permeability resulting in oedema (Kitchen, 2002).

Though it may be plausible that hyperthermia may lead to malformations and increased fatalities in animals, it is hard to accept it as a cause for foetus malformations and deaths in human. In the absence of experimental evidence, it is unlikely that the temperature of the human uterus will increase 4°C just from being in the vicinity of LF or ELF.

Human studies have failed to present sufficient evidence on these adverse reactions due to the difficulty in replicating study findings (Adair, 1999), the lack of definition and measurements to RF exposure and the possibility that participants were subjected to other sources of RF, which were not monitored during the study. All of

these are confounding factors that could lead to misclassifying the real size of exposure and the risk associated with it (Swerdlow, 1996).

2.7 ADVERSE EFFECTS OF PSWT

Therapeutic diathermy machines can be a source of occupational hazard (Coppell, 1988; Delpizzo and Joyner, 1987). These observations were underpinned by the fact that EM waves emitted from SW machines can propagate freely in air (Scott, 2002) without a need for a medium, making it difficult to concentrate the energy in the area treated (Docker et al, 1994; Martin et al, 1991). This risk of electro-pollution is increased by the small treatment cubicles and the cramped conditions in some hospitals (Coppell, 1988), which could subject other patients present within the vicinity of operating equipment to increased risk of unintentional EM strays.

Kallen et al (1992) examined the incidence of congenital malformations among physiotherapists over a five year period. Using a mailed questionnaire, they studied 33 physiotherapists with offspring of congenital malformation compared to 63 therapists who were used as controls. They reported that the 33 physiotherapists who had babies with congenital malformation used SW daily compared to the controls. However, the authors failed to measure the duration of exposure. Furthermore, although malformation was associated with increased use of SW by the therapist while they were pregnant, closer examination to the data reveals the contrary. Among the 33 with severe reported infant malformation, nine physiotherapists reported the use of SW daily and 2 used it often, this is in comparison to 15 who never used it and 7 who seldom used SW and still they had malformed infants. All these findings mean that there were other factors that were not accounted for by the authors and might have been responsible for the reported findings.

Hamburger et al (1983) have reported incidents of heart pain among male physiotherapists using SW. The study used a postal survey and unfortunately, had a low response rate and no other record in the literature has further examined such claims. Taskinen et al (1990) found that pregnant physiotherapists using SW for more than 5 hours a week are at more risk of spontaneous abortion than those using it for shorter durations. The incidence of abortions could be escalated if the therapist is beyond 10 weeks gestation period and is a frequent user of higher doses with her patients (Taskinen et al, 1990). Discordant conclusions were obtained by Lerman et al (2001). They found that for therapists to have abnormal infants, SW exposure must exceed 10 hours a week and not 5 hours (p=0.002). However, both studies failed to report and measure the complete EMF exposure profile (occupational versus residential) making it hard to accept one finding as opposed to the other. It could also be argued that Lerman et al may have missed some of the adverse effects of exposure as a result of their classification system which divided exposure to either less than 10 and more than 10 hours which makes it less sensitive than Taskinen et al (1990) (who divided exposure to less than 5 hours and more than 5 hours), this is besides the absence of a rationale for their classification.

In disagreement with the above studies, Larsen et al (1991) found no statistical difference between therapists exposed to SW compared to those who were not in terms of congenital malformation. Their findings however, have related congenital anomalies with longer EMF exposures (p<0.05). A small difference, though not significant, was found between prematurity of male infants exposed to longer durations of SW compared to those with shorter exposures. No association was found between reduced fertility and exposure or between length of gestation and SW exposure. Their findings were not supported by genetic causes for differences in outcome between male/female

infants. This study was a retrospective case report which collected data through telephone interviews and such method is more likely to be subjected to recall bias (Polit et al, 2001; Bowling, 1997)

Guberan et al (1994) examined the gender ratio of offspring in Swiss physiotherapists. A questionnaire was sent to all the physiotherapists who were members of the Swiss Federation of Physiotherapy. In a sample of 1030 (response rate 79.5%) it was found that there was no difference between the exposed and non-exposed physiotherapists in offspring gender ratio or in the prevalence of low birth weight infants. They also found that the electrode type (air space plates, circuplode), duration of exposure per week, and the distance from the SW machine did not play a significant role in the findings. Although these findings were in disagreement with Larsen et al (1991), it could be speculated that the large size employed in Guberan et al study might have accounted for this difference. Similar to the previous study Guberan et al, used a retrospective approach, with the questionnaire being the tool to collect the data. In the questionnaire they asked therapists to recall detailed information such as the number of times they have been exposed to SW in the first month of their pregnancies, how many times per week they worked within a distance of less than or more than one meter. These questions demand a remarkable memory and lot of recall, which could bias the findings.

Although the majority of studies have associated SW exposure to adverse reproductive outcomes, these studies have failed to account for other confounding factors for abortions (Taskin et al, 1990) such as heavy lifting, bad posture (West and Gardner, 2001; Hollis, 1992) and workload. Moreover, some studies employed a retrospective design where they have used medical records to trace incidents of abortions. Nevertheless, data obtained in this manner could be endangered by the loss of

some files (Polit et al, 2001), hence the files may not give a true representation to the actual status. Furthermore, almost all studies have mainly used self- reporting questionnaires as a tool to obtain information on EMF exposure. Self-reporting is considered a source of potential recall bias if substantial amount of time has elapsed (Heiman, 1995). The reliability of the reporting could also be further endangered by the heightened public awareness on a sensitive issue such as EM exposure (Shaw and Croen, 1993; Taskin et al, 1990).

Additionally, although the above studies have shown association between EMF exposure, abortions and foetus malformation (Ouellet-Hellstrom and Stewart, 1993; Larsen et al, 1991; Hamburger et al, 1983; Kallen et al, 1992; Taskin et al, 1990; Stellman and Stellman, 1980), no causal relationship can be established from those studies due to the nature and methodology of these studies and the absence of quantitative measurements.

2.8 ELECTROMAGNETIC RADIATION (EMR) AROUND PSWT MACHINES

Studies on the strength of EMF around SW machines found differences according to the PSWT make, mode of application (continuous or pulsed), and treatment setting (Shields, 2003; Coppell, 1988; Skotte, 1986).

The type of electrode used could affect the stray irradiation around PSWT unit. Capacitive electrodes recorded higher E field than drum electrodes and inductive coil (Lau and Dunscombe, 1984). In agreement with these findings are the findings of Skotte (1986) who reported that air space electrodes were associated with higher stray emission followed by circuplode. Interestingly, although both monode and circuplode are inductive applicators, the level of unwanted radiation associated with their use is

different, the authors however, did not specify the make of these electrodes, as such it could be speculated that the alignment and configuration of the coil within the treatment head was responsible for this difference. Coppell (1988) measured EMR from a distance of 1m around a PSWT machine. Findings confirmed that air space electrodes were associated with 10 times higher values of stray emission when compared with pad electrodes and 100 times higher radiation levels than inductive electrodes. These findings on air-space electrodes were further supported by Martin et al (1991).

Tzima and Martin (1994) have evaluated the stray of E and H fields of several SW machines in pulsed and continuous mode and with different electrode configuration. Air spaced electrodes were found to emit more EMR when used on continuous mode compared to pulsed, with field extending above National Radiation Protection Board (NRPB) (1993) levels to 0.8-1.1 m in continuous and 0.4-0.8 m in pulsed. The strength of the field was also found to decrease with increasing distance from the unit. Although the authors have described the positions from where measurements were taken, description to dose on which they set the SW machines was not complete, information such as PRR, and MP were lacking.

The E field was found to be higher near the electrodes while the H field was highest near the cables (Shields, 2003; Martin et al, 1991). As such it is expected by standing at the end of a diathermy console opposite to the applicator instead of the front of the unit the amount of unwanted EMR exposure is expected to decrease (Li and Feng, 1999; Skotte, 1986).

Li and Feng (1999) measured EMR intensities from a distance of 30, 100, 150 cm from a SW machine. They measured the strength of both E, H fields at the level of the knee, waist and hand of the operator. Although the authors found that the operator exposure to be below the recommended levels, the strength of the measured field was

found to be variable in different directions around SW machine. The highest recorded value was in front of the diathermy at a distance of 30 cm at the level of the knee.

Li and Feng (1999) and Skotte (1986) found that both E and H were higher at the front of the unit rather than at the back. Fields were found to be 55A/m and 0.19V/m in the former study, 19.2A/m, and 0.22V/m in the latter. In conflict with the above findings, Coppell reported values that E field strength were between –0.011 to 0.32 times higher and the H field was 0.015-1.6 times higher than the recommended values at the back of SW unit and recommended that the design of the unit console be changed to avoid over exposure to physiotherapists. Though it is hard to accept one study over the other due to differences in methodology and nature of measurements, all those studies confirm that there is a potential safety issue with SW that demands care from operators. Studies have presented different values for the strength of E and H fields possibly because of the difference in SW makes or SW dose employed during testing (which is not reported in those studies).

The size and placement of the electrodes on patient body also plays a role in the strength of the field distribution. Field strength was found to be proportional to the size of the electrode. A 20-30% increase in field strength was demonstrated when the electrode diameter was increased from 6 to 14 cm (Tzima and Martin, 1994). Contrary to these findings were the results of Shields (2003) who found on 8 SW machines and two different sized electrodes (4 medium electrodes were compared to 4 small electrodes from different PSWT makes) that the medium electrodes did not always emit higher field strength compared to drum electrodes and commented that electrode size and effects on the field strength is only important when measuring from single unit. However, such differences disappear when multiple units are compared as other factors come into play such as the make and the power output of each unit. Moreover, given

that SW units have different power outputs, when units with higher output were compared with units having lower power outputs for EMR, contrary to the common belief, units with higher power outputs did not always emit higher stray radiation and similar units did not always emit the same level of radiation. Such findings imply that findings from studies should not be extrapolated to all makes of SW units and should not be taken as gold standards but as guidelines and modification should made as seen necessary depending on the working circumstances.

The arrangement of the electrodes is another factor that could affect the strength of the field around SW machines. Co-planer arrangement was found to emit lesser stray field compared to contra-planer (Tzima and Martin, 1994). The distance between the electrodes and the area treated seems to play a role in the size of EMR emitted. The extent of the field was found to be proportional to the distance between the treated area and the electrodes, with less stray emission with closer applications (Lau and Dunscombe, 1984). These findings were in agreement with Tofani and Agnesod (1984) who also reported a proportional relationship. Martin et al (1991) supported Tofani and Agnesod and commented that with an increase from 10 to 30 mm the field is expected to increase 10-30%, and this is expected to cause uneven heating and concentrate the EMF field under the treatment head (Section 2.2.2).

Shields (2003) argues that even with similar treatment settings, the field strength around the electrodes could vary according to the type of unit used (Shields, 2003). However, a downfall of many of the previous studies is that they failed to give sufficient details on the type of electrodes used, their arrangement, and the SW make to allow for comprehensive comparisons.

General practice recommendations state that conductive PSWT units emit the lowest stray radiation as such a distance of 0.5m is sufficient. Although CSP guidelines

recommend that a 1 meter distance is the safe working distance, recent work by Shields (2003) has shown that increasing the distance to 1m is essential in order to ensure that physiotherapists exposure to EMR is below NRPB (1993) recommendations. Such findings were reached following the measurement to EMR emitted from inductive CSWD and inductive PSWT in eight units of different makes.

These findings are not definitive as field strength could be altered in the clinical setting due to the use or the presence of metallic furniture around the treatment area, another SW machine operating within a distance of 2 m, and the therapist standing in close proximity to SW cables (Coppell, 1988; Delpizzo and Joyner, 1987). Each of these factors could play a role in creating alternative conduction path, distorting the EMF (Docker et al, 1994).

It could be argued that the majority of these studies were undertaken in laboratory setting with units that have been serviced and calibrated for that purpose. Shields (2003) has demonstrated that many of SW units used in hospitals are not monitored regularly for output and performance. Examining 20 machines from different hospitals in Ireland, it was found that they were not functioning to their required specifications. For example, it was found that some of these units have unreliable timers, the output was at times 45% higher than the selected dose and in other instances, it was 26% lower than was expected.

Additionally, the majority of those studies used a phantom of saline, which is more homogenous than human tissues. This makes direct extrapolation from research findings to the clinical setting difficult due to the difference in real and the displayed power outputs of those machines.

Studies have shown that therapists average exposure time during a treatment is around 3 minutes (Stuchly et al, 1982), which may lead to the speculation that with such

short exposures EMR exposures are unlikely to exceed the recommended levels by NRPB (which state that over a 6 minute period, maximum E field exposure should not exceed 61 A/m, and maximum H field exposure should not exceed 0.16 V/m, SAR of 10 W/cm^2). However, no quantitative measurement to physiotherapists EMR exposure were undertaken, and all studies have reported findings from questionnaires with no actual measurements, such safety issues warrants further research.

2.9 CONCLUSION

This chapter has presented background knowledge on the mechanism of PSWT, its indications and contra-indications. Many of the issues raised are not founded by experimental research and are mostly anecdotal. Despite that, these theories have been largely accepted as a foundation for PSWT actions. Effective and safe use of PSWT necessitate that more research is conducted.

This chapter has also summarised the occupational hazards associated with the use of PSWT. Epidemiological studies have not presented a definite correlation between the use of PSWT and congenital malformation or PSWT and abortion. Studies on the strength of the field have shown that physiotherapists are safe provided that they work in a distance that is at least 1 meter from PSWT units. Literature, however, lacks studies that quantitatively measure the durations and the extent of therapists EMR exposure and hence quantify the actual risk.

The next two chapters will discuss the physiological effects of PSWT and the clinical trials conducted on various pathological conditions in order to examine the evidence behind PSWT clinical use.

CHAPTER 3

LITERATURE REVIEW ON THE PHYSIOLOGICAL EFFECTS OF PSWT

3.0 INTRODUCTION

The application of PSWT is believed to be associated with dilation of blood vessels, increase in blood flow, reduction in blood viscosity, and increase in skin and muscle temperature (Low and Reed, 2000). A considerable number of studies have examined the application of PSWT on the maximum settings when PSWT is thermal (Garret et al, 2000; Draper et al, 1999, Bricknell and Watson, 1995); as such, a reasonable understanding exists with regard to the physiological effects of PSWT in the thermal mode. However, its mechanism of action and interaction with biological systems when it is set on lower doses and is believed to generate little or no sensory thermal effect is still unclear.

This chapter is a critical evaluation of the studies conducted to-date on the physiological effects of PSWT, the review will focus on the studies that have examined blood flow, and nerve conduction velocity, skin, and muscular temperature, as these variables will be used in succeeding experimental sections. The search strategy for the literature review is explained in Appendix G.

3.1 LITERATURE REVIEW

3.1.1 PSWT and skin/muscle temperature

Six research papers were located discussing the effect of PSWT on skin temperature (Wessman and Kottke, 1967; Valtonen et al, 1973; Heick et al, 1991; Oosterveld et al, 1992; Draper et al, 1999; Garret et al, 2000).

Using the indirect reflex method of heating, Wessman and Kottke (1967) investigated the effect of the abdominal heating on the temperature of both the leg and the foot. On 10 normal women (age 21 and 22 years) blood flow, blood pressure, SkT, and oral temperature were measured following abdominal heating for 80 minutes. Blood

flow was measured using a boot shaped plethysmograph, SkT was measured using iron constantan thermocouples taped to the right foot, the pads of big toe and little toe, the sole, the dorsum of the foot, right calf, pad of thumb and little finger and the dorsum of the hand, and another thermocouple was attached to the forehead. Temperature was recorded every 2.5 minutes. Oral temperature was recorded using a mercury thermometer, pulse rate (PulsR) was taken from the wrist and blood pressure was estimated by auscultatory method. Although no significant relation was found between SkT and blood flow, a measurable increase in calf and foot temperature was evident, accompanied by an increase in oral temperature and PulsR measurements. The authors however failed to mention the dose of PSWT, and did not explain the rationale for using a small sample (n = 10) of only women aged 21 and 22. Moreover, no rationale was given for the choice of long treatment duration especially that 80 minutes of PSWT is a regime that is difficult to transfer to a hospital setting.

Valtonen et al (1973) compared the effect of irradiating the abdomen with PSWT and CSWD on lower limb SkT in a sample of ten healthy females. Three treatment protocols were employed. CSWD was applied using a pad electrode placed under the sacrum and a condenser electrode placed over the abdomen. The second CSWD protocol was achieved using the hinged type drum (Diplode) over the abdomen. With both protocols the CSWD was set to deliver gentle mild heat. The third protocol was the PSWT (Diapulse machine, circuplode electrode, 65 μsec, 600 pps, MP 38 W). All treatments were administered for 15 minutes on three consecutive days. Temperature was measured from the lower limb every 5 minutes using thermocouples. Findings have shown that the increase in SkT peaked at 15 minutes after application. There was no statistical difference between the three modes of application despite PSWT recording the greatest increase compared to continuous. Despite the small

sample size the findings suggests the importance of selecting the proper treatment duration if beneficial effects are to be gained from the treatment. The authors however, failed to mention the site of temperature thermocouples on the lower limb and there was no reporting of statistical analysis.

In 1991, Heick et al studied the safety of applying PSWT and US on eight women with a copper intrauterine device. The women were complaining from perimenopausal bleeding and were hospitalised in order to do curettage. The treatment was given to the lower abdominal skin while the patients were in the operating theatre and are under general anaesthesia. Temperature was measured from both the uterus and the rectum using two types of glass/ethanol thermometer one with copper and the other without. PSWT was delivered using Ultratherm at intensity 3, PP 400W for 20 min, US was given at 1.5W/cm^2 for 5 minutes. They concluded that both modalities were safe to apply as no temperature above 38.1°C was recorded with both modalities, and as they expected the thermometer with metal content recorded higher temperature than the one without. Despite the small number employed in the study, the sample had been further divided into 2 treatment groups. According to the authors no control group was used because the increase in uterine temperature was minute, a reason that was not clearly justified because the need to include a control group should come at the planning stage and not after collecting the data. The dosage for both the US and PSWT were not comprehensively mentioned. No rationale was given for using two types of thermometers especially as the one with metal component would always record higher temperature than the one without due to the heating effect. Additionally, with all patients unconscious during the application of PSWT, this study carries an ethical issue.

Oosterveld et al (1992) conducted a study to examine the effects of topical heat and cold on intra-articular and skin temperature. Forty two healthy students were

recruited for the study. Subjects were randomly assigned to one of four groups: group 1 was treated with ice chips placed in plastic bag over the anterior knee for 30 minutes. The knee of group 2 was cooled with nitrogen-cold air for 6.4 minutes. Group 3 was treated with PSWT for 15 minutes. The treatment was delivered using a Curapuls 419 unit with MP of 180W, electrodes (condenser field method) were placed on the medial and lateral sides of the knee. In the fourth group the knee was treated with lingo-paraffin for 10 minutes. Intra-articular temperature was measured using intraflon infusion needle inserted into the joint and its position was confirmed by radiography. SkT was measured using a medical thermometer attached to medial surface of the knee. Skin fold measurements (SFM) were taken from the biceps, triceps, subscapular muscles, and iliac crest.

There was a recorded decrease in SkT with both ice chips and nitrogen cold air, this reduction however, did not reach statistical significance. Joint temperature also decreased with the two modalities however it was only statistically significant with ice chips ($p<0.001$). Heat generated from the application of lingo paraffin was higher than the heat produced with PSWT ($p<0.001$) both in skin and joint temperature. The latent effect of heat and cold modalities has shown different results. The recorded drop in intra-articular temperature with ice chips and nitrogen cold air was evident even after 3 hours post treatment unlike the heat produced by lingo-paraffin and PSWT, which returned to baseline reading before 3 hours. Although the exact time the heat modalities took to revert to baseline readings was not mentioned, the findings suggest that cold treatment offered a larger window for interventions such as stretching and exercise post treatment. No significant association was noted between SFM and SkT or intraarticular temperature. Furthermore, no baseline temperature recording was available for the PSWT group and this was due to the difficulty in administering PSWT with metal in the

joint cavity as such the mean readings from other groups was used for analysis, doing this the authors failed to mention whether the groups were comparable at baseline or not.

Draper et al (1999) studied the nature of temperature increase and decay in the gastrocnemius muscle in 20 healthy college students following the administration of PSWT. The temperature was measured intramuscularly (by the insertion of a thermistor which was pulled out when PSWT was turned on) at 5, 10, 15 and 20 minutes during the application of PSWT and 5 and 10 minutes post treatment. PSWT was applied for 20 minutes at 800pps, 400μsec, and MP of 48W. An increase in temperature of about 4°C was detected at a depth of 3 cm. The heat peaked at 15 minutes after which it levelled for 5 minutes and started to decline slowly with around 1 degree per 5 minutes. In the study the output of PSWT was interrupted every 5 minutes to take temperature measurements as such it could be speculated that the reported temperature increase is not the true cumulative effect. Moreover, it was argued that the heating pattern with inductive applications is not selective, meaning that with heating of deep tissues there will be excessive thermal build up in superficial tissues (Ward, 1980) as such it would have been interesting if the authors had compared the temperature of skin and superficial adipose tissue to the muscle temperature recorded.

Another study was conducted by Garret et al (2000) to compare the amount of temperature rise and decay of both PSWT and US in the triceps surae muscle of 16 healthy students. The temperature was measured intramuscularly by using three thermistors placed at 3 cm depth and 5 cm apart. Half the sample received PSWT followed by US and the rest received the opposite. PSWT was delivered using Megapulse given for 20 minutes at 48W MP, PRR 800 Hz, 850 μsec interburst interval, PD 400 μsec, PP 150W, while US was given in the continuous mode at 1MHz, intensity

of 1.5W/cm² for 20 minutes. With both modalities the middle point in the muscle demonstrated the highest increase (4.58±0.87°C for PSWT and 0.09±0.56°C for US) in temperature (p<0.05). The tissues treated with US took 14.88±4.7 minutes to return to baseline reading while it took PSWT 38.50±6.61 minutes to return to baseline reading. The authors concluded that PSWT is more effective in heating and retaining heat when large areas are the target. The conclusion reported in this study cannot be taken as a real difference between US and PSWT, for two main reasons. Firstly: during the experiment the authors left the thermistor needle in the muscle to record minute by minute change in temperature during US application. This leads to the speculation that the increase in temperature reported could be the joint increase of needle and muscle temperature. Secondly: the baseline temperature reading for the US was always higher with all the subjects who received US as the second modality in their randomisation, this could mean that not enough time was given to the muscle to recover after PSWT and this may have affected the overall findings of this study.

The latter two studies described above have utilised MP of 48W. This setting represents the maximum output of Megapulse units. No other attempts were made to examine other power settings despite the wide range of parameters available.

3.1.2 PSWT and blood perfusion

Two research papers (Morrissey, 1966; Erdmann, 1960) and one conference abstract (Burden and Mitchell, 2000) were located discussing the relation between PSWT and blood flow. Erdmann (1960) examined the effect of radiating the epigastrium on the blood flow in the feet of 20 adults. In a controlled temperature room, 20 fasting healthy subjects ranging in age between 25 to 38 years were recruited. Blood flow was measured from the second toe of each foot using plethysmography.

Temperature was recorded every two minutes from the dorsum of the foot, rectum and the skin under the treatment head using thermocouples. The treatment head was applied to the epigastrium (with power outputs being increased gradually from PP 410W to PP 1025W). The authors recorded a noticeable increase in blood flow that was proportional to the gradual increase of intensity. Blood flow started to increase in the first 8 minutes with a plateau reached within 35 minutes of application. The blood flow reading went back to baseline after 30 minutes post treatment. The increase in temperature was 2°C in the foot and ranged between 0.5°C to 1.5°C under the treatment head. There was no change in rectal temperature.

These findings unfortunately can not be related to the amount of energy delivered to the subjects because the treatment parameters reported by the authors (intensity 4 or 5) are not transferable to other PSWT devices, especially as some of the parameters and the make of the PSWT are not reported. The authors also failed to analyse their findings statistically, and the results reported were merely descriptive.

On 28 normal subjects (aged between 20-39 years) Morrissey (1966) studied the effects of three PSWT protocols (irradiation of the leg for 15 minutes, irradiation of the eqigastrium for 15 minutes, irradiation of the calf followed by irradiation of the epigastrum for 15 minutes) on BVol using MP of 40W (600 Hz) and 80W (2000 Hz). Changes in BVol were measured before and after the treatment from calf and foot pre treatment, every 2 minutes during the treatment and post treatment using venous occlusion plethysmography. SkT was recorded using iron copper thermocouples from the foot and calf. Results showed that significant increase in BVol was noted with 80W MP and not with 40W. The report however lacks comprehensive statistical description, with unclear reporting of the significance level. Furthermore, one of the applications included applying PSWT to the calf followed by irradiating the epigastrium for 15

minutes, it was not mentioned whether the 15 minutes was divided into 2, which means that each part was treated for 7.5 minutes (this could mean that both areas received lower power outputs compared to other groups). The description could also mean that both the calf and the epigastrium were treated with 15 minutes each, which may have resulted in more energy outputs being delivered to the mentioned area. All of which would makes it difficult to compare the findings of the 3 applications directly to each other. Furthermore, the part of the experiment which examined the effects of 80W was done on only 4 subjects which raises the question of the validity of the conclusions.

Nineteen healthy subjects were employed in a single blind experimental design to investigate the effects of PSWT on blood flow in the quadriceps muscle (Burden and Mitchell, 2000). The sample was divided into a treatment and a placebo group. The treatment group received 15 minutes of PSWT (Megapulse II, 65 μsec, 400pps, MP 3.25W) and the other group received the same time of treatment with the equipment not turned on. The blood flow using volumetric plethysmograph was measured 3 times: after 15 minutes baseline, after 15 minutes treatment, after 15 minutes recovery. Findings suggest that PSWT administered at these parameters significantly increases blood flow in the treated area. Unfortunately, no other findings were available as this was a poster abstract from a conference and the study was not published (the co-author was contacted and the study was an undergraduate project).

3.1.3 PSWT and peripheral nerves

The effect of applying PSWT on peripheral nerves was examined by Currier and Nelson (1969) and Abramson et al (1966).

Abramson et al (1966) examined the effect of experimentally changing local circulation and temperature on ulnar and median nerve conduction velocities on 29

healthy adults. Blood flow was measured using venous occlusion plethysmograph, muscle temperature was measured at a depth of 3.5 cm using copper thermocouples.

In first part of the experiment the plethysmograph was filled with histamine and a current strength of 10 to 15 mA was applied for 25 minutes to aid ion transfer to the body. Skin and muscle temperature were measured before, during and after treatment. In the second part of the experiment SW was administered for 25 minutes while the arm was exposed to either a temperature bath of 93.2°F or of 39.2°F. Two air spaced electrodes were used, one placed on the shoulder and another one on the wrist. Temperature, and motor nerve conduction was measured before and after treatment. The water in the plethysmograph was heated using a heating coil while water cooling was maintained using a refrigeration unit incorporated into the plethysmograph. Findings revealed that there was a significant ($p<0.05$) increase in motor conduction in the 93.2°F bath. There was also a measured increase in blood flow and temperature (no significance level was mentioned). In the 39.2°F bath there was a significant ($p<0.05$) decrease in median and ulnar nerve conduction velocity, skin, subcutaneous and muscle temperature with no significant difference noted on the blood flow (no significance level is reported). Histamine by ion transfer caused no increase in motor nerve conduction of ulnar or median nerves and tissue temperature but a significant increase in blood flow in the forearm. Given this, the authors concluded that the changes in blood flow do not play a significant role in changing motor nerve conduction unlike the small change in tissue temperature, which may alter the nerve velocity considerably. Although both nerves shown similar trend of increase and decrease in velocity there was a difference in the magnitude of the response to the environment around the nerve whether it was hot and cold. Results revealed a greater increase with the ulnar nerve, though no explanation was proposed for that. Unfortunately, the work above has used a

technique that is not utilised in hospitals and one that might have some safety issues, with no rationale given for the reason of enclosing the arm with water at certain temperature and no justification for the choice of temperatures for water baths.

Currier and Nelson (1969) conducted a study on 10 healthy subjects (22-37 years). They examined the effects of active exercise (riding bicycle ergometer for 5 minutes with 60 repetition per minute) and passive heating (SW; irradiating the lumbosacral area for 20 minutes, PRR 13.56 Hz) on motor nerve conduction velocity. Delivering supramaximal stimuli of 100 μsec repeated every 1 second, they measured motor nerve conduction in the peroneal nerve. The recording electrodes were positioned 4 cm apart with the proximal electrode placed over the belly of the muscle (extensor digitorum brevis) and the distal electrode over the tendon of the muscle. SkT was monitored along the course of the nerve at the site of the electrodes using a thermocouple. Rectal and oral temperature was measured using standard clinical thermometers. Although both treatment programmes resulted in an increase in nerve conduction velocity, exercise resulted in a greater increase (3.36m/sec) compared with the increase with PSWT, which was not significant (p>0.05). Despite the findings not being significant (p>0.05) diathermy has shown a greater CorT increase (0.33°C) compared to Exercise (0.09°C). The authors of this work did not report the dosage they used for the PSWT and whether it was used on the pulsed or the continuous mode. Their non-significant results reported could be attributed to the small number of subjects employed in their study.

3.1.3.1 Animal studies

Wilson and Jagadeesh (1976) have examined the effects of PSWT on the rate of nerve regeneration. In 132 rats they divided the median and ulnar nerve in the rats forefoot and removed a segment that measured 2 mm, they reapposed the nerve ends and closed the skin. Half the sample was treated with PSWT for 15 minutes a day, the rest acted as controls. The rate of regeneration was monitored using nerve conduction studies and histology. It was found that nerve conduction in some of the treated rats returned after 12 days, though it required that the stimulus strength be ten times higher than it was before surgery. After 30 days all rats had normal NCV compared to the controls, which after 60 days only showed a flicker in the response. Histology examination showed fibrosis around the nerve in the controls. There was less fibrosis and scarring in the treated group. It was found that large diameter fibres were slower than small fibres in reappearing.

The same authors conducted another study on cats, which underwent hemicordotomies. The cats were treated with half an hour daily for a month with Diapulse (field strength of 50 milliwatt per square cm and 400 PRR). After 3 months the animals were sacrificed and dissected. As with the previous experiment, the scarring in the treated group was less with an abundance of regenerating neurons showing in histology.

With both experiments insufficient details were mentioned on treatment equipment and parameters, electrode type, and statistical analysis. The second experiment on cats the sample size was not mentioned.

Raji and Bowden (1983) conducted a study to investigate the effects of PSWT on the regeneration of the common peroneal nerve in rats. The left common peroneal nerve was exposed and crushed above the knee in half the sample (n=12) while it was cut with a razor in the other half (n=12). In both groups, a 3 cm section was removed

from the nerve. The right side acted as a control. PSWT (Diapulse) was delivered on 400 pps, PD 65 μsec, PP 15.2W, for 15 minutes a day. Animals were paired and one was treated with active PSWT and the other was treated with sham PSWT. Temperature was measured every 5 minutes before intervention, immediately after PSWT, and for an hour after PSWT. It was measured from the skin, rectum, and deep tissues using thermocouples and an electrical resistance thermometer, the depth of the measured tissues was not mentioned. Animals were sacrificed at 3½ days, one week, two weeks, three weeks, and four weeks and at eight weeks post operation for dissection. Response to treatment was accomplished using microscopy, photographs and functional activity level (playing, gait, grooming, absence of foot dorsiflexion, presence or absence of toe spreading). There was a significant increase in temperature recorded with all three recordings ($p<0.05$) during treatment. SkT declined gradually after treatment reaching baseline reading within 35 minutes. There was rapid functional recovery both after crushed and sectioned nerves with a difference in times. Whether the nerve was crushed or sutured there was less swelling and adhesion in the treatment group compared to sham treated group. However, insufficient information was provided on the difference in time scale of recovery in crushed and sectioned nerves. The ambient temperature fluctuation was around 5°C, which means that its effects on the outcome cannot be discarded. The animals were placed on the PSWT treatment head during irradiation which means whole body irradiation not leg treatment has been administered. This means the amount of energy delivered to the animal in relation to its size is large as such direct extrapolation of findings to human should be done with caution.

Another study was conducted by Raji (1984) to investigate the effects of PSWT on nerve repair. The peroneal nerve in 24 rats was cut with a razor and the skin above the nerve was sutured after ensuring that the ends of the nerve were in apposition. The

other leg in each rat served as control. PSWT (Diapulse) was set on peak power 4, 400 PRR for 15 minutes in half the sample while the other half received sham PSWT. A calibrated thermograph was used to measure skin, rectal and deep tissue temperature every 5 minutes before treatment, during the treatment and post treatment for an hour. Functional rat activities was monitored in terms of playing, gait, grooming, absence of foot dorsiflexion, presence or absence of toe spreading. Paired animals were sacrificed 3½ days, one week, two weeks, three weeks, four weeks and at eight weeks for dissection. Outcome was compared in terms of myelinated nerve fibre counts, and axon diameter measurement. There was a recorded temperature increase of 3.6°C in skin, 4.4°C rectal, and 3.6°C in the deep tissue post treatment, though the depth of measurement was not mentioned. There was a significant difference between the treated and non treated group in the size and magnitude of adhesions and fibrosis at the site of surgery ($p< 0.01$). The untreated group showed more adhesions and fibrosis which made dissection more difficult compared to the treated group. A progressive improvement in function and regeneration with newly formed collagen fibrils, less swelling of stumps, evidence of axonal sprouting, accelerated phagocytosis and fibroblastic activity. There was an increase in the number of vessels within the endoneurium at and above the site of trans-section in the treated group. The outcome of this study however is promising in terms of the effects of therapeutic SW on nerve regeneration, and the fact that less adhesion existed around the nerve post sectioning is promising and could have its clinical implications, however, more investigations on humans are a prerequisite to validate the outcome on human.

A study conducted by Zienowicz et al (1991) examined the effect of pulsing SW on nerve regeneration. In the first part of the study, they looked at the interaction between the timing of the nerve surgery, and the process of healing in n=48 rats divided

into eight groups. In a complex procedure, the rats either underwent an immediate repair or delayed nerve repair (after 5 days). At each stage, the rats were either assigned standard care or PSWT (coil electrode, PRR 2 Hz, PD 20 μs, amplitude 3G) for 4 hours per day for 5 days. Rats were assessed at day 45, 75, 105 and 140 for walking ability and functional level. The results of this phase demonstrated that the timing of pulsing PSWT was a crucial factor in the rate of recovery. Immediate pulsing of PSWT delayed the healing compared to delayed treatment (after 5 days).

The second phase was undertaken to determine the effect of exposure time on the rate of healing. Ninety rats were divided into 6 groups each containing 15 rats. Group 1 had no PSWT, group 2 had PSWT only before surgery, group 3 had PSWT before surgery and post surgery for 5 days, group 4 had PSWT before surgery and after surgery till day 165, group 5 had PSWT only after surgery for 5 days and group 6 had PSWT post surgery till day 165. PSWT parameters were set the same as phase 1. Rats were evaluated on day 1, 21, 45, 75, 105, and 165. The results showed no difference between groups. Unfortunately the authors fail to mention the carrying frequency of their equipment, only mentioned the parameters of their treatment, as such difficult to speculate whether it was of 27.12 MHz or not. In addition, in the second phase of the study details were not provided on the time of exposure, which was varied with different groups and a major factor in judging the study outcome.

Despite the very limited number of experimental studies undertaken to examine the effects of PSWT and nerve conduction, the findings of the above mentioned studies point to a direction of interaction between PSWT and the process of regeneration of peripheral nerves. Such mechanism warrants further exploration.

A Summary of the studies discussed above is presented in Table (3.1)

Study	Sample Size	Power calculation	Blind	random	control	Treatment Dose						Other intervention	Outcome measures	Findings
						Machine Brand make	PD (μ sec)	PRR (Hz)	T (min)	PP (W)	MP (W)			
Erdman, 1960	20	NM	NM	NM	NM	NM	NM	NM	NM	410-1025	NM	PSWT for epigastrium followed by feet	PPG for bl flow Thermocouples for SkT	Bl ↑ in 8 min, levelled within 35 min Mean SkT under Rx head 0.5C-2 No change in RT 30 min post Rx, temp went to baseline
Morrissey, 1966	28	NM	NM	NM	NM	NM	NM	NM	NM	NM	40 80	Irradiating leg 15 min Irradiating epigastrium 15 min Irradiating leg +epigastrium for 15 min	PPG for bl flow Copper thermocouples for SkT	Significant increase in bl with 80W but not 40W
Abramson et al, 1966	29	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	PPG filled with histamine PPG filled with hot water PPG filled cold water	NCV for median and ulnar PPG for bl flow Copper thermocouples for IMT	Heat ↑ NCV, bl flow, SkT Cold bath ↑ in NCV, IMT, SkT, not bl flow Histamine did not alter NCV but changed bl flow significantly Higher ↑ with ulnar compared to median
Voltonen et al, 1973	10	NM	NM	NM	NM	Diapulse	65	600	15	NM	38	Rx given abdomen CSWD using pad electrode and condenser, mild heat, 15 min CSWD using circuplode, mild heat, 15 min	Thermocouples for SkT	All intervention ↑ SkT At 15 min highest recording of SkT compared to 5 min
Wessman & kottke, 1967	10	NM	NM	NM	NM	NM	NM	NM	80	NM	16	PSWT on abdomen	PPG for bl flow Thermocouples for SkT in feet and leg Mercury thermometer for OT PulsR measured from wrist Bl pressure estimated by auscultatory method	No significant relation between SkT and bl flow ↑in calf and foot temperature ↑ in OT ↑ in PulsR

Table (3.1) Summary of studies conducted on the physiological effects of PSWT

Study	Sample Size	Power calculation	Blind	random	control	Treatment Dose						Other intervention	Outcome measures	Findings
						Machine brand	PD μ sec	PRR Hz	T min	PP W	MP W			
Currier and Nelson, 1968	10	NM	NM	NM	NM	NM	NM	NM	20	NM	NM	Ex 5 min riding ergometer bicycle Lumbosacral SW	NCV (100μsec, every 1 sec) in Peroneal nerve Clinical thermometer for RT & OT	↑ NCV was higher with Ex compared to PSWT CorT ↑ was higher with PSWT compared to Ex
Heick et al, 1991	8	NM	NM	NM	NM	Ultratherm	NM	NM	20	400	NM	US 1.5W/ cm^2 5 min on abdomen with IUD	Thermometer for RT and uterus temperature	Both modalities are safe to use No increase above 38.1 was recorded
Oosterveld et al, 1992	42	NM	NM	Yes	NM	Curapuls 419	NM	NM	15	NM	180	Ice chips 30 min Nitrogen cold air for 6.4 min Lingo paraffin 10 min Rx given to knee	Infusion needle for IAT Medical thermometer for SkT SF triceps, biceps, subscapular, iliac crest	No statistical difference in SkT between ice chip and nitrogen air There was statistical difference in joint temp with ice and cold air Wax ↑ SkT more than PSWT Latent effect of cold therapy is longer than heat therapy
Draper et al, 1999	20	NM	NM	NM	NM	NM	400	800	20	NM	48	None	Needle therrmistor for IMT in gastrcnemius at 3 am depth	↑ IMT by 4°C Heat peaked after 15 min, levelled for 5 min and started to ↓
Burden and Mitchell, 2000	19	NM	Yes	Yes	Yes	Megapulse II	65	400	15	150	3.25	Rx on quadriceps	PPG for bl flow	↑ bl flow
Garrett et al, 2000	16	NM	NM	NM	NM	Megapulse	400	800	20	150	48	US 1MHz, 1,5W/cm^2 Half sample started with US followed by PSWT and the rest was given opposite	Needle thermistor for IMT at proximal, middle and distal points at triceps surae	Middle point displayed highest ↑ in IMT PSWT displayed higher temp ↑ compared with US

NM: not mentioned, PPG: plethysmograph, SkT: skin temperature, IMT: intramuscular temperature, IAT: intra-articular temperature, OT: oral temperature, RT: rectal temperature, Rx: treatment head, IUD: intra uterine device, ↑: increase, ↓:decrease

Table (3.1) Summary of studies conducted on the physiological effects of PSWT

3.2 DISCUSSION

The previous sections have reviewed the literature on the experimental studies conducted to-date with PSWT. The review covered areas such as the interaction between PSWT and blood flow, nerve conduction, skin and muscular temperature and nerve regeneration.

Although some studies have demonstrated that PSWT may have some effect on changing body temperature or blood perfusion, absence of the treatment dosage used makes these reports of limited value. The paucity in the number of studies conducted highlights the importance of conducting more studies that examine wider ranges of treatment parameters and subject PSWT for further extensive experimentation in order to be able to state with certainty that the effects observed with treatment are a genuine response not just a possible placebo effect. Additionally, researchers in the field need to pay more attention to the quality and the amount of reporting for their work in order for it to be informative.

To illustrate the point discussed above on the quality of the published reports, the studies discussed above were further classified according to their quality of reporting in the Table (3.2).

Study Author & Year	Topic	MP of PSWT	Random Allocation	Blindness	Control group	Power calculation
Erdman, 1960	Blood flow	16	NM	NM	NM	NM
Abramson et al, 1966	Motor nerve conduction	NM	NM	NM	NM	NM
Morrissey, 1966	Blood flow	40, 80	NM	NM	NM	NM
Wessman & kottke, 1967	Blood flow, temperature, pulse	NM	NM	NM	NM	NM
Currier and Nelson, 1968	Motor nerve conduction	NM	NM	NM	NM	NM
Voltonen et al, 1973	Blood flow	38	NM	NM	NM	NM
Oosterveld et al, 1992	Core & intra-articular temperature	180	Yes	NP	NM	NM
Draper et al, 1999	Intramuscular temperature	48	NM	NM	NM	NM
Garrett et al, 2000	Intramuscular temperature	48	Yes	NM	NM	NM
♦Burden and Mitchell, 2000	Blood flow	3.25	Yes	Yes	Yes	NM

Table (3.2) Quality of the studies conducted on the physiological effects of PSWT

♦Abstract from conference proceedings

NP: not possible, due to the nature of the modalities involved

It can be seen from Table (3.2) that the studies conducted to date on the physiological effects of PSWT were scarce in number and the majority were not controlled and a lot of the information crucial for making informed clinical decision is lacking. Such issues justify the importance of conducting studies that utilise carefully controlled methodology and cover wider ranges of setting of PSWT.

3.3 CONCLUSION

Given the amount of time that PSWT has been employed clinically, it is surprising that only a very small number of studies have examined its efficacy in terms of changes in physiological parameters. At present there is very little evidence to support the athermal physiological effects. The work conducted however was only on healthy subjects with no attempts to explore the physiological reactions of a patient population, with the majority of the studies examining the maximum setting of PSWT

machine. More experimentation is still needed to elucidate PSWT mechanism of action especially on the lower power settings.

CHAPTER 4

LITERATURE REVIEW ON PSWT EFFICACY

4.0 INTRODUCTION

PSWT has been used by physiotherapists for decades to manage a wide range of pathologies. It has been the source of interest for many researchers in the last few years, especially with surveys in the UK showing it to be one of the top three modalities employed by therapists in the clinical setting (Pope et al, 1995). PSWT has been used clinically to reduce pain, enhance the rate of healing, encourage the resolution of haematoma and oedema and reduce the symptoms associated with OA and RA (Scott 2002; Low and Reed, 2000). Nevertheless, a lot of uncertainty exists regarding the efficacy of PSWT and how to best set its parameters.

This chapter reviews the literature published to date discussing the use of PSWT with various conditions. Following the reporting of the studies, a compilation of the dosage was made and examination of their impact on the outcome was undertaken in attempt to explore further the concept of windows of effectiveness with PSWT. The studies discussed cover areas such as rheumatology, musculoskeletal conditions, wound healing and pain. Search strategy is explained in Appendix G.

The term SW will be used when no parameters are mentioned that could identify whether the application was on pulsed or continuous mode.

4.1 RHEUMATOLOGY

Several research papers were located examining the effect of PSWT on "arthritic" symptoms in the knee (Ganguly et al 1996; Klaper-Moffett et al 1996; Jan and Lai 1991; Leclaire and Bourgouin 1991; Svarcova et al 1988; Quirk et al, 1985). In general the findings of the studies were in favour of positive outcomes with the majority reporting improvement in function and reduction in pain (Ganguly et al 1996; Klaper-Moffett et al 1996; Jan and Lai 1991; Leclaire and Bourgouin 1991; Quirk et al, 1985).

In studies where PSWT was compared to other treatments or other interventions it was found to be more effective than placebo (Klaper-Moffett et al 1996; Quirk et al, 1985) and no better than US, IFC, Exercise (Ex), and stretching (Ganguly et al 1996; Jan and Lai 1991; Leclaire and Bourgouin 1991; Svarcova et al 1988; Quirk et al, 1985).

Early work was conducted by Quirk et al (1985) who randomly allocated 38 patients complaining from OA knees, into three experimental groups: group 1 had Ex and IFC, group 2 had Ex and SW and group 3 had Ex alone. IFC was given for 10 minutes, 0-100 Hz rhythmical frequency followed by 5 minutes at 130 Hz. SW was delivered for 20 minutes using capacitive electrodes, and no other parameters were reported. All groups performed exercises twice daily: straight leg raise repeated twice for 30 times with a 10 minutes hold, and free knee flexion repeated 10 times twice a day. Patients were encouraged to continue taking their medication. All treatments were given 3 times a week for a period of 4 weeks except the exercise group who had to attend less frequently. Outcome measures were ROM, Ex endurance (which included the distance walked and the number of stairs the patient can manage), maximum knee girth, subjective pain measurements (using visual analogue scale (VAS) and a verbal scoring technique), and functional capacity, which included gait, method of climbing the stairs and the use of a walking aid. The outcome was measured by an impartial physiotherapist before the start of the trial, on completion of the trial, 3 and 6 months post trial. All three groups showed improvement in the level of pain (IFC $p<0.002$, SW $p<0.05$, Ex $p<0.03$) and an overall improvement in their clinical condition (IFC $p<0.004$, SW $p<0.02$, Ex $p<0.03$), however no protocol was better than the other. Although electrotherapy had a significant effect on increasing knee ROM ($p<0.05$), none of the protocols had any effect on knee girth. There was a general deterioration in all groups in 3 month follow up, however the overall condition remained to be better

than the pre-treatment status. Unfortunately, the authors failed to mention SW parameters, and whether the application was on pulsed or continuous mode. They also failed to provide enough information on the 4th follow up which was 6 months post trial. No information was mentioned regarding the method by which patients were randomised into groups or what factors were used to match patients.

Another study conducted by Svarcova et al (1988) compared the effects of treating OA with US, galvanic current, and PSWT. The study employed 180 patients complaining from either unilateral or bilateral hip and knee OA. Patients were divided into 3 groups of 60 patients each. There was no mention of whether the patients were randomised or just divided into experimental groups. Half the patients in each group were given Ibuprofen 400mg twice daily and the other half was given placebo tablets to further assess the analgesic effects of physiotherapy modalities with and without medication. US was administered for 5 minutes to the knee medially, posteriorly and laterally with the US treatment head moved at a velocity of 5 cm/sec, no other dose parameters were given. Galvanic current was applied for 20 minutes at a current density of 0.1 mA /cm^2. PSWT was given for 2 minutes medially and another 2 minutes laterally with a PP 700W and PRR of 46 pps using either Curapuls or Diapulse. All patients received 10 treatments at 2 day intervals over a total of 3 weeks. Pain level was assessed after 5th and 10th session using VAS, and was also assessed on completion of the trial by both the patient and physician using excellent, good, no benefit and worse criteria. No statistical difference was noticed between all three types of physiotherapy, however a better outcome was obtained when active treatment (electrotherapy) and drug were combined. The study however, did not use a control group and the time of exposure for PSWT was very short and unlikely to achieve therapeutic effects. The authors also failed to discuss the reliability and the reproducibility of the scale used to

rate treatment outcome. As such it is speculated that the outcome measures used were not stringent or reliable enough to detect differences between groups. Furthermore, the authors used 3 different machines to deliver galvanic current (Eltron D, Dinapuls 424 or Diadynamics) and the same was done with SW treatments (Curapuls and Diapulse). The output of that equipment is not necessarily the same, as such it was expected that the amount of energy delivered to the tissues was not identical which reveals a flaw in the methodology and a lack of consistency, which may have affected the findings.

The work above was followed by another study conducted by Jan and Lai (1991). They examined the effect of applying PSWT to 61 female patients complaining of either unilateral or bilateral OA knees. The patients were either assigned to electrotherapy or electrotherapy with Ex (straight leg raise for 200 repetition a day) for 4 times a week. The sample was divided into four groups US, SW, US and Ex, SW and Ex. Treatment was randomised but it was not mentioned how this was achieved. The treatments were continued until significant or total relief was detected. Electrotherapy was either US for 10 minutes or PSWT for 20 minutes, no other description of the US or PSWT dose was given. Pre and post trial assessment was done using functional incapacity score (FIS), peak torque flexion and extension using Cybex II isokinetic dynamometer. The outcome was rated according to X-ray findings using a Standard Radiographs of Arthritis Scale, Body Mass Index, Peak Torque for knee flexors and extensors and FIS. Patients responded positively to the treatments with no significant difference among the four groups ($p<0.05$). The findings however, point towards better outcomes when electrotherapy was combined with Ex. The findings of this study were of limited clinical value as the study was not controlled, the authors failed to mention electrotherapy parameters whether it was for US or SW and also the mode of the SW application (continuous or pulsed). Additionally, the authors failed to mention whether

patients were randomly assigned to groups or whether they were divided into groups according to convenience and how were the experimental groups matched at baseline.

In contrast with those findings, Leclaire and Bourgouin (1991) have reported PSWT to have no benefit over placebo treatment. In a triple blinded trial (where patients, therapist, and investigators were blinded from the purposes of the trial), and according to a comprehensive inclusion criteria, 47 patients with periarthritis of the shoulder were randomised and matched to either a treatment (SW, hot pack, Ex) or a placebo group (hot pack and Ex). PSWT was given using Magnetopulse for 30 minutes at PRR of 10 Hz for the first 6 sessions, and at PRR 15 Hz onward till session 16 and then at 30 Hz PRR from session 17 to the last session. Treatment was administered 3 times a week for 12 weeks or until complete remission of symptoms. All patients were also given hot packs for 20 minutes, 5 minutes passive glenohumeral stretching, 10 minutes pulley exercise, and 20 minutes active non-assisted wooden stick Ex. Changes in movement was recorded at baseline and monthly thereafter however there was no reporting on how movement was evaluated. Changes in pain level were recorded at baseline and weekly thereafter using VAS. A similar scale was used to assess activity. Authors concluded that PSWT was no better than control although no control was employed as all patients in both experimental groups received a hot pack, and Ex. The authors however, failed to mention the rationale for the choice of the treatment parameters or the reason for giving a certain dose for the first 6 sessions then changing it in the next 9 sessions then again changing it for the last few sessions. Furthermore, outcome whether it was pain or level activity was only assessed subjectively using VAS.

In a clinical trial by Ganguly et al (1996) 35 patients with rheumatoid polyarthritis were randomly assigned to either active or placebo PSWT treatment. They

used a specially designed PSWT unit by the authors. The unit delivers a train of pulses with duration of 0.2 ms and inter-pulse period of 0.7 ms, no parameters were given for the PRR, PP or MP. Treatments were given to every affected joint 3 times a week for 15 minutes. Outcomes measures were pain, tenderness, swelling, joint functional disability. Patients were evaluated weekly, and at 3, 12, 18 months post trial. Both the seropositive and the seronegative groups demonstrated improvement with the latter demonstrating better results. This study however did not use a control group, neither did the authors mention clearly the treatment parameters such issues detracts from the value of findings. Moreover, the methodology was not standardised as 11 of the 35 were having medical, surgical, gynaecological problems for which they were taking treatment. The eleven patients were later withdrawn from the study because of their absenteeism and irregularity of treatment. It was not mentioned clearly though at what stage this was done and whether their initial data were entered into the statistical analysis. The authors chose the most affected joint for analysis as such there was no uniformity in the analysis.

Klaber-Moffett et al (1996) conducted a double blind study on 30 patients complaining from hip and knee OA. Following an inclusion and exclusion criteria patients were randomly assigned to dummy PSWT, control group, or active PSWT group. All patients underwent all experimental conditions. PSWT was delivered using Ultratherm IIS 601, circuplode for 15 minutes on 23W MP, and PF 82 Hz for 3 weeks. Therapists were blinded from treatment and placebo. PSWT was achieved using equipment modified by manufacturer where half the numbers on the dial are inactive and the other half were active. PSWT was used following a pilot study on 45 subjects. Three PSWT protocols were employed to deliver 23W MP a mode that was considered athermal by the authors (200 pps, 110 pps, 82 pps). Outcome measures were a battery of

Study	Sample Size	Condition	Blind	Random	Control	Treatment Dose						Other intervention	Outcome measures	Findings
						Machine make	PD (μ sec)	PRR (Hz)	T (min)	PP (W)	MP (W)			
Quirk et al (1985)	38	OA knee	NM	Yes	NM	NM	NM	NM	20	NM	NM	IFC 10 min, 0-100Hz followed by 5 min 130 Hz Placebo Ex twice daily, straight leg raising x30 Knee flexion x10	ROM Ex endurance: walking distance, no of stairs Knee girth VAS Functional analysis	Rx group ↓ in pain ↑ functional level No change in knee girth No protocol was better than other (p<0.05)
Svarcova et al (1988)	180	OA hip and knee	NM	NM	NM	Diapulse Curapuls	NM	46	4	700	NM	Half sample Ibuprofen 400mg US 5 min Galvanic current 20 min, intensity 0.1mA/cm^2	FIS Isokinetic flexor and extensors	No statistical difference between groups
Jan and Lai (1991)	61	OA knee	Yes	Yes	NM	NM	NM	NM	20	NM	NM	US 10 min US/ Ex SW/Ex	X-ray Body mass index Peak knee flexors and extensors FIS	Improvement recorded with no protocol better than other (p>0.05)
Laclaire and Bourgouin (1991)	47	Peri-arthritis shoulder	Yes	Yes	Yes	NM	NM	10 15 30	30	NM	NM	All pt received 20 min hot pack, 5 min stretching, 10 min pulley ex, 20 min wooden stick ex	Movement amplitude VAS ADL	↓ in pain level Improve disability score ↑ ROM
Ganguly et al (1996)	35	RA knee, MCP	NM	Yes	NM	NM	40	NM	15	NM	NM	Placebo	Pain level, Joint spasm Deformity, swelling Functional disability	General improvement in parameters monitored
Klapper Moffett et al (1996)	92	OA knee and hip	Yes	Yes	Yes	Ultramed	NM	200 110 82	15	NM	23	Placebo Control group	Pain evaluation ADL General Health questionnaire	Both active treatment and placebo achieved better outcome compared to control Placebo returned to baseline on follow up

MP: mean power, NM: not mentioned, nm: nanometer, PP: peak power, T: time, ADL: activities of daily living, Rx: treatment, FIS: Functional incapacity score, pt: patient, MCP: metacarpophalangeal

Table (4.1) Summary of clinical trials on Rheumatology

subjective tests (pain diaries, VAS for local and referred pain, nature of pain, general health questionnaire, activities of daily living (ADL). All patients were taught simple hip and knee Ex. Assessment was carried out pre/ post trial and a follow up was done after 3 weeks. Summary of all studies can be found in Table (4.1).

Findings have showed no significant difference between placebo and active treatment groups. The placebo group reported more reduction in pain though this did not reach statistical significance.

Interestingly, patients who were on the waiting list for surgery have reported better outcomes than those who were not awaiting surgery denoting a possibility of placebo effect. The authors have used MP of 23W as an athermal mode of treatment however, this mode has been shown repeatedly in the literature to be thermal (Murray and Kitcken, 2000; Bricknell and Watson, 1995). Moreover, the study has only employed subjective outcome measures, which may be less sensitive in picking up differences between groups eventually ending in insignificant results.

In summary, the studies above had their flaws however, their limited contribution to the literature cannot be ignored. The studies have presented equivocal evidence on PSWT effectiveness with rheumatology, though the trend is towards positive outcomes. This limited evidence highlights the need for conducting more randomised trials to clarify the role of PSWT in rheumatology.

4.2 MUSCULOSKELETAL

4.2.1 Subdeltoid bursitis

Early reports on the use of PSWT for soft tissue injury were published in 1961 by Ginsberg (Ginsberg, 1961). The reported cases were on sub-deltoid bursitis. The outcome of conditions treated over a period of 15 years were collated and analysed. The

PSWT machine employed for the study was built by the author and operated on a frequency of 27.12 MHz. Ninety four subjects were treated with PRR 600 Hz, intensity 6 for 10 minutes at the affected site and another 10 minutes at PRR 400 Hz intensity 4 directed at the liver and the adrenals. Findings were encouraging in that 86 of those subjects had partial to complete recovery with X-ray signs of Ca^{++} re-absorption. Unfortunately, the author failed to mention the number of sessions given to patients to reach these findings. There was inadequate reporting of the treatment parameters (power setting whether it was PP or MP). The study was also lacking a control group and statistical analysis, which makes it hard to exclude the effect of chance on the findings.

4.2.2 Ankle sprain

Several research papers were located examining the effect of PSWT on ankle sprain (McGill, 1988; Barker et al, 1985; Pasila et al, 1978; Wilson, 1974; Wilson, 1972). The use of PSWT with ankle sprain was found to be better than CSWD (Pasila et al, 1987; Wilson et al, 1974), and placebo (McGill, 1988; Santiesteban and Grant, 1985; Barker et al, 1985; Wilson, 1972).

Wilson (1972) conducted a study employing 40 patients complaining of ankle sprain (36 hours) to either a placebo PSWT or active PSWT (n=20 in each group, it was not clear whether they were randomised or not). Patients were matched for age, weight, sex and degree of trauma. The PSWT group was treated with Diapulse (65 μsec) for an hour daily for a period of three days (no other parameters were mentioned). The ankle in both groups was bandaged and all patients were given same standard care (Ex, and instruction). Assessment was done pre and post trial for swelling, pain and disability according to a grading system that was developed by the authors. Findings were in favour of PSWT treatment with improvement in pain, disability, and swelling ($p<0.05$).

The same author (Wilson , 1974) conducted another trial to examine the effect of PSWT on ankle sprain, however, instead of using placebo, active PSWT was compared to CSWD. CSWD was applied via an inductothermy cable wrapped around the foot and ankle, intensity 2, no other parameters were mentioned. Two fifteen minute treatments were given in one hour for 3 days. PSWT was delivered as in Wilson (1972). Using same number of patients and same outcome measures, improvement was noticed after 3 days and results were in favour of PSWT with 82.8% improvement with PSWT compared to 44.2% with CSWD. However, this kind of improvement is expected as the energy delivered differed with the two modalities (complete hour in PSWT compared to two 15 minutes with CSWD). Despite the difference in application time, the findings suggest that a better outcome is associated with longer treatment duration. The authors failed to report full parameters such as the frequency and the power setting of PSWT machine.

Pasila et al (1978) conducted a study to examine the effects of both Diapulse and Curapuls on ankle and foot sprain. Three hundred patients were randomised into three groups: Diapulse, Curapuls and placebo PSWT, with n =100 in each group. Diapulse was given on MP 38 W, Curapuls was given on MP 40 W and no other parameters were mentioned. Treatment was delivered for 20 minutes. Outcome measures were muscle strength measurements using dynamometer, ROM, gait impairment. Weight bearing on toe and heel was also measured but it was not clearly described how it was done. Swelling was measured by tape and by fluid displacement. Treatment did not change muscle strength, or affect weight bearing. There was a small change but not statistically significant on ROM. There was a significant decrease in swelling in the Curapuls group ($p<0.01$), significant improvement in gait has been found with the Diapulse group ($p<0.01$). Although the groups were matched at baseline the difference in findings with

the two PSWT machines was interesting, the authors did not propose any explanation for it. The authors also failed to mention full treatment parameters.

In a double blind, non-controlled clinical trial Barker et al (1985) investigated the therapeutic effects of PSWT on lateral ligament sprain of the ankle. Seventy three subjects were randomly assigned to active or placebo PSWT (Therafield Beta, PRR 640 pps, low intensity). Treatment lasted for 45 minutes on three consecutive days. Outcome measures were ROM using goniometer, gait analysis using a purpose designed walkway, pain levels using VAS, and swelling using water displacement techniques. Assessment was done pre and post treatment. All patients received elbow crutches, advice to elevate the leg, analgesics (paracetamol) and the ankle was bandaged. The authors concluded that there was no statistical difference between the two groups however the active PSWT was superior to placebo treatment. Findings were reported in terms of active and control group while the authors have used active and placebo group. No rationale was given for the choice of treatment duration and the PSWT parameters were not comprehensively mentioned.

In a double blind trial McGill (1988) explored the effect of PSWT on 37 patients between the ages of 16-60 who had sustained a lateral ligament injury to the ankle 48 hours previously. The subjects were randomly allocated to a placebo PSWT or a PSWT group (Bosch Ultramed, PRR 82 Hz, intensity 6, MP 16.9W, 15 minutes for 3 consecutive days). Treatment was decided according to a number that was pulled out in the randomisation stage. Both groups were given tubigrip, advice, axillary crutches, analgesics and a diary to record drug consumption and the number of hours the leg was kept elevated. Patients were assessed by a blinded therapist prior to and after the treatment using water displacement for ankle oedema, VAS for pain levels, and the amount of medication consumed. The blinded therapist also analysed gait, colour of the

ankle, ankle mobility and static muscle strength. No significant difference was noted between the groups in the variables monitored. However, because the study was not controlled and traditional treatment (which included advice, analgesics, crutches and tubigrip) was continued with both experimental groups it was difficult to exclude the effect of natural course of healing.

4.2.3 Hand injuries

In a large trial Barclay et al (1983) conducted a study on 230 patients complaining from hand and thumb injury. Subjects were paired and assigned to either a control group (n=116) or a treatment group (n=114). PSWT was delivered using a monode with PP 975W for two 1/2 hours daily. Patients in both the control and the active group received conventional treatment, which was not described. Patients were assessed before and after the trial and on day 3,5,7 post treatment for swelling using water displacement, disability and pain following categorical criteria developed by the author. The non-injured hand was used as a control for the same patient. Findings were in favour of PSWT as the results have shown it to relieve pain, reduce swelling, and improve function in patients who have sustained a hand injury in the last 36 hours. However, the authors failed to mention the duration of the treatment course when using PSWT for the findings to be of value clinically. It was not clear whether they treated patients using the PP of the PSWT or they were only reporting the PP of the machine they used. Moreover, if the maximum PP was used to treat recent injuries this means that the patients were in danger of exacerbation of their symptoms because of the possibility of heat developing in the tissues.

Summary of the studies can be found in Table (4.2).

Study	n=	Condition	Blind	Random	Control	Treatment Dose						Other intervention	Outcome measures	Findings
						Machine brand	PD (μ sec)	PRR (Hz)	T (min)	PP (W)	MP (W)			
Ginsberg (1961)	94	Sub-deltiod bursitis	NM	NM	NM	Designed by author	NM	NM	20	NM	NM	10 min liver application 10 min shoulder application	X-ray findings Patient reporting	86% had partial to complete recovery
Aronofsky (1971)	90	Dental wound	NM	NM	Yes	Diapulse	65	600	15	975	NM	Control group 2 PSWT group (group 1 PSWT pre-post op, Group 2 PSWT only post op)	VAS Subjective clinician evaluation of improvement	Pre-post operative group demonstrated best results compared to control or post operative group ($p< 0.05$)
Wilson (1972)	40	Ankle sprain	NM	Yes	NM	NM	65	NM	60	975	NM	Placebo PSWT 60 min	VAS Swelling Disability	Active PSWT achieved twice as better results as placebo
Wilson (1974)	40	Ankle sprain	NM	Yes	NM	NM	65	NM	60	975	NM	CSWD 2x 15 min daily	VAS Swelling Disability	PSWT achieved better results than CSWD
Bentall and Eckstein (1975)	62	Orchidopexy	NM	Yes	NM	Diapulse	NM	500	20 10	NM	NM	20 min local, 1 min intensity 4 epigastrium	Polaroid camera Circumferential measurement	Increase rate of healing
Pasila et al (1978)	300	Ankle sprain	NM	Yes	Yes	Diapulse Curapuls	NM	NM	20 20	NM	38 40	Placebo PSWT	Muscle strength ROM Circumference and oedema measurement Weight bearing evaluation	No significant difference between PSWT groups and placebo
Goldin et al (1981)	67	Open wound	Yes	Yes	Yes	NM	NM	400	NM	975	25.3	Placebo group	% of healing judged visually	Faster healing rate with active group, reported 90% improvement compared to 29% in placebo
Nicolle et al (1982)	19	Blepharo-plasty	Yes	NM	Yes	NM	NM	1000	24hr	NM	NM		Swelling Bruising	Out of 19 patients 11 improved, 2 worsen and did not respond to Rx
Barclay et al (1983)	230	Hand injuries	NM	NM	Yes	Diapulse	NM	NM	30x2	NM	293-975	Placebo PSWT	VAS Swelling Disability	Active PSWT lead to 3 times improvement compared to placebo group

Study	n=	Condition	Blind	Random	Control	Treatment Dose						Other intervention	Outcome measures	Findings
						Machine brand	PD (μ sec)	PRR (Hz)	T (min)	PP (W)	MP (W)			
Barker et al (1984)	50	Post op wound	Yes	Yes	Yes	NM	NM	250	60	NM	NM	Placebo PSWT	Fluid balance Presence of bowel sounds Level of tenderness	No change in fluid tolerance Bowel sounds ↓ with active PSWT
Barker et al (1985)	73	Ankle sprain	Yes	Yes	Yes	Therafield Beta	NM	640	45	NM	NM	Placebo PSWT	VAS ROM Gait analysis Oedema measurement	No significant difference between active and placebo PSWT
McGill (1988)	31	Ankle sprain	NM	Yes	NM	Bosch Ultramed	NM	82	15	NM	19.6	Placebo PSWT	Oedema measurement VAS Drug consumption Weight bearing evaluations	No significant difference between active and placebo PSWT

MP: mean power, NM: not mentioned, nm: nanometer, PP: peak power, T: time, ADL: activities of daily living, Rx: treatment, FIS: Functional incapacity score

Table (4.2) Summary of clinical trials on musculoskeletal

4.3 WOUND HEALING

4.3.1 Laboratory studies

4.3.1.1 Experimental wound healing

Only two laboratory research papers were located examining the effect of PSWT on the rate of wound healing (Hill et al, 2001; Badea et al, 1993). Both studies have presented evidence on PSWT effectiveness.

In 1993, Badea et al investigated the effect of PSWT irradiation on the rate of microbial growth in a sample of cells prepared in the laboratory, a setting that was designed to replicate the open wound situation. Their experiment was divided into several parts.

In the first part of the study, the specimens were irradiated with PSWT at maximum setting for 30 minutes. The aim of this phase was to discover if the application of PSWT at maximum setting would result in adverse reactions. The specimen was then irradiated with PSWT at 8 hours and 12 hours of growth, and an increase in cell number was demonstrated. They concluded from this part of the experiment that it was safe to apply PSWT for open wounds, as its application was not associated with any increase in bacterial growth. It was not clear though how did they reach this conclusion and how they extrapolate their conclusion to human wound healing.

They then repeated the same protocol but with the specimens at 30, 60, 90 minutes of growth (to represent different stages of the healing process). They found that PSWT interaction with the cell culture was most intensive at a narrow window between 60-90 minutes but not at 30 minutes. The authors have linked their findings to the active potentials and transport processes across the membrane that accompanies different phases of wound healing. Although the findings suggest a time window for effectiveness with PSWT it is hard to accept the findings due to lack of reporting of

comprehensive methodology and failure of the authors to explain in what way was the laboratory specimen seen as a wound.

In a similar laboratory setting, Hill et al (2001) investigated the effect of PSWT on human fibroblast. Using four single blind trials, adult fibroblast and chondrocytes were incubated for 5 days. The fibroblasts were irradiated with PSWT at MP of 48W for 10 minutes in order to explore if there was any kind of interaction between fibroblast and exposure to PSWT. It was found that the cell division increased significantly (p<0.001) with this application.

In the second part of the study the relation between the amount of energy and the rate of fibroblast proliferation was studied. On a sample of 16 cultures 7 exposure dosages were used (MP of 1, 3, 4, 8, 12, 48W). It was found that the best results were obtained with MP 12W (improvement was judged based on cell count). However, the PRR, PD was not reported for the above mentioned MP(s).

This was followed by another phase of the study, which was planned to investigate the effect of different patterns of energy on fibroblast proliferation. For this part of the study MP of 6W was delivered in three combinations (100 µsec/ 400 Hz-200 µsec/ 200 Hz- 400 µsec/ 100 Hz). This was done in order to examine the effect of different combinations PRR and PD with the same MP on cell number. On 11 samples, no statistical difference was found between different combinations. However, the investigators have demonstrated in the previous section that 12W has resulted in the highest fibroblast count, nevertheless they used 6W just because it was possible to reproduce 3 different pulse patterns using Megapulse II.

In the final part of the study, the effect of applying PSWT with different exposure durations was examined in relation to the rate of chondrocyte proliferation. A constant MP of 6 W was used with four exposure times of 5, 10, 15, and 20 minutes. On 91

samples, it was found that cell proliferation varied considerably with different exposure times. The highest level of proliferation was seen with a 5 minute application compared to longer treatments. The work on low output of 6W has clearly provided evidence for the window of effectiveness with specimens demonstrating response at a narrow time and energy window. Moreover, it was not mentioned the set up for irradiation and how many samples were irradiated at one time. The importance of that lies in the difference in field strength between the centre and the periphery, which may affect the field density if more than one sample was irradiated at the same time.

The above work suggests a positive outcome and favourable findings when the effect of PSWT was examined on the rate of cell proliferation. Although laboratory studies lack the thermodynamic mechanism found in human and may be considered not representative to human reactions (Luben, 1996), they still remain very crucial to the development of a clear understanding on PSWT interaction with biological systems. Studies conducted in laboratories enable researchers to have precise control on the experimental setting, and provide more possibilities for manipulating variables (Cleary, 1996). As such they remain the core of many advances in understanding cellular biology (Luben, 1996), by providing possible molecular mechanism for the effects of PSWT, and shedding some light on time/energy window suggested by previous work on EMF (Watson, 2000; Cleary, 1996; Luben, 1996).

4.3.2 Postoperative wound healing

Several research papers were found examining the effect of PSWT on postoperative wound healing (Arghiropol et al, 1992; Grant et al, 1989; Santiesteban and Grant; 1985; Nicolle et al, 1982; Bentall and Eckstein, 1975; Aronofsky, 1971). All studies reported reduction in pain, swelling, oedema and enhanced rate of healing.

Aronofsky (1971) examined the effect of PSWT on dental wounds. The treatment was delivered in two parts using a Diapulse (15 minutes, 600 pps, intensity 6), administered 24 hours prior to surgery and for another 15 minutes immediately before surgery. The operated site was then irradiated with PSWT for 10 minutes post surgery on the same dose and then again, at 24, 48, and 72 hours post surgery. Ninety patients were divided into 3 groups. Group 1 (n=30) had PSWT pre and post surgery, group 2 (n=30) had PSWT only post operative, and group 3 (n=30) had no PSWT. It was not mentioned if the sample was randomised or just divided into groups and whether there was a blinding of the patients or assessors. Outcome measures were size of oedema, pain, inflammation and swelling, which were recorded using a scale (none, moderate, good, fair, and poor). Despite all outcome measures being subjective, the author has reported substantial improvement for group 1 (pre-and post treatment) followed by group 2 when compared to control. Inflammation was present in 6.7% in group 1, and 53.3% in group 2 and in 76.7% in the control. The authors did not mention how soon postoperatively PSWT was given as this could have its clinical implications. No rationale was given for the choice of treatment duration or treatment dose.

In a double blind trial by Bentall and Eckstein (1975) the efficacy of PSWT was examined in relation to children undergoing orchidopexy. Fifty paired children were included in the study to undergo either active or sham PSWT treatment. PSWT was applied using Diapulse locally (550 pps, intensity 5, 20 minutes), followed by epigastrium application (500 pps, intensity 4, 10 minutes). The treatment was repeated 3 times a day for 4 days. Outcome measures were a series of photographs taken at different intervals, pre and postoperative circumferential measurements of oedema, bruises, and discolouration of the scrotum. All these variables were followed and compared from both subjective (photographs and amount of operative correction

needed) and objective (circumference measurement) data. Findings revealed that both direct measurement of circumference and other subjective findings demonstrated an increase in the speed of healing along with a quick return to normal appearance. However, no control group was used, as it would be interesting to gauge the level of recovery to the natural process of recovery. Additionally, detailed analysis of the rate of recovery of both treated and placebo group was lacking. No rationale was given regarding the choice of the parameters, or the reason for the epigastrum application, and the dose level reported is not transferable between equipment especially with the brand of PSWT not reported.

An interesting study was conducted by Nicolle et al (1982) to investigate the postoperative reaction to blepharoplasty. Authors used a small rechargeable, portable device that operated on 27.12 MHz. The device had a square pulse of 100 μsec and a coil of 6 cm in diameter. The coil was adjusted with a loop in the shape of a spectacle that could be held in place by bandages. Twenty one patients were recruited. Although outcome measures were subjective based on photographs taken on several occasions after the operation, the authors reported that six cases showed complete recovery and 11 showed remarkable improvements. Unfortunately, neither the PP nor the MP for the PSWT was mentioned and the same for the duration of exposure. Moreover, it is speculated that the function of portable PSWT might have been different from a therapeutic machine employed clinically despite operating on the same carrying frequency. It was not mentioned whether the investigators were blinded or not as this may have biased the outcome.

Santiesteban and Grant (1985) have conducted a study to examine the effects of active and placebo PSWT on wound healing. Fifty patients with foot surgery were recruited for the study (n=25 in each group). PSWT was delivered twice (immediately

after surgery, and 4 hours post first application) for 30 minutes, 95 μsec, power 12 (120 PP), 700 pps. Outcome measures were length of hospital stay, and analgesic consumption. Results showed that the PSWT group consumed less drugs and their length of stay was shorter than the placebo group. However, examining the data it could be seen that the difference in hospital stay between the two groups was 8 hours, which did not constitute a big difference. It could be added that because traditional treatment was continued, the limited reporting of statistics and the subjective outcome measures taken, it is hard to relate improvement to the effect of PSWT alone.

In accordance with the above findings was Grant et al (1989) who investigated the effect of PSWT on soft tissue injury by comparing the rate of recovery of perineal trauma after childbirth using either PSWT or US. Four hundred and fourteen subjects were randomly assigned to active US, active PSWT, or placebo modalities. US was given at a frequency of 3 MHz, pulse 1:4, intensity 0.5 W/cm² for 2 min, PSWT was given with Megapulse on 100 pps, 65 μsec for 10 minutes. Therapy was started 12 hours after delivery for 3 days. Outcome measures were extent of oedema, bruising, haemorrhoids, and analgesia taken. Over 90% of all women in all groups felt better with the treatment given. However, there was no significant difference between the groups immediately, 10 days, or at three months post treatment. It could be argued that the non-significant results could be due to the outcome measures employed, which were subjective and may not be sensitive in detecting the change.

Arghiropol et al (1992) studied the effect of using PSWT on the rate of healing of surgical wounds in 25 patients. Ten patients were randomly assigned to a control group and the other 15 constituted the PSWT group. PSWT (Diapulse) was started on the second day post operative, and was applied daily for one week for a period of 15 minutes on 400 pps, intensity 4 followed by hepatic application (600 pps, intensity 6, 30

minutes). Only the hepatic application was continued for the second week. They included the hepatic application in order to investigate the relation between the production of plasma fibronectin (which is a glycoprotein synthesized by the liver and was associated with wound healing) and healing process initiated by PSWT. Objective measures included laboratory tests, fibronectin count, blood tests, appearance of oedema, bruise, and haematoma. Laboratory findings were also correlated with other objective outcomes measures such as level of haematoma and oedema. Increase in fibronectin concentration was observed as an indication of the increase in the rate of wound healing, which is a subjective outcome measure. However, the authors failed to mention the sites of the wounds. It is expected that different body parts may react differently to the applied current (Odia and Aligogun, 1988) and this may have effect on the rate and the speed of their recovery. It was not mentioned why the PSWT application on the operated area was stopped and only the hepatic application was continued.

4.3.3 Skin graft

Goldin et al (1981) examined the effect of PSWT on the rate of skin graft healing. They employed patients aged between 15-65, with a medium thickness split skin graft. Patients were randomised to either a placebo PSWT or an active treatment (Diapulse, 30 minutes, 400 pps, 65μs, PP 975W). They had 29 patients in PSWT group and 38 patients in the placebo group. Treatment was given preoperatively, and 6 hours post operative on the donor site for seven days. Outcome measures were pain severity, analgesic consumed, and percentage of wound healing. Patients were assessed by a blinded physician. Healing rates were 59% for active group and 29% for placebo group. Although the rationale for using the above mentioned parameters was not reported, and

despite the limited statistical analysis of the findings, the study demonstrated that PSWT does have a potential role in aiding the healing of wounds. Unfortunately, the wound healing was expressed in percentages, and no definition was given to the scale used to assess the different stages of healing.

4.3.4 Skin ulcers

A limited number of research papers were located discussing the interaction between PSWT and pressure sores (Salzberg et al, 1995; Comorosan et al, 1993; Itoh et al, 1991; Todd et al 1991). PSWT was effective in reducing skin ulcers (Itoh et al, 1991) though the improvement was governed by the method of application (Salzberg et al, 1995). Active treatment was also better than placebo (Comorosan et al, 1993).

Itoh et al (1991) conducted a study to evaluate the effects of PSWT on the rate of healing of stage II and stage III skin ulcers. Seven patients with stage II and thirteen with stage III ulcer were recruited. All patients selected for the study had received conventional treatment for at least 8 weeks with no benefit. Subjects had ulcers at varying sites (sacrum, buttock, heel, leg, foot, right malleolus and knee), the subjects also varied in the duration and the size of the ulcer. All patients continued to receive conventional treatment (cleansing of the wound, and dressing). PSWT was delivered using Diapulse drum electrode, 600 Hz, power 6, for 30 min twice daily with approximately 8 hours in between applications. The wound was evaluated in terms of visual observations, measurement of size, coloured photographs. Results shown that stage II ulcers took 1-6 weeks for full recovery while stage III ulcers took between 1-22 weeks. The number of subjects in each group was small with no control group, which makes it difficult to rule out the effect of natural recovery on the improvement levels

obtained. No definition was given to nature of ulcer in stage II or III. Moreover, no statistical analysis was employed.

Todd et al (1991) investigated in a double blind study the effects of PSWT on 19 patients with resistant varicose ulcers. Subjects were either entered into an active group (dressing, PSWT) or inactive group (dressing, dummy PSWT). Treatment was given twice weekly for five weeks, using Megnetopulse 1500 (coil electrodes). The reporting of the dose was vague and incomplete (field strength was "60" and the intensity was 5 Hz, treatment was given for 15 minutes). Outcome measures were ulcer size, lower leg girth, pain severity, and presence of infection. Both groups showed overall reduction in ulcer size; however the results were in favour of the active group (though not statistically significant, the mean decrease in ulcer size was 2.77% compared to controls 1.16%). There was no significant difference between active and placebo PSWT in girth measurement, pain level and the presence of infection. The study has employed a small sample size which was divided into 2 groups. The small sample size might have contributed to the non-significant results. There was incomplete reporting of treatment parameters such as power setting and the pulsing mode. The study lacks enough information on how the outcome measures were assessed. Examining the data it could be seen that the patients in the two groups were matched for gender and age but not ulcer size. There was a difference in the mean ulcer size between the groups (the active group had larger mean ulcer size). This difference at baseline may have been responsible for the non-significant results.

In a later report by Comorosan et al (1993), 30 elderly patients were employed in a double blind study to examine the effects of PSWT on decubitus ulcer of buttock, sacrum, knee, back, heel and leg area. The patients were randomly assigned into control (conventional treatment i.e. dressing), placebo (conventional treatment with sham

were not compatible at baseline as all patients with large ulcers were in the placebo group and only one big ulcer was in the control group. With grade III ulcer best results were demonstrated in the active group (70.6% for active and 20.7% for placebo). In both groups the site of the ulcer was not mentioned, the treatment parameters were lacking, grade III ulcer had only 10 patients, which were further divided into placebo and active group. The authors repeatedly report that they employed a control group where in fact they used a placebo and an active treatment group.

4.3.5 Pressure sores

Seaborne et al (1996) examined the effects of non-thermal application of PSWT on pressure sores. They employed 20 non-ambulatory patients between 60 and 101 years, who had a pressure sore on trochantric or sacral region in an ABAB repeated measures design. Treatment was delivered in weeks 2 and 4 while weeks 1, 3, 5 were taken as baseline measurements. Subjects were randomly allocated into four groups. PSWT was delivered using Curapuls 419 with PD fixed at 400 μsec, and PP 700W. Two groups were given PRR 20 pps, MP 5.6W using either capacitive or inductive electrodes as such patients were treated with the above parameters with either E or H field; the same was done with the remaining two groups but the treatment combinations were changed to PRR 110 pps, MP 30.8W. E field was delivered via a coplanar technique using air space electrodes while H field was delivered using a circuplode. Routine nursing dressing was maintained throughout the study. All treatments were for 20 minutes twice a day for 2 weeks. An independent assessor took measurements of the size of the wound weekly over a 5-week period by tracing the wound using a paper and a pen (reliability of the method was reported by the authors). All four protocols showed reduction in the size of the ulcer, with significant difference between the groups

showing in week 4 (p<0.007) and week 5 (p<0.001). Findings were better with H field (5.6W) followed by E (5.6W) followed by H (30.8W) and least effective was E (30.8W). The study however, used the ABAB design where subjects act as their own controls. This design is not preferable where the treatment applied has a latent reaction (Kazdin, 1982). Therefore, it was difficult to conclude that the improvement was only related to PSWT treatment especially that nursing care was continued. Interestingly, the positive significant outcome obtained with PSWT on week 4,5 is an indication of the cumulative effect of PSWT with wound healing which is in accordance with the literature discussed earlier (Gray et al, 1995).

However, there was an ethical issue with this study, as the majority of participants were confused and some were asleep for the entire treatment. The authors perceived that there was no need for consent. However, despite all the flaws in this study it is of interest to mention that it is one of the very few studies that reported full description of treatment protocol and dose.

It is expected that PSWT may assist healing by changing the local nervous system rather than the cell activity alone. It is plausible that changes in nerve supply to the vessels in the damaged area have a direct effect on the redistribution of blood to the tissues. Moreover, PSWT is believed to activate the sodium pump resulting in the repolarising of the depolarised cells in the injured area which may restore the ionic level of the cell membrane to pre injured state (Scott, 2002). Such theorises need be validated before being accepted as a confirmed mechanism of PSWT action. Moreover, despite the many downfalls of the above-mentioned studies, the literature is in favour of using PSWT on pressure sores with the studies generally demonstrating positive outcomes.

Summary of the studies discussed above can be found in Table (4.3).

Study	n=	Condition	Blind	Random	Control	Treatment Dose						Other intervention	Outcome measures	Findings
						Machine brand	PD (μ sec)	PRR (Hz)	T (min)	PP (W)	MP (W)			
Santiesteban and Grant (1985)	50	Post op wound (foot)	NM	Yes	Yes	NM	95	700	30	NM	NM	Control Group	Drug consumption Hospital stay	Drug consumption reduced by half with active group Reduce hospitalisation time
Grant et al (1989)	373	Perineal trauma sustained during labour	Yes	Yes	Yes	NM	100	65	10	NM	NM	PUS, 3MHz, intensity 0.5W/cm^2 ration 1:4, 2min	Drug consumption VAS Subjective perineum evaluation (visual)	No significant difference between all treatment groups
Itoh et al (1991)	22	Pressure sore	NM	NM	NM	NM	65	600	30	NM	NM		Time to healing	Reduction in healing time
Todd et al (1991)	19	Varicose ulcer	NM	Yes	NM	Magnetop lus 1500			15			Traditional treatment	Ulcer size, leg girth, pain, infection	No statistical difference between group No change in pain, or girth or infection
Arghiropol et al (1992)	25	Post op wound		Yes	Yes	NM	NM	400 600	15 30	NM	NM	Control group	Blood analysis (level of fibronectin)	Level of fibronectin returned to normal in treated group
Comorosan et al (1993)	30	Pressure sore	Yes	Yes	Yes	NM	65	600	30	NM	NM	Placebo group Control group	Degree of improvement	Better outcome with active PSWT compared to poor outcome with placebo and control group
Salzberg et al (1995)	30	Pressure sore	Yes	Yes	Yes	NM	NM	NM	30	NM	NM	Placebo PSWT	Pressure sore measurements Pressure sore photographs Time to healing	Reduction in ulcer size Reduction in healing time
Seaborne et al (1996)	20	Pressure Sore	NM	Yes	NM	NM	400	20 20 110 110	20x2	700	5.6 30.8		Pressure sore measurement	No significant difference between all PSWT groups All PSWT Rx resulted in positive outcome

*: PSWT machine was especially designed for the study and is not one of the commercial available units
MP: mean power, NM: not mentioned, nm: nanometer, PP: peak power, T: time, ADL: activities of daily living, Rx: treatment, FIS: Functional incapacity score

Table (4.3) Summary of clinical trials on wound healing

4.3.6 OTHERS

An interesting report was published by Lightwood (1989) on the positive outcomes of PSWT with post surgical soft tissue conditions, RA, OA, pain, back pain, delayed bone healing and even spina bifida and stroke. The application was not according to the usual textbooks or manufacturer's instructions (15 to 20 minutes and maximum of 30 minutes) but instead treatment durations lasted for a minimum of 1 hour and were usually repeated several times a day. Unfortunately, no treatment parameters were mentioned in this report. All conditions demonstrated remarkable improvements in enhancing the rate of tissue healing. The author failed to report the outcome measures employed in the study and how recovery was judged and as such it was hard to judge the reliability and validity of these measures and to accept the findings without caution.

Barker et al (1985) examined in a double blind study the effect of applying PSWT to the abdomen post surgery to stimulate peristalsis. A portable PSWT that utilised 27.12 MHz, MP 12 W, pulses of 0.1 millisecond were delivered for an hour twice daily. Fifty patients were randomised to either a treatment (n= 26) or a control (n= 24) group. Outcome measures were fluid balance, abdominal girth, and bowel sounds recorded by stethoscope taped to the abdomen for 15 minutes. Results showed that the return of bowel sounds was quicker with the active group, however findings were not statistically significant and were not associated with passage of flatus or restoration of fluid balance. There was no mention to the type of surgery the patient underwent or the type of electrodes used.

Although the authors have reported that they have used athermal mode of PSWT, the long duration of application may have been responsible for developing heat in the tissues, which may have been responsible for lack of significant results.

PSWT) and a treatment group (Diapulse, local application on site of ulcer: 600 pps-30 minutes- intensity 6 twice a day; hepatic application: 400 pps- intensity 4 - 20 minutes-1/day). Patients were monitored daily by observation and weekly by colour photography following categorical scale (excellent, very good, good, fair, poor, no improvement). Poor to no improvement was noted in control and placebo group. PSWT group showed good to excellent results with the complete healing achieved between 1-4 weeks for stage II and between 2-8 weeks for stage III ulcer for all patients. These results were accompanied with disappearance of wound exudates after 48-72 hours. Findings have demonstrated beneficial effects of PSWT on pressure sores at stages II and III. Although the authors have reported the intensity they used with their patients (4, and 6) the numbers are meaningless unless the brand of the PSWT machine is reported and so is PP and MP. The outcome measures they used were subjective and no reliability information was mentioned on the scale they used for assessing the rate of ulcer improvement.

In agreement with the studies reported above are the findings of Salzberg et al (1995). They examined the effect of PSWT on 30 spinal cord injured patients with ulcer. Patients were stratified according to the stage of the ulcer (20 had stage II, and 10 had stage III). All patients continued to receive moist saline dressing. Patients were randomised to receive a treatment or a placebo treatment, though there was no description of how this was achieved. Treatment was delivered using Diapulse but no treatment dose was mentioned. Patients, and therapists were blinded from the treatment. The ulcer was measured and photographed weekly, full recovery was taken as the end point for analysis. The active group of stage II ulcer demonstrated better results compared with placebo (recovery of active group 84%, recovery of placebo group 40%, p=0.01), with shorter duration to achieve recovery. However, patients in stage II ulcer

Livesley et al (1992) have studied the effect of applying PSWT on displaced fracture of the neck of humerus. Forty eight patients were randomised to receive either active PSWT (Curapulse) or placebo PSWT. Treatment was administered for 30 minutes, intensity 3, PRR 35 pps, 300 maximum pulse power. Outcome measures were pain using VAS, analgesics consumption, muscle strength, ROM using goniometer, and function using European Shoulder Association Assessment Charts. Patients were also evaluated 1,2, and 6 month later. Findings showed no significant difference between the two groups.

Although muscle wasting and strength were assessed it was not mentioned how this was accomplished. Additionally, the scales used for assessing the outcome were mostly subjective.

Buzzard et al (2003) examined the effects of PSWT on oedema following calcaneal fractures in 39 patients with unilateral and bilateral fractures. Patients were allocated to either PSWT (Curapuls 403, 26 Hz, 200 μsec, twice daily for 15 minutes using circuplode) or ice therapy (Cryocuff adjusted to 30 mm Hg six times a day for 20 minutes). Outcome measures were circumference measurement using tape measure and ROM. Although both modalities have shown improvement, no modality was reported to be superior.

However, it could be argued that no control group was used as such the role of natural improvement cannot be ruled out. The sample was randomised to groups but the procedure followed was not described. Furthermore, although the study involved repeated measurements over the course of the experiment no reliability studies for investigators were mentioned nor how consistency was ensured when swelling and ROM were measured between days. Additionally, the study employed patients with

Study	Sample Size	Condition	Blind	Random	Control	Treatment Dose						Other intervention	Outcome measures	Findings
						Machine make	PD (μ sec)	PRR (Hz)	T (min)	PP (W)	MP (W)			
Livesley et al (1992)	48	Neck of humerus fracture	Yes	Yes	Yes	NM		35	30	300	NM	Placebo PSWT	VAS Drug consumption Muscle wasting Muscle strength ROM Functional assessment	No significant difference between groups
Buzzard et al, 2003	39	Oedema after fracture	NM	Yes	No	Curapulse 403	26	200	15x2	NM	NM	Cryocuff adjusted to 30 mm Hg six times a day for 20 minutes	Swelling, ROM	No significant difference between two groups

MP: mean power, NM: not mentioned, nm: nanometer, PP: peak power, T: time, ADL: activities of daily living, Rx: treatment, FIS: Functional incapacity score

Table (4.4) Summary of clinical trials on fractures

bilateral fractures however, it was not mentioned whether they were treated as one case or 2 cases in the analysis. Summary of the studies can be found in Table (4.4).

4.4 PAIN

Several studies have investigated the therapeutic effects of PSWT on pain. Studies have looked at pelvic pain (Varcaccio-Garofalo et al; 1995; Jorgensen et al, 1994), temporomandibular pain (Gray et al, 1994), back pain (Wagstaff et al, 1986) and pain of trigger points (McCray and Patton, 1984). Studies have related PSWT application to positive outcomes (Varcaccio-Garofalo et al; 1995; Jorgensen et al, 1994; McCray and Patton, 1984) others have found no significant difference between PSWT and laser or CSWD, but findings were better than placebo (Gray et al, 1994).

McCray and Patton (1984) randomly assigned 19 patients to two experimental groups. The groups were either treated with superficial heat (hot pack) or PSWT. Using the algometer to measure threshold to pressure, both modalities were compared for efficacy. It was found that PSWT increased the pain threshold by 56% compared to 47% with hot pack. Results were superior with very sensitive pressure points compared to the moderately sensitive. However, care need to be taken when accepting these findings as the total number of subjects (n=19) was further divided into 2 subgroup leaving 9 in one group and 10 in the other, making it difficult to conduct meaningful statistical analysis. This is besides absence of a control group, insufficient reported information on blinding or the randomisation process, and lack of enough explanation on how trigger points were divided into slightly, moderately, and severely sensitive.

In 1986, Wagstaff et al compared the effect of pulsed versus continuous short wave on low back pain. Twenty three patients were randomly divided into 3 groups. The modes of treatments were: continuous (n=8, no parameters were reported), pulsed

(n=8, 82 Hz, MP 23.2W, PP 700W), pulsed (n=12, 200 Hz, MP 23.4W, PP 300W). Patients were treated twice for 15 minutes in a 3 week period. Findings were evaluated in terms of pain pre and post treatments. All groups demonstrated significant relief of pain (continuous $p<0.01$, 82 Hz $p<0.0005$, 200 Hz $p< 0.005$). Both pulsed modalities demonstrated superior outcome (with no significant difference between the 82 Hz and 200 Hz) compared to continuous ($p<0.05$). However, there was no reporting on the chronicity of the back pain and whether acute pain has responded the same as the chronic pain. Additionally the number of patients in each group was small and the treatment parameters were not mentioned in full.

In a double blind randomised controlled trial Reed et al (1987) examined the effect of PSWT on inguinal herniorrhaphy. Forty three patients were randomised to two groups (active and placebo PSWT). Treatment was given twice daily for 15 minutes, PRR 320 pps, PD 60 μsec, maximum output 1W. Post analgesic drugs were standardised and given when required to control the pain. Outcome measures were pain (using VAS, immediately, 24 and 48 hours post operation), drug consumption. There was no significant difference between the two groups in pain and analgesic consumed. There was no difference between the two groups one week after discharge in pain level and in swelling at the wound site. However, the study did not use a control group. Additionally, the investigators used portable PSWT which may be different from commercial PSWT employed in clinics and which may have different carrying frequency than 27.12 MHz. It could be added that the outcome employed were subjective and may have been responsible for the insignificant results.

In a double blind placebo controlled trial Foley-Nolan et al (1990) have examined the effect of PSWT on persistent neck pain. Twenty patients were recruited complaining of neck pain for more than 8 weeks, all patients had pain that was

irresponsive to other conservative treatments. They were randomly assigned to either active (n=10) or placebo collar (n=10). The placebo group was given sham treatment for the first 3 weeks and replaced by the active treatment group for another 3 weeks. PSWT was delivered via a soft cervical collar (utilised 27.12 MHz, MP 1.5 mW/cm^2, weighed 100 gram, that operated on battery) 8 hours a day. At entry patients were assessed for blood count, ESR, biochemical profile, and they were also assessed for neck movement (following a criteria full, one third, two third of the range), pain (using VAS) each session. Half way in the trial (3 weeks) subjects were asked to rate their improvement on a categorical scale. By the end of trial (6 weeks) there was no difference in pain level or ROM between the two groups although both have displayed reduction in pain level and improvement in ROM. However, the authors failed to mention why the placebo group changed regime half way to the active collar. Additionally the process of randomisation to experimental groups was not explained. It could be added that because drug consumption was not standardised between groups, it was difficult to judge its influence on the outcome especially with the absence of a control group.

Foley-Nolan et al (1992) conducted a study to examine the effects of PSWT on acute whiplash injury. In a double blind study, 40 subjects were randomised to either active (collar with PSWT generator, weight 100 gram, MP 1.5 milliwatt / cm^2, PD 60 μsec, PRR 450 pps, 8 hours a day for 12 weeks) or dummy PSWT. Patients were instructed to exercise their neck five times a day. Initial examination consisted of history taking, X-ray and physical examination. Patients were assessed at week 2,4, and 12 in terms of analgesics consumption, pain level (using VAS), ROM (using full range, two third or one third criteria) and subjective reporting of progress. Results showed decrease in pain and analgesics consumption, with an increase in ROM. The study however was not controlled and the criteria for assessing ROM was subjective.

Additionally throughout the course of the study a lot of patients were lost to traditional treatment as the treatment given in the experiment did not have any effect on their symptoms, however, it was not clear whether they were entered into the analysis or were excluded.

Jorgensen et al (1994) conducted a study on seventeen females complaining of pelvic pain (ranging from acute, sub acute and chronic). They were treated with PSWT for a period of 15-30 minutes. Although the treatment dosage was not reported, no control group was employed, and it was not mentioned whether the pulsed or the continuous mode was used, no information on the dosage, the authors reported 90% improvement in all but two cases, which makes it hard to accept the conclusion without questioning its validity.

Gray et al (1994) have evaluated the effect of four electrotherapy modalities on patients with temporomandibular pain. One hundred and thirty nine subjects were allocated randomly to one of five groups: CSWD (mild heat, 10 min), PSWT (60 μsec, 100 pps, 20 minutes), US (pulsed 2:1, 2 minutes, 3 MHz, 0.25W/cm^2), laser (4 joules, 904 nm, 3 minutes) or placebo treatments. Outcome measures were the rate of improvement immediately after treatment and 1,2, and 3 months later. Objective measurements included the ROM of jaw opening, joint tenderness, and presence of joint sounds. Assessments were performed by both the oral surgeon and the physiotherapist. Patients showed improvement in the level of pain, tenderness, ROM. All modalities led to similar degrees of improvement. Although both the treatment and the placebo groups demonstrated similar findings post treatment, follow up has shown the symptomatic improvement of the placebo group to decline from 53.9% to 19.2% unlike treatment groups, which maintained the improvement (70.9% post treatment and 74.3% post

follow up). The placebo group did not demonstrate a correlation between reported improvement and objective measurements unlike other treatment groups.

There was a little variation in the time scale of improvement (patients treated with SW or PSWT reported their peak improvement in 2nd week while Laser and US reported maximum improvement in week 3 of treatment). No statistical difference was noticed between the four electrotherapy modalities although all four were better than placebo (the difference between treatment groups and placebo was only statistically significant at follow up). Unfortunately, the authors failed to mention the power setting of the PSWT treatment and although some parameters were mentioned it was hard to calculate the MP due to absence of reporting of the type of Megapulse used (senior or Megapulse II as each has different PP). The same study was published again as Gray et al (1995) reporting the same findings and same interpretations.

Findings were contradicting with regard to effectiveness of PSWT with pain, while Gray et al (1994) presented positive outcomes, Wagstaff et al (1986) have presented negative outcomes. Differences in outcome could be due to the site of the condition treated, which was TMJ in the former study and the back area in the latter, the severity of the symptoms, the difference in sample size or it could be related to the dose, employed by both investigators.

In 1995, Varcaccio-Garofalo et al used equipment called the thelf system; this equipment emits EMF and utilises a frequency of 27.23 MHz. Employing 64 patients complaining of chronic pelvic pain, the treatment was administered daily for 2 hours, PRR was 64 pps in first hour and 320 pps in the second hour. The whole treatment lasted between 20-40 days. Outcome measures were pain severity, disability, and psychosocial adjustments. Pain had completely disappeared in 61% of patients, while

Study	Sample Size	Condition	Blind	Random	Control	Treatment Dose						Other intervention	Outcome measures	Findings
						Machine make	PD (μ sec)	PRR (Hz)	T (min)	PP (W)	MP (W)			
McCray and Patton (1984)	19	Trigger point pain	NM	Yes	NM	NM	NM	NM	20	NM	NM	Hot pack 20 min	Pain threshold using algometer	No statistical difference between SWD and HP however, SWD was more effective than hot pack
Wagstaff et al (1986)	23	LBP	NM	Yes	NM	Curapuls	NM	200 82	15	300 700	23.4 23.3	CSWD	VAS	Better outcome with PSWT compared to CSWD No difference between PSWT groups
Reed et al (1987)	43	Post operative pain	Yes	Yes	Yes	Therafield Beta	60	320	15	1	NM	Placebo group	VAS Drug consumption	No significant difference between PSWT and placebo
Foley-Nolan et al (1990)	20	Chronic neck pain	Yes	Yes	NM	Collar PSWT	NM	NM	8hr	NM	1.5 mW	Placebo group	VAS ROM Subjective patient reporting on the outcome	↓ level pain ↑ ROM readings
Foley-Nolan et al (1992)	40	Whiplash injury	Yes	Yes	NM	Collar PSWT	60	450	8Hr	NM	1.5 mW	Placebo group	VAS ROM Subjective reporting of outcome Drug consumption	↓ pain level ↑ ROM less drug consumption by treated group
Gray et al (1994)	176	TMJ pain	Yes	Yes	NM	Mega-pulse	60	100	20	NM	NM	SWD, mild heat, 10 min US, 0.25W/cm^2, 3MHz, 2:1, 2 min Laser 4 Joules, 3 min, 904 nm Placebo	VAS ROM Tenderness Presence of joint sounds	Improvement in all groups Significant improvement between Rx groups and placebo at follow up

Study	Sample Size	Condition	Blind	Random	Control	Treatment Dose						Other intervention	Outcome measures	Findings
						Machine make	PD (μ sec)	PRR (Hz)	T (min)	PP (W)	MP (W)			
Gray et al (1995)	139	TMJ pain	Yes	Yes	Yes	NM	NM	100	20	NM	NM	CSWD 10 min PUS $0.25W/cm^2$, 3MHz, 2 min Laser $4J/cm^2$, 3 min	Tenderness ROM of mouth opening Joint sounds Patient reporting of improvement	No difference between all treatment Significant difference between placebo and treatment groups (PSWT, CSWD, PUS, laser)
Varcaccio-Garofalo et al (1995)	64	Pelvic pain	NM	NM	NM	Thelft	NM	64 320	1hr x2	NM	NM		Pain reporting, disability, depression, anxiety	↓ pain level during treatment, nut not on follow up

MP: mean power, NM: not mentioned, nm: nanometer, PP: peak power, T: time, ADL: activities of daily living, Rx: treatment, FIS: Functional incapacity score, mW: milliwatt

Table (4.5) Summary of clinical trials on pain

23% experienced relief during the treatments but started to complain when the treatment was terminated. Patient depression, marital adjustments, and inappropriate health care utilisation all were decreased. This study, although it reported positive outcome did not employ a control group.

Additionally, the protocol employed for the study was hard to replicate (daily treatment, 2 hours PSWT for a period between 20-40 days) in the clinical setting due to time constraints. The number of sessions delivered to patients was variable and the end point for analysis was not identified. The scales used for evaluating the effect of treatment on psychological, disability, health, depression and anxiety were not mentioned nor is the reliability of these scales.

Despite the methodological flaws in reporting some of the above studies (absence of control, limited reporting of dosage and the lack of statistical information), all findings were in favour of a positive interaction between PSWT and the relief of pain. The quality of the studies urges for the conduction of more rigorous studies and better reporting of methodology and outcome. Summary of the studies can be found in Table (4.5).

4.5 ANIMAL STUDIES

4.5.1 Surgical wounds

A study was conducted by Brown and Baker in 1987 on 32 rabbits to examine the effect of PSWT on the rate of healing of surgical wounds. The rabbits were either assigned to an experimental group 1 (n=8, treatment for 8 days) or experimental group 2 (n=8, treatment for 16 days). The other half of the sample was assigned to either control group 1 (n=8, observation for 8 days) or control group 2 (n=8, observation for 16 days). Xylocaine was injected into the lateral head of the gastrocnemius to induce tissue

damage. PSWT was introduced 24 hours after injury using Magnatherm (MP 12W, 1600 pps, this was increased to 4000 pps at a later stage of the treatment, treatment was administered twice daily for 20 minutes). Results showed that PSWT did not alter the rate of healing. These are two major drawbacks with this study. Firstly: the investigators used one machine to deliver the treatment to two animals at a time and this may have resulted in distortion of the EMF applied. Secondly: with animals it is always hard to concentrate the field in the area treated given the size of the animal body, as such it is expected that other body parts may have been under the influence of EMF and may have affected the overall findings. The authors have changed the parameters of treatment throughout the course of the experiment however, no rationale was given and there were instances when the reporting was not clear. All these factors beside failure to control possible confounding variables could have resulted in insignificant findings.

Despite the very limited scientific values of these studies, extrapolating findings from animal to human should be done with extreme care due to differences in size, in shape and in physiology. Animals react differently to the same amount of EM when applied to human tissue due to the difference in ratio in the size of the tissue to wavelength, which will result in different internal fields (Durney and Christensen, 2000; Markov and Colbert, 2000).

4.6 DISCUSSION

There is a growing emphasis on basing clinical decisions on best available evidence. Randomised clinical trials (RCT) have been viewed as the highest level of evidence in terms of their ability to answer clinical questions (Gray, 1997). However, the challenge for physiotherapists in the field of electrotherapy is the paucity of RCTs. While acknowledging the insights into electrotherapy practice offered by the

aforementioned studies, they nevertheless provide a limited perspective being not controlled or lacking important reporting such as the mode of application (whether PSWD or CSWT) or treatment protocols, absence of dose reporting, and power setting (Gray et al, 1994; Sweetman et al, 1993; Quirk et al, 1985) and explanation on the validity and reliability of their outcome measures.

Moreover, in many cases the investigators recruited a large enough sample at the initial phase of the study but this number is usually divided into 2 or more sub groups that are rarely matched at baseline for certain characteristics. As a result, the study ends with small number of subjects in each experimental subgroup. This limits the generalisation of the findings with the results being obtained from a very small sample and also reduces the confidence in the nature of the analysis.

Additionally, very limited number of papers have mentioned the subject's compliance and the dropout rate and very rarely a power calculation is undertaken. An added area of weakness was the failure to describe sufficient statistical details. All of the above detracts from the clinical value of any given study and limits its implication.

It is crucial that all information related to the treatment dosage is reported in the published papers for the findings to be of relevance clinically (Markov and Colbert, 2000). In the clinical setting, if therapists were to plan optimal treatment regime, they would have to choose the appropriate dosage by combing a variety of parameters, which include the PD, PRR, and the power output. Scott (2002) argues that MP is the critical parameter hence it must be reported unlike PD or PRR. The work by Hill et al (2001) have shown that changing parameters such as PD and PRR while keeping MP the same did not alter the outcome. Wagstaff et al (1986) have demonstrated that by keeping the MP at 23W and changing the treatment combination, the outcome of the two modes of treatments was not statistically significant on back pain. Despite that, it is not sufficient

to report only MP as PP differs between various PSWT machines and too few investigations have been conducted to compare the same MP from different machines on treatment outcomes. As such, until such assertion is validated, it is safer to report all treatment parameters including PRR, PD, MP, PP and duration of exposure.

As discussed earlier, due to the scarcity of the information reported on the dosage, the literature offers little direction for clinicians in terms of a dose-response relationship. The biological effects of EM application are dose-specific (Watson, 2000; Rubik et al, 1992) and the relation is not linear, which means that increasing the applied energy does not necessarily culminate in better results. This was seen with studies such as Hill et al (2001), Leclaire and Bourgouin (1991), Wagstaff et al (1986) where varying the combination of the treatment parameters and keeping MP constant or increasing MP outputs does not always mean improvement in outcomes. As such, it is only the proper frequency at the proper duration that may result in a clinically useful result (Rubik et al, 1992). All of this creates a state of uncertainty and confusion when it comes to the clinical decision-making process.

The work on low frequency of EMF has revealed the concept of therapeutic windows. That is to say, certain reactions are likely to occur at certain frequencies, or at given durations of exposures (Cleary, 1994). Despite both frequency and amplitude windows being evident with ELF from experiments conducted on human and animals (Binhi and Goldman, 2000), it is not clear whether these findings are transferable to the frequency of 27.12 MHz due to the very limited amount of work that has been conducted to-date on this frequency. In addition, although those findings have been used to explain the reaction of different tissues to PSWT, there is little evidence to suggest that humans will react similarly to different frequencies. Previous experimental work has associated some frequencies with certain biological behaviours. An example

would be the frequency of 15 Hz and 72 Hz were found to increase bone density and improve the rate of delayed and non-union bone healing (Buch et al, 1993; Tabrah et al, 1990; Aaron et al, 1989). The work on the frequency of 50-60Hz have been associated with permanent changes to enzyme activity, suppression of mitotic activity, and an increase in the incidence of chromosomal aberrations as such they were linked with cancer (Moses and Martin, 1993; Khalil and Qassem, 1991). ELF on the other hand, was found to improve performance of multiple sclerosis patients (Richards et al, 1998). Unfortunately, no similar work has been conducted on frequencies used in physiotherapy treatments such as the frequency of 27.12 MHz used in PSWT or 1 and 3 Hz used in US or other therapeutic modalities however, it would be wise not extrapolate findings directly from frequency to the other based on the reporting above.

Regardless of the considerable number of studies reported, it is hard to reach a dose-response conclusion regarding which doses better suit which condition due to the lack of information reported. Table (4.6) summarises the studies above in terms of the reported dose. The table was constructed with the objective of relating outcomes and exploring the concept of a window effect with PSWT. Unfortunately, it was hard to reach a conclusion as a consequence of the amount of information missing, all of which demonstrates the poor quality of studies in the field of PSWT.

Study	PSWT make	PP	MP	PD	PF	Intensity	Time	Type of electrode
Pain								
McCray and Patton, 1984	Magnotherm							Inductor coil
Wagstaff et al, 1986	Curapuls	700 300	23.2 23.4		82 200		15	Circuplode
Aronofsky, 1971	Diapulse	975	65		600	6	15	
Gray et al, 1994	Megapulse			60	100		20	
Jorgensen et al, 1994							15-30	
Varcaccio-Garofalo et al, 1995	Thelft							
Stiffness								
Yung et al, 1986	Erbotherm 110						20	Condencer
Rheumatology								
Quirk et al, 1985							20	Condeser

Study	PSWT make	PP	MP	PD	PF	Intensity	Time	Type of electrode
Svarcova et al, 1988	Curapuls or Diapulse	700			46		4	
Jan and Lai 1991							20	
Leclaire and Bourgouin 1991	Magnetopulse				10 15 30	30G 40G 60G	30	
Ganguly et al, 1996				0.2			15	
Moffett et al 1996	Ultratherm IIS 601		23		82		15	Circuplode
Wound healing								
Ginsberg, 1961					600 400	6 4	10	
Aronofsky 1971	Diapulse	975		65	600	6	10, 15	
Wilson, 1974	Diapulse			65		2	60	Inductothermy cable
Bentall and Eckstein 1975	Diapulse				550 550	5 4	20 10	
Goldin et al 1981	Diapulse	975		65	400		30	
Nicolle et al 1982				100				
Barclay et al 1983		975					30x2	Monode
Barker et al, 1985	Therafield Beta				640		45	
McGill 1988	Bosch ultramed		16.9		82	6	15	Circuplode
Grant et al 1989	Megapulse			65	100		10	
Arghiropol et al 1992	Diapulse	975			400 600	4 6	15 30	
Itoh et al 1991	Diapulse	975			600	6	30x2	Circuplode
Todd et al 1991	Magnetoplus 1500				5		15	Coil
Comorosan et al 1993	Diapulse	975			600 400	6 4	30x2 20	Circuplode
Salzberg et al 1995	Diapulse	975						Circuplode
Seaborne et al 1996	Curapuls 419	700	5.6 30.8	400	20 110		20	
Laboratory studies								
Badea et al (1993)							30	
Hill et al (2001)	Megapulse II	150	48				10	
			1,3, 4,8, 12,4 8, 6	100, 200, 400	400, 400 100		10	
			6				5,10,1 5, 20	

Table (4.6) Summary of the quality of reporting treatment dose, shaded area resembles missing treatment parameters

It is of interest to mention that PSWT appears to be a safe therapeutic modality as none of the studies have reported deleterious outcomes. The findings also relate higher levels of energy to good outcomes. This approach seem to have its support in the literature with Low (1995) arguing that whilst superior results were reported with dose above 100J/ 24 hours, lesser success rates were obtained with a dose of 40J/ 24 hours and no

effect was obtained with lower doses. The work of Low however did not include all the studies conducted on PSWT and as such the reported findings may have been biased.

The majority of the work conducted to-date on PSWT examined its effects on musculoskeletal and wound healing and this may have been responsible for the size of the evidence in favour of its use on soft tissue injury compared to other conditions. Findings also suggests that best results were obtainable when PSWT was applied more than once a day and if it was applied directly after injury (within 36 hours).

Another area of interest is the combination of local and hepatic application especially that the findings of the reported studies have showed promising results. The theory underpinning this practice was that the application of PSWT to the liver could increase the synthesis levels of plasma fibronectin (which is a type of glycoprotien) associated with the formation of clot, which is a necessary process for, wound healing (Arghiropol et al, 1992). With the majority of the studies that examined this technique being outdated, further research into the effectiveness of this approach should be undertaken to explore its implications clinically.

Attention should be paid to the reporting of carrying versus the modulated frequency. When interpreting research findings on frequencies within the radio-frequency band, a clear distinction needs to be made between the carrying frequency and the modulated frequency. PSWT operates at a carrying frequency of 27.12 MHz, while the output of this frequency is modulated and delivered to the tissues in bursts with various repetition rates (1-7000 Hz). The published reports on other frequencies rarely make this distinction between the two types of frequencies. For example, a frequency of 15 Hz could be taken to mean a carrying frequency or a repetition rate, which constitute different treatment outputs and would have different implications on the outcome. The reason for this confusion could be caused by the fact that the majority

of the physiotherapy literature that examines the physiological effects of PSWT on the tissues originated in different disciplines and most of the experiments were conducted by physiologists, biochemists or mechanical engineers who have different categorisations and interests in the EMF.

As mentioned earlier the aim of this chapter was to summarize research work conducted to-date and to compile evidence on PSWT with different conditions, compare and identify areas of homogeneity in results and in windows of effectiveness. However, there was no consensus in the work discussed above on a common window effect but instead there were results that indicated an incidence of isolated windows. The reason being that a great diversity of treatment parameters was employed in the trial protocols. Treatment durations ranged between 10 minutes to 6 hours with all showing positive results. The mode of applying PSWT was also controversial with the application ranging from daily to two or 3 times a week with no method apparently being superior to the other. The findings also suggest that PSWT may have multiple rather than one intensity window of effectiveness. However, until further work is conducted to overcome these limitations, the available evidence on PSWT remains to be of little direct value in directing the clinical decision.

The literature review has covered and analysed studies, both clinically based and laboratory based, to evaluate the nature of the evidence and the amount of support it holds for many conditions. Unfortunately, many reports did not quote the dose applied, a lot of information regarding the frequency, the type of equipment was not mentioned. With the finding of many studies pointing towards a positive outcome, it could be argued that the reported outcome is not merely a coincident or a placebo effect, there must be a mechanism underpinning these observations. However, this mechanism is yet to be elucidated.

Additionally, numerous of studies appear to have failed to demonstrate a difference between placebo and active treatment groups possibly because of methodological flaws or lack of genuine effect between the dose examined and placebo. Moreover, a lot of the studies have resulted in no significant statistical difference between the experimental groups. This however, does not mean that PSWT is ineffective, but could rather mean a small sample size and the possibility of using tests that were not powerful enough to detect a difference (Eng, 2003; Karlsson et al, 2003).

4.7 CONCLUSION

Many modes of PSWT treatments have not been subjected to scientific scrutiny or controlled clinical trials, though as such, absence of evidence on effectiveness does not necessarily mean the treatment is worthless. Furthermore, lack of statistical significance does not mean the treatment examined is futile clinically. Research in the area of PSWT efficacy is fragmented and of a mixed quality warranting more quality experimentation.

While many of the claims on PSWT remain unproven, replication of some of the key experiments is crucial to establish the finding's credibility. Studies should not be dismissed as lacking real effects when they identify inconclusive findings, instead they need to be replicated with more robust methodologies and larger sample sizes. The fact that a lot of work failed to reach statistical significance might be related to the number of subjects employed or the low sensitivity of the methodology or the outcome measures utilised, especially if the effect one is looking for is small or the possibility that the treatment is actually ineffective.

Despite the insufficient quality of the evidence reported in the majority of the studies, the literature points towards positive outcomes with pressure sore, wound healing and

pain relief. However, the evidence in favour of the relief of arthritic symptoms is still inconclusive.

CHAPTER 5

AN AUDIT OF THE CONTEMPORARY CLINICAL USE OF PSWT

5.0 INTRODUCTION

PSWT is one of the electrotherapy modalities used by physiotherapists since the 1880's. It was used as a focus for the current study being one of the popular and frequently used modalities among therapists in UK (Robertson and Spurritt, 1998; Kitchen and Partridge, 1996; Pope et al, 1995). Surprisingly, the growing clinical use of PSWT, was not associated with a growing body of evidence. There exists a dearth in the data available on the frequency, mode and use of PSWT in outpatient clinics in England. Given that very limited number of investigations has examined the nature of clinical use of PSWT, an exploratory audit was undertaken to examine and extract evidence of use from therapists' documentations. Reports have invariably described evidence that physiotherapists are not integrating their documentation skills into their daily record keeping (Hill et al, 1997; Turner and Whitfield, 1996). However, no reports have been identified that examined the quality of therapist's documentation with regard to electrotherapy.

Documentation is an essential and integral part of physiotherapy practice. It is a tool for communication between caregivers, and as a result needs to be of high quality. Given that the success of any medical intervention is judged from its outcome, record-keeping becomes a crucial method of monitoring the quality of service delivered to patients (Sumner et al, 2000). The importance of keeping efficient records has always been emphasized by the Chartered Society of Physiotherapy (CSP) due to its great impact on the safety, continuity and quality of patient care (CSP, 1996). Maintaining high quality records is vital for the profession in a climate where demonstrable clinical effectiveness and measurement of outcomes are of central importance (Hicks, 1999). Given the above it was determined that a study that aimed to appraise the practice through documentation would be valuable.

5.1 AIMS OF THE STUDY

- To evaluate the standards of the written content, the amount of information documented, and its significance on patient care in a sample of eight randomly selected outpatient clinics across England.
- To compare the current practice with CSP guidelines and the existing evidence.
- To extract documented evidence on the use and efficacy of PSWT from these files.
- To generate clinically relevant questions, derived from practice to be used in the development of a questionnaire (second phase of the study).

5.2 METHODOLOGY

5.2.1 Sample selection

The total population of the study was defined as UK physiotherapists who use PSWT routinely in their daily practice. To identify the sample there was a need to limit the number of the hospitals within each health region. This process started by including all health authorities that contained four or more hospitals within them in a table (health authorities and hospitals' names were obtained from the IHSM - Health and Social Services Year Book, 1999-2000). There was a need to define the health authorities that will be entered to the draw because some of the authorities only contained two or three hospitals. Limiting the authorities to those containing four or more allows the researcher the flexibility of the choice between hospitals if the request for conducting the audit was rejected by the selected hospital.

All the health authorities that were entered in the draw were assigned a number and these numbers were used to construct a table (Table 5.1). The researcher picked up a number randomly out of a hat and the health authority that corresponded to that

number was chosen. The draw was repeated eight times each time for a different health region.

Strata 1	Trent	1	2	3	4	5	6	7	8	9	10	11			
Strata 2	West Midlands	1	2	3	4	5	6	7	8	9	10	11	12		
Strata 3	Northern Yorkshire	1	2	3	4	5	6	7	8	9	10	11	12		
Strata 4	South East	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Strata 5	South West	1	2	3	4	5	6	7	8						
Strata 6	Eastern	1	2	3	4	5	6	7	8						
Strata 7	London	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Strata 8	North West	1	2	3	4	5	6	7	8	9	10	11	12	13	14	

Table (5.1) The table used for stratifying the health authorities within each region

The health authorities were chosen following stratified random sampling (SRS). This approach was used as it overcomes the problem of simple random sampling in obtaining unrepresentative sample by chance, hence has the advantage of reducing the sampling error (Rice and Ezzy, 2000). Moreover, the population lends itself to this approach being already divided into eight groups or strata. Randomisation has the advantage of ensuring that all characteristics of interest were equally distributed between the groups and all authorities have an equal and known probability of being chosen (Rice and Ezzy, 2000; Jenkins et al, 1998).

After limiting the number of health authorities and following inclusion/exclusion criteria the hospitals within the chosen authorities were arranged in lists according to their size (using the bed number as a reference). Starting at the top of the list the hospital with the highest number of beds was selected.

The manager of the physiotherapy department in that hospital was then contacted by phone to enquire about their willingness to participate and to negotiate access. In cases where approval was obtained a letter, explaining the purpose of the project followed

(Appendix A.1). However, if access was denied by the manager, the next hospital down the list was contacted and the same procedure was repeated.

5.2.2 Inclusion criteria

- The hospital should have an outpatient practice that uses PSWT as a routine treatment in patient care.

5.2.3 Exclusion criteria

- Mental hospitals
- Children hospitals
- Ambulance services

These hospitals were excluded, as it is unlikely that these facilities will be using PSWT in their treatment to patients and even if they do it would not be in sufficient numbers to meet the objectives of this work.

5.3 THE PROCEDURE

With the intention of exploring the nature of PSWT use in outpatient clinics, a data collection form (Appendix A.2) was devised. It was divided into six sections as follows:

- Number of patients treated with PSWT compared to the number of patients seen in the department at the time of the audit
- Number of sessions given until discharge (i.e. until PSWT was stopped)
- The most common conditions treated with PSWT
- The dose of clinical treatment parameters

- The frequency of use of PSWT for each patient (number of sessions per week)
- Treatment outcome (whether the patient has improved, deteriorated, or remained the same)

All the files found in the physiotherapy departments at the time of the study were audited looking for records that had information on PSWT treatments. When these files were located, they were analysed in the light of the auditing tool. The information collected contained details on numbers of patients, frequencies of attendance and the nature of PSWT use.

5.4 ETHICAL ISSUES

The proposed plan of action for the audit was endorsed by the ethical committee of Radiology and Physiotherapy in University of Hertfordshire (Appendix A.3).

A consent form (Appendix A.4) was signed by either the manager or someone on their behalf in all the hospitals chosen consenting to the study and approving its purpose and access to patient notes.

All the written reports and the data gathered were coded to ensure anonymity and confidentiality to patients, their therapists, and the hospital visited. No file number, patient names, or therapist's name were included in the reported results. For further security all documents and printouts were stored in a locked place where only the researcher had access to them.

5.5 RESULTS

Eight hospitals one from each of the eight health regions were chosen randomly to represent the practice with PSWT across England. Results are presented below under the following headings:

- Treatment time
- Mode of delivering PSWT
- Treatment outcomes
- Conditions treated.

One thousand seven hundred and fifty files were examined among which one hundred ninety two files had useful information relevant to this investigation. From Table (5.2) it can be seen that the percentage of PSWT use among therapists in the hospitals visited ranged between 8-13%.

Code of hospital	No of files examined	No of patients treated with PSWT	Percent of use
1	280	36	12.9
2	178	19	10.7
3	293	35	12.0
4	195	17	8.7
5	316	34	10.8
6	141	16	11.3
7	156	13	8.3
8	191	22	11.5
Total	1750	192	

Table (5.2) Proportion of PSWT use

These files were judged in terms of quality of documentation and the results are presented in Table (5.3). The files were judged against the requirements of CSP (1996) for quality of documentation which stated that files should include information on power (mean, peak), time of irradiation, method of coupling, pulsing regime, patient

position, PSWT make, and when applicable the consent form. According to this list none of the files in any of the hospitals visited met the requirement.

File description	No of files	Percentage
Files without full description to the treatment delivered	192	100
Files with incomplete reported Dosage	169	88
Files without treatment time reported	0	0
Files without frequency of sessions reported	36	18.8
Files without outcome reported	73	38
Files without progression updates reported	133	69.2

Table (5.3) The nature of documentations in the eight hospitals
Total number of observations is 192

Eighty eight percent of the files were lacking a complete description on dosage parameters. Around 70% had hardly any information about treatment progression and were lacking continuous updating. In around 20% of files there was nothing to indicate the plan of treatment in terms of frequency of sessions per week or the total number of sessions for which the therapist intends to see the patient. Interestingly, all the files had details on treatment duration. All of the above reflects low practice standards and poor quality of documentation.

5.5.1 Treatment time

In all the hospitals visited, the time of applying PSWT varied between 5-20 minutes (Table 5.4). The most common duration for using PSWT was 10 minutes and this was reported by 41% of the therapists. In second rank was 15 minutes (31.8%) followed by 20 minutes (9.9%).

Treatment time	Frequency of occurrence	Percent
5	9	4.7
10	79	41.1
11	2	1.0
12	12	6.3
13	10	5.2
15	61	31.8
20	19	9.9
Total	192	

Table (5.4) Treatment times as reported in the files

5.5.2 Mode of delivering PSWT

Over half the sample (56.8%) administered PSWT once a week (Figure 5.1). 19.7% of the therapists applied it twice a week and only 4.7% applied it 3 times a week. Although 18.8% of therapists did not specify the frequency of use, it could be inferred that since information on PSWT was only mentioned once in patient's notes, the treatments was only administered once (single session). This gives a majority of 75.6% of therapists using PSWT once a week with the majority of conditions.

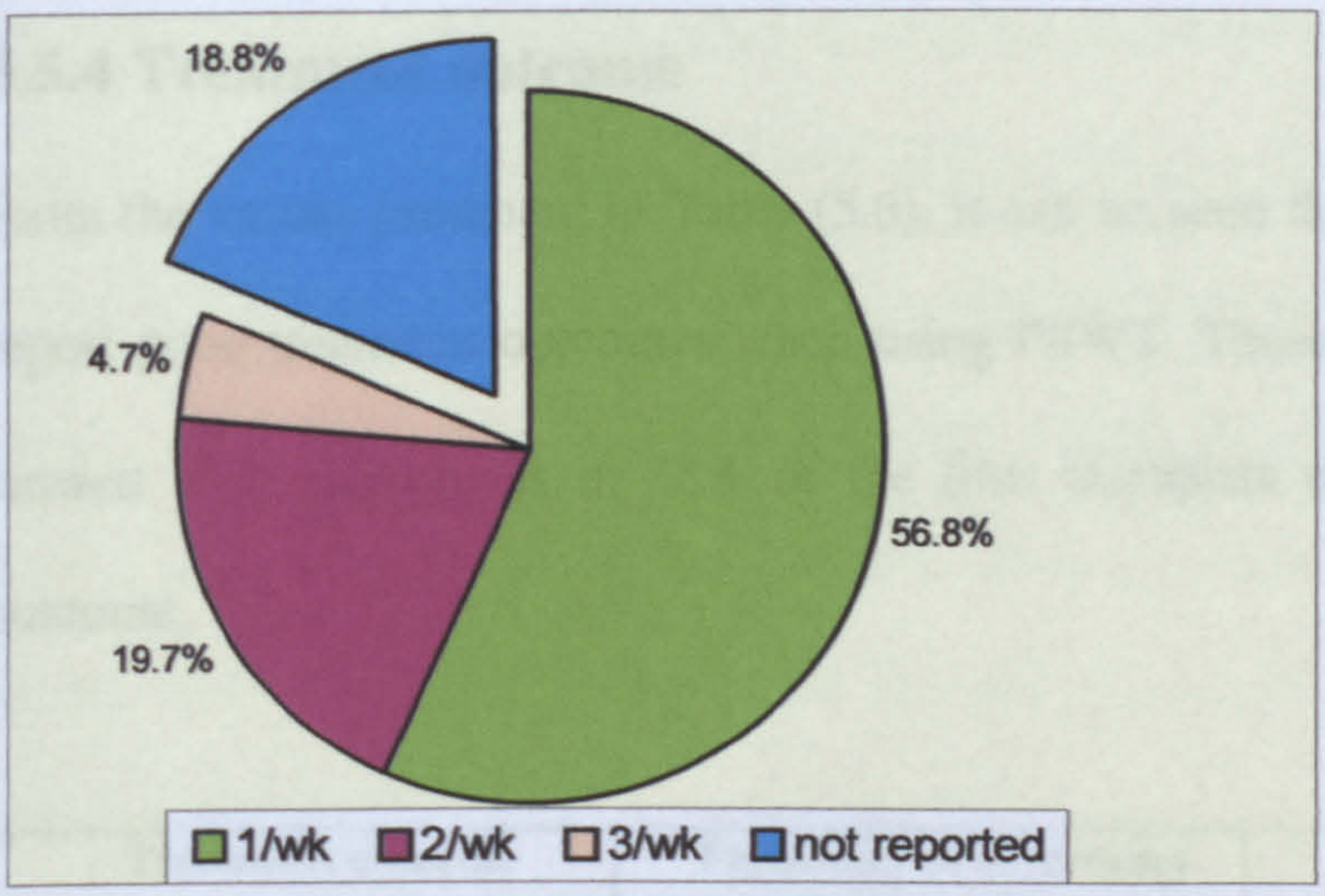


Figure (5.1) Frequency of PSWT use as reported by therapists in patient's notes

5.5.3 Treatment progression

In files where the use of PSWT was mentioned more than once, the treatment progression was further investigated. Three major approaches appear to have been

adopted by therapists to progress a treatment plan: to increase the dose, decrease it or leave it the same. The majority opted for increasing the dosimetry (either by increasing the time or any other parameter on the machine console).

Examining Table (5.5), best results were obtained by either increasing the dose or by leaving it the same; the worst results however, were obtained when the dose was decreased.

↑ Dosage				↓ Dosage				Leave dosage the same			
Better	Worse	NR	STHS	Better	Worse	NR	STHS	Better	Worse	NR	STHS
19	3	14	3	3	5	3	2	5	-	2	-
48.7%	7.7%	35.9%	7.7%	23 %	38.5%	23%	15.4%	71.4%	-	28.6%	-
Total		39		Total		13		Total		7	

Table (5.5) Treatment progression
NR: not reported, STHS: stayed the same
* The percentage is calculated from the number files with pertinent information on dose progression divided by the total number of files

5.5.4 Treatment outcome

From the values presented in Table (5.6), it can be seen that the majority of therapists report good treatment outcomes when using PSWT. These results however, should be viewed with caution, as in 38% of the files therapists did not report the treatment outcome.

Treatment outcome	Frequency of occurrence	Percent
Not reported	73	38.0
Better	69	35.9
Worse	34	17.7
Same	16	8.4
Total	192	

Table (5.6) The outcome of treatment as reported in the files

5.5.5 Classification of treated conditions

The conditions treated with PSWT were diverse. Therefore there was a need to construct a unified language or a framework for classifying them. At first it was decided to use the International Classification of Impairment, Disabilities, and Handicap (1980) (ICIDH), the widely used classification system by physiotherapists. However, this classification system was found to cover problems of social and physical dimension besides being non-diagnostic. Several other preliminary categorising schemes were attempted by the researcher and their suitability were examined, unfortunately non fulfilled the intended aim.

The International Classification of Disease (1994) (ICD) was identified as the best option. The ICD is a statistical classification of disease. It allows users to transform diagnosis and diseases into alphanumeric codes. This system is mainly used to record, analyse, interpret, and compare mortality and morbidity data from different countries. The classification criterion is based on dividing disorders to families with alphanumeric coding scheme (one letter followed by three numbers). The system was determined to be sufficiently comprehensive, with the scheme of families of disease adding more breadth and flexibility. The classification allows for coding of a wide range of information using a standardised methodology that permits communication across members of the disciplines and across different disciplines and facilitate comparison of data from different sources.

It is of interest to mention that there was more conditions under each category than the ones used for this study, however, only the ones that related to the findings were utilized.

5.5.6 Conditions treated

All the conditions accumulated were grouped and classified using ICD (Figure 5.2). The categories relevant to the study were as follows:

- **Arthropathies**: RA, OA, joint pain
- **Dorsopathies**: spondylosis
- **Osteopathies**: fractures
- **Soft tissue disorders**: muscle tear, muscle strain, epicondylitis, rotator cuff syndrome, tendon impingement, dislocation, subluxation, bursitis, ligaments and meniscus problems
- **Other musculoskeletal and connective tissue disorder**: positional vertigo, post operative conditions
- **Diseases of oral cavity**: temporomandibular disorders (TMJ)

Table (5.7) presents the classification of conditions with the number of cases in each group.

Condition	No of cases	% of occurrence
Diseases of oral cavity & Jaws	7	3.6
Dorsopathies	13	6.8
Other musculoskeletal and connective tissue disorder	16	8.4
Osteopathies	21	10.9
Arthropathies	62	32.3
Soft tissue disorders	73	38
Total	192	

Table (5.7) Classification of disorders according to ICD

In order to rank the conditions in terms of the most prevalent, further sub-classification to the three top categories in Table (5.7) is needed. Table (5.8) includes the sub-classification of arthropathies, soft tissue disorder and osteopathies which represent the highest occurrence among other conditions.

CLASSIFICATION OF DISORDERS ACCORDING TO ICD

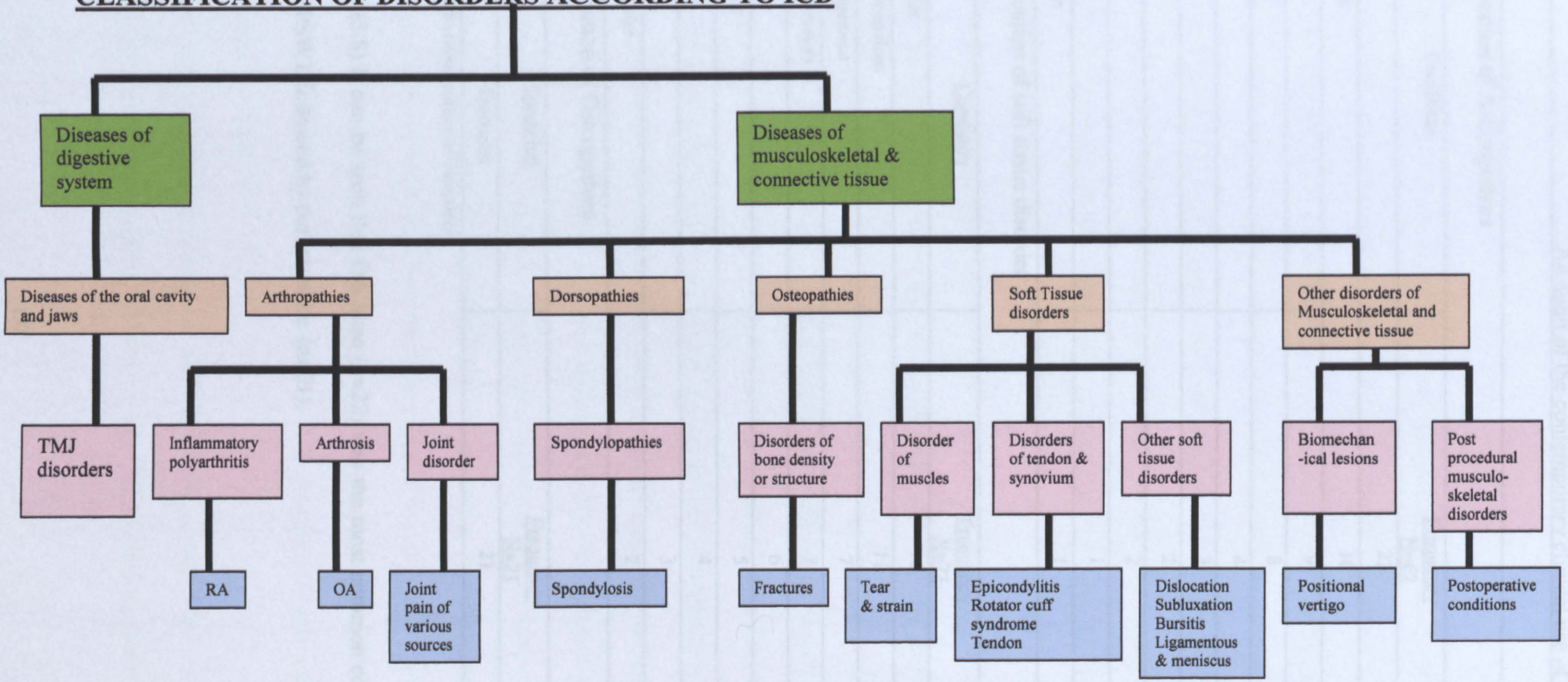


Figure (5.2) Classification of conditions according to ICD
The ICD had a lot of other classifications and sub classification that were not reported in this graph as they were not related to the current work

Sub classification of Arthropathies	
Condition	Frequency N=62
OA knee	22
Low back pain	10
RA	9
Shoulder pain	8
Hip pain	4
OA hip	3
Hand pain	2
Elbow pain	2
OA shoulder	1
Sacroiliac pain	1
Sub classification of soft tissue disorder	
Condition	Frequency N=73
Muscle disorder	16
Disorders of synovium	11
Tendon impingement	7
Tendon inflammation	7
Dislocation	6
Tendon rupture	5
Subluxation	4
Bursa disorder	3
Meniscus disorder	2
Sub classification of Osteopathies	
Condition	Frequency N=21
Fractures	21

Table (5.8) Sub-classification of disorders

From Table (5.8) it can be seen that OA knee (n=22) was the most common condition treated with PSWT followed by the fractures (n=21).

5.6 DISCUSSION

The study was based on an audit, which was undertaken to examine therapists' documentation skills relative to the standards of practice, compare the written standards with the current CSP guidelines and explore the nature of use of PSWT in the clinics so that relevant questions are developed in the questionnaire (second phase of the study). The audit was undertaken in eight randomly selected outpatient clinics representing the eight health regions in England. Although the study was conducted on a small sample, this sample was randomly chosen from wide geographical locations to allow for practice variation.

Unfortunately, the structure of some of the records examined did not allow for evaluating neither the full process nor the comprehensive quality of care delivered to patients. One of the most interesting findings of this study was the amount of information lacking from the files. The documented rationale explaining therapists' actions was absent in many files. The problem list was not always identified, and the time for achieving treatment goals was not always mentioned. Feedback on patient improvement was lacking and progress notes were not always updated with changes in treatment parameters. In the majority of files examined, only the pre-treatment status of the patient is mentioned in full and little if any is reported on the patients after cessation of the treatment with PSWT. Furthermore, in many cases the therapist altered the treatment plan without specifying the reasons underpinning this change or whether the patient got better, worse or did not respond to that alternation. Generally, the files examined did not meet the CSP (1996) objectives of facilitating communication and ensuring continuity of care.

Safety guidelines recommended that records should include notes on power, time of irradiation, method of coupling, pulsing regime, and any special feature of the

treatment (Docker et al, 1994). Furthermore, the CSP has always encouraged its members to record sufficient details for the notes to be understood and easily replicated by another physiotherapist (CSP, 1996). The guidelines have also urged therapists to draw a problem list with the time needed to achieve the treatment goals. Both the plan and the progress notes need to be recorded and updated. All of this is underpinned by the fact that documentation is a method of communication between members of the profession and the rest of the multi-disciplinary team and is a mean of protecting therapists in cases of litigation.

Regrettably, the aim of the treatment, which is crucial information, was not mentioned in the majority of the files, consequently, it was difficult to judge the reason for using PSWT with certain conditions such as positional vertigo.

The data gathered did not facilitate the production of common trends in treatment dosimetry, as the majority of records did not include enough information regarding treatment parameters (PD, PRR, PP and MP). Therapists did not seem to follow a specified way of selecting treatment parameters. It was therefore impossible to link the nature of dosimetry to the condition treated. Although the author attempted to calculate the MP from the parameters documented, the scarcity of the information provided did not facilitate this.

Additionally, a wide range of PSWT equipment were seen in the sampled departments. Given that different PSWT machines deliver different outputs even if they were set on the same parameters (Forster & Palastanga, 1985) it is crucial that this information is documented in patient's files. As such the author saw that it would not be meaningful to compare and extrapolate parameters of one machine to the other. It was interesting to note that the parameters for other modalities such as IFC or TENS were mentioned in full which suggest that absence of this crucial information is not due to

lack of time to document full treatment plan but possibly therapists' understanding and knowledge about this modality.

Progression in the treatment plan however, was achieved by changing one of the dosage parameters (time, PD or PRR), which is an acceptable practice. There was little agreement on the approach adopted, as some therapists progress by increasing the dose and others by reducing it. However, it was evident that increasing the dosage seems to result in better outcomes. This may be related to the accumulative effect of the dosage in the tissue that may override tissues threshold hence produce improvement (Cleary, 1996).

The current audit has revealed that only time, PRR, and PD were mentioned regularly in the files. A point of concern is that therapists rarely report parameters units (μsec, Hz), and because there is no evidence that the numbers used for PD, and PRR are interchangeable, reporting them in this manner could be of limited value for those who will replicate the treatment or for those researching the files. Examples of the way therapist document treatment parameters in the files (100, 200, 20′) or (200, 800,8 min).

A surprising finding was that most treatments were administered once only for duration of 10 minutes, nevertheless the outcome was good improvement. This practice is not in accordance with the available evidence as there was nothing in the literature nor in the manufacturer's recommendation that supports such a practice. Manufacturers recommend a minimum of 15 minutes for most conditions. Moreover, measuring intra-muscular temperature Draper et al (1999) demonstrated that the peak of physiological response could be reached in 15 minutes when the MP was set to 48W. These findings were based on the maximum increase in muscle temperature. Therefore, it could be speculated that treatment times of 5, 8 or even 10 minutes are less likely to result in therapeutic effects as lower settings are expected to take longer periods to affect

pathology if the effects are to be reached through temperature increase. Although a non-thermal mechanism could be taking place, no evidence exists that treatment periods of 5 or 8 minutes could have a detrimental effect on the patient's condition.

Despite the work being conducted on small sample, the frequency of use of PSWT among various outpatient clinics was ranging between 11-13% which was in agreement with Foster et al (1999) who conducted a bigger survey across England and Ireland with a sample of 2654 (response rate 58.3%). This verifies that the findings of this work carry a great promise of being representative of the actual clinical practice despite the size limitation.

The results of this investigation have reflected a plethora of diverse ranges of practice styles adopted by physiotherapists in various clinics. It also revealed a lack of uniformity and consensus, an issue that could be attributed to the effect of experience and clinical expertise developing throughout the years.

5.7 CONCLUSION

Patient's notes are a source of evidence and a method of evaluating the process and the outcome of interventions. Findings of this study have demonstrated that physiotherapists fail to adopt a systematic method of documentation. Such practice is in direct conflict with what is urged by the CSP. If therapists are to evaluate their practice against evidence, files need to be well documented and updated; otherwise, it is almost impossible to assess effectiveness.

The result of this audit was surprising in that none of the files examined fulfilled the CSP standards of documentation, 88% of those files did not have reproducible treatment plan in terms of dosimetry. This deficit in the quality of documentation is a source of concern from a professional and a legal standpoint.

While the findings of this work are sample-specific, they were nonetheless informative and have provided a wealth of information on the nature of the current practice with PSWT.

CHAPTER 6

A SURVEY OF PSWT USAGE IN ENGLAND

6.0 INTRODUCTION

Non-thermal agents are gaining an increased popularity, as therapists expand their use of low levels of energy to induce tissue healing (Watson, 2000; Kitchen and Partridge, 1996). PSWT is one of the electro-physical agents that is claimed to operate in the non-thermal mode and still result in therapeutic effects (Martin et al, 1990; Forster and Palastanga, 1985). It is a modality that is widely employed by physiotherapists across UK (Pope et al, 1995), yet, despite that, a lot of speculation surrounds its use, little is known on why or how to best apply it (Robertson and Spurritt, 1998). PSWT is therefore an under-explored modality (Pope et al, 1995), given the lack of researched literature in the field.

With the lack of published work on the nature of PSWT use in the clinical settings, it is assumed that physiotherapists are working according to practice standards and the best available evidence. This notion is not entirely true as physiotherapists are largely accused of basing their practice on observations and anecdotal evidence (Harris, 1996; Riddoch & Lennon, 1990). However, the survival of the profession in a climate of evidence based practice and budget driven care (Bury, 1996), demands that therapists demonstrate the efficacy of their services to policy-makers, consumers, and professional colleagues (Hick, 1999).

Given the above, it is imperative to conduct studies that validate clinical practice, and explore the criterion of patient care, especially given that a limited amount of information exists on therapist's beliefs, and factors affecting their choices to electro-physical modalities (Kitchen, 1995a). The objectives of conducting this nationwide survey were two fold: Firstly: to address and follow further the issues that have evolved from the audit on a wider sample. Secondly: to disclose the contemporary standards of

clinical practice and the impact of the interaction with evidence, and experience on the nature of the clinical practice in outpatient clinics.

6.1 AIMS OF THE STUDY

- To explore the nature of the current use of PSWT in outpatient clinics in England
- To explore practice standards with PSWT in outpatient clinics
- To explore the factors governing clinical decisions with PSWT
- To develop dosage protocols based on clinical practice using theoretical case studies (to be used in the next experimental phase)

6. 2 METHODOLOGY

6.2.1 The development of the study tool

A questionnaire was developed based on the literature reviewed and the exploratory study (audit) undertaken in phase one. A mixture of both open-ended and close-ended questions were employed. Close-ended questions were used in areas where enough understanding exists about the topic, while the free text questions were used elsewhere.

The close-ended questions used in this questionnaire required respondents to tick a box. By using close-ended questions the number of the subjects unwilling to answer or compose lengthy written responses are expected to decrease (Polit et al, 2001). However, close-ended questions are criticised of being superficial (Polit et al, 2001; Bowling, 1997), and restricting in that they force respondents to choose an answer from a list, which may not meet their needs. Moreover the questions may be irrelevant or uninteresting to the respondent, and there is always the possibility that the researcher

may have overlooked some areas that could have influenced the study validity (Polit et al, 2001; Rees, 1997). However, it is anticipated that by basing the work on the findings of the exploratory study, such obstacles have been largely overcome.

Open ended questions on the other hand, although time consuming to analyse are rich in valuable information (Polit et al, 2001; Oppenheim, 2000). The questionnaire at hand utilized an equal distribution of both modes of questioning.

The sequence of the questions is another critical area in planning a questionnaire. The intention was that the questions (in this phase of the questionnaire) asked earlier do not influence or give direction to the questions that follow. As a result, some questions that belong to the same section did not follow each other in sequence to avoid giving hints to respondents about the answers. This was done to reduce biased responses (Monette et al, 1998).

Cormack (1996) highlighted that a main disadvantage linked with the use of questionnaires is that the sample may be altered if the questionnaires were inappropriately answered by a person who is not from the intended sample (in this case the questionnaires being answered by a therapist who is not using PSWT in practice). Such an issue was not seen as a threat to this study as dealing with professionals is different from conducting public surveys where such problems may be encountered.

The length of the questionnaire is a decisive factor as it may boost or lower the response rate (Heiman, 1995). There is no hard and fast rule governing the length of the questionnaire, but a general rule is to keep it less than 5 pages long and filling it however, should not take more than 30 minutes (Monette et al, 1998). This questionnaire is 3 pages long and is anticipated to take less than 15 minutes to fill. Moreover, to improve the response rate and to stimulate respondent's interest and

encourage them to complete the questionnaire, a light green paper was used (Ballinger and Davey, 1998).

The questionnaire consisted of 17 items divided into several sections, each conveying an issue of practice. The first section was concerned with the demographic information of the respondents such as year of graduation, years of experience, and current post. Although it is preferred to avoid starting questionnaires with personal information as some respondents may lose interest (Heiman, 1995), the approach adopted in this study was known as the funnel approach (Lydeard, 1991) where the questions gradually increase in difficulty, smoothly leading the respondent to the harder questions.

Both the year of qualification and years spent working with electrotherapy were collected as they were thought to reveal different angles of practice. It was anticipated that the age and years of qualification might not indicate the actual number of years the therapist spent working with electrotherapy. This is because of the time spent working in different departments (e.g. inpatient or outpatient) or the time taken out of work or the possibilities of part time hours.

The second part of the questionnaire, comprised questions that were designed to elicit therapists' existing experience, and general knowledge on PSWT. The third part of the questionnaire covered the standards of practice and tackled issues such as documentation in patient's notes, general use of PSWT (time of application, frequency of use, progression and termination of treatment), and satisfaction with the literature.

The fourth section of the questionnaire introduced hypothetical case studies to therapists on OA. This section was added to the questionnaire to provide the researcher with guidelines to plan a treatment protocol for the subsequent phases of the project

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Definition, classification and clinical picture of OA can be found in Appendix B.6

(examination of the physiological effects associated with the application of PSWT on healthy subjects and OA patients). The main plan of the questionnaire is further explained in the Table (6.1).

Domain	Content	Question Number
Demographic information	Clinical grade Year of qualification- Years of experience in electrotherapy	1-2-3
Therapists' general knowledge on PSWT	Conditions treated Aims of treatment Factors affecting therapists choice Knowledge about the literature	7-9-10-11-16
Standards of practice	Documentation Application/ general use (Time of administration, frequency of use) Progression/ Termination of treatment Satisfaction with outcome	8 4-6 14-15 12-12a-12b 13
Theoretical case studies		16a-16b 16c

Table (6.1) The basic plan of the questionnaire

6.2.2 Pilot study

The pilot study was carried out in one of the local general hospitals. Polit et al (2001) define a pilot study as a trial run of the major study. It helps in identifying the unanticipated problems, checking the accuracy of the instrument, assessing its reliability and refining the data collection method hence allowing the study to progress smoothly enhancing optimal results.

The questionnaire was piloted with 8 physiotherapists. The respondents also completed an extra form for comments on the questionnaire clarity and ease of comprehension (Appendix B.1). According to the pilot sample it took them between 10-15 minutes to complete it. Their comments however, did not raise major concerns, although minor modifications were subsequently made to the terminology and the lists of choices provided for some questions before distribution of the final version (Appendix B.2).

Answers obtained from the pilot group did not differ significantly from what was anticipated based on the audit work.

6.2.3 Sample selection

The first intention was to select a random sample of therapists identified by contacting the CSP. However, the primary reason for rejecting this sampling procedure was the possibility of ending with a sample which although random and representative fails to fulfil the inclusion criteria (therapist must be working in outpatient clinic and is using PSWT on regular basis). Instead, the forms were sent to the managers of randomly chosen hospitals.

All the general hospitals of the eight health regions were entered the randomising process. The hospitals were stratified, given a code and entered into a table in the proper strata that corresponded to their health authority.

The questionnaire was approved by the ethical Committee of Radiology and Physiotherapy (Appendix 3) The sample was randomly drawn by the researcher who picked a number out of a hat. The manager of the physiotherapy department in that hospital was then sent an introductory letter (Appendix B.4) explaining the aims of the study and seeking co-operation. The covering letter also explained who was conducting the research, how the sample was chosen, the potential benefits to participants and to the profession as a whole.

Enclosed with the letter were four forms to be distributed by the manager to members of staff whom they see eligible (therapists working in outpatient clinic and is a frequent user to PSWT). Three hundred and sixty questionnaires were sent to 90 outpatient clinics. The hospitals covered the eight health regions across England. This large

number of hospitals was included to convey the diversity found in the preliminary work (audit) and to reflect regional variations.

On completion of the questionnaire therapists were asked to place the form in the stamped self addressed (SAE) envelope provided and send it to the researcher. As the questionnaires were coded according to the name of the hospital, it was possible to calculate how many forms came from each hospital.

Each therapist was asked in the covering letter (Appendix B.5) to complete the questionnaire and was assured that their responses were voluntary, and would remain confidential. To further ensure anonymity, physiotherapists were contacted through their managers and were not asked to write down their names. By asking the manager to distribute the forms and by asking the therapists to fill them in and return them in the provided envelope neither the manager nor the researcher are able to identify those who participated in the questionnaire, hence ensuring respondent confidentiality.

Follow up letters were sent when the forms stopped coming in. According to James and Bolstein (1990) follow up could boost the response rate by up to 20%. Given this, all those who did not respond or return the questionnaires, were sent a follow up letter through their managers, who was asked to remind their staff to fill the forms and send back the remaining questionnaires. All the forms received after the designated date mentioned in the follow up letter were ignored.

Responses were then entered into a file, and data were analysed descriptively using SPSS package (version 11).

6.3 DATA ANALYSIS

Data were analysed descriptively using the statistical package for the Social Sciences Software Program (SPSS-11). The replies for the open-ended questions (free text comments) were analysed using content analysis (Oppenheim, 2000), where answers were grouped into themes, collapsed, summarised into simple statements, and coded. Close-ended questions were analysed using frequencies.

6.4 RESULTS

Three hundred and sixty questionnaires were sent to 90 hospitals in the eight health regions across England.

Out of 360 forms sent out, 210 were returned giving a response rate of 58.3%. After the follow up letter 59 more forms were received raising the response rate to 68.8%. Total received was 269 forms, the valid forms were 247 (Table 6.2).

Before follow up				**After Follow up**				
	No.		No.		No.		No.	In Total
Returned	210	Completed	198	Returned	59	Completed	49	247
		Not completed	12			Not completed	9	22
Not returned	150			Total not returned	91			

Table (6.2) Response rate before and after follow up

The number of hospitals that were included in the survey from each region is shown in Table (6.3).

Region	Eastern	London	South East	South West	Trent	West Midlands	North West	Northern & Yorkshire
No	8	15	15	7	10	11	13	11

Table (6.3) The number of hospitals selected from each health region

Although the number of the hospitals in each region is not identical, this reflects the size of the health authority.

6.4.1 Demographic information

The data revealed that the majority of therapists were senior II (49%) and senior I (32%). Further explanation of the characteristics of the sample is presented in Table (6.4).

Clinical grade	Frequency	%
Basic grade	18	7.3
Senior II	121	49.0
Senior I	79	32.0
Clinical specialist	7	2.8
Superintendent IV	4	1.6
Superintendent III	18	7.3

Table (6.4) Characteristics of the sample according to the clinical grade

The years of experience in the field of electrotherapy for the sample are presented in Table (6.5). The table shows that 50% of the sample had between 1 and 5 years of experience in the field of electrotherapy. The overall years of experience as physiotherapists however, ranged between few months to 44 years with a mean of 11 ± 0.8 years.

Years of experience	Frequency	%
1-5 years	125	50.6
6-10 years	65	26.3
11-15 years	21	8.5
16-20 years	26	10.5
21-25 years	5	2.0
More than 25 years	5	2.0

Table (6.5) Years of experience in the field of electrotherapy

6.4.2 Standards of practice

The length of the treatment session with PSWT ranged between 5 minutes to 30 minutes. However, the 10 minutes treatment time was the model response and was the mostly preferred by therapists as shown in Table (6.6).

Treatment durations	Frequency	%
5 min	6	2.4
8 min	53	21.5
10 min	99	40
12 min	31	12.6
15 min	38	15.4
20 min	9	3.6
25 min	7	2.8
30 min	4	1.6

Table (6.6) Treatment durations

As for the frequency of use, therapists were asked to report the number of times they use PSWT for each patient. The frequency ranged between daily use to less than once a week, with the twice weekly being the most common answer (48.2%). More information is presented in Table (6.7).

Treatment frequency	Frequency	%
Daily	15	6.1
3/week	46	18.6
2/week	119	48.2
1/week	26	10.5
Less than 1/week	41	16.6

Table (6.7) Frequency of administering treatment

As for the satisfaction with treatment outcomes, the majority of therapists (72.4%) reported a good outcome with PSWT compared to 26.3% who thought that PSWT has no effect on the outcome (Table 6.8).

Treatment outcome	Frequency	%
Excellent	8	3.2
Good	171	69.2
Poor	23	9.3
Indifference	42	17.0
Missing values	3	1.2

Table (6.8) Treatment Outcome

6.4.3 Therapist's general knowledge on PSWT

The sample reported several aims for using PSWT. These aims are mentioned below according to their priority with most frequent reported first:

1. To reduce pain (43.7%)
2. To reduce swelling (27.1)
3. To reduce inflammation (17%)
4. To promote wound healing, and increase cell activity in the area surrounding the affected site (8.5%)
5. To improve circulation (2.4%)
6. To increase ROM, and improve mobility (0.8%)
7. To achieve placebo (0.4 %), to increase tissue extensibility (0.4%), to decrease nerve irritability (0.4%)

The survey results revealed that PSWT was used to treat a wide range of conditions. These conditions were classified using the ICD and are displayed in Table (6.9).

Diseases of musculoskeletal System	Arthropathies	OA, RA
	Spondylopathies	Spondylosis, *ankylosing spondylitis*
	Osteopathies	Fractures, *Osteoprosis*
	Soft tissue disorders	Muscle tear, muscle sprain, epicondylitis, capsulitis, subluxation, dislocation, bursitis, ligament and meniscus problems
	Other musculoskeletal disorders	Post operative conditions
Diseases of digestive system	Oral cavity disorders	TMJ
Diseases of nervous system	Nerve, nerve root & plexus disorder	*Nerve injuries*, *facial palsy*

Table (6.9) Classification of conditions according to ICD. Conditions shown in italics are addition to the conditions reported in the audit

Conditions mentioned above further confirm the audit findings and add a few categories (shown in italics).

The majority of the sample 222 (89.9%) surveyed preferred to use PSWT as a sole modality. It was not clear though if the choice to use PSWT as a sole modality was due to time constraints, departmental guidelines or the outcome obtained. A small number 22 (8.9%), combined their treatment with other modalities (responses arranged according to their frequency of occurrence)

1. US (5.3%), laser (5.3%)
2. Hot pack (1.2%), or IFC (1.2%)
3. Ice (0.4)

The reasons given for combining modalities were as follows:

- Therapists combine US with PSWT believing that the patient may benefit further from the local effects of the micromassage attributed to US.
- A small number of therapists believed that superior effects could be gained from administering two modalities in comparison to one due to the possible placebo effects it may have on patients.
- Therapists who reported using PSWT with IFC believed that IFC has more immediate and better results with pain, and if combined with PSWT additional improvement to the blood supply could be obtained in and around the affected area.
- PSWT is thought to be the last resort by some therapists who thinks that the use of PSWT may trigger a healing process that was not achieved by other modalities
- No reasons were given for combing PSWT with a hot pack and cold pack.

Combining modalities did not have a profound effect on the outcome. Findings demonstrate that the most reported outcome was good regardless of whether the therapist combined the treatment with another modality or not (Table 6.10).

Outcome	**Combing PSWT with other modalities**			
	Combine treatment	**%**	**Do not combine treatment**	**%**
Excellent	1	4.5	9	3.2
Good	14	63.6	156	70.6
Poor	3	13.6	22	9
Indifference	4	18.2	38	17.2
Total	22		225	

Table (6.10) Effects of combing modalities on the outcome

When writing in patient's notes therapists explain their treatment plan by reporting treatment time, PD, PRR and the part treated. Other parameters are mentioned though not so frequently. Table (6.11) shows the elements mentioned in patient's notes to describe a treatment plan with PSWT.

Parameters mentioned	**%**
Pulse width	96.8
Pulse repetition rate	96.4
Part treated	96
Treatment time	96
Power output	23.9
Patient position	13
Type of equipment used	10.5
Patient consent	7.3
Type of electrode	6.9
Treatment frequency	5.7
Outcome	5.7

Table (6.11) Parameters recorded in patient file

The decision to terminate the treatment if the patient was not responding was usually made after 3 sessions have been given to the patient. Further information is revealed in Table (6.12).

Termination of treatment	Frequency	%
1 session	8	3.2
2 sessions	73	29.6
3 sessions	113	45.7
4 sessions	33	13.4
More than 4 sessions	19	7.7
Missing values	1	0.4

Table (6.12) Number of session before terminating the treatment

However, if the patient was responding and the therapists decided to progress the treatment, it is usually done by changing more than one parameter simultaneously. The results also demonstrate that 21.2% prefer to change nothing, and 15.2% preferred to change the treatment time. Further description can be seen in Table (6.13).

Treatment progression	Frequency	%
Change modality	2	0.8
Pulse width	7	2.8
Pulse rate	8	3.2
Treatment time	38	15.3
Nothing	56	22.6
More than 1 settings a time	136	55.0

Table (6.13) Different approaches used by therapists to progress their treatment

The choice of treatment dosage is usually determined by several factors. The survey results are ranked according to their importance:

1) Stage of the disease (acute, sub-acute or chronic) (59.2%)
2) General symptoms of the patient (17%)
3) Site of lesion (13.2%)
4) Personal experience (5.3%)
5) Published literature (3.6%)
6) Equipment manual (1.2%)
7) Discussion with colleges (0.5%)

When respondents were asked about the factors that could determine their preference to PSWT among other electrotherapy modalities they ranked their answer as follows:

1) Patient signs and symptoms (80.6%)
2) Previous experience (16.2%)
3) Recommendation from senior therapists or physicians (2%)
4) Familiarity with the machine (0.8%)
5) Availability of equipment (0.4%)

The interaction between experience as a whole in the field of physiotherapy and in the field of electrotherapy was further analysed using Chi square test (X^2) test to examine its effect on the therapist's decisions. Results are shown in Table (6.14).

Variable	X^2	Df	Correlation
Experience Vs treatment outcome	0.311	15	NS
Years since qualification Vs outcome	0.068	15	NS
Experience Vs satisfaction with literature	0.283	5	NS
Years since qualification Vs satisfaction with literature	0.858	5	NS
Experience Vs treatment time	0.000	35	S
Years since qualification Vs treatment time	0.000	35	S
Experience Vs frequency of use	0.108	20	NS
Years since qualification Vs frequency of use	0.019	20	S
Years since qualification Vs combining treatment	0.627	5	NS
Experience Vs combining treatment	0.047	5	S
Experience Vs treatment progression	0.675	25	NS
Years since qualification Vs treatment progression	0.022	25	S
Years since qualification Vs treatment termination	0.022	20	S
Experience Vs treatment termination	0.066	20	NS

Table (6.14) Interaction between experience and the nature of practice
S: significant relationship, NS: not significant

Interesting findings have emerged from further analysis of the results. The years of experience in electrotherapy field seems to affect the choice to combine PSWT with other modalities significantly. While the years since qualification seems to have more effect on determining physiotherapist' choices with regard to the frequency of applying a treatment, treatment progression and termination. Deciding on the length of the session with PSWT appears to be affected by the years of experience as a physiotherapist in total and in electrotherapy field in particular.

Experience was always second as the most important factor in decision after the nature of the condition. This may be caused by the lack of clear evidence on PSWT effectiveness, especially given that more than half the sample (58%) were not satisfied with the quality and the amount of the existing literature as could be seen in Figure (6.1).

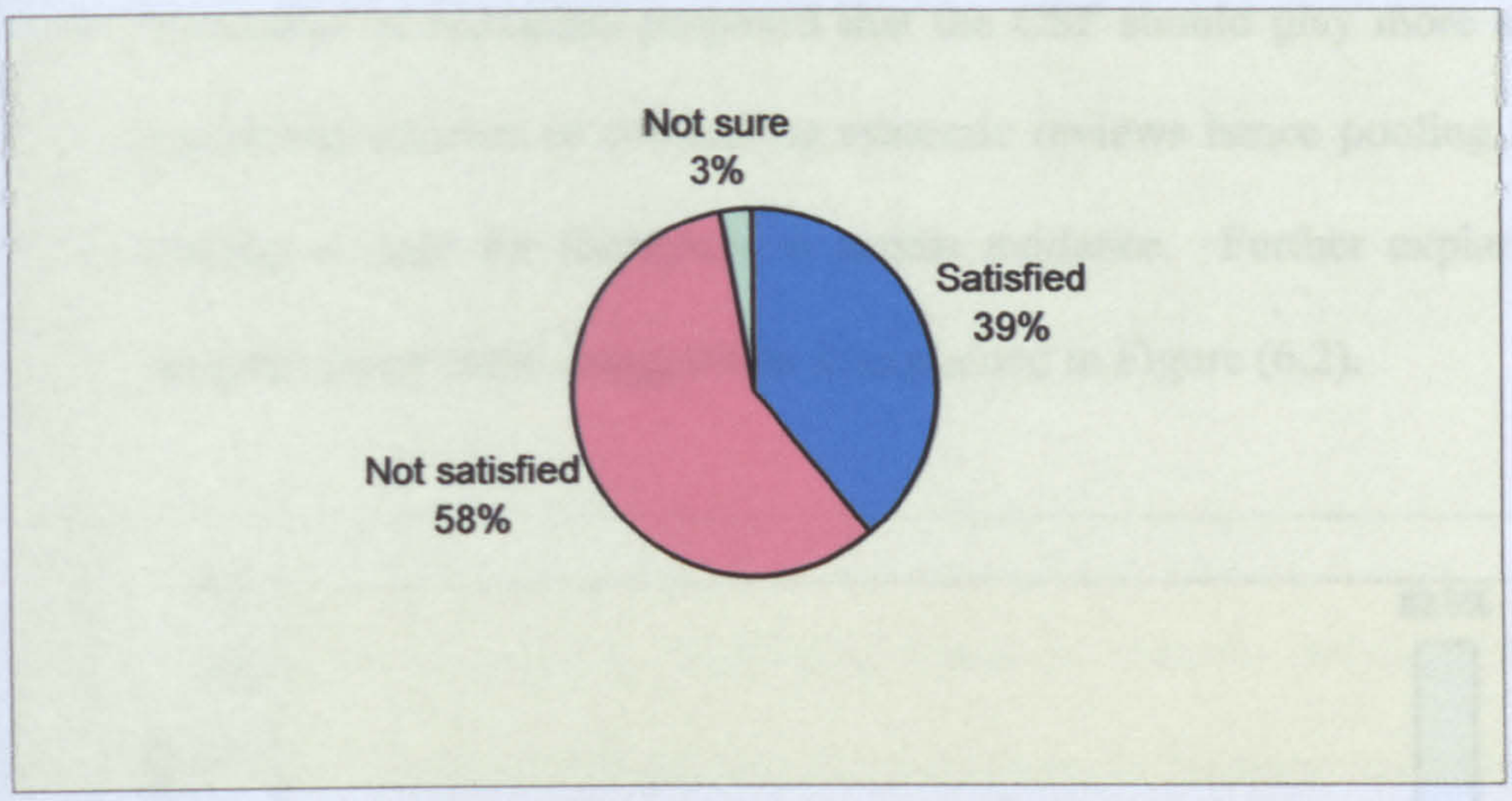

Figure (6.1) Therapists' satisfaction with the literature on PSWT

The therapists advocated the following solutions to improve their satisfaction with the literature.

1- Up to date and recent well conducted controlled trials are needed, as most of the studies are outdated.

2- Specific trials on treatment parameters, and the effectiveness of a given treatment on a single condition.

3- Research results should be made more available. Clinicians do not have the time, the resources nor the knowdge to search various databases for such information.

4- More credible studies are needed. Some studies have used treatment protocols that are unrealistic to apply in NHS setting. As a result studies are seen to be ailented from the clinical setting. Therapists prefer that the studies are

conducted in a clinical setting instead of a laboratory to allow for extrapolating the findings to clinical practice.

5- The use of clear and less vague terminology is paramount in order to increase the readership.

6- A number of therapists proposed that the CSP should play more active role in organising courses or conducting systemic reviews hence pooling study results making it easy for therapists to access evidence. Further explanation to the frequencies of these suggestions is explained in Figure (6.2).

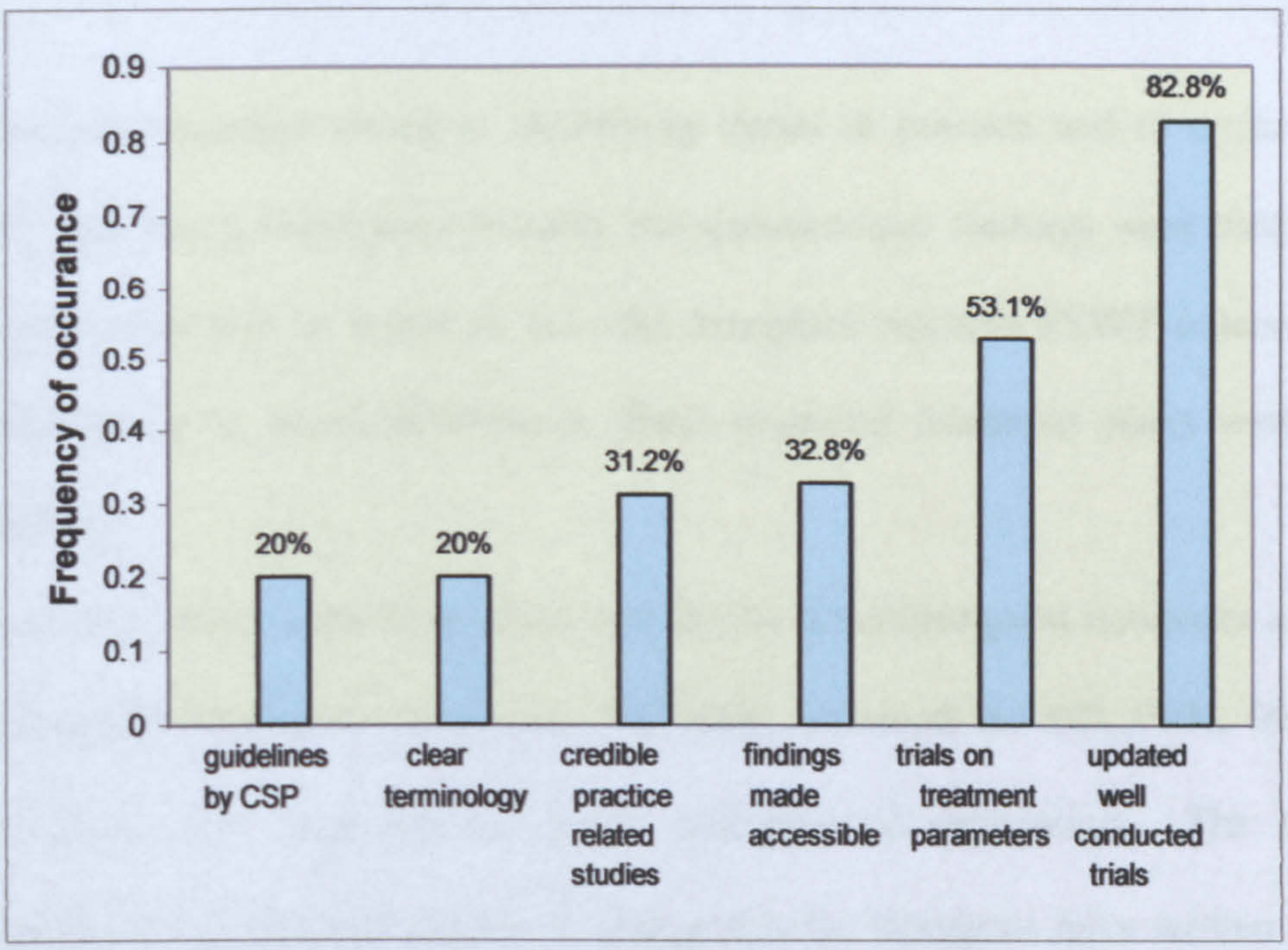

Figure (6.2) Suggestions to improve satisfaction with the literature

6.4.4 Theoretical case studies

The case studies presented in the last section of the questionnaire were intended to guide the experimental work at later stages of the project by providing guidance to the researcher to plan the treatment dosage. The cases were to describe acute, sub-acute and chronic knee OA. Although it was not expected that therapists would come up with

identical choices, it was anticipated that their replies would identify trends that could direct planning the next experimental phase. Results for the 3 conditions are shown in Table (6.15).

Disease stage	Time (min)	Frequency per week	PRR (Hz)	PD (μsec)	MP (W)
Acute	15	2	200	100	3W
Sub-acute	10	2	200	100	3W
Chronic	20	2	800	200	24W

Table (6.15) Therapist's proposed plans for the theoretical case studies (the values reported in the table represent the most frequent answers)

As this questionnaire aimed at identifying trends in practice and to understand how PSWT was being employed clinically, the questionnaire findings were further divided into two subgroups in terms of how the therapists reported PSWT outcomes (either excellent/good or poor/indifference). Their proposed treatment plans were analysed accordingly.

Two dosage tables were formulated, one for the Excellent/good outcomes and another for the poor/indifference outcomes. The table contained the PD, PRR, frequency of administering the treatment per week, and time of application. The tables also contained all the probable ranges of dosage that the therapists have written down, and their first choice (highest occurrence) is highlighted in each section for ease of comparison.

Dividing the findings according to the outcome was undertaken in an attempt to find out whether therapists who obtain good outcomes with their patients have a certain trend in choosing the dosage in relation to those who were not satisfied with the outcome. Results are displayed in Table (6.16) and Table (6.17).

	Case 1 Acute OA		Case 2 Chronic OA with acute exacerbation		Case 3 Chronic OA	
Range of PD reported (μsec)	20 65 100 200 400	1st choice	20 40 65 100 200 400	1st choice	20 65 100 200 400	1st choice
Range of PRR reported (Hz)	50 65 100 200 400 800	1st choice	50 100 200 400 800	1st choice	100 200 400 800	1st choice
Range of treatment duration reported (min)	8 10 12 15 20 30	1st choice	8 10 12 15 20	1st choice	10 12 15 20	1st choice
Range of treatment frequency reported	1 2 3 5	1st choice	1 2 3 5	1st choice	1 2 3 4	1st choice

Table (6.16) Table of suggested treatments for those reporting good/excellent outcomes for the 3 cases

	Case 1 Acute OA		Case 2 Chronic OA with acute exacerbation		Case 3 Chronic OA	
Range of PD reported (μsec)	65 100 200 400	1st choice	20 40 65 100 200 400	1st choice	65 100 200 400	1st choice
Range of PRR reported (Hz)	50 100 200 400 800	1st choice	50 100 200 400 800	1st choice	50 100 200 400 800	1st choice
Range of treatment time reported (min)	10 12 15 20	1st choice	8 10 15 20 30	1st choice	10 15 20 30	1st choice
Range of treatment frequency reported	1 2 3	1st choice	1 2 3	1st choice	1 2 3	1st choice

Table (6.17) The suggested treatment plans for those who reporting poor/indifference outcome (first choice according to most common reporting

A clear pattern was seen in the choice of PD and PRR for the three proposed conditions. Those who reported good outcome opted to use low dosage with less time for acute and sub-acute conditions. Therapists also tend to increase the dosage and the time for chronic conditions. The treatment parameters identified by therapists who report poor outcomes were almost the same suggesting that they were not selective in their dosage,

a practice that therapists are known to use when not sure on the dosage to apply (Kitchen, 1995b).

Observations have showed that the use of 15 minutes as an initial treatment time with a PD of 100 μsec and PRR of 200 pps for acute conditions resulted in best outcome. The same dosage was proposed for sub-acute knee OA but with shorter treatment duration (10 minutes). With chronic conditions, a time of 20 minutes, a PD of 200 μsec and PRR of 800 pps seem to produce the desired effects.

These parameters will be examined later in both the laboratory and clinical trials for validation of effectiveness or lack of effectiveness.

6.5 DISCUSSION

This nationwide survey was conducted to explore the nature of PSWT use in outpatient clinics, and further explore the issues that emerged from the audit.

Employing a questionnaire as a tool for the study was because of the advantage of covering a large sample of people (Hicks, 1999; Burns and Grove, 1993). By using questionnaires, the possibility of the researcher influencing respondents' answers intentionally or unintentionally is considerably reduced (Hicks, 1999). Moreover, by maintaining confidentiality and anonymity, respondents are more likely to provide honest accounts of their experience and current knowledge (Cormack, 1996).

6.5.1 Response rate

According to Babbie (1995) a response rate of 50% is adequate for analysis. However, Oppenheim (2000) and Barker (1991) emphasised that a response rate of above 60% shows a well-conducted research tool. Monette et al (1998) supported the above view stressing that high response rate allows for generalisation to a wider

population. A low response rate on the other hand, lowers the researchers confidence in extrapolating findings as the characteristics of those who refused to participate may have been different from those who returned the questionnaire (Monette et al, 1998).

In this study 360 questionnaires were mailed to ninety hospitals in the eight health regions in England. This has the advantage of collating data from a wide geographical area.

In order to have a good response rate the subjects in this study were provided with SAE to return the questionnaire. They were not rushed in answering back, thus conveying to therapists that the researcher appreciated their busy schedule. The questionnaire did not require respondents to provide their names. This feature maintained confidentiality and as such may have increased the likelihood that the respondents were objective (Babbie, 1995). Subjects were not asked to fill in a consent form and their participation was accepted as consent to the study. The SAE were not coded according to participants instead it was coded according to hospitals to assure therapists that there was no way of identifying any individual respondents and hence may have reduced biased responses, and might have had the added advantage of increasing the response rate.

The initial response rate for this questionnaire was 58.3%, this was boosted to 68.8% after follow up. The number of forms received back from each hospital varied between one to four forms according to the size of PSWT use in that facility. However, all the hospitals made the effort to participate either by filling the forms in and sending them back to the researcher or by the manager sending a note to the researcher with the unfilled questionnaires stating that the eligible physiotherapists have been contacted, and the unfilled forms were being sent back.

Monette et al (1998) argued that respondents usually react better to surveys that are directly related to them. The high response rate in this study may support this notion

and suggests that therapists are in need of studies that may provide some practice directions, an issue that was previously raised in the literature by Ide (1990). The response rate may further indicate that physiotherapists were aware of their role in the contribution to research and the evidence base of their profession.

6.5.2 The sample

The response rate (n=247, 68.8%) was considered sufficiently high to be representative of the intended population in the eight health regions across England, especially with the replies being received from all regions and including all the clinical grades. Although fifty percent of the sample had between 1 and 5 years of experience, this did not mean that half the sample were junior physiotherapists. The 1-5 years referred to the years of experience in the field of electrotherapy, the overall years of experience however, ranged between a few months to 44 years with a mean of 11 ± 0.8 years of experience in the field of physiotherapy.

In an attempt to determine the extent to which respondents differ from non-respondents, the author contacted the CSP to obtain the percentage of therapists in different posts hence examining any bias that may have resulted from non response or the randomisation process. However, these attempts failed, as there was no response from the CSP.

Unlike previous surveys conducted in England where the sample was limited to either a sample of convenience or some of the local health authorities, this survey has covered large sample from all health regions around England. As such the results have an added advantage of being representative of the current practice.

6.5.3 Frequency of use

The majority of the findings are in agreement with the audit data in phase 1 of the research. Curiously, in the audit the most common mode of applying PSWT was once per week compared to twice in this phase of the study, this may be caused by the broader range and the large sample surveyed.

Pope et al (1995); and Kitchen and Partridge (1996) have reported PSWT to be a widely used modality with the latter study reporting that more than half their respondents using PSWT more than once a week. The findings of the current study are in agreement with these results. Almost three quarters (72.9%) of the sample in this study use PSWT more than once a week and out of those, 48.2% were using it twice weekly. Such results refute the speculation that PSWT is losing its popularity (Prentice and Draper, 2001) and confirm the regional differences identified previously in the literature (Baxter et al, 1991; Lehmann and DeLateur, 1990; Ziskin et al, 1990).

The duration of the treatment with PSWT varied between 5-30 minutes, with 10 minutes being the most commonly used. These results are in agreement with the first part of the study (audit). It is interesting that both sections of the work have shown that 10 minutes is the most common practice with regard to PSWT durations. This could reveal an area of mismatch between practice and research. Studies conducted on PSWT efficacy usually administer the treatment for 15-30 minutes. This means that the research findings are not in accordance with practice and may not inform the clinical decision, which could explain why therapists are relying on their experience when it comes to deciding the best treatment.

6.5.4 Mode of use

As for the strategy of applying PSWT, therapists were asked about the number of sessions given to patients before deciding that PSWT is of limited value. The majority (45.7%) preferred to wait for 3 sessions before they judged that the treatment was not working and there was a need to terminate it. These findings are in agreement with Kitchen (1995b) who reported that therapists believe that 2-4 session is the maximum that should be given because if no improvement was seen by then it is unlikely that any improvement would be seen at all. The findings are in accordance with the available evidence (Hayne, 1984) and are further suggesting that therapists are looking for the cumulative effect of applied treatment.

Examining the approach adopted by therapists to progress treatments revealed a degree of confusion as changing two or three parameters at one session reveals uncertainty of the effect that each element may have on the output and hence on the patient response. However, adopting this approach leaves therapists unclear on which factor has brought patient improvement or deterioration. Results were in disagreement with Kitchen (1995b) who found from a sample of 5 therapists, that treatment is progressed in terms of time or intensity and therapists tend to change one or the other. Differences in outcome could be caused by the small sample employed in that study or the fact that Kitchen used interviews and subjects tend not to tell what they feel when they are in a one to one situation (Cormack, 1996).

Findings have also revealed that there was a belief among therapists (9%) that combining modalities will have superior outcomes compared to single modality. Although these notions have not been validated by clinical trials, it has been referred to in the literature in several occasions (Kitchen, 1995b; Gray et al, 1994).

According to the literature, PSWT may have several therapeutic effects. The sample was asked to report the aims they were trying to achieve when choosing PSWT as a treatment modality. The lists of aims reported by the sample revealed a state of confusion between the short and long term aims. Although it was not part of the question to specify short and long term goals, it was expected that therapists could differentiate between direct and indirect effects of the treatment. For example, improving ROM and mobility will not result from PSWT application alone but from incorporating an exercise program as an adjunct to treatment.

In agreement with some of the work conducted on treatment goals, pain relief was highlighted being the top of the list (Kitchen, 1995b). The mechanism by which PSWT can relieve pain is not understood but several theories have been proposed. Though still anecdotal, it has been widely accepted that PSWT can reduce pain by inhibiting the sensory impulses transmission, this in turn may lead to a sedative effect in the treated area. However, if the cause of pain is inflammatory, the pain is expected to reduce as a result of the vasodilatation and absorption of the exudates accumulating in the tissues (Ward, 1980). The pain resulting from muscle spasm could reduce as a consequence of vasodilatation and the removal of access lactic acid and other metabolic products in the muscle that cause muscle soreness (Kitchen, 2002).

Interestingly, the number of therapists who believe in the placebo effect of PSWT was greater than those who believed in its effects on tissue extensibility or nerve growth. The placebo effect of PSWT has been demonstrated repeatedly in the literature (Klaber-Moffett et al, 1996; Foley-Nolan et al, 1992; Foley-Nolan et al, 1990; Reed et al, 1987) and its effect on patients cannot be denied.

Despite the fact that therapists use PSWT to promote bone growth, not enough evidence exists to support that, and the majority of the experimental work was conducted on ELF

especially the carrying frequency of 15 Hz, and 75 Hz (Fredericks et al, 2000; Landorf, 1998; Rubin et al, 1993).

Muscle spasm is one of the aims that appeared in the list as a reason for using PSWT. There is no evidence to suggest that PSWT may work directly on the muscle to relive spasm however, by improving the circulation and clearing waste products resulting from muscle contraction, certain degree of muscle relaxation may occur, though there is no experimental evidence to support these claims.

The majority (89.9%) of those surveyed preferred to use PSWT as a sole modality and not to combine it with other electrotherapy modalities. These results are in disagreement with Kitchen and Partridge (1996) that electro-physical agents are rarely used in isolation, though their survey was looking at combining four modalities (US, SWD, PSWT and Laser) with each other and with any other physiotherapy interventions. Thirty eight percent of their sample opted for combining modalities. Over half of those 38% combined PSWT with US, and 2.6% combined PSWT with laser. The reason given for these combinations was the same as the one of respondents in this study that is to augment the effect of the treatment and to treat more than one type of tissue at a time.

Although no direct evidence could be obtained from the literature to support combining electro-physical modalities, three possible reasons could be speculated. Since the depth of penetration and the nature of the anatomical structure each modality may stimulate is different, targeting more than one level of tissue could have superior therapeutic effect. Secondly: the net energy resulting in the tissues as a result of combining modalities may have better effect in augmenting and triggering the healing process. Thirdly: switching between modalities may overcome the plateau response patients may show as a result of using a single modality (Kitchen, 1995b).

The fact that the majority of therapists prefer to use PSWT as a sole modality should direct future research, so that experimentation serves to inform clinical needs and the research findings becomes of more use to therapists.

The continuous development in the field of electrotherapy (Pope et al, 1995; Wadsworth and Chanmugam, 1983) requires that physiotherapists constantly update their knowledge of research, techniques and machines (Roberstson and Spurritt, 1998). However, therapists in this study commented that literature is not filtering through to them, aside from the other issues of difficult language that drives therapists away. Additionally, with much of the electrotherapy literature being published in non-physiotherapy journals (Turner and Whitfield, 1996; Mitchell, 1993), it would be expected that a wealth of information goes by unnoticed by the busy therapists (Sahrmann, 1998). Therapists in the study however have suggested that compiling studies in databases by the CSP is needed. This intiative has already started by forming the electrotherapy interest group which was formed by a group of individuals with interest in the field of electrotherapy.

6.5.5 Conditions treated

Previous studies have used several different methods to classify conditions, but none have attempted to use ICD classification employed in this study, possibly because this classification was originally meant for physicians and epidemiologists. The ability of this classification system to embrace large number of categories highlighting its wide flexibility as a classification system and its potential benefit to physiotherapists.

The conditions reported by the sample confirmed those reported in the audit. Other conditions were added to the list such as ankylosing spondylitis, osteoprosis, nerve

injuries, and facial palsy. The addition of new cases could be attributed to the large sample size included in the survey compared to the audit.

6.5.6 Documentation

The issue of documentation was raised in the first section of the study (audit) and was also detected in the questionnaire. The majority of therapists opted for describing their treatment plan with only PD, PRR, and the duration of application. Given that PSWT machines have different PP, different outputs will be delivered by different units even if they were set on the same parameters (Forster & Palastanga, 1985). As a result it becomes imperative that all relevant information such as type of equipment, and MP are mentioned. Factors such as patient position, site of application, electrode placement and type are crucial for treatment repeatability hence need to be mentioned. The CSP has always encouraged its members to record adequate details for the notes to be understood and easily replicated by another physiotherapist (CSP, 1996). The guidelines have also urged therapists to draw a problem list with the time needed to achieve the treatment goals. Both the plan and the progress notes need to be recorded and updated. All of this is underpinned by the fact that documentation is a method of communication between members of the profession and the rest of the multi-disciplinary team and is a mean of protecting therapists in cases of litigation.

Interestingly, a small number of therapists mentioned the patient consent. Consent is defined by the Department of Health as the voluntary and continuing permission of the patient to receive a particular treatment based on adequate knowledge of the purpose, nature, likely effects and risks of that treatment (DOH, 2001). Consent is about treating patients as co-partners in the decision making process. This right may only be overridden if harm to the patient may occur (Wear, 1993). However, patients

appearing in the department should not be viewed as consent to the treatment. Physiotherapists have a duty to clearly inform their patients about the proposed treatment. Patients must be informed about risks, benefits and alternative treatment using simple language (CSP, 1996). However, the reason for not mentioning it could be due the notion that PSWT is thought to be *athermal* modality, hence there is no need to warn the patient (Forster & Palastanga, 1985). It is a legal requirement for therapists to document it in the patients' notes (Wear, 1993) to protect themselves from legal action (Armstrong et al, 1997). The CSP rules states that oral and implied consent are accepted in physiotherapy practice (CSP, 1996) as such it is assumed that possibly because consent is obtained once at the initial visit of any patient and is not repeated in every session, it was not reported in the questionnaire.

The findings of this work is in agreement with Turner and Whitfield (1999) who in a survey of 320 therapists reported experience to be the second most important source for decision making after intial eduction. The current study has examined the effect of overall years of experience and the years of experience in the field of electrotherapy on the clinical decision making. The years of experience in the electrotherapy field seems to have a significant relationship with the choice of treatment time and whether to combine the PSWT treatment with other modalities or not, while the years since qualification seems to have more effect on determining the physiotherapists' choices with regard to the treatment, frequency of use, treatment progression and termination. It could be speculated from these results that the overall years as a physiotherapist seem to define therapist choices more than the years spent in electrotherapy and may be because of the lack of available evidence therapists tend to extrapolate work experience from different fields of physiotherapy to electrotherapy.

Results demonstrate that even with the increasing pressure on therapists to base their practice on evidence, therapists still follow their intuition to guide them through their practice. The survey conducted by Sheilds (2003) has shown that the use of PSWT was not influenced by evidence as the choice to use the modality was mainly influenced by space, availability, and cost and that evidence ranked 6^{th} in the list. These findings were consistant with the current findings as the available literature and equipment manual were ranked at the bottom of the list denoting their minimal role in influencing therapists' decisions.

6.5.7 The nature of the clinical decision with PSWT

The findings of this study along with those of the audit have raised issues about the interaction between both the evidence, and the nature of the clinical decision with regard to PSWT.

According to Hunink et al (2001) and March (1984), rational decisions are made following the knowledge of the available choices, the alternatives to consider and choose from, and the consequences stemming from these available choices. This means that for a clinician to make a rational decision, a clear understanding of two basic factors should proceed:

1- The reason for choosing PSWT when a range of electro-physical modalities is available.

2- How to best tailor the dosage (MP, PP, frequency of application, time of application) according to patient needs.

However, a lot of dispute still embraces those issues. In order to know why a given modality is chosen there needs to exist enough knowledge on its proven effects. The amount of experimental work conducted on PSWT remains limited and the outcome of

these studies is not conclusive. A general rule is to use low dose for acute conditions and slightly higher dose for sub-acute and even higher for chronic with no definitions to what is meant by low and high dose and what is the boundary between them. With some suggesting a combination of high PP and high PRR (Cameron et al, 1999) and others emphasising the role of a single parameter such as short PD (Low and Reed, 2000) or high pulse power (Wadsworth and Chanmugam, 1983). However, all of these suggestions resemble attempts to provide a method of categorising treatment parameters, these attempts remain to be anecdotal and lack experimental validation.

New technological advances have led to the production of new generations of PSWT machines with user friendly screens and pre-programmed advice offering the "*best*" treatment parameters based on the "*best*" available scientific evidence. Although such devices are thought of as being in accordance with the move towards evidence-based practice, the quality of the evidence provided is questionable as it is governed by the quality of the trials conducted and marketing needs. Moreover, according to many, the evidence in the field of electrotherapy especially with PSWT is fragmented and provides little direction to clinicians (Markov and Colbert, 2000).

Additionally, deciding on the *right* dosage is a complex issue that is not easily resolved. The area of dosage is complex due to the lack of a tool that quantitatively measures the amount of power absorbed by different tissues in the treated area especially with the power meter on the PSWT console showing the amount of output delivered by the equipment with no indication to how much is being absorbed by the tissues (Delpizzo and Joyner, 1987). The application of PSWT is associated with no or minimal skin sensation, and this could vary between subjects depending on the sensitivity of skin thermoreceptors. As such it is hard to depend on patient thermal sensation to judge the intensity of the field.

Moreover, given the number of combinations that PSWT machine can be set in (Table 6.18) and the number of these combinations that have not been subjected to investigation for effectiveness, it becomes evident that the literature has little to offer clinicians (Dyson, 1994). Consequently, therapists are left to rely on their personal experience, trial and error, and intuition to guide them through their practice (Turner and Whitfield, 1999; Green, 1991). Clinicians are forced to integrate their theoretical knowledge, and clinical expertise in what is called the empirical reasoning (Wulff and Gotzsche, 2000). One major disadvantage in adopting empiricism as a philosophy for practice is that it fosters the techni- physiotherapist and supports the move away from professionalism as it could retard the personal and possibly the professional growth and denies the active pursuit for new information as individuals lose interest in searching for new information and only utilise their reservoir of knowledge (Wolf, 1986).

PD	PRR	PP	Pulse modes	Possible combinations
6	5	Fixed (150 W)	3	90
20-40-65-100-200-400 (μsec)	50-100-200-400-800 (Hz)		1:3 - 2:3 – 3:3	

Table (6.18) Example of the possible combinations when setting PSWT machine. Parameters resemble Megapulse Senior

Basing decisions on experience alone could also obscure the thoroughness of the subjective and objective assessment obtained at the assessment stage into routine approaches (those that have been tried and was seen to be working). In doing so therapists are dismissing other available options and basing their practice on habit and convenience rather than rationale (Watt, 1985).

All of the above results in fragile decisions that are easily overturned and dismissed (March, 1984). Such behaviour may manifest itself in the frequent alterations to a treatment plan without a clear underpinning rational, a behaviour that was widely detected when patient's files were audited.

The state of the current practice could be a representation of the poor quality of the evidence and the lack of clear clinical guidance. Such issues justify the importance of conducting further trials that explores PSWT effectiveness. Trials should be directed to investigate the interaction between EMF and biological tissues on both healthy and patient population. Trials conducted on healthy subjects allow for understanding the PSWT mechanism of action and obtaining normative data, while trials on patients allow for the understanding of diseased tissue reactions to the applied energy.

6.5.8 Theoretical case studies

Three case studies were presented in the last section of the questionnaire in order to provide a basis for deciding on the dose to test when examining the physiological effects of PSWT. This was done to overcome the pitfalls of the majority of the published reports when they examine arbitrary doses with no rationale presented. By basing experimentation on clinical practice, the findings of this work will be of more value to clinicians.

The three cases presented were intended to represent acute, sub-acute and chronic states. Two of those cases will be subjected to experimentation which are the acute and the chronic. Findings in Table (6.16) reveal that both acute and sub-acute conditions appear to be treated similarly by therapists with the same MP.

There appears to be no selectivity in treating the 3 conditions as therapists preferred to treat patients twice a week regardless of the chronicity of the disease. This may have been caused by the therapists' load rather than the condition treated because it is expected that acute cases be treated more than sub-acute more than chronic (Low and Reed, 2000).

An interesting trend has emerged from the data suggesting that selec treatment parameters is associated with better treatment outcome. This selecti to be explored further and studied in future research as it may throw some ligh nature of the clinical decision with PSWT and possibly in the area of selecting a the field of electrotherapy.

Based on the reporting of therapists summarised in Table (6.17) and (6.18) was decided that 100 μsec-200 pps –10 minutes and 200 μsec –800 pps -10 minutes would be used for the laboratory and clinical trials. It was decided to standardise the time for the two conditions to prevent time from becoming a confounding factor and altering the results by delivering more energy to the tissue making it hard to compare the results of the two conditions.

6.6 CONCLUSION

The findings suggest that PSWT is a modality that is used to reduce pain, swelling and inflammation. It was demonstrated that the years of experience in the field of electrotherapy seems to shape therapists' decisions on whether to combine PSWT with other modalities, choice of treatment time while experience as a whole in the field of physiotherapy seems to affect therapists' choices to frequency of treatment, and treatment progression. As little is known on the process of decision making in the field of electrotherapy, further research is warranted in order to understand the underpinning reasons for this behaviour.

ocumentation is an area that needs further attention, as it was evident from this survey ıg with the previous audit section that the quality of documentation is poor and needs improved for the information to facilitate treatment plan replication and to protect ts against legal litigation.

CHAPTER 7

PHYSIOLOGICAL, ANATOMICAL AND MEASUREMENT PRINCIPLES

7.0 INTRODUCTION

This chapter will provide a physiological and anatomical background to the outcome measures, and description of the range of instruments available for measuring them. The chapter will be dealing with blood perfusion, skin and core temperature, and nerve conduction velocity (NCV). They were chosen as primary outcome measures due to their close reflection to changes in the thermoregulatory system besides being widely used non-invasive parameters that reflect the body reaction to exogenous EMF (Rivner et al, 2001; Buschbacher, 1998).

In the trial that will be conducted on a patient population, along with the primary outcome measures mentioned above, there will be measurement of secondary outcome factors which include pain, muscle strength, and ROM. These outcome measures were included in an attempt to reflect both subjectively and objectively the observations reported by the patients and correlate that with changes in primary variables measured during the treatment.

7.1 PRIMARY OUTCOME MEASURES

7.1.1 Body Temperature

Skin and core temperature are two physiological parameters that are often monitored for therapeutic and research purposes in order to track the thermal effects of external exposure to either hypothermia or hyperthermia.

SkT can be measured using various SkT probes that can be affixed to any area of the body. With the skin being superficial it is subjected to different variations in the environment. Therefore, both air temperature and humidity have a direct effect on SkT

as they control the amount of evaporation, conduction, convection, and radiation and hence the thermoregulatory mechanism (Houdas and Ring, 1982).

Core temperature (CorT) is a reflection of the heat in the blood perfusing the thermoregulatory receptors in the hypothalamus (Betta et al, 1997). CorT undergoes a process of rhythmical variation with the lowest recorded in the early hours of the morning (between 2-5 am), the temperature then starts to increase during the day, reaching its maximum at about 5 pm, then starts to fall down gradually. This cyclic variation is known as the circadian cycle and is known to affect the overall temperature variation by a range of 0.5-1.5°C (Houdas and Ring, 1982). A variation of up to ±0.6°C in CorT temperature is considered normal when taking repeated measurements (Guyton, and Hall, 2000).

The hypothalamus is the ideal place for measuring CorT. However, since it is hard to measure the temperature at the hypothalamic region, a variety of alternative body sites have been sought to monitor body temperature. CorT can be measured from either natural or artificial cavities. These cavities provide a place for measuring the temperature with minimal environmental disturbances. They include the rectum, the mouth, the ear, bladder, and sometimes the vagina. There is also what is called artificial cavities and these include the axilla, the groin, area between the thighs when the legs are crossed, and in the space between the two palms if they were kept together (Erickson and Kirklin, 1993; Houdas and Ring, 1982).

The tympanic site, offers a close reflection of the thalamic temperature because of the anatomic proximity and shared vascularization as such is considered one of the best sites to measure CorT (Betta et al, 1997; Houdas and Ring, 1982).

Various devices can be used to measure CorT such as liquid in glass thermometers, electric thermometers, digital thermometers, infra-red thermometers and the tympanic thermometers.

The tympanic thermometer is a hand held probe that detects thermal radiation from the ear canal (Dowding et al, 2002; Erickson, 1983). The tip of the probe is inserted into the auditory canal and the wave guide within the probe directs the infra-red radiation from the tympanic membrane to infra-red sensor. Inside the probe is a sensor unit that contains the detector which converts the infra-red radiation to an electrical signal and an electronic unit that processes the electrical signal and displays it as a reading (Betta et al, 1997).

Tympanic thermometers have the ability to measure core temperature in seconds (Beckstrand et al, 1996, Erickson, 1983) with minimal distress to the subject (Johnson et al, 1991) making them more practical. Although tympanic thermometers have been shown to record underestimated values for CorT, this deviation in the recorded temperature was found to be consistent within the same make and not affected by the distance between the probe tip and the targeted tissues (Betta et al, 1997; Pontious et al, 1994).

7.1.2 Blood perfusion

Blood can be measured and monitored in terms of flow, volume, and movement. Although there may be other ways of measuring blood, in this review the above three are grouped under blood perfusion.

Blood perfusion can be monitored using a range of either invasive or non-invasive techniques. These techniques are based on measuring the physical movement of blood.

The invasive techniques include radioisotope clearance, flourescein injection, venous occlusion plethysmography (VOP), thermal clearance. Non-invasive techniques include Laser Doppler Flowmetry (LDF), and photoplethysmography (PPG). Both LDF and PPG, allow monitoring of blood perfusion with minimal discomfort to the subject being non-invasive.

PPG is an instrument that provides qualitative (Nitzan et al, 1998) measure of tissue BVol (Figure 7.1). It can be applied virtually to any blood bearing tissue (Swain and Grant, 1989). Using the electro-optic technique either with a tungsten lamp or an infrared light, the PPG provides a qualitative measure of the cardiovascular pulse wave found throughout the human body (Nitzan et al, 1998) in tissues up to 3.3 mm deep (Schultz-Ehrenburg and Blazek, 2001). PPG utilises an infrared light, as it is relatively well absorbed in the blood and weakly absorbed in other tissues; thus allowing for observations to changes in blood volumes with reasonable contrast (Schultz-Ehrenburg and Blazek, 2001).

When the skin is illuminated with the infrared light, the light is absorbed, reflected, or scattered in the tissues and in the blood. The part of light reflected is picked up by a photo-detector and the size and the shape of the pulse waves is analysed as a function of BVol changes. Depending on the volume of blood in the tissues the light detected would either increase or decrease. The amount of light absorbed by the probe is inversely related to the volume of blood (Babchenko et al, 2001; Nitzan et al, 1998). The amount of light reflected depends on the attenuation of the tissues, the amount of blood in the vessels of the skin, and the variation in the BVol by time (Swain and Grant, 1989).

During systole, blood is ejected from the left ventricle into the peripheral vascular system, increasing arterial blood content and decreasing the amount of light emitted.

The maximal value of PPG corresponds with end of diastole when the blood volume is minimal (Babchenko et al, 2001).

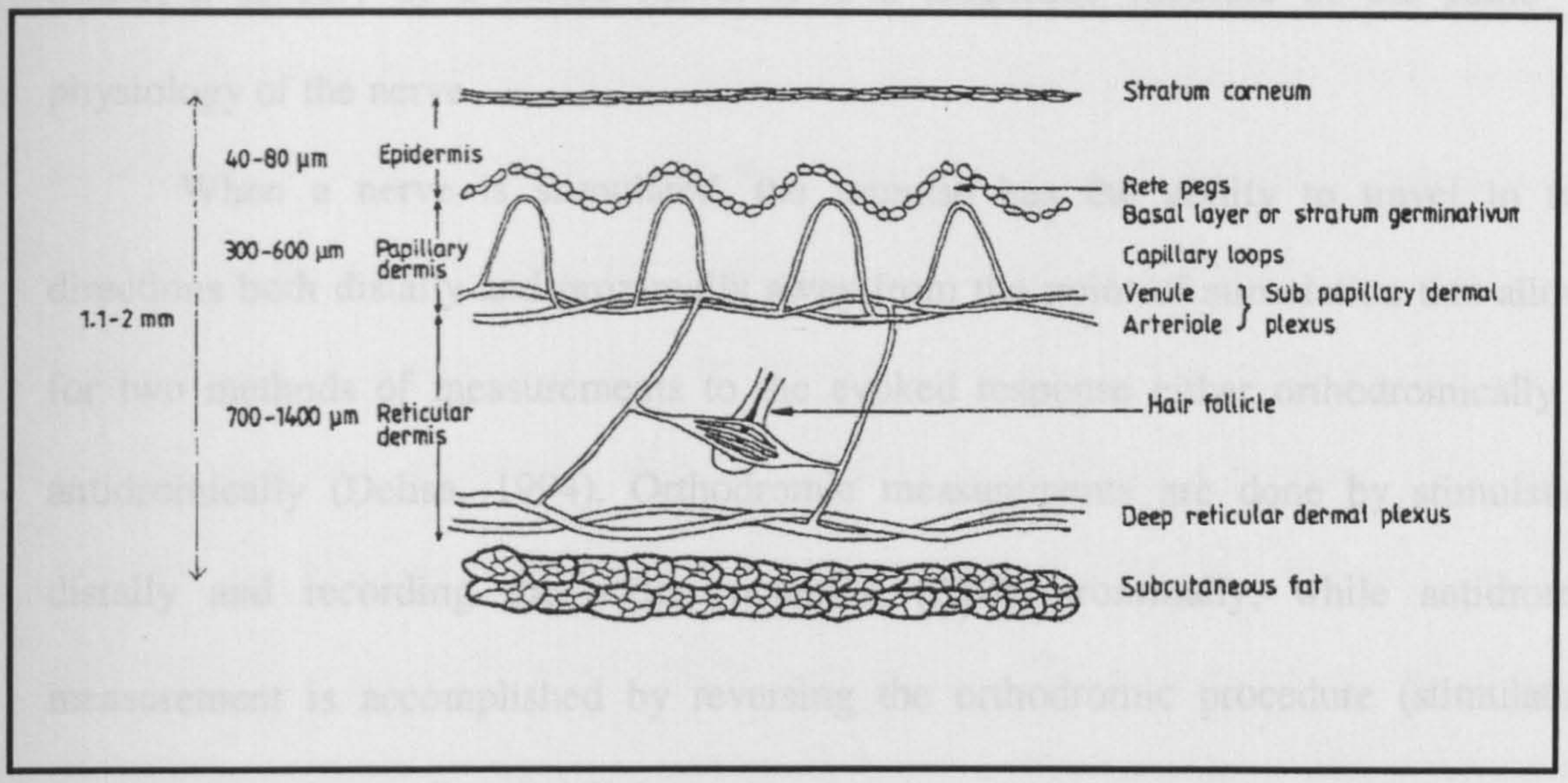

Figure (7.1) Distribution of blood vessels in the skin (from Swain and Grant, 1989)

However, because PPG is normally affixed to the skin, it carries the disadvantage of recording signals that are not related to the actual changes in blood perfusion. Motion artefacts can be seen when the subject moves or the probe moves in relation to the skin. The recorded signal could also depend on the degree of pigmentation in the tissues, and the initial blood volume in the area (Schultz-Ehrenburg and Blazek, 2001).

PPG is known to produce comparable results with VOP (De Trafford and Lafferty, 1984) and LDF (Almond et al, 1988). It has considerable degrees of sensitivity even in cases of temperature alternation (Lindberg, 1991; Almond et al, 1988).

7.1.3 Nerve conduction velocity

NCV studies refer to the study of the speed of impulse conduction along a motor, a sensory or a mixed nerve. It is a diagnostic measure of the patho-physiology of the nerve.

When a nerve is stimulated, the impulse has the ability to travel in two directions both distally and proximally away from the point of stimulation this allows for two methods of measurements to the evoked response either orthodromically or antidromically (Delisa, 1994). Orthodromic measurements are done by stimulating distally and recording the action potential (AP)* proximally, while antidromic measurement is accomplished by reversing the orthodromic procedure (stimulating proximally and recording distally).

Several devices exist that can be used to measure nerve conduction, though they may differ in shape, almost all have the same components. The recording unit, a stimulator to deliver the impulse, an amplifier to magnify the recorded signal and keep unnecessary interference signals (noise) as low as possible using either high or low filters. Some units may also have audio amplifier and a speaker to allow the acoustic examination of the potential. The recorded signal is either displayed on an oscilloscope or directly on the monitor depending on the measuring unit used. The amplitude of the potential is determined by the sensitivity control which typically ranges between 5 to 10000μV. The potentials can be displayed using oscilloscope, and recorded using Polaroid photography, paper or tape recording (Oh, 1996).

Nerves are usually stimulated using a square-wave stimulus. The stimulating signal can vary between 0.05 to 1 msec, however the longer the duration of the impulse, the more painful the stimulus to the subject. The response is usually obtained by increasing the intensity gradually from zero to the supramaximal level. It is

recommended that the stimulus is delivered with a rate of 1 stimulus per second as it is desirable for both the patient (less painful) and the investigator (to allow for better examination to the function of the neuromuscular transmission) (Oh, 1996).

Three sets of electrodes are needed for NCV studies; ground electrodes to reduce stimulation artefacts, lowers interference and noise and a set of stimulating and recording electrodes to deliver the stimulus, and pick up the AP. While some equipment may use one set of recording and one set of stimulating electrodes others may use two sets of recording electrodes and two sets of stimulating electrodes (Oh, 1996). Additionally, although some may refer to the ground electrode as a reference electrode (Oh, 1996; Dong and Livesone, 1983) negating its effects on the measured signal, it actually contributes to the AP waveform shape by distorting the initial deflection at baseline and elongating the onset latency if misplaced. As such, the signal recorded can be distorted by the site of the ground electrode. It was found that by altering the reference or indifferent electrode placement, NCV could change by up to 1.5m/sec (Phongsmart et al, 2002).

NCV can be measured using either needle or surface electrodes. Surface electrodes are usually attached to the body while needle electrodes are inserted directly into the muscle. Both techniques have their advantages and disadvantages. Surface electrodes are easy to apply however, are not capable of recording a single AP nor can they record AP of short duration. An inherent difficulty with surface electrodes is controlling the number of fibres, and the size of the fibres that react to the external stimulus delivered. Different nerves have different electrical thresholds this in turn results in impulses travelling at various speeds along the nerve fibres. Small nerves need

*Definition and basis of AP can be found in Appendix C.1

stronger stimulation in order to be excited and impulses usually travel more slowly compared to larger sized fibres. Additionally, large diameter fibres tend to respond quicker than small diameter non-myelinated ones (Oh, 1996). Consequently, the evoked response picked up by the recording electrodes is the summation of impulses of different nerves with the fastest nerve composing the first parts of the AP recorded. To overcome this problem stimulation should be performed at supra-maximal level to ensure the stimulation of all nerve fibres and a consistent response.

NCV is the product of dividing distance by time (onset latency). Distance is taken as the distance between the centre of the stimulating electrode to the centre of the recording electrode if one set of electrodes is used or the distance between two stimulating sites divided by the conduction time between the two stimulating electrodes if two sets are used (Oh, 1996; Dong and Livesone, 1983).

Sensory and motor responses can be measured quantitatively using the distinct components of the signal. These components are the onset latency, which is measured in milliseconds and is defined as the time between the introduction of a stimulus and the initial deflection of the evoked response. The amplitude of a response, which is measured in micro or millivolts, and is defined as the vertical displacement from the baseline and the peak of the negative peak in motor recording or peak to peak distance in sensory recording. Other components include the duration of the response (Dong and Livesone, 1983).

NCV recordings vary with age, temperature, segment of the nerve (distal or proximal), between different nerve types (Rivner et al, 2001; Buschbacher, 1998) and obesity (Rutkove, 2001).

Temperature plays a significant role in the conduction velocity, and the shape of the signal recorded. However, in cases where the temperature can not be controlled,

correction can be made by either heating the part or recalculating the conduction velocity at lower temperatures using special equations (Rutkove, 2001; Delisa, 1994).

7.2 SECONDARY OUTCOME MEASURES

7.2.1 Body fat

There are several methods of measuring body fat. These methods include SFM using callipers, hydrostatic weighing, anthropometrics variables, height-weight ratio (BMI), bioelectric impedance (BEI), dual energy X-ray absorptiometry, magnetic resonance imaging (MRI) and air displacement plethysmography.

SFM were found to provide similar estimates of body density than methods such as hydrostatic weighing (Young et al, 1998), ultrasound (Weits et al, 1986), anthropometrics variables (Jackson and Pollock, 1985) and near infrared spectrophotometry (Eaton et al, 1993). Results from SFM were also found to be comparable with BEI, dual energy X-ray absorptiometry, and MRI (Kwok et al, 2001; Nicholson et al, 2001; Wattanapenpaiboon et al, 1998).

SFM is a method of calculating body fat from body density using specific or general equations (Cyrino et al, 2003). It is a measure of the thickness of two layers of skin and the underlying subcutaneous fat (Heyward and Stolarczyk, 1996). Given that a third of body fat is located subcutaneously (Jackson and Pollock, 1985) and that the fat layer is not evenly distributed throughout the body, different equations use different combination of anatomical sites (ranging from 2 sites to 10 sites) in order to have an overall estimate of fat distribution (Cyrino et al, 2003; Riegerova and Pridalova, 2002). Several predictive equations have been developed to calculate body density, Durnin and Womersley (1974), Jackson and Pollock (1987), Jackson et al (1980) are the mostly used.

Scherf et al (1986) compared equations used by Jackson and Pollock with Durnin and Womersley and hydrostatic weighing and found that although the findings were comparable the error margin with Durnin and Womersley equations was within 6.6% while it was within 0.7% of body fat with Jackson and Pollock.

A lot of disagreement exist on the proper method of measuring Skinfold. While some discusses the importance of taking the measurement over the fold (He et al, 1999; Clasey et al, 1997). Jackson and Pollock (1985) argue that it can be taken horizontally, obliquely or vertically depending on the site. Other factors such as the technician skill, type of calliper and equations employed (Lehman et al, 1984), all could play a role in the accuracy of the reading. Controversies also exist on the side of measurement. There is no Conesus on the side of the body, the measurements need to be taken from (Heyward and Stolarczyk, 1996). While Lehmann et al (1988) recommended that all measurements need to be taken on the right side, Harrison et al (1988) compared measurements taken from both sides and found no significant difference. As such for consistency the side measured needs to be standardised. All of the above necessitate that investigator reliability be established prior to data collection.

7.2.2 Muscle strength

Muscle strength can be measured either manually or mechanically. Manual muscle testing (MMT) is based on grading the strength of the muscle against the examiner or the gravity resistance using a 5-point grading scale that ranges from poor to normal. Mechanically, muscle strength can be measured using many methods, most popular is the myometer, Cybex, and grip meters.

The hand held myometer is a method of quantitatively measuring muscle strength and providing a direct recording of force output. Its construct validity with the

Cybex was shown to be high (r = 0.8). Being less expensive, portable and consuming less time to record a measurement, it becomes a practical alternative to Cybex II (Andrew et al, 1996). Hayes et al (2002) tested 3 methods for assessing the shoulder strength in patients with shoulder pathology (MMT, myometer, and spring scale myometer). Hand held myometer has shown the highest reliability with all shoulder movements (ICC value ranging between 0.79-0.92) except internal rotation (ICC value between 0.7-0.72). The investigators suggested that higher levels of reliability are expected with normal subjects. Reliability of hand held myometer was also demonstrated with elderly (Wang et al; 2002).

Myometer could be challenging with strong and athletic individuals especially if the examiner is physically weak. This problem is mostly seen with testing the hip musculature as such the use of anchoring station (Nadler et al, 2000) or a belt resisted method where the subject body weight adds more stability is advisable (Kramer et al, 1991) however, both devices are still under examination for reliability.

Although the myometer is associated with high level of intra-examiner (95-96%) and inter-examiner (91-95 %) reliability (Schreuders et al, 2000), its reading could be affected by the position of the joint due to the change in lever arm which may show as a change in the force exerted without an actual change in strength (McMahon et al, 1992). It also depends on the examiners strength and ability to hold against the resistance of the patient as such may exhibit variability that is not related to isometric muscle strength (Ford-Smith et al, 2001). This variability was found to be between 9-24% intra-assessor and 37-52% inter-assessor reliability (Schreuders et al, 2000).

In testing muscle strength, the movement can be done using either make or break technique, that is to either break or make the movement. Although both make and break methods measure maximal voluntary muscle strength, the force produced by the

break test is greater than the force produced by the make test (Stratford and Balsor, 1994; Bohannon, 1986). The break testing has been shown to provide more reliable and accurate measurements (Phillips, 2000). It can be performed by asking the subject to exert maximal force against the examiner or the testing device while the examiner opposes the movement to overcome the patient effort until the joint gives away. While in the make testing the examiners asks the subject to exert maximal force against the myometer for a period of 3-5 seconds (Bohannon, 1986).

7.2.3 Range of motion

Several methods have been employed by therapists to quantify joint range of motion. Joint ROM can be measured using the universal goniometer (full circle), computerised pendulum orthoranger, fluid based goniometer, parallelogram goniometer, or the inclinometer.

The universal goniometer was found to be more accurate than computerised orthoranger (Clapper and Wolf, 1988) and more reliable than fluid based goniometer (Chiarello and Savidge, 1993; Rheault et al, 1988). The reliability of a goniometer readings is accepted to be accurate to within 5° for upper limb movement and 6° for lower limb motions (Clapper and Wolf, 1988), however, some have argued that no inferences should be made for changes less than 10° (Bovens et al, 1990).

Goniometeric reliability can differ according to several factors such as the starting position, joint measured, interference of therapists fingers with the placement of the goniometer, goniometric placement and pressure applied (Somers et al, 1997; Bovens et al, 1990; Clapper and Wolf, 1988).

Despite the limitations and the variable range of reliability associated with the use of the goniometer, standardising the testing positions and establishing the

researchers reliability prior to conducting any trial can aid in reducing errors in measurements and increasing the reliability range (Rome and Cawiesn, 1996).

7.2.4 Visual analogue scale (VAS)

VAS is a widely used self-report method of measuring almost any symptoms or behaviour. VAS has been used for years to assess changes in pain level and monitor its severity. Conventionally, patients are presented with a 100 mm line and are asked to place a mark that would correspond to their symptom. The line is anchored on both ends with words or numbers that represent the extreme to the variable studied such as no pain -worst pain.

Essentially, pain is of a multi-dimensional construct, consisting of sensory, affective, evaluative, cognitive and behavioural elements. Despite having a face validity (Sim and Arnell, 1993), VAS can only measure the intensity component of the sensory dimension of pain (Sim and Waterfield, 1997). Although this may suggest low content validity, limiting interferences with regard to other scales, VAS was highly correlated to other measures used to assess pain such as McGill questionnaire (Scrimshaw and Maher, 2001) and computerised VAS (Jamison et al, 2002).

VAS has been shown to be sensitive to the increase and decrease in pain than the fixed interval scales (Bolton and Wilkinson, 1998) or McGill questionnaire (Scrimshaw and Maher, 2001). It was shown to be a valid measure when evaluated for both chronic and experimental pain (Price et al, 1983), and the young and old population (Tiplady et al, 1998). Consistency of VAS was found to increase by increasing the number of assessments made, and by assessing pain over several days (Jensen and McFarland, 1993), possibly because of a learning effect.

Reliability with VAS depends on the ability of the subject to place a mark where they intend to put it. Babul (1994) evaluated the memory of pain in 77 subjects undergoing orthopaedic surgery. Hourly pain rating, and post surgery ratings, were obtained for 48 hours and compared it to retrospective pain memory. Retrospective pain rating was found to be highly correlated (r = 0.89) with hourly reports, providing support for the reliability and the accuracy of subjects when recalling the rate of pain. However, observers cannot accurately assess the subjective experience of another person. Apparent discrepancies in self reported pain might be seen in the mismatch between the score assigned to pain when patients, health care workers and caregivers were compared. It was reported that health professionals and caregivers always rate pain lower than that actually experienced by the patient (Clark et al, 2003; Miaskowski et al, 1997; Eu et al, 1994). These observations can be attributed to several factors. Caregivers tend to think that patients overreact when expressing their pain because of the anxiety (Bisseret, 1981), physicians on the other hand evaluate pain in terms of the worst pain they have experienced when treating patients (Estrada et al, 1997).

VAS can be administered either in a vertical or in a horizontal format (Price et al, 2003; Gift, 1989) both of which were highly correlated. VAS can also be administered using numerical or verbal values. However, no method was found to be superior as both were strongly correlated and can be used interchangeably depending on the purpose of the study (Bijur et al, 2003, Mantyselka et al, 2001). It was found that the failure rate with VAS ranges between 7%-11% in terms of reproducibility (Ogon et al, 1996; McGuire, 1984). The failure, is influenced by the way the question is asked or the explanation made rather than the orientation or the wording of the scale (Ogon et al, 1996).

. According to Gallagher et al (2001) and Todd et al (1996) a difference of 13 mm or 1.3 cm on VAS represents the minimum clinical significant difference although other have accepted 9 mm to be the minimum acceptable difference (Deloach et al, 1998).

7.3 CONCLUSION

This chapter have described the various methods available for measuring BVol, Skin and core temperature, NCV, body fat, muscle strength, ROM and pain level. It was undertaken to decide on the best approach to measure the primary and the secondary measures with sufficient reliability to ensure the validity of the data collected. Based on the review it was decided to use PPG to measure BVol, tympanic thermometer to measure CorT, skin calliper and Jackson and Pollock equations for men and women to measure body fat, hand held myometer to measure muscle strength, classic goniometer to measure ROM, and horizontal VAS to measure pain level.

The next chapter will discuss issues related to reliability, validation of the acquisition system in a series of pilot laboratory experimentation.

CHAPTER 8

PILOT LABORATORY EXPERIMENTS

8.0 INTRODUCTION

In chapters five and six a work was reported that explored the nature of PSWT use in outpatient clinics. This chapter provides validation of the acquisition system, examination of the recorded signal, and pilot experiments aiming at developing the experimental protocol that will be used for the subsequent trials. Two trials will be conducted to measure the changes in BVol, SkT and NCV as a result of irradiating the knee joint with PSWT. The intended plan of the experiments was to take the measurements from both limbs simultaneously. Measurements will also be taken before, during and after PSWT administration. As such it was crucial that the interaction between the EMF and the measuring instrument, the quality of the signal recorded be studied beforehand.

The pilot study was also conducted to check the accuracy of the parameters used as outcome measures, explore the feasibility, practicality of the experiment protocol and the reliability of the measuring device.

8.1 THE PILOT AIMS

1. To calibrate the gain of the biopotential amplifiers
2. To examine the effect of distance between the data acquisition system and the PSWT (Megapulse) machine on the measured signal.
3. To examine the ability of the electrodes to detect changes in the physiological signal when under the effect of PSWT
4. To examine the time taken by various electrodes to return to baseline reading after being subjected to PSWT
5. To examine the effect of the distance between the PSWT (Megapulse) treatment head and a phantom on the measured signal.

6. To examine the effect of different external noises on the recorded signal.
7. To examine the nature of pulse signal derived from PPG
8. To compare the magnitude and the nature of interference between two PSWT machines (Megapulse, and Phyaction Performa+) on the acquisition system
9. To examine the developed experimental protocol for practicality on a small group of subjects

The work was undertaken in four parts:

Part 1 deals with calibrating the acquisition system (aim 1).

Part 2 deals with validation of the acquisition system, and examination of the variables affecting the signal quality in general such as the distance between the acquisition system and the PSWT machine, and the stability of electrodes under PSWT (aim 2-8).

Part 3 deals with comparing the nature of interference from two PSWT machines on the data acquisition system (aim 8).

Part 4 deals with the experimental pilot work and recommendations to improve the quality of data collected in the next two trials (aim 9).

PART 1: EQUIPMENT CALIBRATION

The signal was recorded using an MP100 (Biopac Systems, Santa Barbara, CA, USA). It is an acquisition system that collects, analyses, stores, and retrieves data. It has 16 input/ output channels and a sampling rate of up to 7000 samples/second. Details of the specification are in Appendix (D.2).

Calibrating the gain of the amplifiers used in the study is essential prior to the start of data collection. Description of the calibration of biopotentials is found in Appendix D.1. The current study will be employing EMG amplifier, PPG amplifier, and SkT amplifier, nerve stimulator (specifications of all amplifiers can be found in Appendix D.2), and PSWT. All of these units were checked regularly for accuracy and when necessary were calibrated to maintain the quality of the recorded signal.

Both the stimulator and the PSWT machine were calibrated by the manufacturer prior to data collection. Although some of the pilot work was undertaken prior to the calibration of PSWT, this did not raise any concerns as according to the technician, no major problems were detected in the unit and as a result no major modifications were made that altered the output accuracy.

8.2 CONCLUSION

The work reported in this section revealed inaccuracy in the EMG and PPG outputs. Calibration was done across the whole range of the gain setting with EMG and on the gain that would be used for collecting data with PPG. This was done because PPG was more sensitive than EMG to the change in the gain setting. Changing the gain alters the zero point of the signal with PGG, and as such it was decided to only calibrate the gain that would be used for acquiring the signal.

All calibrations were done following the manufacturer's instructions. Thereupon and throughout the conduct of the rest of the pilot experimentation, the amplifiers were checked weekly by the researcher and recalibrated when necessary.

The next section will involve validation of the acquisition system, examination of the nature and the accuracy of the recorded signal. This was considered essential prior to data collection to ensure the validity of data collected and reported.

PART 2: VALIDATION OF THE ACQUISITION SYSTEM

The administration of PSWT is associated with the emission of both E and H fields (Section 2.2). This field is known to extend several meters from the applicator (Shields, 2003; Tzima and Martin, 1994; Coppell, 1988). Thus it was crucial to explore whether the field surrounding PSWT equipment was strong enough to interfere with the function of the data acquisition system. Such work was seen fundamental in order to determine the safe working distance for both pieces of equipment. The effect of EMR was also examined on the nature and accuracy of the recorded signal and methods of improving the quality of the data collected are discussed.

Ethical approval for the pilot was obtained from Ethical Committee of Radiography and Physiotherapy in University of Hertfordshire (Appendix D.3).

8.3 EQUIPMENT

8.3.1 PSWT machine

Experimentation was done using a Megapulse Senior machine (Electro-Medical Supplies, Greenham, Ltd; UK).

Megapulse is a therapeutic machine that can deliver both continuous and pulsed SW. In the pulsed mode it can deliver short pulses, which are adjustable in duration (20 - 400μsec) and PRR (50-800 Hz) enabling the operator to vary the output. The peak output however, is fixed at 150 watts, while the mean output varies depending on the parameters selected. The pulses can be delivered either continuously (3:3), two thirds of the time (2:3) or one third of the time (1:3). The applicator houses the silver-plated copper coil and has 4 turns and an outside diameter of approximately 140 mm. The electric field is suppressed by a faradic screen adjusted in front of the coil (personal

communication with manufacturer). As the coil is wrapped around the extremity, the magnetic field is restricted to the inside circumference of the applicator (Figure 8.1)

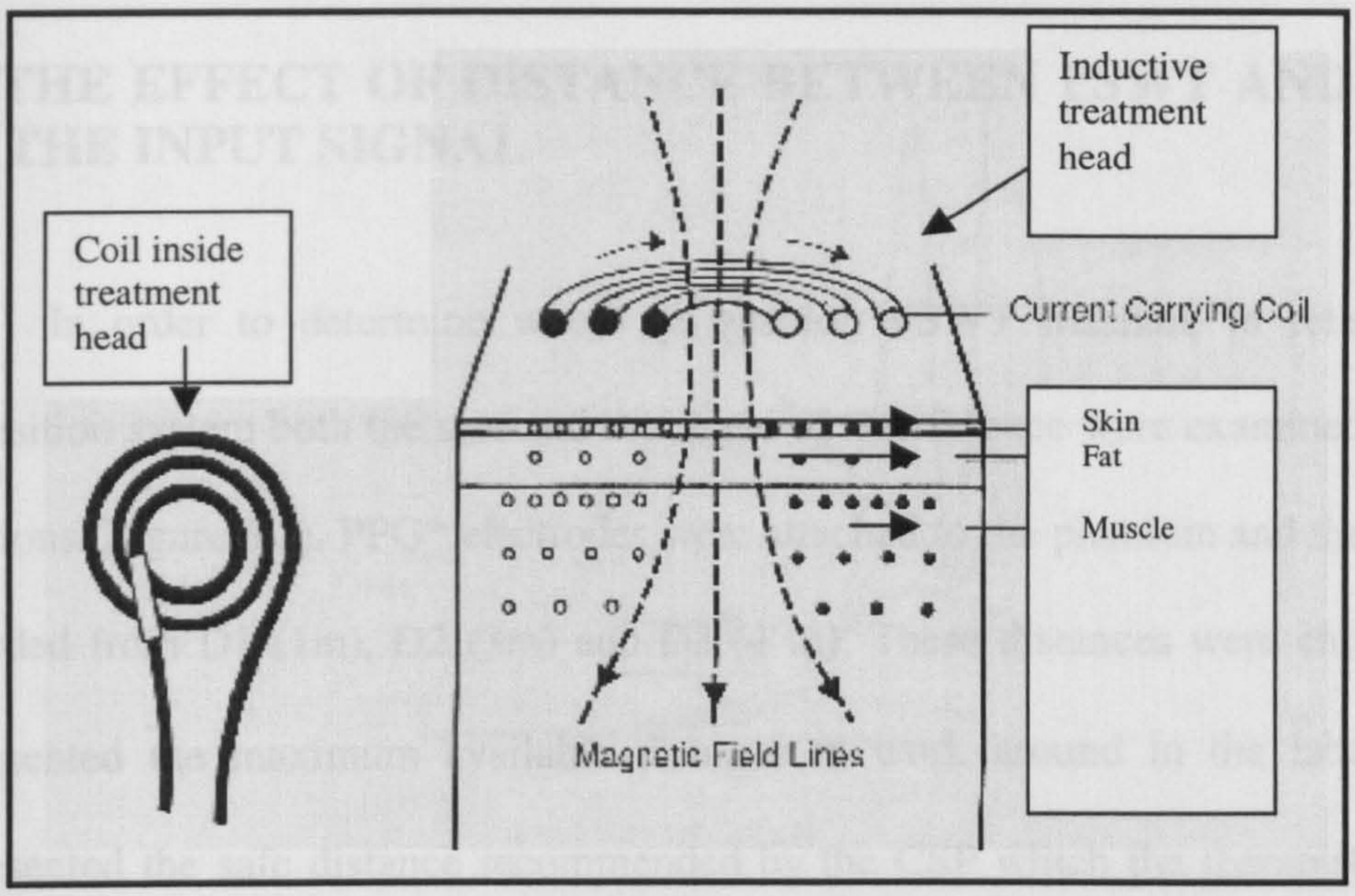

Figure (8.1) EMF penetration with drum electrode (adapted from Hand, 1990)

8.3.2 Phantom

There was a need to use a phantom to complete the circuit and ensure that the PSWT machine was working under a suitable load. Although the use of subjects would provide better representation of the expected response, subjecting volunteers to PSWT repeatedly in order to plan the experimental protocol was unjustified.

The phantom used was a saline bag. Saline phantoms were previously employed by other investigators to study EMR around SW machines (Martin et al, 1991; McDowell and Lunt, 1991; Martin et al 1990; Skotte, 1986). The conductivity of saline used was 0.9% NaCl which is similar to muscle conductivity of .84-1.08 (Ward, 1980).

Although the majority of testing was conducted on a phantom, some of the testing was conducted on subjects (ethics form can be found in Appendix D.3).

8.4 THE EFFECT OF DISTANCE BETWEEN PSWT AND MP 100 ON THE INPUT SIGNAL

In order to determine where to position PSWT machine in relation to the acquisition system both the size and the shape of interference were examined from three locations (Figure 8.2). PPG* electrodes were attached to the phantom and the signal was recorded from D1 (1m), D2 (3m) and D3 (4 m). These distances were chosen as 4 m represented the maximum available distance to work around in the laboratory, 1m represented the safe distance recommended by the CSP which the therapists can work around. The 3m reading was taken as an intermediate value between the two readings to complete the overall picture on how the field would vary with distance. The same was repeated with SkT** probes and EMG*** electrodes attached to the phantom. The Megapulse head was placed in close proximity to the phantom. During measurement the recording system is left in place while the PSWT device was moved to the above mentioned distances.

An interference band was observed (Figure 8.3 a-b) that was superimposed on the input signal recorded by MP100. This interference band was picked up as soon as the PSWT machine was turned on. The field was extensive such that it was picked up even with a distance of 4m between the two pieces of equipment (the maximum laboratory setting is 4m).

*The unit has an infrared light source (860 nm ± 90 nm), and a detector (a photo diode), positioned in reflection or transmission mode). Specification of PPG in Appendix D.2

**TSD 102D rapid response thermistor, sensitivity <83 μ°C, specification of SkT amplifier in Appendix D.2

*** Ag-AgCl pre-gelled paired (dual) electrodes (41 mm x 82 mm x 1.5 thick foam), The ground electrode is a 35 mm diameter general purpose pre-gelled electrode Ag-AgCl., specification of EMG amplifier in Appendix D.2

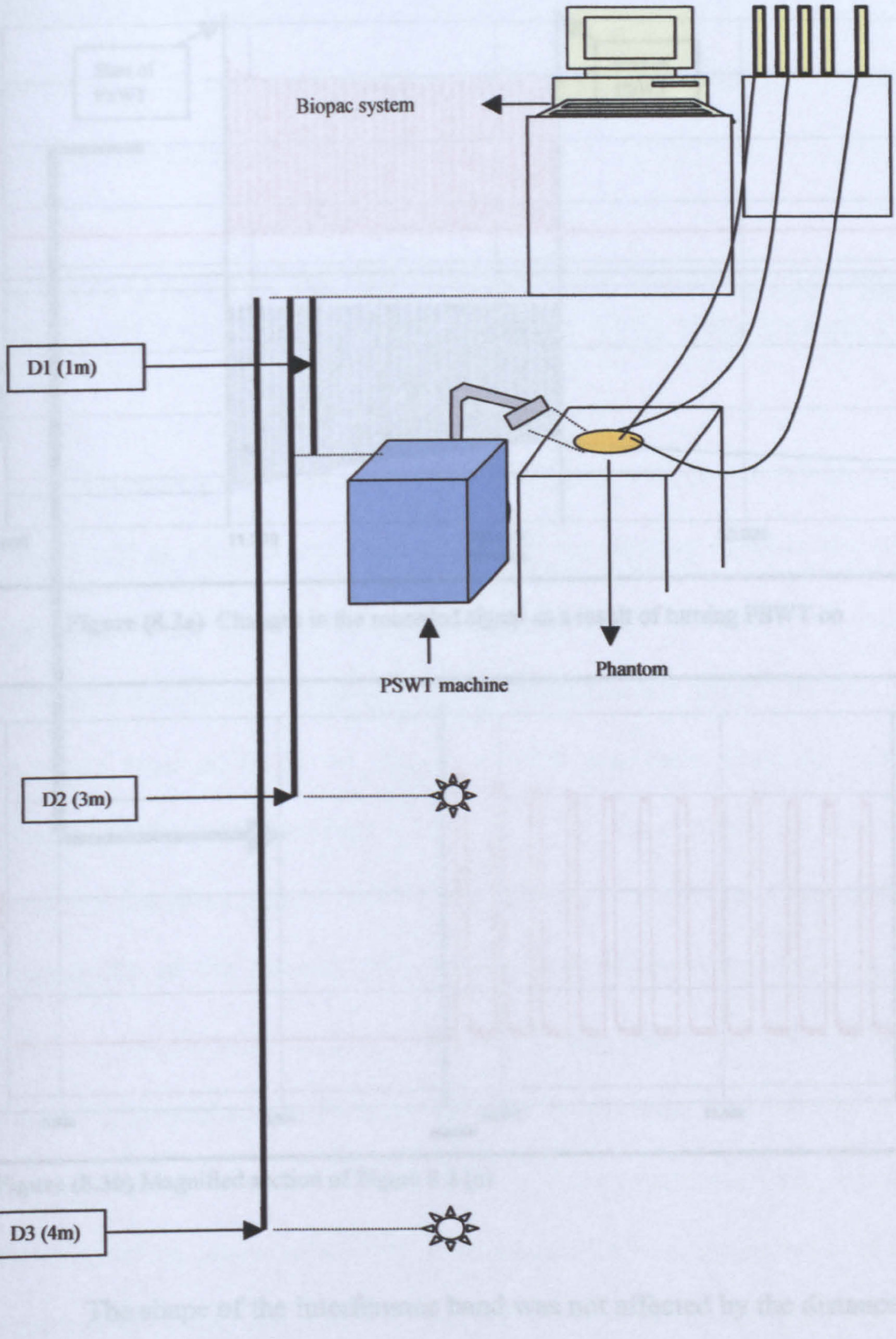

Figure (8.2) Laboratory arrangement for testing EMR

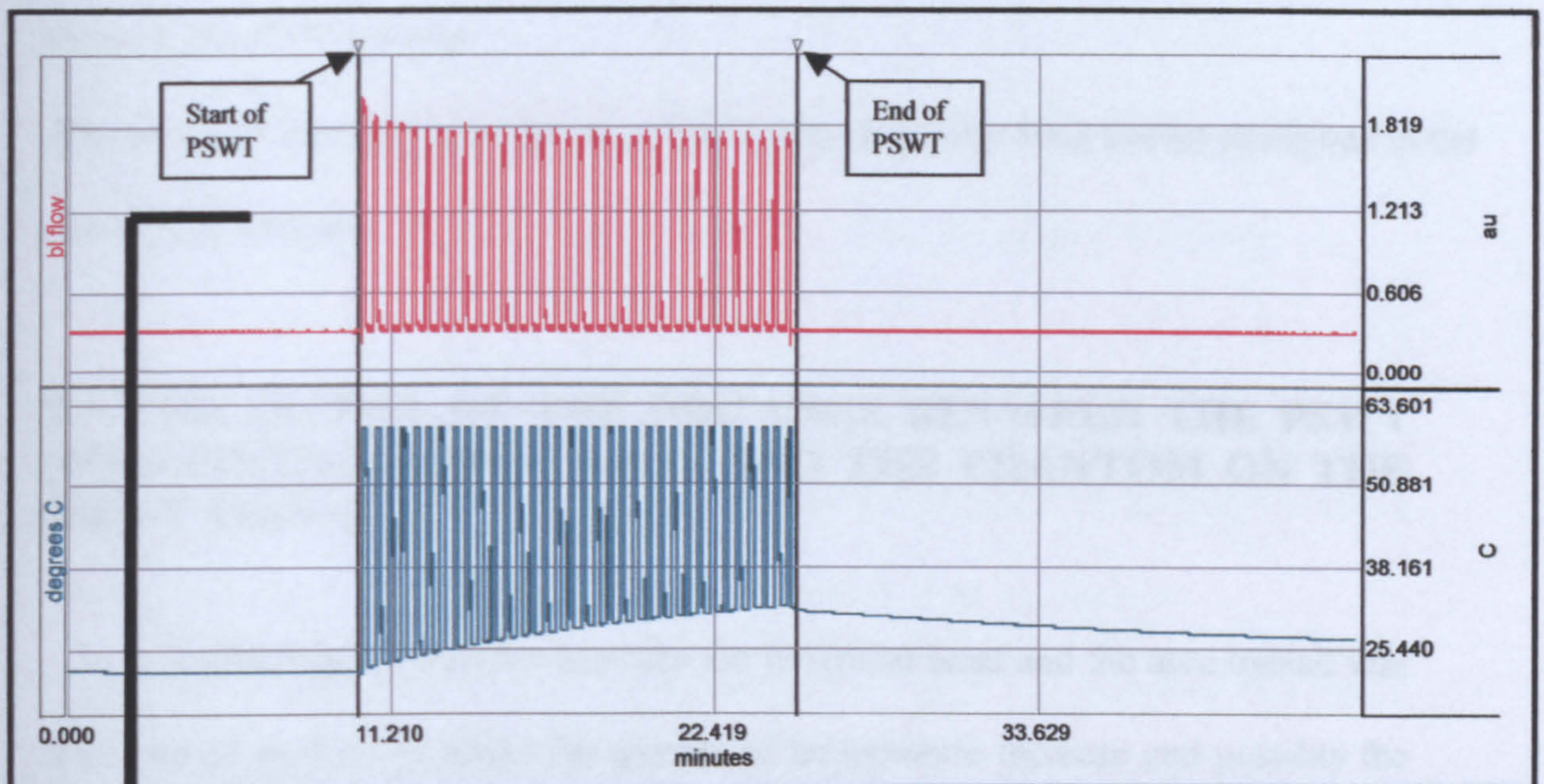

Figure (8.3a) Changes in the recorded signal as a result of turning PSWT on

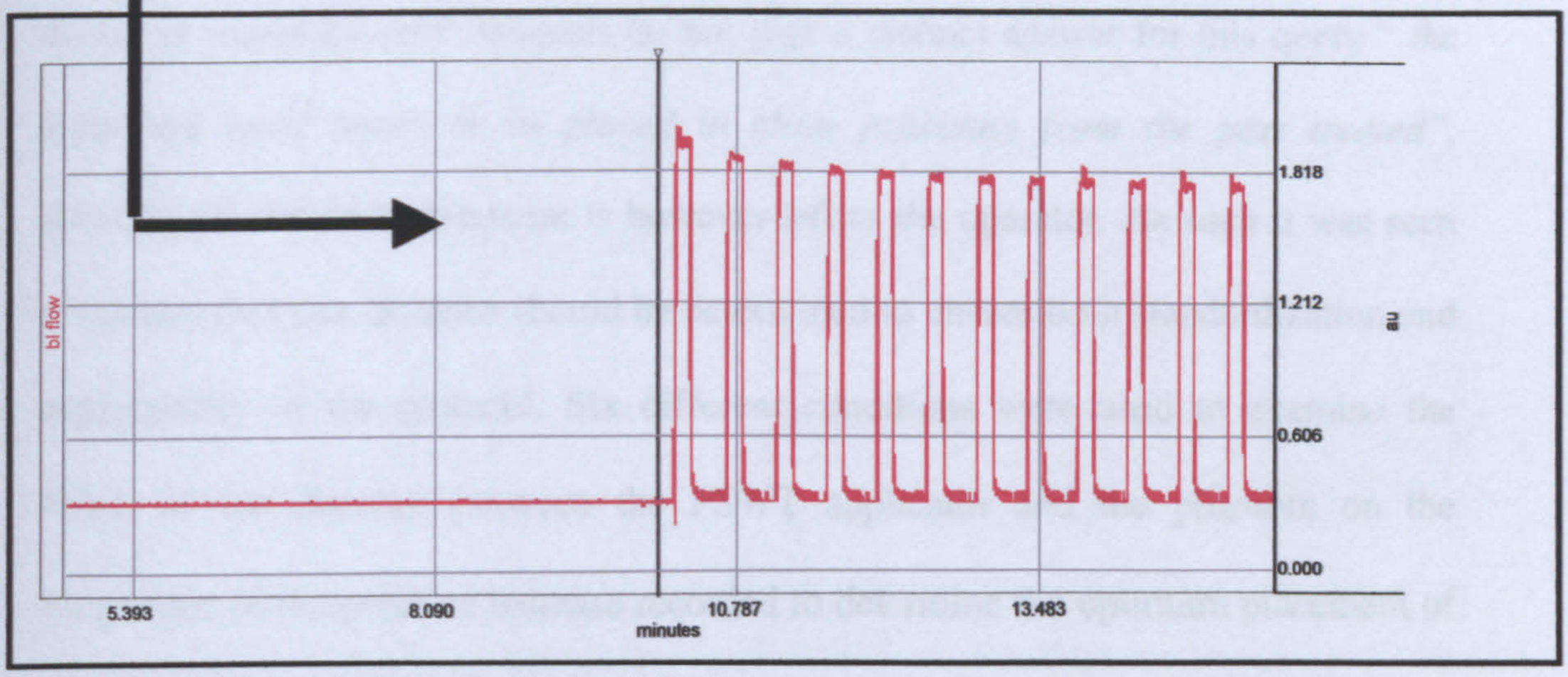

Figure (8.3b) Magnified section of Figure 8.3 (a)

The shape of the interference band was not affected by the distance or the type of electrodes used to record it. The band was consistent in appearance and was reflecting the pulsed output of the SW machine. The pulses were rectangular in shape with a pulse period of 9.8±0.2 sec and an interpulse interval of 16.2±0.2 sec. These measurements were consistent regardless of the pulsing mode (1:3 - 2:3 -3:3) or the dose. This band

was named electronic interference band (EIB) to distinguish the interference pulses from those of the PSWT output.

The nature of the signal and the factors affecting its quality were further examined in the subsequent sections.

8.5 THE EFFECT OF THE DISTANCE BETWEEN THE PSWT (MEGAPULSE) APPLICATOR AND THE PHANTOM ON THE INPUT SIGNAL

Specifying the distance between the treatment head and the area treated was seen crucial as it could affect the amount of temperature increase and possibly the changes recorded in BVol. Electrotherapy literature, whether those found in text books or manufacturers' manuals do not give a distinct answer for this query " *the treatment head needs to be placed in close proximity from the part treated*", deciding on the best placement is however left to the operator. As such it was seen necessary that this distance should be determined to ensure both standardization and repeatability of the protocol. Six different conditions were used to examine the effect of the distance between the PSWT applicator and the phantom on the magnitude of temperature increase recorded to determine the optimum placement of the applicator in relation to the treated site. All experiments were conducted using the temperature probe, which was attached using adhesive tape to the phantom. The temperature of the phantom was checked between conditions and was allowed to return to baseline before another reading was taken. The baseline temperature reading for the phantom was 18.4°C. The room temperature was 21°C with all the conditions. Two treatment doses were chosen to represent high and low output.

Condition 1: the treatment head was placed in contact with the phantom, Megapulse setting was PD 100μsec, PRR 200 Hz, MP 3W, irradiation time 15 minutes.

Condition 2: the treatment head was 1 inch away from the phantom, Megapulse setting was PD 100μsec, PRR 200 Hz, MP 3W, irradiation time 15 minutes.

Condition 3: the treatment head was 1.5 inch from the phantom, Megapulse setting was PD 100μsec, PRR 200 Hz, MP 3W, irradiation time 15 minutes.

Condition 4: the treatment head was in contact with the phantom, Megapulse setting was PD 400μsec, PRR 800 Hz, MP 48 W, irradiation time 15 minutes.

Condition 5: the treatment head was 1 inch away from the phantom, Megapulse setting was PD 400μsec, PRR 800 Hz, MP 48W, irradiation time 15 minutes.

Condition 6: the treatment head was 1.5inch away from the phantom, Megapulse setting was PD 400μsec, PRR 800 Hz, MP 48W, irradiation time 15 minutes.

Findings of the 6 conditions are summarised in Table (8.1). Trials were repeated 10 times for each condition, the value reported represents the mean.

Condition	**PSWT setting**	**↑ in temperature of phantom (°C±SD)**
Treatment head in close contact with the phantom	100μs, 200Hz, MP 3W, 15 min	0.85 ± 0.11° C
Treatment head 1" away from the phantom	100μs, 200Hz, MP 3W 15 min	0.52 ± 0.09° C
Treatment head 1.5" away from the phantom	100μs, 200Hz, MP 3W 15 min	0.08 ± 0.11° C
Treatment head in close contact with the phantom	200μs, 800Hz, MP 24W, 15 min	4.42 ± 0.39° C
Treatment head 1" away from the phantom	200μs, 800Hz, MP 24 W, 15 min	3.15 ± 0.57° C
Treatment head 1.5" away from The phantom	200μs, 800Hz, MP 24W, 15 min	2.37 ± 0.37° C

Table (8.1) Conditions employed to test the relation between treatment head and increase in temperature

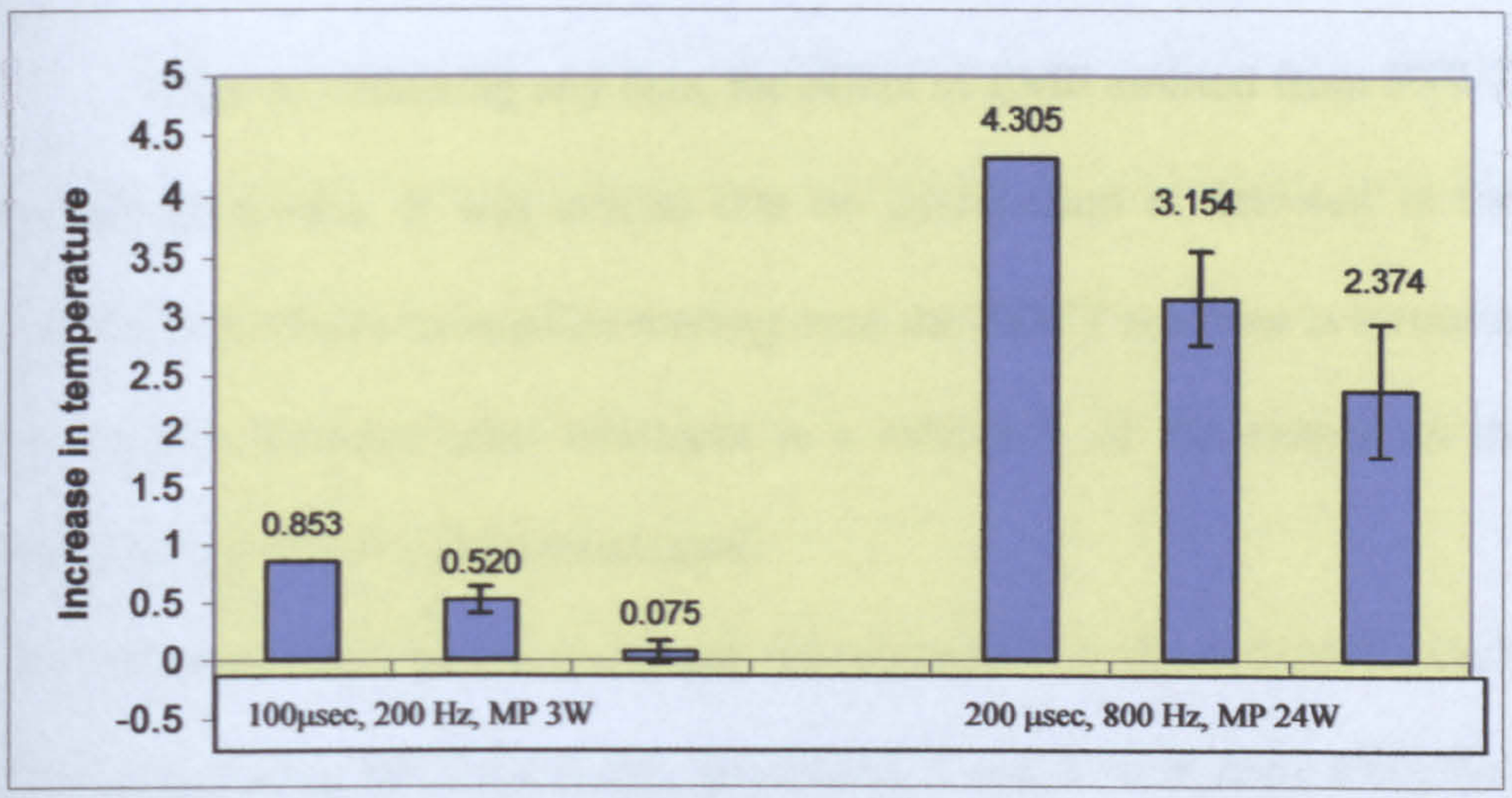

Figure (8.4) Change in temperature following two treatment protocols (each column represents the mean of 10 repetitions ±SD)

It can be seen from Table (8.1) and Figure (8.4) that there was an inverse relationship between the distance between the phantom and the applicator and the increase in temperature. Therefore to ensure repeatability and consistency of the experimental protocol and standardisation of the experimental setting a cardboard innovated by the author was used (23 cm long, 20 cm wide and 15 mm thick). This board will be used in the experimental trials conducted in the laboratory and in the hospital.

From the findings above, it was not clear though whether the increase in the temperature was caused by the heating of the temperature probe or warming up of the fluid inside the saline bag. For safety reasons this issue warranted further investigation before any experimentation is conducted on subjects. The experiments were conducted on temperature probes, as it was possible to follow changes in temperature as a result of PSWT irradiation unlike the PPG and EMG, which were resistant to change in temperature.

8.6 POST IRRADIATION EFFECTS ON THE ELECTRODES

Prior to collecting any data, the effect of EMF emitted from PSWT was examined on the electrodes. It was crucial that no dysfunction is detected in the ability of the electrodes to return to baseline reading once the PSWT machine is turned off ensuring that the tracing recorded after treatment is a reflection of the change in the physiological function and not of a disturbed signal.

The effect of EMF on the electrodes was examined in 6 conditions, conditions 1 and 4 were done using PPG electrodes, conditions 2 and 5 were done using SkT probes, and conditions 3, and 6 were done using EMG electrodes.

Condition 1: PPG electrodes were attached to the phantom using adhesive tape, recording of the signal was commenced for 15 minutes (5 minutes baseline, 5 minutes treatment, and 5 minutes post treatment period). PSWT was set on the maximum dose (MP 48W, PRR 800, PD 400 μsec) to represent the worst case scenario. Changes in the recorded signal were observed and remarks made.

Condition 2: SkT probes were attached to the phantom using adhesive tape, recording of the signal was commenced for 15 minutes (5 minutes baseline, 5 minutes treatment, and 5 minutes post treatment period). PSWT was set on the maximum dose (MP 48W, PRR 800, PD 400 μsec) to represent the worst case scenario. Changes in the recorded signal were observed and remarks made.

Condition 3: Ag-AgCl EMG electrodes were attached to the phantom using adhesive collars, recording of the signal was commenced for 15 minutes (5 minutes baseline, 5 minutes treatment, and 5 minutes post treatment period). PSWT was set on the maximum dose (MP 48W, PRR 800, PD 400 μsec) to represent the worst case scenario. Changes in the recorded signal were observed and remarks made.

Condition 4: Same as condition 1 but instead of attaching the electrodes to the phantom they were attached to the knee of a volunteer using non-allergic adhesive tape. PPG electrodes were attached to the base of the patella on the anterior knee while the subject is lying on the plinth.

Condition 5: Same as condition 2 but instead of attaching the electrodes to the phantom they were attached to the knee of a volunteer using non-allergic adhesive tape. SkT probes were attached to the base of the patella on the anterior of the knee while the subject is lying on the plinth.

Condition 6: Same as condition 3 but instead of attaching the electrodes to the phantom they were attached to the knee of a volunteer using adhesive collars. EMG electrodes were attached to the base of the patella on anterior knee while the subject is lying on the plinth.

With both PPG and EMG electrodes the input signal returned to a baseline reading immediately after the PSWT was turned off. This happened regardless of whether the electrodes were attached to a phantom or to a subject. However with the temperature probes there was an instant increase in the temperature (picked up in the first 10-13 sec subsequent to turning PSWT machine on). It continued to mount throughout the time of irradiation and only started to decline after the cessation of PSWT. These findings are in agreement with the previous section. No speculation can be made as to the cause of temperature increase recorded. It was not clear whether the increase in temperature recorded was a measure of heating up of the temperature probe or heating of the fluid inside the saline bag, this issue was investigated further in the following section.

The ability of the PPG and EMG electrodes to return to baseline readings means that the measurements taken from the subjects at the recovery period (after treatment

time) can be analysed as a representation of the subjects' physiological reactions to PSWT treatment. However, this cannot be said for the changes recorded post treatment using temperature probes until further exploration of the increase in temperature is commenced.

8.7 EXAMINING THE NATURE OF THE TEMPERATURE INCREASE IN TEMPERATURE PROBES

To further analyse the nature of temperature increase, it was vital to distinguish between temperature increase as a result of warming up of the electrodes or warming up of the liquid inside the phantom. In order to examine this, 6 experimental conditions were used with 3 different output powers. The whole experimental session was 30 minutes, 10 minutes baseline, 10 minutes PSWT, and 10 minutes recovery post treatment. To avoid any build up of heat that may interfere with the analysis, enough time was left between sessions to allow the temperature to return to baseline before any data were collected. The dose was either 200μsec-400 pps- MP 12W-10 minutes, or 400 μsec- 400 pps-MP 24 W-10 minutes, or 400μsec -800 pps -MP 48W- 10 minutes. Temperature probes were attached to the phantom using adhesive tape. They were either left recording while being exposed to PSWT, or were removed before the PSWT machine was turned on, and then returned to record the post treatment period. The distance between the phantom and the treatment head was standardised using the cardboard described earlier (Section 8.10). Each condition was repeated 5 times and the mean was used for analysis.

Figure (8.5) shows the schematic representation of the experiments and the time taken for analysis. It was decided to use the 5 minutes because of the difficulty in using one minute to one minute analysis, the period before treatment was stable while the period post treatment was changing as a result of cooling of the phantom. As such it was decided to

use the mean of points for better representation. The change in temperature pre and post treatment was noted and compared. Summary of the results is shown in Table (8.2).

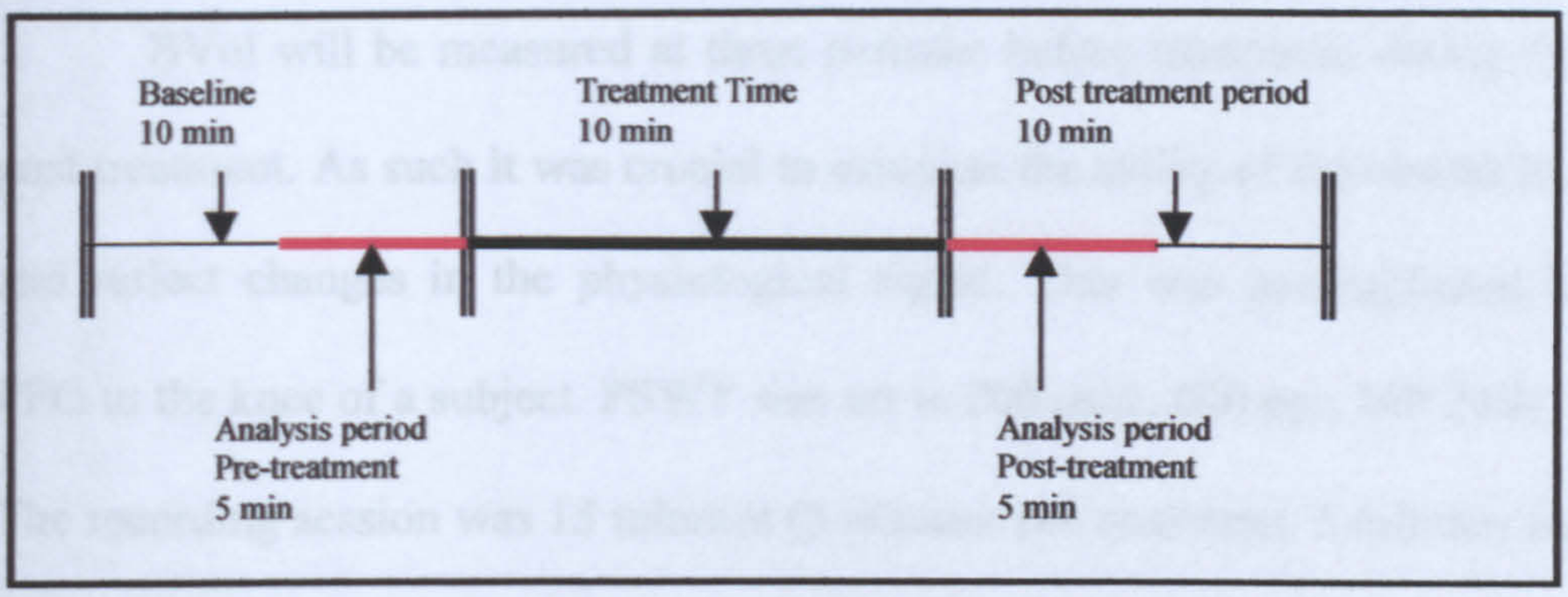

Figure (8.5) Schematic representation on the period taken for analysis

200µsec-400pps (12W)		400µsec-400pps (24 W)		400µsec-800pps (48W)		
Electrodes removed	Electrodes in place	Electrodes removed	Electrodes in place	Electrodes removed	Electrodes In place	
0.785	0.985	0.830	1.615	0.925	2.712	Mean increase in temperature °C

Table (8.2) Increase in temperature following 3 testing protocols
*The mean was calculated for the last 5 minute in baseline and first 5 minutes recovery time
The value reported in the table is the mean of the 5 repetitions.

From the table above it could be seen that the temperature increase recorded was proportional to the MP applied. A higher dose resulted in a higher increase in temperature. Furthermore, the amount of increase was higher when the probes were left in place compared to when they were removed prior to irradiation. The findings suggest that the increase was the result of 2 components: heating of the metal inside the temperature probe and the fluid inside the phantom.

These findings have implications for the interpretation of the results. In order to avoid misleading conclusions and for safety reasons, it was decided that the temperature probes be removed at the time of exposing subjects to PSWT and be returned for measurement at the recovery period. The site of recording would be marked to ensure consistency and reproducibility.

8.8 THE ABILITY OF PPG ELECTRODES TO CONVEY CHANGES IN BVol WHEN UNDER PSWT EFFECTS

BVol will be measured at three periods: before treatment, during treatment and post treatment. As such it was crucial to examine the ability of the electrodes to measure and reflect changes in the physiological signal. This was accomplished by attaching PPG to the knee of a subject. PSWT was set to 200 μsec, 800 pps, MP 24W, 10 minutes. The recording session was 15 minutes (5 minutes pre treatment, 5 minutes treatment and 5 minutes post treatment).

Figure (8.6 a, b) shows the signal and a magnified portion of the signal. It could be seen that despite the superimposing EIB, the shape and the changes in the PPG signal could still be seen in the off pulse period.

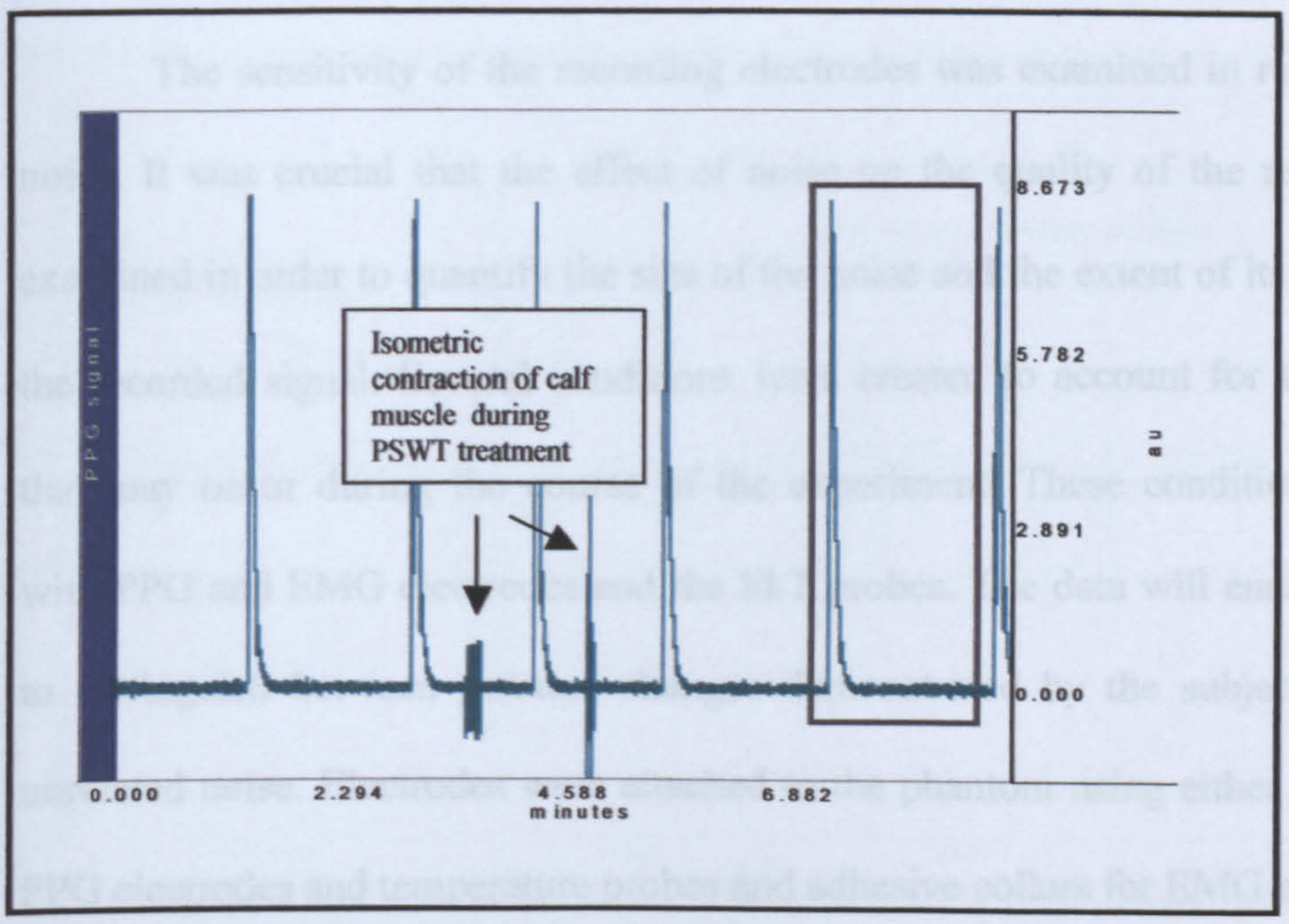

Figure (8.6 a) Changes in PPG when under PSWT effect. With the PPG placed on the knee, the changes in underlying signal as a result of isometric contraction could still be seen even with the superimposed EIB.

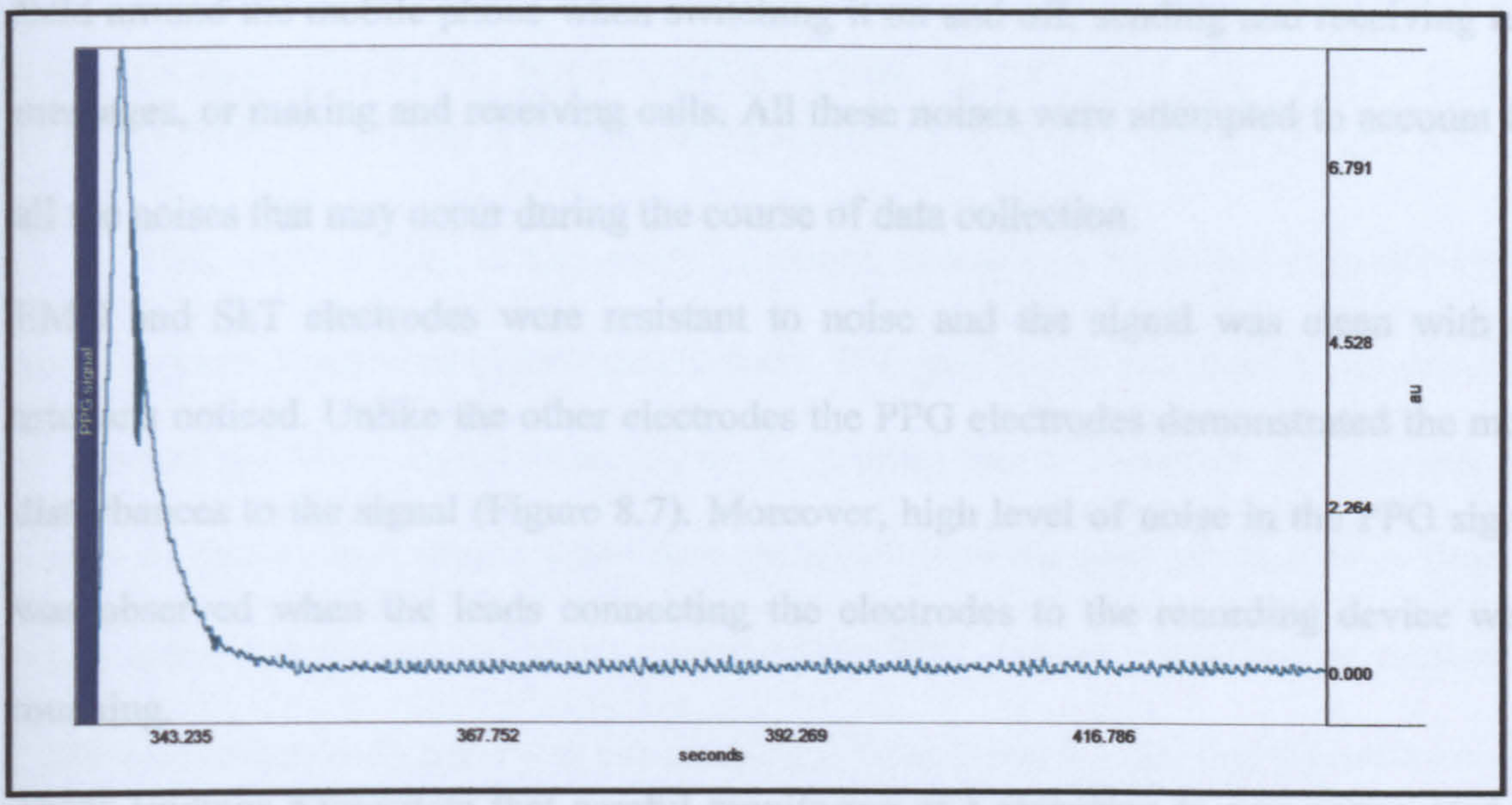

Figure (8.6 b) Magnified section of Figure (8.6-part in square) of PPG signal when under the effect of PSWT. It could be seen that even with the superimposing EIB the pulsating nature of blood signal can still be detected

8.9 EFFECTS OF DIFFERENT EXTERNAL NOISES ON THE INPUT SIGNAL

The sensitivity of the recording electrodes was examined in relation to external noise. It was crucial that the effect of noise on the quality of the recorded signal be examined in order to quantify the size of the noise and the extent of its interference with the recorded signal. Several conditions were created to account for the natural noises that may occur during the course of the experiment. These conditions were repeated with PPG and EMG electrodes and the SkT probes. The data will enable the researcher to distinguish between genuine changes demonstrated by the subjects and any other unrelated noise. Electrodes were attached to the phantom using either adhesive tape for PPG electrodes and temperature probes and adhesive collars for EMG electrodes.

The electrodes were attached to the phantom, and the variation in the recorded signal was observed as a result of generating artificial sounds. These sounds included the sounds of moving pieces of furniture such as chairs, slamming doors and drawers, the

field around the mobile phone when switching it on and off, sending and receiving text messages, or making and receiving calls. All these noises were attempted to account for all the noises that may occur during the course of data collection.

EMG and SkT electrodes were resistant to noise and the signal was clean with no artefacts noticed. Unlike the other electrodes the PPG electrodes demonstrated the most disturbances to the signal (Figure 8.7). Moreover, high level of noise in the PPG signal was observed when the leads connecting the electrodes to the recording device were touching.

These findings necessitate that careful monitoring and recording to any unexpected or unwanted event during the course of acquisition is paramount to avoid misleading or faulty interpretations of findings.

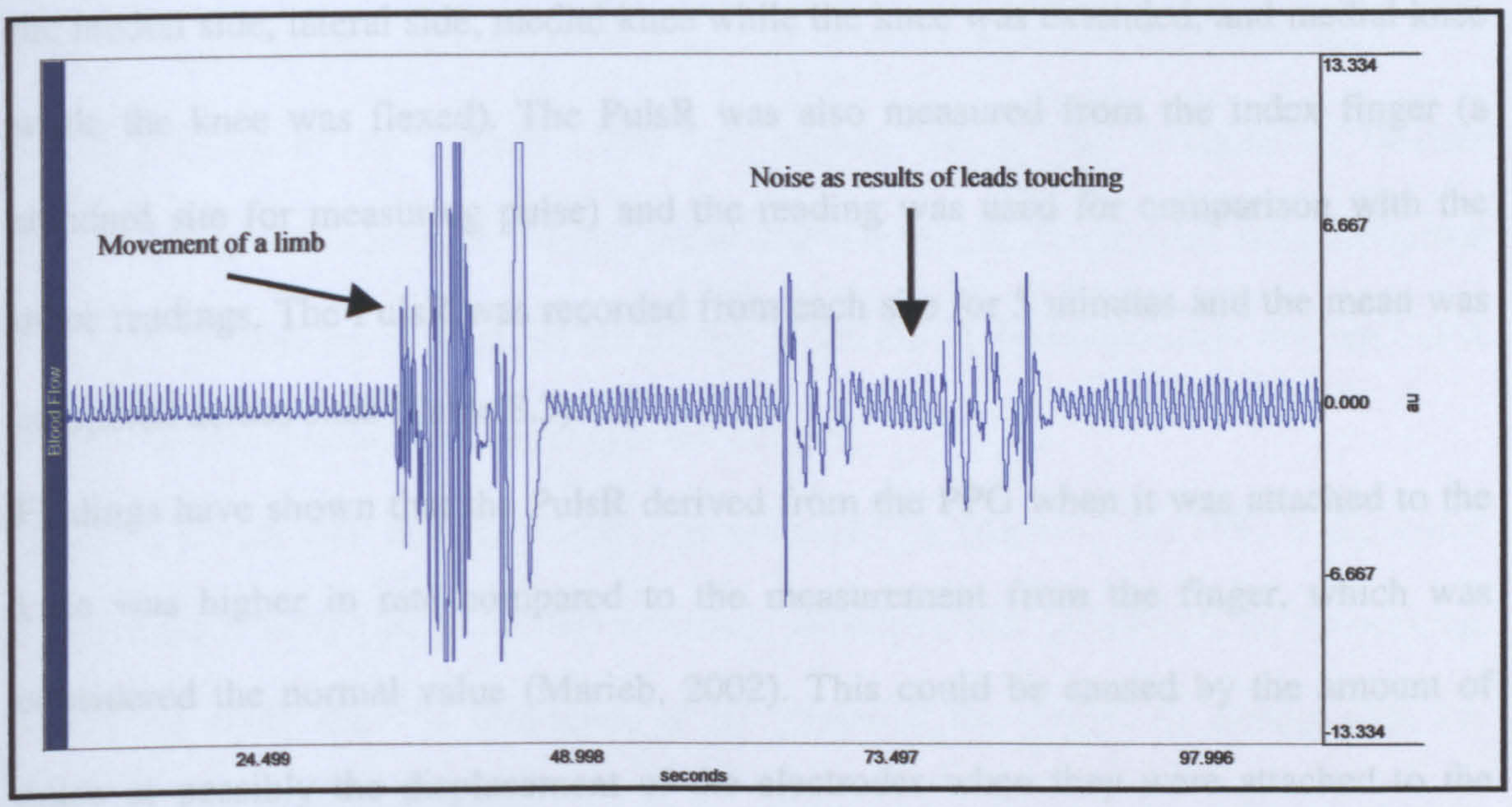

Figure (8.7) The effect of noise on the input signal

8.10 COMPARISON BETWEEN THE NATURE OF THE PulsR WHEN MEASURED FROM DIFFERENT ANATOMICAL SITES

PPG will be used in this study to record changes in BVol and measure PulsR from the knee. According to the manufacturer, PPG probes (or transducers) are expected to measure the blood signal from any tissue bearing blood. However, PPG probes are known to convey best results when they are attached to the pads of the toes or fingers, being areas rich in arteriovenous anastomosis. PPG probes reliability in measuring PulsR from other body parts was not examined. Thus it was crucial that the nature of the signal and the PulsR derived be of sufficient quality before using it as an outcome measure.

The above notion was examined on a volunteer (the experimental condition was repeated 4 times the same day over 3 days and every time the same outcome was obtained). The PPG electrodes were attached to different sites around the knee (big toe, the medial side, lateral side, medial knee while the knee was extended, and medial knee while the knee was flexed). The PulsR was also measured from the index finger (a standard site for measuring pulse) and the reading was used for comparison with the other readings. The PulsR was recorded from each site for 5 minutes and the mean was compared across sites (Table 8.3).

Findings have shown that the PulsR derived from the PPG when it was attached to the knee was higher in rate compared to the measurement from the finger, which was considered the normal value (Marieb, 2002). This could be caused by the amount of noise or possibly the displacement of the electrodes when they were attached to the knee, which may have disturbed the signal.

	Big toe	Medial Knee (knee flexed)	Medial Knee (knee extended)	Lateral knee	Index finger
	BPM	BPM	BPM	BPM	BPM
Test 1	147.92	148.12	145.6	147.17	74.38
Test 2	143.98	147.95	148.5	148.59	72.27
Test 3	145.60	144.13	146.5	144.51	74.97
Test 4	147.190	143.12	144.8	144.41	76.98
Test 5	145.24	148.63	146.8	148.92	77.54
Mean	145.98±0.89	145.39±1.72	146.44±0.70	146.72±1.29	75.22±1.16

Table (8.3) PulsR values obtained from different sites, shaded area resembles normal values. The reported values are the mean ± SD (the value reported is the mean of 1 minute interval over 5 minutes)

Hitherto, it was decided to use PPG to reflect changes in BVol in the knee, and to use another device to record the PulsR.

8.11 COMPARISON BETWEEN PulsR READING USING TWO DIFFERENT DEVICES

The previous section has raised issues about the accuracy of the pulse signal measured by MP100 when the PPG was placed around the knee joint. As such there was a need to compare the pulse value obtained by MP100 to another validated device.

It was decided to use Tunturi (TPM-400, Japan), which was validated by Watson (1994). Using a volunteer the Tunturi probe was attached to the ear lobe using a clip and was set to display the continuous fluctuation in the PulsR. Measurements were recorded by the researcher minute by minute for ten minutes.

With the Biopac MP 100 the PulsR was measured by attaching the PPG to the index finger using a Velcro strap. MP100 recorded continuous real time PulsR for 10 minutes. The mean of 60 seconds was taken to be compared for minute by minute with the Tunturi Table (8.4).

	PulsR measured using Tunturi	PulsR derived from PPG signal
Min 1	86.2	86.2
Min 2	78.9	78.7
Min 3	77.3	76.8
Min 4	77.9	77.5
Min 5	77.4	76.9
Min 6	84.3	82.4
Min 7	84.5	84.9
Min 8	75.3	74.1
Min 9	77.3	76.6
Min 10	78.6	78.1

Table (8.4) The mean PulsR readings taken by the two devices, each raw with MP 100 is the mean of 60 seconds.

Table (8.4) suggested a strong resemblance between the PulsR reading when measured using the MP100 or Tunturi. Pearson correlation coefficient revealed r = 0.98, the correlation was significant at p=0.01. Both readings were plotted as a scatter graph (Figure 8.8) that further confirmed the strong correlation between the two sets of readings.

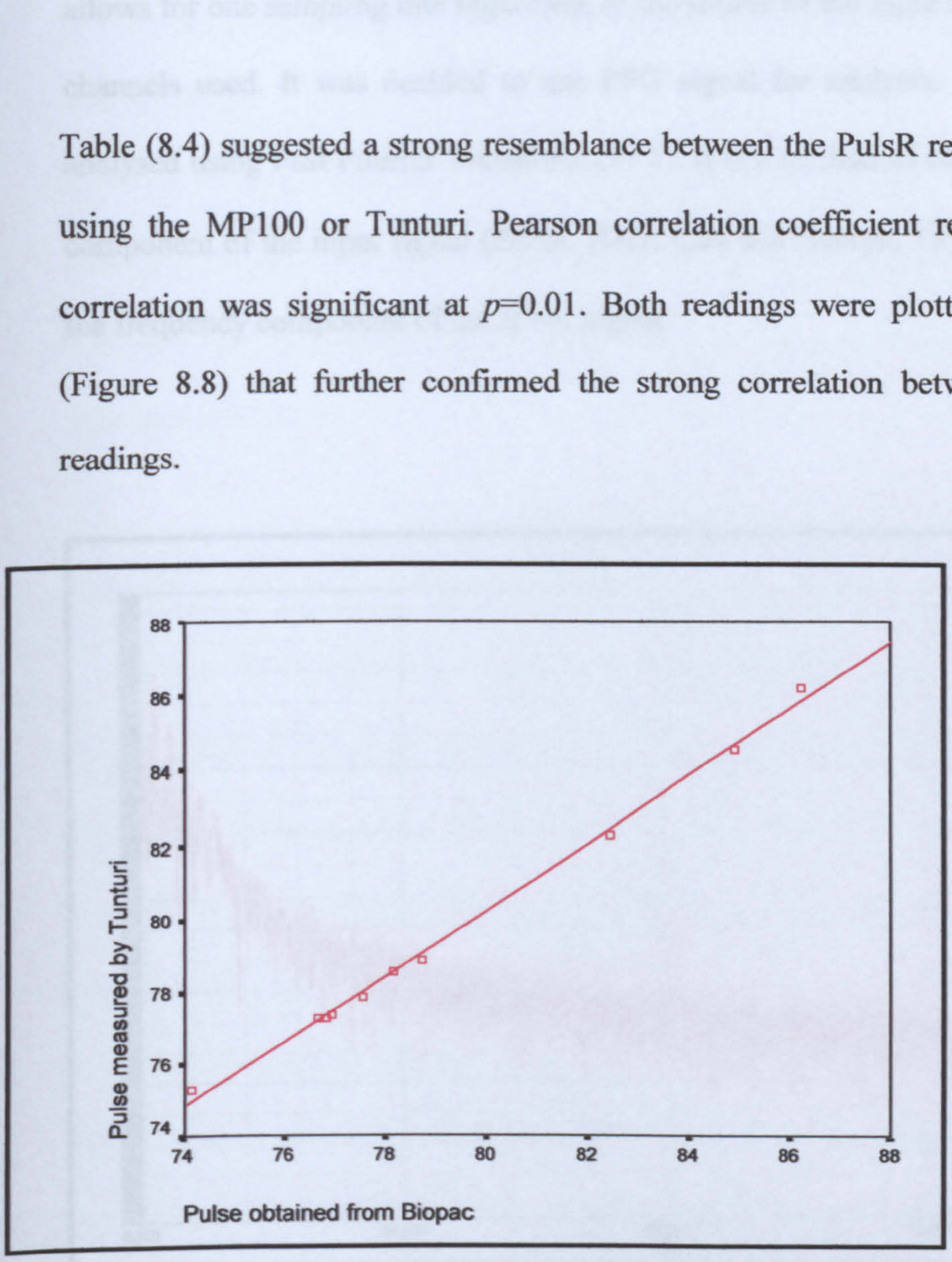

Figure (8.8) Scatter graph of the PulsR measured using Biopac MP100 and Tunturi

Given this it was decided to use Tunturi to measure PulseR and use PPG to monitor BVol from the knee during the experiment.

8.12 SAMPLING RATE

In order to decide the most appropriate sampling rate to use for collecting the data, there was a need to find the frequency of the input signal. The Biopac MP 100 allows for one sampling rate regardless of the source of the input signal or the number of channels used. It was decided to use PPG signal for analysis. The blood signal was analysed using Fast Fourier Transform (FFT). It is a method of computing the frequency component of the input signal (Zonst, 2000; Chu and George, 1999). Figure (8.9) shows the frequency component of the BVol signal.

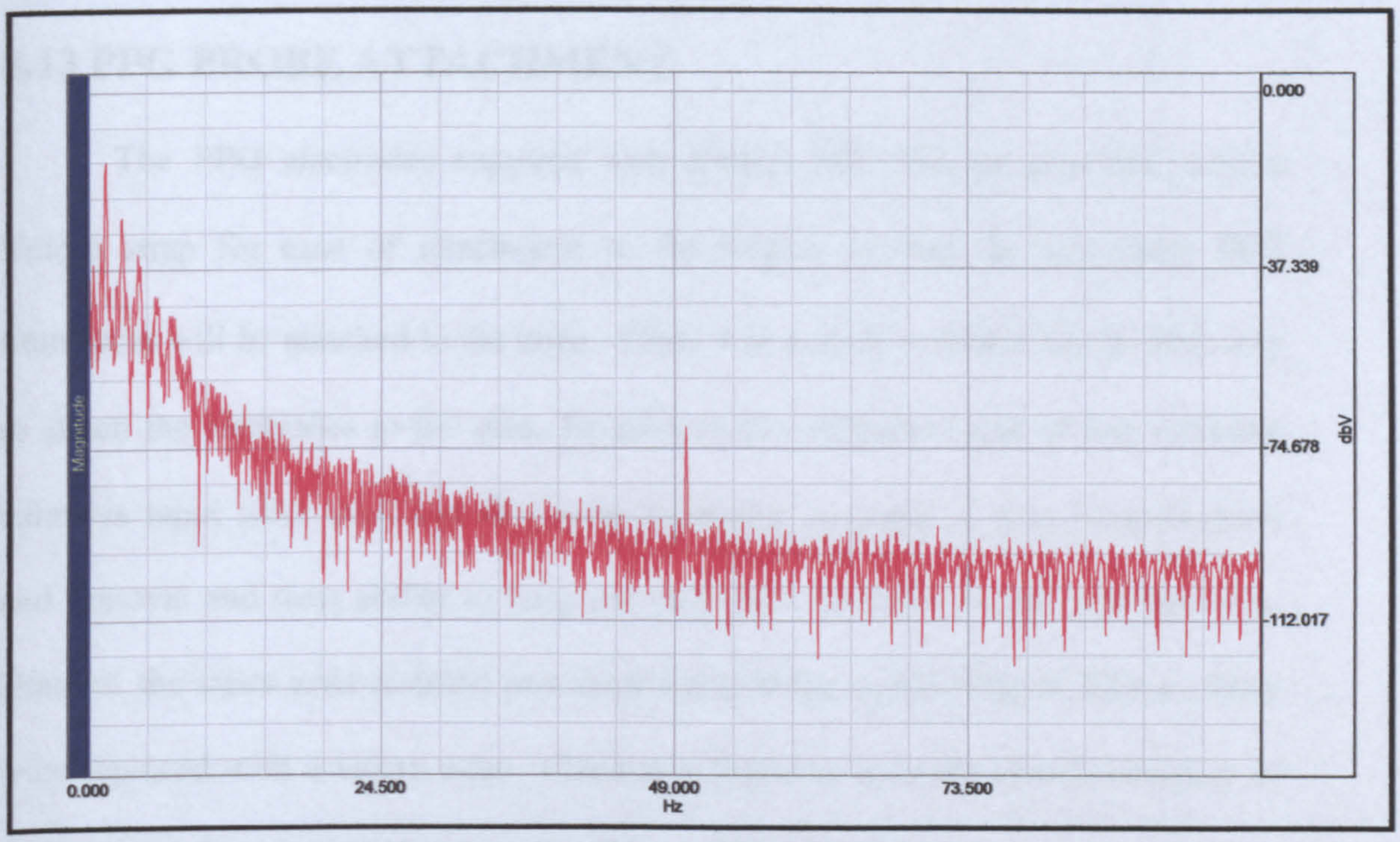

Figure (8.9) A trace of PPG signal using FFT. FFT was used to reveal the frequency component. Same graph was obtained whether the signal was sampled on 200 samples/second or 500 samples/second

The graph shows the frequency response up to 50 Hz. According to the literature it is enough to set the sampling rate to twice the frequency of the variable studied (Zonst, 2000; Chu and George, 1999). According to the manufacturer's recommendation the sampling rate should be set at 3-4 times the frequency of interest. This means that a sampling rate of 200 Hz will be enough to capture the characteristics of the signal. From the literature it was found that the majority of studies that have examined the hemodynamics characteristics of the blood signal using PPG have employed a sampling rate of 500 Hz.

Given this both sampling rates (200 samples/second-500 samples /second) were compared and no difference was noticed in the nature of the signal measured. Therefore it was decided that a sampling rate of 200 samples /second will be used in the laboratory and clinical trials.

8.13 PPG PROBE ATTACHMENT

The PPG electrodes supplied with Biopac MP 100 are provided with a Velcro strap for ease of attachment to the fingers or toes. In this study PPG transducer will be attached to the knee. There was a need to search for the best way to attach the electrodes to the skin. To achieve this different types of non-irritating adhesive tapes were used and they were examined in terms of ease of application and removal and their ability to keep the electrodes in close contact with the skin. None of the tapes used resulted in a clear trace of the signal (Figure 8.10 a). They were replaced with a velcro strap, which was found to give the closet reflection of the signal as the one recorded from the fingers (Figure 8.10 b).

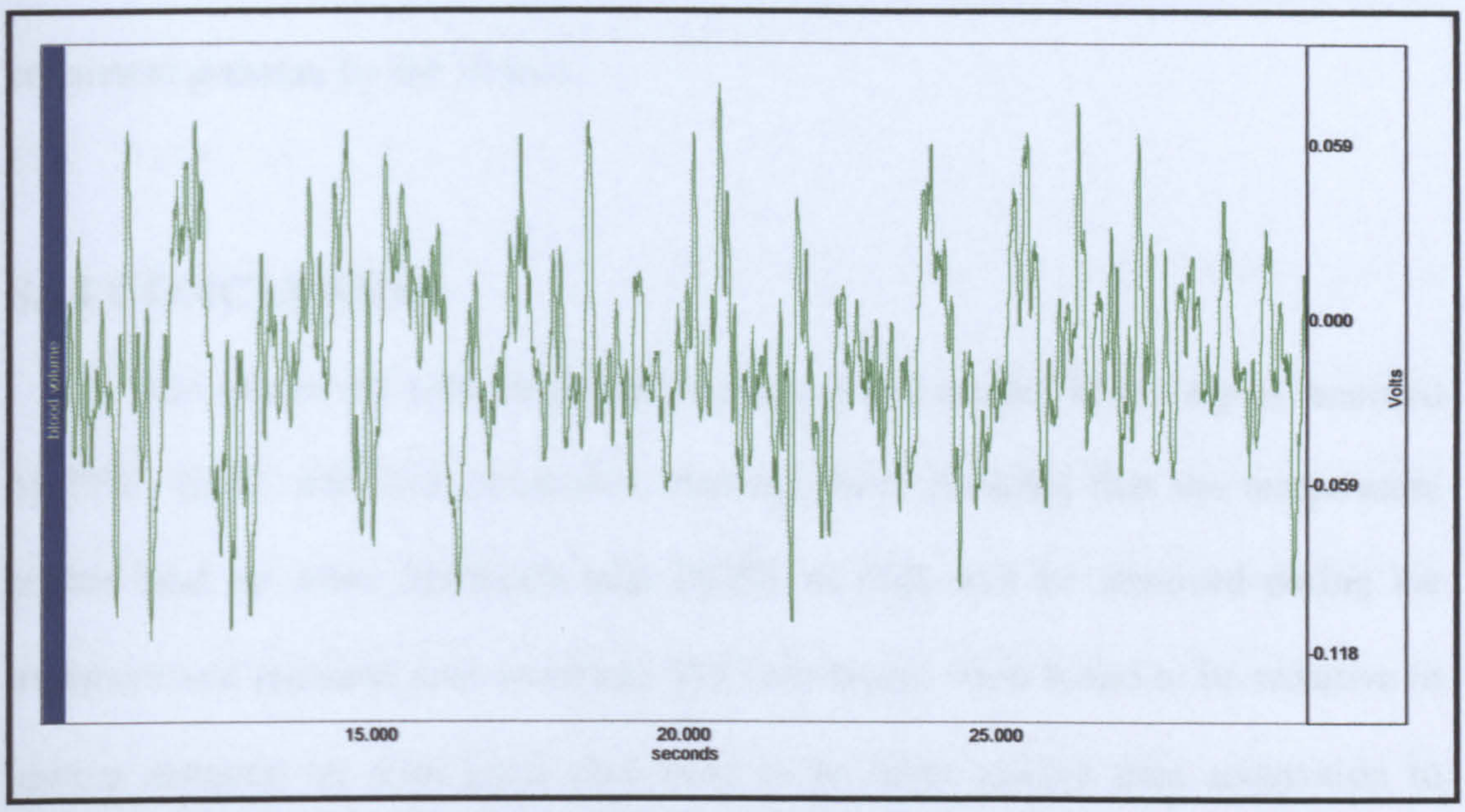

Figure (8. 10 a) The shape of the PPG signal when using an adhesive tape

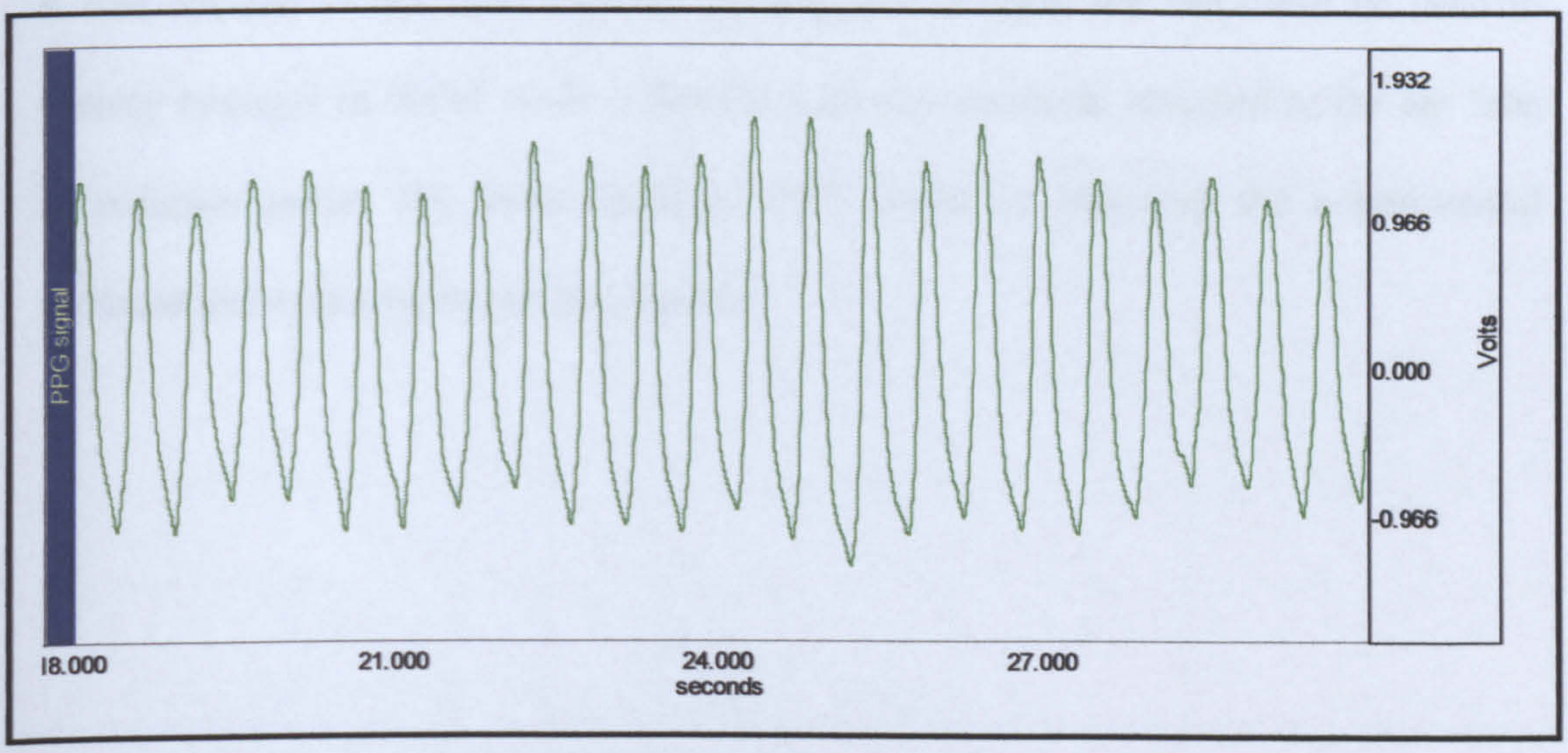

Figure (8.10 b) The shape of the PPG signal when using a velcro

The strap will be wrapped around the knee to secure the PPG in place during the experiment.

It is acknowledged that the skin is not homogeneous and the measured value is greatly dependent on the location of the probe (Swain and Grant, 1989) as such all attempts

were made to ensure the repeatability of the electrode placement and to ensure consistent pressure by the Velcro.

8.14 CONCLUSION

Part two of the pilot examined the nature and quality of the signal recorded by PPG, EMG, and SkT electrodes. Findings have revealed that the temperature probes heat up when irradiated with PSWT as such will be removed during the treatment and replaced post treatment. PPG electrodes were found to be sensitive to motion artefacts as such extra care need to be taken during data acquisition to instruct subjects not to move during the experiment and to ensure that leads are not touching. Pilot experimentation has also shown that PulsR derived from PPG when it was applied to the knee was not reliable and as such the PPG will be used to convey changes in BVol while a Tunturi with the electrode attached to the ear lobe to measure pulse. All these findings were crucial in planning the experimental protocol and ensuring better data quality.

PART 3: COMPARING THE NATURE OF INTERFERENCE BETWEEN TWO PSWT MACHINES

8.15 INTRODUCTION

Examining the effect of Megapulse on the recorded signal (Section 8.9), it was thought that the use of an alternative PSWT machine might be associated with lower levels of EMF, lesser EIB and a cleaner recorded signal. The Phyaction Performa (PP+) was the only PSWT machine that could mimic all the outputs of Megapulse hence it offered an attractive device that can be used instead. However, before employing PP+ in the study it was necessary to examine its effect on the recorded signal with the MP 100.

Almost all commercial PSWT machines utilise a carrying frequency of 27.12 MHz, and work on the same basic physical manufacturing principles, it is not known however, if they can be used interchangeably. Different machines are built to employ different peak outputs, different combinations of PD and PRR (Table 8.5). Some authors have treated different makes of PSWT as one (Svarcova et al, 1988) while others have suggested that they are dissimilar (Forster and Palastanga, 1985). The work by Pasila et al (1987) comparing the effects of a Diapulse to a Curapuls has confirmed that PSWT machines are different. Table (8.5) shows different manufacturing characteristics of some PSWT machines.

Model	Pulse width (μsec)	Pulse Frequency (Hz)	Peak power (W)	Manufacturer
Curapuls	400	15-200	1000	Enraf-Nonius
Ultratherm	400	20-180	400	Siemens
Megapulse Senior	20-400	50-800	150	Electro Medical Supplies
Phyaction Performa +	65-400	25-1125	200	Gymna Uniphy
Therapulse	65-400	12.5-400		Chattanooga Group Ltd

Table (8.5) Specifications of some of PSWT machines (although other makes of PSWT machines are available, the ones mentioned here are those reported by the surveyed sample in Chapter 6).

All of this necessitates, that the PP+ be compared to the Megapulse and the effect of both machines on the recorded signal be examined before deciding on which unit to be used for the study.

8.16 AIMS

- To examine whether Megapulse machine can be used interchangeably with PP+ and which machine will result in a better quality signal.

Both the Megapulse senior and PP+, were compared in terms of:

- The effect of interaction between EMF and the MP 100 on the recorded signal
- The shape of EIB as recorded by MP100
- The duration of the pulse as recorded from EIB
- The duration of the inter-pulse period as recorded from EIB
- The thermal component with the two machines measured from a phantom

Figure (8.11) Phyaction Performa machine
(Gymna Uniphy, Australia)

8.17 EQUIPMENT

PP+ (Figure 8.11) is a PSWT machine that utilises 27.12MHz frequency, and a main voltage of 230V±15% at 50/60 Hz (the equipment could be used in both the thermal and athermal modes of treatments). It can deliver the energy via the 14 cm thermoplode, which can be used with one or two channels. It has a PP of 200W(it could vary depending on whether one electrode or two electrodes are used). The PRR ranges between 25-1125 Hz if one channel is used or 25-800 Hz if the two channels are in use.

The PD ranges between 65-400μs. In addition, the time allowed for treatment ranges between 0-60 minutes. The PP per arm is 90 W if one channel is used and 64 W if the two channels are in use. Superior to other PSWT equipments it has an indication mode where the clinicians can choose from a wide range of pathologies and their preset treatment programmes.

As mentioned earlier Megapulse (Figure 8.12) is a machine that can deliver both CSWD and PSWT. In the pulsed mode it can deliver short pulses, which are adjustable in duration (20-400μs) and PRR (50-800Hz) enabling the operator to vary the output. The peak output is fixed at 150 W, while the mean output is dependent on the treatment parameters selected. The pulses can be delivered either continuously (3:3), two third of the time (2:3) or one third of the time (1:3).

The characteristics of the two machines are displayed in Table (8.6).

Figure (8.12) Megapulse Senior (Electro-Medical Supplies, Greenham, Ltd; UK).

Description	Megapulse S	PP+
PD (μsec)	20-400	65-400
Treatment time (minutes)	0-29	0-60
PP (W)	150	200
PRR (Hz)	50-800	25-1125 (if one channel is used) 25-800 (if two channels are used)
Electrode	Circuplode	Thermoplode
Mode	Continuous /pulsed	Continuous / pulsed

Table (8.6) Comparison between Megapulse and PP+

The PP+ was utilised because it was the only PSWT machine that could mimic the settings of Megapulse hence providing a basis for comparison. In all the conditions examined both PSWT machines were set to 400μsec-800Hz, MP 48 W (the maximum setting for Megapulse) to provoke the worst case scenario.

8.18 THE EFFECT OF INTERACTION BETWEEN PSWT MACHINES AND MP100

As was shown from the previous pilot experimentation that both PPG and EMG behave the same under the influence of EMF and neither electrodes heat up. It was decided to use PPG electrodes to examine the nature of interaction between MP100 and both PSWT machines.

The above notion was examined in 2 conditions:

Condition 1: The PPG electrodes were attached to the phantom using adhesive tape, the recording session was 30 minutes (10 minutes baseline, 10 minutes PSWT and 10 minutes recovery post treatment), PP+ was set to 400μsec-800 Hz, MP 48 W.

Condition 2: The PPG electrodes were attached to the phantom using adhesive tape, the recording session was 30 minutes (10 minutes baseline, 10 minutes PSWT and 10 minutes recovery post treatment), Megapulse was set to 400μsec-800 Hz, MP 48 W.

In both conditions the distance between the treatment applicator and the phantom was standardised using the template. The conditions were repeated 5 times and the outcome was the same.

Both PSWT devices generated different signal shapes and both had affected MP 100 differently. The EIB disappeared once the PSWT (whether it was PP+ or Megapulse) machine was turned off and the signal went back to baseline reading (Figure 8.13-8.15).

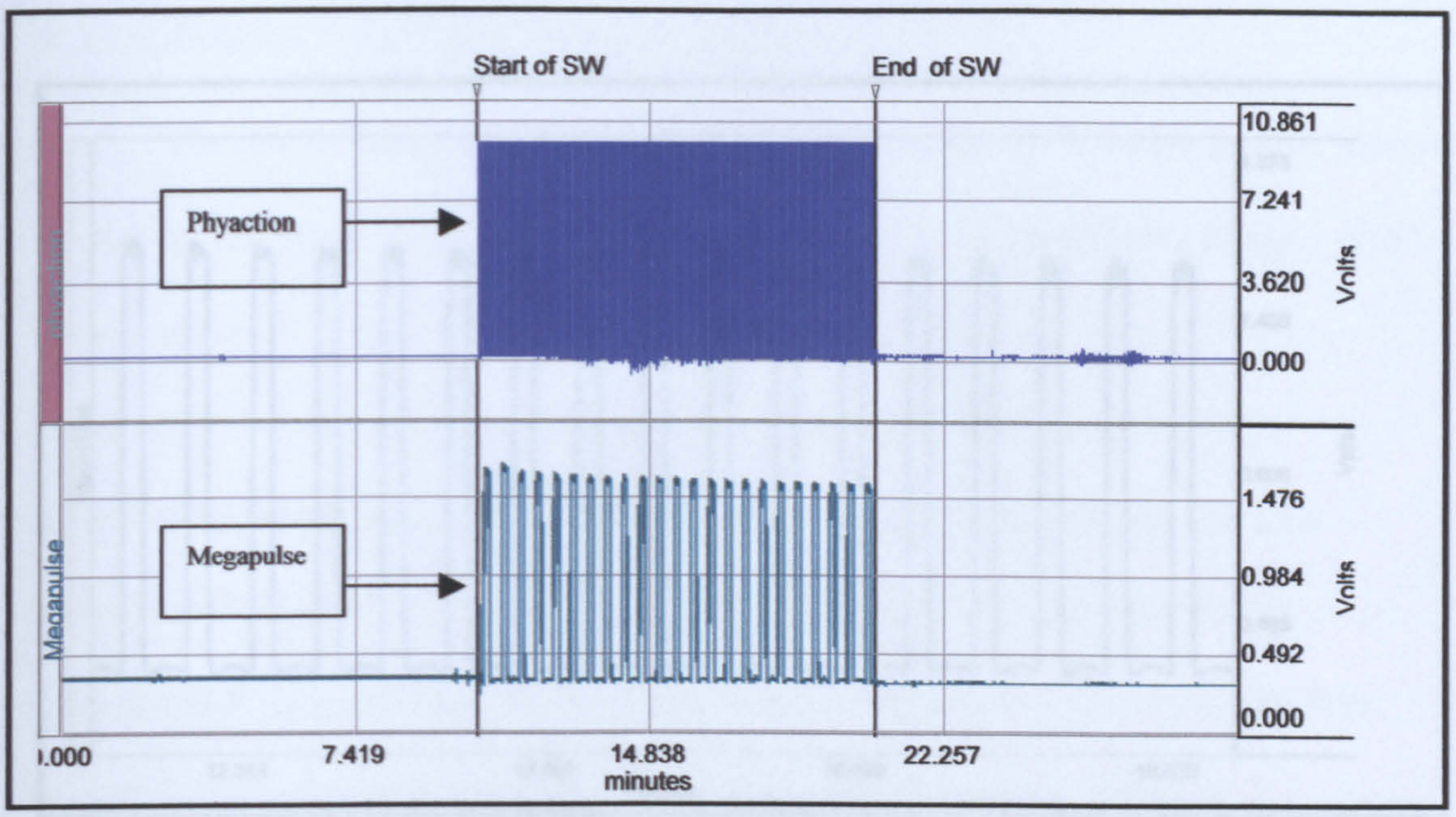

Figure (8.13) The shape of EIB with Megapulse and PP+. It could be seen that due to the massive size of EIB from PP+, it was not possible to fit the two signals to the same scale

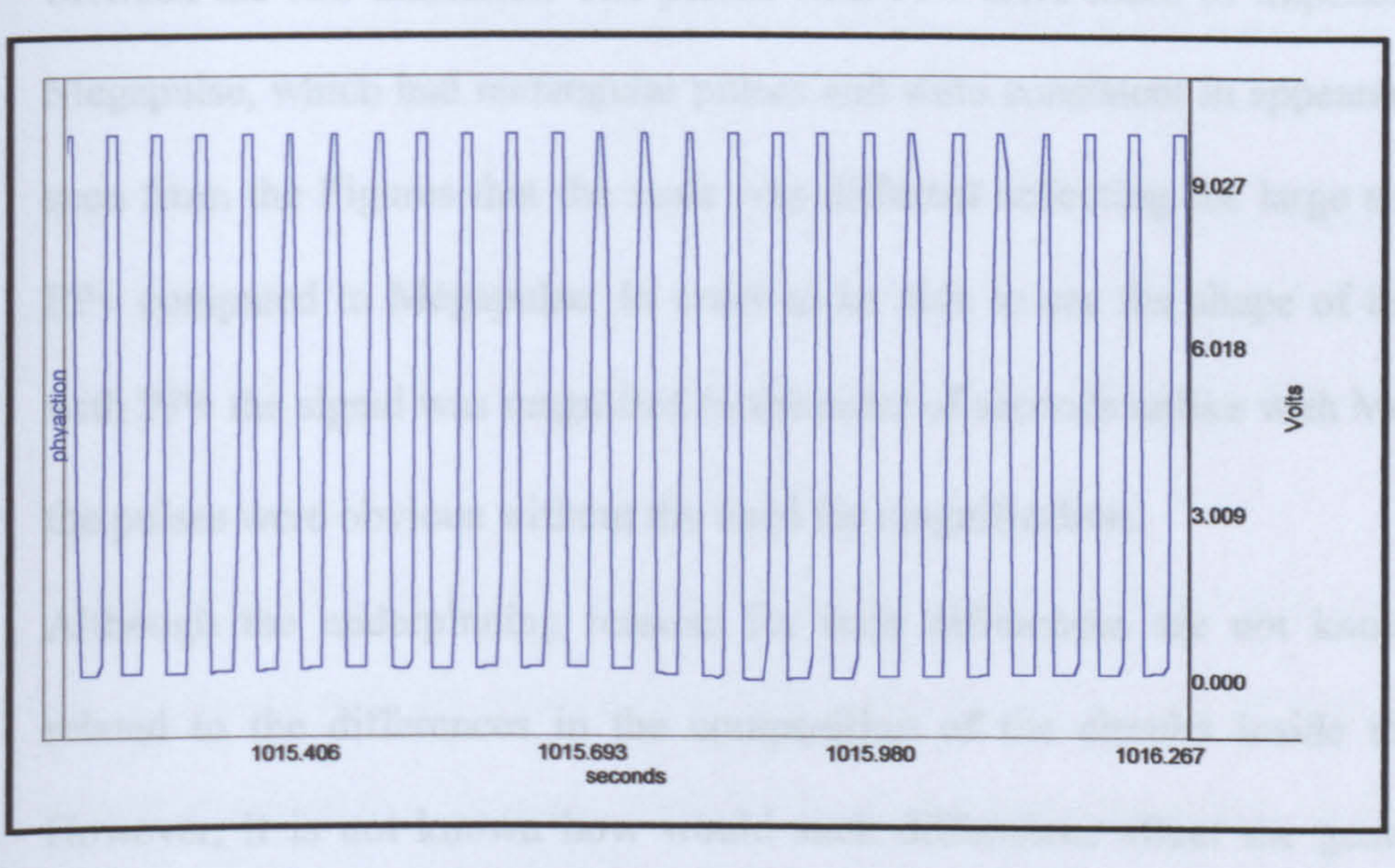

Figure (8.14) The shape of EIB with Phyaction performa + (amplified from Figure 8.13)

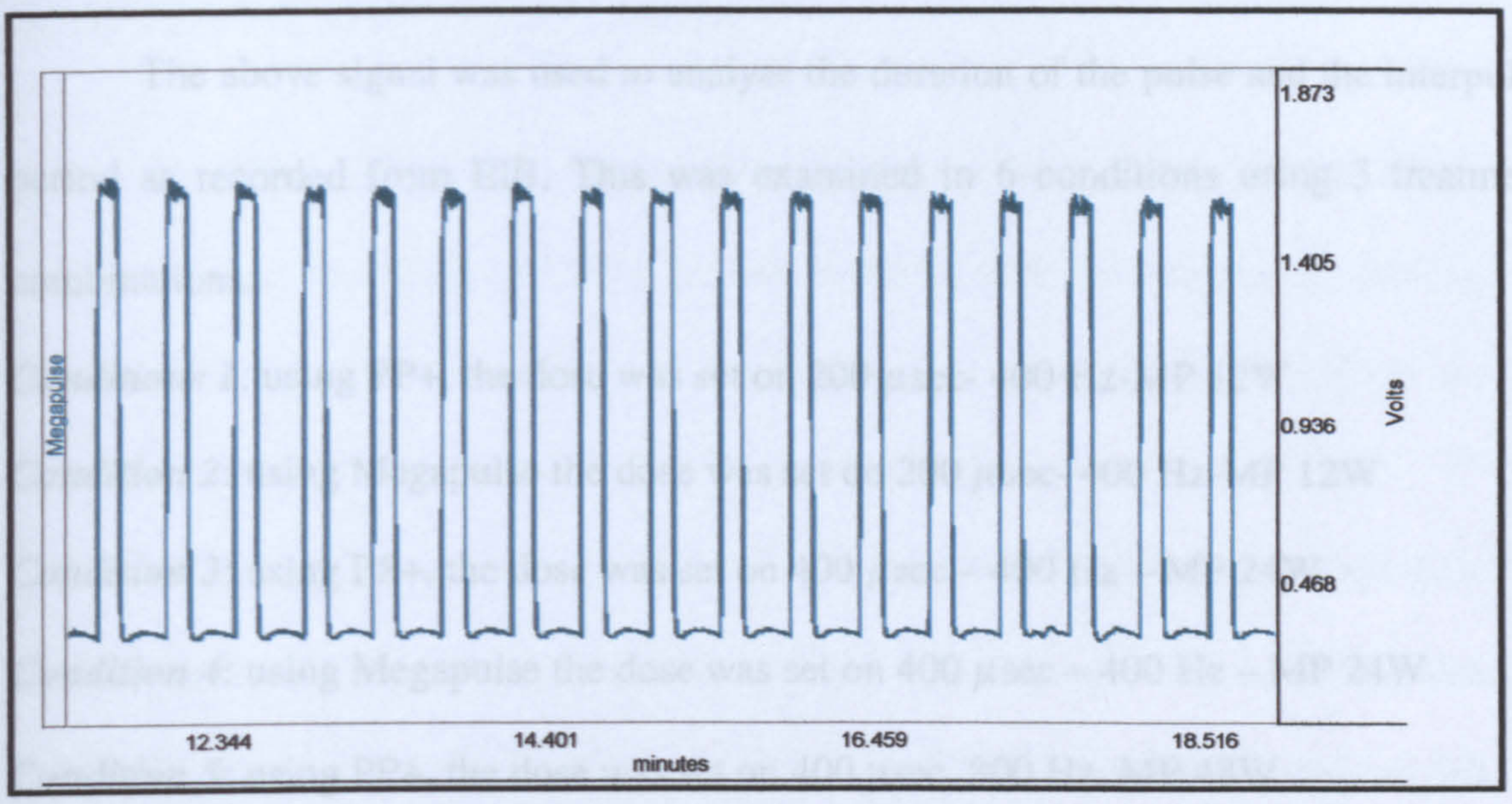

Figure (8.15) The shape of EIB with Megapulse (amplified from Figure 8.13)

The Figures above demonstrate the difference in appearance in the EIB pulse between the two machines. The pulses with PP+ were more of trapezoid shape unlike Megapulse, which had rectangular pulses and were consistent in appearance. It could be seen from the Figures that the scale was different reflecting the large size of EIB with PP+ compared to Megapulse. In order to be able to see the shape of the pulse clearly with PP+ the signal was magnified to the order of seconds unlike with Megapulse where the pulses were obvious without the need for magnification.

Although the underpinning reasons for such differences are not known it could be related to the differences in the composition of the circuits inside the PSWT unit. However, it is not known how would such differences affect the general therapeutic effects of each machine.

8.19 CHARACTERISTICS OF EIB

The above signal was used to analyse the duration of the pulse and the interpulse period as recorded from EIB. This was examined in 6 conditions using 3 treatment combinations.

Conditions 1: using PP+, the dose was set on 200 μsec- 400 Hz-MP 12W

Condition 2: using Megapulse the dose was set on 200 μsec- 400 Hz-MP 12W

Condition 3: using PP+, the dose was set on 400 μsec – 400 Hz – MP 24W

Condition 4: using Megapulse the dose was set on 400 μsec – 400 Hz – MP 24W

Condition 5: using PP+, the dose was set on 400 µsec, 800 Hz, MP 48W

Condition 6: using Megapulse, the dose was set on 400 µsec, 800 Hz, MP 48W

Each condition was repeated 10 times with both machines. The mean value for each setting was analysed separately. It was found regardless of the dose, the duration of the pulse was the same. Table (8.7) shows the mean and SD for PD and inter-pulse period,

	Megapulse	PP +
PD	9.77 ± 0.2μsec	22.50±2.7 μsec
Duration of inter-pulse	16.21±0.2 μsec	21.25±2.3 μsec

Table (8.7) EIB for both the Megapulse and Phyaction Performa +, values reported represent mean ± SD

When comparing the two PSWT machines, there was a difference in the on/off ratio. The on: off period with Megapulse was 1:1.8 while the on: off period with PP+ is 1:1. Such differences although they may seem small, their cumulative effect on tissues may not be trivial.

8.20 THE THERMAL COMPONENT WITH THE MEGAPULSE AND PHYACTION PERFORMA

The effect of EIB was also tested on the temperature probes. Section (8.11, 8.12) examined the effect of PSWT on heat build up with the temperature probes, this section examines the effect of irradiation and post irradiation effects on temperature probes using both PP+ and Megapulse.

Both PSWT machines were set to 400μsec and 800 Hz, MP 48 Hz for 10 minutes. The electrodes were attached to a phantom using adhesive tape. The recording was repeated 3 times and each time it gave similar results. The effect of EMF on the temperature probes with both machines is shown in Figure (8.16).

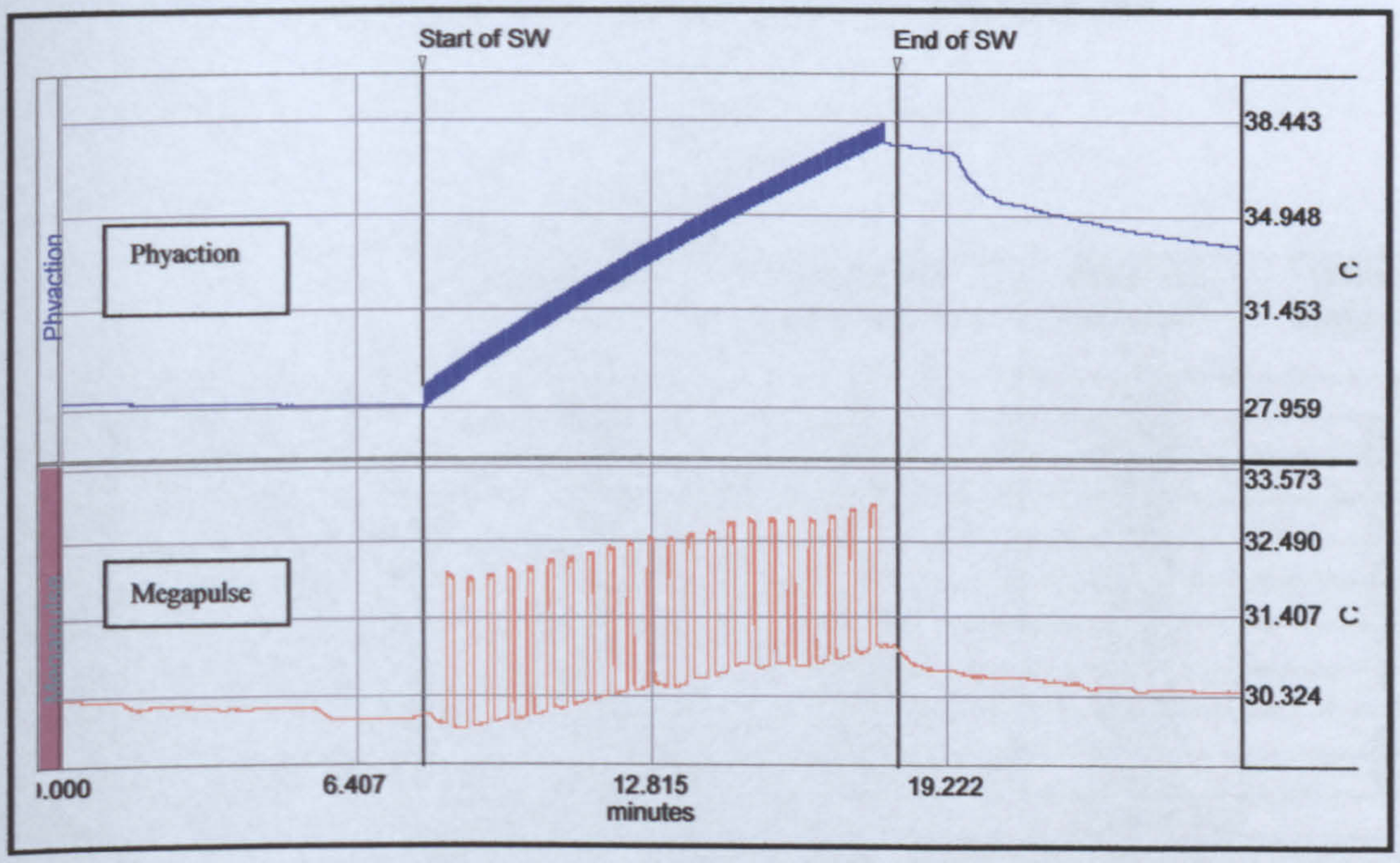

Figure (8.16) The effect of turning on Phyaction performa + and Megapulse on temperature signal

The shape of the pulses of the EIB can still be seen with the Megapulse however, with PP+ it was shown as a thick block. The graph also demonstrates that the amount of temperature increase with PP+ being higher than the Megapulse.

To further examine the effect of increase in temperature on the post treatment period, the same conditions as the above were repeated however, this time MP 100 was left to record the post irradiation period for 40 minutes in order to monitor the rate of decline in the temperature after turning PSWT machine off. Electrodes were left in place during irradiation.

Table (8.8) displays the temperature increase with the two machines during and post PSWT irradiation. Temperature has increased by 1.69 °C with the Megapulse while the increase was 14.15 °C with PP+ after 10 minutes of irradiation.

At 40 minutes post treatment, the temperature was still 6.38°C above baseline reading for PP+ while it declined to 0.38°C above baseline for the Megapulse. Figure (8.17) demonstrates the rate of temperature decay with the two machines.

	Megapulse Senior °C	Difference in temperature °C	Phyaction Performa + °C	Difference in temperature °C
Pre-administration (T0)	23.87	0	23.44	0
End of treatment (T1)	25.56	1.69	37.59	14.15
5 min post treatment (T2)	24.81	0.94	35.38	11.94
10 min post treatment (T3)	24.64	0.77	33.87	10.43
15 min post treatment (T4)	24.52	0.65	32.78	9.34
20 min post treatment (T5)	24.43	0.56	31.90	8.46
25 min post treatment (T6)	24.36	0.49	31.23	7.79
30 min post treatment (T7)	24.30	0.43	30.64	7.2
35 min post treatment (T8)	24.27	0.40	30.20	6.76
40 min post treatment (T9)	24.25	0.38	29.82	6.38
Mean ±SD	24.50±31.68		31.68±2.38	

Table (8.8) Temperature decay with the Megapulse senior and Phyaction Performa + over a period of 40 minutes. This example is typical of all the trials performed. Difference in temperature is the value of the temperature at point Tn – temperature at T0

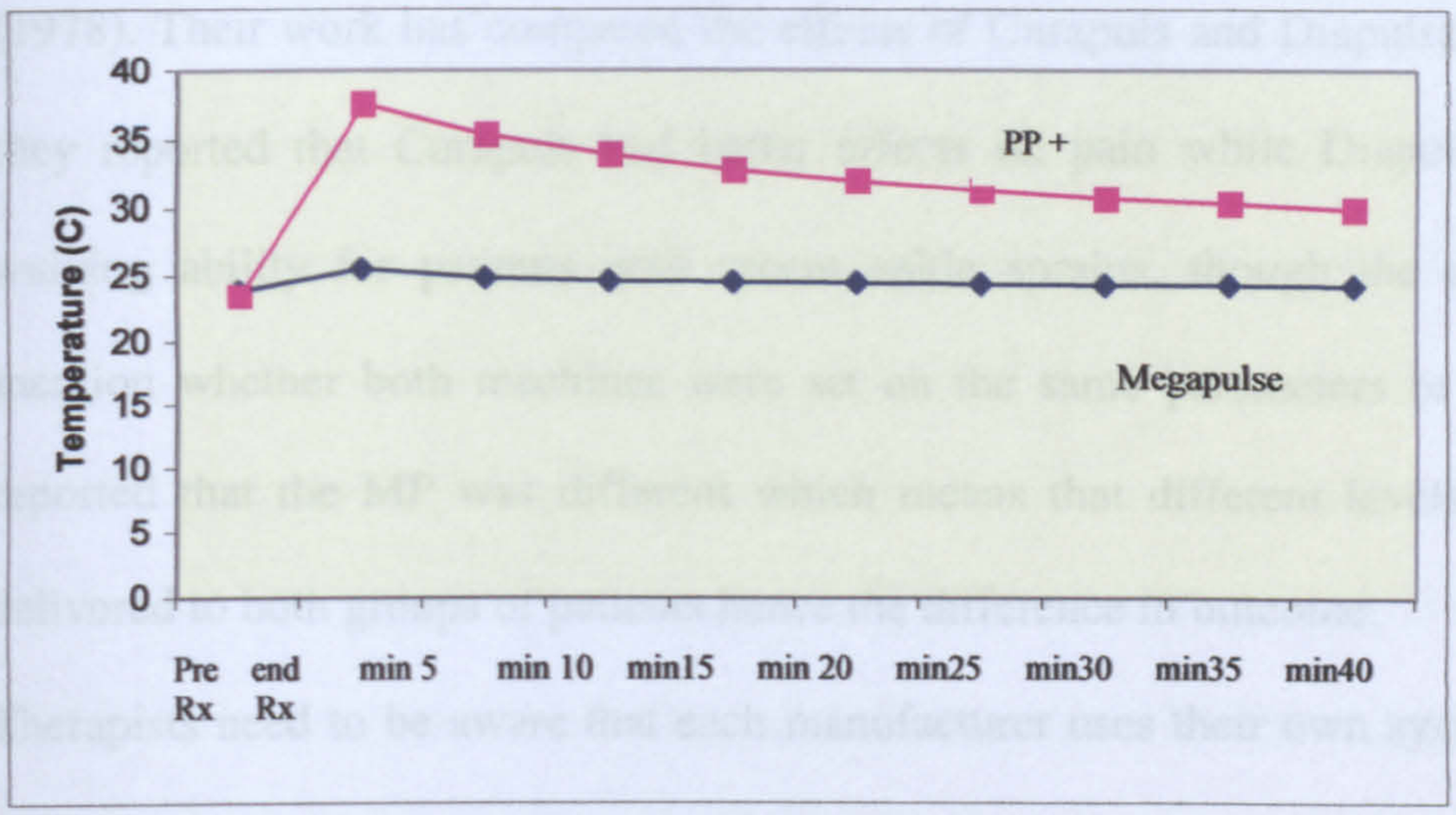

Figure (8.17) The rate of temperature decay with two machines. (Horizontal scale resembles the time post irradiation shown in 5 minutes period, the graph shows a typical response. Rx: treatment)

8.21 IMPLICATION OF THE FINDINGS

The above comparisons were not meant to cover all aspect of differences between the two machines. It is however to examine whether Megapulse and PP+ could be used interchangeably during the experiment.

PSWT machines are different though they utilise the same carrying frequency. Findings in this part have shown that both PP+ and Megapulse machines can be set on the same parameters however the stimulating pulse as measured from EIB and its characteristics are different. The differences observed could be related to the shape of the coil inside the applicator which could be helmhlotz, or cylindrical. The difference in outcome could also be related to the diameter of the encapsulated coil within the treatment head (Hand, 1990).

Theses results are in agreement with Foley-Nolan (1990) and Hayne (1984) who argued that although identical settings could be achieved with two PSWT machines of a different make, the resultant outcome might not be the same. As such, their therapeutic

effects may differ. Support to these findings were found in the study by Pasila et al (1978). Their work has compared the effects of Curapuls and Diapulse on ankle sprain, they reported that Curapuls had better effects on pain while Diapulse improved the walking ability for patients with recent ankle sprains, though the authors failed to mention whether both machines were set on the same parameters or not. They only reported that the MP was different which means that different levels of energy were delivered to both groups of patients hence the difference in outcome.

Therapists need to be aware that each manufacturer uses their own system and methods of characterising their product, making comparison between different models difficult. The findings of this work highlight the importance of efficient documentation of treatment parameters. The audit work conducted by the author has revealed that therapists fail to assign units (μsec or Hz) to the numbers they use to describe their treatment with PSWT, making it hard to distinguish between PD or PRR. Moreover, only in isolated occasions the machine name was noted in the file. The problem is made worse if the department has more than one type of PSWT machine. This creates confusion in understanding the treatment and may result in discontinuity in whatever beneficial effect obtained by the treatment. As a result affecting the overall outcome of the treatment and therapist's satisfaction with this equipment.

8.22 CONCLUSION

The work conducted in this section was not intended to examine all the differences between PP+ and Megapulse machine, and although it needs to be validated with more equipment it has highlighted two main issues. Firstly: the evidence provided by some reports on the efficacy or lack of efficacy with some brands of PSWT machines

is not necessarily transferable to all PSWT makes. As such care should be taken when extrapolating research findings.

Secondly: the current work highlights the importance of documenting PSWT specification when reporting outcome in published articles or describing a treatment in patient file.

In the experimental work the author had the option of using either Megapulse or PP+. However, following the pilot work it was apparent that Megapulse was the best option and this was based on comparing the mode by which PSWT affected the acquisition system, shape of the pulse, duration of on/off ratio and some of the factors contributing to the thermal component with the two machines.

PART 4: DEVELOPING THE EXPERIMENTAL PROTOCOL

8.23 INTRODUCTION

The previous sections of the pilot work were devoted to the validation of the acquisition system, examination of the nature and the characteristic of the signal picked up by the electrodes and calibration of the various units employed for collecting the data. This section includes a description and examination of the validity and practicality of the protocol developed for both the laboratory and the clinical trials and as such, is considered a pilot study for both trials. The amendments made to the protocol are discussed at the end of the section, prior to its application in the main experimental phases. No reporting of findings will be included in this section as results are reported and analysed following the actual experimental studies.

8.24 METHODOLOGY

The study protocol was approved by the ethical committee of Radiography and Physiotherapy (Appendix D.3).

All experiments were conducted in the Physiotherapy Research Laboratory at the University of Hertfordshire by the same investigator.

8.24.1 Subjects allocation to experimental groups

Ten healthy subjects were recruited from University of Hertfordshire students and staff. The sample included 2 males and 8 females with an age range between 19-47 years (36.5±11.2 years-mean ±SD).

The study was a same subject single blinded trial, which means that all the 10 subjects were blinded to the nature of the treatment given to them. They had to attend for 3 times to take part in the 3 experimental conditions.

On the first visit, each subject selected a sequence paper at random that determined the order of the 3 experimental sessions. Subjects were randomly assigned to one of three groups, two treatments (high or low dose PSWT) and one control (Figure 8.18). Condition 1 had a 10 minutes treatment with PP 150W, PD 200μsec, PRR 800 Hz, which gave a mean power of 24 W. Condition 2 had 10 minutes treatment with PP 150W, PD 100μsec, PRR 200 Hz, and MP of 3W. All treatments were applied using Megapulse Senior (Section 8.8.1). The dose used for the experiment is based on proposed treatment plans suggested by physiotherapists (Section 6.5.4). Condition 3 was the control condition where subjects had to lie on the plinth for 10 minutes and measurements were taken with no treatment applied. Treatment was delivered using a drum electrode applied to the front of the knee.

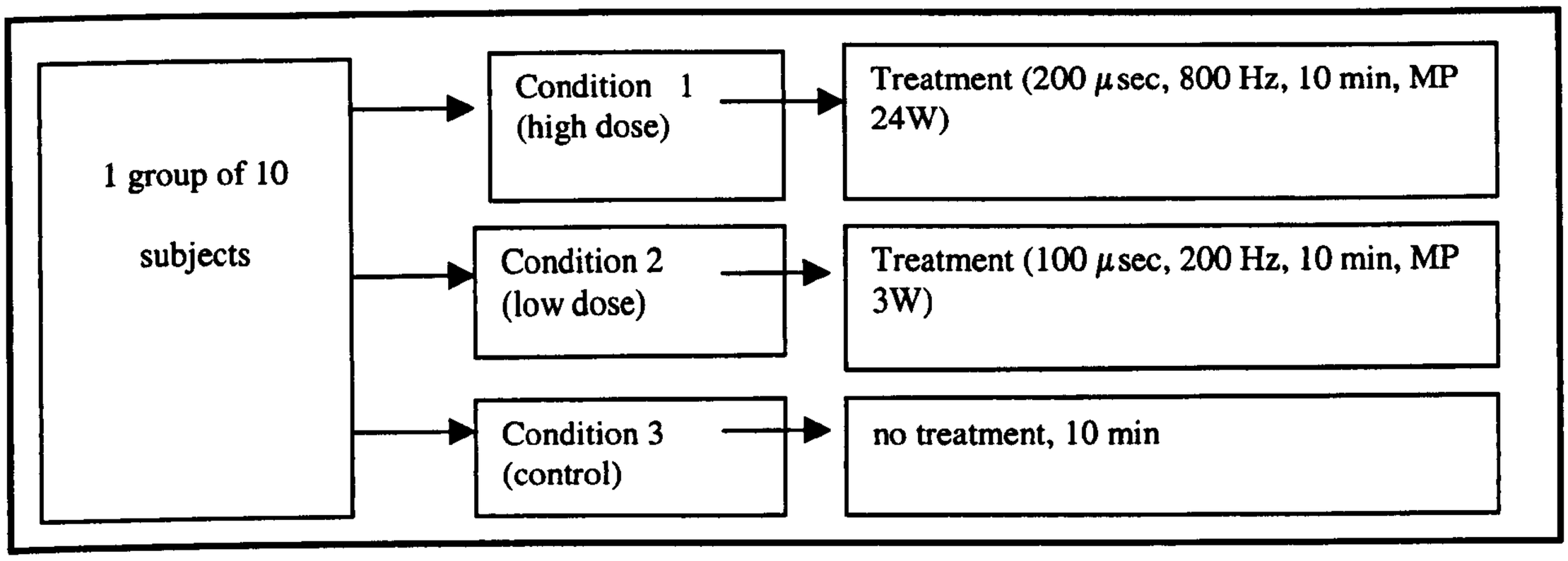

Figure (8.18) Schematic representation of the different experimental groups

There were six possibilities for randomisation (Table 8.9) The sequence paper was returned to the container once the order of the sessions was written down by the researcher so that all subject had the same number of options each time they withdraw the order of their sessions.

Session 1	Session 2	Session 3
1	2	3
1	3	2
2	1	3
2	3	1
3	1	2
3	2	1

Table (8.9) Table for randomisation
1 (24 W), 2 (3W), 3 (control)

8.24.2 Procedure

Subjects were asked to attend for three appointments with at least 2 days in between the sessions to allow for the effect of previous treatment to recede hence washing out any latent effect of the PSWT treatment (Cleary, 1996). Subjects were asked to attend at the same time for the three sessions to minimise the effect of CorT variation on the outcome (Guyton and Hull, 2000; Houdas and Ring, 1982). Furthermore, all subjects were asked to refrain from smoking, drinking coffee and exercise at least one hour before the trial to minimise their effect on circulatory system as a result of the changes in metabolism (Drust et al, 2003). They were asked not to exercise because of the possibility that fluid may shift between tissues and eventually increase SFM reading (Jackson and Pollock, 1987).

On the day of the trial, subjects were presented with an information sheet (Appendix D.4) and were asked to read it, this was followed by a briefing on the procedure and time to enquire about any issues of concern. Contra indications were checked (Appendix D.5), and a consent form (Appendix D.6) was signed by all the subjects. Subjects were excluded from the study if their SFM was above 40 mm for two main reasons. Firstly: because of the possible effects that a thick layer of adipose fat may have on PSWT penetration (Hand, 1990; Ward, 1980) and consequently the physiological effects gained from the treatment. Secondly: body fat calculation for subjects above 40 mm have been found to be unreliable (Kwok et al, 2001; Jackson and Pollock, 1987) and that reliability decreases with obesity (Scherf et al, 1986).

Subjects were asked to wear shorts for ease of measurements. Skinfold (Appendix D.7), height, and weight were measured for all subjects. Height and weight were taken using an electronic kit (Marsden Weighing Machine Group Ltd, BMB-620, Tanita Corporation, Japan)(Figure 8.21). All information that could reveal the subject's identity was kept in a secure place where only the investigator could gain access.

All the testing procedures were conducted in the physiotherapy research laboratory with a room temperature between 23°C and 26°C. The window in the laboratory was kept shut during the experiment to prevent significant fluctuation of the air temperature. In order to prevent unnecessary distraction, and to minimize the effect it may have on subjects' comfort, the laboratory door was kept closed throughout the experiment with a sign to limit access. Both the room humidity and temperature were monitored and recorded before and after each experimental session (Thermo Hygro-RS 212-124-China).

Subjects were asked to lie supine on a plinth throughout the experiment. They were allowed 15 minutes before the start of the experiment to acclimatise to laboratory temperature and to allow the vital signs to stabilise. This period was also used to attach electrodes to the subject's knees after cleaning the skin with alcohol wipes and abrading it with fine sand paper. Subjects were instructed to remain still throughout the experiment as this may alter blood flow in the limb and disturb the recorded signal (Section 8.14). All measurements were taken from subjects' right knee to ensure consistency. The procedure for conducting the trial started with 10 minutes baseline measurements, followed by NCV measurement, and was followed by 10 minutes of PSWT treatment (as shown in Figure 20). At the end of the treatment session, NCV was taken again and this was followed by another 10 minutes for post treatment measurements. The plan of the experiment is further explained in Figure (8.20). The experimental setting is shown in Figure (8.19, 8.21).

Figure (8.19) Placement of the Megapulse treatment head during the trial

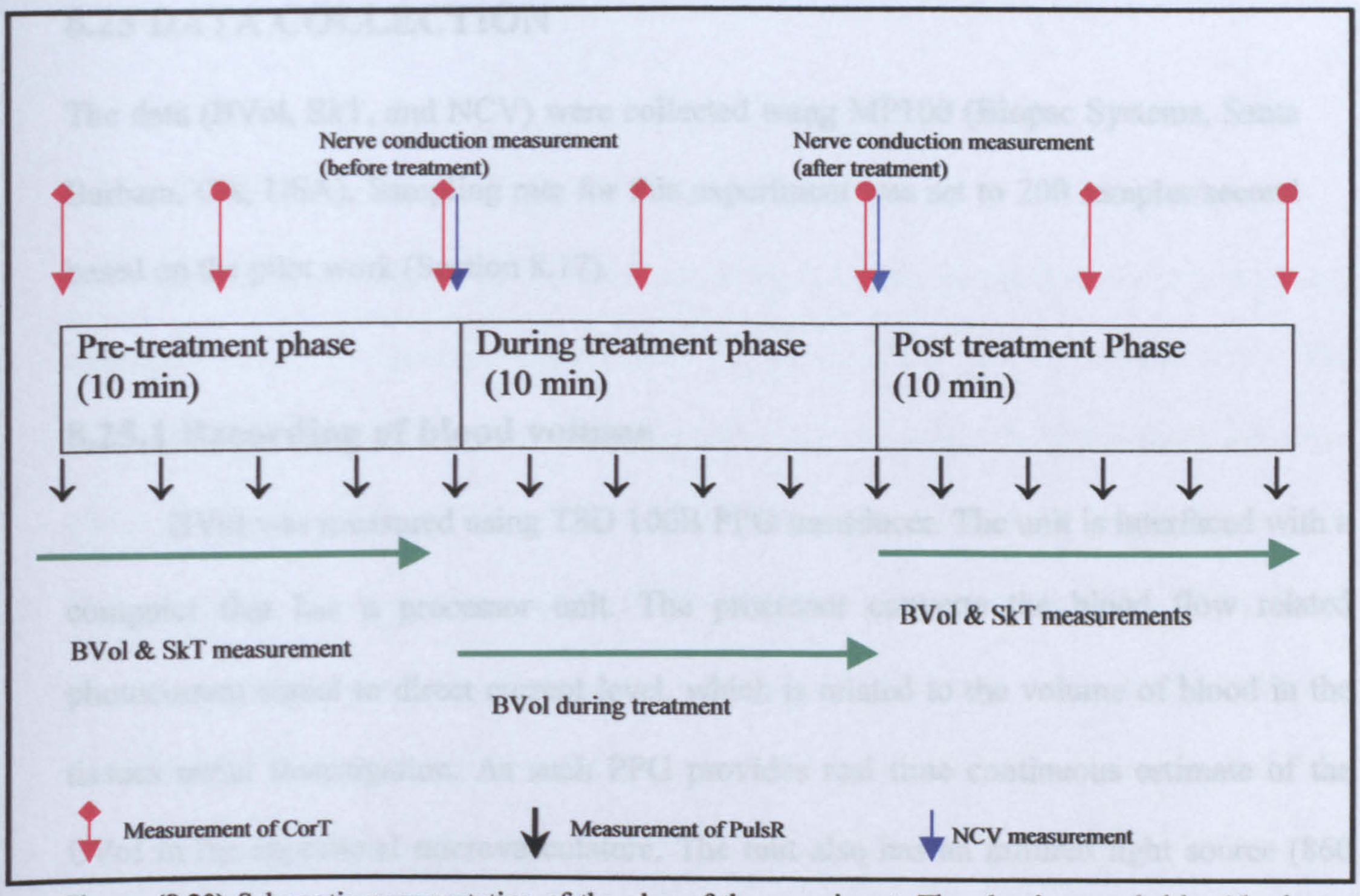

Figure (8.20) Schematic representation of the plan of the experiment. The plan is preceded by 15 minutes stabilisation time, which is not shown in the drawing

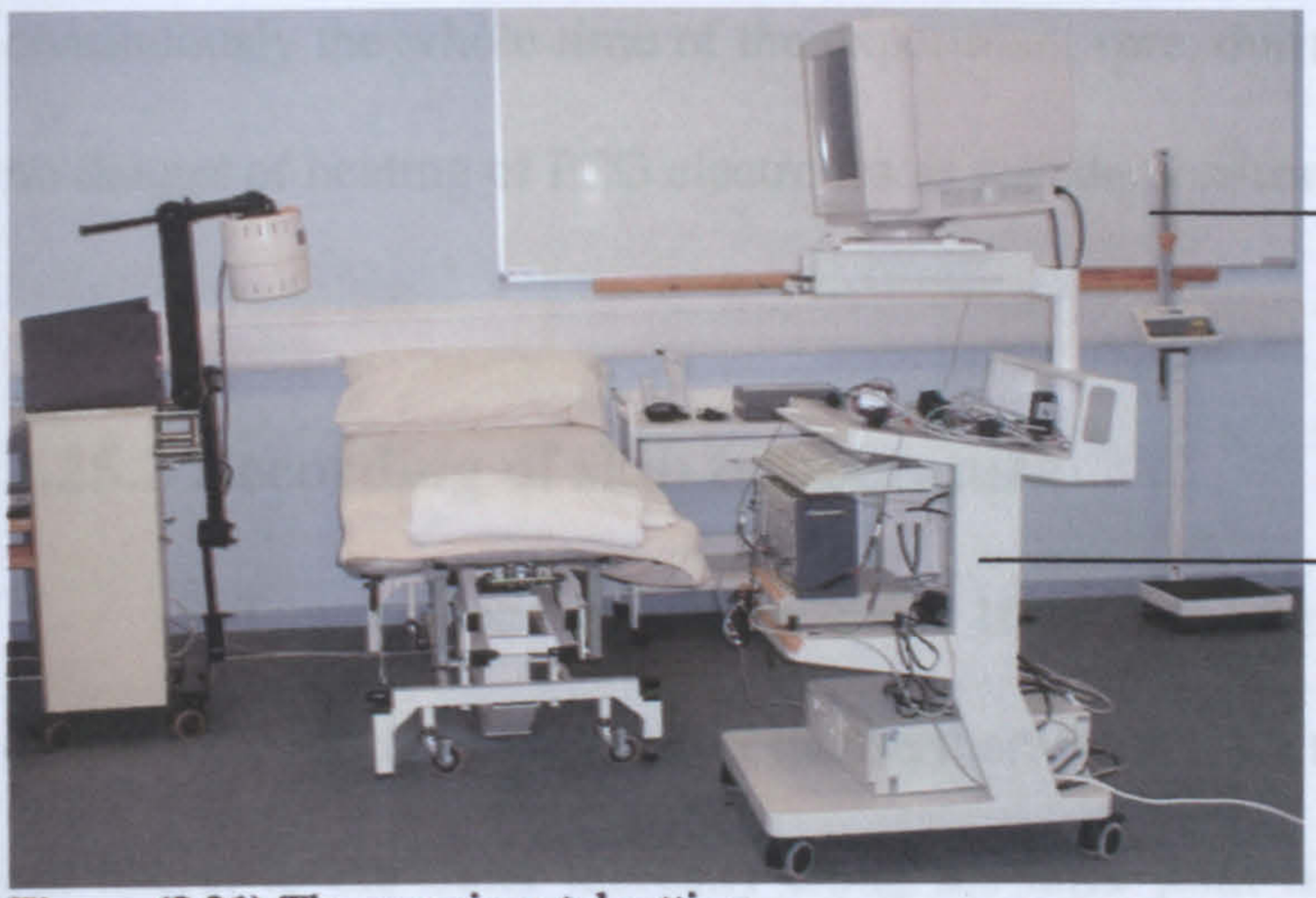

Figure (8.21) The experimental setting

8.25 DATA COLLECTION

The data (BVol, SkT, and NCV) were collected using MP100 (Biopac Systems, Santa Barbara, CA, USA). Sampling rate for this experiment was set to 200 samples/second based on the pilot work (Section 8.17).

8.25.1 Recording of blood volume

BVol was measured using TSD 100B PPG transducer. The unit is interfaced with a computer that has a processor unit. The processor converts the blood flow related photocurrent signal to direct current level, which is related to the volume of blood in the tissues under investigation. As such PPG provides real time continuous estimate of the BVol in the superficial microvasculature. The unit also has an infrared light source (860 nm ± 90 nm), and a detector (a photo diode, positioned in reflection or transmission mode). The PPG probe was placed 2 cm medial to the tibial tubrosity along the knee joint line (Figure 8.24). The probe was secured in place using a Velcro strap. BVol was monitored

continuously the whole time of the experiment (pre, during and post treatment). There was no danger of heating of PPG electrodes as was demonstrated in Section (8.11).

8.25.2 Recording of skin temperature

SkT was measured using SKT 100B amplifier module (sensitivity <83 μ°C) connected to TSD 102D rapid response thermistor. The temperature probe was attached 2 cm lateral to the tibial tubrosity along the knee joint line (Figure 8.24). The probe was secured in place using a non-allergic tape. Real time continuous SkT was measured pre and post treatment for 10 minutes. During the treatment the temperature probe was removed because of the heating of the metal element within the probe (Section 8.11 and 8.12).

8.25.3 Recording of NCV

In this study, motor NCV of the deep branch of the common peroneal nerve was measured antidromically. First attempts were made to measure NCV in the femoral nerve. The femoral nerve was chosen as it supplies the quadriceps muscle, which lies under the direct effect of PSWT treatment head. The femoral nerve was rejected for two main reasons. Firstly: because the femoral nerve becomes superficial in the groin area (Oh, 1996). It was difficult to locate the exact site of the nerve at this sensitive area, which could jeopardise reliability of the test. Secondly: the recommended points for measuring the nerve lie outside the treatment area (the two points for stimulation and recording are in the groin area and 10 cm below that). All of this necessitated the search for another alternative, which was the common peroneal nerve.

8.25.3.1 Anatomy of common peroneal nerve

The common peroneal nerve (Figure 8.22) emerges from lumbar 4,5 sacral 1, then travels in through the lumbosacral plexus into the sciatic nerve alongside the tibial nerve. In the thigh it innervates the short head of the biceps femoris muscle. Above the popliteal fossa it gives off the lateral cutaneous nerve of the calf, which innervates the lateral upper leg, the nerve then travels laterally around the neck of the fibula. It then divides into superficial and deep branches. The superficial branch supplies the ankle evertors (peroneus longus and brevis), sensation of the lower lateral aspect of the leg and ankle. The deep branch supplies the dorsiflexers (tibialis anterior, extensor digitorum longus and brevis, extensor hallucis longus and peroneus tertius) of the foot and toes, sensation between the first and the second toe (Mendell et al, 2001).

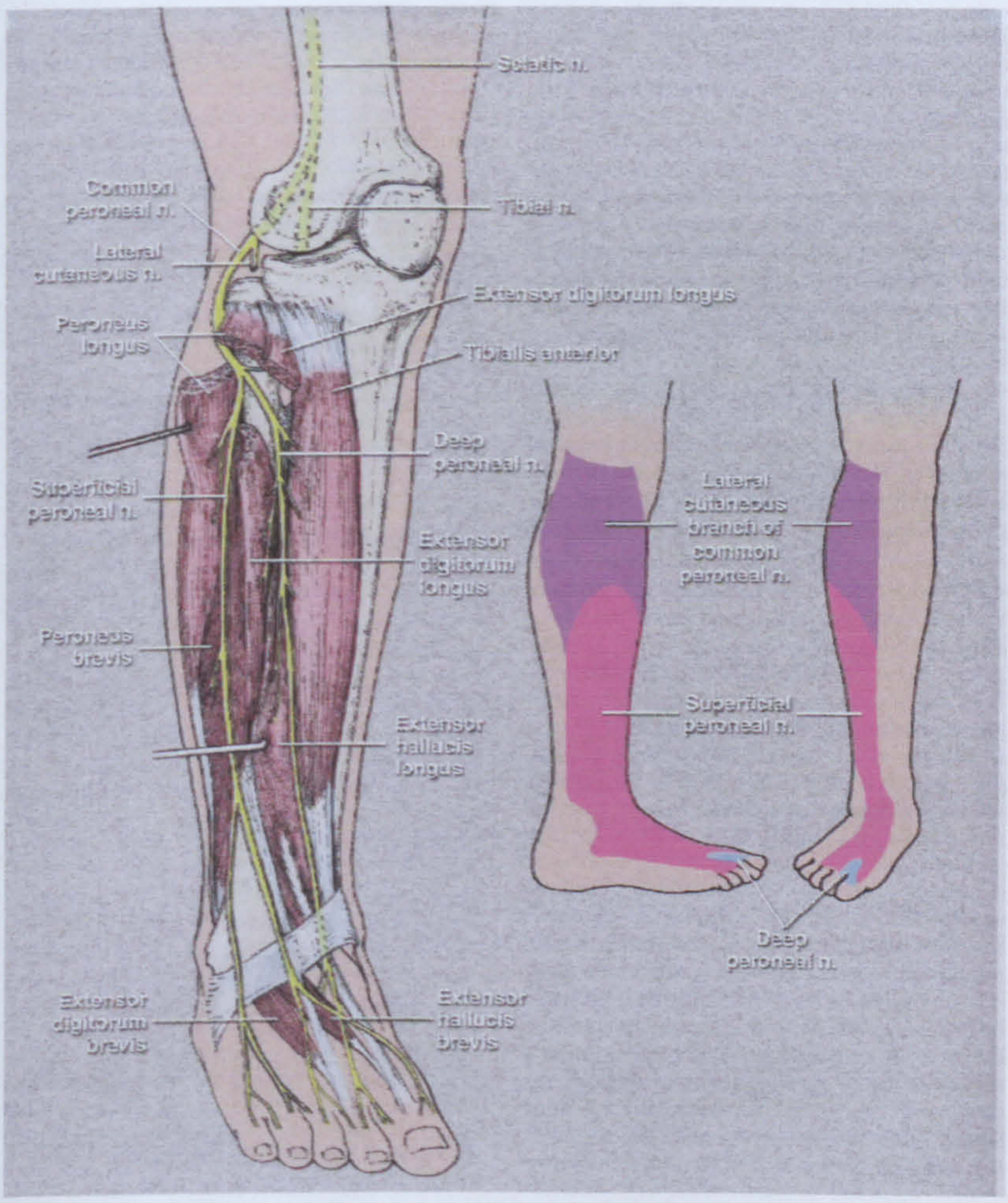

Figure (8.22) The course of the common peroneal nerve (from Mendell et al, 2001)

8.25.3.2 Instrument

The unit used to record NCV interfaced with MP 100 and consisted of a stimulator (STM 100C- Figure 8.23) module and EMG 100B unit. The stimulator allowed for 20V maximum peak to peak output.

Both the stimulator and the EMG module were set according to the manufacturer's recommendation. The stimulus consisted of square pulse of 0.2 ms duration. The sampling rate was set to 10000 samples /second. The stimulus was increased gradually until a visible contraction was detected and a clear response was recorded by the MP100 (Section 8.31.2). The stimulating and recording electrodes consisted of Ag-AgCl pre-gelled paired (dual) electrodes (41 mm x 82 mm x 1.5 thick foam), which were 41 mm apart centre to centre. The ground electrode was a 35 mm diameter general purpose pre-gelled electrode Ag-AgCl.

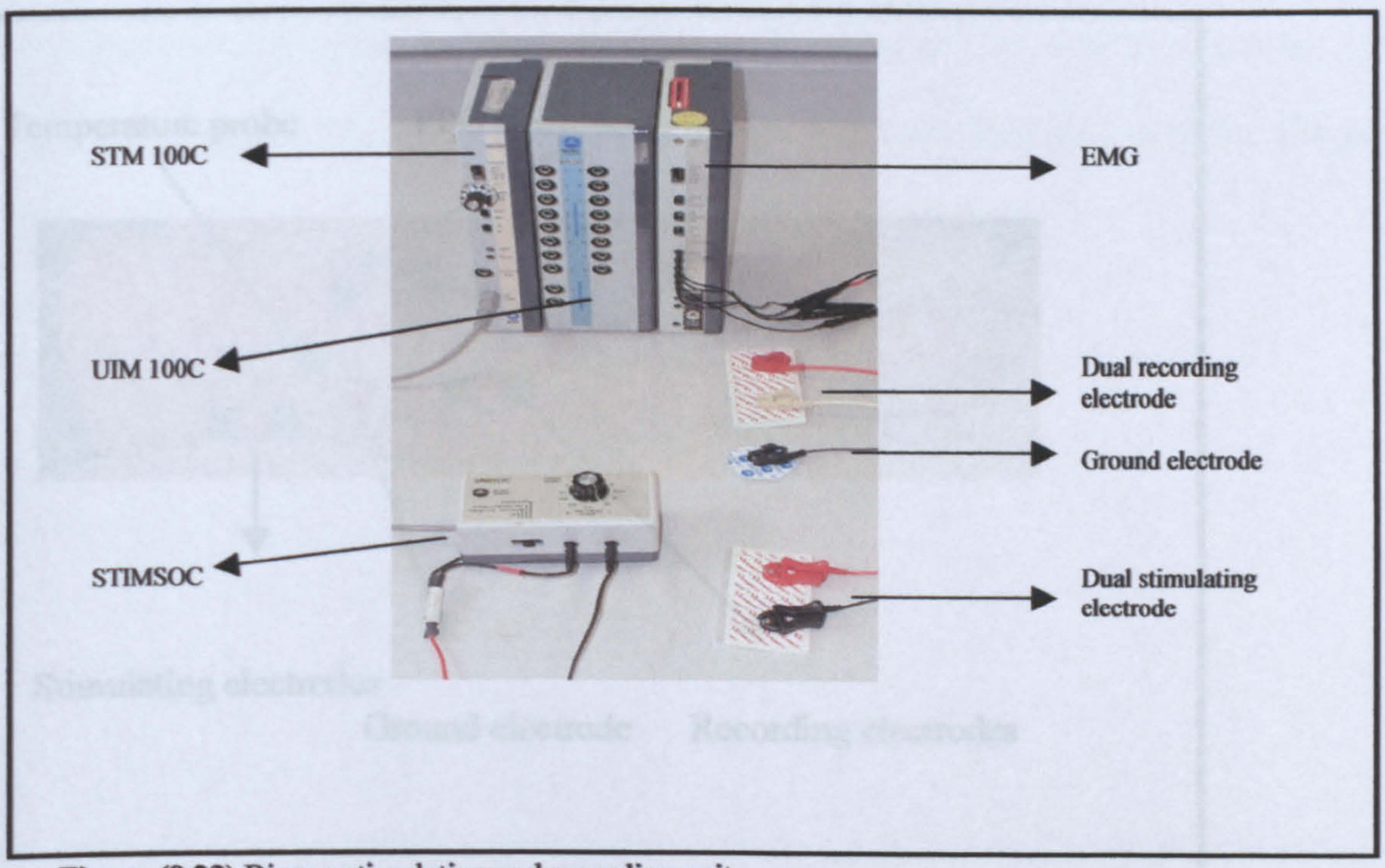

Figure (8.23) Biopac stimulation and recording unit

Both legs were prepared by wiping them with alcohol to remove skin oils or sweat. The skin was then abraded with fine sand paper to remove scaly skin, reduce skin resistance to the applied current and to enhance skin conductivity (Oh, 1996; Dong and Liveson, 1983). Electrodes were placed following the methodology adopted by Campagnolo et al (2000) and Devi et al (cited in Oh, 1996). A stimulating electrode was used to identify the course of the nerve and to determine the best sites for recording and for stimulation. The stimulation electrodes were placed inside the lateral border of the popliteal fossa, in line with the patella. The recording electrode was placed on the motor point of tibialis anterior muscle at the junction of the upper 1/3 and lower 2/3. The ground electrode was placed between the stimulating and recording electrodes (on the lateral tibial condyle) (Figure 8.24). All recordings were done antidromically where the nerve fibres were stimulated proximally and the response was recorded distally (Oh, 1996).

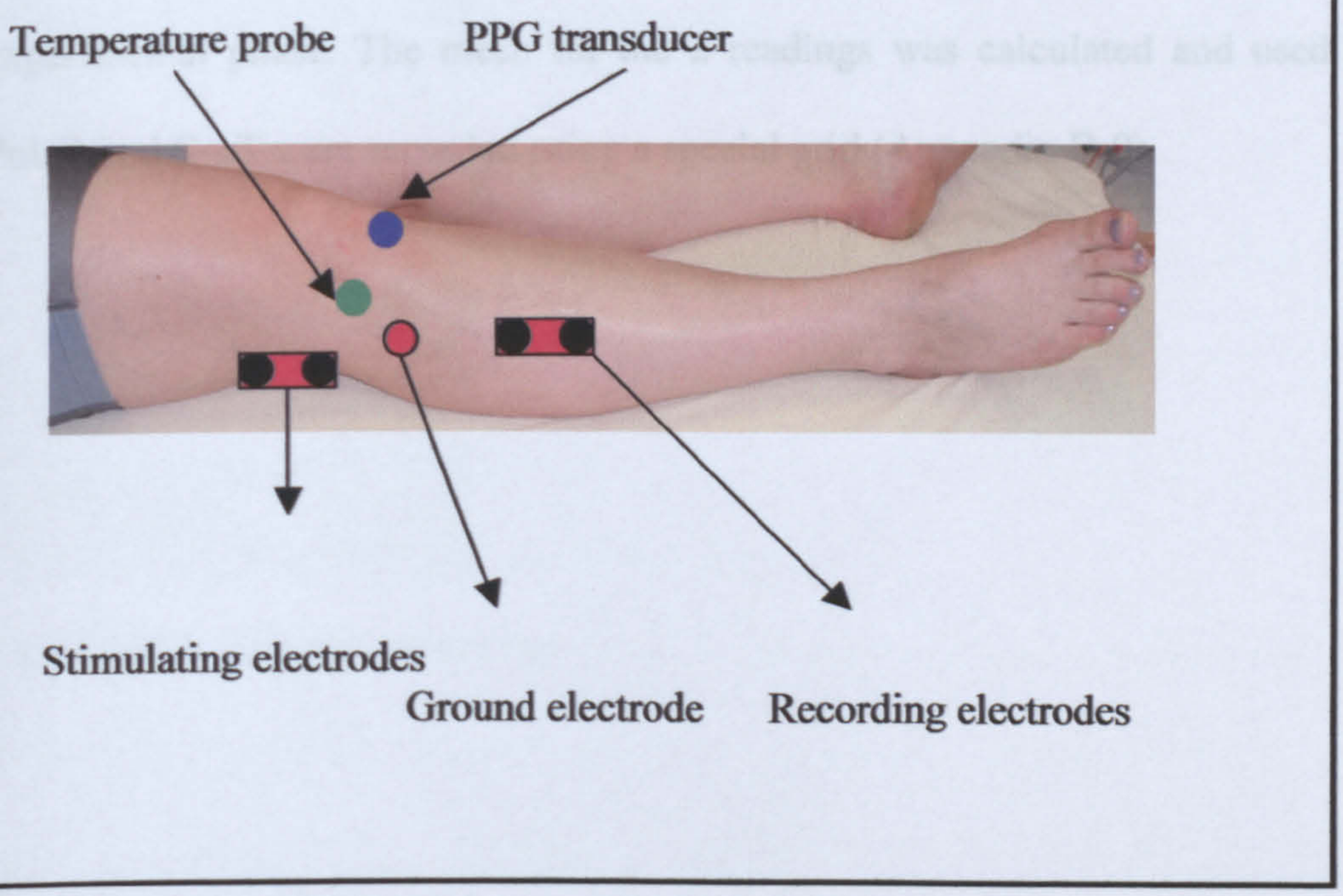

Figure (8.24) Electrodes placement

Because the electrodes were to be removed during treatment and replaced after PSWT administration, the electrodes sites were marked for reproducibility. Nerve conduction was measured at minute 10 after the baseline measurement and at minute 20 immediately after the treatment (Figure 8.20).

8.25.4 Recording of pulse rate and core temperature

The pulse rate was recorded from the right ear lobe using a Tunturi unit (TPM-400, Japan) (Figure 8.25) every 2 minutes. The mean of the PulsR readings for each phase (pre-during treatment and post treatment) was used for analysis.

The CorT was recoded using Tympanic Thermometer (Figure 8.26) (Ivac Medical Systems, Model 2090, San Diego, California). The CorT was measured from the left ear twice during the recording period, that is every 5 minutes, as the CorT is not expected to vary significantly (Guyton and Hall, 2000) in a 10 minute period, which is time for each experimental phase. The mean for the 2 readings was calculated and used for analysis. PulsR and CorT were recorded using a special grid (Appendix D.9).

Figure (8. 25) Tunturi unit

Figure (8. 26) Tympanic Thermometer

8.25.5 Measurement of body fat

The calliper used in the study was the Lafayette model 01127 (Bissell Healthcare Company, UK). It was employed for the trial as it was designed with the assistance of Dr. Andrew S. Jackson, co-author of the Jackson-Pollock skinfold equations employed for the current study.

Subjects stood in a relaxed posture while measurements from the right side were taken. The three sites for skinfold were marked according to guidelines from Jackson and Pollock (1987) and anthropometric standardization reference manual (Lehmann et al, 1988). Measurements were taken from triceps, abdominal and iliac area for women and from triceps, subscapular, and chest for men (Appendix D.7). The measurements were taken by the same researcher 3 times and the mean was used for analysis. The researcher reliability using Lafayette was calculated with Pearson Correlation Coefficient r and was found to be between 0.957-0.991, p =0.01. Full description of the findings could be found in Appendix (D.8).

8.25.6 PSWT unit

All treatments were administered using Megapulse Senior treatment unit, which was fully serviced and calibrated by the manufacturer prior to the start of the trial. The parameters for PSWT were selected based on therapist's answers to the theoretical case studies in section 2 of the questionnaire (Section 6.5.4).

Although the Megapulse unit allows the adjustment of the pulses for one third, two third or all the time it was seen appropriate to choose 3:3 mode as not all the PSWT machines will have the advantage of controlling the pulse delivery mode. By doing this, it is expected that the MP chosen will be representative of the majority of the

PSWT equipment available in the clinical environment. Moreover, choosing 1:3 or 2:3 means that the power will be delivered to the subjects either 1/3 or 2/3 of the time.

In order to prevent subjects from observing the setting and predicting their experimental group, the Megapulse console was fitted with a cover that measured 21 cm high. The indictor light on the treatment head was also covered as this could give subjects some indication as of whether the treatment was on or off Figure (8.27). This was done in order to minimise its effects on subject's biofeedback (Low and Reed, 2000).

A drum electrode was used to deliver the treatment and was applied to the anterior of the knee. To standardise the distance between the treatment head and knee, the template (23 cm long, 20 cm wide, 15 mm thick) was used. All treatments were delivered using drum electrode placed at the front of the knee.

Figure (8.27) PSWT used for the trial

The equipment was warmed up before the actual use on subjects to allow it to come to room temperature (Docker et al, 1994). Inspection of the mains lead and casing for faults was completed before each application.

Room temperature and humidity were recorded each session before and after data collection.

8.26 MAIN OBSERVATIONS AND AMENDMENTS MADE TO THE PILOT PROTOCOL

This section will not report the findings of the study, as it was only a pilot to examine the feasibility of the experimental protocol. Emphasis however will be made on the alternations made to the improve the quality of the methodology used for data collection.

8.26.1 Stabilisation of temperature probes

The effect of removing the probes during the treatment and re-attaching them post treatment resulted in the effects seen in Figure (8.28). It could be seen from the graph that the temperature electrodes take some time to stabilize, although the manufacturer has stated in the manual that they were quick response electrodes. The duration of this acclimatisation could vary from one subject to the other, however, with most subjects it lasted for the whole period of recording which was 10 minutes.

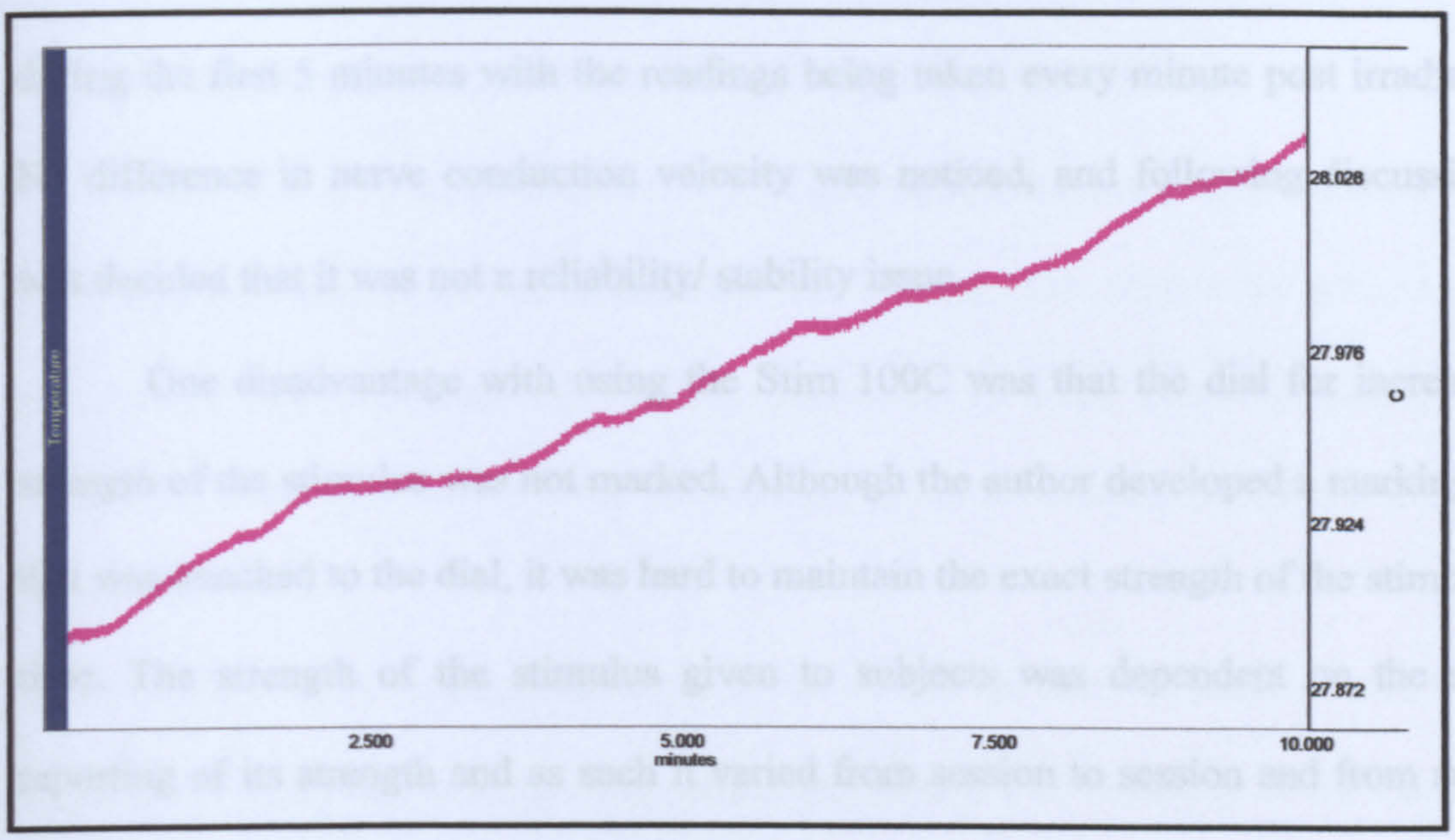

Figure (8.28) Time needed for temperature probes to stabilise

This was found to occur because during the irradiation periods the electrodes were left exposed to the environment temperature. To overcome the above problem the temperature probes were attached to subjects' ankle when removed from the knee, in this way they will maintain the subject temperature and reduce the time needed to recover when re-attached. Additionally, the placement of the electrodes at the ankle provided sufficient distance from the treatment applicator in terms of the probe heating and subject safety.

8.26.2 Stabilisation of nerve conduction electrodes

Having identified the time it took temperature probes to acclimatise to skin temperature, there was a need to examine the time it took nerve conduction electrodes to stabilise after being re-attached. The same protocol was adopted for attaching electrodes and applying the treatment, the electrodes were then removed for treatment and re-attached for post treatment recording. The NCV reading was repeated 5 times

during the first 5 minutes with the readings being taken every minute post irradiation. No difference in nerve conduction velocity was noticed, and following discussion it was decided that it was not a reliability/ stability issue.

One disadvantage with using the Stim 100C was that the dial for increasing the strength of the stimulus was not marked. Although the author developed a marking system that was attached to the dial, it was hard to maintain the exact strength of the stimulus each time. The strength of the stimulus given to subjects was dependent on the subject's reporting of its strength and as such it varied from session to session and from subject to subject. Therefore, it was decided to avoid reporting all the variables that relates to amplitude such as negative and positive peak amplitude and only to report the onset latency, and response duration. Amplitude refers to the number and the synchrony of the fibres being tested (Dong and Liveson, 1983). It is not a reliable (Oh, 1996; Delisa, 1994; Dong and Liveson, 1983) characteristic of the nerve and could vary up to 43% (Raynor et al, 1997) and sometimes up to 70% if the electrode were misplaced (Bromberg and Spiegelberg, 1998). Figure (8.29) shows the characteristics of the motor nerve signal when measured with Biopac MP 100.

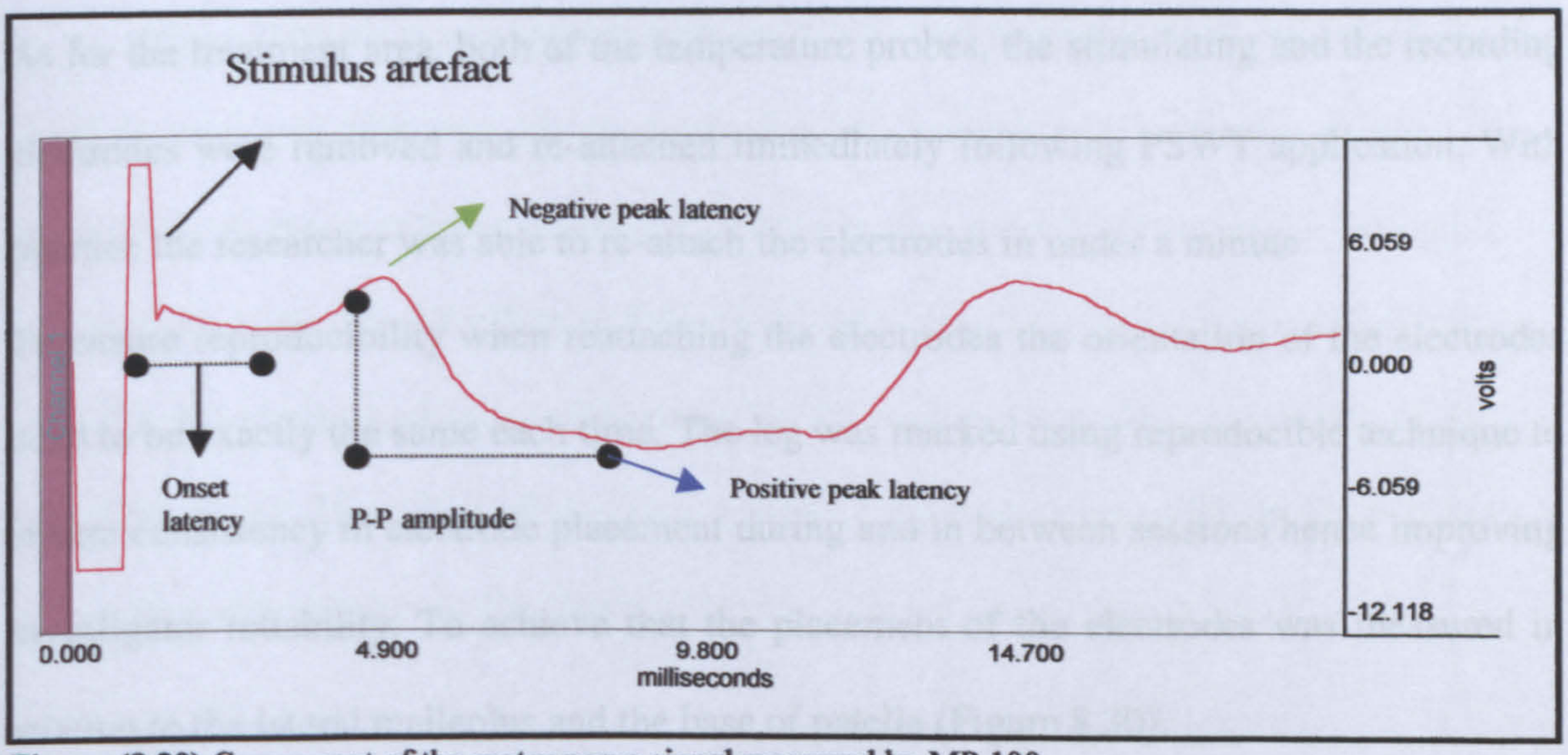

Figure (8.29) Component of the motor nerve signal measured by MP 100

8.26.3 Time to re-attach the nerve conduction electrodes

The procedure adopted for the study necessitated that the temperature and nerve electrodes be removed before irradiation with PSWT. The reason for removing the temperature electrodes was explained in Section (8.11-8.12). Nerve electrodes were removed because they have a metal component, which is considered a contra-indication for applying PSWT.

This procedure however resulted in loss of the data in the first 3-4 minutes after PSWT treatment because this was the time needed to reattach the electrodes to the skin. This time was seen very long in comparison to the period used for recording and could cause the loss of valuable information about the patient's response.

In an attempt to reduce the total time lost, it was decided to leave the electrodes on the non-treated side as they did not constitute a real threat to safety, not being in the immediate field of irradiation. By leaving the electrodes in place there is a need to acknowledge that skin underneath the electrodes in the non-treated area may not undergo the same reaction to removing and reattaching adhesive electrodes as the other leg and this may have its implication on the findings. However, this is a confounding variable that needed to be accepted at this level.

As for the treatment area, both of the temperature probes, the stimulating and the recording electrodes were removed and re-attached immediately following PSWT application. With practice the researcher was able to re-attach the electrodes in under a minute.

To ensure reproducibility when reattaching the electrodes the orientation of the electrodes need to be exactly the same each time. The leg was marked using reproducible technique to ensure consistency in electrode placement during and in between sessions hence improving investigator reliability. To achieve that the placement of the electrodes was measured in relation to the lateral malleolus and the base of patella (Figure 8.30).

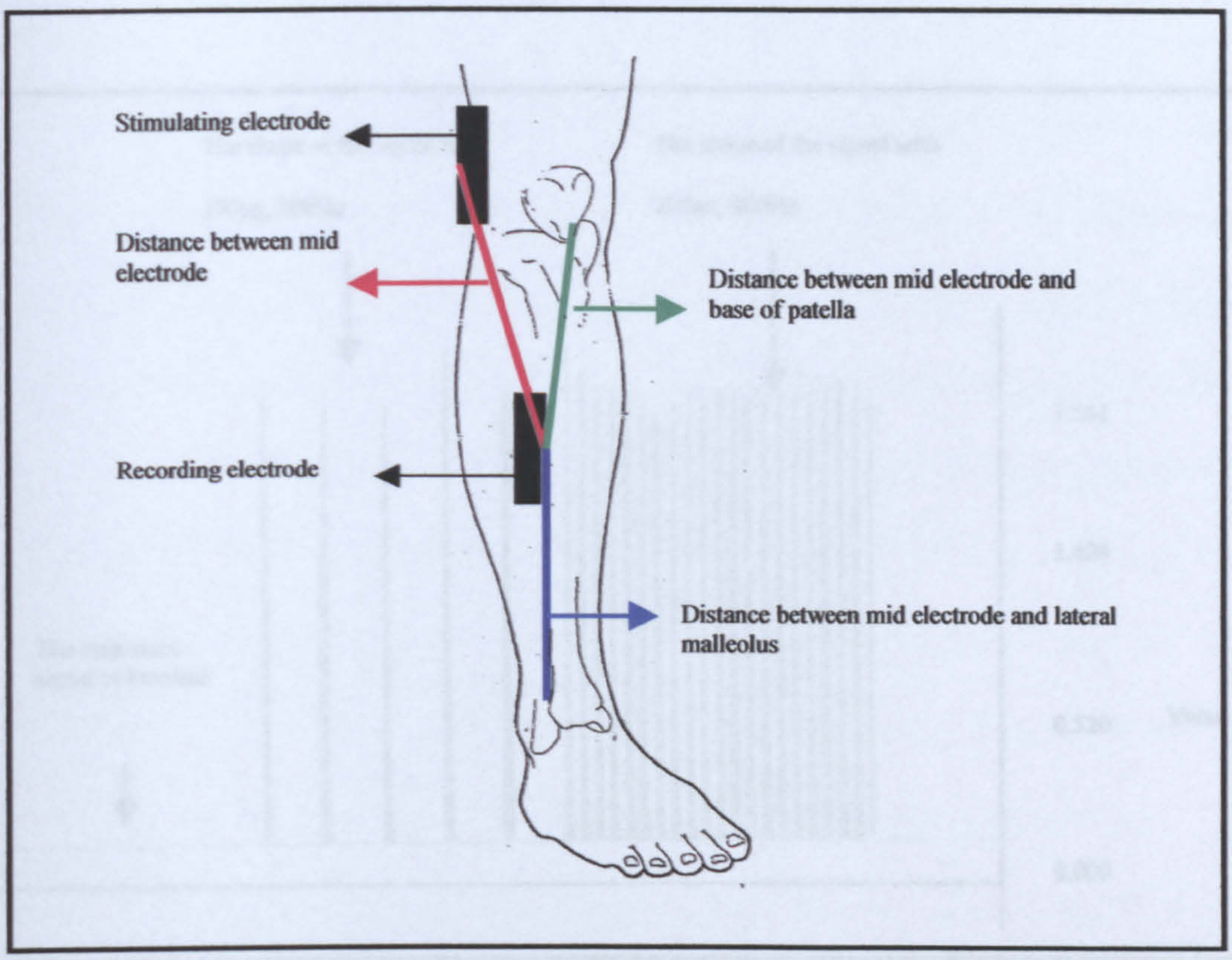

Figure (8.30) Measurements taken to ensure orientation of the electrode

With the control group the nerve electrodes were left in place the whole time of the experiment.

8.26.4 Eliminating the EIB contamination from the recorded signal

It has been shown in the pilot Section (8.9) that the recorded BVol signal was contaminated with EIB, and this contamination was picked up even from a distance of 4 m, which is the maximum distance available in the research laboratory. Although it was hard to eliminate the effect of EIB on the physiological signal, it was possible to quantify its effects and judge the extent of its interference with the nature of the recorded signal. The effect of the two modes of treatments that will be used in the succeeding experiments on the shape of the signal is shown in Figure (8.31).

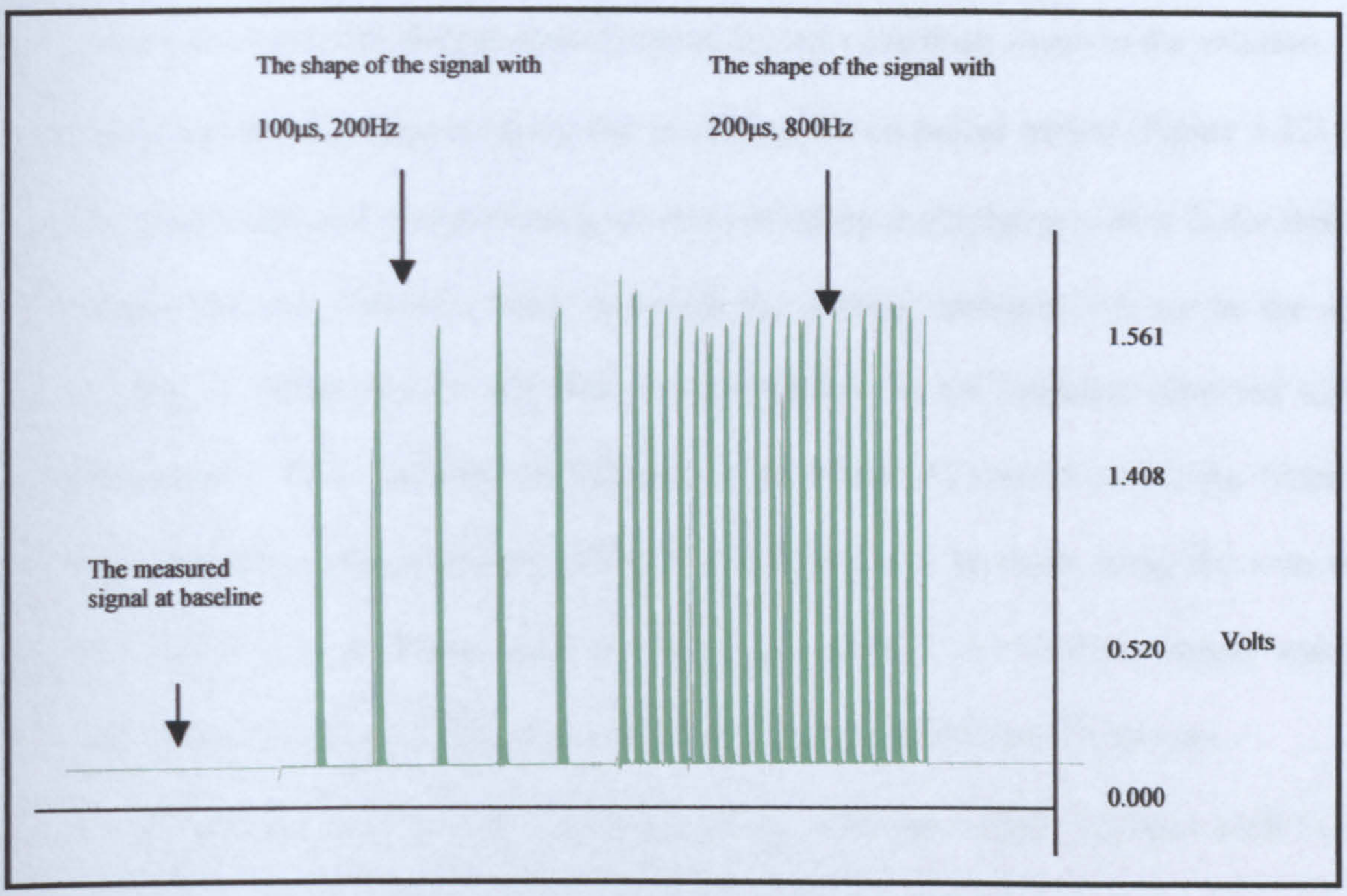

Figure (8.31) The effect of PSWT on the shape of the blood volume signal, it could be seen that the inter-pulse period remained at baseline reading regardless of the superimposing EIB

The work that had been conducted to date either examined the pre/post effect of PSWT (Garret et al, 2000; Oosterveld et al, 1992) or has interrupted the treatment time for measurements of the variables (Draper et al, 1999). The attempts to include the "during treatment" period in the analysis is a unique feature of this study and may help explain further part of the mechanism of PSWT action.

Due to the scarcity of the work in this field there was a need to identify a novel method to overcome the effect of EIB interference with the data collected.

The first attempt was to filter the interference from the physiological signal. Different filters with different settings were tried, however these attempts were not successful as

the input signal was also filtered out at the time of the on pulse period. Personal communication with Biopac manufacturer did not contribute much to the solution.

There was another way of taking out or cutting the on pulses period (Figure 8.32) from the acquisition and compensating for this period by multiplying with a factor that will replace the lost treatment time. Although the reading obtained will not be the actual reading, it would provide the closest representation to the response observed without interference. This method was rejected as this had left uneven recording times and because comparisons between different conditions will be done using the area under the curve, it was shown that adopting this method for analysis might result in misleading findings, as the area in between different conditions would vary.

It was decided later to use a function in the software called "connect ends" (was also recommend by manufacturer in UK following personal communication). This function has left the recorded time unchanged, which made comparing the area under the curve for both modes of therapy plausible. In this function the last point in the recorded signal was joined by a line with the first point in the following signal superimposing the PPG signal. The mean value for this period was always found to be zero. Given that there was 11 periods of EIB with the high dose, 7 periods of EIB with the low dose, and 6 EIB pulses with the placebo dose, this meant that there was 3.84 minutes lost when high dose was applied, 1.13 minutes when low dose was applied, and 0.83 minutes when placebo PSWT was applied.

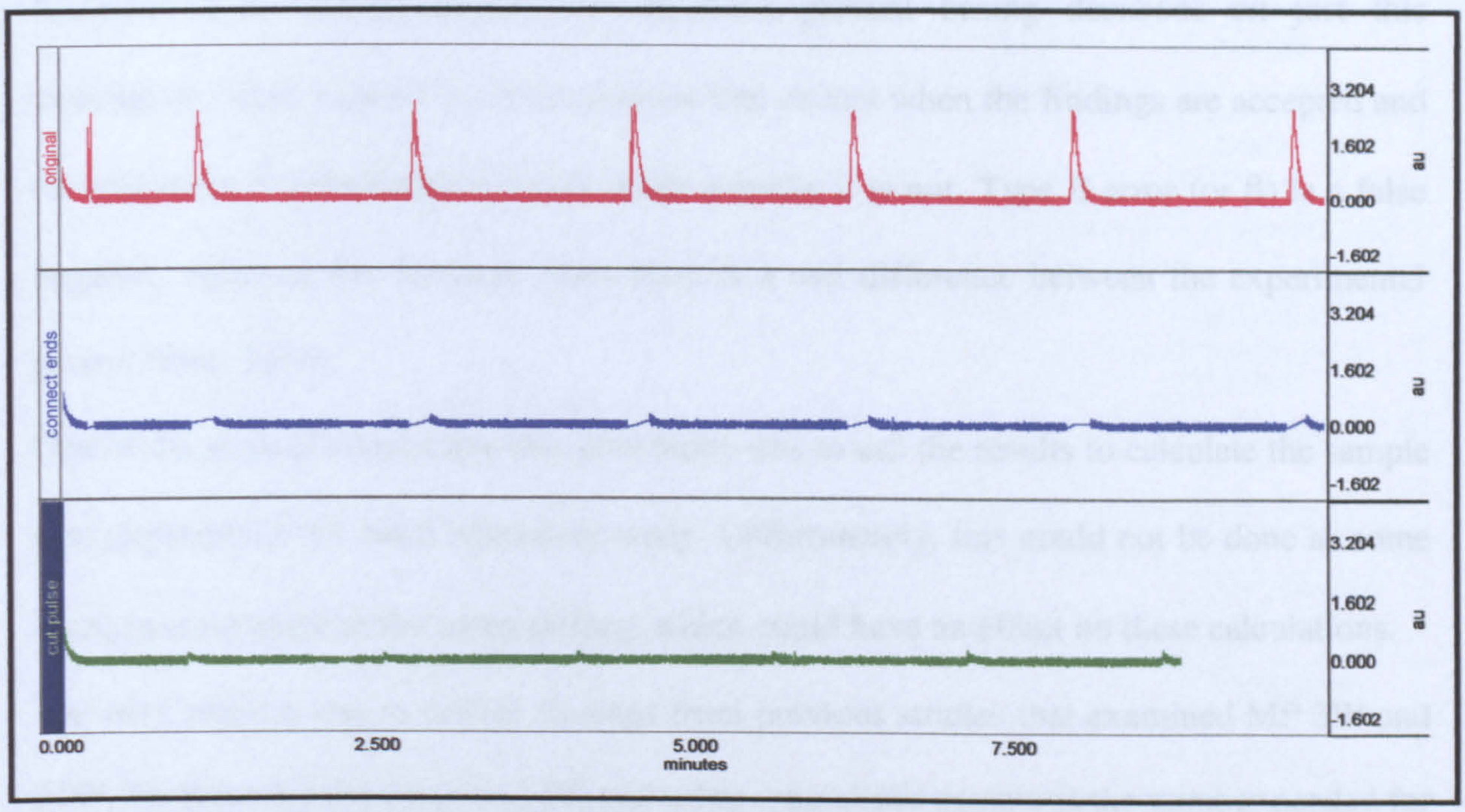

Figure (8.32) The graph shows the shape of the original signal (line 1-red), the shape of the signal after using the connect end function (line 2-blue), the shape of the signal after cutting the pulses (line 3-green)

8.26.5 Sample size

One of the essential features in conducting good trials is planning the sample size at the design stage. Power analysis and sample calculation minimises the number of patients required to answer the research question. Conducting too small a study wastes resources on a trial that may end up with inconclusive findings. Conducting too large studies on the other hand, could deny potential treatment benefits from patients randomized to placebo or a previous standard treatment (Bailey et al, 1994).

The number of the sample is usually based on several factors such as minimum expected difference between the different groups (also known as effect size or treatment size), estimated measurement variability, statistical power, significance criterion and whether a one tail or a two tail hypothesis will be used. Although the golden rule is that the larger the sample size the less chance there will be in reporting type I or type II errors. (Eng, 2003;

Karlsson et al, 2003), ethical considerations prevent basing decisions on just this assumption. Type I (or α) is a false positive that occurs when the findings are accepted and the treatment is considered effective when actually it is not. Type II error (or β) is a false negative, rejecting the findings when there is a real difference between the experimental groups (Eng, 2003).

One of the aims of conducting this pilot study was to use the results to calculate the sample size required for the main laboratory study. Unfortunately, this could not be done as some changes were made to the methodology, which could have an effect on these calculations.

The next attempt was to collate findings from previous studies that examined MP 3W and 24W. By knowing the mean and SD and using specialised equations the number needed for the current study can be determined (as discussed with the department statistician).

Regrettably, these efforts were unproductive, as the published studies did not report enough statistical information, and none has considered sample size calculation. Moreover, only one study was done using 3.25 W but because it was an abstract from a conference and insufficient data could be obtained from it (personal communication with the institute that conducted this study revealed that it was an undergraduate student project).

Table (8.10) summarises the studies from the literature in terms of quality and the amount of information reported.

Study Author & Year	Topic	Sample size	Mean power of PSWT	Mean and SD of variance	Treatment outcome
Erdman, 1960	Blood flow	20	16	No	Indirect irradiation ↑ peripheral blood flow
Abramson et al, 1966	Motor nerve conduction	42	No	Mean but not SD	↑ Conduction speed
Morrissey, 1966	Blood flow	26	40	Yes	Blood flow ↑ after direct muscle irradiation
Wessman & Kottke, 1967	Blood flow, temperature, pulse	10	No	No	↑ Blood flow
Currier and Nelson, 1968	Motor nerve conduction	10	No	Yes	↑ Conduction speed
Oosterveld et al, 1992	Core & intra-articular temperature	42	180 W	Yes	PSWT ↑ both skin & intra-articular temp
Draper et al, 1999	Muscle temperature	20	48	Yes	↑intra-muscular temperature
Garrett et al, 2000	Muscle temperature	16	48	Yes	PSWT heats large areas better than US
♦Burden and Mitchell, 2000	Blood flow	19	3.25	No	↑ blood flow

Table (8.10) The quality of the studies conducted on PSWT

♦Abstract from conference proceedings

Therefore, it was decided to use retrospective power analysis (Eng, 2003; Karlsson et al, 2003) where the data from the laboratory study are used to calculate the number of subjects needed.

8.27 CONCLUSION

This chapter has presented the laboratory work that identified the confounding factors, which may interfere adversely with the course of the succeeding experiments. The work has shown that although the temperature probes were fast response they took up to 10 minutes to acclimatise to subject's body temperature after being removed during PSWT application, and this was observed with the majority of subjects. To overcome that and to allow temperature probes to maintain body temperature it was decided not to leave them exposed to environmental temperature during PSWT

irradiation but instead to attach them to the subject's ankle. Stabilisation of the electrodes was not a reliability issue with NCV electrodes.

Another important issue that has emerged from the pilot experiment was that it takes around 3-4 minutes to re-attach NCV electrodes to the subject's knee after being removed for PSWT application. To reduce this time the electrodes will be left attached on the non-treated side and only be removed from the treated side. This has reduced the lost time to less than a minute.

Furthermore, the findings have shown that it was difficult to eliminate the effect of EIB on the recorded signal, however, it was possible to quantify its effects by adopting a function in the software that still allowed for comparison of the area under the curve in all the experimental conditions. Although the use of this function led to the loss of around 3 minutes from the recording in the high dose it was the closest representations to the changes that could be seen during PSWT application. However, given that very limited number of studies examined the effects of PSWT during irradiation, the current work remains to be of great importance even with this confounding variables.

The fact that with all the studies conducted on the physiological effects of PSWT, it was not possible to use them to calculate a sample size highlights the importance of improving the quality of the trials conducted and increasing the amount of information reported for the reports to be of value.

The next phase of this research will examine the physiological effects of PSWT on healthy subjects using the improved protocol developed in the current pilot work.

CHAPTER 9

THE PHYSIOLOGICAL EFFECTS OF PSWT ON HEALTHY SUBJECTS

9.0 INTRODUCTION

Recent surveys in UK have shown that PSWT is one of the most commonly used electrotherapy modalities among physiotherapists (Shields, 2003, Kitchen and Partridge, 1996; Pope et al, 1995). The literature review (Chapter 4) has demonstrated that the evidence supporting PSWT use in different pathological conditions is lacking, nevertheless PSWT has been accepted clinically to be useful in conditions such as soft tissue injuries (traumatic, operative), arthropathies (RA, OA), nerve regeneration and pain reduction.

It is thought that PSWT works by increasing blood flow, decreasing joint pain and stiffness, reducing inflammation, accelerating wound healing and aiding the faster resolution of oedema (Kloth and Ziskin, 1996). These effects have only been examined in a limited number of studies most of which are of low methodological quality. The PSWT mechanism of action has stirred long debates with some arguing that temperature change is the main factor responsible for all the reactions observed, and that PSWT achieves its physiological actions through heating the tissues and increasing the blood supply to the heated area (Lehmann and DeLateur, 1990; Ward, 1980). On the other hand, there were those who expounded the non-thermal effects of PSWT through restoration of cells' membrane potentials, an interaction that is believed to occur at both molecular and ionic levels (Cleary, 1996; Adey, 1988; Hayne, 1984).

With the mechanism of action being an area of dispute, many trials have focused on PSWT effectiveness and its possible physiological effects. The downfall with the majority of these trials was that they focused on the maximum output of PSWT machines and neglected other ranges. Maximum output is associated with a definite increase in SkT (Garrett et al, 2000, Murray and Kitchen, 2000; Bricknell and Watson, 1995), and an output that is rarely used in clinics (based on researcher's own

investigations (Chapter 5) and communication with therapists). Moreover, physiotherapists prefer to use the minimum level of energy possible to achieve the desired physiological responses, as it is associated with minimal side effects (Low and Reed, 2000). Given the above, it is unlikely that therapists will be employing the maximum setting of PSWT in the clinics. Though these studies are informative, they are of limited value to physiotherapists in informing their clinical decisions. The limited trials on the non-thermal mode warrant further research.

With the current status of the literature, PSWT effects on BVol and SkT remain inconclusive, and the area of PSWT effects on peripheral nerves remains under researched, all of this necessitates the conduction of further investigations.

Given this, the current study was set to examine the effects of low dose and high dose PSWT on BVol, SkT and nerve conduction in treated and non-treated limbs. One of the objectives of this trial was to investigate both the thermal and the non-thermal effects produced by PSWT via a single blinded trial on healthy subjects. Using a high dose (MP 24W) and a low dose (MP 3W), the physiological effects were compared to a placebo dose (0.05W) and a control group.

9.1 STUDY HYPOTHESIS

Ho_1: Irradiating the knee for 10 minutes with MP of 24 W will not result in a change in BVol, SkT and NCV in the treated side.

Ho_2: Irradiating the knee for 10 minutes with MP of 3 W will not result in a change in BVol, SkT and NCV in the treated area.

Ho_3: Irradiating the knee for 10 minutes with MP of 24 W will not result in a change in BVol, SkT and NCV in the non-treated area.

Ho_4: Irradiating the knee for 10 minutes with MP of 3 W will not result in a change in BVol, SkT and NCV in the non-treated area.

Ho_5: Irradiating the knee for 10 minutes with MP of 24 W will not result in a change in CorT and PulsR.

Ho_6: Irradiating the knee for 10 minutes with MP 3 W will not result in a change in CorT and PulsR.

9.2 METHODOLOGY

9.2.1 Sample recruitment and allocation to experimental groups

The study design was approved by the ethical committee of Radiography and Physiotherapy in University of Hertfordshire (Appendix E.1). Thirty one healthy subjects were employed in a within subjects design as such each subject acted as its own control. The sample had 7 males and 24 females recruited from University of Hertfordshire students and staff.

Subjects were assigned randomly to experimental groups. The randomisation was accomplished using Table (9.1) and following the same procedure in the pilot for collecting the data (Section 8.25).

Session 1	Session 2	Session 3	Session 4
1	2	3	4
1	2	4	3
1	3	2	4
1	3	4	2
1	4	2	3
1	4	3	2
2	1	3	4
2	1	4	3
2	3	4	1
2	3	1	4
2	4	1	3
2	4	3	1
3	1	2	4
3	1	4	2
3	2	1	4
3	2	4	1
3	4	1	2
3	4	2	1
4	1	2	3
4	1	3	2
4	2	1	3
4	2	3	1
4	3	1	2
4	3	2	1

Table (9.1) Sequences for randomisation, 1 (24 W), 2 (3W), 3 (placebo), 4 (control)

All 31 subjects attended for 3 sessions, which represented high, low and placebo. Those who were able to attend for a fourth session (n=14) took part in the control group. The high dose was administered using PP 150 W, MP 24W, PD 200μsec, PRR 800 Hz, for 10min. The low dose was applied on PP 150 W, MP 3W, PD 100μsec, PRR 200 Hz for 10min. The placebo PSWT was accomplished with PP 150 W, PD 20µsec, PRR 50 Hz for 10 minutes. These parameters resembled the lowest output for the Megapulse and resulted in a MP of 0.05W. The subjects in the control group were required to lie on the plinth for 10 minutes where measurements are taken and no treatment was administered. Further clarification of group distribution is explained in Figure (9.1).

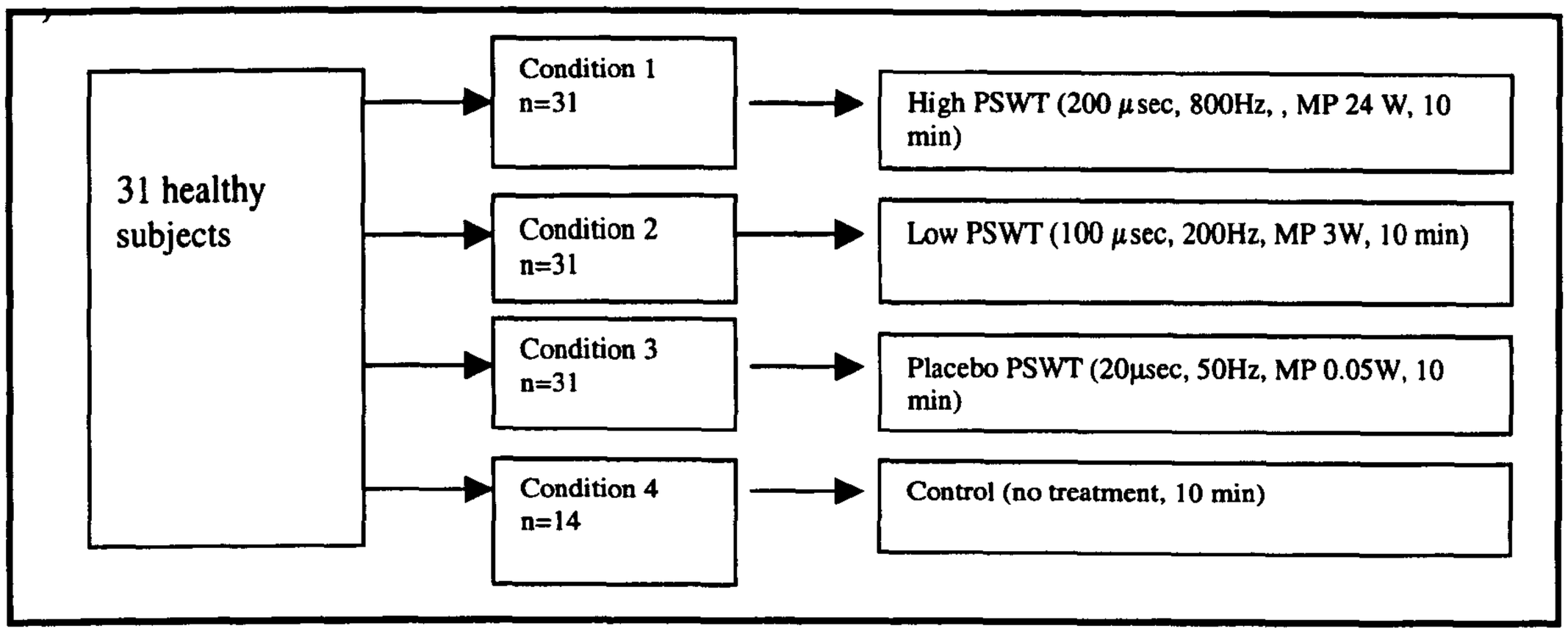

Figure (9.1) Schematic representation of the different experimental groups

Measurements to BVol, SkT and NCV, PulsR, and CorT were taken in three periods; a baseline (measurement taken before turning PSWT on for a period of 10 minutes), treatment (during the administration of PSWT for a period of 10 minutes), and recovery (post treatment for 10 minutes). At the beginning of each session subjects were asked about the nature of their activities in the last 2 hours prior to attending to the experiment (Appendix E.2) to note any activities that may affect the data collected. At the end of each session subjects were asked few questions about their thermal sensation with the treatment, and how well they could guess their treatment (Appendix E.3). Room humidity and temperature were monitored and measured before and after data collection. The protocol of treatment and the data was collected following the methodology outlined in the pilot study (Section 8.24)

9.2.2 Data analysis

All data were analysed using repeated measure analysis of variance (ANOVA), a test designed to compare group results for differences (Hicks, 1999). With every variable and before applying the ANOVA, normality and homogeneity of variance were examined. It was crucial that these two assumptions are met before considering using

ANOVA as any violation to these assumption will result in erroneous significant level and a false F value (Field, 2002).

Normality was examined using Kolmogorov-Smirnov and Shapiro-Wilk tests. These tests compare the data to a normally distributed set of scores. Non-significant results means that the data are not significantly different from the pre programmed set of data hence it can be accepted to be normally distributed. Whilst some argue that this assumption need to be met before ANOVA is used (Field, 2002), others (Bland, 1995; Winer et al, 1991) debate that parametric tests such as ANOVA can still be used and demonstrate robustness even if the data have been occasionally not following the normal distribution.

The homogeneity of the variance was examined using Manuchley's Test for Sphericity. This analysis basically tests that the variance between all variables are roughly the same (Winer et al, 1991). If this value is significant then the assumption is violated. SPSS provides corrected values for sphericity with adjustment made to the degrees of freedom. For the purpose of this analysis and the clinical trial in Chapter 10 the corrected values in Greenhouse-Geisser will be reported whenever F value needed correction.

Significant F value indicates that at least two conditions are likely to represent a real relationship and that the dependant variable varies with the levels of the factor. However, it does not determine which means are different from which other means unless the factor examined had two levels.

Within subjects contrasts were performed to examine the existence of differences in the levels of the variable. A post hoc comparison (Bonferroni) was conducted to compare all possible pairs of conditions. It was done on all statistically significant findings to

determine which experimental group was significantly different from the rest of the groups and under what conditions (Fields, 2002).

Correlation between BVol, SkT, NCV, PulsR, CorT and the anthropometric data (age, height, weight, and % of body fat) was achieved using Pearson-Product Moment Correlation Coefficient in order to examine whether there was a relationship between any of the anthropometric variables and the results (Hicks, 1999). Environmental conditions were analysed using one way ANOVA.

The factors used with ANOVA analysis were **condition**, which had 4 levels (high dose, low dose, placebo PSWT and control), **phase**, which had 3 levels (baseline, treatment, and recovery or post treatment period), and **side**, which had two levels (treated and non-treated). With each variable, a different level of each factor was analysed depending on the period when the data were collected.

9.2.3 Sample size calculation

Determining the sample size prior to conducting any experimental trial is crucial as it determines the power by which a test is able to detect a statistical difference between the experimental groups when a real difference exists (Eng, 2003). As such conducting a pilot study is crucial to determine the size of the anticipated difference between the groups (Bailey et al, 1994).

One of the aims of conducting the pilot study in part four (Section 8.24) was to decide on the size of the difference between the experimental groups. However, the changes made to improve the methodology prevented that. Therefore, it was decided to use a retrospective sample size calculation. In this type of calculation the sample is calculated based on the results obtained after a certain amount of data has been collected. Very little is mentioned in the literature on the optimal amount of data that

need to be gathered before this sort of analysis is conducted, and it seems that it is the researcher's responsibility to decide on what best suits their objectives.

In the current study after collecting 17 full sets of data, the information was used to calculate the number of subjects needed using a specialised software (www.calculators.stat.ulca.edu/powercalc)*. Based on SD, effect size, significance level $\alpha < 0.05$ and a power of 0.8, the number of subjects needed was determined (Table 9.2). Twenty six subjects were needed in the BVol group, 31 subjects were needed in SkT group and 37 subjects were needed in NCV group. The literature usually provides information on how to calculate sample size when one variable is studied, however, when more than one variable is examined like in the current study the information was scarce. It was agreed to include 31 subjects given the difficulty encountered in recruiting the subjects, time limitation and financial constraints.

Variable	α	Power of the test	Number needed
Blood volume	0.05	0.8	26
Skin temperature	0.05	0.8	31
NCV	0.05	0.8	37

Table (9.2) Findings of sample calculation (based on n=17 subjects)

9.2.4 Body fat equations

The choice of equations for calculating body density (BD) was based on the ability of the equation to accommodate large variation in age and percentage of body fat, without inflating the estimation error. Two different equations were employed for men and women because of the inherent difference in fat distribution in both genders; with men having more fat in the chest and women having most fat at the abdomen and waist (Jackson and Pollock, 1987; Jackson and Pollock, 1985). Moreover, using two

Software was developed by Barry W Brown, Department of Biomathematics, USA, Houston, based on a book by Thompson S (1992) Sampling, New York, Wely. (Chapter 4)

equations accounts for the variation in age and percentage of body fat that may be encountered in the laboratory and clinical trials.

The equations used to calculate BD (Jackson and Pollock, 1987; Jackson and Pollock 1985; Jackson et al, 1980) were:

Equation (9.1) for men BD=1.109380- 0.0008267 (X_2) + 0.0000016 (X_2)² - 0.0002574 (X_3)

(X_2 sum of triceps, chest and subscapular skinfold, X_3 age in years)

Equation (9.2) for women BD= 1.0994921-0.0009929 (X_3) + 0.0000023 (X_3)²- 0.0001392 (X_4)

(X_3=sum of triceps, abdominal and suprailium skinfold, X_4 is the age in years)

The percentage of body fat was calculated using the widely used Siri equation (1961)

Equation (9.3) % F = [(4.95/ BD) - 4.5] / 100

9.3 RESULTS

Thirty one subjects were recruited for the study. Subjects ranged in age between 19-48 years. Summary of the demographic data is presented in Table (9.3). More analysis can be found in Appendix (E.4). Raw data is presented on a floppy disk at the back of the thesis.

N=	Age (years)	Sex		Height (cm)	Weight (kg)	Fat%	Dominant side	
		Male	Female				Right	Left
31	26±7.22	7	25	167.8±8.98	70.15±12.35	23.67±7.08	27	5

Table (9.3) Demographic data of the subjects

Subjects' randomisation is presented in Table (9.4).

Session 1		Session 2		Session 3		Session 4	
Treatment	**Frequency**	**Treatment**	**Frequency**	**Treatment**	**Frequency**	**Treatment**	**Frequency**
24 W	7	**24 W**	11	**24 W**	12	**24 W**	9
3 W	11	**3 W**	10	**3 W**	5	**3 W**	7
Placebo	9	**Placebo**	7	**Placebo**	9	**Placebo**	13
Control	4	**Control**	3	**Control**	5	**Control**	2
	n =31		n =31		n =31		n =31

Table (9.4) The sequence of treatments

9.3.1 Blood volume results

A 4*3*2 (condition, time, side) repeated measure ANOVA was used to examine the main effects and interaction between factors. The experimental conditions had 4 levels (control, placebo, high dose and low dose), time had 3 levels (before, during, and after treatment) and side had 2 levels (treated and non-treated).

Running the ANOVA, it was found that the value for condition was significant for sphericity (p = 0.002), the interaction between condition/ phase (p=0.000), and condition/ phase/ side (p=0.000).

The Kolmogrov-Smirnov test for normality have shown occasional data, which are not significant however, it was not considered a threat to the outcome.

Results show that there was a significant main effect for condition ($F_{(1.860, 22.316)}$=18.949, p=0.000), a significant main effect for phase ($F_{(2,24)}$=61.428, p=0.000), a significant interactive effect between condition/ phase ($F_{(2.250, 26.998)}$=26.533, p=0.000), and a significant interactive effect between condition/phase/side ($F_{(1.902, 22.828)}$=2.448, p= 0.000). There was no main effect for side ($F_{(1,12)}$=4.287, p=0.061) and no interactive effect for condition/side ($F_{(3,36)}$=1.239, p=0.310), no interactive effect for phase/side ($F_{(2,24)}$=1.622, p=0.218).

Using contrast to compare the levels of the independent variables, there was significant effect of different levels of conditions (high/control – low/control – placebo/control). There was a significant effect between "before treatment" to "during treatment" and "during treatment" results to "after treatment", and there was a significant effect between treated and non-treated side. Findings are displayed in Table (9.5).

Source	Condition	Phase	Side	Significance	
Condition	High vs control			.000	S
	Low vs control			.000	S
	Placebo vs control			.042	S
Phase		Before vs after		.051	NS
		Before vs during		.000	S
Side			Treated vs non treated	.061	NS
Condition vs phase	High vs control	Before vs after		.009	S
		Before vs during		.000	S
	Low vs control	Before vs after		.064	NS
		Before vs during		.009	S
	Placebo vs control	Before vs after		.099	NS
		Before vs during		.006	S
Condition vs side	High vs control		Treated vs non treated	.133	NS
	Low vs control		Treated vs non treated	.110	NS
	Placebo vs control		Treated vs non treated	.530	NS
Phase vs side		Before vs after	Treated vs non treated	.682	NS
		During vs after	Treated vs non treated	.049	S
Condition vs phase vs side	High vs control	Before vs after	Treated vs non treated	.102	NS
		During vs after	Treated vs non treated	.033	S
	Low vs control	Before vs after	Treated vs non treated	.619	NS
		During vs after	Treated vs non treated	.042	S
	Placebo vs control	Before vs after	Treated vs non treated	.952	NS
		During vs after	Treated vs non treated	.227	NS

Table (9.5) Main effects and contrast analysis of BVol (significant results are highlighted in red). S: significant, NS: non significant

To examine whether the difference, was statistically significant a post hoc test (Bonferroni) was used. Results show that there was significant difference between all phases of condition except between placebo and low, and for before to during treatment and before and after treatment. Findings of post hoc test are displayed in Table (9.6).

Source	Condition	Significance	
Condition	High vs low	.001	S
	High vs placebo	.032	S
	High vs control	.000	S
	Low vs Control	.002	S
	Placebo vs Control	.253	NS
	Low vs placebo	1.000	NS
Phase	Before vs after	.153	NS
	Before vs during	0.000	S

Table (9.6) Post hoc results of BVol (significant results are highlighted in red), S: significant, NS: non significant

These results mean that there was a statistically significant increase in BVol with the high dose, low dose, and placebo condition. This extent of increase was higher with the

24W compared to low dose and placebo . There was no statistical difference between changes recoded with the low dose and the placebo dose in BVol. The non-treated side (Figure 9.3) displayed changes that mirrored the treated side (Figure 9.2) but with lesser degree.

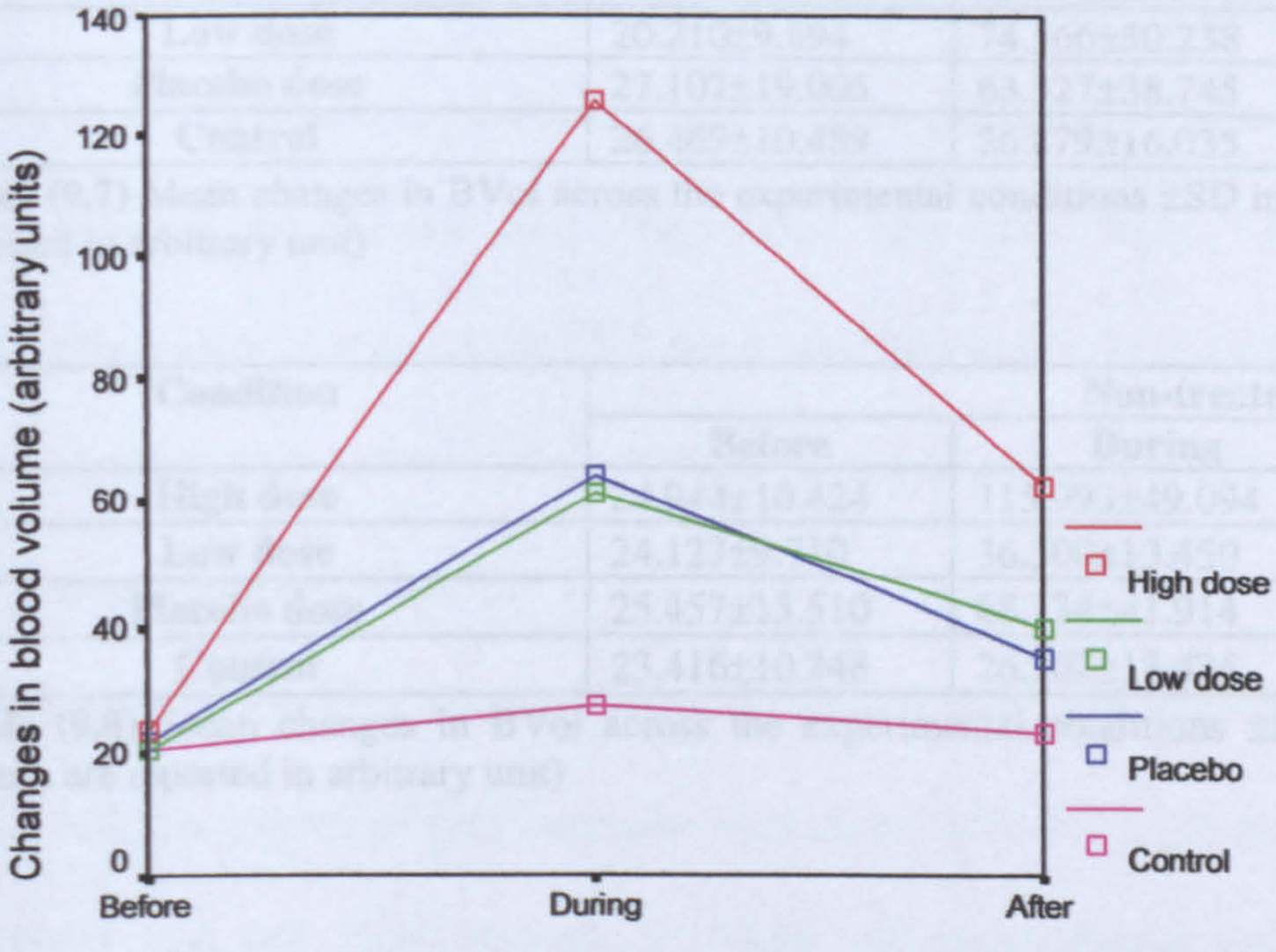

Figure (9.2) The changes in the four experimental conditions in the treated side

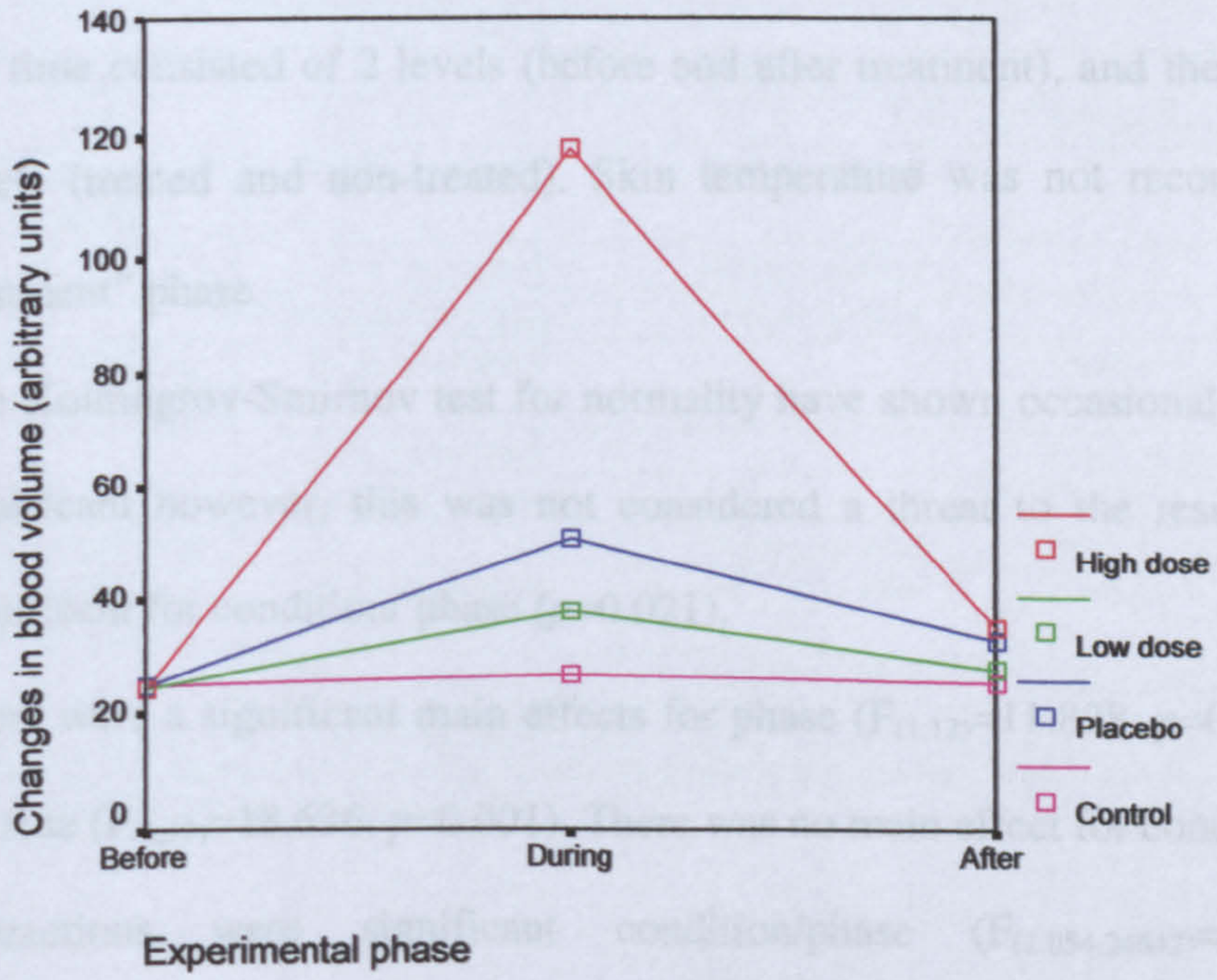

Figure (9.3) The changes in the four experimental conditions in the non-treated side

Mean changes in BVol across the four experimental conditions is presented in Table (9.7) for the treated side and in Table (9.8) for the non-treated side. More analysis can be found in Appendix (E.4).

Condition	Treated		
	Before	During	After
High dose	30.709±11.985	134.223±71.309	74.937±56.316
Low dose	20.210±9.894	74.566±50.238	38.852±24.169
Placebo dose	27.107±19.005	63.327±38.745	37.652±31.434
Control	26.469±10.489	26.879±16.035	22.965±9.176

Table (9.7) Mean changes in BVol across the experimental conditions ±SD in the treated side (values are reported in arbitrary unit)

Condition	Non-treated		
	Before	During	After
High dose	24.944±10.424	115.993±49.094	23.121±12.821
Low dose	24.127±9.710	36.300±13.450	27.954±14.142
Placebo dose	25.457±15.510	68.734±41.914	31.395±18.712
Control	23.416±10.248	26.102±13.425	24.074±16.160

Table (9.8) Mean changes in BVol across the experimental conditions ±SD in the non-treated side (values are reported in arbitrary unit)

9.3.2 Skin temperature results

A 4*2*2 (condition, time, side) repeated measure ANOVA was used to analyse SkT data. The condition consisted of 4 levels (control, placebo, high dose, and low dose), the time consisted of 2 levels (before and after treatment), and the side consisted of 2 levels (treated and non-treated). Skin temperature was not recorded in the "during treatment" phase.

The Kolmogrov-Smirnov test for normality have shown occasional data, which are not significant however, this was not considered a threat to the results. Sphericity was significant for condition/ phase (p=0.021).

There were a significant main effects for phase ($F_{(1,12)}$=11.828, p=0.005), a main effect for side ($F_{(1,12)}$=18.636, p=0.001). There was no main effect for condition (p=0.277). All interactions were significant condition/phase ($F_{(2.054,24642)}$=11.606, p=0.000),

condition/side ($F_{(3,3)}$=6.888, p=0.001), phase/side ($F_{1,12)}$= 33.959, p=0.000), condition/phase/side ($F_{(3,36)}$=21.056, p=0.000).

Contrast analysis has showed that there was a significant effect of phase between before and after treatment (p=0.005), in the side between treated/non treated (p=0.001). There was a significant interactive effect between the high dose and the control in the treated and non-treated limb (p=0.006). There was an interactive effect in the before and after treatment in the treated and non-treated side (p=0.000). There was a significant interactive effect between the high dose and the control in the before and after treatment in the treated and non-treated (p=0.000). Using post hoc (Bonferroni) none of the above difference were significant.

The results mean that although high dose, low dose and placebo conditions increased SkT and the extent of that increase was more with the high dose, the amount of that increase was not large enough to reach statistical significance. Results of contrast analysis are shown in Table (9.9). Further analysis can be found in Appendix (E.4).

Source	Condition	Phase	Side	Sig.	
Condition	High vs control			.846	NS
	Low vs control			.416	NS
	Placebo vs control			.096	NS
Phase		Before vs after		.005	S
Side			Treated vs non treated	.001	S
Condition vs phase	High vs control	Before vs after		.002	S
	Low vs control	Before vs after		.220	NS
	Placebo vs control	Before vs after		.587	NS
Condition vs side	High vs control		Treated vs non treated	.006	S
	Low vs control		Treated vs non treated	.282	NS
	Placebo vs control		Treated vs non treated	.750	NS
Phase vs side		Before vs after	Treated vs non treated	.000	S
Condition vs phase vs side	High vs control	Before vs after	Treated vs non treated	.000	S
	Low vs control	Before vs after	Treated vs non treated	.067	NS
	Placebo vs control	Before vs after	Treated vs non treated	.356	NS

Table (9.9) Contrast analysis of main effects and interactions (significant results are highlighted in red)
S: significant, NS: non-significance

Mean changes in SkT across the four experimental conditions are displayed in Table (9.10). Changes in SkT in the treated side and non treated side are shown in Figure (9.4).

		SkT before treatment (°C)	SkT after treatment (°C)
High Dose	**Treated**	26.758±1.372	28.710±1.143
	Non treated	27.155±1.365	27.601±.990
Low dose	**Treated**	27.495±1.233	27.830±1.176
	Non treated	28.135±1.366	28.009±1.134
Placebo	**Treated**	27.647±1.236	27.626±1.310
	Non treated	28.448±1.233	28.498±1.257
Control	**Treated**	26.883±1.158	26.994±1.486
	Non treated	27.527±1.467	27.750±1.585

Table (9.10) Summary of mean changes in SkT across the experimental conditions ±SD

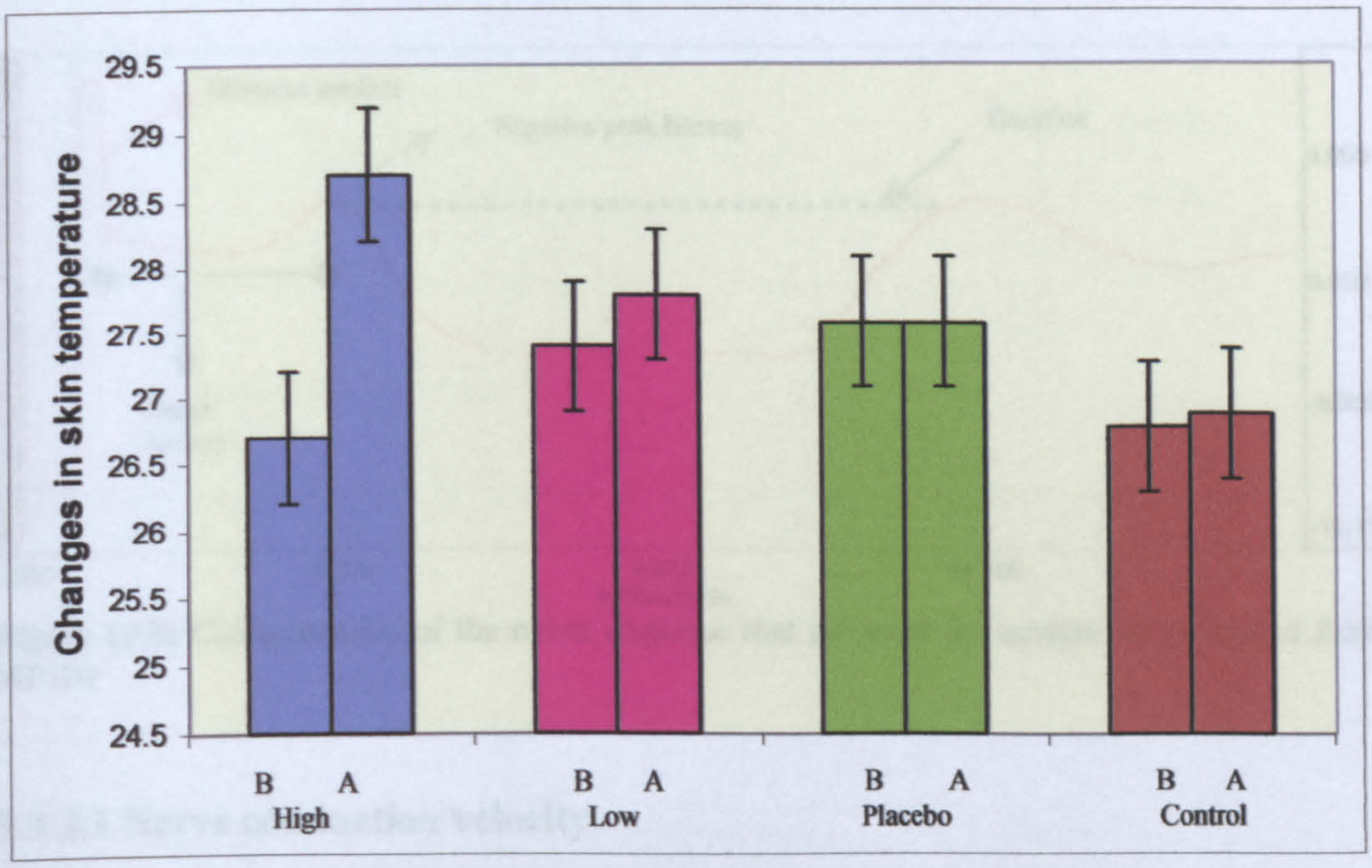

Figure (9.4) Changes in SkT in the treated side before and after treatment across the experimental conditions, B: before treatment, A: after treatment

9.3.3 Nerve stimulation results

A 4*2*2 (condition, phase, side) repeated measure ANOVA was used to analyse the data collected from the peroneal nerve. Condition had 4 levels (control, placebo, high dose and low dose), phase had 2 levels (before and after treatment), and side had 2 levels (treated and non-treated).

The data collected on the nerve stimulation was analysed using the onset latency (measured from the end of the stimulus to the negative peak), duration of the response was measured from the negative peak to the next negative peak (Figure 9.5) and the NCV was calculated by dividing the distance by the onset latency. Distance was measured as the length between the centres of the recording and the stimulating electrodes using a tape measure (Oh, 1996; Delisa, 1994; Dong and Liveson, 1983, personal communication with the manufacturer).

Duration of the response will also be reported as it reflects the number and the synchrony of the fibres contributing to the response (Dong and Liveson, 1983).

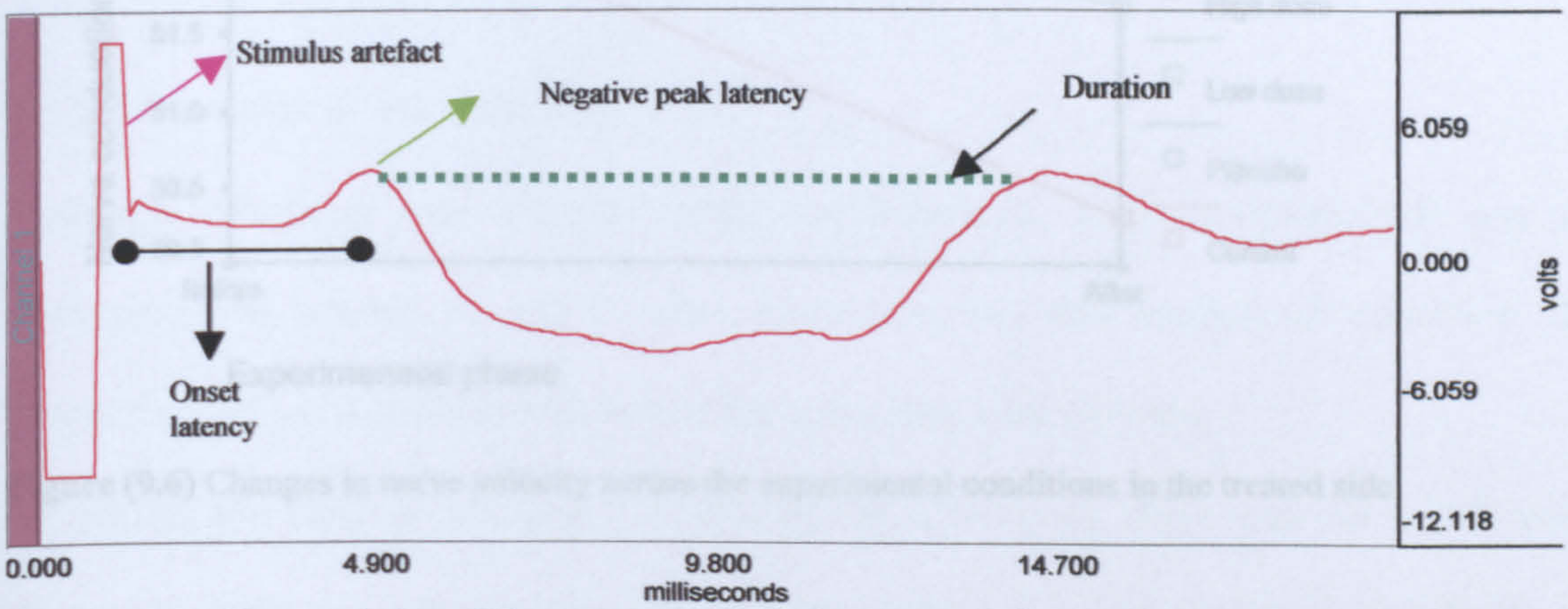

Figure (9.5) Characteristics of the nerve response that are used for analysis as measured from Biopac MP100

9.3.3.1 Nerve conduction velocity

Sphericity was not assumed with the interaction between condition/phase, and the interaction between condition/phase/side. The Kolmogrov-Smirnov test for normality has shown occasional data, which are not normally distributed.

There was no main effect of condition ($F_{(3,36)}$=0.612, p=0.612), no main effect of side ($F_{(1,12)}$=0.076, p=0.787), but a main effect of phase ($F_{(1,12)}$=10.561, p=0.007). The majority of the interactions were non significant, condition/phase ($F_{(1.437,17.246)}$=4.674, p=0.033), condition /side ($F_{(3,36)}$ = 0.172, p=0.915), phase/side ($F_{(1,12)}$=1.176, p=0.299),

condition/phase/side ($F_{(3,36)}$= 0.749, p=0.530). Using contrast analysis there was no significant differences between condition levels: high/control (p=0.097), low/control (p=0.322), placebo/control (p=0.401). More analysis can be found in Appendix (E.4).

The changes in NCV across the four experimental conditions is shown in Figure (9.6)

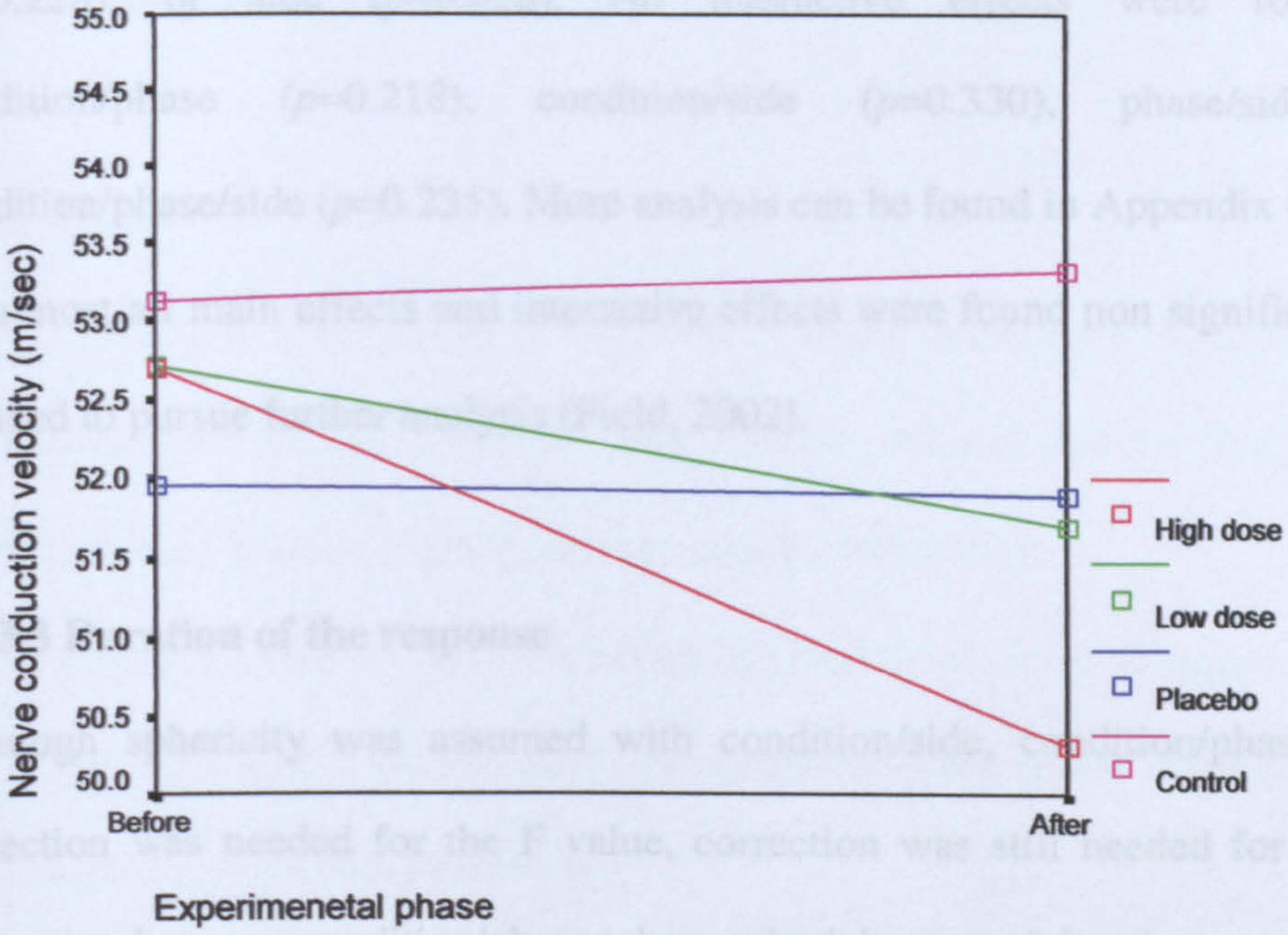

Figure (9.6) Changes in nerve velocity across the experimental conditions in the treated side

The mean change in NCV across the experimental conditions is presented in Table (9.11).

		NCV before (m/sec)	NCV after (m/sec)
High Dose	**Treated**	51.828±2.838	49.278±3.135
	Non treated	51.668±2.859	50.581±3.407
Low dose	**Treated**	52.076±2.949	51.309±2.891
	Non treated	51.893±2.938	51.770±3.226
Placebo	**Treated**	51.755±3.161	52.317±3.695
	Non treated	51.666±2.963	51.738±2.974
Control	**Treated**	52.813±3.434	52.893±3.857
	Non treated	52.724±3.780	52.617±3.759

Table (9.11) Mean changes in NCV across the experimental conditions ± SD in the treated and non-treated side

Results show that there was a decrease in NCV in the treated side. Low dose and placebo condition displayed a very small change in NCV, which were not significant.

9.3.3.2 Nerve onset latency

Sphericity was significant for condition (p=0.048), the interaction between condition/phase (p=0.000), condition/side (p=0.001), and condition/phase/side (p=0.000). There was a main effect of phase (p=0.035), no main effects of condition (p=0.228), or side (p=0.428). No interactive effects were found between condition/phase (p=0.218), condition/side (p=0.330), phase/side (p=0.189) condition/phase/side (p=0.235). More analysis can be found in Appendix (E.4).

As almost all main effects and interactive effects were found non significant, there was no need to pursue further analysis (Field, 2002).

9.3.3.3 Duration of the response

Although sphericity was assumed with condition/side, condition/phase/side and no correction was needed for the F value, correction was still needed for condition, the interaction between condition/phase where sphericity was violated.

Examining the main effects and interactions for differences, there was not a difference in duration between all experimental conditions ($F_{(1.877,\ 22.522)}$=2.124, p=0.114). Phase was significant ($F_{(1,12)}$=9.515, p=0.009), this significance was between high and control in the before and after treatment (p=0.029). Side was not significant ($F_{(1,12)}$=0.244, p=0.630). The following interactions were significant: condition /phase ($F_{(1.571,\ 18.853)}$= 3.795, p = 0.018), phase/side ($F_{(1,12)}$=15.003, p =0.002). The interaction between duration/side and duration/phase/side were not significant (p=0.072, p=0.302 respectively).

Post hoc tests revealed that none of the above relationships reached statistical significance. More analysis can be found in Appendix (E.4).

These findings reveal that although the treatment conditions did not alter the outcome when viewed separately, when examined in relation to the results of before and after treatment or the treated and the non-treated side the results show significance. Although the duration of the response has changed with the treatment, none of the doses applied seemed to have profound effect on the outcome.

9.3.4 Pulse rate results

A 4*3 (condition, time) two way ANOVA was used to examine the difference between the experimental groups. Condition had 4 levels (control, placebo, high dose and low dose); time had 3 levels (before, during and after treatment).

Using ANOVA, there was no main effect detected in condition ($F_{(3,36)}$=1.214, p=0.318), or in phase ($F_{(2,24)}$=0.217, p=0.807). Interaction between phase and condition was not significant ($F_{(6,72)}$=1.603, p=0.159).

The mean change in PulsR values ± SD across the four experimental conditions is displayed in Table (9.12). More analysis can be found in Appendix (E.4).

Condition	PulsR before treatment (bpm)	PulsR during treatment (bpm)	PulsR after treatment (bpm)
High Dose	69.216±11.699	68.900±11.429	68.940±10.75
Low dose	68.372±13.937	69.203±13.426	69.226±13.201
Placebo	68.230±13.696	68.193±14.086	69.183±14.204
Control	73.187±9.644	72.557±9.569	71.757±9.414

Table (9.12) Mean changes in PulsR across the experimental conditions ± SD. bpm: beat per minute

The findings above demonstrate that the different experimental conditions did not have an effect on the PulsR.

9.3.5 Core temperature results

A 4*3 (condition, time) two ways ANOVA was used to examine the difference between the experimental groups. Condition had 4 levels (control, placebo, high dose and low dose), time had 3 levels (before, during and after treatment).

The sphericity assumption was met for the phase (p =0.414), condition (p= .351) and the interaction between condition/ phase (p = 0.333), and hence the no correction to F is needed.

There was a main effect of condition ($F_{(3,36)}$=3.928, p=0.016) which was significant with the high dose (p=0.045). There was a main effect in phase ($F_{(2,24)}$= 6.015, p=0.008) which was significant with before and after treatment (p=0.024). There was no interaction effect between condition and phase ($F_{(6,72)}$=0.1.209, p=0.311).

Results show that the high dose has led to increase in CorT when compared to other conditions.

The mean change in CorT before, during and after treatment is summarised in Table (9.13). More analysis can be found in Appendix (E.4).

Condition	CorT before treatment (°C)	CorT during treatment (°C)	CorT after treatment (°C)
High Dose	34.763±0.514	34.761±0.396	34.795±0.433
Low dose	34.810±0.346	34.918±0.294	35.002±0.386
Placebo	34.862±0.336	34.951±0.354	34.948±0.338
Control	34.830±0.433	34.975±0.423	34.925±0.399

Table (9.13) Mean changes in CorT across the experimental conditions ± SD

9.3.6 Ambient temperature

Using repeated measure ANOVA sphericity was only violated for condition. There was a main effect of condition ($F_{(2.471,29.66)}$=3.369, p=0.029), and a main effect on phase ($F_{(1,12)}$=6.943, p=0.022). The difference was not statistically significant when the post hoc test for all the levels of the condition were examined and compared.

This means that there was a change in room temperature before and after the data collection, however, this did not alter the outcome obtained with various variables examined during the experimental conditions as confirmed by the post hoc test. More analysis can be found in Appendix (E.4).

The mean change in room temperature before and after the experiment in the four experimental conditions is presented in Table (9.14).

Condition	Room temperature before (°C)	Room temperature after (°C)
High Dose	23.933±1.257	24.133±1.166
Low dose	24.166±0.949	24.200±0.924
Placebo	24.066±1.172	24.200±1.156
Control	24.000±0.784	24.000±0.784

Table (9.14) Mean changes in room temperature across the experimental condition ± SD

9.3.7 Ambient humidity

Sphericity was met with all the factors. There was no main effect of condition ($F_{(3,36)}$=2.119, p=0.115), no main effect of phase ($F_{(1,12)}$=0.000, p=1), no interactive effect between condition/ phase ($F_{(3,36)}$=2.215, p=0.103).

This means that there was no significant change in room humidity that could have affected the outcomes of the various variables examined.

The mean change in room humidity before and after the experiment in the four experimental conditions is presented in Table (9.15). More analysis can be found in Appendix (E.4).

Condition	Room humidity before (%)	Room humidity after (%)
High Dose	31.200±2.455	31.433±2.192
Low dose	29.666±3.994	29.400±3.926
Placebo	30.300±3.611	30.233±3.682
Control	32.785±1.188	32.642±1.336

Table (9.15) Mean changes in room humidity across the experimental condition ± SD

To summarise all the above, there was a significant change in BVol with the high dose (24W) and low dose (3W) in the during and post treatment periods when the results were compared to the control group. This difference was statistically significant between baseline readings and "during treatment" readings but not between the baseline and recovery "post treatment" period. Although the placebo group displayed a change in BVol in the during treatment period, this change did not reach a statistical significance.

There was a measured increase in SkT with high dose of 24W (mean increase 1.9±1.119°C), low dose (0.335±0.668 °C) and no change with placebo dose (-0.020±0.438°C). The change recorded with the high dose and low dose did not reach statistical significance.

There was a measured reduction in NCV with high dose (-2.550±2.014 m/sec), low dose (-1.433±3.769 m/sec), and placebo (0.562±2.451 m/sec). This change did not reach a statistical significance.

Both PulsR and CorT did not change significantly in response to the interventions. Although it was difficult to control the temperature in the laboratory, the change in room temperature and humidity between before and after treatment did not have an effect on the outcome.

9.3.8 Correlation between anthropometric data and experimental conditions

Using Pearson-Product Moment Correlation Coefficient, there was a correlation at $p<0.05$ between PulsR and age, BVol and height. There was a correlation between PulsR and fat % at $p<0.01$. Summary of the results can be found in Table (9.16).

	BVol	SkT	NCV	Pulse rate	CorT
Age	NS	NS	NS	S (p<0.05)	NS
Height	S (p<0.05)	NS	NS	NS	NS
Weight	NS	NS	NS	NS	NS
Fat %	NS	NS	NS	S (p<0.01)	NS

Table (9.16) Summary of correlations between anthropometric data and the primary variables recorded during the experiment (significant results are highlighted in red). S; significant, NS: non-significant

9.3.9 Results of the blinding questionnaire

All the subjects in the trial were asked a few questions at the end of each session to judge the effectiveness of the blinding used in the study. Subjects were asked whether they thought that the PSWT machine was on or off. Fifteen subjects in the high dose have given correct answers, and they justify their answer with the heat they felt under the treatment head. The number of subjects decreased to 8 with the low dose and to 2 subjects in placebo; however, when subjects were asked, "*how sure were they that the PSWT machine was on*?" except for the high dose when subjects reported thermal sensation, the answers were only a guess (Table 9.17).

	High dose	Low dose	Placebo
Yes	15	8	2
No	5	8	12
Not sure	10	13	16
Did not attend	1	2	1

Table (9.17) Description of the answers to the question: "*Do you think that PSWT machine was working during the session?*"

When subjects were asked whether they thought that the session was a treatment or not, 14 in the high dose group, 7 in the low dose group, 1 in the placebo, and 5 in the control were able to guess correctly. The same as with the previous question the answers were guesses except for the high dose when thermal sensation was reported (Table 9.18).

	High dose	Low dose	Placebo
Correct answer	14	7	1
Wrong answer	16	22	29
Did not attend	1	2	1

Table (9.18) Description of the answers to the question: "*Do you think your session was a treatment, placebo or a control session*?

Subjects were also asked about the thermal sensation under the treatment head, 11 have felt heat with high dose, 1 subject has felt heat with low dose, and none have felt anything with the placebo dose (Table 9.19).

	High dose	Low dose	Placebo
Yes	11	1	-
No	17	27	27
Not sure	2	1	3
Did not attend	1	2	1

Table (9.19) Description of the answers to the question: "*Did you feel any heat under the treatment head?*"

9.4 DISCUSSION

The effects of PSWT on SkT and BVol have been studied before, however, the majority of the studies have focused on the maximum dose with MP of 48W. Moreover, although there were other studies that examined lower PSWT outputs, the limited reporting of substantial information needed for judging the quality of the studies and the absence of reporting of full treatment parameters, the diverse methodologies, and the arbitrary choice of dosage limit their clinical value. No published reports have been found that employed MP of 3W or 24 W to be used for comparison with the current study.

The study employed 5 dependent and 2 independent variables. The dependent variables were the change in SkT, change in BVol and change in NCV, PulsR, and CorT. The independent variables were the treatment dose and the side (treated or non-treated knee).

9.4.1 Blood volume

It is argued that PSWT serves no physiological action other than heating the tissues and increasing the blood supply through the treated area (Wilson, 1974). This

study has provided evidence that there could be an increase in the circulating blood even with very minimal increase in SkT as was seen with the 3W and the placebo dose, which could possibly be attributed to the athermal effects.

Though PSWT at 3W did not elicit a significant increase in BVol post treatment, it did produce a considerable rise in BVol during the treatment. The increased recording of PPG output provides an estimate of the change in BVol in the treated area. This increase in the recorded signal could be explained by the joint result of the increase in haematocrit, and the expansion of intravascular volume (Jespersen and Pedersen, 1986) as a result of a decrease in arterial system compliance (Babchenko et al, 2001). Moreover, given that the change in BVol in the vessels corresponds to the change in vessel diameter (Lindberg, 1991) it is expected that the increase in BVol noticed in both treatment conditions (high, low) is associated with vasodilatation.

Morrissey (1966) reported that there was no statistical change in peripheral blood flow after irradiating the calf with PSWT at MP of 40W for a period of 15 minutes. The findings of the current study challenge this, and demonstrate that there was a significant increase in BVol with 24W, 3W and with placebo condition during treatment. This difference was not significant for the increase in BVol for post treatment period. Although the current study employed lower MP, the increase in BVol could be attributed to the difference in methodology and sensitivity of the measuring device employed.

There was a 2.5 fold measured increase in BVol with 24W, these findings carry clinical implications. In cases where swelling or haematoma are present, this dose should not be used as it may exacerbate the symptoms by dilating blood vessels and increasing the amount of interstitial fluid.

Lack of statistical significance between the outcome of 3W and placebo conditions means that energies as low as 3W could be no better than placebo as the amount of energy is very small to achieve therapeutic results. However, it is of interest to mention that no published work has identified whether findings from trials conducted on healthy subjects are transferable to patient population.

9.4.2 Skin temperature

It has been argued that pulsing the output of PSWT could eliminate the thermal effects associated with its application. Bricknell and Watson (1995) have demonstrated a definite heat perception that was felt after 7minutes of exposure with MP of 10.8W. Murray and Kitchen (2000) have shown that definite thermal sensation can be experienced if the MP was 21.19 ± 8.27W. The distance between the treatment head and the treated area was 4 mm in Bricknell and Watson, but it was not mentioned in the Murray and Kitcken study.

The current study has examined the effect of MP 3W and MP 24 on SkT. Findings demonstrated that there was a mean increase of 1.9±1.119°C in SkT post high dose and a mean increase of 0.335±0.688°C with the low dose. The number of subjects however, who reported a thermal sensation was 11 (42.3%) with the high dose and 1 subject (0.3%) with the low dose. This difference in findings could be attributed to several reasons. The distance between the treatment head and the treatment area (Lehmann et al, 1969) which could either increase or decrease the amount of circulating air underneath the treatment head and as such change the perception of thermal sensation. Another factor could be the dose employed which was the maximum setting of the PSWT with Bricknell and Watson. A third factor could be the difference in the equipment employed (Diapulse in Murray and Kitchen and Curapuls in Bricknell and

Watson) in comparison to Megapulse. Each of these machines has a different PP (975W with Diapulse, 200W with Curapuls 403 and 150W with Megapulse Senior). Previous pilot work by the author has showed that different PSWT machines do not behave the same (Section 8.15-8.20). Moreover, it could be added that the thermal sensation reported in the above studies have shown different results probably because different body parts have different temperature sensitivity to heat and this could be affected by the difference in somatosensory representation or the difference in vascularisation in different body parts (Odia and Aligogun, 1988), hence the time needed to feel the heat on the front of the thigh could be different from the front the knee. The implication of these findings is that the skin is not always a reliable source for detecting changes in thermal build up.

In dispute with the literature that have shown a definite thermal sensation with MP as low as 10.8W, Morrissey (1966) has demonstrated that with an MP of 40W, there was no statistical significant increase in SkT. The findings of the current study have also shown statistical non-significant increase in SkT with 24W, despite the measured temperature increase that reached 2°C. However, this increase although not statistically significant could have detrimental effects on treatment outcome with conditions such as RA or OA or soft tissue inflammation, where slight increase in temperature may exacerbate the symptoms (Hosie and Dickson, 2000).

Temperature increase in the current study was around 2°C for the high dose and below 1°C with both the low dose and the placebo application. This increase in temperature was found to go back to baseline or slightly above baseline after termination of PSWT only when the MP was 3W or 0.05W in placebo. These findings are in agreement with Tenforde (1996) who stated that with athermal exposure or when the increase in tissue temperature does not exceed 1°C, the effects were found to be

reversible upon termination of the exposure. These findings imply that if the thermal effect was the aim of the treatment the dose needs to either be increased or the time of exposure needs to be increased to allow the delivery of higher outputs of energy to the tissues.

The increase in temperature associated with PSWT use is expected to increase metabolism and speed up chemical reactions (Ward, 1980). It is expected that for each 1°C increase in tissue temperature, there could be 13% increase in the rate of metabolic reaction (Kitchen, 2002). Research has shown that the intramuscular temperature needs to increase to at least 39°C and some say to 41°C in order to gain therapeutic effects (Noonan et al, 1993). The application of 24W was associated with 1.9±1.119°C increase in SkT as such could be expected to increase metabolism and speed up chemical reactions, consequently be of therapeutic value.

Findings with the high dose have shown an increase in SkT of around 2°C above baseline reading. Although intramuscular temperature was not measured, it is expected that with energy delivered at MP 24W and irradiation time of 10 minutes therapeutic effects may be obtained. Lehmann et al (1983) have demonstrated on human tissue substitute substances that the SAR ratio of muscle to fat heating with inductive electrodes could reach up to 2.67 times higher. This could mean that the deep tissue temperature may have increased to a possible 4°C degree. In an efficient circulatory system it is expected that no build up of heat will develop due to the dissipation of heat by the circulating blood. These findings are of major concern in cases with incompetent thermoregulatory system where areas of hot spots may develop. Although the authors did not use a Megapulse machine with the eight units examined they were able to demonstrate that this ratio could vary between equipments. As such

no definite conclusion can be drawn unless such findings were validated with Megapulse.

Findings also suggest that the increase in SkT could be measured when the subject does not report thermal sensation. These results may have safety issues signifying that the skin is not always a reliable source for judging the thermal component of the treatment. Further work is warranted in this area to examine this supposition.

9.4.3 Nerve conduction velocity

Unlike other electrotherapy modalities, NCV have been examined in modalities such as laser, transcutaneous electrical nerve stimulation and IFC (Cramp et al, 2000a; Cramp et al, 2000b; Walsh et al, 2000), PSWT on the other hand has received almost no attention. A limited number of studies that are outdated have examined the effect of PSWT on NCV (Currier and Nelson 1969; Abramson et al, 1966). It is a commonly accepted belief that increasing tissue temperature increases NCV and a decrease in tissue temperature decreases NCV (Rutkove, 2001; Delisa, 1994). Contrary to what was expected, a slowing of nerve velocity was recorded in the current study. PSWT does not have the ability to stimulate sensory or motor nerves, because pulses need to be at least 0.1 ms long to have excitatory effect on muscle or nerve. The usual pulse time with PSWT is around 1 over 50^{th} of a μs as such the time of pulse is too short to stimulate nerves (Low and Reed, 2000).

The results obtained in this experiment could be explained by the change in temperature around the measured nerve. In the majority of NCV studies, the segment of the nerve studied is usually under the direct application of cold or heat. In the current study, while the front of the knee was irradiated with PSWT, the common peroneal

nerve was stimulated from the posterior aspect of the knee. This site was chosen for stimulation as the nerve was most superficial at this point. With the increase in SkT at the front of the knee, there might have been redistribution of BVol as a result of the vasodilatation occurring anteriorily and vasoconstriction occurring elsewhere (Marieb, 2002). This could have decreased the temperature of the tissues around the nerve and might have resulted in a decrease in NCV. Unfortunately as no measurement to SkT or BVol was undertaken at that area no firm conclusion could be drawn. A possible method of avoiding this for future studies would be by studying NCV in the femoral nerve as this nerve supplies the quadriceps, which is a muscle in the direct area of the treatment or possibly measuring from a different body part.

Additionally as the near nerve temperature adjusts slowly to changes in temperature when the source is applied externally (Halar et al, 1980), it could be speculated that the treatment time applied may have not been long enough to cause warming of the area around the nerve. This mechanism could be responsible for pain reduction experienced by patients as stimulation to the afferent nerve fibres (being mediated by the morphine receptors in the brain) makes them work as a counter irritant, closing the gate control (Low and Reed, 2000). Though no direct conclusions could be drawn with regard to the effects of increase in SkT on the change of temperature around the nerve, pervious work has demonstrated that the near nerve temperature could differ by 1.7°C in response to changes in SkT (De Jesus et al, 1973; Behse and Buchthal, 1971) though this may vary between individuals (Rutkove, 2001).

Another interpretation to the current findings could be that the decrease in NCV detected is a possible mechanism by which PSWT works. However, since very few studies have been found on the effect of PSWT on nerve conduction, and they cannot be compared to the current study due to difference in equipment used and methodology

employed, further studies in the field need to be conducted to gain further insight into PSWT mechanism of action.

The application of PSWT is associated with a decrease in pain level. The mechanism of this decrease is not fully understood. Further work in the area of interaction between nerve conduction and PSWT application is warranted, as it needs to be explored whether the nerve velocity plays a role in pain reduction as reported by patients.

The duration of the response is a measure of the number of fibres contributing to the response. A change in either the shape or an increase in duration could mean asynchrony in the number of fibres responding to a stimulus (Dong and Liveson, 1983). The current study did not demonstrate a significant change in the duration of the contraction although there was a recorded increase with both 3W and 24W, an issue that need to be investigated further.

During the experiment, NCV electrodes were left on the non-treated side to reduce post irradiation delay (Section 8.27.3). By leaving the electrodes in place there is a need to acknowledge that the skin underneath the electrodes in the non-treated area may not undergo the same reaction to removing and reattaching adhesive electrodes as the treated leg and this may have its implication on the findings. However, this is a confounding variable that needed to be accepted at this level.

An inherent difficulty with nerve conduction studies is reliability. Even with extreme standardising procedure the percentage of error for the measured value could vary between 4-5% (Dong and Liveson, 1983). This problem may have been improved by the extensive piloting procedures conducted by the researcher before conducting the laboratory and clinical trials.

Change in body part temperature is known to alter NCV (Rutkove, 2001). It is advisable to warm the part in cases where the limb is cold. This was not accomplished in this study as warming up the part could alter the response obtained by the variables studied. Despite that the room temperature ranged from 23-26°C during the course of the study, it did not vary more than 1°C during any one treatment period as such is not expected that it affected the values recorded.

Although comparable readings were obtained bilaterally within individuals, side to side differences were detected. This may be related to the nature of the measuring device. Such differences were not alarming as it was reported previously in the literature (Morita et al, 2002; Bromberg and Jaros, 1998). This could be caused by the difference in nerve diameter, the strength of the stimulus which determines the number and the size of the activated nerves. This issue was taken into consideration and the amount of normal variability was calculated to be 1.6m/second. This means that all changes above this value are considered real changes and not fluctuation in recording due to methodological issues.

9.4.4 Others

The findings of the current study have shown that the application of PSWT is associated with a placebo effect and this is in accordance with many of the findings reported in the literature (Klaber-Moffett et al. 1996; Foley-Nolan et al, 1992, 1990; Reed et al, 1987). The study has also shown that the use of a low dose application, culminates in similar findings to placebo PSWT. Such findings may have their implication on the choice of parameters and time of exposure as these findings implies that lower power outputs could be no better than placebo in relation to the physiological

parameters investigated. However, the use of very low power outputs needs to be examined in the patient population before they are discarded clinically.

In all conditions it was found that the increase in the variable studied whether it was BVol, SkT or NCV was directly proportional to the amount of energy applied. The fact that the response obtained during the treatment and was lost for the post treatment period (3 W) or was not statistically significant (24W) could indicate that higher energies need to be applied to preserve the treatment effects. The conclusions that could be drawn from the above findings were that the increase in SkT is associated with an increase in BVol and a decrease in NCV.

The measurements were taken from both sides because the work on other frequencies of EMF has shown a "cross talk" effect between treated and non-treated side (Tabrah et al, 1990). Findings of this study concurs with Tabrah et al (1990) findings as the response seen in the non-treated side was found to mirror the treated side but with smaller magnitude.

Although there was significant correlation between height and BVol, and between PulsR, and age and PulsR and fat%, with the absence of a trend among other variable it is doubtful that these resemble important findings.

One of the drawbacks of laboratory testing is that experiments are done on young healthy subjects, the majority of whom are university students. In the current study, subjects with a wide age range were included in the study to enable better generalisation on a wider age range of patients.

The findings of the current study may have implications with regard to the decisions that therapists need to consider when deciding on efficacy of different treatment parameters.

In summary the findings of this experiment support the null hypothesis with regard to effects of high dose on SkT and NCV and reject the null hypothesis with regard to effects of high dose on BVol. The findings also support the null hypothesis with regard to the effects of low dose on BVol/ SkT/ NCV, the effects of high dose on CorT and PulsR, the effect of low dose on CorT and PulsR, and the effect of both low dose and high dose on the non-treated side.

9.5 CONCLUSION

The effect of applying PSWT at two different treatment doses was examined in thirty one healthy subjects. The results demonstrated a significant increase in BVol with both 24W and 3W during treatment. It was demonstrated that the post treatment effects of the treatment was not significant possibly because of the amount of energy delivered to the tissues. This could be overcome by increasing the time of exposure or using higher energy output. Such issues may have their implication in the clinical decision process by physiotherapists.

Subjects with a wide age range were included in the current study; however this does not facilitate extrapolation to patient population as patient may react differently to the same stimulus.

In the next phase of the thesis the same study will be replicated with osteoarthritic patients in order to explore the effect of PSWT on SkT, BVol and NCV on the clinical picture of OA patients.

CHAPTER 10

PHYSIOLOGICAL EFFECTS OF PSWT ON OSTEOARTHRITIC PATIENTS

10.0 INTRODUCTION

PSWT is one of the electrotherapeutic modalities that have been used by physiotherapists in UK for decades; nonetheless, the knowledge about its clinical use and rationale for dosage selection is scant (Kitchen, 1995b). The literature reviewed (Chapter 4) has demonstrated that evidence from clinical trials is controversial and that published reports have failed to describe their treatment protocols thoroughly, making it hard for therapists to reach consensus on the appropriate dosage to administer with various conditions (Murray and Kitchen, 2000).

It has been argued that the diseased tissues react differently from healthy tissues when exposed to exogenous energy (Bricknell and Watson, 1995) suggesting direct extrapolation of research findings between healthy and patient population is unwise. Although this assumption has been accepted for some time, it has not been validated by experimental work. The majority of research papers have examined the physiological effects of PSWT on healthy subjects with little attention paid to patients' physiological response to electrotherapeutic modalities. This highlights the importance of further research in this area (Murray and Kitchen, 2000).

The audit conducted (Chapter 5) has shown OA to be one of the most common conditions seen in physiotherapy outpatient clinics. Between 34%-42% of the sample comprised from 86 therapists in one of England health authorities reported that PSWT is the treatment of choice for acute, and for moderate and severe OA (Green, 1991). A survey by Shields (2003) has revealed that one of the reasons for considering the purchase of new PSWT units was the belief that it was effective with arthritic conditions. The volume of literature on PSWT use for OA is limited in number and of controversial outcomes (Section 4.1). A

literature review on OA and the use of PSWT has shown that the majority of the published studies have examined the effect of a course of treatment with PSWT in comparison to other forms of treatments and those who compared more than one mode of PSWT to each other failed to provide sufficient details on the dosage.

Given the above, this study aimed to examine the effects of high and low doses of PSWT on OA patients. Three modes of PSWT treatments were administered (24W, 3W, and placebo) and their effects on SkT, BVol, and NCV were compared to a control group. This study is unique in that the variables examined with OA patients will be compared to healthy subjects using the same experimental protocol and equipment. Findings of this study are expected to help substantiate the effect of some modes of treatments that have not been validated before by clinical trials.

10.1 METHODOLOGY

The study was conducted in the Physiotherapy Department in Lister hospital. Before commencing the trial ethical approval was granted from East & North Hertfordshire Hospitals Local Research Ethics Committee (Appendix F.1) and approval of the Physiotherapy Manager was obtained (Appendix F.2).

10.1.1 Patient recruitment

Patients in the waiting list of the department who were diagnosed as OA knee were treated as potential candidates for the trial. Patients were contacted by phone and were questioned using the American College of Rheumatology list (Table 10.1). In cases where the patients agreed to participate, they were given an appointment to visit the department

and an information package was sent to them by mail. The package contained an explanatory letter about who is conducting the trial, the underpinning aims for the study, and the course of the experiment. The package also contained a contra-indication form (Appendix D.5), a consent form (Appendix D.6) and an information sheet (Appendix D.4). Twenty six subjects participated in a same subject design which meant that each subject had to attend for 4 sessions to take part in high dose, low dose, placebo and control session.

1	2	3	4
Clinical and laboratory	**Clinical and radiographic**	Clinical (1)	**Clinical (2)**
Knee pain	Knee pain	Knee pain	Knee pain
Must have at least 5 of 9:	Must have at least 1 of 3:	Must have at least 3 of 6:	Must have at least 4 of 6:
Age > 50 years	Age > 50 years	Age > 50 years	Age > 50 years
Stiffness < 30 minutes	Stiffness < 30 minutes	Stiffness < 30 minutes	Stiffness < 30 minutes
Crepitus	Crepitus	Crepitus	Crepitus
Bony Tenderness	Osteophytes	Bony Tenderness	Bony Tenderness
Bony enlargement		Bony enlargement	Bony enlargement
No palpable warmth		No palpable warmth	No palpable warmth
ESR <40 mm/hour			
RF <1:40			
SF OA			

Table (10.1) OA classification according to the American College of Rheumatology (adapted from Altman, 1991, Altman et al, 1990; Altman et al, 1986).
ESR = erythrocyte sedimentation rate; RF = rheumatoid factor; SF OA = synovial fluid signs of OA (clear, viscous, or white blood cell count <2,000/mm^3).

The study was conducted following the same protocol used with healthy subjects (Section 8.24).

On arrival on the first day, the contra-indications were checked again. A brief patient history was taken using the form in Appendix (F.3). Muscle strength, ROM, pain level, height, weight, and SFM were taken.

10.1.2 Muscle strength measurement

Knee flexors and extensors strength was measured using hand held myometer (Penny and Giles Instrumentation Ltd., England - Figure 10.1). The patient was asked to lie prone on a plinth, with the knee flexed to 90° degrees and the myometer was placed 10 cm above ankle joint posteriorly (Bohannon, 1997; Andrews et al, 1996). Although the previous authors performed the test with their subjects seated with hip and knee at 90° flexion, in the current study it was seen more appropriate for the patients to lie down prone as this will enable the researcher to use her body weight and body mechanics to better resist the movement.

The myometer was applied perpendicular to the area tested. The break method (Section 7.2.2) of testing was used, where subjects were instructed to increase their effort gradually

Figure (10.1) Hand held Myometer

to maximum when they heard the word "now", and were told to stop contracting when the investigator finishes counting till 5. Subjects were shown the movement and were asked to perform it to confirm their understanding. The peak reading was recorded. The test was repeated 3 times and the mean was used for analysis. A five second rest was allowed

between tests to avoid fatigue (Phillips et al, 2000) longer periods of rest were given when seen necessary.

10.1.3 ROM measurement

The universal goniometer was used to measure ROM. The axis of the goniometer was aligned with the knee joint; the stationary arm was aligned along the femur pointing towards the greater trochanter. The movable arm was aligned parallel to the fibula pointing towards the lateral malleolus. The movement was shown to the patients and they were allowed to practice the movement a couple of times before recording the actual measurement. All measurements were taken by the same investigator to improve reliability (Brosseau et al, 2001). The error margin for the researcher was found to be ±3° (Appendix F.4).

10.1.4 Pain level measurements

Pain was measured using VAS. Pain is a major reason for OA patients to seek physiotherapy interventions. Evaluation of pain in OA is necessary to assess the effectiveness of any intervention (Wessel, 1995)

Patients were presented with a line that measured 100 mm. The line was anchored at the extremes with "no pain" at one end and the "worst pain imaginable" at the other end (Figure 10.2).

Patients were asked to mark their pain pre and post each session to represent the severity of their pain. Patients were presented with a different sheet of paper every time to ensure that they were blinded from their previous marking (Tiplady et al, 1998; Hagino et al, 1996).

Figure (10.2) Visual analogue scale

A ruler was then used to assign a numerical value to the mark; the value was used for analysis.

All patients were encouraged to continue to use any type of medication they were taking prior to the entry in the trial.

At the end of all the sessions subjects were asked to answer few questions to evaluate the efficacy of the treatment in general (Appendix F.5).

10.2 INCLUSION CRITERIA

All patients classified by the author as having OA following the American College of Rheumatology Classification for clinical 1 and clinical 2 (Table 10.1) were included in the trial.

10.3 EXCLUSION CRITERIA

- Patients having any of the contra-indication listed in Appendix (D.5)
- Patients receiving physiotherapy
- Patients having OA as secondary to other conditions
- Patients having OA Hip
- Patients who had intra-articular injection in the knee joint within the last month
- Obese patients (fat % more than 40 mm). Obese patients were excluded as the application of a high dose of 24W may be associated with increase in temperature and although patients may not report heat, this does not mean that heat is not developing in deeper tissues. Moreover, fatty layer has the tendency to develop hot spots as a result of heat accumulating in the tissues (Ward, 1980).

10.4 DATA ANALYSIS

Measurement of BVol, CorT, PulsR was taken before, during and after intervention. Measurement of NCV and SkT were taken before and after the intervention (NCV electrodes has metal component hence contra-indication to PSWT, and the SkT probes heats with PSWT). Measurements of secondary measures were taken pre and post PSWT administration to provide a baseline data and information about the rate of change and intervention efficacy.

Data were analysed following the same methodology in Section 9.2.2. All statistical data was computed using SPSS software (version 11). Differences between groups was determined using ANOVA and significant results were examined for statistical significance using Bonferroni Post Hoc. Pearson's Correlation Product Coefficients was used to

correlate age, gender, height, weight, and SFM, with measurements taken on BVol, SkT, NCV, PulsR and CorT. Data were also checked for normality and homogeneity of the variance before the start of any analysis. In cases where sphericity was not assumed the corrected F value from Greenhouse- Geisser was reported.

Functional improvement was assessed following a small scale questionnaire (Appendix F.5) that was developed by the investigator based on the general symptoms of OA. Findings were reported in terms of frequencies.

10.5 RESULTS

Fifty two patients were approached by the researcher for the study. Table (10.2) displays the numbers of patients recruited and those who completed the trial. Out of the 26 patients entered the study, 24 completed the sessions and 2 attended two sessions only. Subjects were asked to attend for 5 sessions although there were 4 experimental settings because patients were measured prior to each experimental session. Baseline measurement was taken before the first session, first measurement for changes in pain, muscle strength and ROM was taken prior to the second session, third measurement was taken before the second session and so on. The mean age of participants was 55.07 years (ranging between 32-80 years), of whom 53.8% (n=14) were women and 46.2% (n=12) were men.

Description	No of patients
Number of patients approached by the researcher	52
Patients refused	15
*Patients excluded before starting	8
Patients withdrawn: a- Withdrawn before starting the trial	3
b- Did not complete the sessions (one patient attended all but placebo session, one patient attended all but control and placebo)	2
Total completing all the experimental sessions of the study	24

Table (10.2) Profile for patient recruited for the study

*: This category contains patients found to fall into exclusion criteria after initial assessment

a: This category contains patients who were given appointments but did not attend.

The sample profile is shown in Table (10.3) and more information can be found in Appendix (F.6). Raw data is presented on a floppy disk at the back of the thesis.

Description	Range	Mean± SD
Age	32-80 years	55.076±11.976
Height	150-190 cm	167.911±10.141
Weight	47.78-109.85 Kg	26.400 ± 6.480
Duration of OA	2 month –20 years	4.66±4.87

Table (10.3) Characteristic of the study sample

Patients were randomised into treatments using the same table from chapter 9 (Section 9.2.1). The result of randomisation is shown in Table (10.4).

Session 1		Session 2		Session 3		Session 4	
Treatment	**Frequency**	**Treatment**	**Frequency**	**Treatment**	**Frequency**	**Treatment**	**Frequency**
24 W	5	**24 W**	3	**24 W**	4	**24 W**	6
3 W	8	**3 W**	8	**3 W**	6	**3 W**	6
Placebo	6	**Placebo**	8	**Placebo**	9	**Placebo**	6
Control	7	**Control**	7	**Control**	7	**Control**	8
	n=26		n=26		n=26		N=26

Table (10.4) Patient randomisation

10.5.1 Blood volume results

Manuchley's test of sphericity was significant for condition, the interaction between condition/side, condition/phase and the interaction between condition/phase/side, with these variables the corrected F value (Greenhouse-Geisser) will be reported. ANOVA analysis has shown a main effect (Table 10.5) for the four experimental conditions ($F_{(2.379,54.719)}$ =32.400). The difference was significant at all levels between high/control (p=0.000), low/control (p=0.001), and placebo/control (p=0.000). There was a main effect for phase ($F_{(2,46)}$=526.731), which was significant between before/after (p=0.000) and between

during/after at (p=0.000). There was a main effect of side between right and left ($F_{(1,23)}$=66.015, p=0.000).

There was a significant interaction effect between condition/phase ($F_{(2.205,\ 50.726)}$=79.514 p=0.000), a significant interactive effect between condition/side ($F_{(2.168,\ 49.867)}$=14.529, p=0.000), a significant interaction between phase/side ($F_{(2,46)}$=73.214, p=0.000), and a significant interactive effect between condition/phase/side ($F_{(1.938,44.579)}$=33.957, p=0.000) at all levels. Using Bonferroni as post hoc all the above differences were statistically significant.

Source	Condition	PHASE	SIDE	Sig.	
Condition	High vs control			.000	S
	Low vs control			.001	S
	Placebo vs control			.000	S
Phase		Before vs after		.000	S
		Before vs during		.000	S
Side			Treated vs non treated	.000	S
Condition * phase	High vs control	Before vs during		.000	S
		Before vs after		.000	S
	Low vs control	Before vs during		.000	S
		Before vs after		.000	S
	Placebo vs control	Before vs during		.000	S
		Before vs after		.000	S
Condition * side	High vs control		Treated vs non treated	.000	S
	Low vs control		Treated vs non treated	.036	S
	Placebo vs control		Treated vs non treated	.084	NS
Phase * side		Before vs after	Treated vs non treated	.000	S
		Before vs during	Treated vs non treated	.000	S
Condition * phase * side	High vs control	Before vs during	Treated vs non treated	.000	S
		Before vs after	Treated vs non treated	.007	S
	Low vs control	Before vs during	Treated vs non treated	.000	S
		Before vs after	Treated vs non treated	.002	S
	Placebo vs control	Before vs during	Treated vs non treated	.029	S
		Before vs after	Treated vs non treated	.003	S

Table (10.5) Contrast analysis for blood volume (significant findings are highlighted in red). S: significant, NS: non significant

Changes in BVol across the experimental conditions are shown in Figure (10.3). The Figure shows that the highest level of increase in BVol was recorded with the high dose, followed by the low dose, then placebo. The increase measured during treatment was higher than that measured for the period post treatment and this was evident with high, low, and placebo. Though this increase declined post treatment, it remained above the baseline level. A summary of the descriptive changes in BVol across the experimental conditions is shown in Appendix (F.6).

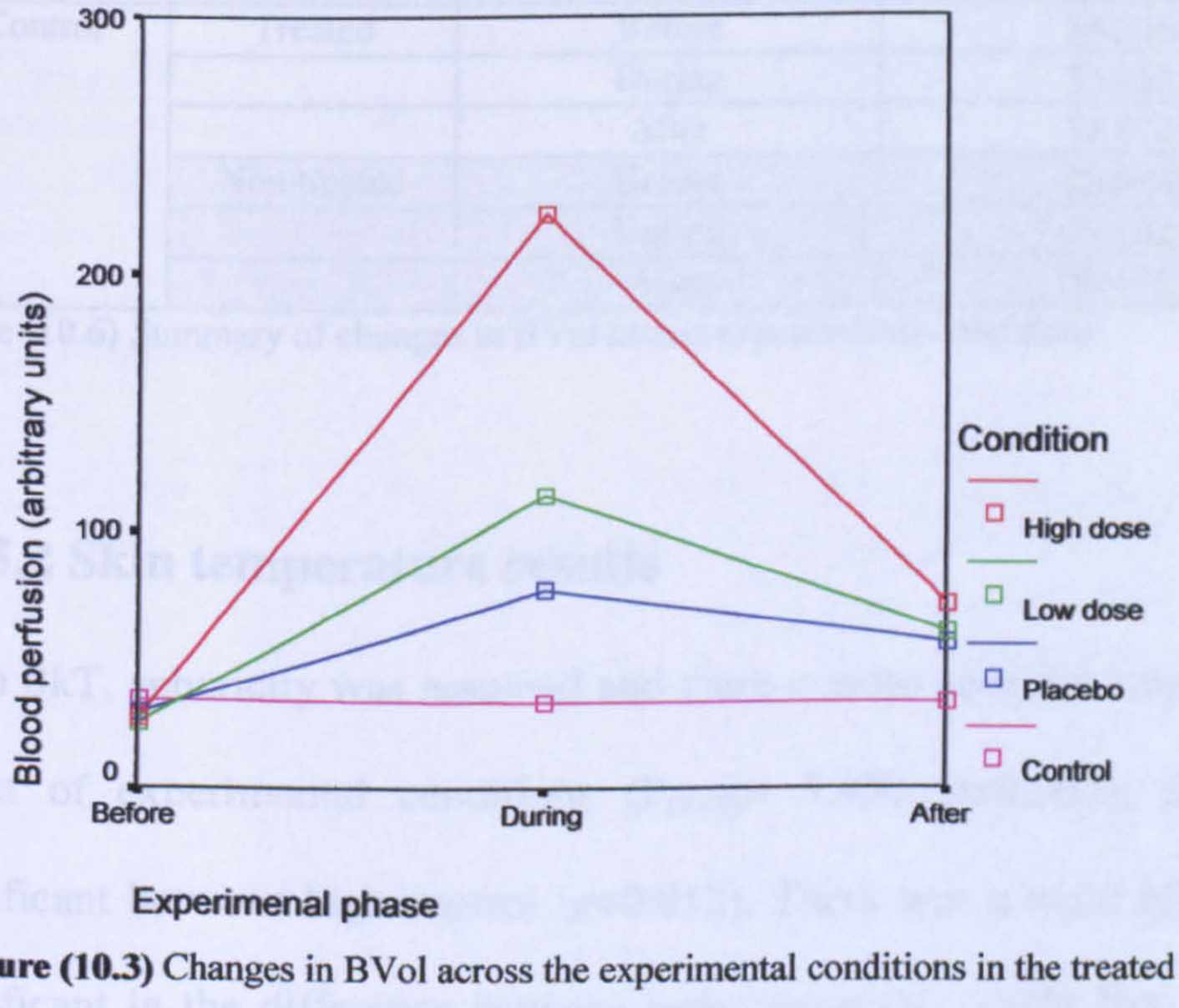

Figure (10.3) Changes in BVol across the experimental conditions in the treated side

Summary of the findings can be found in Table (10.6)

Condition	Side	Treatment phase	Mean ±Std. Deviation
High	Treated	Before	27.742±17.653
		During	220.743±68.750
		After	71.171±39.868
	Non treated	Before	23.303±13.895
		During	69.252±43.607
		After	43.161±33.087
Low	Treated	Before	24.590±20.083
		During	108.469±55.444
		After	57.218±32.993
	Non treated	Before	24.683±17.802
		During	55.107±26.249
		After	37.916±22.500
Placebo	Treated	Before	30.142±17.806
		During	76.895±29.303
		After	56.702±25.624
	Non treated	Before	23.016±11.856
		During	54.040±22.738
		After	32.627±15.553
Control	Treated	Before	34.336±18.673
		During	33.455±17.464
		After	33.872±18.957
	Non treated	Before	29.694±13.371
		During	29.152±14.929
		After	29.170±16.468

Table (10.6) Summary of changes in BVol across experimental conditions

10.5.2 Skin temperature results

With SkT, sphericity was assumed and there was no need for correction. There was a main effect of experimental conditions ($F_{(3,69)}$= 5.400, p=0.002), this difference was only significant between high/control (p=0.012). There was a main effect of phase, which was significant in the difference between before/after ($F_{(1,23)}$=76.704, p=0.000). There was no main effect for side ($F_{(1,23)}$=0.517, p=0.480). There was an interaction effect between condition/ phase ($F_{(3,69)}$=30.119, p=0.000), an interaction between condition/side

($F_{(3,69)}$=7.317, p=0.000), and an interaction between phase/side ($F_{(1,23)}$=50.020, p=0.000), and there was a 3rd level interaction between condition/phase/side ($F_{(3,69)}$=21.830, p=0.000), there was significant interaction between high/control for the before/after measurement in the treated/non treated side (Table 10.7).

However, when post hoc test was used, none of these relationships reached statistical significance.

Source	Condition	Phase	Side	Sig.	
Condition	High vs control			.012	S
	Low vs control			.461	NS
	Placebo vs control			.832	NS
Phase		Before vs after		.000	S
Condition *phase	High vs control	Before vs after		.000	S
	Low vs control	Before vs after		.611	NS
	Placebo vs control	Before vs after		.148	NS
Condition * side	High vs control		Treated vs non treated	.000	S
	Low vs control		Treated vs non treated	.464	NS
	Placebo vs control		Treated vs non treated	.750	NS
Phase *side		Before vs after	Treated vs non treated	.000	S
Condition *phase * side	High vs control	Before vs after	Treated vs non treated	.000	S
	Low vs control	Before vs after	Treated vs non treated	.396	NS
	Placebo vs control	Before vs after	Treated vs non treated	.385	NS

Table (10.7) Contrast analysis of skin temperature (significant findings are highlighted in red), S: significant, NS: non-significant

Condition	Side	Treatment phase	Mean±Std. Deviation
High	Treated	Before	28.974±1.743
		After	31.048±1.667
	Non treated	Before	28.931±1.689
		After	29.281±1.737
Low	Treated	Before	27.955±1.432
		After	28.369±1.471
	Non treated	Before	28.397±1.541
		After	28.492±1.582
Placebo	Treated	Before	28.444±1.410
		After	28.414±1.391
	Non treated	Before	28.623±1.159
		After	28.599±1.212
Control	Treated	Before	28.300±1.192
		After	28.554±1.139
	Non treated	Before	28.439±1.401
		After	28.546±1.265

Table (10.8) Changes in skin temperature across the experimental conditions

Table (10.8) provides a summary of the changes in skin temperature across the experimental conditions. Figure (10.4) is a box plot showing the increase in SkT in the four experimental conditions. The graph shows that there was a minimal change in the experimental conditions for placebo and low conditions in the before and after PSWT administration. The increase in high dose was the greatest as could be seen from the shift in the position of the box plot for the high after condition.

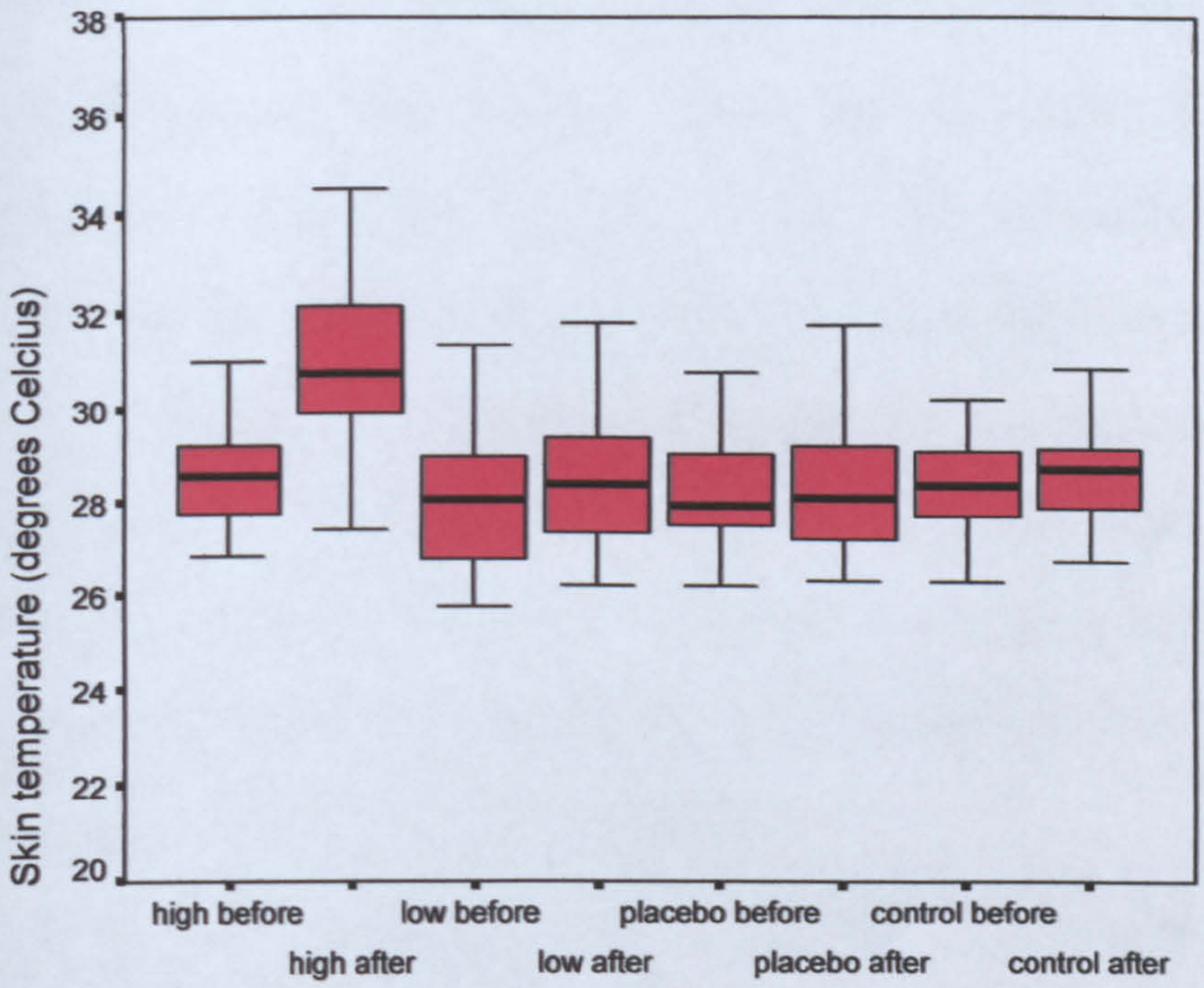

Figure (10.4) Changes in skin temperature across the experimental conditions in the treated side

This means that only the high dose have increased skin temperature significantly.

10.5.3 Nerve stimulation results

10.5.3.1 Nerve conduction velocity

Manuchley's test of sphericity was non-significant for all variables except for the 3rd level interaction between condition/ phase/ side where the corrected F value (Greenhouse Geisser) will be reported. There was a main effect for condition ($F_{(3,69)}$=6.070 p=0.001), the difference was between high/control (p=0.000), low /control (p=0.002), placebo/control (p=0.031). There was a main effect for phase in the before and after treatment ($F_{(1,23)}$=39.841 p=0.000). There was a main effect for side between the treated and non-treated knee ($F_{(1,23)}$=8.772 p=0.007). There was an interaction effect between condition/phase ($F_{(3,69)}$=12.748 p=0.000), and an interaction effect between phase/side ($F_{(3,69)}$=7.446, p=0.012). Post hoc tests (Bonferroni) revealed a statistical significance between high/control (p=0.000), and low/control (p=0.014). Further description to main effects and interactions following contrast analysis is shown in Table (10.9). Figure (10.5) shows the changes in NCV recorded for the before and after PSWT administration across the experimental conditions in the treated side.

Source	Condition	Phase	Side	Significance	
Condition	High vs control			.000	S
	Low vs control			.002	S
	Placebo vs control			.031	S
Phase		Before vs after		.000	S
Condition * phase	High vs control	Before vs after		.000	S
	Low vs control	Before vs after		.000	S
	Placebo vs control	Before vs after		.207	NS
Condition *side	High vs control		Treated vs non treated	.339	NS
	Low vs control		Treated vs non treated	.295	NS
	Placebo vs control		Treated vs non treated	.165	NS
Phase * side		Before vs after	Treated vs non treated	.012	S
Condition *phase * side	High vs control	Before vs after	Treated vs non treated	.521	NS
	Low vs control	Before vs after	Treated vs non treated	.237	NS
	Placebo vs control	Before vs after	Treated vs non treated	.255	NS

Table (10.9) Contrast analysis of NCV, (significant findings are highlighted in red), S: significant, NS: non-significant

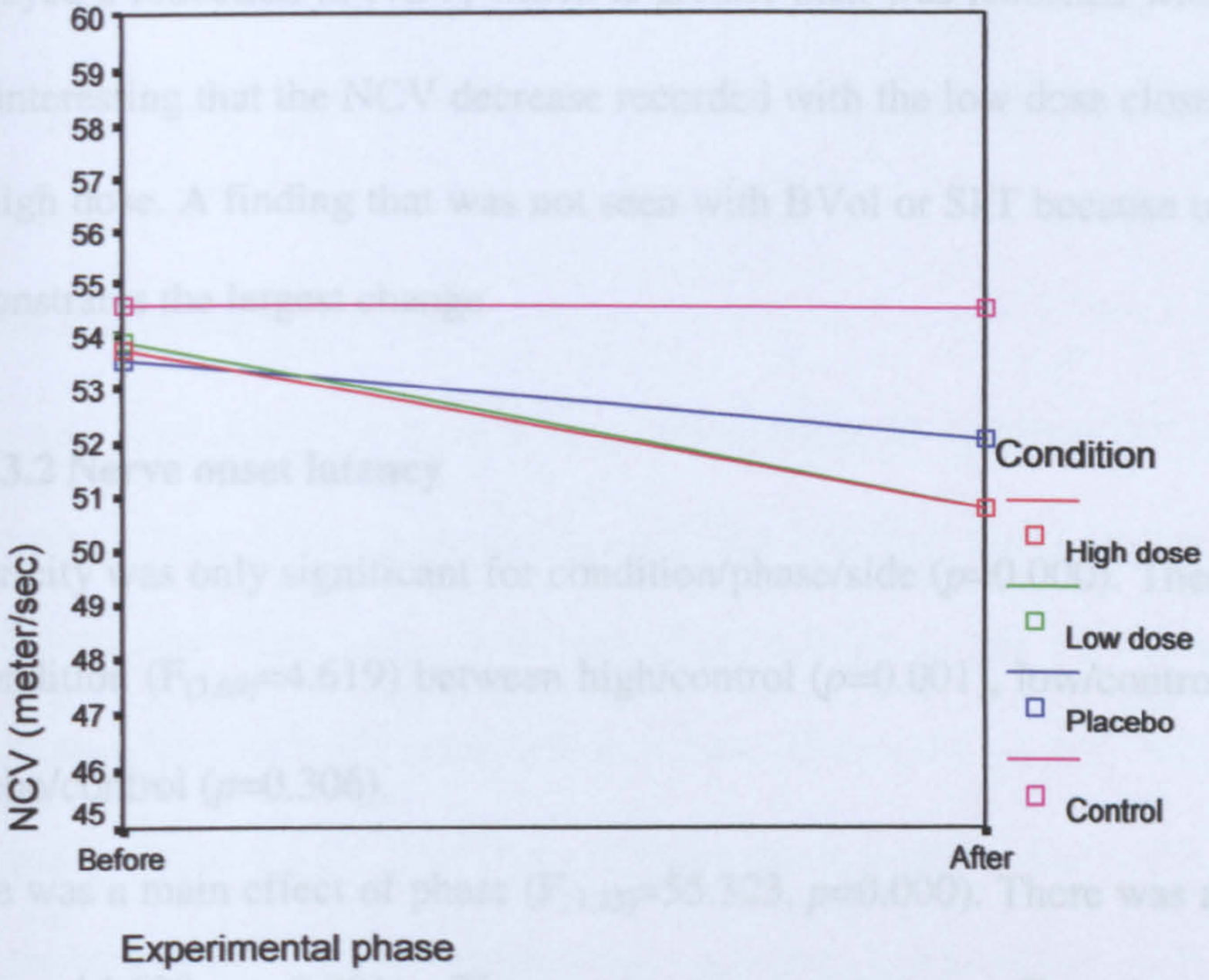

Figure (10.5) Line plot of the changes in NCV across the experimental conditions in the treated side

Condition	Side	Treatment phase	Mean±Std. Deviation
High	Treated	Before	53.659±1.876
		After	50.227±4.147
	Non treated	Before	54.159±1.763
		After	51.847±2.760
Low	Treated	Before	53.885±2.140
		After	50.848±4.122
	Non treated	Before	53.922±2.073
		After	52.017±2.920
Placebo	Treated	Before	53.433±1.969
		After	52.024±4.740
	Non treated	Before	53.968±2.036
		After	54.093±2.169
Control	Treated	Before	54.586±1.798
		After	54.601±1.972
	Non treated	Before	54.464±2.116
		After	54.458±2.167

Table (10.10) Summary of changes in NCV across experimental conditions

Summary of the experimental conditions is presented in Table (10.10). Figure (10.5) shows the decrease in NCV with the high dose, low dose and placebo. Both high and low dose displayed a reduction in NCV, which is greater than was recorded with the placebo group. It is interesting that the NCV decrease recorded with the low dose closely resembled that of the high dose. A finding that was not seen with BVol or SkT because usually the high dose demonstrates the largest change.

10.5.3.2 Nerve onset latency

Sphericity was only significant for condition/phase/side (p=0.000). There was a main effect of condition ($F_{(3,69)}$=4.619) between high/control (p=0.001), low/control (p=0.002), but not placebo/control (p=0.306).

There was a main effect of phase ($F_{(1,23)}$=55.323, p=0.000). There was a main effect of side ($F=_{(1,23)}$=14.520, p=0.001). There was no interactive effect between condition/side ($F_{(3,69)}$=1.395, p=0.252). There was no interactive effect between phase/side ($F_{(1,23)}$=2.322, p=0.141), no interactive effect between condition/phase/side ($F_{(1.865,42.980)}$=0.446, p=0.629). Post Hoc test revealed a statistical significant difference between high/control (p=0.004) and low/control (p=0.009).

This means that both the high and the low dose have affected nerve onset latency significantly.

10.5.3.3 Duration of the response

Sphericity was violated for condition/phase and condition/phase/side. There was no main effect of condition ($F_{(3,69)}$=1.429, p=0.242), no main effect of phase ($F_{(1,23)}$=1.895, p=0.182), no main effect of side ($F_{(1,23)}$=1.064, p=0.313). There was no interaction between

condition/phase ($F_{(1.446,33.248)}$=1.971, p=0.126), condition/side ($F_{(3,69)}$=1.874, p=0.142), phase/side ($F_{(1,23)}$=2.639, p=0.118), or between condition/phase/side ($F_{(1.723,39.619)}$=1.625, p=0.191). More analysis can be found in Appendix F.6. This means that none of the experimental conditions have affected nerve response duration.

10.5.4 Pulse rate results

Using two way ANOVA there was no main effect of condition ($F_{(3,69)}$=0.148, p=0.930), There was a main effect of phase ($F_{(2,46)}$=5.381, p=0.008) in the before and after conditions which was lost when phase was viewed in relation to the experimental conditions No interactive effect between condition and phase ($F_{(6,138)}$=.812, p=0.562). More analysis can be found in Appendix F.6. Summary of pulse rate is found in Table (10.11).

This means that none of the experimental conditions had an effect on PulsR.

Condition	Mean±Std. Deviation
24W-mean pulse before	66.807±13.070
Mean pulse during	68.034±13.163
Mean pulse after	67.753±12.436
3W-mean pulse before	66.313±10.911
Mean pulse during	66.138±10.856
Mean pulse after	65.707±10.357
Placebo-mean pulse before	65.339±12.684
Mean pulse during	66.612±13.251
Mean pulse after	66.544±12.560
Control-mean pulse before	63.589±9.338
Mean pulse during	64.425±11.489
Mean pulse after	64.858±10.790

Table (11.11) Summary of change in pulse rate in the experimental conditions

10.5.5 Core temperature results

Using two way ANOVA, there was no main effect of condition ($F_{(3,69)}$=1.461, p=0.233), there was a main effect of phase ($F_{(1.604,\ 36.893)}$=3.736, p=0.042) between before and after

which was lost when phase was viewed in relation to the experimental conditions. No interactive effect between condition/ phase ($F_{(3.917,\ 90.082)}$=0..937, p=0.445). Summary of core temperature is found in Table (10.12).

This means that although there was a change in CorT, none of the experimental conditions resulted in significant increase.

Condition	Mean±Std. Deviation
24W- mean core temp before	34.942±.524
Mean core temp during	34.900±.423
Mean core temp after	34.943±.491
3W- mean core temp before	34.711±.318
Mean core temp during	34.819±.250
Mean core temp after	34.832±.374
Placebo mean core temp before	34.867±.265
Mean core temp during	34.976±.257
Mean core temp after	34.980±.253
Control mean core temp before	34.920±.520
Mean core temp during	35.018±.314
Mean core temp after	35.052±.350

Table (10.12) Summary of core temperature in the experimental conditions

10.5.6 Ambient temperature

Using one way ANOVA there was no main effect of condition ($F_{(3,69)}$=0.225, p=0.879), no main effect of phase ($F_{(1,23)}$=1, p=0.328), there was no interactive effect between condition/ phase ($F_{(3,69)}$=1, p=0.398).

This means that ambient temperature did not affect the outcome in any of the experimental conditions.

10.5.7 Ambient humidity

Using one way ANOVA there was no main effect of condition ($F_{(3,69)}$=0.733, p=0.536), no main effect of phase ($F_{(1,23)}$=2.902, p=0.102), no interactive effect ($F_{(3,69)}$=0.799, p=0.499). This means that ambient humidity did not affect the outcome obtained with the four experimental conditions.

10.5.8 Correlations with anthropometric data

Using Pearson Correlation Coefficient, no significant correlation was found between BVol, SkT, NCV, PulsR, CorT and the anthropometric data except for SkT and weight (p<0.05). More detail is can be found in Table (10.13).

		Age	Height	Weight	Fat percentage
Bvol	Pearson Correlation	-.245	.148	.282	-.226
	Sig. (2-tailed)	.227	.470	.162	.268
SkT	Pearson Correlation	-.030	-.102	.390	.279
	Sig. (2-tailed)	.883	.621	.049	.167
NCV	Pearson Correlation	.035	.319	.021	.076
	Sig. (2-tailed)	.867	.112	.920	.711
PulsR	Pearson Correlation	.066	-.241	-.291	.242
	Sig. (2-tailed)	.750	.236	.149	.234
CorT	Pearson Correlation	.055	.206	.085	.138
	Sig. (2-tailed)	.789	.313	.678	.500

Table (10.13) Summary of correlations, (significant findings are highlighted in red), S: significant, NS: non - significant

10.5.9 Visual analogue scale results

Sphericity was violated for condition hence the corrected F values will be reported. Using one way ANOVA there was a main effect of condition ($F_{(3.153,72.527)}$=10.303, p=0.000). This difference was found significant between high/ baseline (p=0.000), low/baseline (p=0.000), placebo/baseline (p=0.000), and control/baseline (p=0.011). Post Hoc test revealed a

statistical significant difference between all the above mentioned conditions (Table 10.14). Post hoc results can be found in Appendix (F.6)

Source	Condition	Sig.	
VAS	High vs baseline	.000	S
	Low vs baseline	.038	S
	Placebo vs baseline	.010	S
	Control vs baseline	.000	S

Table (10.14) Changes in VAS across experimental conditions, (significant results are highlighted with red), S: significant,

10.5.10 Muscle strength results

Using a one way ANOVA, there was a main effect for muscle strength ($F_{(2.445,56.230)}$=7.592, p=0.001). A significant difference was found between baseline and high dose (p=0.005). Post hoc test revealed a marginal statistical significance between baseline/ high dose (p=0.051). Further findings can be found in Table (10.15). More results are presented in Appendix (F.6).

Source	Condition	Sig.	
Muscle	High vs baseline	.051	S
	Low vs baseline	.238	NS
	Placebo vs baseline	.725	NS
	Control vs baseline	.517	NS

Table (10.15) Changes in muscle strength across experimental conditions, (significant results are highlighted in red), S: significant, NS: non-significant

10.5.11 Range of motion results

Using a one way ANOVA, changes in ROM between baseline and other experimental conditions were significant between high and baseline only (p=0.02). Further findings can be seen in Table (10.16). Complete data profile can be found in Appendix (F.6).

Source	Condition	Sig.	
ROM	High vs Baseline	.02	S
	Low vs Baseline	.264	NS
	Placebo vs Baseline	.442	NS
	Control vs Baseline	.146	NS

Table (10.16) Changes in ROM across experimental conditions, (significant results are highlighted in red), S: significant, NS: non-significant

Table (10.17) summarises treatment outcome with the different conditions. In Figure (10.6) it could be seen that when PSWT was administered for 10 minutes there was improvement in 77% of the patients with 24W, 61.5% with 3 W, and an interesting 39% improvement with placebo. These findings are based on patient reporting, and outcome of VAS (the percentage was calculated by dividing the number of subject improved by the total number of subjects).

Treatment	Improved	Stayed the same	Deteriorated
High (24W)	20 (76.9%)	5 (19.2%)	1 (3.84%)
Low (3W)	16 (61.5%)	9 (34.6%)	1 (3.84%)
Placebo (0.05W)	11 (38.5%)	14 (53.8%)	0
Control	3 (11.5%)	21 (84.6%)	0

Table (10.17) Summary of treatment outcome with the experimental condition

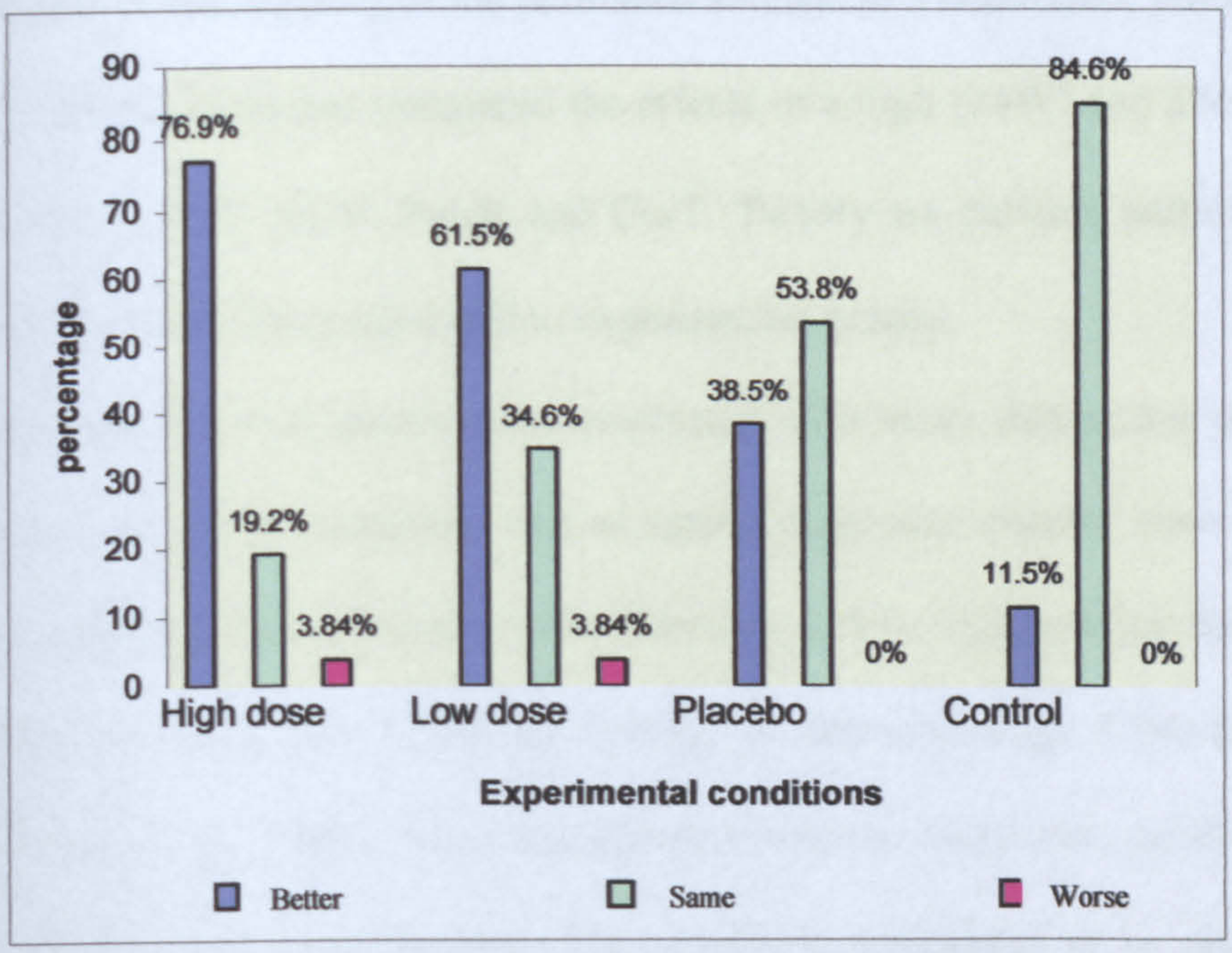

Figure (10.6) Treatment outcomes with experimental conditions

10.5.12 Functional status

Following the small scale questionnaire, it was found that 87.5% (n=21) of patients experienced lower levels of pain, 83.3% (n=20) of patients felt better in their general status compared to when they started the treatment. 75% (n=18) of patients felt that the treatment reduced their pain when ascending the stairs, while 45.8% (n=11) felt that PSWT helped them with their pain when descending the stairs. More results can be found in Appendix (F.6).

10.6 DISCUSSION

The literature reviewed in Chapter 3 has showed that the evidence in favour of the use of PSWT with OA knees is still inconclusive with some reporting positive outcomes

and others reporting negative outcomes and this is because of the nature and the poor quality of the majority of the published studies. In a controlled, placebo single blinded trial, the current study has compared the effects of a high (24W) and a low (3W) dose of PSWT on BVol, SkT, NCV, PulsR and CorT. Twenty six patients participated in the study and they were randomly allocated to experimental groups.

Studying OA has always been associated with many difficulties due to the lack of clear definition of the condition, lack of agreed diagnostic criteria, poor correlation between X-ray and the patient clinical picture (Doherty, 1994). This problem has been overcome in this study by using the American College of Rheumatology Classification (Altman, 1991, Altman et al, 1986). This classification system takes into account the clinical picture, laboratory and X-ray findings and as such is considered to be one of the comprehensive systems of classifying OA besides being a widely cited source in the literature.

There was a need to establish a diagnostic criterion as many patients were referred to the physiotherapy department in Lister Hospital, where this study was conducted, diagnosed as knee pain. Having a classifying system allowed for enrolling patients with similar symptoms and closer baseline point.

At the planning stage of this trial and in the laboratory trial, there was a need to take a decision regarding how to space out the sessions. The decision at that time was taken to space them by a minimum of 2 days based on the available literature. The reference was electrotherapy textbooks along with manufacturers' manual (Wadsworth and Chanmugam, 1983). The results of the current work suggests that PSWT at the dose given in this experiment has a latent or a carry over effect that lasts for a day and symptoms return to pre-treatment status the following day. This could mean that none of the findings reported

is the result of a build up of energy or a consequence of the latent treatment effects. Furthermore, given that improvement reverts to pre-treatment status after a relatively short period could suggest that the energy delivered is not sufficient to maintain therapeutic effects over time, and hence need to be increased either by administering daily treatment or by increasing treatment duration. However, such notions need to be validated in further experimentation before they are accepted clinically.

Following the collection of 20 sets of data, a reverse sample size calculation was performed using the same software in Section 9.2.3. The mean values for change in BVol, SkT, NCV were used to calculate the number of subjects needed for the trial. Based on SD, effect size, and significance level $\alpha < 0.05$ and a power of 0.8, the number of subjects needed was determined to be 13 when BVol results were analysed, 11 when nerve conduction results were analysed and 10 when SkT were analysed. However, it was decided to go for the twenty six patients recruited at the initial stage of this study for two main reasons. Firstly: unlike other studies when it is not ethical to recruit large number of patients and being denied treatment, the current study is a same subject design and all patient will have the advantage of getting treatment while still waiting for their turn in the waiting list.

Secondly: appointments have already been given and patients were expecting to get treatment and it would be unprofessional to cancel them.

10.6.1 Blood volume

According to Hand (1990) with inductive PSWT, the heating is expected to be 80% more in deeper tissues compared to superficial. There was almost 10 times increase in BVol

during the treatment in 11 out of 26 patients with the high dose and 4 out of 26 in the low dose. These readings declined to 2 out of 26 with the high dose and none in the low dose group when baseline readings were compared to post treatment period. As mentioned in the pervious chapter, no speculation can be made about muscle temperature, however such an increase in BVol could be associated with an increase in the internal temperature, and increase in metabolic activity in the muscles (Kitchen 2002) hence better treatment outcomes as was demonstrated in the findings. However, this remains speculative and would need to be confirmed experimentally.

The majority of the patients in this study reported that the relief of symptoms was felt within 1 or 2 hours after the treatment. This aspect of PSWT mechanism has not been explored before in the literature and needs further experimentation in order to find out whether this phenomenon is specific to the doses used in this trial or is it a mechanism by which PSWT works. It is also interesting to see whether this observation does occur with the continuous mode of SW.

10.6.2 Skin temperature

There was a significant increase in SkT recorded with the high dose. This increase was around 2°C, which is similar to that recorded in the laboratory study (Chapter 9). The increase with the low dose was less than 0.4°C. The fact that minimal increase in SkT was recorded (was not statistically significant) with the low dose suggests that the changes seen in BVol could be a possible micro-thermal reaction. Similar amount of increase was recorded by both Erdman (1960) and Bricknell and Watson (1995).

It was observed that the increase in temperature with the high and low dose did not reach a plateau which could mean that further increase in SkT could occur if the treatment duration was extended. It could also mean that although the examined dose has altered SkT, BVol, and NCV, it may not be the optimum treatment duration, thus other durations need to be examined as it may lead to better treatment outcomes.

10.6.3 Nerve conduction velocity

It has long been accepted that the high frequency current delivered by PSWT does not have any direct effect on motor and sensory nerves as the duration of the impulse required to stimulate a nerve should be more than 0.01 ms (Oh, 1996). High frequency currents have a pulse duration of 0.001 ms which is shorter than the pulse required to stimulate a nerve (Kitchen 2002; Forster and Palastanga, 1985). Findings from the laboratory experimentation in Chapter (9) have demonstrated that the application of PSWT is associated with a decrease in NCV. Administering PSWT on OA patients has also demonstrated a significant reduction in NCV with both treatment and placebo groups. This reduction was with the high dose in the laboratory trial, and with the high and the low dose in the current study. Interestingly, the decrease in NCV in the low dose was similar to the high dose. Such a reaction was not seen with the amount of increase in BVol or increase in SkT as a higher increase was consistently associated with high dose and smaller amounts of increase were associated with low dose but in no experimental condition have the two doses displayed similar findings. The current study has demonstrated that, contrary to previous reports (Currier and Nelson, 1969; Abramson et al 1966), the increase in temperature is not

always associated with increase in NCV. Although the underpinning reasons are not very clear, possible interpretations of the findings have been presented in Section (9.4.3).

It was noticed when performing the NCV studies that patients needed between 60-90% of the stimulus strength to stimulate their motor points and result in visible contraction, while healthy subjects in the laboratory trial considered 50% of the stimulus strength very painful. Muscle contraction with healthy subjects was also seen around 40% of stimulus strength with the majority of the subjects. The reason underpinning this observation is not known however, it could be speculated that with the long history of pain, there might have been an increase in patients threshold to noxious stimulus. Other reasons could be changes in nerve conduction characteristics in association with the disease process, an area that warrants further research.

10.6.4 Secondary outcome measures

Outcomes measures such as muscle strength, ROM and pain level were included in the study to provide data that will help link changes in physiological parameters measured with the improvement or deterioration in function reported or objectively measured. Pain was assessed being one of the prime symptoms in OA (Peat et al, 2001). Although ROM and muscle strength are not expected to improve dramatically as a result of applying PSWT, apparent changes in muscle strength are expected to result from the decrease in pain level.

The intention was to measure pain, muscle strength, and ROM before and immediately after treatment, however, after taking the measurement with 7 patients it was found that no patient have reported a change in the level of pain, ROM or muscle strength immediately

after the treatment. Therefore, it was decided that there was no benefit to continue taking these measurements immediately post treatment and to continue taking them prior the start of each treatment session only before the application of PSWT.

10.6.4.1 Visual analogue scale

VAS was employed in the study in order to reflect changes in pain level as a result of the applied treatment. VAS has been criticized of being unidimensional because it only resembles the sensory side and fails to reflect the multi-dimensional construct of pain namely the affective, evaluative, cognitive and behavioural elements (Sim and Waterfield, 1997). Despite that it was employed because it was easy to use by patients and requires almost no reading or verbal skills (Collins et al, 1997). Furthermore, as, the study involves ongoing assessment of pain, it is important that the scale used be short, rapid, reliable and a valid measure.

Reduction of pain could be the resultant of counterirritant effect which is mediated by the effect of morphine receptors in central nervous system and the possibility of pain moderation caused by enkephalins and endorphins (Field and Basbaum, 1999; Lehmannn and DeLateur, 1990).

According to Gallagher et al (2001) and Todd et al (1996) a difference of 13 mm or 1.3 cm on VAS represents the minimum clinical significant difference while others have accepted 9 mm to be the minimum acceptable difference in pain level for a clinical change in patient's pain level (Deloach et al, 1998). In this study 16 patients (61.5%) showed clinical improvement according to these criteria (13 mm) with the high dose. There was a 42.3% improvement with the low dose, 23% improvement with placebo and an interesting

19.2% improvement with the controlled condition where no treatment was applied. All of this highlights the role that placebo effect plays in patient response to the delivered (or not) treatment.

Two patients reported an increase of pain (one after high dose and one after low dose), both patients reported the pain after the first session and this may be caused by the testing procedure which demanded greater effort from the knee muscles in order to achieve the maximum isometric strength. This also places the joint in ranges, which the patient usually tries to avoid in order to avoid pain

10.6.4.2 Muscle strength

Unlike the findings of Chastain (1978) who demonstrated that subjects demonstrated an increase in their isometric strength following a 20 minutes of SW application, the findings of the current study did not find any difference between the pre and immediately post treatments periods. There are several factors that could be responsible for those observations. It could be the duration of the treatment, which was 20 minutes in the Chastain study and 10 minutes in the current study. Moreover, the mode of application was different it was continuous in Chastain trial and it was pulsed in this study. The current findings were in agreement with Quirk et al (1985) and Pasila et al (1978), who demonstrated that using PSWT with OA patients does not result in an increase in muscle strength. The findings provide evidence to the faulty belief of therapists that PSWT could increase muscle strength. A belief that have appeared repeatedly in the literature and was one of the findings of the survey conducted in Chapter 6.

Although it was not directly related to the objective of this trial, this finding was worth reporting. Initial examination has revealed that almost all patients had muscle spasm around the knee, which is expected to limit the ability of the muscle to exert its maximum effort. Although the PSWT dose applied is not expected to alter the state of the spasm dramatically, a certain degree of relief is expected to occur as a result of the increase in blood supply and the reduction of pain. This is expected to be one of the reasons for the significant apparent increase in muscle strength and ROM recorded with the high dose intervention.

10.6.4.3 Joint stiffness

The functional scale developed by the researcher for the purpose of the current study to follow changes in functional status with patients has revealed interesting findings. It was found that almost all patients have reported a decrease in joint stiffness and a smoother movement after PSWT treatment. Patients have also reported that less time is needed to overcome the stiffness in the joint after periods of immobility. Unfortunately, no quantitative measurements were taken to measure the degree of stiffness. These effects are expected to occur as a result of decrease viscosity of synovial fluid and reduce the resistance to joint movement (Scott, 2002). Effects of PSWT on stiffness was documented in the literature (Yung et al, 1986), however, this study used the continuous mode of SW. No other work has been identified that examined the same topic, therefore it warrants further exploration.

To state that a treatment is effective, it must produce a change in function and not just a change in outcome detected by the researcher. The current study has demonstrated

that applying PSWT at either 3W or 24W is associated with subjective reporting of improvement that was validated by objective measurements.

In partial disagreement with Pasila et al (1978) who reported that applying PSWT on MP 40W does not alter ROM, the current study has showed a significant improvement in ROM with 24W but not 3W or placebo.

10.6.5 Placebo effect

The placebo group was employed in the current study to mask the treatment allocation hence eliminate the subjective effects of the treatment which could bias the results (Wall, 1992).

Although it was expected that patients will only report improvement after actual treatments (3W or 24W), it was interesting to have 39% of the sample reporting improvement after a placebo treatment. There was one patient who even felt heat with placebo application. This confirms the strong placebo role in the clinical improvement of patients and demonstrated its associated role with the use of PSWT. This also reinforces the need to include a placebo group in future experiments with PSWT to quantify its effects and judge the genuine effect of PSWT before any generalisations on the results are made.

In disagreement with Klaber-Moffett et al (1996) who demonstrated that there was a difference between the outcome of active and placebo group on OA knees and hips, the current study has shown 39% of the patients in the placebo group felt better. This improvement was shown in the level of pain and function and was confirmed by physiological measurements. Additionally, in any medical intervention the placebo effect accounts for 30-40% of symptom relief (Gifford, 1998). Previous experimental work

conducted on healthy subjects has demonstrated that the effect of a placebo treatment on the treated side gives a response that is similar to 3 W MP.

More interestingly, is the 19.2% improvement seen with the control condition where no treatment was applied. It seems that by attending sessions and being in hospital where patient's complaints are heard and cared for has an impact on how patients' bodies react to no actual treatment. This is possibly an effect mediated by higher centre in the brain. All of this highlights the role that placebo effect plays in patient improvement.

In all experimental conditions, similar to the laboratory trial, the non-treated side has demonstrated changes that mirrored the changes in the treated side with effects that are smaller in effect and are lost once the PSWT machine is turned off.

Based on the findings of this work, the null hypothesis of the high dose was rejected, the null hypothesis of the low dose was rejected, the null hypothesis of the effect of treatment on the non-treated side was rejected and only the null hypothesis on CorT and PulsR were supported.

10.7 CONCLUSION

The clinical study examined the effect of applying PSWT at 3W and 24W MP to patients with OA knees. The effect of PSWT was examined in single blinded placebo controlled trial. It was found that both power levels led to an improvement in the measured variables (BVol, SkT, and NCV). The high dose led to improvement in the general status of the patients (decrease in the pain level, increase in muscle strength and increase in ROM). The placebo group demonstrated changes that were similar to the low dose outcome.

Findings provide support to the positive effects associated with applying PSWT to patients with OA knee. Further detailed evaluation to the longer term effects of the measured variables needs to be undertaken. Future trials need to relate the duration of the disease and the severity of the symptoms with the response to the treatment.

CHAPTER 11

GENERAL DISCUSSION AND CONCLUSION

11.0 INTRODUCTION

PSWT is one of the most commonly used electrotherapy modalities among physiotherapists. Recent surveys have shown it to be one of the top three electro-physical modalities employed in outpatients clinics in England and Ireland (Foster et al, 1999). It has been used for decades to manage a myriad of conditions such as wound healing, arthropathies, and nerve regeneration (Low and Reed, 2000). Despite the relatively long history of PSWT use, very little is known about its bio-effects and mechanism of action. It is argued that the increase in tissue temperature is the main factor responsible for the biological reactions observed such as the increase in blood flow, dilatation of blood vessels, increase in metabolism rate.

Another area that continues to stir long debates is the unresolved issue about PSWT dosage. Considerable confusion exists between clinicians with respect to the application of PSWT due to the wide range and the variety of methods available for setting the treatment parameters. Literature, contributed very little to resolve this dispute with the majority of the studies failing to report the full profile of the dosage used and the rationale behind it.

The current project was set to explore some of the possible mechanisms of interaction between PSWT and biological systems. Although several attempts to examine the physiological effects of PSWT on SkT and BVol had preceded the current work, two downfalls could be found in the previous work. Firstly: a large number of experiments had focussed on the maximum setting of PSWT machine, a setting that was proved to be thermal, and very few attempts were undertaken to explore other ranges of PSWT dose. Secondly: the majority of the work conducted to-date was based on investigator's intuition and arbitrary choices of dosage with no rational given for the choice of the experimental protocol.

With therapists increasingly moving towards applying lower levels of energy and preferring athermal to thermal modes of treatments (Watson, 2000; Kitchen, 1995b), PSWT has become a widely used modality being employed clinically more than CSWD (Shields, 2003; Kitchen, 1995b). Surveys have confirmed it to be one of the top three electrotherapy modalities used in physiotherapy after US and IFC (Foster et al, 1999; Pope et al, 1995). Despite this popularity, PSWT remains an under-explored therapeutic modality (Pope et al, 1995) and the one with least paid attention in terms of researching its efficacy (Kitchen, 1995a).

The literature reviewed (Chapter 3 and Chapter 4) has demonstrated that the majority of laboratory and clinical studies on PSWT were of poor quality, lacking crucial information on treatment parameters, sufficient information on the inclusion/ exclusion criteria, blinding and statistical analysis making them of limited clinical value. Furthermore, almost all the studies have employed treatment doses that were chosen arbitrary without any justification given for their choice.

This research program was planned with PSWT efficacy being the main focus. In order to examine this, a series of experimental protocols were developed and executed. The program started with an audit (Chapter 5) that gave an overview on the nature of use, the documented evidence on PSWT efficacy as could be ascertained from therapists' notes, and the quality of the therapists' documentary skills with regard to PSWT. The audit was used to define areas in clinical practice that needed further exploration. It was also used to define the content of the questions that were later used in the survey (Chapter 6). The nationwide survey involved a wider sample and a broader base of information such as techniques employed by therapists when using PSWT, their general use, treatment progression and termination. The questionnaire also contained case studies on OA for therapists to construct treatment plans. These proposed plans

were the basis of choice of the treatment parameters that were later employed in the controlled randomised laboratory trial (Chapter 9). The evolution of experimentation from laboratories to clinical settings is expected to move the research to a new and better status in terms of the nature of evidence, hence enriching practice and improving the nature of patient care. Given this, a controlled randomised trial was conducted on patients with OA (Chapter 10) following the same protocol used in the laboratory experiment.

This chapter will summarise the previous chapters; it will bring the main findings of different chapters together and present the wider picture of the research, its clinical implication and areas for future research.

11.1 AUDIT

Published reports have examined therapist documentation in general however, no work have been identified to date that examined the quality of therapists' documentations in outpatient clinics with regards to PSWT, hence the importance of the current audit. A number of interesting findings have emerged from this audit. The audit was conducted in 8 randomly chosen hospitals that were selected to represent the clinical practice in all the health regions in England. The audit (Chapter 5) has identified the poor written standards of patient's notes as a priority area that needs to be addressed. It was surprising that from the entire sample of files examined (n=192), none had a complete profile that described treatment according to CSP standards. It has also shown that the amount of documentation is neither complete nor comprehensive and does not convey the nature of care delivered to patients. The standard of the files was not in accordance with CSP recommendation in that they lack crucial information necessary for treatment replication, the problem list, and the time for achieving treatment goals.

Feedback on patient improvement was lacking and progress notes were not always updated with changes in treatment parameters. In the majority of the files examined, it was not clear though why the pre-treatment status of the patients is mentioned in full and very little is reported on the patients after cessation of the treatment with PSWT. In cases when therapists alter the treatment plan, no rationale was given. The arbitrary recording of power levels of a treatment is inadequate in an environment that demands therapist to justify their treatments and rationalise their choices. All of this puts therapists at a disadvantage when it comes to protecting their rights against litigation and providing quality patient care.

Another issue that emerged from the audit was in relation to treatment progression. Three major approaches appear to have been adopted by therapists to progress a treatment plan (therapists either increase, decrease, or leave the dose the same). The majority opted for increasing the dosimetry either by increasing the time or any other parameter on the machine console. Best results were obtained by either increasing the dose or by leaving it the same; the worst results however, were obtained when the dose was decreased (Section 5.5.3).

From the audit it was found that OA was the most common condition seen in outpatient clinics in England, as such it was employed for the paper-based case studies in the survey.

11.2 NATIONWIDE SURVEY

Chapter 6 was a nationwide survey that examined the nature of PSWT usage on a wider sample of physiotherapists (n=247) in 90 randomly selected outpatient clinics across England. Results have shown that pain relief was the main goal for using PSWT, despite the lack of clear documented evidence on PSWT mechanism of action with

pain. It was expected that reduction of bruising, inflammation, oedema or healing of soft tissue to be at the top of the list given the amount of literature that has investigated these conditions.

Another important finding was that a large number of therapists (40%) use PSWT for a duration of 10 minutes while 22% use it for 8 minutes. Experimentation on the other hand, employs treatment of longer durations (15 or sometimes 20 minutes). This mismatch between practice and research findings could be the reason for therapists describing research as alienated and that research findings may not be transferable to clinical setting.

The majority of therapists surveyed (70%) reported that they were satisfied with the outcome of PSWT with their patients, this may have been responsible for the continued use of this modality clinically despite the inconclusive evidence provided by the experimental work in the area.

Combining modalities and interventions have been reported in the literature before (Kitchen, 1995 a,b; Gray et al, 1994). The findings of this work confirmed the belief that using more than one modality will boost the treatment outcome. Such supposition needs to be examined in laboratory and clinical setting to justify its use clinically and mechanism of action. Interestingly, a state of confusion has been detected in the way therapists progress their treatment plan. It is interesting that 57% choose to change all parameters in the same session and only 3% prefer to change PRR, and 2.5% prefer to change PD. The effect of changing one or more parameters has not been discussed sufficiently in the literature and needs to be explored experimentally. The findings have also revealed a mismatch between short and long term goals of treatment with PSWT being believed to restore ROM and improve function.

It is expected that therapists rely on experience to make clinical decisions. In this survey, attempts were made to separate the years since qualification from years therapists spent working in outpatient with electrotherapy in order to identify the effects of experience in the field of electrotherapy on the process of decision making. It is interesting that the years of experience as a whole determines the frequency of applying a modality, treatment progression and termination while the experience in the field of electrotherapy has its impact on the choice of treatment duration and whether to combine modalities or not. These findings are an important part in the clinical decision making process and it is crucial that these issues are explored further as it may shed some light on the reason behind both the poor and the excellent treatment outcomes obtained by therapists when using PSWT.

The theoretical case studies employed in the last section of the questionnaire revealed that both acute and sub-acute conditions are perceived the same hence treated with the same MP. Interestingly, it was found that regardless of the severity of the condition, it would still be treated twice a week, which raises the question of whether this was judged by experience or it was related to patient load and departmental policy.

When the findings from the proposed plans were divided in terms of good and bad outcomes (as reported by therapists) it was interesting to find out that those who reported a good outcome opted to use low dosage with less time for acute and sub-acute conditions. Therapists also tended to increase the dosage and the time for chronic conditions. In contrast, those who reported poor outcome appeared to make no distinction in their choices with different stages of the disease, suggesting that they were not selective in their dosage. This approach to treatment has been discussed earlier in the literature and is bound to occur when clinicians are not sure on the dosage to apply (Kitchen, 1995b).

Based on the most commonly reported responses, it was decided to use PD of 100 μsec, PRR of 200 Hz, MP 3W, and PD of 200 μsec, PRR of 800 Hz, MP 24W as the two treatment protocols for the experimental groups.

It is of interest to mention that with both the audit and the survey, it was found that best outcomes were obtained when the dose was increased to progress the treatment or left the same and the worst results were obtained when the dose was decreased during the sessions. Although electrotherapy textbooks have provided a vague explanation, it is expected that by increasing the dose other levels of the tissues and possibly other structures with different thresholds are overcome hence better results are obtained. However when the dose is left the same the tissues may reach a state of plateau after which no other change can be seen. This may be related to the cumulative effect of the dosage in the tissue that may override tissue thresholds and hence produce improvement (Cleary, 1996).

11.3 LABORATORY TRIAL

The current thesis was undertaken to provide some explanation on the mechanism of action of PSWT. This modality has been accused of being no better than placebo; nevertheless it is still being employed clinically. This raises the question of whether the majority of these trials have missed out on the beneficial effects of PSWT due to the way they have been executed. Almost all studies conducted on PSWT examined modes of treatment and have chosen dosage arbitrarily without justifying the reason underpinning their choices. In an attempt to overcome that, this study derived the dosage from theoretical case studies presented to physiotherapists. OA was chosen as the focus of the case studies being the most commonly seen condition in outpatient

clinics as revealed from the audit. Hence it could be argued that the dose selection in this experimentation was dictated by practice and as such is expected to better inform it.

The pilot experiments undertaken prior to the completion of the laboratory experiments compared two PSWT machines. Although it was not one of the main remits of this thesis to examine differences and similarities between PSWT makes and models, it was a complementary part of the pilot experimental work to conduct a limited comparison between two PSWT makes (Megapulse and Phyaction Performa +). The findings provided evidence that even when two PSWT are set on the same parameters they may exhibit different characteristics. Although these findings need to be elucidated further, their importance is in two areas. Firstly: it is crucial that researchers report the make of the equipment they use in their experimentation as each model and make has its own manufacturing features that may govern its effects. Secondly: it is not wise to use research findings interchangeably as the amount of energy delivered which is one of the main factors in the outcome obtained varies with the machine used.

The laboratory trial has shown that using a MP of 24 W increased BVol in the treated area, raised the temperature of the treated part (2°C) and reduced NCV but not to a statistical significant level when applied for 10 minutes. Low intensity PSWT (3W) on the other hand, was found to increase the amount blood circulating the treated area, resulted in an non-significant increase in SkT (less than 1°C) and did not reduce NCV significantly. Placebo treatment was found to have the same effect as low dose PSWT.

The change in BVol in low and placebo conditions were found to go back to baseline after the PSWT is turned off suggesting that higher levels of energy need to be applied or possibly longer treatment duration in order to allow enough time for the tissues to preserve treatment effects. While none of the above conditions had a

significant effect on CorT or PulsR, the high dose has increased CorT in post treatment period.

One of the aims of this laboratory work was to examine the mechanism of pain reduction associated with the use of PSWT. Unlike other electrotherapy modalities such as TENS, and IFC, PSWT does not stimulate Aβ afferent fibres (Low and Reed, 2000). It was long thought that heat can decrease pain, however the exact mechanism is not yet known. It is believed that heat can stimulate afferent nerve fibres closing down the pain gate (Low and Reed, 2000). It is also believed that heat influences muscle spindles, nerve endings and golgi tendon organs leading to a decrease in gamma afferent activity and a decrease in muscle tone. The increase in BVol means that pain provoking metabolites such as prostaglandins and bradykinins are removed from the tissues hence less pain is experienced (Lehmann and DeLateur, 1990).

An important issue that needs to be standardised with PSWT application is the distance between the treatment head and the treated part. This factor is one of the reasons underpinning different findings when it comes to thermal sensation and other physiological effects. Although the distance between the treatment head and the part treated is very important in treatment outcomes, not enough attention was paid to it. It is not enough to state that the treatment head is held in close proximity to the part treated. There should be guidelines to the distance, should the applicator be touching the part treated or should it not and if not how far should it be. This is an area that urges immediate definition in the literature to ensure safe use and treatment repeatability.

Although laboratory trials on healthy subjects are accused of presenting findings that do not represent patient population and are alienated from the real world, the findings of this work are still important in that they have examined parameters that were

not previously considered in the literature, hence they have provided normative data on physiological reactions.

11.4 CLINICAL TRIAL ON OA PATIENTS

Twenty six patients with OA knees were recruited for the study. In a within subject design each subject was exposed to 4 experimental conditions (high dose, low dose, placebo PSWT, and control) in a random sequence. Both the protocol and the treatment dose were identical to that employed in the laboratory trial. Results have shown that high dose was associated with significant increase in BVol, SkT and a significant reduction in NCV.

Low dose was associated with significant increase in BVol and a significant reduction in NCV but the increase in SkT did not reach statistical significance.

The placebo condition was associated with a significant increase in BVol, a significant decrease in NCV and an increase in SkT which did not reach statistical significance. The control group although have displayed small fluctuations in the values of the variables examined none though reached statistical significance.

These results were associated with significant decrease in pain levels in all the experimental conditions. Only the high dose was associated with a significant increase in apparent muscle strength and ROM. Though not directly related, the improvement in ROM is expected to be secondary to the reduction in pain levels (mean VAS value on baseline 5.438±1.661 mm, mean VAS value with the high dose 3.446±1.755 mm, mean VAS value with the low dose 3.711±2.271 mm). The changes in physiological parameters were associated with an improvement in functional status which was reflected in easier movements and an improvement in the general patient condition compared to when patient first started the sessions. Although the reduction in pain

recorded in this study may have several explanations as explained in the previous section, it may be one of the effects of PSWT that needs further exploration. Interestingly the non-treated side exhibited reactions that mirrored the treated side but to a lesser extent.

PSWT has been accepted to reduce joint stiffness by reducing synovial fluid viscosity (Scott, 2002; Yung et al, 1986) despite the lack of the experimental evidence that supports these claims. The reporting by patients on reduction in joint stiffness and smoother movement experienced after treatment could provide some evidence for the above theories, though experimentation is still needed to validate that.

11.5 PLACEBO EFFECT

Despite the well-established role of placebo in medicine (Biller-Anrorono, 2004; Fuente-Fernandez and Stoessl, 2004), only few controlled clinical trials in physiotherapy have compared various modes of PSWT treatment, evaluated and quantified the size of placebo associated with them. This could be one of the reasons for accepting many of PSWT effects as being only a placebo response (Svarcova et al, 1988). Although the placebo effect was first quantified by Beecher to be 53% (Kienle and Kiene, 2001), this percentage no longer stands, as more recent experimentations have reported the placebo effect to be as high as 70% in some cases (Vase et al, 2002; Gifford, 1998). Kienle and Kiene (2001) refute the above claims and argue that such results lacks evidence of therapeutic effects and studies findings can easily be attributed to methodological flaws. The current study has demonstrated that these non-specific effects (placebo) are measurable change in physiological reactions and symptom behaviour that the author was able to quantify with both placebo and the control group.

The placebo effect is an integral part of treatment with electrotherapy modalities. Over the years therapists were found to use it to increase patient co-operation and satisfaction (Kitchen, 1995b). The survey conducted by the author has also demonstrated that some therapists use PSWT as a placebo modality. With placebo treatment PSWT resulting in 39% improvement (as found in the current study) its impact on the outcome cannot be ignored.

It is interesting that low intensity PSWT was no better than placebo when applied to healthy subjects however when patients were involved, low intensity was shown to result in a significant change in many of the variables examined. Although the reason is unclear it could be because that lower thresholds increased sensitivity of patient's systems making their tissues more sensitive to exogenous energy compared to healthy subjects (Bricknell and Watson, 1995). Another reason could be the long history of pain makes patients believe in whatever modality applied to them and believe in its efficacy.

11.6 COMPARISON BETWEEN HEALTHY AND PATIENT POPULATION RESPONSE TO TREATMENT

Several studies have shown that PSWT is no better than placebo (Klaber-Moffett et al 1996; Quirk et al, 1985) and others have shown that it resulted in outcomes that are better than placebo (Gray et al, 1994; Comorosan et al, 1993; McGill, 1988; Barker et al, 1985; Wilson, 1972). The current study concurs with all of those studies in that it is the amount of energy delivered to the tissues and the type of tissue treated are two determining factors for the outcome. PSWT could result in outcomes that are similar to placebo if the dose was insufficient to trigger a physiological reaction; however when this threshold is overcome the outcome was

found to be significantly superior to placebo. All of this provides evidence on the existence of a window effect. The work conducted in this research program demonstrates that the MP is one of the factors affecting outcome. The treatment time is another important factor as it could increase or decrease the net energy delivered to the tissues.

Comparison of the outcome from the laboratory and clinical trials is presented in Tables (11.1-11.4). From the tables and the data presented in Chapter 9 and 10 it could be seen that in the laboratory trial there was a significant increase in the high dose in BVol for "before treatment" vs "during treatment" (p=0.033), and an associated increase in SkT (p=0.000). With the low dose there was a significant increase in BVol in the "before treatment" vs "during treatment" (p=0.042).

In the clinical trial, with the high dose there was an increase in BVol in the "before treatment" vs "after treatment" (p=0.000) and "before treatment" vs "during treatment" (p=0.007), there was an associated increase in SkT (p=0.000), and a reduction in NCV (p=0.000). The low dose has increased BVol in the "before treatment" vs "after treatment" (p=0.000) and "before treatment" vs "during treatment" (p=0.002), decreased NCV (p=0.000). The placebo PSWT has only increased BVol in the "before treatment" vs "after treatment" (p=0.024) and "before treatment" vs "during treatment" (p=0.003) and did not affect other parameters.

By employing a same subject design, subjects acted as their own controls hence minimized individual variations between groups. Treatments were also randomised to overcome the effect of order on the outcome (Hicks, 1999).

		Healthy (treated)			OA (treated)		
		Before	**During**	**After**	**Before**	**During**	**After**
Blood volume (arbitrary units)	High	30.709±11.985	134.223±71.309	74.937±56.316	27.742±17.653	220.743±68.750	71.171±39.868
	Low	20.210±9.894	74.566±50.238	38.852±24.169	24.590±20.083	108.469±55.444	57.218±32.993
	Placebo	27.107±19.005	63.327±38.745	37.652±31.434	30.142±17.806	76.895±29.303	56.702±25.624
Skin temperature (°C)	High	26.758±1.372		28.710±1.143	28.974±1.743		31.048±1.667
	Low	27.495±1.233		27.830±1.176	27.955±1.432		28.369±1.471
	Placebo	27.647±1.236		27.626±1.310	28.444±1.410		28.414±1.391
NCV (m/sec)	High	51.828±2.838		49.278±3.135	53.659±1.876		50.227±4.147
	Low	52.076±2.949		51.309±2.891	53.885±2.140		50.848±4.122
	Placebo	51.755±3.161		52.317±3.695	53.433±1.969		52.024±4.740

Table (11.1) Summary of mean changes in BVol, SkT and NCV in treated side across the experimental conditions

		Healthy (non treated)			OA (non treated)		
		Before	**During**	**After**	**Before**	**During**	**After**
Blood volume (arbitrary units)	High	24.944±10.424	115.993±49.094	23.121±12.821	23.303±13.895	69.252±43.607	43.161±33.087
	Low	24.127±9.710	36.300±13.450	27.954±14.142	24.683±17.802	55.107±26.249	37.916±22.500
	Placebo	25.457±15.510	68.734±41.914	31.395±18.712	23.016±11.856	54.040±22.738	32.627±15.553
Skin temperature (°C)	High	27.155±1.365		27.601±.990	28.931±1.689		29.281±1.737
	Low	28.135±1.366		28.009±1.134	28.397±1.541		28.492±1.582
	Placebo	28.448±1.233		28.498±1.257	28.623±1.159		28.599±1.212
NCV (m/sec)	High	51.668±2.859		50.581±3.407	54.159±1.763		51.847±2.760
	Low	51.893±2.938		51.770±3.226	53.922±2.073		52.017±2.920
	Placebo	51.666±2.963		51.738±2.974	53.968±2.036		54.093±2.169

Table (11.2) Summary of mean changes in BVol, SkT and NCV in non treated side across the experimental conditions

		Laboratory trial			Hospital trial		
		Before	**During**	**After**	**Before**	**During**	**After**
Pulse rate (bpm)	High	69.216±11.699	68.900±11.429	68.940±10.75	66.807±13.070	66.807±13.070	66.807±13.070
	Low	68.372±13.937	69.203±13.426	69.226±13.201	68.034±13.163	68.034±13.163	68.034±13.163
	Placebo	68.230±13.696	68.193±14.086	69.183±14.204	67.753±12.436	67.753±12.436	67.753±12.436
Core temperature (°C)	High	34.763±0.514	34.761±0.396	34.795±0.433	34.942±.524	34.942±.524	34.942±.524
	Low	34.810±0.346	34.918±0.294	35.002±0.386	34.900±.423	34.900±.423	34.900±.423
	Placebo	34.862±0.336	34.951±0.354	34.948±0.338	34.943±.491	34.943±.491	34.943±.491

Table (11.3) Summary of PulsR and CorT across the experimental conditions

		Healthy subjects	OA patients
Blood	High	Significant increase in blood volume in "during treatment" period, effect of treatment decreased in the "post treatment" period but remained to be significant	Significant increase in blood volume "during treatment" and "post treatment"
	Low	Significant increase in blood volume "during treatment" and effect was lost after termination of PSWT, values returned to baseline reading	Significant increase in blood volume in the "during treatment" period and post treatment period
	Placebo	Significant increase in blood volume "during treatment" and the effect was lost after termination of PSWT, values returned to baseline reading	Significant increase in blood volume in the "during treatment" and "post treatment" period
Skin temperature	High	Significant increase in skin temperature	Significant increase in skin temperature after treatment
	Low	Change in temperature was not significant	Change in temperature was not significant
	Placebo	Change in temperature was not significant	Change in temperature was not significant
NCV	High	Change was not significant	Significant decrease in NCV post treatment
	Low	Change was not significant	Significant decrease in NCV post treatment
	Placebo	Change was not significant	Non significant decrease in NCV post treatment
Pulse rate	High	Change was not significant	Change was not significant
	Low	Change was not significant	Change was not significant
	Placebo	Change was not significant	Change was not significant
Core temperature	High	Change was not significant	Change was not significant
	Low	Change was not significant	Change was not significant
	Placebo	Change was not significant	Change was not significant
Age	Correlations	Age was correlated with pulse rate	No correlation
Height		Height was correlated with changes in blood volume	No correlation
Weight		No correlation	Weight was significant with the change in skin temperature
Fat %		Fat % was correlated with pulse	No correlation

Table (11.4) Summary of the changes in the variables examined in both laboratory and clinical trial

It is expected that with the increase in tissue temperature which reached 2°C with the high dose in both the healthy and patient population, there might have been a production of a histamine like substance, stimulation of sensory cutaneous nerve endings and the release of mediators by both axon reflex and local spinal cord reflex, all of which results in vasodilatation. Heat is also expected to increase metabolic rate, enhance cellular activity and increase chemical reactions as such result in efficient muscle contractions (Lehmann and DeLateur, 1990).

Results from both trials have demonstrated that the greatest increase in blood flow was observed during the treatment. However, due to the warming up of the temperature thermistor during PSWT and for safety issues, it was decided to measure change in SkT post treatment only. It is expected that the changes in SkT would be the highest during treatment and to decline post treatment as was shown with BVol measurements.

Similar to other studies (Cramp et al, 2001; Kurvers et al, 1997), the current study has shown that a significant increase in BVol is not always associated with a significant increase in SkT which could suggest that thermal build up and dilatation of blood vessels are not the only mechanism of PSWT action. It is of interest that the magnitude of the reaction measured is proportional to the amount of energy delivered as such greater responses are recorded with high dose followed by the low dose.

The results from both trials where further analysed to examine whether the difference was statistically significant using unrelated t-test. The findings were analysed in terms of the during and after treatment data and the magnitude of change for the during (during-before values), and after (after–before values) treatment periods. Findings show that the change in the during period was significant with the high, and low dose with blood volume data. The after results were significant with low dose and

the placebo condition. The magnitude of change for the during-before period however, was significant with the high, and low dose.

Skin temperature data were significant for the period after treatment with the high, low and placebo, however the magnitude of change was not significant.

With NCV results the magnitude of change after treatment was significant with low dose only. Findings are displayed in Tables (11.5-11.7).

			Laboratory (High dose)							
			Blood volume				Skin temperature		Nerve conduction	
			During	During-Before	After	After-Before	After	After-Before	After	After-Before
Clinical trial	Blood volume	During	*p*=.000 df= 54 t=.744							
		During-Before		*p*=.000 df=54 t=-4.693						
		After			*p*=.777 df=54 t=.285					
		After-before				*p*=.952 df=54 t=.061				
	Skin temperature	After					*p*=.000 df=43.349 t=-6.029			
		After-before						*p*=.636 df=52.289 t=-.477		
	Nerve conduction	After							*p*=.238 df=53 t=-1.195	
		After-before								*p*=.419 df=53 t=.818

Table (11.5) Summary of t-test results with blood volume with high, significant results are highlighted in red

			Laboratory (Low dose)							
			Blood volume				Skin temperature		Nerve conduction	
			During	During-Before	After	After-Before	After	After-Before	After	After-Before
Clinical trial	Blood volume	During	p=0.20 df= 54 t=-2.400							
		During-Before		p=0.024 df=54 t=-2.323						
		After			p=0.023 df=45.227 t=-2.345					
		After-before				p=0.034 df=54 t=-2.175				
	Skin temperature	After					p=0.134 df=54 t=-1.520			
		After-before						p=0.642 df=54 t=-0.468		
	Nerve conduction	After							p=0.691 df=53 t=0.400	
		After-before								p=0.009 df=32.672 t=2.760

Table (11.6) Summary of t-tests results of low dose, significant result are highlighted in red

			Laboratory (Placebo dose)							
			Blood volume				Skin temperature		Nerve conduction	
			During	During-Before	After	After-Before	After	After-Before	After	After-Before
Clinical trial	Blood volume	During	p=0.153 df= 54 t=-1.448							
		During-Before		p=.195 df=54 t=-1.311						
		After			p=.018 df=54 t=-2.444					
		After-before				p=.006 df=54 t=-2.874				
	Skin temperature	After					p=.034 df=54 t=-2.176			
		After-before						p=.949 df=54 t=.064		
	Nerve conduction	After							p=.677 df=53 t=.419	
		After-before								p=.056 df=53 t=1.951

Table (11.7) Summary of t-test for placebo condition, significant results are highlighted in red

11.7 WINDOWS OF EFFECTIVENESS

The concept of windows of effectiveness has been discussed previously in the literature (Section 2.4.1). According to this concept the different carrying frequencies of EMF if applied at certain intensities could affect different target tissues (Trock, 2000). It is expected that outside these frequencies (intensities) the energy delivered will lack effects to trigger physiological reactions (Watson, 2000) because it is believed that cells can only absorb energy in narrow windows (Charman, 1990). Windows have been discussed in terms of time, intensity, amplitude, and energy (Trock, 2000; Cleary, 1996). Transferring this concept to PSWT, some have argued the existence of an amplitude window that requires pulses of certain shapes and frequencies (Low, 1995). It could be also argued that as the carrying frequency of therapeutic PSWT is fixed at 27.12 MHz (though not the only frequency for PSWT, but the widely used), there could exist a time and an amplitude window. The time window means that positive reactions to treatment could occur at certain durations of exposure while the amplitude window is dependent on how high or how low the pulse frequency and duration are being set. Both time and amplitude contribute to the total energy delivered to the tissues, therefore it could be debated that it is a window of energy with PSWT rather than multiple of windows (Figure 11.1).

Unpublished work by Watson and Evans (www.electrotherapy.org), and Wagstaff et al (1986) have demonstrated that manipulating the treatment parameters while stabilising MP have resulted in same outcomes. This was also confirmed by laboratory experiments by Hill et al (2001) on human fibroblasts. Though it needs further validation, it could be debated that it is the MP rather than individual parameters that could alter outcome.

However, the problem with such concept is that it is not yet clear whether the MP delivered from PSWT that have PP of 150W would be interchangeable with MP with PSWT machine with PP of 1000W for example. This area still lacks exploration and intensive investigation as to whether MP between PSWT of different makes can be used interchangeably. Finding the answer to such notions would save a lot of researchers' time and unify their efforts instead of working in tangents with little benefit.

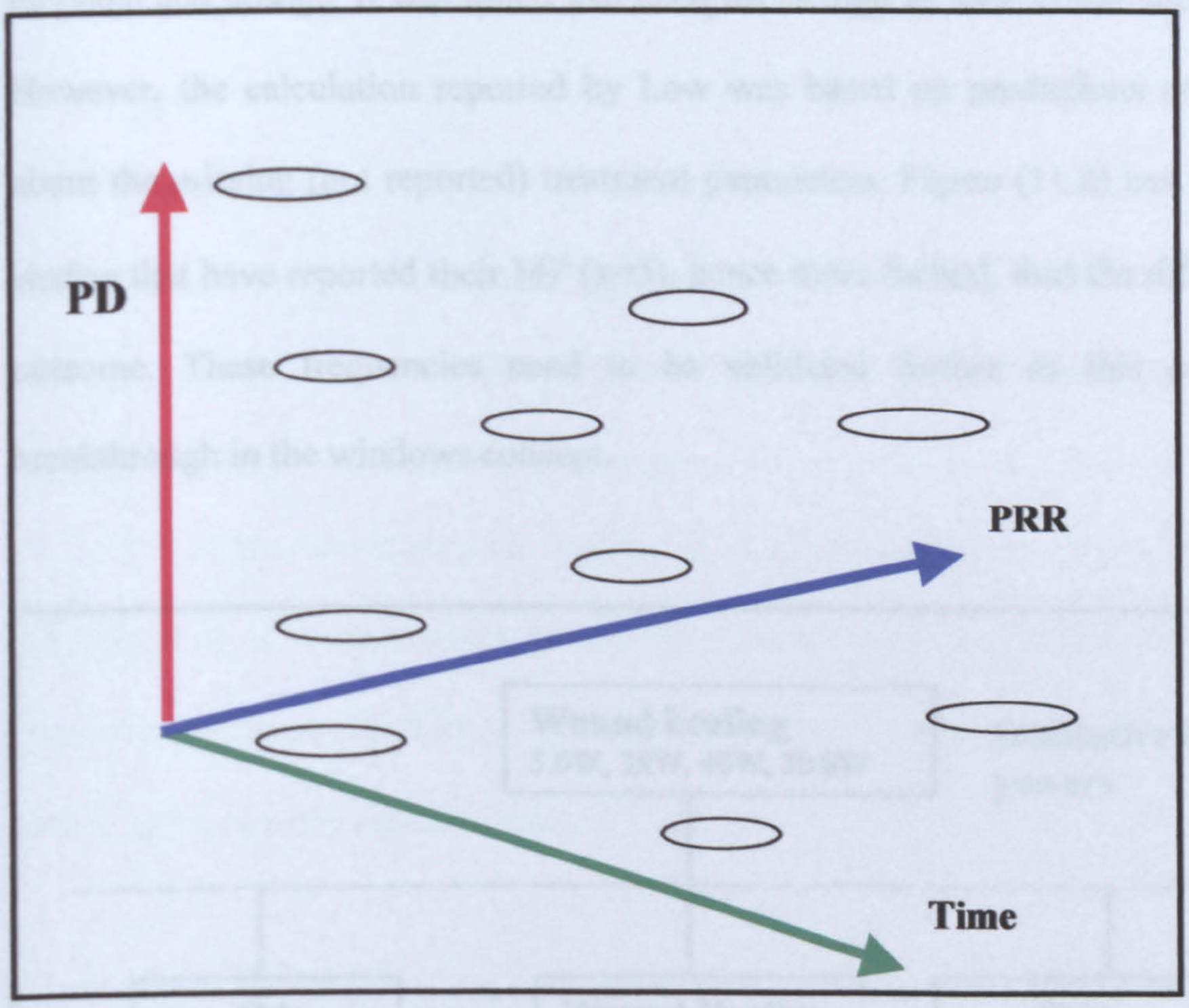

Figure (11.1) The concept of windows with PSWT

It was suggested in the literature that increasing numbers of therapists are moving towards using low doses of energy to achieve therapeutic effects (Watson, 2000) possibly because of the belief that lower levels of energy are expected to trigger physiological reactions with minimal side effects (Low and Reed, 2000). These were

only assumptions mostly based on individual observations with minimal investigations perused.

Interesting findings have emerged from reviewing the literature along with the findings from this research program. All the work that has been conducted on MP ranging between 23-29W has been shown to be beneficial clinically (Figure 11.2). Mean powers outside these ranges were either ineffective or no better than placebo treatments. Low (1995) has also attempted to collate studies' findings to find out common trends in outcome and dosage. It was found that energies as high as 38W could also be effective. However, the calculation reported by Low was based on predictions or assumptions about the missing (not reported) treatment parameters. Figure (11.2) has only included studies that have reported their MP (n=5), hence more factual, thus the difference in the outcome. These frequencies need to be validated further as this could mean a breakthrough in the windows concept.

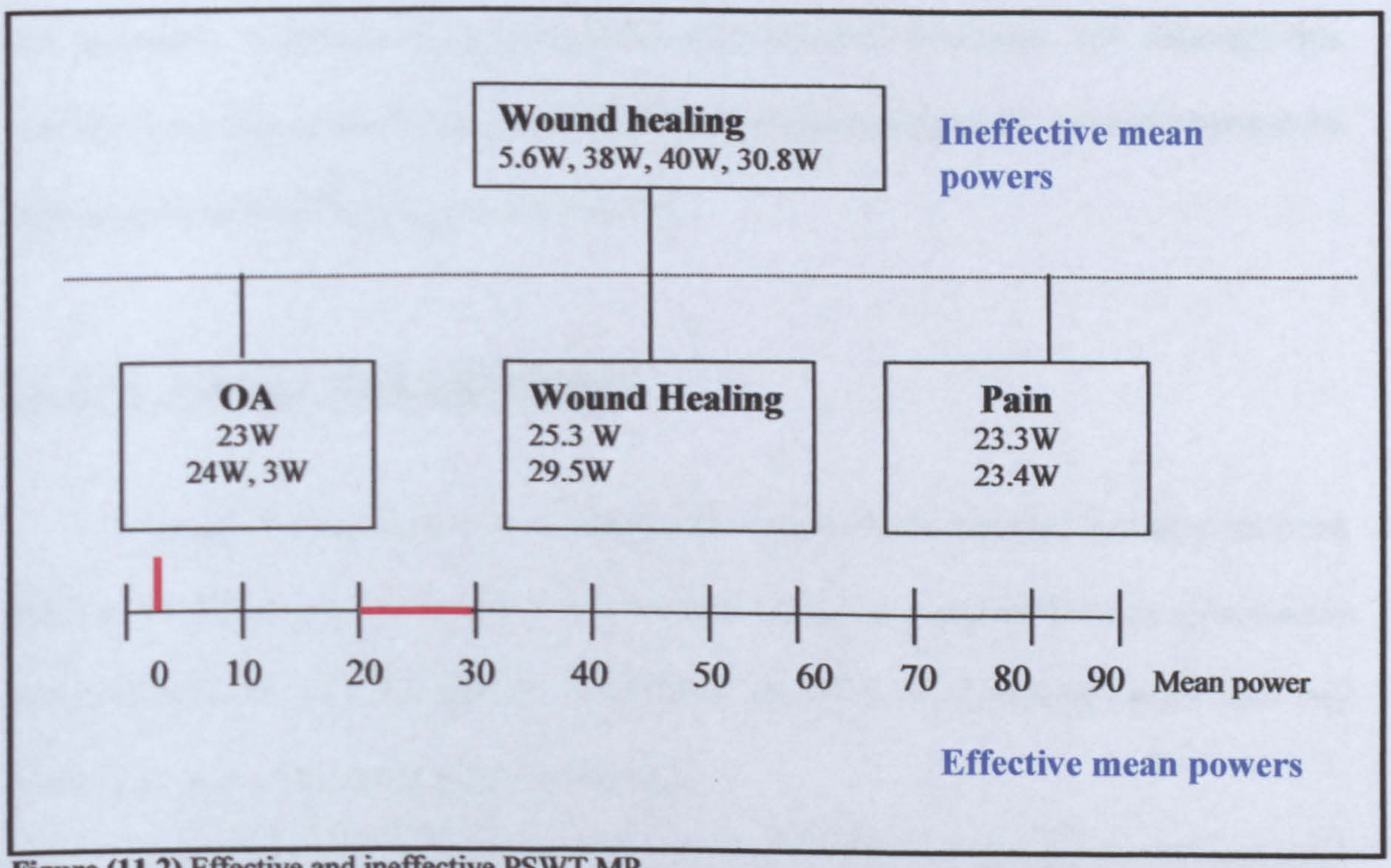

Figure (11.2) Effective and ineffective PSWT MP

The point to consider is that only the studies that have been conducted on pathological conditions or have mentioned their MP are included in the above Figure. There are other studies that were not included due to absence of full reporting. Studies that have been conducted on physiological parameters and have demonstrated positive outcomes were not included as it was unwise to extrapolate that they would be of therapeutic value just because they were able to increase the amount of circulating blood or increase tissue temperature.

As argued by Watson (2000) the window effect is dependent on the sensitivity of the tissues. Acute tissues are more sensitive than chronic tissues, which are more sensitive than healthy tissues. This is an assumption that has never been examined experimentally before. The current study was one of the first attempts to demonstrate by delivering the same amount of energy to healthy and patient population that diseased tissues are indeed more sensitive to energy.

All of the above suggest that power needs to be specific to provoke particular cell response, it remain to be theoretical with minimal evidence, and although this concept is starting to be the driving thought for many investigations, attempts need to be both at cell and pathological condition level.

11.8 CLINICAL IMPLICATION

In order for research to be informative, it needs to be focused and derived from practice as with the work at hand. The current work has revealed crucial information about the nature of clinical practice with PSWT. Issues such as documentation were one of the main areas that needed urgent attention.

Additionally, in a nation that is partly dependent on electrotherapy (Murphy, 1993) it becomes crucial that various modes of application be validated for efficacy.

Although the use of both 3W and 24W was employed clinically, the current work is one of the few if not the only one that has attempted to validate these modes with both healthy and patient populations.

The findings of the experimental work have demonstrated that similar amounts of energy could result in different outcomes when applied to healthy and patients' population. The findings provide evidence for the claim that healthy subjects and patients do not respond similarly to interventions. The findings of the current study clearly indicate that the non-significant results reported by the majority of the studies could be caused by the nature of the sample. Healthy tissues could have higher thresholds hence require higher levels and possibly greater intensities to achieve statistically significant results. Similar findings to the present work have been demonstrated by Ek et al (1985) although was done on the effects of massage, their findings concur with the current study that patients react differently to healthy subjects. Hitherto, given that PSWT was intended to be used with patient populations, its physiological and therapeutic effects should be examined on the intended population to facilitate extrapolation of results.

Half the sample in the clinical trial has demonstrated a 10 fold measured increase in BVol with 24W, these findings could carry clinical implication. In cases where swelling or haematoma are present, this dose should not be used as it may exacerbate the symptoms by dilating blood vessels and increasing the amount of interstitial fluid. The significant increase in BVol demonstrated in the radiated area could mean that PSWT can be used in musculoskeletal treatment and wound healing to aid the removal of toxins and exudates from the injured site.

The mechanism of the increase in BVol was seen to be mediated by the increase in heat with the high dose. It is not clear though how the increase in BVol was achieved

when the increase in temperature was only 0.5°C (low dose). Such findings may suggest a microthermal mechanism that warrants further research.

With a measured increase of 2°C, the high dose is considered a thermal mode of PSWT. Care should be taken when using it with patients due to the detrimental effect it may have on treatment outcome when used with conditions such as RA or OA or soft tissue inflammation, where slight increase in temperature may exacerbate the symptoms (Hosie and Dickson, 2000).

Prentice and Draper (2001) argue that an increase of around 1°C is useful for mild inflammation, and an increase between 2-3°C is helpful in reducing pain and muscle spasm whereas an increase of 3-4°C is necessary to cause tissue extensibility. If these assumptions are based on experimentation, this could mean that the use of 24W for 10 minutes could be useful in reducing pain and the use of 3W is useful in reducing inflammation. These notions remain to be theories until validated.

Given that different combinations of PSWT result in same findings if the MP was kept the same (Hill et al, 2001; Wagstaff et al 1986) it could be argued that the findings of the current work can be extrapolated to all combination of Megapulse that result in either 3 or 24W. The next step is to examine whether MP from different PSWT makes can be used interchangeably as this will help reduce the confusion in the literature.

The fact that patients experienced symptom relief that lasted for a day and returned the following day has implications for planning follow up sessions. Based on these findings sessions should be given either daily or every other day for best results. The reporting that PSWT helps relieve stiffness is crucial in helping therapists decide the proper modality to use when faced with such complaint. Hence the results of the

current work are crucial in helping therapists reach a clinical decision when it comes to PSWT efficacy.

It is surprising that both the audit (Chapter 5) and the questionnaire (Chapter 6) have shown that only a small proportion of physiotherapists use PSWT for 20 minutes and the majority use it for 10 minutes or 15 minutes. The experimental literature however is conducting the majority of research with 20 minutes. Furthermore, based on the survey findings, only 4.7% applied PSWT 3 times a week, while the majority of the studies administer and examine the effect of PSWT treatments when applied 3 times a week. These are areas of mismatch and where the research does not reflect the clinical needs and hence not necessarily informs practice. This gap between theory and practice need to be reduced and one of the ways forward is a collaborative approach between academics (with their research experience) and clinicians (facing the clinical problems) to identify both the literature and the clinical gaps. Instead of working in isolation and adding more to the state of literature confusion. Working together could improve the state and the nature of the evidence.

Based on the outcome of this research program, some key guidelines can be put forward that could improve the quality of the care delivered to patients:

- Files need to be comprehensive in terms of the amount of information documented. All files need to contain information on the type of equipment used, MP, PP, PD, PRR, patient position, patient consent, type of electrode, and treatment time to facilitate reproducibility of treatment.
- Patients files need to be updated regularly with changes in treatment plan with rationale for any change undertaken.

- Progression of treatment dose should involve change of one parameter in order to know which variable had brought about the improvement or the deterioration
- MP of 3W and MP of 24W were found to be effective with OA patients in terms of increasing blood volume, increasing skin temperature and reducing NCV. The recorded changes observed in the physiological parameters have manifested themselves in the reduction of pain felt in the knee joint, and the reported smoothness of movement felt by the patients when ascending and descending the stairs.
- The application of 24W was associated with 2°C increase in skin temperature as such is expected to exacerbate symptoms when diseases such as RA or OA are in the active stage and the inflammation is in progress. PSWT application in these circumstances should therefore be avoided.
- Based on patients reporting it was found that PSWT was an effective electrophysiological modality in reducing joint stiffness.
- The dose delivered in the clinical trial (100μsec, 200 Hz, 10 min, 3W and 200μsec, 800 Hz, 10 min, 24W) resulted in a decrease in patients' symptoms that lasted for a day. This could mean that treatments need to be delivered either daily or every other day to maintain the accumulative effect of the treatment.

11.9 CONCLUSION

Throughout this experimental programme the question of PSWT efficacy was the focal point. All the experiments conducted contributed to the understanding of the nature of the clinical use of PSWT and its mechanism of action, as such have fulfilled the main aims.

Novelty in this project could be seen in employing a qualitative approach to explore practice and derive the experimentation protocol. This was done, as it is expected that there are many treatments that have been developed by physiotherapists (either by experience or by trial and error) throughout the years that lack evidence of effectiveness. Hence by developing protocols based on clinical practice the findings are expected to be more informative, instead of experimenting on arbitrary doses and imposing findings upon clinicians. As such the current work has subjected clinical practice to validation.

The project conveyed the nature of practice and use with therapists' common beliefs on PSWT. It has examined and compared the outcome of high and low doses of PSWT in a controlled blinded study. Another unique feature of the current experimental work was the examination of NCV, an area that has hardly received any attention with PSWT. Moreover, by replicating the same experimental protocol with patients in the clinical setting, this project is a step forward in the direction of a comprehensive understanding to the interaction between EMF at the frequency of 27.12 MHz with both healthy and diseased tissue. Moreover, this study is one of the very few if not the only one, which quantified the effect of placebo, associated with PSWT application and confirmed it with physiological measurements.

The findings of the current work, whether presented positive or negative outcomes, have presented some kind of evidence on the window effect. The work conducted on the frequency of 27.12 MHz and the current work suggested that this frequency holds promises for therapeutic efficacy. Although the ongoing challenge is to establish the precise dosimetry capable of initiating the healing process, the findings of the current work has shown that both low intensity (3W) and high intensity (24W) PSWT are effective in altering physiological responses in healthy and OA population.

Additionally, by basing the laboratory experiment on the findings of a nationwide survey it is expected that the findings will be of value to a wide sector of clinicians in the process of clinical decision-making. Moreover, by replicating the laboratory experiment in the clinical setting, it is expected that the current work have bridged the divide between theory, laboratory, and clinical environment and with this research tackling areas that were not examined thoroughly the findings of the present research extends the existing knowledge and contributes significantly to the literature on PSWT.

11.10 LIMITATION OF THE STUDY

- Although it is acknowledged that blinding the investigator when collecting the data reduces bias, this was difficult to achieve in both the laboratory and the clinical trial due to the nature and the complexity of the data acquisition system. However, given the time it would take to train another investigator and the limited resources, blinding of the investigator was accepted as a limitation to the current study.
- Due to the warming up of the temperature sensors the decision was made to take measurement post treatment only. There might have been a significant increase in SkT during PSWT application as was measured with BVol, and this may have been missed as result of that. This problem can be avoided in the future by using heat resistant thermocouples.
- Although PPG electrodes can be used on any tissue bearing blood (according to the manufacturer), its ability to function maximally is dictated by the area sampled. The beds of fingers and toes are known to have areas rich in arteriovenous anastomsis (Lindberg and Oberg, 1991) hence are the best places

for measuring BVol. However, because toes were not shown to display a similar reaction to treatment as the area under the treatment head it was decided to measure from anterior knee and bear in mind its limitation.

- The environment where the experiments were conducted (whether it was the laboratory or the hospital) was not thermostatically controlled. Nevertheless attempts were taken to limit the effect of temperature fluctuation on the outcome. This point needs to be taken into consideration when conducting or comparing laboratory trials to clinical trials.
- The values obtained with PPG are dependent on the pressure of the probe against the skin as this could increase or decrease the amount of light reflected and absorbed by the probe. Although all attempts were made to standardise that, it is necessary to acknowledge that there could be slight differences between individuals, which might have affected the results.

11.11 AREAS FOR FUTURE INVESTIGATIONS

Future research will be presented in two sections; those that emerged from reviewing the literature and those that stemmed from the direct results of the current investigations

Future research based on the literature reviewed

- Whilst much experimentation has been done on OA knees, a very limited number of trials have examined the role of various electrotherapy modalities on OA hip.
- Literature has shown promising results with the use of portable EMF equipment in treatment of oedema, wound healing and fracture, these types of equipment

are rarely used in physiotherapy. Further exploration to the possibility of using them could save therapist time, as they do not require that the patient attend as frequently to the hospital.

- Hepatic applications have been shown to result in beneficial effects on PSWT outcomes. This area warrants further exploration whether clinically or in the laboratory setting.
- There is a need to develop an instrument that could be worn by therapists and is capable of measuring the duration and the extent of exposure to EMR. With such device it is possible to limit unwanted exposure and quantify the actual risk associated with the use PSWT.

Future research based on the current research program

- The literature reviewed has discussed the possibility of the latent effects of RF at a frequency of 27.12 MHz to last up to 4 days, the patients in this trial reported that the symptom relief lasted for a day. This observation warrants further investigation. Such findings could be of great importance to clinicians for better planning of follow up treatments.
- The issue of written against oral consent need to be explored further with regard to electrotherapy and possibly link that with actual incidents to investigate whether there is a real need for a written consent or is it enough to obtain an oral consent. A retrospective study that looks into the cases of litigation against therapists would be interesting and of vital importance.
- Exploration to the optimal approach to progress treatment plans need to be undertaken. The current work has shown that increasing the dose results in better outcomes when compared to reducing it. The work should also explore what

parameters need to be manipulated to obtain the best results. Although this issue has been discussed in the literature, claims were not based on experimentation.

- More research needs to be conducted to explore whether MP value is interchangeable between PSWT machines of different makes. This aspect of research is very important to reduce the state of confusion and unify researchers' efforts.
- The current work has shown that PSWT reduces pain, the mechanism underlying these observations need to be examined in further experimentations.
- PSWT was shown to decrease stiffness and according to patients' reports it helped them move easier. There is no identified work that examined the effect of PSWT on stiffness, an area that warrants further experimentation.

CHAPTER 12

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APPENDICES

APPENDIX A.1

LETTER TO PHYSIOTHERAPY DEPARTMENT MANAGERS

Dear
Date / /

My name is Maryam Almandil, and I am a physiotherapy PhD student from University of Hertfordshire. I am undertaking a research program on the effectiveness of Pulsed Short Wave Therapy.

As part of my structured research program I am evaluating therapists documentation with regard to Pulsed Short Wave Therapy. Eight hospitals have been chosen randomly to represent the clinical practice in the eight health regions. The protocol of the investigation has been approved by the Ethical Committee of Radiology and Physiotherapy in University of Hertfordshire.

The study will involve a visit from me to your premises, where I will look through the files and examine them in terms of quality and content. It is expected that my presence will not cause any disturbance to the course of the work in your department.

The information collected will be treated with strict confidentiality. No information will be reported that would disclose the hospital, therapists or patient identity.

This letter is to inform you that your hospital is one of those chosen to be in my investigation. If you have no objection on the purpose of the study I would be very grateful if you could decide on a date when I can visit your department. However, if you think that my visit is not possible in the time being, please accept my apology for the inconvenience and thank you for your time.

For further information please do not hesitate to contact me on the address below.

Yours truly,
Maryam Almandil

University of Hertfordshire
Department of Physiotherapy
Hatfield campus
College Lane
Hatfield Herts
AL10 9AB
Or call at 01707 284000 Ext 2054
e-mail: almary22@hotmail.com

APPENDIX A.2

DATA COLLECTION FORM FOR AUDIT

Name of authority:
Name of region:
Name of hospital: Code of the hospital:
Type of PSWT equipment:
No of files examined: No of patients treated with PSWT in the department:

No	Age	Condition	PSWT parameters	ttt time	Frequency of sessions	Outcome	Remarks

APPENDIX A.3

ETHICAL APPROVAL FOR AUDIT

ETHICS COMMITTEE OF THE DEPARTMENTS OF RADIOGRAPHY AND PHYSIOTHERAPY

Radiography/Physiotherapy
(delete as necessary)

Protocol Number:	RPEC.100.2.01
Name of Investigator:	Maryam Almandil
Name of Supervisor:	Tim Watson
Title of Study:	An Audit to Investigate Physiotherapy Practice with Pulsed Short Wave Diathermy (PSWD).
Dates of Study:	Academic Year 2000/01
No. of Subjects:	N/A

1) I support the approval of the study without pre conditions. YES ✔

2) I support the approval of the study, subject to the following:

   a) essential pre conditions which will affect the granting of approval:

   b) general recommendations and comments which will **not** affect approval:

3) I do **NOT** support approval of the study for the following reasons:

Signature Janet High Date: 22/02/01
Chair of Ethics Committee

RPEC.100.2.01
(JDN.20.2.01)

APPENDIX A.4

CONSENT FORM FOR PHYSIOTHERAPY MANAGERS

I..... (Name)

.....(Position)

Health Region:.....

Health authority:.....

Acknowledge the work carried out by Miss Maryam Almandil as part of her PhD project. I am aware that she will be examining patients' files to gather information on how physiotherapists record their practice with Pulsed Short Wave Therapy. I also acknowledge that confidentiality will be maintained and no hospital, patient or therapist name will be included in the reporting of the final results.

I appreciate that contributing to such a study will enrich physiotherapy knowledge base and hopefully result in better patient service.

I hereby give my signature as consent

Signature:.....

Stamp of the department:

APPENDIX B.1

<u>Please use this form to add in any comments or suggestions regarding:</u>

Clarity of questions (wording):

.....
.....
.....
.....

Sequence and ordering of questions:

.....
.....
.....
.....

Layout and presentation:

.....
.....
.....
.....

Length of the questionnaire:

.....
.....
.....
.....

What other questions do you think need to be added to the questionnaire to throw more light on the nature of the clinical use of Pulsed Short Wave Diathermy in outpatient clinics?

.....
.....
.....
.....

APPENDIX B.2

QUESTIONNAIRE

1- What is your clinical grade?……..

2- When did you qualify?……..

3- How long have you been working in the outpatient clinic as a whole (whether in this hospital or in other hospitals)? ……..

4-How long is your *usual* treatment time with Pulsed Short Wave Diathermy? ……

5- What type of Pulsed Short Wave Diathermy equipment do you use? (*Please specify the model and the manufacturer*)

……

6- What best describes your preferred approach to the *frequency of use with patients* when using Pulsed Short Wave Diathermy?
Tick the most appropriate answer

- ☐ Daily
- ☐ 3 times a week
- ☐ Twice a week
- ☐ Once a week
- ☐ Less than once a week

7- For what conditions would you use Pulsed Short Wave Diathermy (*give the 5 most common conditions, arrange according to priority*)

……
……
……
……
……

8- List the parameters that you need to record in patient's notes to describe your treatment plan with Pulsed Short Wave Diathermy?

……

……

9- What determines your choice to treatment dosage?
Rank your answers in order of priority from 1-8, with 1 being the most important

- ☐ Site of lesion
- ☐ Equipment manual
- ☐ Discussion with colleagues
- ☐ Personal experience
- ☐ Knowledge gained through undergraduate training
- ☐ The published literature (books, journals)
- ☐ The stage of the disease (acute, sub-acute, or chronic)
- ☐ Patient general symptoms (pain, swelling, etc)

10- Rank the reasons that determine your choice to apply Pulsed Short Wave Diathermy in preference to other electrotherapy modalities.
Rank your answers in order of priority from 1- 5, with 1 being the most important

- ☐ Patient's signs and symptoms
- ☐ Previous experience
- ☐ Recommendation by the physician or senior physiotherapist
- ☐ Familiarity with the machine
- ☐ Availability of the machine

11- List the outcomes (aims) that you are trying to achieve when choosing Pulsed Short Wave Diathermy as a treatment modality
Your answer should be ranked according to priority

.....

.....

.....

.....

12 -Do you *usually* combine the application of Pulsed Short Wave Diathermy with other electrotherapy modalities?
Tick the appropriate box

- ☐ Yes
- ☐ No

If No proceed to Question 13

If your answer is YES proceed to questions 12a/ 12b

12- a- Specify the modality (ultrasound, laser, interferential etc) that you would *usually* combine with Pulsed Short Wave Diathermy

.....

12- b- What is your aim of combing the two modalities?

.....

.....

13- How would you rate your treatment outcome with Pulsed Short Wave Diathermy? Tick the appropriate box

☐ Excellent ☐ Good ☐ Poor ☐ Indifference

14- After how many sessions do you stop using Pulsed Short Wave Diathermy if there is no reported improvement?

.....

15- If your patient is improving with Pulsed Short Wave Diathermy administration, what parameters would you change to progress your treatment?

.....

16- Do you think that the existing literature on Pulsed Short Wave Diathermy helps informs your decisions (as a clinician) on treatment parameters?

- ☐ Yes
- ☐ No

If yes proceed to question 17, if no proceed to question 16-a

16-a If No, how could this be improved?

.....

17- What dosage would you select for the following patients (*all patients have no contraindication to using* Pulsed Short Wave Diathermy)
These case studies are meant to be answered with regard to **Pulsed Short Wave Diathermy**, therefore Do not advocate other types of treatment

17- a- 43 years old female complains of osteoarthritis of the knee (right) for less than a year; she suffers dull aching pain that is present all the time. Most of her pain is after activity (especially if the activity involves standing or walking), she has trouble standing up after sitting.
Please specify your parameters
Pulse width (μsec).....
Pulse rate (pps).....
Mean power (W).....
Time (min).....
Frequency of administering the treatment per week.....

17- b- 62 male patient complains of osteoarthritis in right knee since 5 years. Main symptom were morning pain and stiffness, pain going down the stairs, occasional swelling. Patient suffered a recent exacerbation of symptoms, was on anti-inflammatory drugs for 3 weeks with little benefit.
Please specify your parameters
Pulse width (μsec) .....
Pulse rate (pps) .....
Mean power (W).....
Time (min).....
Frequency of administering the treatment per week.....

17 - c- 71 female complains of osteoarthritis of both knees (more than 10 years) with reduced range of motion, crepitus on movement and dull pain present all the time. Pain increases when using stairs or when walking on uneven ground. Her knees are swollen most of the time.
Please specify your parameters
Pulse width (μsec).....
Pulse rate (pps).....
Mean power (W).....
Time (min).....
Frequency of administering the treatment per week.....

Thank you for completing this questionnaire

APPENDIX B.3

ETHICAL APPROVAL FOR THE QUESTIONNAIRE

ETHICS COMMITTEE OF THE DEPARTMENTS OF RADIOGRAPHY AND PHYSIOTHERAPY

~~Radiography~~/Physiotherapy
(delete as necessary)

Protocol Number:	RPEC.100(part2)3.01
Name of Investigator:	Maryam Almandil
Name of Supervisor:	Tim Watson
Title of Study:	A Survey to Examine the use of Pulsed Short Wave in Outpatient Clinics in Britain.
Dates of Study	Academic Year 2000/01
No. of Subjects	288

1) I support the approval of the above study without pre-conditions. YES ✔

2) I support the approval of the study, subject to the following:

a) essential pre-conditions which will affect the granting of approval:

b) general recommendations and comments which will **not** affect approval:

3) I do **NOT** support approval of the study for the following reasons:

Signature N. Hopwood
Chair of Ethics

Date: 21/3/01

21/3/01

APPENDIX B.4

LETTER TO THE MANAGER OF PHYSIOTHERAPY DEPARTMENT

Dear
Date / /

My name is Maryam Almandil, a PhD student from University of Hertfordshire. Originally, I am a physiotherapist and currently I am conducting a series of investigations as part of my structured program for a PhD in electrotherapy. At the moment I am involved in carrying out a nationwide questionnaire focused on the effectiveness of Pulsed Short Wave Therapy (PSWT). The questionnaire examines the rationale and the factors affecting therapists' choices with this modality. The ultimate aim of this study is to help therapist challenge their beliefs and current use to PSWT. The results of this study are also expected to help therapists in the process of clinical decision-making. However, the goals of this study can only be made possible by your co-operation.

Your hospital has been chosen randomly among the other hospitals within your health authority to be part of this survey. As the manager of the department I am seeking your help in identifying those working in the outpatient department and using PSWT with their patients. Enclosed are 4 questionnaires to give to whom you think will be suitable candidates for this study.

I appreciate all the help you could offer

For further inquiries do not hesitate to contact me on the following address
University of Hertfordshire
Department of Physiotherapy
Hatfield campus
College Lane
Hatfield Herts
AL10 9AB
Or call at 01707 284000 Ext 2054

Thank you

Yours truly,
Maryam Almandil

APPENDIX B.5
LETTER TO PHYSIOTHERAPISTS (survey)

Dear Colleague;

My name is Maryam Almandil, a PhD student from the Physiotherapy Department in University of Hertfordshire. As part of my PhD I am conducting a nationwide survey. This questionnaire is part of a series of investigations I am conducting on the effectiveness of Pulsed Short Wave Therapy. Having worked as a physiotherapist in the outpatient clinic for many years I think that deep understanding of electrotherapy modalities is one of the key issues to a successful treatment. Equipment such as Pulsed Short Wave Therapy demand greater attention as literature presents conflicting evidence on their efficacy. This questionnaire is structured to examine your preference, choices, and understanding of the theory behind Pulsed Short Wave Therapy. I strongly believe that practitioners are better qualified to address their clinical problems; hence sharing your experiences and opinions becomes a strong informative tool to this project.

Your hospital has been chosen randomly among the other hospitals within your health authority. The manger of your department, helped identify the therapists working with Pulsed Short Wave Therapy, hence, those identified are not known to me.

All envelopes are coded with numbers. These numbers are meant to act as indicator of the response rate (in case a follow up letter is needed). Therefore, it plays no role in identifying the individuals. Confidentiality will be maintained throughout the study, and the published results will not uncover the identity of the respondents or their hospital.

Dear colleague, if you decided to participate in this survey, after receiving your copy of the questionnaire, please take few minutes to answer the questions. All the questions are there for a reason therefore, I would be most grateful if you could answer them all. The last section of the questionnaire deals with cases on osteoarthritis (OA). OA was chosen following an exploratory auditing investigation in the area.
After answering all the questions, use the self- addressed envelope provided to post the questionnaire back to me

Your co-operation is deeply appreciated.

To obtain a copy of the results, get in touch with me on the following address

University of Hertfordshire
Department of Physiotherapy
Hatfield campus, College Lane
Hatfield, Herts
AL10 9AB
Or call at 01707 284000 Ext 2054

Thank you,
Yours truly,
Maryam Almandil

APPENDIX B.6

OSTEOARTHRITIS

OA which is also known as hypertophic arthritis or degenerative joint disease is the most common non-inflammatory arthropathy seen in adults (Nguyen and Marks, 2002). In a population of 100,000, 3000 will be complaining of OA (Clarke, 1999) with the bulk being OA of the lower limb (Green, 1991) and the knee joint being the most frequent (Peat et al, 2001).

OA accounts for 30% of disability in women over 80 years (Clarke, 1999). It is known to cause destruction of the articular cartilage and subchondral bones (Cicuttini et al, 2001). The cartilage serves to provide smooth articular surface and to distribute the biomechanical forces across the bone surface. The ongoing changes in the biomechanical environment of the joint as a result of the disease can lead to remodelling in the subchondral and trabecular bone, which is characterised by loss of water content, proteoglycan, and collagen along with a decrease in the number of chondrocytes. These changes besides the fissuring and ulceration soften the cartilage making it more prone to damage. This alters joint biomechanical behaviour even further, and the degeneration of more cartilage initiates a cycle that may end up in additional loss of the articular cartilage and permanent joint loss (Bailey and Mansell, 1997; Wu et al, 1990). Advanced conditions may show subchondral bony cysts, and the formation of spurs or osteophytes. The inception and progression of OA can be aggravated by factors such as knee alignment, injury and biomechanical insults to the joint (Sharma, 2001).

Jones et al (2004) demonstrated in a sample of 372 subjects, that heavier older subjects tend to show more radiographic changes. Joint space narrowing was associated with cartilage volume loss. Even with very minor OA degeneration there was 11-13% cartilage loss. This magnitude of loss was similar in men and women.

Lindsey et al (2004) in a group of patients complaining from OA knee (21 controls, 21 mild OA, 32 severe OA) demonstrated by using MRI that there was an increase in bone density in the medial compartment with thickening of the trabacular bone and these changes were correlated with the severity of the disease (chronic cases show more changes). They also demonstrated that bone loss with arthritis occurs not only on the diseased side but also on the opposite compartment.

OA is associated with deep, diffuse, and dull pain, which is usually worse as the day progresses. Pain increases with activity and decreases with rest and could be associated with stiffness after immobility that lasts for few minutes. Symptoms usually affect daily life and change the patient's daily routine making accomplishing simple tasks very demanding (Nguyen and Marks, 2002). The mechanisms that lead to pain remain unclear (Creamer et al, 1996). Pain fibers are present in several structures that are often affected by the pathologic processes in OA knee, including the joint capsule, ligaments in and around the knee joint, the outer third of the meniscus, possibly the synovium, the periosteum and the bone marrow (Heppelmann, 1997). Cartilage loss and alterations in patella volume on arthroscopy appears to show substantial correlation with pain and disability (Hunter et al, 2003).

The clinical metrology of OA is complex because of the changing clinical presentation. OA may be symptomatic or not, and may be associated with normal or abnormal radiographs, may have symptoms that are also common in RA or ankylosing spondylitis. That is why it is hard to find a satisfactory classification criterion. OA severity has been classified for years according to the radiographic appearance. X-ray

has been the traditional method of diagnosing OA pathological processes. Features such as joint space narrowing, subchondral sclerosis and osteophyte formation can be used to judge the severity of the condition (Spector and Hart, 1992). This method however, has been criticized of being insensitive to change due to the possibility of measurement error and the radiographic grading system being semi-quantitative. Normal X-ray also lacks the ability to detect changes in cartilage and even if they do it is very hard to relate the changes to the disease stage. Moreover, less than 50% of people with evidence of OA on plain radiographs do not have symptoms related to their clinical findings (Spector and Hart, 1992), as such poor relationships have been reported between the severity of the reported knee pain and the degree of radiographic change (Cicuttini et al, 1996).

OA can also be classified as being primary or secondary. It is considered primary if the cause was idiopathic. However it is classified secondary if the cause was mechanical, congenital or systemic. Mechanical causes could be trauma, previous inflammatory arthritis, and hyperlaxity while congenital causes could include hip dysplasia, slipped epiphysis, and Lægg-Perthe's disease. Systemic causes could include anything from acromegaly, hypothyroidism, haemochromatosis, haemoglobinopathies to neuropathies (Dequeker and Dieppe, 1998).

Another system of classification that is widely used is the classification of the American College of Rheumatology, which utilises symptoms, laboratory findings and X-ray manifestations. The system allows for the choice between categorising patients according to clinical and laboratory symptoms, clinical and radiographic symptoms, clinical 1 or clinical 2 (all were found to be over 90% sensitive to the symptoms) (Altman, 1991, Altman et al, 1990; Altman et al, 1986).

Due to the pathogenesis being inconclusive, management of OA is largely dependent on conservative measures (Nguyen and Marks, 2002). The management of OA ranges from pharmacological, non-pharmacological to surgical corrections. Patients with varying degrees of OA are often referred to physiotherapy outpatient clinics where various modalities such as short wave (pulsed and continuous), US, IFC, electrical stimulation, Ex, mobilisations, hot and cold packs and hydrotherapy may be used. There is a lack of consensus on the best methods to approach this condition among therapists (Nguyen and Marks, 2002; Green, 1991) and this may be caused by the difficulty in determining the structure causing the pain. Other non-pharmacological interventions include patient education, weight management, orthosis or assistive devices (Pendleton et al, 2001; Hochberg et al, 1997), and wedged foot insole (Pham, 2004). None of the interventions above have enough evidence to support its efficacy possibly because of the small number of studies that examined these interventions or the methodological flaws in the published reports (Harley and Walsh, 2001).

PSWT is one of the modalities employed by physiotherapists to manage the symptoms associated with OA (Nguyen and Marks, 2002). It has been used for mild, moderate and severe OA and was found to be favoured by therapists after exercise, and mobilisation (Green, 1991). It is used with the aim of minimising symptoms such as pain, swelling, muscle weakness and loss of function (Nguyen and Marks, 2002). However, there is not enough evidence to support the above aims. Interestingly, despite the lack of evidence that PSWT could have a direct effect on the muscle spasm or weakness, it has been widely accepted by physiotherapists that it does increase muscle strength and relieve spasm.

In general, trials conducted on OA and PSWT were in favour of positive outcomes with the majority of these trials reporting improvement in function and reduction in pain (Ganguly et al 1996; Klaber-Moffett et al 1996; Leclaire and

Bourgouin, 1991; Jan and Lai, 1991; Quirk et al, 1985). In studies where PSWT was compared to other treatments or other interventions it was found to be more effective than placebo (Quirk et al, 1985; Klaber-Moffett et al 1996) and no better than other active groups such as US, IFC, Ex, and stretching (Quirk et al, 1985; Svarcova et al 1988; Jan and Lai 1991; Leclaire and Bourgouin 1991; Ganguly et al 1996).

Despite the number of studies that examined the efficacy of PSWT with OA, the findings of these studies needs to be viewed with caution as these reports lack significant information about treatment dose, methodology, and statistical analysis that are needed to judge the quality of the outcome. Such an issue justifies the conduction of more trials that investigate the therapeutic effects of PSWT on OA.

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APPENDIX C.1

ACTION POTENTIAL

Basis Of The Action Potential (AP)

(Marieb, 2001, Oh, 1996)

Normal cell membrane exhibits different permeabilities to ions such as Na^+ and K^+. At rest it is most permeable to K^+ while it is relatively impermeable Na^+. Although each ion has some tendency to move across the membrane, ion pumps are used to maintain the ion gradients, this creates a resting membrane potential of -70 mV. The selectivity of the channels results from the diameter of the channel and the charge arrangements of amino acids lining the channel. Ions do not pass through a channel by themselves, each individual ion has highly structured water molecules surrounding it. This covering of water is called a hydration sphere, and it is the diameter of the sphere surrounding the ion which determines the functional diameter of the ion.

AP is a transient depolarization of the membrane where the inside of the neuron becomes less negative, this usually lasts for 1-2 milliseconds. With depolarization there is a change in membrane potential (from -70 mV to ~ +30 mV).
The depolarization phase of the AP is triggered by the opening of voltage-sensitive sodium channels, which are normally closed at rest. This causes a sudden increase in sodium permeability making the inside of the neuron more positive with respect to the extracellular fluid.
There are also specific voltage-sensitive channels for potassium which open during AP. These channels begin to open at the same time as the sodium channels, but the increase in permeability for potassium proceeds more slowly than the sodium channels. They are different from Na^+ channels in that they have only a single activation gate which opens when threshold is reached. The increase in potassium permeability is maintained until this activation gate closes. The increase in potassium permeability lasts longer during the AP than does the increase in sodium permeability because there is no inactivation gate to close the channel prematurely. This activation gate closes when the membrane potential has sufficiently repolarized.
In the resting state, the activation gate is closed and the inactivation gate is open.
Sodium ions can pass through the channel only when both gates are open.

Stimulating the neuron directly by using an electrical stimulus can increase the membrane potential above threshold (threshold is the membrane potential at which the activation gate opens) and generate AP. If the nerve is stimulated in the middle, the AP moves in two directions: orthodromic, towards the axon terminal and antidromic, toward the dendrites. The increased positive charge content inside the neuron causes a change in the activation gate portion of the sodium channel, opening them. The rapid depolarization causes a second voltage-sensitive change in the channel: the inactivation gate closes, and sodium permeability falls back to normal, even though the activation gate is still open. The activation gate then closes slowly while the inactivation gate is closed.

It is impossible to generate a second AP during the time that the inactivation gate is closed. This period occurs from the peak of AP until repolarization dips below the threshold and it is called the absolute refractory period. It is the period when no AP can be produced no matter how strong the stimulus. This period is followed by another period called the relative refractory period where stimulus of sufficient strength could result in AP.

Conduction of action potential

The AP generated in the axon travels along the axon and, eventually, on to other neurons or excitable cells, such as muscles. Thus, AP move a little way down the membrane. As this positive charge moves, two things happen: some of the charge is short-circuited, lost to the extracellular fluid. Secondly: the charge remaining inside the neuron depolarizes the area which it enters and opens the voltage-sensitive sodium channels. This causes fresh positive charge to enter the neuron in the new location, replenishing the AP by replacing the positive charge which was short-circuited. The rejuvenated AP then proceeds to move further along the axon, opening new sodium channels as it proceed the length of the axon.

Conduction is faster with myelinated fibres. The AP travels through salutatory conduction where the impulse jumps from one Node of Ranvier to the other being the sites where voltage-sensitive sodium and potassium channels are concentrated, unlike non-myelinated fibres where the conduction is slow. Axons are not insulated with myelin hence this decreases the rate of loss of positive charge as it moves along the membrane, which means that the AP has to move longer distance along the membrane before it regenerated.

APPENDIX D.1

CALIBRATION OF BIOPOTENTIAL AMPLIFIERS

Calibrating the gain of the PPG biopotential amplifiers

Examination of the gain of both PPG biopotential amplifiers was done by starting the acquisition and observing the starting point signal. The first channel read 0.3V while the second channel read 0.2 V above baseline (Figure1), both channels needed calibration.

The baseline signal was rescaled following the manufacturer' instructions and by using the zero adjusts screw at the top of the front face of the module. Setting all dials according to the manual, the MP 100 was turned on to acquire the electrical noise which was shown on the screen as spiked wave form. The screen was adjusted to show amplitude between ±10 V (the maximum amplitude that can be collected on the recording window of the monitor). Using a small screwdriver, the zero adjust was turned until the baseline of the signal read 0.000 V. Figure (2) shows the amplified signal with the noise reduced to the minimum. This procedure was done at a gain of 100, the same gain that would be used to collect data. It was not appropriate to calibrate the signal at other gain setting as different gains change the zero starting point of the signal.

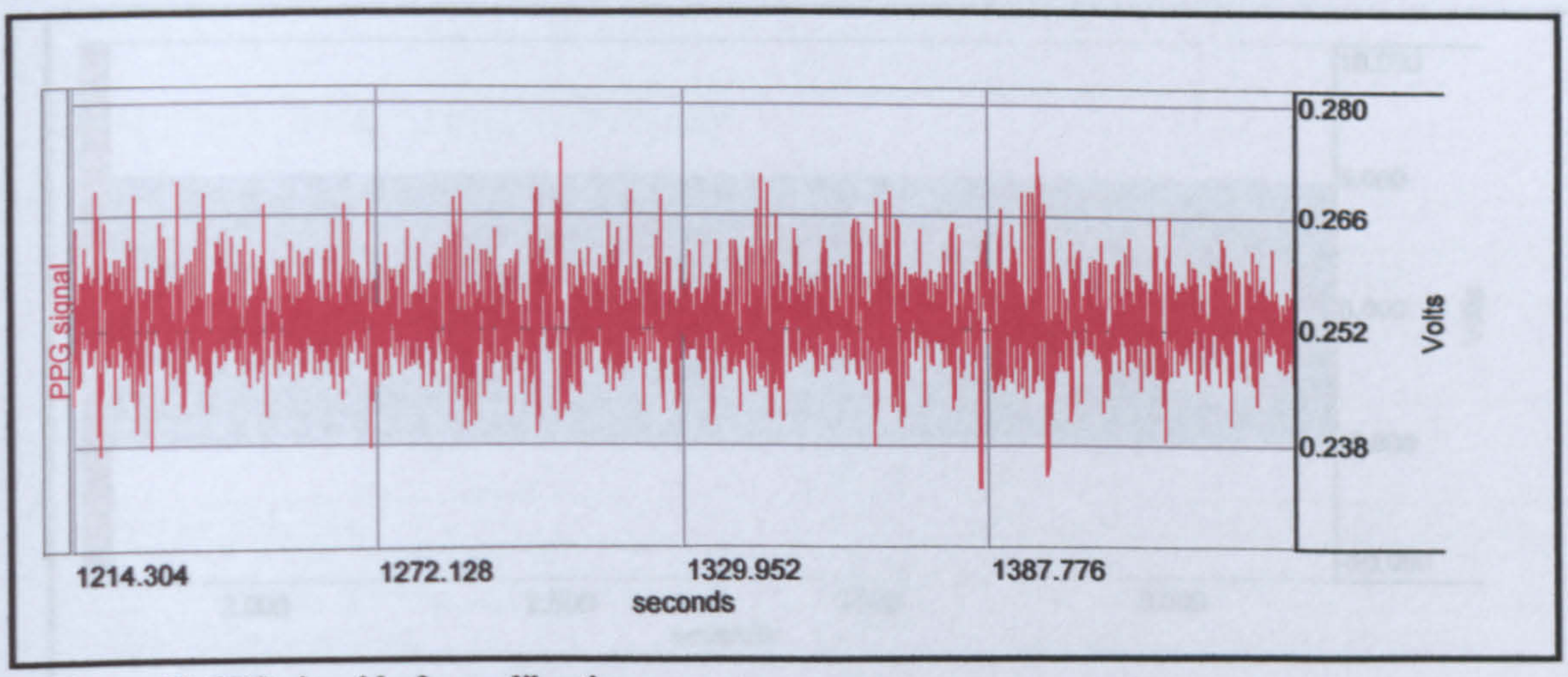


Figure (1) PPG signal before calibration

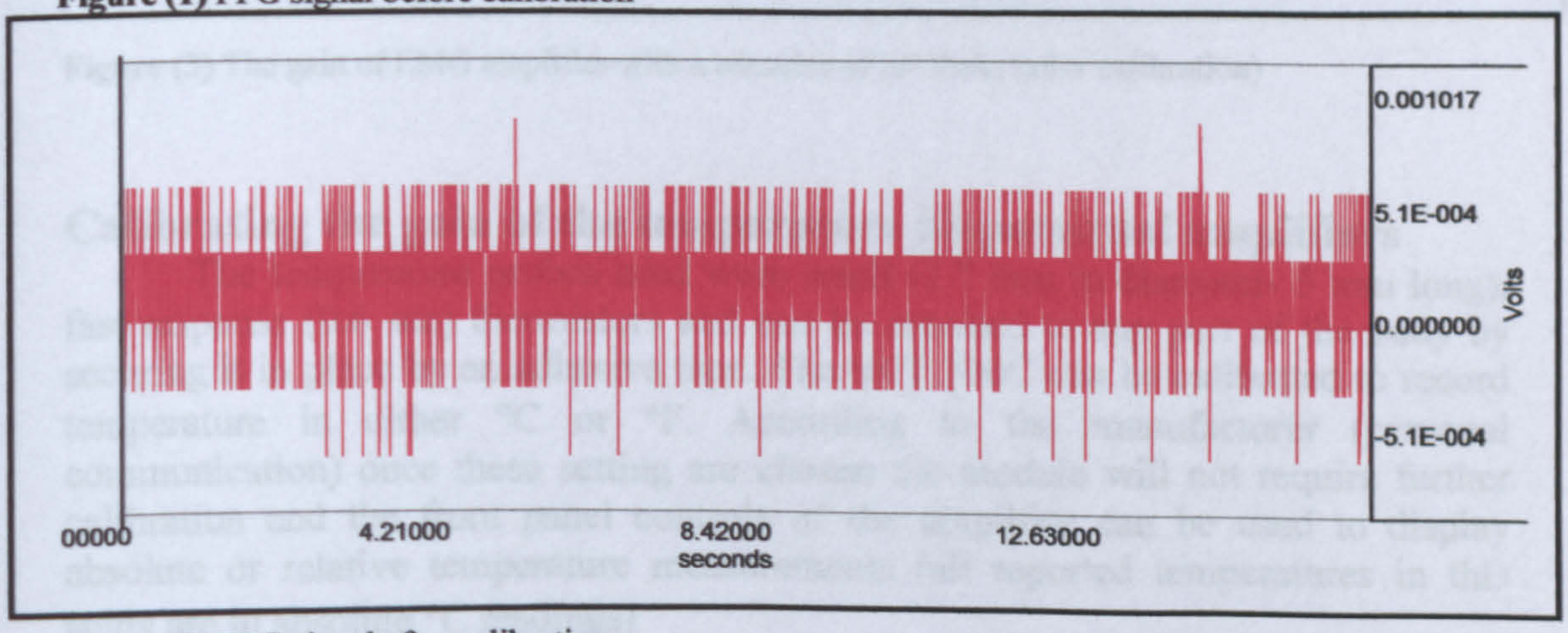


Figure (2) PPG signal after calibration

Calibrating the gain of the EMG biopotential amplifiers

The gain of both EMG biopotential amplifiers was tested by turning on the acquisition system and observing the signal. Both channels read an excess of 0.3V from the baseline, which meant that both channels needed calibration.

Calibrating the channels was done following the instruction provided by the manufacturer, which involves using a known stimulus signal. A special output cable (CBLCAL) was used to attenuate the recorded signal and re-route it back into the amplifier where it is amplified by the selected gain setting.

A 5V sinusoidal signal with a frequency of 10Hz was delivered via the UIM100A stimulator. Data were collected and peak-peak amplitude was measured using a specialised function in the software. The voltage was measured using the following formula:

Equation (1): Measured Voltage = (Stimulator Input Voltage) * (1/1,000) * (Biopotential Amplifier Gain Setting).

Since the amplifier gain was set to 1,000, the CBLCAL attenuation (1/1,000) will be cancelled and as result, the measured voltage will equal the stimulator input voltage, which is 5V (Figure 3). Checking the accuracy of the calibration was done by using the peak detection mode.

The EMG was calibrated on all the possible gain setting 500, 1000, 2000, and 5000, then it was set to 2000 the gain that would be used in the study and was calibrated again.

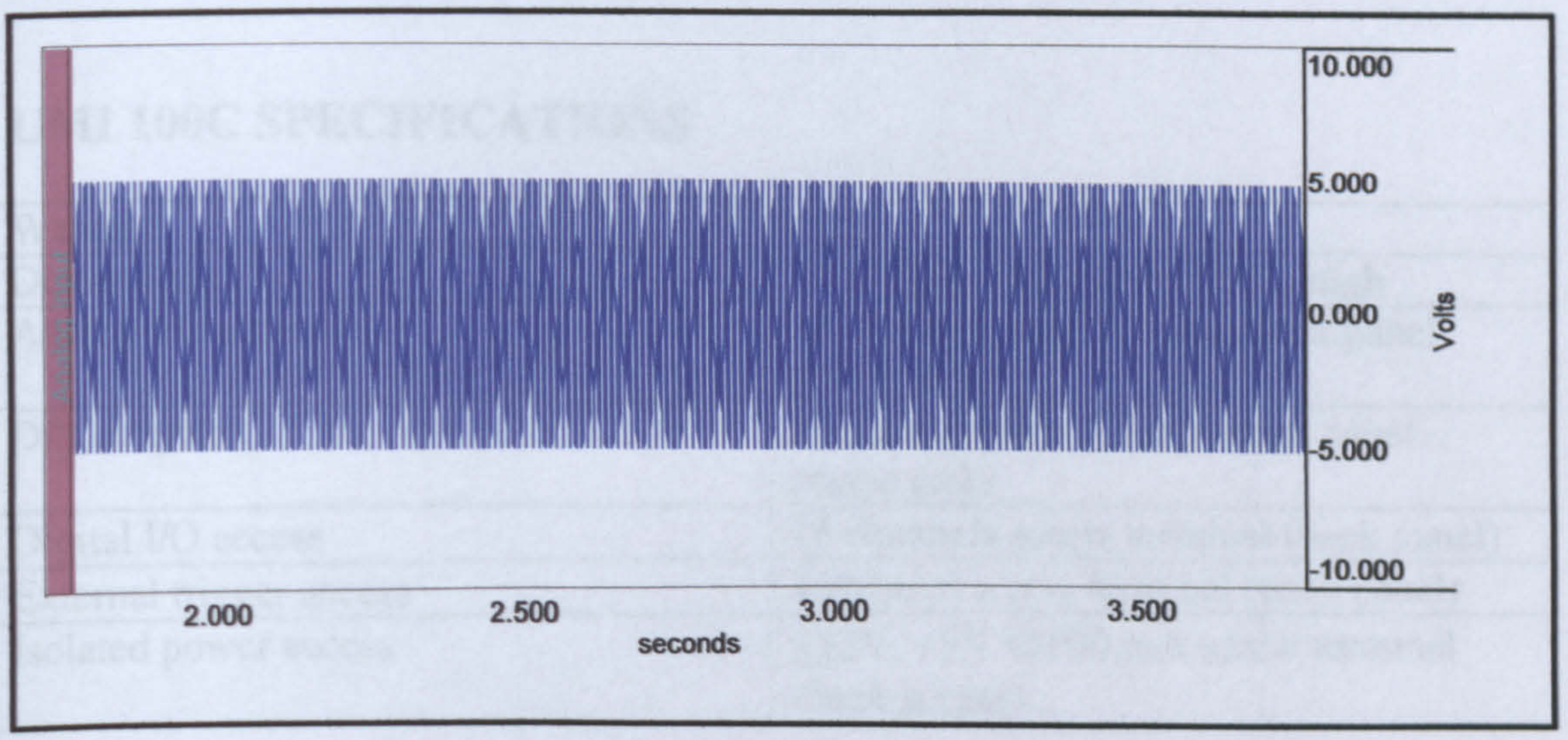


Figure (3) The gain of EMG amplifier with a stimulus of ±5 Volts (after calibration)

Calibrating the gain of the temperature biopotential amplifiers

The temperature probes used were small (1.7 mm in diameter- 5 mm long), fast response (0.6 sec) thermistors and can be attached to any part of the body by securing it in place by an adhesive tape. The SKT 100C can be calibrated to record temperature in either °C or °F. According to the manufacturer (personal communication) once these setting are chosen the module will not require further calibration and the front panel controls of the amplifier can be used to display absolute or relative temperature measurements (all reported temperatures in this study are in absolute °C readings)

APPENDIX D.2
BIOPAC SPECIFICATION

EMG SPECIFICATIONS

Gain	500, 1000, 2000, 5000
Low Pass Filter	500, 5000 Hz
High Pass Filter	1, 10, 100 Hz
Input voltage range	±10 V
Output voltage range	±10 V
Gain 500 1000 2000 5000	 ±20 mV ±10 mV ±5 mV ±2 MV
Noise voltage (10-500 Hz)	0.2 μv

UMI 100C SPECIFICATIONS

Weight	520g
Dimensions	7cm wide, 11cm deep, 19cm high
Analog I/O access	16 channels with 3.5 mm front panel phone jacks
D/A outputs	2 channels with 3.5 mm front panel phone jacks
Digital I/O access	16 channels screw terminal (back panel)
External trigger access	1 channel screw terminal (back panel)
Isolated power access	±12V, +5V @100 mA screw terminal (back access)

STIMULATOR 100C SPECIFICATIONS

Stimulus output voltage	20V peak-peak maximum value
Minimum pulse width	10µsec
Input sources	Da0, DA1, pulse (I/O 15) CH16
Polarity control	Manual or digital control (Digital I/O 7, H-POS, L-NEG
Attenuation control	Manual or digital control
Attenuation control range	128dB (digital I/O, 0-6, LSB MSB)
Attenuation resolution	1dB
Indicators	Pulse, current limit
Uniphasic pulse width	10µsec
Biphasic pulse resolution	25µsec
Biphasic pulse width	50µsec
Arbitrary wave resolution	25µsec

STIMISOC SPECIFICATIONS

Weight	190g
Dimention	10 cm wide, 5 cm deep, 4.5 wide
Output via	3.5mm mono phone jack
Bipolar voltage stimulation	2 setting (1:5), (1:10) 1:5 maximum output voltage is 100V peak to peak, 1:10 of stimulation voltage 1:10 mode maximum voltage output is 200 peak to peak, 1:20 of stimulation voltage
Current setting	0.01, 0.02, 0.05, 0.1, 0.2, 0.5, 1, 2, 5, 10, 20, 50 mA
Pulse width range	50 µsec – 2 msec
Maximum pulse energy	160 mJ
Sine wave frequency range 100 Hz, 5000 Hz	Isolation capacitance 120pf Isolation voltage 1500VDC

PPG 100C SPECIFICATIONS

Gain	10, 20, 50, 100
Low pass Filter	3 Hz, 10 Hz
High Pass filter	DC, 0.05 Hz, 0.5 Hz
Noise voltage	0.5 µV
Output range	± 10 V
Input signal source	TSD 200
Excitation	6V

SKT 100C SPECIFICATION

Gain	5, 2, 1, 0.5 °F/V also can be calibrated in °C	
Low pass filter	1 Hz, 10 Hz	
High pass filter	DC, 0.05 Hz, 0.5 Hz	
Sensitivity	180 µ°F 100 µ°C	
Output range	± 10 V	
Gain	Range °F	Range °C
5	40-140	5-60
2	70-110	22-43
1	80-100	27-37
0.5	85-95	30-35

APPENDIX D.3

ETHICAL APPROVAL OF THE PILOT

ETHICS COMMITTEE OF THE DEPARTMENTS OF RADIOGRAPHY AND PHYSIOTHERAPY

Radiography/Physiotherapy
(delete as necessary)

Protocol Number: RPEC/100(Part 3)/06/01

Name of Investigator: Maryam Almandil

Name of Supervisor: Dr Tim Watson

Title of Study: A study to examine the physiological changes that accompany pulsed short wave administration (pilot study)

Dates of Study: Academic Year 2000/01

No. of Subjects: 16

Subject information sheet:

1) I support the approval of the study without pre conditions.

2) I support the approval of the study, subject to the following: ✓

   a) essential pre conditions which will affect the granting of approval:

      Rewrite some questions so that they are more sensitive

   b) general recommendations and comments which will **not** affect approval:

      Review use of phraseology in subject information sheet, suggest that you discuss this with your supervisor.

3) I do **NOT** support approval of the study for the following reasons:

Signature [signature] Date: 12/6/01
Chair of Ethics Committee

APPENDIX D.4

INFORMATION SHEET

Pulsed Short Wave Therapy is a popular modality among therapists, it has been used for many years to treat a variety of musculoskeletal conditions. Despite this wide use, its mechanism of action is not yet understood. The current study is conducted with the aim of having a better and a deeper understanding into the physiological effects of this modality. The study will involve examining the effects of applying pulsed electromagnetic energy to the knee joint and measurements to the accompanying reactions in terms of blood volume, skin temperature and nerve conduction velocity.

The procedure of the study will be as follows:

- On arrival, you will be briefed about the study protocol (do not hesitate to ask about any issue of concern).
- Next you will be given a form to fill in to exclude any contraindication (this is to ascertain that you do not have a problem that might react adversely with the treatment modality applied).
- Then you will be given a consent form to sign.
- You should bring with you comfortable clothes (shorts) to wear, as this will facilitate ease of movement and of measurements.
- Next measurements to your height, weight, and body fat will follow.
- You will lie on a plinth, and inspection to the area to be treated will be done by me to exclude further contra-indications.
- Skin test to the area to be treated will be undertaken to ensure that you have a normal skin reaction.
- The area around the knee will be wiped with alcohol to clean it and to remove signs of dirt, or sweat.
- A fine type of sand paper will be used to reduce skin resistance to the applied current.
- Leads will be connected to your knees on both sides, to measure changes in skin temperature, blood volume, and nerve conduction velocity.
- After attaching the leads, measurements will be taken for 10 minutes.
- The treatment head will then be placed in close contact to your knee and the treatment will start.
- I will remain with you in the room for the whole time of the experiment; therefore do not hesitate to report any unpleasant feeling or discomfort.
- When the treatment time has elapsed, you will hear the sound of a timer, I will then remove the treatment head and the measurements will continue for another 10 minutes.
- The treatment time will be 10 minutes, however, the overall time that you need to be in the laboratory varies between 50 – 60 minutes for the first session and 45-50 minutes for the following sessions.

Please remember NOT to

smoke

exercise

eat or

drink

1 hour prior to the experiment

Thank you for being part in this study

For further inquiries do not hesitate to contact me either by
e-mail me on almary22@hotmail.com
or visit me in room 2F 381

Researcher:
Maryam Al-Mandil

APPENDIX D.5
CONTRA INDICATION LIST

Please fill in the appropriate circle	**YES**	**NO**
Do you use a hearing aid?	O	O
Do you complain from ear infection?	O	O
Do you complain from hypersensitivity to heat?	O	O
Do you have high fever?	O	O
Do you have any skin problems that may be exacerbated by heat?	O	O
Do you complain from blood pressure abnormalities?	O	O
Do you have any cardiac disorder?	O	O
Do you have a metal implanted in any part of your body?	O	O
Do you wear a pacemaker?	O	O
Have you sustained an injury to your knees within the last three month?	O	O
Have you sustained an injury to your back in the last month?	O	O
Have you ever complained from venous thrombosis or phlebitis?	O	O
Have you ever complained from any arterial disease in your legs?	O	O
Have you ever complained from Tuberculosis?	O	O
Have you ever complained from any malignant diseases (cancer)?	O	O
Are you currently receiving any treatment or medication?	O	O

If yes please print down your medication

.....

.....

.....

Participant name **Participant signature**

APPENDIX D.6

SUBJECTS CONSENT FORM

Title of the research project: A study into the effectiveness of Pulsed Short Wave Therapy

	YES	NO
The purpose of this study has been explained to me	☐	☐
I have been informed of the details of my involvement in the study	☐	☐
My questions regarding this study have been answered to my satisfaction	☐	☐
I understand that I am not obliged to take part in this study and may withdraw at any time without the need to justify my decision and without affecting my care in any way	☐	☐
I understand that any personal information obtained as a results of my participation in this study will be treated as confidential and will not be made publicly available	☐	☐

I, the undersigned, agree to take part in this study

Signature of the subject _____

Name of subject _____
(Please print)

Signature of the investigator:

Name of the investigator: Maryam Almandil

Status of investigator: PhD student Date:

APPENDIX D.7

PROCEDURE FOR MEASURING SKINFOLD

Reference (Jackson and Pollock, 1985, Lehman et al, 1988)

Sites for measuring skinfold in women

Triceps: over the triceps midway between acromion and the olecranon process. The site is determined by a tape measure with the elbow flexed 90°. Test is done with the subject standing and the investigator behind the subject. The calliper is placed perpendicular to the skinfold.

Suprailium: an oblique (45 from horizontal), the skin is grasped posterior to the midaxillary line, immediately above the iliac crest. The test is done with the subject standing.

Abdomen: vertical fold taken at a distance of 2 cm from the umbilicus

Sites for measuring skinfold in men:

Chest or pectoral: a skinfold is picked up on the anterior axillary fold in a line directed to the nipple. Measurements are taken while the subject is standing.

Triceps: over the triceps midway between acromion and the olecranon process. The site is determined by a tape measure with the elbow flexed 90°. Test is done with the subject standing and the investigator behind the subject. The calliper is placed perpendicular to the skinfold.

Subscapular: the fold is taken along the diagonal line connecting the vertebral border of the scapula to 1-2 cm below the inferior angle of the scapula.

APPENDIX D.8

RELIABILITY WITH SFM

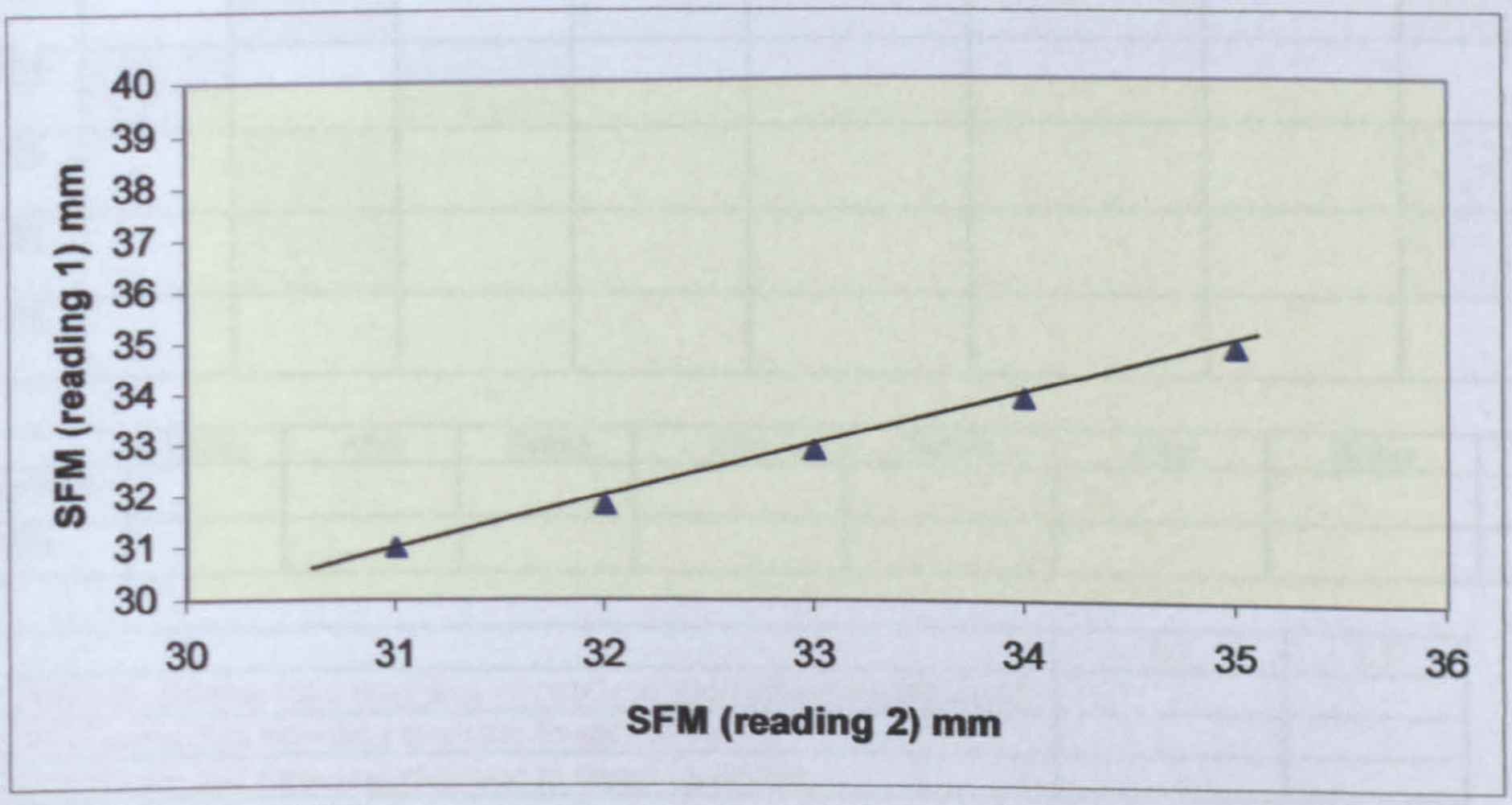
Intertester reliability with skin fold measurements:

Skinfold measurements (SKF) are known to be affected largely by the operators skill (Heyward and Stolarczyk, 1996; Lohman, 1992). As the SFM will be taken on the first visit only and it will not be repeated between days it was seen crucial to establish the researcher test re-test reliability for the same day.
The trials were conducted in the same day with a minimum of 30 minutes in between trials to avoid having any skin marks guiding the researcher when placing the caliper.
The reliability was established by measuring the abdominal skinfold in 5 subjects (4 female and 1 male).
Summary of the findings is shown in the table.

Same day measurements		
	Reading 1(mm)	Reading 2(mm)
1	31	31
2	33	32
3	35	35
4	32	31
5	34	34

Fat measurement of the abdominal area taken in the same day

Using Pearson Correlation Coefficient test the r values have shown highly related sets of data with r =0.957, p =0.01
Error margin for the researcher was found to be ±1mm



Scatter graph of SFM

Subject

APPENDIX D.9

TEMPERATURE/ PULSE SHEET

Order of sessions:

	High (24 W)		Low (3 W)		Placebo		Control	
Time to stabilise								
	PulsR	CorT	PulsR	CorT	PulsR	CorT	PulsR	CorT
min 0								
min 2								
min 4								
min 5								
min 6								
min 8								
min 10								
min 12								
min 14								
min 15								
min 16								
min 18								
min 20								
min 22								
min 24								
min 25								
min 26								
min 28								
min 30								

	Before	After	Before	After	Before	After	Before	After
Temperature								
Humidity								

	RT	LT
Inter-electrode distance (mid recording electrode to mid stimulating electrode)		
Distance between mid recording electrode to apex of pattela		
Distance between mid recording electrode to lateral malleolus		

APPENDIX E.1

ETHICAL APPROVAL FOR LABORATORY STUDY

University of Hertfordshire

Hatfield Campus
College Lane
Hatfield Herts
AL10 9AB

Switchboard (01707) 284000
Minicom (01707) 284000
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Vice-Chancellor
Professor Neil K Buxton

April 1st 2004

To whom it may concern

Maryam Almandil received approval from the Radiography and Physiotherapy Ethics Committee for her pilot study on June 12th 2001 (protocol number RPEC/100(part3)/06/01). The study had two elements, a laboratory experiment and a questionnaire. Her request for to extend the size of her sample for the laboratory experiment was discussed and approved at the committee meeting held on 16th April 2002.

Janet High (Mrs.)
Chair of the Radiography and Physiotherapy Ethics Committee
Department of Allied Health Professions
Faculty of Health and Human Sciences
Direct line (01707) 284963
Fax (01707) 284977

APPENDIX E.2

Subject

CHECK LIST FOR 2nd, 3rd, 4th SESSIONS

	2nd session		3rd session		4th session	
	Yes	No	Yes	No	Yes	No
Do you have any comments from the last session?						
Did you sustain an injury since the last time I saw you?						
Have you eaten in the last 2 hours?						
Did you do strenuous sports in the last 2 hours?						
Did you drink coffee, alcohol in the last 2 hours						
Did you smoke in the last 2 hours?						
Are you menstruating?						

Subject

APPENDIX E.3

BLINDING QUESTIONNAIRE

BEFORE TREATMENT

1. Have you experienced PSWT before?
   ☐ Yes ☐ No
2. How long ago was that?

3. For what reason?

4. What do you think you would feel during PSWT treatment?

AFTER TREATMENT

(24W)

1. Do you think that PSWT machine was working during the session?
☐ Yes ☐ No ☐ I don't know
2. How sure are you?
☐ Very sure ☐ I think I am sure ☐ I am not sure
3. Do you think your session was a?
☐ Treatment ☐ Placebo ☐ Control ☐ I don't know
4. Did you feel any heat under the treatment head during the treatment?
☐ Yes ☐ No ☐ I am not sure

(3W)

1. Do you think that PSWT machine was working during the session?
☐ Yes ☐ No ☐ I don't know
2. How sure are you?
☐ Very sure ☐ I think I am sure ☐ I am not sure
3. Do you think your session was a?
☐ Treatment ☐ Placebo ☐ Control ☐ I don't know
4. Did you feel any heat under the treatment head during the treatment?
☐ Yes ☐ No ☐ I am not sure

(Placebo)

1. Do you think that PSWT machine was working during the session?
☐ Yes ☐ No ☐ I don't know
2. How sure are you?
☐ Very sure ☐ I think I am sure ☐ I am not sure
3. Do you think your session was a?
☐ Treatment ☐ Placebo ☐ Control ☐ I don't know
4. Did you feel any heat under the treatment head during the treatment?
☐ Yes ☐ No ☐ I am not sure

(Control)

1. Do you think that your session was?
☐ Treatment ☐ Placebo ☐ Control ☐ I don't know

APPENDIX E.4

RESULTS FROM LABORATORY EXPERIMENT

	Age	Sex	Height (cm)	Weight (kg)	Fat%	Dominant side
1	21	female	162	50.86	19.65	LT
2	21	female	159	52.8	18.9	RT
3	23	female	169	57.36	19.58	RT
4	23	female	158.3	93.74	30.06	RT
5	19	female	165	86	30.62	RT
6	29	male	171	82.06	14.84	RT
7	22	female	162.5	86.48	33.55	RT
8	20	female	163	55	19.29	RT
9	26	male	172.8	68.76	14.49	RT
10	20	female	196.4	61.22	28.12	LT
11	29	female	168.9	59.2	21.43	RT
12	33	male	173	78	16.78	LT
13	25	female	152	44.56	23.84	RT
14	22	female	171.8	75.5	22.7	RT
15	30	female	172.5	60.72	17.25	RT
16	23	female	171.5	82	39.47	RT
17	29	male	182	79.8	11.62	RT
18	20	male	173.5	65	13.7	RT
19	33	female	166.8	88.12	30.12	RT
20	20	female	172.92	77.92	31.51	RT
21	19	female	170.5	73.78	25.03	RT
22	23	female	171.8	73.8	25.21	RT
23	23	female	172	70.88	25.02	RT
24	23	female	154.5	74.42	26.21	RT
25	32	female	158.81	61.81	31.62	LT
26	19	female	162	49.9	19.72	LT
27	38	female	171.2	70.34	25.01	RT
28	48	female	152.6	64.9	35.93	RT
29	44	male	166	82.01	25.83	RT
30	21	male	169	78.2	11.34	RT
31	23	female	179	72	21.66	RT

Summary of demographic profile of the subjects

SUMMARY OF BLOOD VOLUME DATA

Tests of Within-Subjects Effects

Measure: MEASURE_1

Source		Type III Sum of Squares	df	Mean Square	F	Sig
condition	Sphericity Assumed	64407.827	3	21469.276	18.949	.000
	Greenhouse-Geisser	64407.827	1.860	34634.122	18.949	.000
	Huynh-Feldt	64407.827	2.187	29452.014	18.949	.000
	Lower-bound	64407.827	1.000	64407.827	18.949	.001
Error(COND)	Sphericity Assumed	40787.762	36	1132.993		
	Greenhouse-Geisser	40787.762	22.316	1827.739		
	Huynh-Feldt	40787.762	26.242	1554.265		
	Lower-bound	40787.762	12.000	3398.980		
phase	Sphericity Assumed	88240 069	2	44120.034	61.428	.000
	Greenhouse-Geisser	88240.069	1.980	44560.074	61.428	.000
	Huynh-Feldt	88240.069	2.000	44120.034	61.428	.000
	Lower-bound	88240.069	1.000	88240.069	61.428	.000
Error(PHASE)	Sphericity Assumed	17237.877	24	718.245		
	Greenhouse-Geisser	17237.877	23.763	725.408		
	Huynh-Feldt	17237.877	24.000	718.245		
	Lower-bound	17237.877	12.000	1436.490		
side	Sphericity Assumed	5169.747	1	5169.747	4.287	.061
	Greenhouse-Geisser	5169.747	1.000	5169.747	4.287	.061
	Huynh-Feldt	5169.747	1.000	5169.747	4.287	.061
	Lower-bound	5169.747	1.000	5169.747	4.287	.061
Error(SIDE)	Sphericity Assumed	14471.088	12	1205.924		
	Greenhouse-Geisser	14471.088	12.000	1205.924		
	Huynh-Feldt	14471.088	12.000	1205.924		
	Lower-bound	14471.088	12.000	1205.924		
condition * phase	Sphericity Assumed	80083.553	6	13347.259	26.533	.000
	Greenhouse-Geisser	80083.553	2.250	35595.403	26.533	.000
	Huynh-Feldt	80083.553	2.795	28656.597	26.533	.000
	Lower-bound	80083.553	1.000	80083.553	26 533	.000
Error(COND*PHASE)	Sphericity Assumed	36219.041	72	503.042		
	Greenhouse-Geisser	36219.041	26.998	1341.548		
	Huynh-Feldt	36219.041	33.535	1080.033		
	Lower-bound	36219.041	12.000	3018.253		
condition * side	Sphericity Assumed	3752.970	3	1250.990	1.239	.310
	Greenhouse-Geisser	3752.970	2.007	1870.288	1.239	.307
	Huynh-Feldt	3752.970	2.410	1557.112	1.239	.309
	Lower-bound	3752.970	1.000	3752.970	1.239	.287
Error(COND*SIDE)	Sphericity Assumed	36336.990	36	1009.361		
	Greenhouse-Geisser	36336.990	24.080	1509.041		
	Huynh-Feldt	36336.990	28.923	1256.355		
	Lower-bound	36336.990	12.000	3028.083		
phase * side	Sphericity Assumed	1829.177	2	914.589	1.622	.218
	Greenhouse-Geisser	1829.177	1.531	1194.722	1.622	.225
	Huynh-Feldt	1829.177	1.710	1069.592	1.622	.223
	Lower-bound	1829.177	1.000	1829.177	1.622	.227
Error(PHASE*SIDE)	Sphericity Assumed	13532.979	24	563.874		
	Greenhouse-Geisser	13532.979	18.373	736.586		
	Huynh-Feldt	13532.979	20.522	659.439		
	Lower-bound	13532.979	12.000	1127.748		
condition * phase * side	Sphericity Assumed	6669.907	6	1111.651	2.446	.033
	Greenhouse-Geisser	6669.907	1.902	3506.099	2.446	.111
	Huynh-Feldt	6669.907	2.251	2962.945	2.446	.100
	Lower-bound	6669 907	1.000	6669.907	2.446	.144
Error(COND*PHASE*SIDE)	Sphericity Assumed	32728.034	72	454.556		
	Greenhouse-Geisser	32728.034	22.828	1433.650		
	Huynh-Feldt	32728.034	27.013	1211.553		
	Lower-bound	32728.034	12.000	2727 336		

Summary of within subjects effects for blood volume

Mauchly's Test of Sphericity[b]

Measure MEASURE_1

Within Subjects Effect	Mauchly's W	Approx. Chi-Square	df	Sig.	Epsilon[a]		
					Greenhouse-Geisser	Huynh-Feldt	Lower-bound
condition	.171	18.919	5	.002	.620	.729	.333
phase	.990	110	2	.946	.990	1.000	.500
side	1.000	.000	0	.	1.000	1.000	1.000
condition * phase	.005	52.128	20	.000	.375	.466	.167
condition * side	.397	9 903	5	.079	.669	.803	.333
phase * side	.694	4.023	2	.134	.766	.855	.500
condition * phase * side	.001	73.982	20	.000	.317	.375	.167

Summary of Sphericity values for factors in blood volume analysis

Pairwise Comparisons

Measure: MEASURE_1

(I) COND	(J) COND	Mean Difference (I-J)	Std. Error	Sig.[a]	95% Confidence Interval for Difference[a]	
					Lower Bound	Upper Bound
High	Low	29.307*	5.342	.001	12.465	46.149
	Placebo	25.569*	7.537	.032	1.807	49.331
	Control	38.846*	4.570	.000	24.439	53.253
Low	High	-29.307*	5.342	.001	-46.149	-12.465
	Placebo	-3.738	5.520	1.000	-21.141	13.664
	Control	9.539*	1.874	.002	3.630	15.448
Placebo	High	-25.569*	7.537	.032	-49.331	-1.807
	Low	3.738	5.520	1.000	-13.664	21.141
	Control	13.277	5.839	.253	-5.131	31.686
Control	High	-38.846*	4.570	.000	-53.253	-24.439
	Low	-9.539*	1.874	.002	-15.448	-3.630
	Placebo	-13.277	5.839	.253	-31.686	5.131

Based on estimated marginal means

*. The mean difference is significant at the .05 level.

a. Adjustment for multiple comparisons: Bonferroni.

Summary of Post hoc test for blood volume

Pairwise Comparisons

Measure: MEASURE_1

(I) PHASE	(J) PHASE	Mean Difference (I-J)	Std. Error	Sig.[a]	95% Confidence Interval for Difference[a]	
					Lower Bound	Upper Bound
Before	During	-38.877*	3.830	.000	-49.523	-28.231
	After	-7.643	3.528	.153	-17.450	2.163
During	Before	38.877*	3.830	.000	28.231	49.523
	After	31.234*	3.784	.000	20.716	41.752
After	Before	7.643	3.528	.153	-2.163	17.450
	During	-31.234*	3.784	.000	-41.752	-20.716

Based on estimated marginal means

*. The mean difference is significant at the .05 level.

a. Adjustment for multiple comparisons: Bonferroni.

Summary of Post hoc test for blood volume (experimental phase)

SKIN TEMPERATURE DATA

Tests of Within-Subjects Effects

Measure: MEASURE_1

Source		Type III Sum of Squares	df	Mean Square	F	Sig.
condition	Sphericity Assumed	14.999	3	5.000	1.340	.277
	Greenhouse-Geisser	14.999	2.692	5.571	1.340	.279
	Huynh-Feldt	14.999	3.000	5.000	1.340	.277
	Lower-bound	14.999	1.000	14.999	1.340	.270
Error(COND)	Sphericity Assumed	134.303	36	3.731		
	Greenhouse-Geisser	134.303	32.307	4.157		
	Huynh-Feldt	134.303	36.000	3.731		
	Lower-bound	134.303	12.000	11.192		
phase	Sphericity Assumed	8.266	1	8.266	11.828	.005
	Greenhouse-Geisser	8.266	1.000	8.266	11.828	.005
	Huynh-Feldt	8.266	1.000	8.266	11.828	.005
	Lower-bound	8 266	1.000	8.266	11.828	.005
Error(PHASE)	Sphericity Assumed	8.386	12	.699		
	Greenhouse-Geisser	8.386	12.000	.699		
	Huynh-Feldt	8.386	12.000	.699		
	Lower-bound	8.386	12.000	.699		
side	Sphericity Assumed	9.898	1	9.898	18.636	.001
	Greenhouse-Geisser	9.898	1.000	9.898	18.636	.001
	Huynh-Feldt	9.898	1.000	9.898	18.636	.001
	Lower-bound	9.898	1.000	9.898	18.636	.001
Error(SIDE)	Sphericity Assumed	6.373	12	.531		
	Greenhouse-Geisser	6.373	12.000	.531		
	Huynh-Feldt	6.373	12.000	.531		
	Lower-bound	6.373	12.000	.531		
condition * phase	Sphericity Assumed	15.224	3	5.075	11.606	.000
	Greenhouse-Geisser	15.224	2.054	7.414	11.606	.000
	Huynh-Feldt	15.224	2.483	6.132	11.606	.000
	Lower-bound	15.224	1.000	15.224	11.606	.005
Error(COND*PHASE)	Sphericity Assumed	15.742	36	.437		
	Greenhouse-Geisser	15.742	24.642	.639		
	Huynh-Feldt	15.742	29.794	.528		
	Lower-bound	15.742	12.000	1.312		
condition * side	Sphericity Assumed	8.612	3	2.871	6.888	.001
	Greenhouse-Geisser	8.612	2.639	3.263	6.888	.002
	Huynh-Feldt	8.612	3.000	2.871	6.888	.001
	Lower-bound	8.612	1.000	8.612	6.888	.022
Error(COND*SIDE)	Sphericity Assumed	15.003	36	.417		
	Greenhouse-Geisser	15.003	31.668	.474		
	Huynh-Feldt	15.003	36.000	.417		
	Lower-bound	15.003	12.000	1.250		
phase* side	Sphericity Assumed	4.017	1	4.017	33.959	.000
	Greenhouse-Geisser	4.017	1.000	4.017	33.959	.000
	Huynh-Feldt	4.017	1.000	4.017	33.959	.000
	Lower-bound	4.017	1.000	4.017	33.959	.000
Error(PHASE*SIDE)	Sphericity Assumed	1.419	12	.118		
	Greenhouse-Geisser	1.419	12.000	.118		
	Huynh-Feldt	1.419	12.000	.118		
	Lower-bound	1.419	12 000	.118		
condition * phase * side	Sphericity Assumed	7.705	3	2.568	21.056	.000
	Greenhouse-Geisser	7.705	2.268	3.398	21.056	.000
	Huynh-Feldt	7.705	2.823	2.729	21.056	.000
	Lower-bound	7.705	1.000	7.705	21.056	.001
Error(COND*PHASE*SIDE)	Sphericity Assumed	4.391	36	.122		
	Greenhouse-Geisser	4.391	27.211	.161		
	Huynh-Feldt	4.391	33.880	.130		
	Lower-bound	4.391	12.000	.366		

Summary of within subjects effects of skin temperature

Pairwise Comparisons

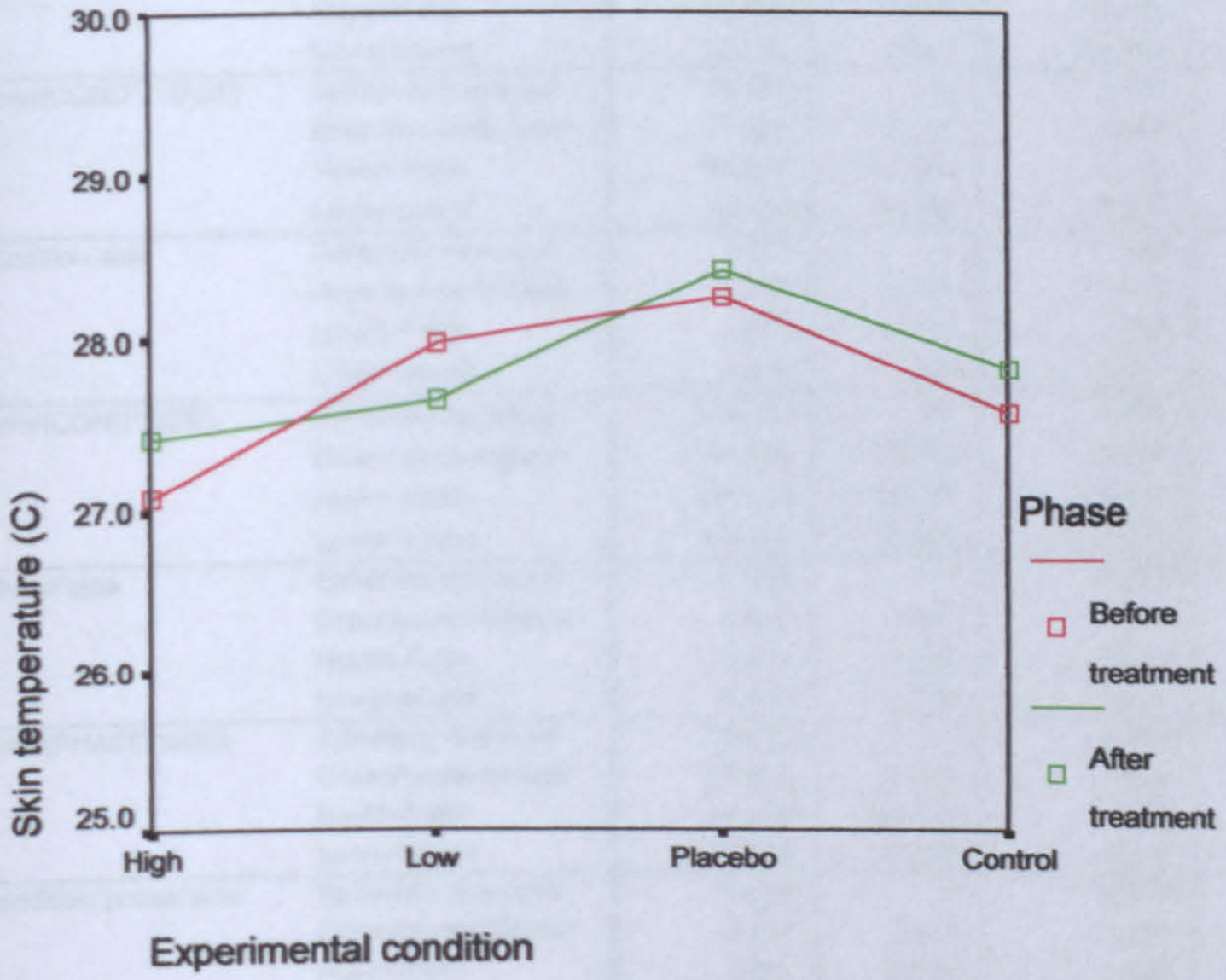
Measure: MEASURE_1

(I) COND	(J) COND	Mean Difference (I-J)	Std. Error	Sig.[a]	95% Confidence Interval for Difference[a]	
					Lower Bound	Upper Bound
high	low	-.304	.364	1.000	-1.451	.843
	placebo	-.600	.340	.617	-1.672	.472
	control	7.845E-02	.395	1.000	-1.168	1.325
low	high	.304	.364	1.000	-.843	1.451
	placebo	-.296	.331	1.000	-1.340	.748
	control	.383	.454	1.000	-1.049	1.814
placebo	high	.600	.340	.617	-.472	1.672
	low	.296	.331	1.000	-.748	1.340
	control	.679	.375	.574	-.504	1.862
control	high	-7.845E-02	.395	1.000	-1.325	1.168
	low	-.383	.454	1.000	-1.814	1.049
	placebo	-.679	.375	.574	-1.862	.504

Based on estimated marginal means

a. Adjustment for multiple comparisons: Bonferroni.

Summary of post hoc results for skin temperature



Changes in skin temperature across the experimental conditions in the non-treated side

DATA FOR NERVE CONDUCTION VELOCITY

Tests of Within-Subjects Effects

Measure MEASURE_1

Source		Type III Sum of Squares	df	Mean Square	F	Sig.
condition	Sphericity Assumed	60.531	3	20.177	.612	.612
	Greenhouse-Geisser	60.531	1.728	35.036	.612	.529
	Huynh-Feldt	60.531	1.992	30.391	.612	.550
	Lower-bound	60.531	1.000	60.531	.612	.449
Error(COND)	Sphericity Assumed	1186.509	36	32.959		
	Greenhouse-Geisser	1186.509	20.732	57.231		
	Huynh-Feldt	1186.509	23.901	49.643		
	Lower-bound	1186.509	12.000	98 876		
phase	Sphericity Assumed	18.993	1	18.993	10.561	.007
	Greenhouse-Geisser	18.993	1.000	18.993	10.561	.007
	Huynh-Feldt	18.993	1.000	18.993	10.561	.007
	Lower-bound	18.993	1.000	18.993	10.561	.007
Error(PHASE)	Sphericity Assumed	21.582	12	1.798		
	Greenhouse-Geisser	21.582	12.000	1.798		
	Huynh-Feldt	21.582	12.000	1.798		
	Lower-bound	21.582	12.000	1.798		
side	Sphericity Assumed	.252	1	.252	.076	.787
	Greenhouse-Geisser	.252	1.000	.252	.076	.787
	Huynh-Feldt	.252	1.000	.252	.076	.787
	Lower-bound	.252	1.000	.252	.076	.787
Error(SIDE)	Sphericity Assumed	39.721	12	3.310		
	Greenhouse-Geisser	39.721	12.000	3.310		
	Huynh-Feldt	39.721	12.000	3.310		
	Lower-bound	39.721	12.000	3.310		
condition*phase	Sphericity Assumed	30.788	3	10.263	4.674	.007
	Greenhouse-Geisser	30.788	1.437	21.423	4.674	.033
	Huynh-Feldt	30.788	1.579	19.494	4.674	.029
	Lower-bound	30.788	1.000	30 788	4.674	.052
Error(COND*PHASE)	Sphericity Assumed	79.038	36	2.196		
	Greenhouse-Geisser	79.038	17.246	4.583		
	Huynh-Feldt	79.038	18.953	4.170		
	Lower-bound	79.038	12.000	6.587		
condition*side	Sphericity Assumed	1.917	3	.639	.172	.915
	Greenhouse-Geisser	1.917	2.198	.872	.172	.862
	Huynh-Feldt	1.917	2.711	.707	.172	.899
	Lower-bound	1.917	1.000	1.917	.172	.686
Error(COND*SIDE)	Sphericity Assumed	134.140	36	3.726		
	Greenhouse-Geisser	134.140	26.379	5.085		
	Huynh-Feldt	134.140	32.537	4.123		
	Lower-bound	134.140	12.000	11.178		
phase*side	Sphericity Assumed	2.677	1	2.677	1.176	.299
	Greenhouse-Geisser	2.677	1.000	2.677	1.176	.299
	Huynh-Feldt	2.677	1.000	2.677	1.176	.299
	Lower-bound	2.677	1.000	2.677	1.176	.299
Error(PHASE*SIDE)	Sphericity Assumed	27.312	12	2.276		
	Greenhouse-Geisser	27.312	12.000	2.276		
	Huynh-Feldt	27.312	12.000	2.276		
	Lower-bound	27.312	12.000	2.276		
condition*phase*side	Sphericity Assumed	4.674	3	1.558	.749	.530
	Greenhouse-Geisser	4.674	2.081	2.245	.749	.488
	Huynh-Feldt	4.674	2.526	1.850	.749	.510
	Lower-bound	4.674	1.000	4.674	.749	.404
Error(COND*PHASE*SIDE)	Sphericity Assumed	74.842	36	2.079		
	Greenhouse-Geisser	74.842	24.977	2.996		
	Huynh-Feldt	74.842	30.317	2.469		
	Lower-bound	74.842	12.000	6.237		

Summary of between subjects effects for NCV

Tests of Within-Subjects Contrasts

Measure: MEASURE_1

Source	Condition	Phase	Side	Type III Sum of Squares	df	Mean Square	F	Sig.
Condition	High vs control			27.808	1	27.808	3.245	.097
	Low vs control			11.342	1	11.342	1.067	.322
	Placebo vs control			15.672	1	15.672	.757	.401
Error(COND)	High vs control			102.826	12	8.569		
	Low vs control			127.604	12	10.634		
	Placebo vs control			248.321	12	20.693		
Phase		Before vs after		4.748	1	4.748	10.561	.007
Error(PHASE)		Before vs after		5.395	12	.450		
Side			Treated vs non treated	6.306E-02	1	6.306E-02	.076	.787
Error(SIDE)			Treated vs non treated	9.930	12	.828		
Condition vs phase	High vs control	Before vs after		50.433	1	50.433	6.329	.027
	Low vs control	Before vs after		3.932	1	3.932	4.013	.068
	Placebo vs control	Before vs after		.545	1	.545	.314	.586
Error(COND*PHASE)	High vs control	Before vs after		95.618	12	7.968		
	Low vs control	Before vs after		11.757	12	.980		
	Placebo vs control	Before vs after		20.829	12	1.736		
Condition vs side	High vs control		Treated vs non treated	3.002	1	3.002	.718	.413
	Low vs control		Treated vs non treated	.381	1	.381	.047	.832
	Placebo vs control		Treated vs non treated	2.221	1	2.221	.542	.476
Error(COND*SIDE)	High vs control		Treated vs non treated	50.189	12	4.182		
	Low vs control		Treated vs non treated	97.812	12	8.151		
	Placebo vs control		Treated vs non treated	49.145	12	4.095		
Phase vs side		Before vs after	Treated vs non treated	2.677	1	2 677	1.176	299
Error(PHASE*SIDE)		Before vs after	Treated vs non treated	27.312	12	2.276		
Condition vs phase vs side	High vs control	Before vs after	Treated vs non treated	18.326	1	18.326	1.014	.334
	Low vs control	Before vs after	Treated vs non treated	22.468	1	22.468	1.579	.233
	Placebo vs control	Before vs after	Treated vs non treated	.175	1	.175	.024	.881
Error(COND*PHASE*SIDE)	High vs control	Before vs after	Treated vs non treated	216.940	12	18.078		
	Low vs control	Before vs after	Treated vs non treated	170.727	12	14.227		
	Placebo vs control	Before vs after	Treated vs non treated	89.260	12	7.438		

Summary of within subjects contrasts for nerve conduction velocity

Mauchly's Test of Sphericity[b]

Measure: MEASURE_1

Within Subjects Effect	Mauchly's W	Approx. Chi-Square	df	Sig.	Epsilon[a]		
					Greenhous e-Geisser	Huynh-Feldt	Lower-bound
condition	.272	13.968	5	.016	.576	.664	.333
Phase	1.000	.000	0	.	1.000	1.000	1.000
side	1.000	000	0	.	1.000	1.000	1.000
conditon*phase	135	21.490	5	.001	.479	.526	.333
condition*side	.584	5.759	5	.332	.733	.904	.333
phase*side	1.000	.000	0	.	1.000	1.000	1.000
condition*phase*side	.502	7 382	5	.195	.694	.842	.333

Tests the null hypothesis that the error covariance matrix of the orthonormalized transformed dependent variables is proportional to an identity matrix.

a. May be used to adjust the degrees of freedom for the averaged tests of significance. Corrected tests are displayed in the Tests of Within-Subjects Effects table.

b.
Design. Intercept
Within Subjects Design: COND+PHASE+SIDE+COND*PHASE+COND*SIDE+PHASE*SIDE+COND*PHASE*SIDE

Pairwise Comparisons

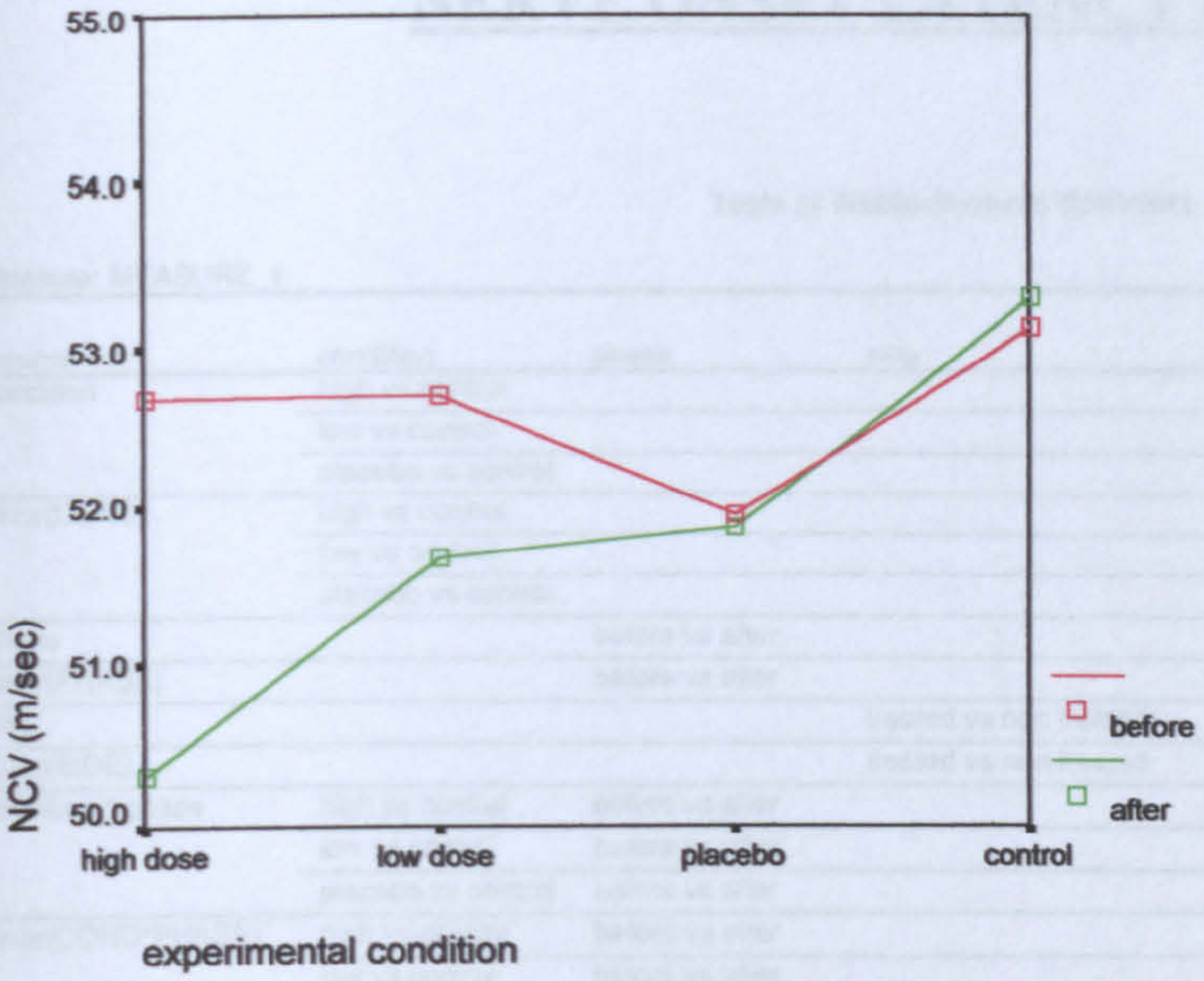
Measure: MEASURE_1

(I) COND	(J) COND	Mean Difference (I-J)	Std. Error	Sig.[a]	95% Confidence Interval for Difference[a]	
					Lower Bound	Upper Bound
high	low	-.529	.546	.352	-1.719	.662
	placebo	-.365	1.363	.794	-3.334	2.605
	control	-1.463	.812	.097	-3.231	.306
low	high	.529	.546	.352	-.662	1.719
	placebo	.164	1.543	.917	-3.198	3.526
	control	-.934	.904	.322	-2.905	1.037
placebo	high	.365	1.363	.794	-2.605	3.334
	low	-.164	1.543	.917	-3.526	3.198
	control	-1.098	1.262	.401	-3.847	1.651
control	high	1.463	.812	.097	-.306	3.231
	low	.934	.904	.322	-1.037	2.905
	placebo	1.098	1.262	.401	-1.651	3.847

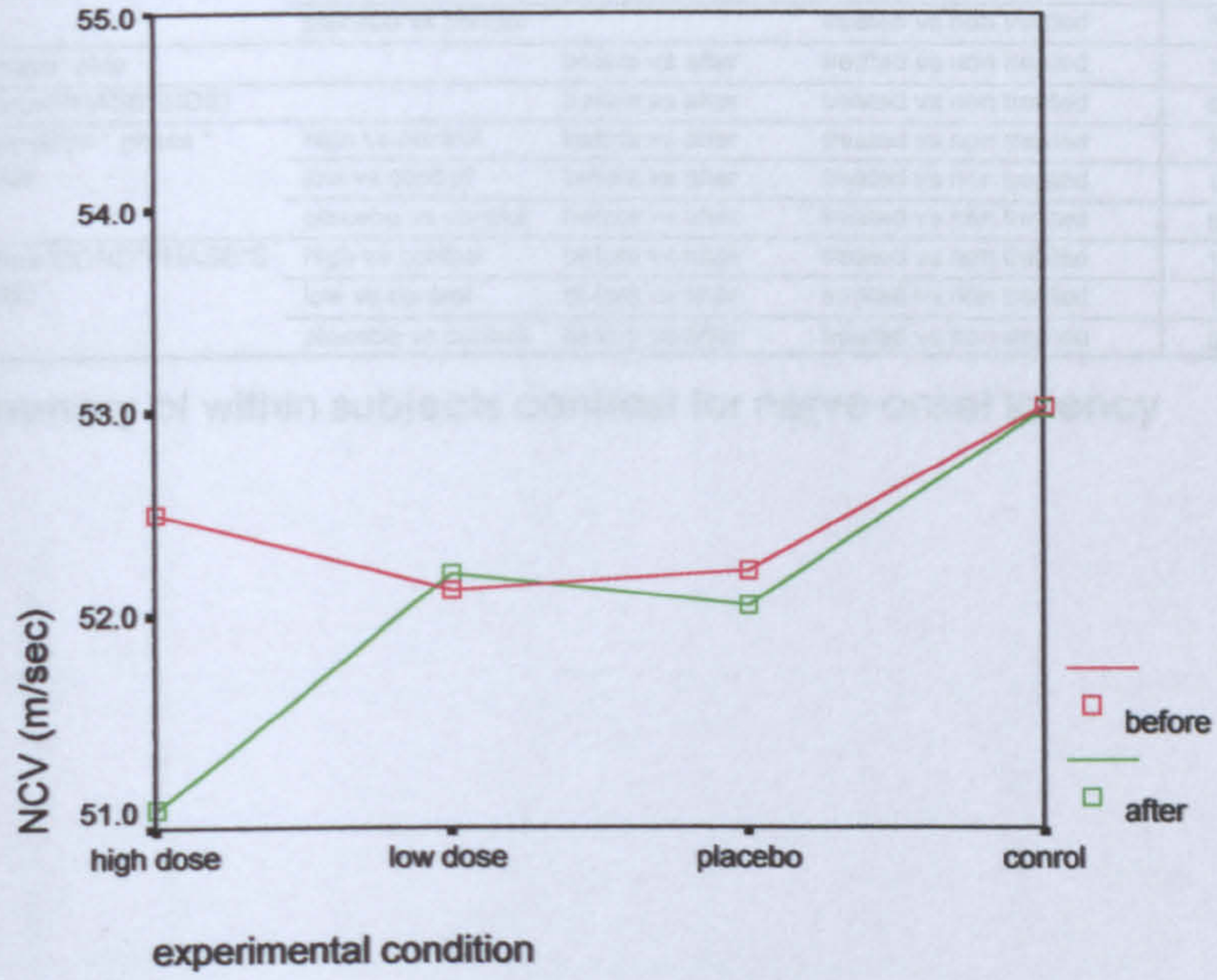
Based on estimated marginal means

a. Adjustment for multiple comparisons: Least Significant Difference (equivalent to no adjustments).

Summary of Post hoc test of nerve conduction velocity



Changes in nerve condition across experimental conditions in treated side



Changes in nerve conduction across experimental conditions in non-treated side

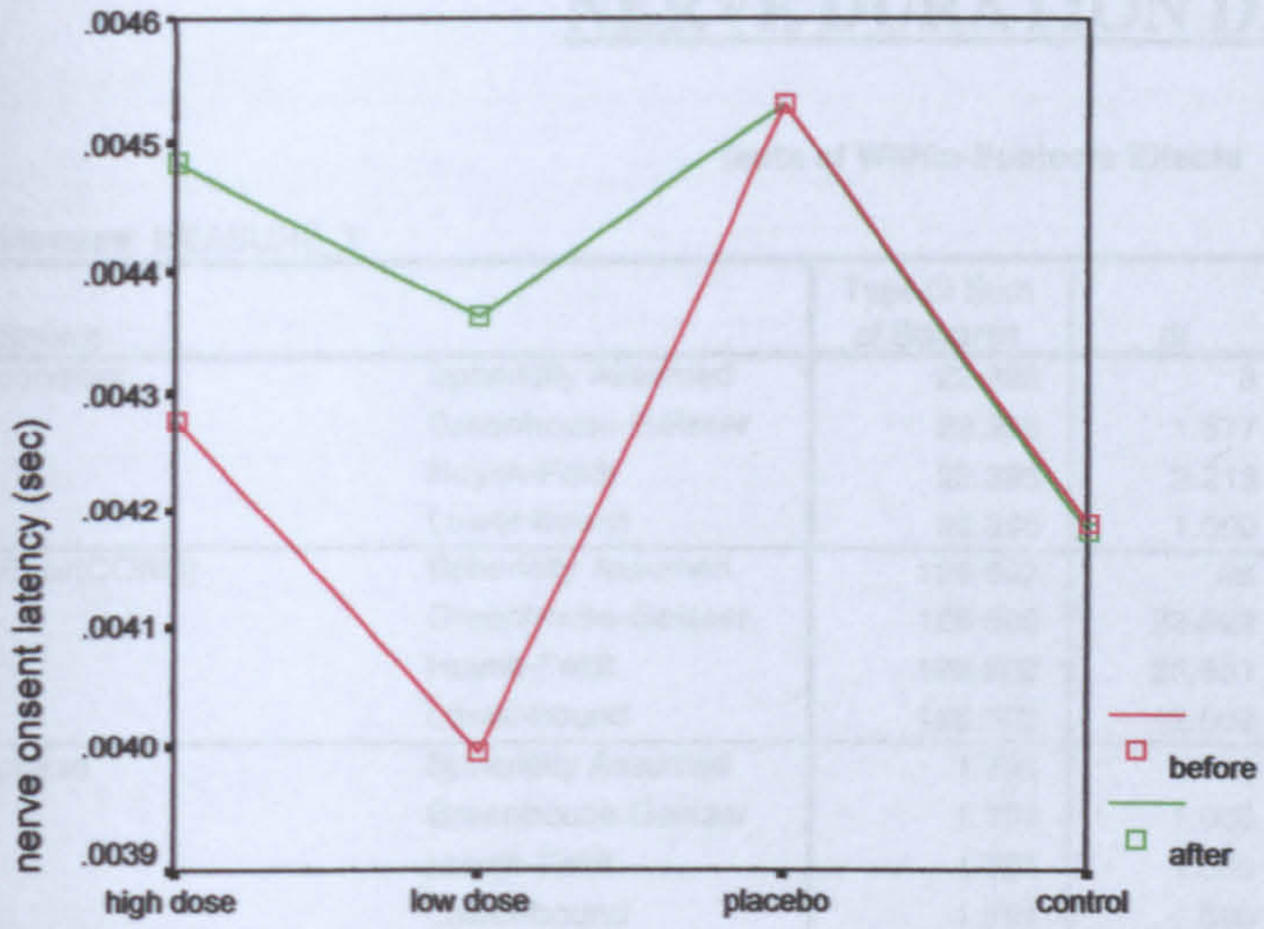
NERVE ONSET LATENCY DATA

Tests of Within-Subjects Contrasts

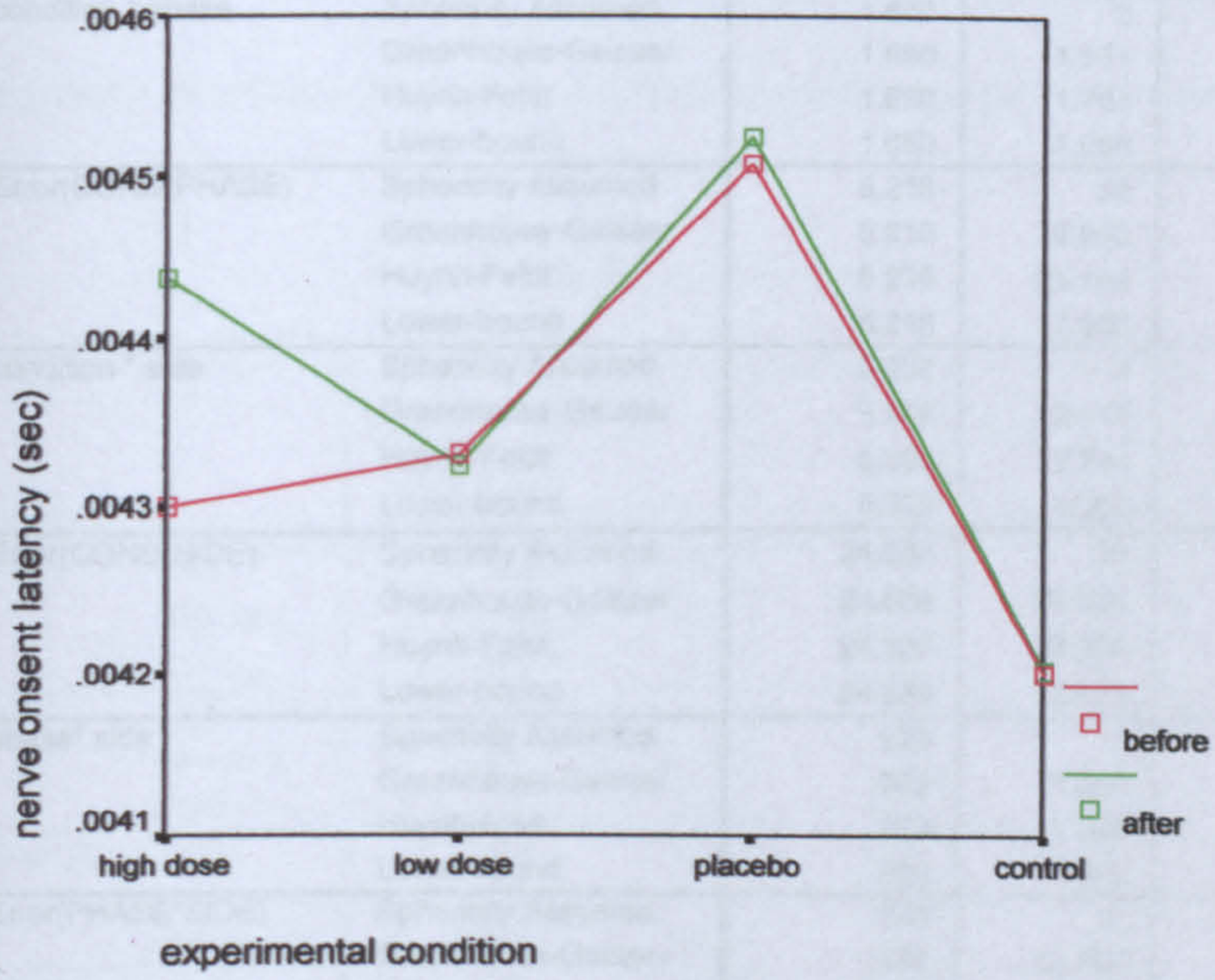
Measure: MEASURE_1

Source	condition	phase	side	Type III Sum of Squares	df	Mean Square	F	Sig.
condition	high vs control			4.235E-07	1	4.235E-07	1.6	.229
	low vs control			4.561E-08	1	4.561E-08	.166	.691
	placebo vs control			1.405E-06	1	1.405E-06	2.7	.127
Error(COND)	high vs control			3.162E-06	12	2.635E-07		
	low vs control			3.301E-06	12	2.751E-07		
	placebo vs control			6.263E-06	12	5.219E-07		
phase		before vs after		1.031E-07	1	1.031E-07	5.6	.035
Error(PHASE)		before vs after		2.190E-07	12	1.825E-08		
side			treated vs non treated	1 406E-08	1	1.406E-08	.673	.428
Error(SIDE)			treated vs non treated	2.506E-07	12	2.088E-08		
condition * phase	high vs control	before vs after		4.043E-07	1	4.043E-07	6.0	.031
	low vs control	before vs after		4.284E-07	1	4 284E-07	1.6	.225
	placebo vs control	before vs after		1.674E-09	1	1.674E-09	.133	.721
Error(COND*PHASE)	high vs control	before vs after		8.140E-07	12	6.783E-08		
	low vs control	before vs after		3.142E-06	12	2.618E-07		
	placebo vs control	before vs after		1.507E-07	12	1.256E-08		
condition * side	high vs control		treated vs non treated	7.039E-09	1	7.039E-09	184	.676
	low vs control		treated vs non treated	2.356E-07	1	2.356E-07	1.2	.296
	placebo vs control		treated vs non treated	9.289E-09	1	9.289E-09	.364	.557
Error(COND*SIDE)	high vs control		treated vs non treated	4.597E-07	12	3.831E-08		
	low vs control		treated vs non treated	2.371E-06	12	1.976E-07		
	placebo vs control		treated vs non treated	3.061E-07	12	2.551E-08		
phase* side		before vs after	treated vs non treated	1.412E-07	1	1.412E-07	1.9	.189
Error(PHASE*SIDE)		before vs after	treated vs non treated	8.749E-07	12	7.291E-08		
condition * phase * side	high vs control	before vs after	treated vs non treated	7.769E-08	1	7.769E-08	493	.496
	low vs control	before vs after	treated vs non treated	1.877E-06	1	1.877E-06	1.9	.190
	placebo vs control	before vs after	treated vs non treated	8.481E-10	1	8.481E-10	.016	.901
Error(COND*PHASE*SIDE)	high vs control	before vs after	treated vs non treated	1.891E-06	12	1.576E-07		
	low vs control	before vs after	treated vs non treated	1.167E-05	12	9.728E-07		
	placebo vs control	before vs after	treated vs non treated	6.268E-07	12	5.224E-08		

Summary of within subjects contrast for nerve onset latency



Changes in nerve onset latency across the experimental conditions in the treated side



Changes in nerve onset latency across the experimental conditions in the non-treated side

NERVE DURATION DATA

Tests of Within-Subjects Effects

Measure: MEASURE_1

Source		Type III Sum of Squares	df	Mean Square	F	Sig.
condition	Sphericity Assumed	22 396	3	7 465	2.124	.114
	Greenhouse-Geisser	22.396	1.877	11.933	2.124	.145
	Huynh-Feldt	22.396	2.213	10.122	2.124	.135
	Lower-bound	22 396	1.000	22.396	2.124	.171
Error(COND)	Sphericity Assumed	126.502	36	3.514		
	Greenhouse-Geisser	126.502	22.522	5.617		
	Huynh-Feldt	126.502	26.551	4.764		
	Lower-bound	126.502	12.000	10.542		
phase	Sphericity Assumed	1.791	1	1.791	9.515	.009
	Greenhouse-Geisser	1 791	1.000	1.791	9.515	.009
	Huynh-Feldt	1.791	1.000	1.791	9.515	.009
	Lower-bound	1.791	1.000	1.791	9.515	.009
Error(PHASE)	Sphericity Assumed	2.259	12	.188		
	Greenhouse-Geisser	2.259	12.000	.188		
	Huynh-Feldt	2.259	12.000	.188		
	Lower-bound	2.259	12.000	.188		
side	Sphericity Assumed	.592	1	.592	.244	.630
	Greenhouse-Geisser	.592	1.000	.592	.244	.630
	Huynh-Feldt	.592	1.000	.592	.244	.630
	Lower-bound	.592	1.000	.592	.244	.630
Error(SIDE)	Sphericity Assumed	29.125	12	2.427		
	Greenhouse-Geisser	29.125	12.000	2.427		
	Huynh-Feldt	29.125	12.000	2.427		
	Lower-bound	29.125	12.000	2.427		
condition * phase	Sphericity Assumed	1.650	3	.550	3.795	.018
	Greenhouse-Geisser	1 650	1.571	1.050	3.795	.050
	Huynh-Feldt	1.650	1.767	.934	3.795	.044
	Lower-bound	1.650	1.000	1.650	3.795	.075
Error(COND*PHASE)	Sphericity Assumed	5.218	36	.145		
	Greenhouse-Geisser	5.218	18.853	.277		
	Huynh-Feldt	5.218	21.199	.246		
	Lower-bound	5.218	12.000	.435		
condition * side	Sphericity Assumed	5.252	3	1.751	2.532	.072
	Greenhouse-Geisser	5.252	2.219	2.367	2.532	.094
	Huynh-Feldt	5.252	2.744	1.914	2.532	.079
	Lower-bound	5.252	1.000	5 252	2.532	.138
Error(COND*SIDE)	Sphericity Assumed	24.889	36	.691		
	Greenhouse-Geisser	24.889	26.626	.935		
	Huynh-Feldt	24.889	32.934	.756		
	Lower-bound	24.889	12.000	2.074		
phase* side	Sphericity Assumed	.929	1	.929	15.003	.002
	Greenhouse-Geisser	.929	1.000	.929	15.003	.002
	Huynh-Feldt	.929	1.000	.929	15.003	.002
	Lower-bound	.929	1.000	.929	15.003	.002
Error(PHASE*SIDE)	Sphericity Assumed	.743	12	6.192E-02		
	Greenhouse-Geisser	.743	12.000	6.192E-02		
	Huynh-Feldt	.743	12.000	6.192E-02		
	Lower-bound	.743	12.000	6.192E-02		
condition* phase * side	Sphericity Assumed	.511	3	.170	1.262	.302
	Greenhouse-Geisser	.511	1.826	.280	1.262	.300
	Huynh-Feldt	.511	2.136	.239	1.262	.302
	Lower-bound	.511	1.000	.511	1.262	.283
Error(COND*PHASE*SIDE)	Sphericity Assumed	4.855	36	.135		
	Greenhouse-Geisser	4.855	21.908	.222		
	Huynh-Feldt	4.855	25.633	.189		
	Lower-bound	4 855	12 000	.405		

Summary of within subjects effects for nerve response duration

Tests of Within-Subjects Contrasts

Measure: MEASURE_1

Source	condition	phase	side	Type III Sum of Squares	df	Mean Square	F	Sig.
condition	high vs control			.162	1	.162	.114	.742
	low vs control			1.981	1	1.981	4.719	.051
	placebo vs control			3.662	1	3.662	1.205	.294
Error(COND)	high vs control			17.093	12	1.424		
	low vs control			5.038	12	.420		
	placebo vs control			36.468	12	3.039		
phase		before vs after		.448	1	.448	9.515	.009
Error(PHASE)		before vs after		.565	12	4.7E-02		
side			treated vs non treated	.148	1	.148	.244	.630
Error(SIDE)			treated vs non treated	7.281	12	.607		
condition * phase	high vs control	before vs after		3.053	1	3.053	6.171	.029
	low vs control	before vs after		.500	1	.500	4.147	.064
	placebo vs control	before vs after		.197	1	.197	1 856	.198
Error(COND*PHASE)	high vs control	before vs after		5.937	12	.495		
	low vs control	before vs after		1.447	12	.121		
	placebo vs control	before vs after		1.273	12	.106		
condition * side	high vs control		treated vs non treated	7.847	1	7.847	5.334	.040
	low vs control		treated vs non treated	.185	1	.185	.152	.704
	placebo vs control		treated vs non treated	1.231E-02	1	1.2E-02	.013	.912
Error(COND*SIDE)	high vs control		treated vs non treated	17.653	12	1.471		
	low vs control		treated vs non treated	14.603	12	1.217		
	placebo vs control		treated vs non treated	11.668	12	.972		
phase* side		before vs after	treated vs non treated	.929	1	.929	15.0	.002
Error(PHASE*SIDE)		before vs after	treated vs non treated	.743	12	6.2E-02		
condition* phase * side	high vs control	before vs after	treated vs non treated	2.588	1	2.588	1.651	.223
	low vs control	before vs after	treated vs non treated	2.862	1	2.862	5.230	.041
	placebo vs control	before vs after	treated vs non treated	.308	1	.308	.504	.491
Error(COND*PHASE*SIDE)	high vs control	before vs after	treated vs non treated	18.812	12	1.568		
	low vs control	before vs after	treated vs non treated	6.568	12	.547		
	placebo vs control	before vs after	treated vs non treated	7.332	12	.611		

Summary of within subjects contrast for nerve response duration

Pairwise Comparisons

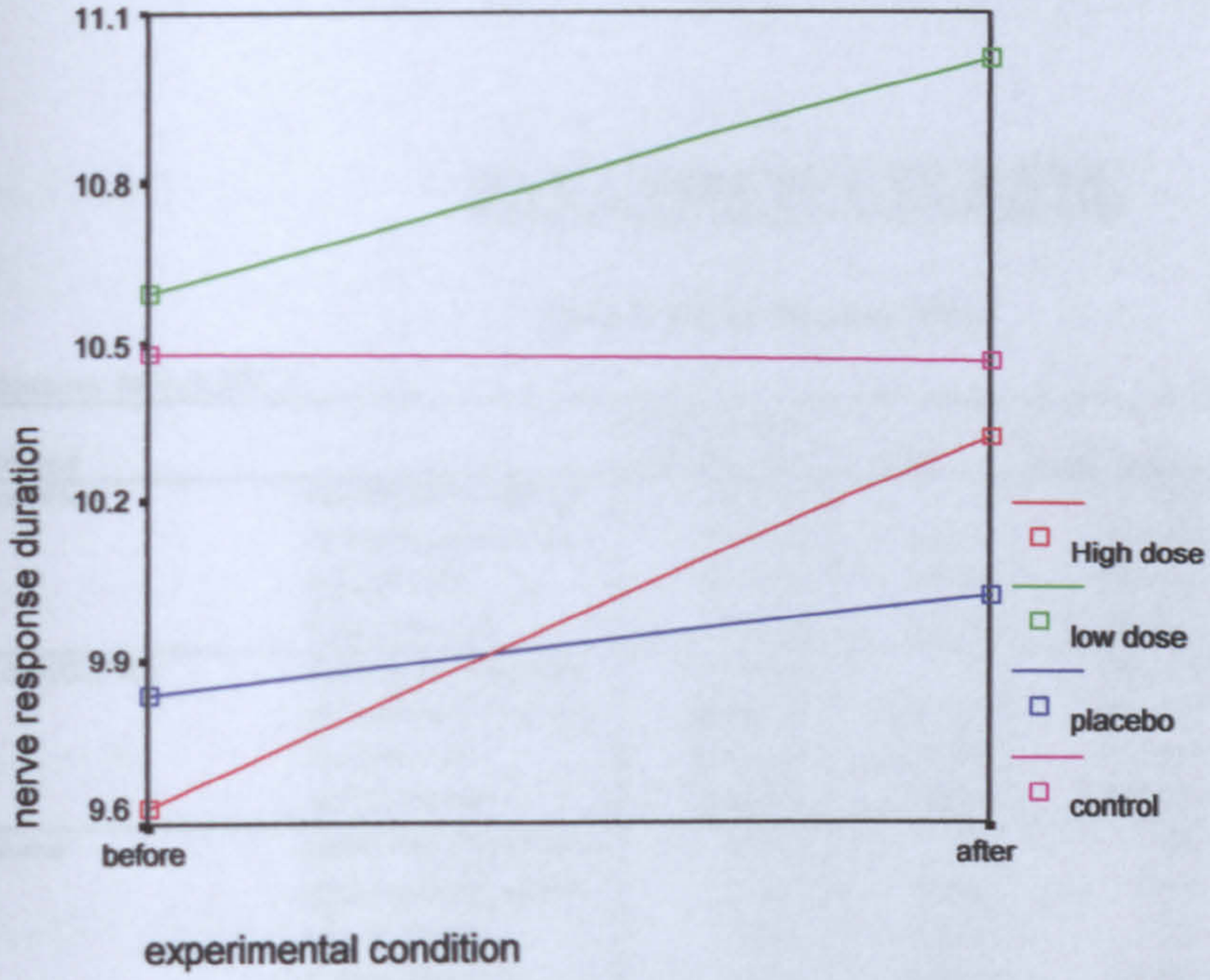
Measure: MEASURE_1

(I) COND	(J) COND	Mean Difference (I-J)	Std. Error	Sig.[a]	95% Confidence Interval for Difference[a]	
					Lower Bound	Upper Bound
high	low	-.502	.254	.428	-1.302	.298
	placebo	.419	.454	1.000	-1.013	1.851
	control	-.112	.331	1.000	-1.155	.932
low	high	.502	.254	.428	-.298	1.302
	placebo	.921	.406	.254	-.358	2.200
	control	.390	.180	.304	-.176	.957
placebo	high	-.419	.454	1.000	-1.851	1.013
	low	-.921	.406	.254	-2.200	.358
	control	-.531	.483	1.000	-2.055	.994
control	high	.112	.331	1.000	-.932	1.155
	low	-.390	.180	.304	-.957	.176
	placebo	.531	.483	1.000	-.994	2.055

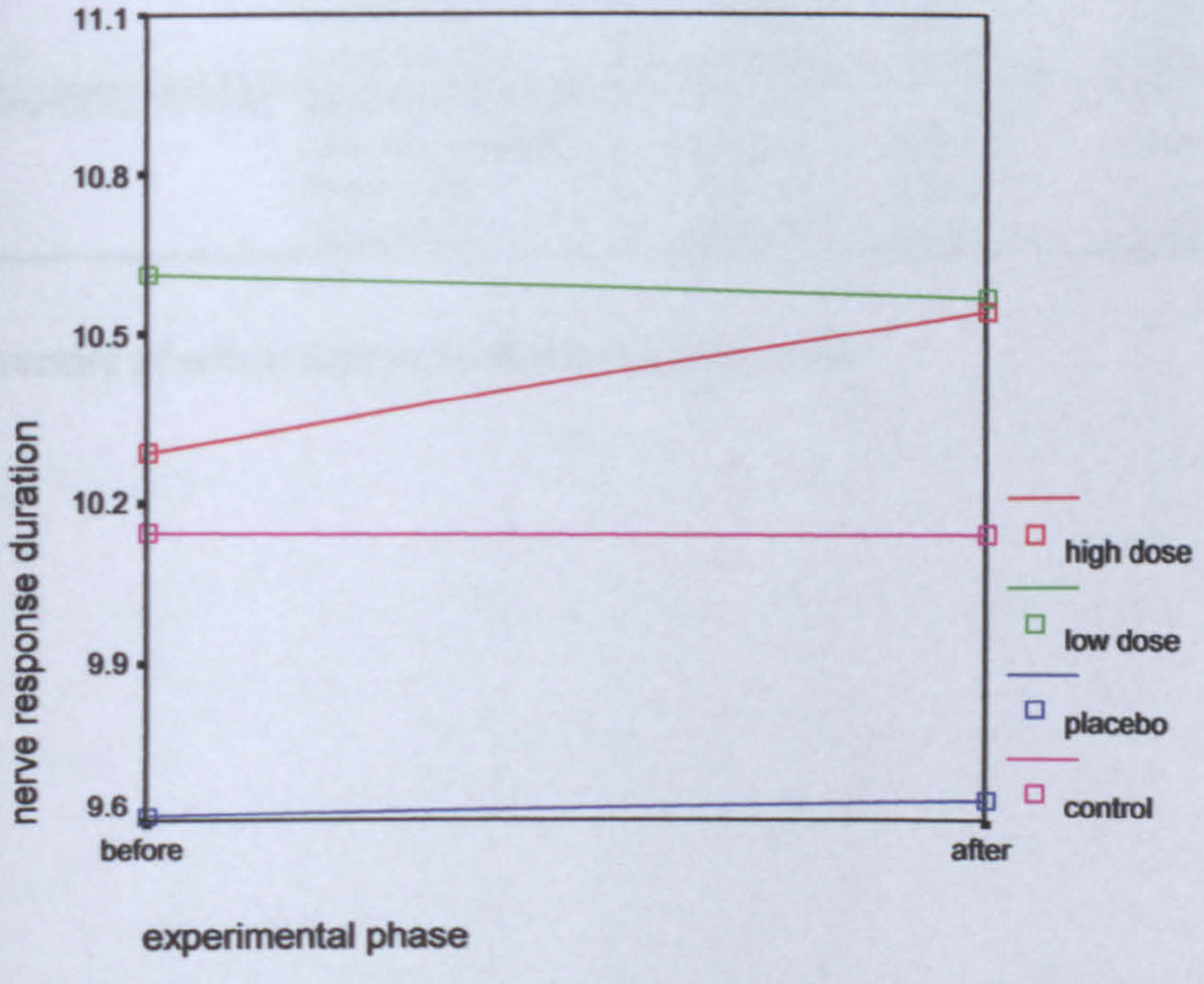
Based on estimated marginal means

a. Adjustment for multiple comparisons: Bonferroni.

Summary of post hoc test for nerve response duration



Changes in nerve response duration across the experimental conditions in treated side



Changes in nerve response duration cross the experimental conditions in the non-treated side

DATA FOR PULSE RATE

Tests of Within-Subjects Effects

Measure: MEASURE_1

Source		Type III Sum of Squares	df	Mean Square	F	Sig.
condition	Sphericity Assumed	473.555	3	157.852	1.214	.318
	Greenhouse-Geisser	473.555	2.429	194.948	1.214	.317
	Huynh-Feldt	473.555	3.000	157.852	1.214	.318
	Lower-bound	473.555	1.000	473.555	1.214	.292
Error(COND)	Sphericity Assumed	4679.254	36	129.979		
	Greenhouse-Geisser	4679.254	29.150	160.525		
	Huynh-Feldt	4679.254	36.000	129.979		
	Lower-bound	4679.254	12.000	389.938		
phase	Sphericity Assumed	2.851	2	1.425	.217	.807
	Greenhouse-Geisser	2.851	1.408	2.025	.217	.729
	Huynh-Feldt	2.851	1.539	1.852	.217	.750
	Lower-bound	2.851	1.000	2.851	.217	.650
Error(PHASE)	Sphericity Assumed	157.702	24	6.571		
	Greenhouse-Geisser	157.702	16.897	9.333		
	Huynh-Feldt	157.702	18.473	8.537		
	Lower-bound	157.702	12.000	13.142		
condition * phase	Sphericity Assumed	36.300	6	6.050	1.603	.159
	Greenhouse-Geisser	36.300	4.240	8.562	1.603	.185
	Huynh-Feldt	36.300	6.000	6.050	1.603	.159
	Lower-bound	36.300	1.000	36.300	1.603	.229
Error(COND*PHASE)	Sphericity Assumed	271.714	72	3.774		
	Greenhouse-Geisser	271.714	50.877	5.341		
	Huynh-Feldt	271.714	72.000	3.774		
	Lower-bound	271.714	12.000	22.643		

Summary of within subjects effects for pulse rate

DATA FOR CORE TEMPERATURE

Tests of Within-Subjects Effects

Measure: MEASURE_1

Source		Type III Sum of Squares	df	Mean Square	F	Sig
condition	Sphericity Assumed	1 548	3	.516	3.928	.016
	Greenhouse-Geisser	1.548	2.364	.655	3.928	.025
	Huynh-Feldt	1.548	2.982	.519	3.928	.016
	Lower-bound	1.548	1.000	1.548	3.928	.071
Error(COND)	Sphericity Assumed	4.728	36	.131		
	Greenhouse-Geisser	4 728	28.373	.167		
	Huynh-Feldt	4.728	35.788	.132		
	Lower-bound	4.728	12.000	.394		
phase	Sphericity Assumed	.454	2	.227	6.015	.008
	Greenhouse-Geisser	.454	1.742	.261	6.015	.011
	Huynh-Feldt	.454	2.000	.227	6.015	.008
	Lower-bound	.454	1.000	.454	6.015	.030
Error(PHASE)	Sphericity Assumed	.906	24	3.774E-02		
	Greenhouse-Geisser	.906	20.906	4.333E-02		
	Huynh-Feldt	.906	24.000	3.774E-02		
	Lower-bound	.906	12.000	7.549E-02		
condition * phase	Sphericity Assumed	.162	6	2.705E-02	1.209	.311
	Greenhouse-Geisser	.162	3.830	4.237E-02	1.209	.320
	Huynh-Feldt	.162	5.849	2.774E-02	1.209	.312
	Lower-bound	.162	1.000	.162	1.209	.293
Error(COND*PHASE)	Sphericity Assumed	1.610	72	2.236E-02		
	Greenhouse-Geisser	1.610	45.957	3.503E-02		
	Huynh-Feldt	1.610	70.186	2.294E-02		
	Lower-bound	1.610	12.000	.134		

Summary of within subjects contrast for core temperature

Pairwise Comparisons

Measure: MEASURE_1

(I) COND	(J) COND	Mean Difference (I-J)	Std. Error	Sig.[a]	95% Confidence Interval for Difference[a]	
					Lower Bound	Upper Bound
high	low	-.232*	.074	.050	-.464	-3.051E-04
	placebo	-.253	.094	.115	-.548	4.219E-02
	control	-.180	.080	.268	-.433	7.320E-02
low	high	.232*	.074	.050	3.051E-04	.464
	placebo	-2.082E-02	.076	1.000	-.260	.219
	control	5.210E-02	.059	1.000	-.134	.238
placebo	high	.253	.094	.115	-4.219E-02	.548
	low	2.082E-02	.076	1.000	-.219	.260
	control	7.292E-02	.103	1.000	-.251	.397
control	high	.180	.080	.268	-7.320E-02	.433
	low	-5.210E-02	.059	1.000	-.238	.134
	placebo	-7.292E-02	.103	1.000	-.397	.251

Based on estimated marginal means

*. The mean difference is significant at the .05 level.

a. Adjustment for multiple comparisons: Bonferroni.

Summary of post hoc test of core temperature

DATA FOR ROOM TEMPERATURE

Mauchly's Test of Sphericity[b]

Measure: MEASURE_1

Within Subjects Effect	Mauchly's W	Approx. Chi-Square	df	Sig.	Epsilon[a]		
					Greenhouse-Geisser	Huynh-Feldt	Lower-bound
room temperature	.675	4.210	5	.521	.824	1.000	.333
phase	1.000	.000	0	.	1.000	1.000	1.000
room temperature * phase	.127	22.128	5	.001	.483	.532	.333

Summary of Mauchly's test for sphericity for room temperature

Tests of Within-Subjects Effects

Measure: MEASURE_1

Source		Type III Sum of Squares	df	Mean Square	F	Sig
ROMT	Sphericity Assumed	12.029	3	4.010	3.369	.029
	Greenhouse-Geisser	12.029	2.471	4.867	3.369	.039
	Huynh-Feldt	12.029	3.000	4.010	3.369	.029
	Lower-bound	12.029	1.000	12.029	3.369	.091
Error(ROMT)	Sphericity Assumed	42.846	36	1.190		
	Greenhouse-Geisser	42.846	29.656	1.445		
	Huynh-Feldt	42.846	36.000	1.190		
	Lower-bound	42.846	12.000	3.571		
PHASE	Sphericity Assumed	.779	1	.779	6.943	.022
	Greenhouse-Geisser	.779	1.000	.779	6.943	.022
	Huynh-Feldt	.779	1.000	.779	6.943	.022
	Lower-bound	.779	1.000	.779	6.943	.022
Error(PHASE)	Sphericity Assumed	1.346	12	.112		
	Greenhouse-Geisser	1.346	12.000	.112		
	Huynh-Feldt	1.346	12.000	.112		
	Lower-bound	1.346	12.000	.112		
ROMT * PHASE	Sphericity Assumed	.567	3	.189	1.788	.167
	Greenhouse-Geisser	.567	1.450	.391	1.788	.200
	Huynh-Feldt	.567	1.597	.355	1.788	.197
	Lower-bound	.567	1.000	.567	1.788	.206
Error(ROMT*PHASE)	Sphericity Assumed	3.808	36	.106		
	Greenhouse-Geisser	3.808	17.401	.219		
	Huynh-Feldt	3.808	19.167	.199		
	Lower-bound	3.808	12.000	.317		

Summary of within subjects effects for room temperature

Tests of Within-Subjects Contrasts

Measure: MEASURE_1

Source	room temperature	phase	Type III Sum of Squares	df	Mean Square	F	Sig.
room temperature	high vs control		4.327	1	4.327	6.553	.025
	low vs control		.173	1	.173	.148	.708
	placebo vs control		1.558	1	1.558	1.230	.289
Error(ROMT)	high vs control		7.923	12	.660		
	low vs control		14.077	12	1.173		
	placebo vs control		15.192	12	1.266		
phase		before vs after	.389	1	.389	6.943	.022
Error(PHASE)		before vs after	.673	12	5.609E-02		
room tempeature* phase	high vs control	before vs after	1.923	1	1.923	3.261	.096
	low vs control	before vs after	7.692E-02	1	7.692E-02	1.000	.337
	placebo vs control	before vs after	.692	1	.692	3.600	.082
Error(ROMT*PHASE)	high vs control	before vs after	7.077	12	.590		
	low vs control	before vs after	.923	12	7.692E-02		
	placebo vs control	before vs after	2.308	12	.192		

Summary of within subjects contrasts for ambient temperature

Pairwise Comparisons

Measure: MEASURE_1

(I) ROMT	(J) ROMT	Mean Difference (I-J)	Std. Error	Sig.[a]	95% Confidence Interval for Difference[a]	
					Lower Bound	Upper Bound
high	low	-.692	.269	.146	-1.540	.155
	placebo	-.923	.366	.161	-2.078	.232
	control	-.577	.225	.150	-1.287	.134
low	high	.692	.269	.146	-.155	1.540
	placebo	-.231	.323	1.000	-1.250	.789
	control	.115	.300	1.000	-.832	1.062
placebo	high	.923	.366	.161	-.232	2.078
	low	.231	.323	1.000	-.789	1.250
	control	.346	.312	1.000	-.638	1.330
control	high	.577	.225	.150	-.134	1.287
	low	-.115	.300	1.000	-1.062	.832
	placebo	-.346	.312	1.000	-1.330	.638

Based on estimated marginal means

a. Adjustment for multiple comparisons: Bonferroni.

Summary of post hoc test for room temperature

DATA FOR ROOM HUMIDITY

Tests of Within-Subjects Effects

Measure: MEASURE_1

Source		Type III Sum of Squares	df	Mean Square	F	Sig.
condition	Sphericity Assumed	70.346	3	23.449	2.119	.115
	Greenhouse-Geisser	70.346	2.714	25.923	2.119	.122
	Huynh-Feldt	70.346	3.000	23.449	2.119	.115
	Lower-bound	70.346	1.000	70.346	2.119	.171
Error(COND)	Sphericity Assumed	398.404	36	11.067		
	Greenhouse-Geisser	398.404	32.564	12.235		
	Huynh-Feldt	398.404	36.000	11.067		
	Lower-bound	398.404	12.000	33.200		
phase	Sphericity Assumed	.000	1	.000	.000	1.000
	Greenhouse-Geisser	.000	1.000	.000	.000	1.000
	Huynh-Feldt	.000	1.000	.000	.000	1.000
	Lower-bound	.000	1.000	.000	.000	1.000
Error(PHASE)	Sphericity Assumed	4.750	12	.396		
	Greenhouse-Geisser	4.750	12.000	.396		
	Huynh-Feldt	4.750	12.000	.396		
	Lower-bound	4.750	12.000	.396		
condition * phase	Sphericity Assumed	3.000	3	1.000	2.215	.103
	Greenhouse-Geisser	3.000	2.573	1.166	2.215	.114
	Huynh-Feldt	3.000	3.000	1.000	2.215	.103
	Lower-bound	3.000	1.000	3.000	2.215	.162
Error(COND*PHASE)	Sphericity Assumed	16.250	36	.451		
	Greenhouse-Geisser	16.250	30.878	.526		
	Huynh-Feldt	16.250	36.000	.451		
	Lower-bound	16.250	12.000	1.354		

Summary of within subjects effects for room humidity

APPENDIX F.1

ETHICAL APPROVAL FOR THE CLINICAL STUDY

East and North Hertfordshire NHS
NHS Trust

East & North Hertfordshire Hospitals
Local Research Ethics Committee

Chairman: Dr Steve Eckersall
Administrator: Mrs Jenny Austin

Our ref: JCA/4.03

7 May 2003

Ambulance Headquarters
Ascots Lane
Welwyn Garden City
Herts
AL7 4HL

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Maryam Almandil
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PhD student
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University of Hertfordshire
Hatfield Campus
College Lane
Hatfield
Herts
AL10 9AB

almary22@hotmail.com

Dear Maryam

Re: ENHLREC/03-04-4/M93 : A study to investigate the physiological effects of pulsed short wave therapy on osteoarthritic patients

The Chairman, on behalf of the Committee, has considered your response to the issues raised by the Committee at the first review of your application on 30th April 2003 as set out in our letter dated 1st May 2003. The documents considered by the Chairman were as follows:

- Application Check List Version 2 dated 2.5.03
- Patient Information Sheet, Version 2 dated 2.5.03
- Consent Form, Version 2 dated 2.5.03
- Protocol, Version 2 dated 2.5.03

The following members were present at this meeting:

Dr S Eckersall, Consultant Anaesthetist (Chairman)
Dr Uthayakumar, Consultant GU Medicine (Vice Chair)
Mr D Grayson, Lay Member
Professor C Hawley, Consultant Psychiatrist
Mr D Jackson, Pharmacy Representative
Dr I King, GP
Mr D Marcus, Lay Member

It is a condition of the approval that you send the Committee an annual report and a copy of the results of your research when it is completed. Please send these to the administrator at the above address.

Please ensure that you have received approval from the Research & Development Department before commencing your research.

In any future correspondence please quote our study reference numbers.

Yours sincerely

Jenny Austin
Administrator - East & North Hertfordshire Hospitals LREC

cc Heather Davies c/o Annabel Thomas, CARD Dept

APPENDIX F.2

LETTER TO PHYSIOTHERAPY MANAGER

Dear
Date / /

I am a PhD student from University of Hertfordshire, Department of Physiotherapy, I am conducting a project on *The Physiological Effects of Pulsed Short Wave Therapy (PSWT) on Osteoarthritic(OA) Patients*. As such I am trying to target hospitals serving patients with OA of the knee joint.
This project is a phase of a series of investigations on PSWT. I have finished collecting normative data on healthy subjects and my next aim is to compare these observations to patients with OA knees.
The study will involve measuring blood volume, skin temperature and nerve conduction velocity in patients complaining from OA knees. Although the study will be conducted by myself, I will need your co-operation in directing me to OA patients (possibly from OA classes or the department waiting list).
I will also need a small place to store my equipments, as it would be laborious to carry the acquisition unit and its cables around with me.
I attached a copy of a letter written for me by my supervisor in support of my work.

Your co-operation is greatly appreciated

Many thanks

Yours truly,
Maryam Almandil

University of Hertfordshire
Department of Physiotherapy
Hatfield campus
College Lane
Hatfield Herts
AL10 9AB
Or call at 01707 284000 Ext 2054
e-mail: almary22@hotmail.com

APPENDIX F.3

GRID FOR PATIENT HISTORY

Age:

Occupation: full time/ Part time

Have you had treatment in physiotherapy department before?

For what condition?

How do you rate the outcome?

For how long have you been complaining from knee problem?

Do you have RT or LT side knee pain?

Does your knee swells?

Do you hear sounds in your knee(s)?

Is it painful when it clicks?

Do you feel your knee stiff after periods of immobility (sitting down or lying in bed)?

How long does the stiffness last?

Does your knee hurts when you climb the stairs?

Is it more going up or down stairs?

Does your pain wakes you up from sleep?

What eases your pain?

Are you regular on any kind of sport?

Do you do any special Ex for your knee?

Have you had an X-ray done to your knee?

What did they tell you the problem was?

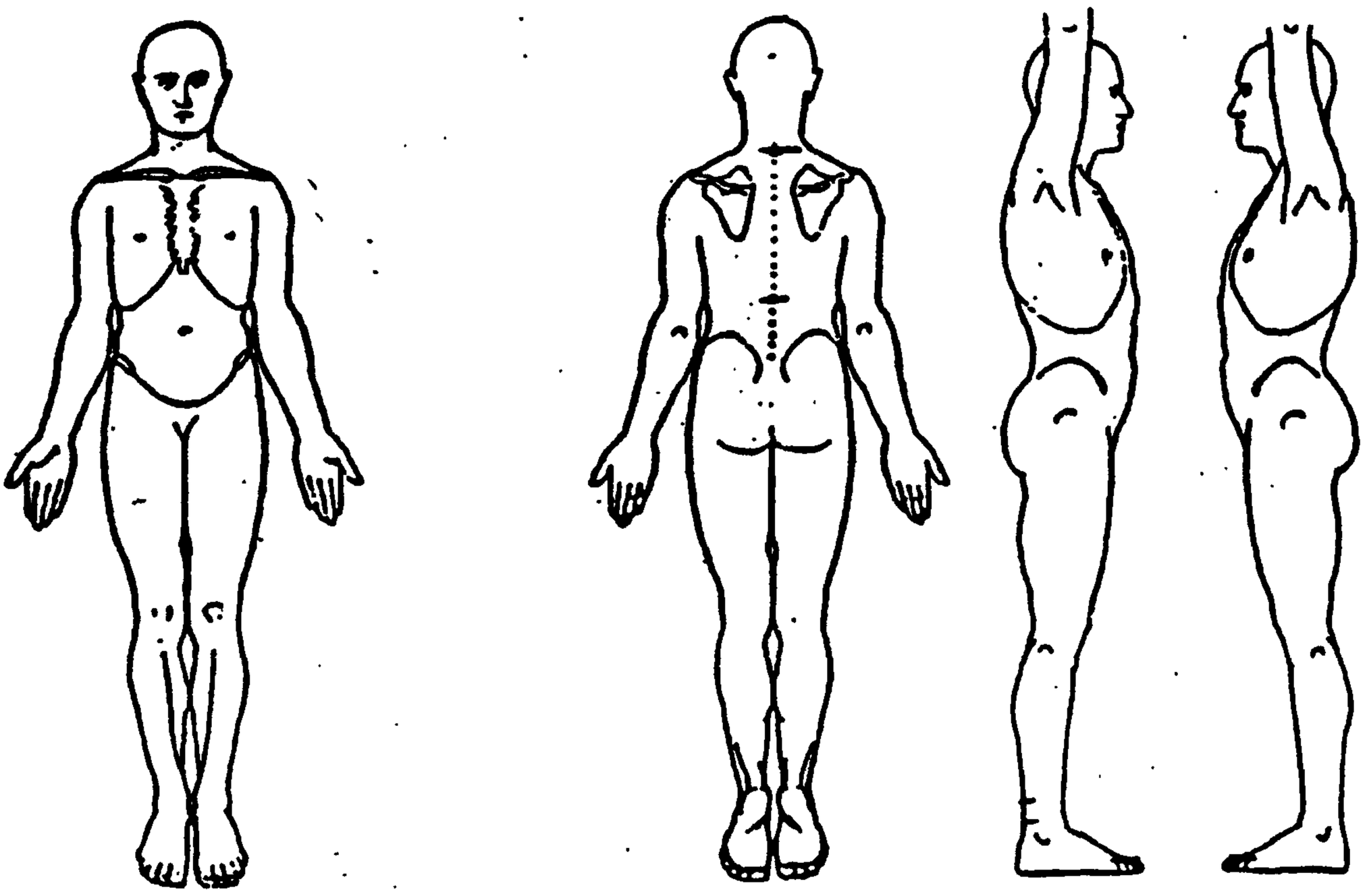
Skinfold measurements

	Measurement 1	Measurement 2	Measurement 3	Mean
Chest				
Triceps				
Suprailium				
Subscapular				
Abdominal				
Fat%				

Special remarks:

Height

Weight



APPENDIX F.4

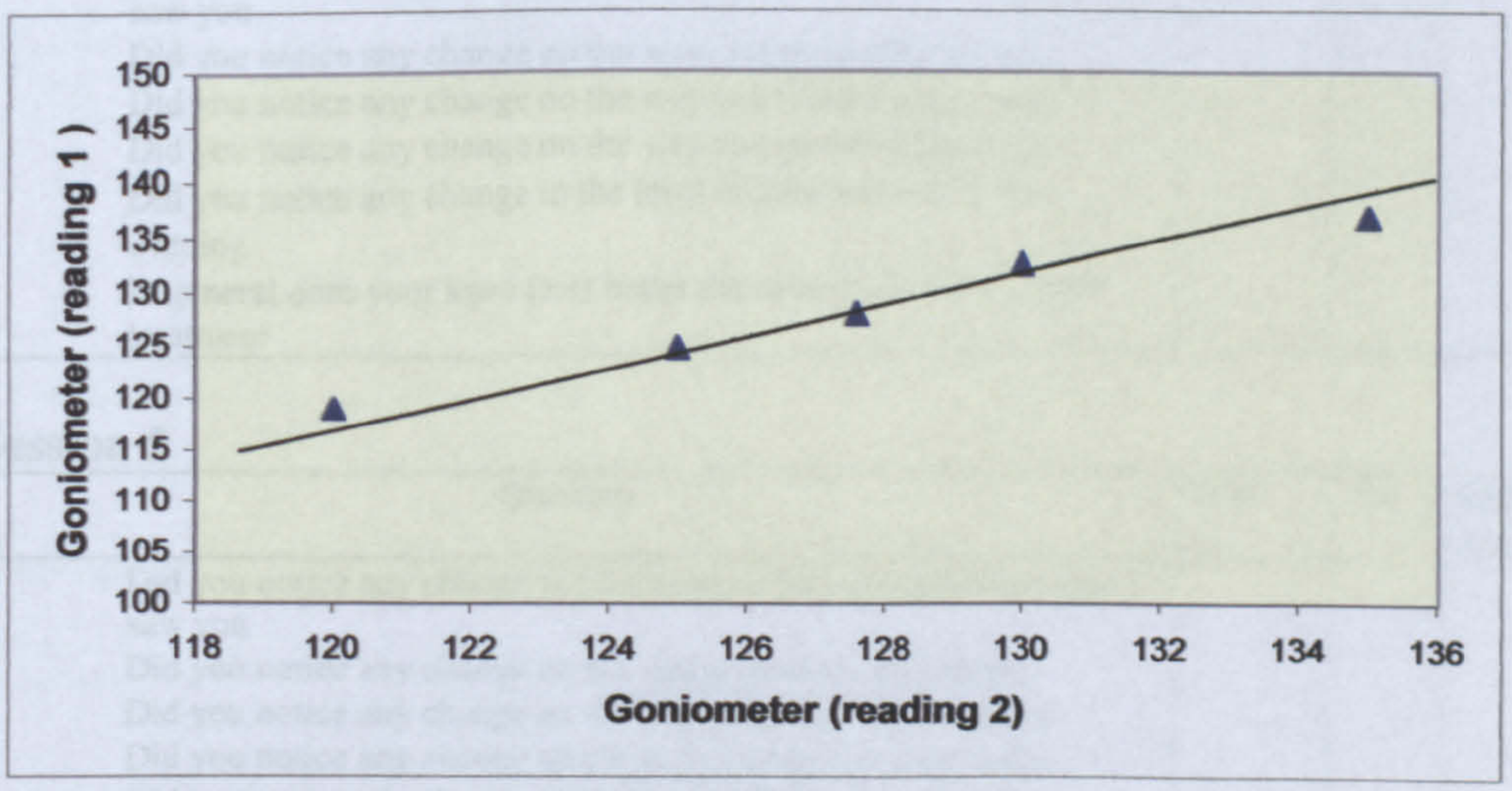
RELIABILITY WITH GONIOMETER

In both the laboratory and the clinical trial, knee ROM was measured every time the subjects attend for the trial. As such it was crucial that the researcher reliability be established for the same day and between days. Using 5 volunteers, knee flexion was measured twice in the same day with 5 minutes in between the measurement. Subjects were also asked to attend the next day for between days reliability. In all the measurements, the knee was not marked and the landmarks were only palpated.

	Same day measurements (°)		Next day measurement(°)
	Reading 1	Reading 2	Reading 3
1	125	125	124
2	120	119	120
3	125	123	124
4	135	134	135
5	130	132	131

Summary of the reading

Using Pearson Correlation Coefficient, the r was found to be 0.967 at $p = 0.007$ for same day measurement and r = 0.985, $p = 0.002$ for between days reliability
The error margin for the researcher was ±3°



Scatter graph of goniometric measurements

APPENDIX F.5

FUNCTIONAL QUESTIONNAIRE

Session 2

Question	Yes	No	Did not have it before
• Did you notice any change in your level of pain since the last time I saw you • Did you notice any change on the way you stand after sitting • Did you notice any change on the way you climb up the stairs • Did you notice any change on the way you go down the stairs • Did you notice any change in the level of pain you feel in the evening • In general does your knee feels better the same or worse after the Treatment			

Session 3

Question	Yes	No	Did not have it before
• Did you notice any change in your level of pain since the last time I saw you • Did you notice any change on the way you stand after sitting • Did you notice any change on the way you climb up the stairs • Did you notice any change on the way you go down the stairs • Did you notice any change in the level of pain you feel in the evening • In general does your knee feels better the same or worse after the I saw you			

Session 4

Question	Yes	No	Did not have it before
• Did you notice any change in your level of pain since the last time I saw you • Did you notice any change on the way you stand after sitting • Did you notice any change on the way you climb up the stairs • Did you notice any change on the way you go down the stairs • Did you notice any change in the level of pain you feel in the evening • In general does your knee feels better the same or worse after the treatment			

Session 5

Question	Yes	No	Did not have it before
• Did you notice any change in your level of pain since the last time I saw you • Did you notice any change on the way you stand after sitting • Did you notice any change on the way you climb up the stairs • Did you notice any change on the way you go down the stairs • Did you notice any change in the level of pain you feel in the evening • In general does your knee feels better the same or worse after the treatment			

APPENDIX F.6

RESULTS FROM CLINICAL TRIAL

	Age	Sex	Height (cm)	Weight (kg)	Fat %
1	39	male	177	93.22	24.42
2	56	female	168.5	67.24	33.53
3	70	male	168.5	76.52	19.7
4	71	male	174	83.6	33.53
5	68	female	161.2	92	33.53
6	50	male	166.5	68.5	33.53
7	40	female	165	71.76	33.53
8	32	male	184	91.78	22.13
9	45	female	165	72	21.5
10	62	female	190	71.5	29.4
11	50	female	183	90.32	21.5
12	51	male	175	95.72	18.98
13	62	male	169	109.85	32.4
14	59	female	161	67.54	32.2
15	73	female	158	84.3	21.9
16	64	male	167.5	75	15.9
17	58	female	157	63.12	30.37
18	65	male	152	64.82	33.99
19	48	female	165	90	32.97
20	42	female	157	87.56	29.3
21	53	female	150	47.78	22.54
22	52	male	181.5	75.76	15.75
23	80	female	160	80.28	18.7
24	48	female	168	90.26	32.84
25	54	male	163	88.7	19.21
26	40	male	179	90.7	23.11

Demographic data of the sample

DATA OF BLOOD VOLUME

Mauchly's Test of Sphericity[b]

Measure: MEASURE_1

Within Subjects Effect	Mauchly's W	Approx. Chi-Square	df	Sig.	Epsilon[a]		
					Greenhouse-Geisser	Huynh-Feldt	Lower-bound
condition	.519	14.231	5	.014	.793	.891	.333
phase	.919	1.850	2	.397	.925	1.000	.500
side	1.000	.000	0	.	1.000	1.000	1.000
condition * phase	.006	105.243	20	.000	.368	.408	.167
condition *side	.587	11.569	5	.041	.723	.801	.333
phase * side	.785	5.338	2	.069	.823	.878	.500
condition *phase * side	.003	122.384	20	.000	.323	.352	.167

Tests the null hypothesis that the error covariance matrix of the orthonormalized transformed dependent variables is proportional to an identity matrix.

a. May be used to adjust the degrees of freedom for the averaged tests of significance. Corrected tests are displayed in the Tests of Within-Subjects Effects table.

b.

Design: Intercept
Within Subjects Design: COND+PHASE+SIDE+COND*PHASE+COND*SIDE+PHASE*SIDE+COND*PHASE*SIDE

Summary of within subject effects for blood volume

Pairwise Comparisons

Measure: MEASURE_1

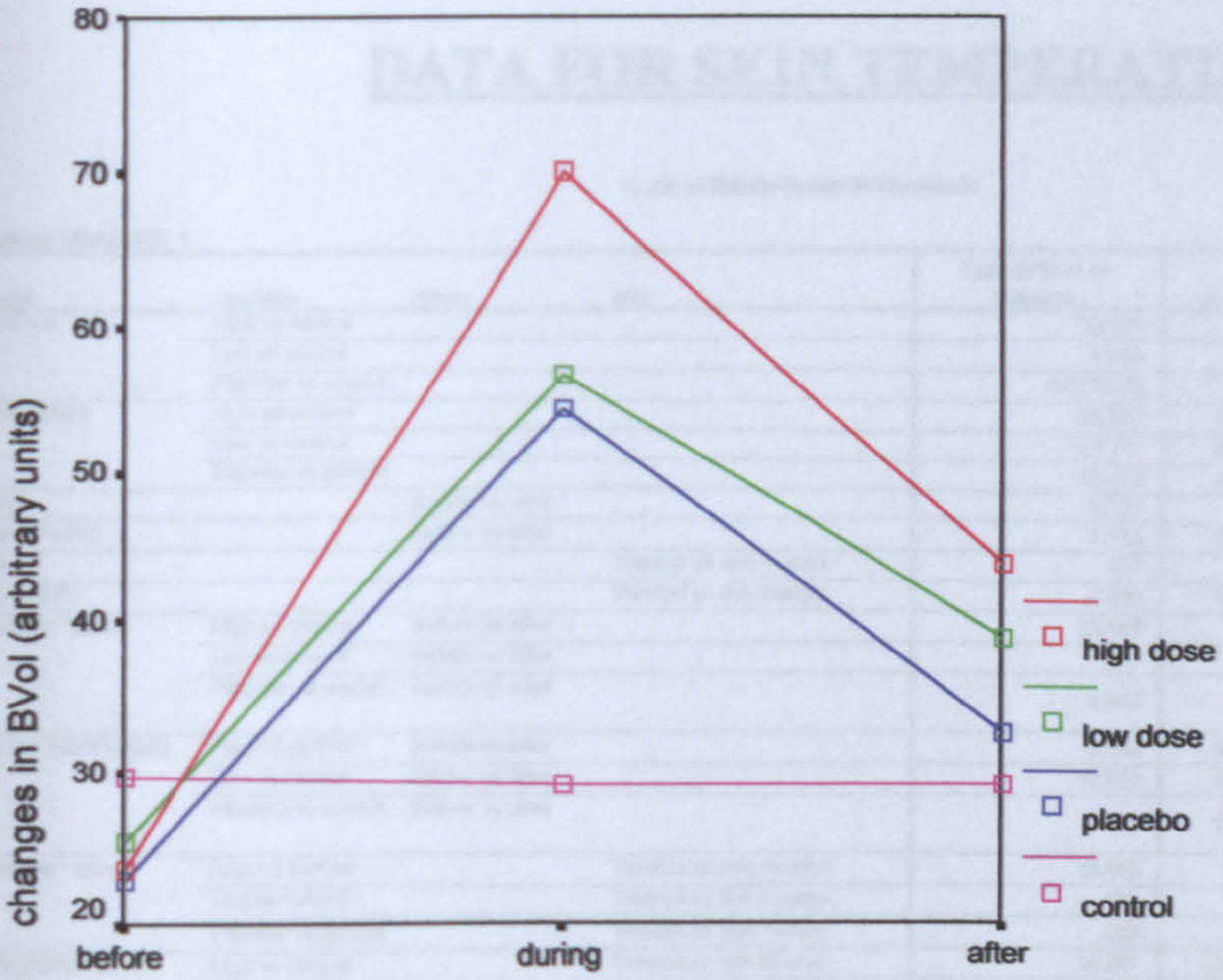
(I) COND	(J) COND	Mean Difference (I-J)	Std. Error	Sig.[a]	95% Confidence Interval for Difference[a]	
					Lower Bound	Upper Bound
high	low	26.097*	5.450	.000	10.366	41.829
	placebo	32.747*	5.331	.000	17.359	48.135
	control	46.522*	4.780	.000	32.726	60.318
low	high	-26.097*	5.450	.000	-41.829	-10.366
	placebo	6.650	4.254	.790	-5.629	18.929
	control	20.425*	5.583	.008	4.310	36.539
placebo	high	-32.747*	5.331	.000	-48.135	-17.359
	low	-6.650	4.254	.790	-18.929	5.629
	control	13.775*	3.281	.002	4.306	23.244
control	high	-46.522*	4.780	.000	-60.318	-32.726
	low	-20.425*	5.583	.008	-36.539	-4.310
	placebo	-13.775*	3.281	.002	-23.244	-4.306

Based on estimated marginal means

*. The mean difference is significant at the .05 level.

a. Adjustment for multiple comparisons: Bonferroni.

Summary of post hoc test for blood volume across the experimental conditions



Line graph of the changes in blood volume across the four conditions in non-treated side

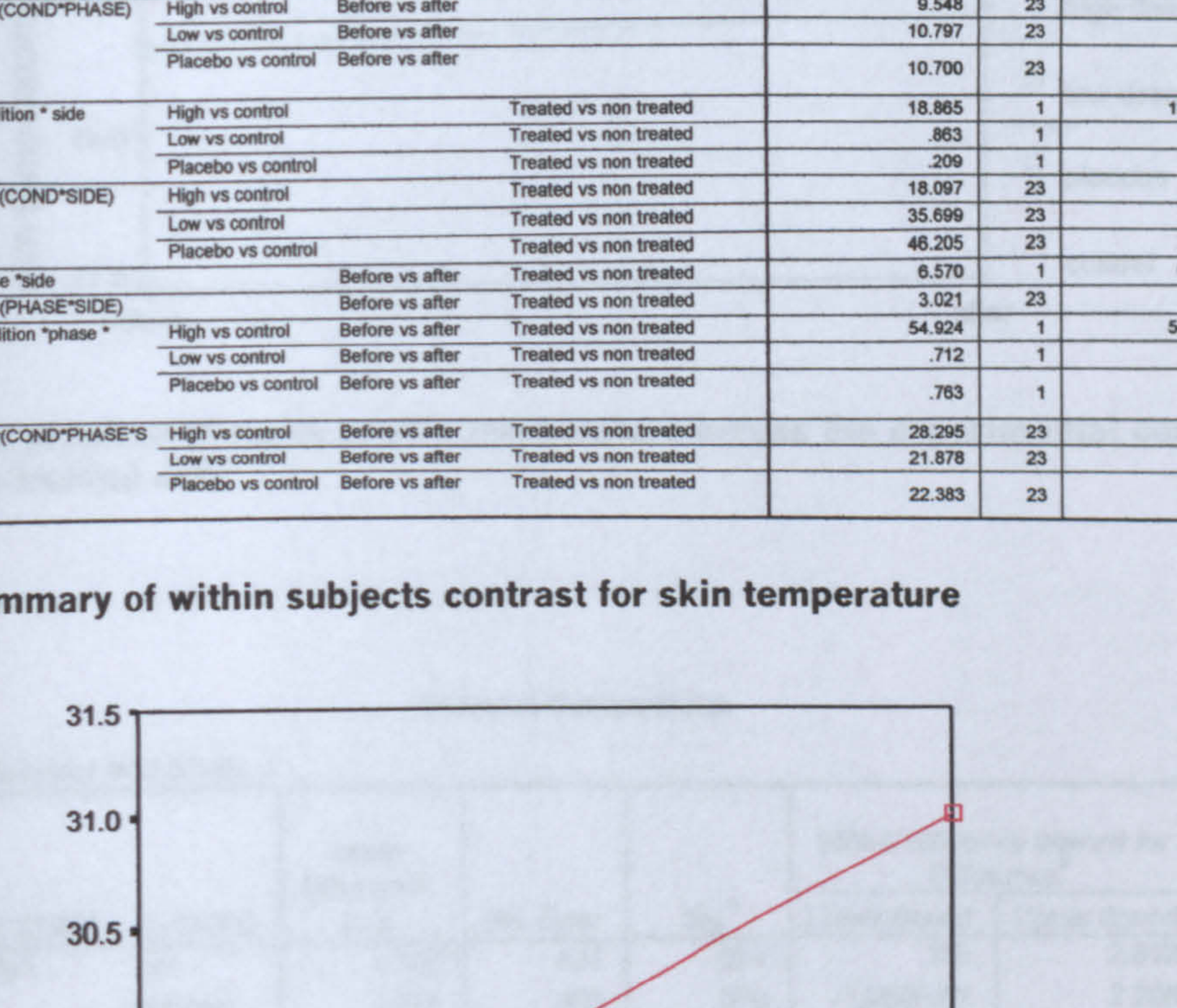
DATA FOR SKIN TEMPERATURE

Tests of Within-Subjects Contrasts

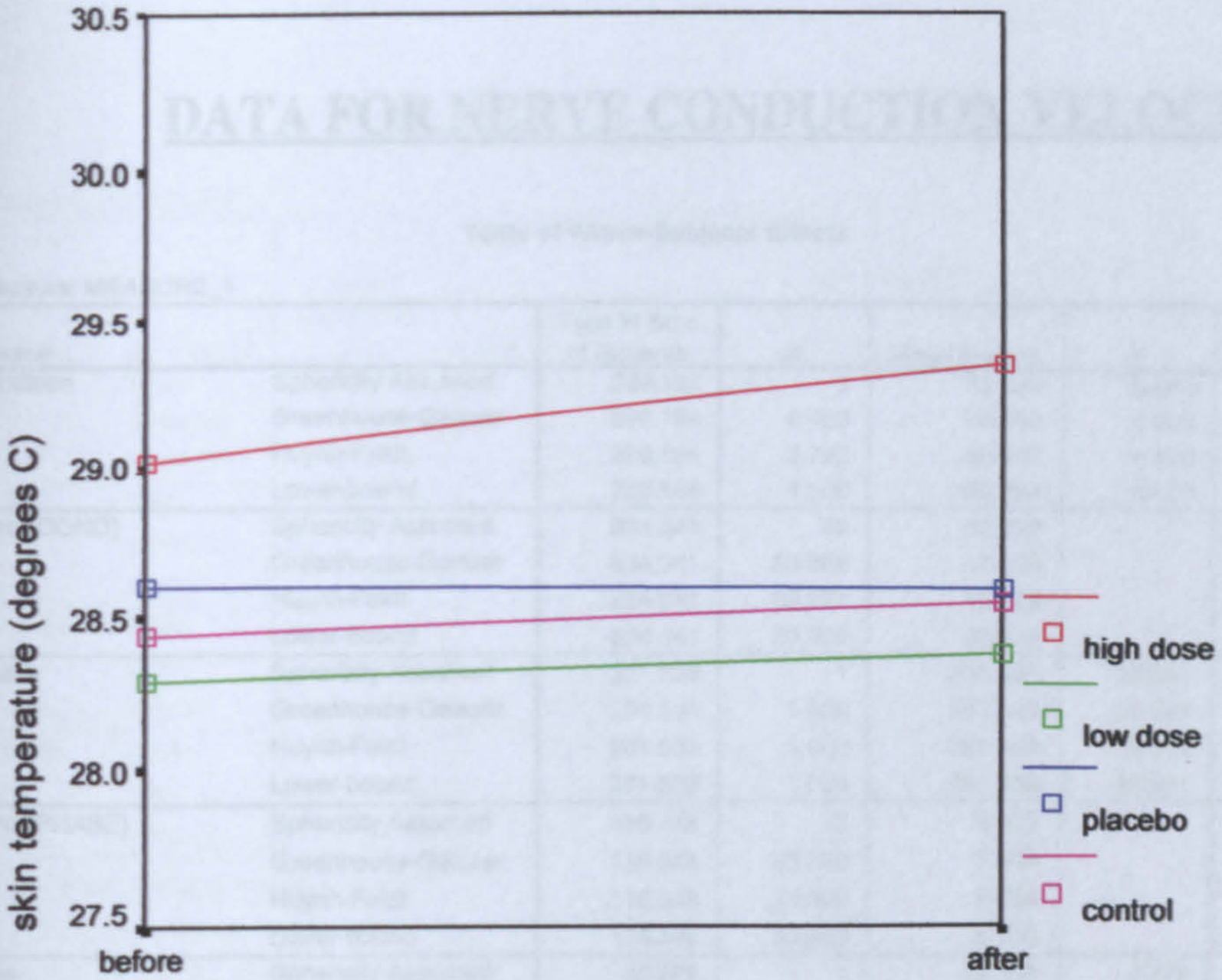
Measure: MEASURE_1

Source	condition	phase	side	Type III Sum of Squares	df	Mean Square	F	Sig.
Condition	High vs control			30.963	1	30.963	7.378	.012
	Low vs control			1.534	1	1.534	.562	.461
	Placebo vs control			9.075E-02	1	9.075E-02	.046	.832
Error(COND)	High vs control			96.527	23	4.197		
	Low vs control			62.711	23	2.727		
	Placebo vs control			45.172	23	1.964		
Phase		Before vs after		3.717	1	3.717	76.704	.000
Error(PHASE)		Before vs after		1.115	23	4.846E-02		
Side			Treated vs non treated	.177	1	.177	.517	.480
Error(SIDE)			Treated vs non treated	7.896	23	.343		
Condition *phase	High vs control	Before vs after		23.455	1	23.455	56.502	.000
	Low vs control	Before vs after		.125	1	.125	.265	.611
	Placebo vs control	Before vs after		1.043	1	1.043	2.243	.148
Error(COND*PHASE)	High vs control	Before vs after		9.548	23	.415		
	Low vs control	Before vs after		10.797	23	.469		
	Placebo vs control	Before vs after		10.700	23	.465		
Condition * side	High vs control		Treated vs non treated	18.865	1	18.865	23.976	.000
	Low vs control		Treated vs non treated	.863	1	.863	.556	.464
	Placebo vs control		Treated vs non treated	.209	1	.209	.104	.750
Error(COND*SIDE)	High vs control		Treated vs non treated	18.097	23	.787		
	Low vs control		Treated vs non treated	35.699	23	1.552		
	Placebo vs control		Treated vs non treated	46.205	23	2.009		
Phase *side		Before vs after	Treated vs non treated	6.570	1	6.570	50.020	.000
Error(PHASE*SIDE)		Before vs after	Treated vs non treated	3.021	23	.131		
Condition *phase * side	High vs control	Before vs after	Treated vs non treated	54.924	1	54.924	44.647	.000
	Low vs control	Before vs after	Treated vs non treated	.712	1	.712	.749	.396
	Placebo vs control	Before vs after	Treated vs non treated	.763	1	.763	.784	.385
Error(COND*PHASE*SIDE)	High vs control	Before vs after	Treated vs non treated	28.295	23	1.230		
	Low vs control	Before vs after	Treated vs non treated	21.878	23	.951		
	Placebo vs control	Before vs after	Treated vs non treated	22.383	23	.973		

Summary of within subjects contrast for skin temperature



Line graph of changes in skin temperature across the experimental condition in the treated side



Line graph of changes in skin temperature across the experimental condition in the non-treated side

Pairwise Comparisons

Measure: MEASURE_1

(I) COND	(J) COND	Mean Difference (I-J)	Std. Error	Sig.[a]	95% Confidence Interval for Difference[a]	
					Lower Bound	Upper Bound
high	low	1.389*	.424	.020	.165	2.612
	placebo	1.074	.400	.079	-7.952E-02	2.228
	control	1.136	.418	.074	-7.112E-02	2.343
low	high	-1.389*	.424	.020	-2.612	-.165
	placebo	-.314	.362	1.000	-1.358	.730
	control	-.253	.337	1.000	-1.226	.720
placebo	high	-1.074	.400	.079	-2.228	7.952E-02
	low	.314	.362	1.000	-.730	1.358
	control	6.149E-02	.286	1.000	-.764	.887
control	high	-1.136	.418	.074	-2.343	7.112E-02
	low	.253	.337	1.000	-.720	1.226
	placebo	-6.149E-02	.286	1.000	-.887	.764

Based on estimated marginal means

*. The mean difference is significant at the .05 level.

a. Adjustment for multiple comparisons: Bonferroni.

Summary of post hoc test for skin temperature

DATA FOR NERVE CONDUCTION VELOCITY

Tests of Within-Subjects Effects

Measure: MEASURE_1

Source		Type III Sum of Squares	df	Mean Square	F	Sig.
condition	Sphericity Assumed	220.194	3	73.398	6.070	.001
	Greenhouse-Geisser	220.194	2.433	90.493	6.070	.002
	Huynh-Feldt	220.194	2.742	80.297	6.070	.001
	Lower-bound	220.194	1.000	220.194	6.070	.022
Error(COND)	Sphericity Assumed	834.341	69	12.092		
	Greenhouse-Geisser	834.341	55.965	14.908		
	Huynh-Feldt	834.341	63.071	13.229		
	Lower-bound	834.341	23.000	36.276		
phase	Sphericity Assumed	201.538	1	201.538	39.841	.000
	Greenhouse-Geisser	201.538	1.000	201.538	39.841	.000
	Huynh-Feldt	201.538	1 000	201.538	39.841	.000
	Lower-bound	201.538	1.000	201.538	39.841	.000
Error(PHASE)	Sphericity Assumed	116.348	23	5.059		
	Greenhouse-Geisser	116.348	23 000	5.059		
	Huynh-Feldt	116.348	23.000	5.059		
	Lower-bound	116.348	23.000	5.059		
side	Sphericity Assumed	38.359	1	38.359	8.772	.007
	Greenhouse-Geisser	38.359	1.000	38.359	8.772	.007
	Huynh-Feldt	38.359	1.000	38.359	8.772	.007
	Lower-bound	38.359	1.000	38.359	8.772	.007
Error(SIDE)	Sphericity Assumed	100.573	23	4.373		
	Greenhouse-Geisser	100.573	23.000	4.373		
	Huynh-Feldt	100.573	23.000	4.373		
	Lower-bound	100.573	23.000	4.373		
condition * phase	Sphericity Assumed	125.616	3	41.872	12.748	.000
	Greenhouse-Geisser	125.616	2 578	48.734	12.748	.000
	Huynh-Feldt	125.616	2.931	42.854	12.748	.000
	Lower-bound	125.616	1.000	125.616	12.748	.002
Error(COND*PHASE)	Sphericity Assumed	226.629	69	3.284		
	Greenhouse-Geisser	226.629	59.285	3.823		
	Huynh-Feldt	226.629	67.418	3.362		
	Lower-bound	226.629	23.000	9 853		
condition * side	Sphericity Assumed	23.078	3	7.693	.792	.502
	Greenhouse-Geisser	23.078	2.846	8.109	.792	.497
	Huynh-Feldt	23.078	3.000	7.693	.792	.502
	Lower-bound	23.078	1.000	23.078	.792	.383
Error(COND*SIDE)	Sphericity Assumed	669.993	69	9.710		
	Greenhouse-Geisser	669.993	65.457	10.236		
	Huynh-Feldt	669.993	69.000	9.710		
	Lower-bound	669.993	23.000	29.130		
phase * side	Sphericity Assumed	15.306	1	15.306	7.446	.012
	Greenhouse-Geisser	15.306	1.000	15.306	7.446	.012
	Huynh-Feldt	15.306	1.000	15.306	7.446	.012
	Lower-bound	15.306	1.000	15.306	7.446	.012
Error(PHASE*SIDE)	Sphericity Assumed	47.279	23	2.056		
	Greenhouse-Geisser	47.279	23.000	2.056		
	Huynh-Feldt	47.279	23.000	2.056		
	Lower-bound	47.279	23.000	2.056		
condition * phase * side	Sphericity Assumed	8.598	3	2.866	.532	.662
	Greenhouse-Geisser	8.598	2.020	4.257	.532	.593
	Huynh-Feldt	8.598	2.215	3.882	.532	.609
	Lower-bound	8.598	1.000	8.598	.532	.473
Error(COND*PHASE*SIDE)	Sphericity Assumed	372.020	69	5.392		
	Greenhouse-Geisser	372.020	46.450	8.009		
	Huynh-Feldt	372.020	50.942	7.303		
	Lower-bound	372 020	23.000	16.175		

Summary of within subject effect for nerve conduction velocity

Pairwise Comparisons

Measure: MEASURE_1

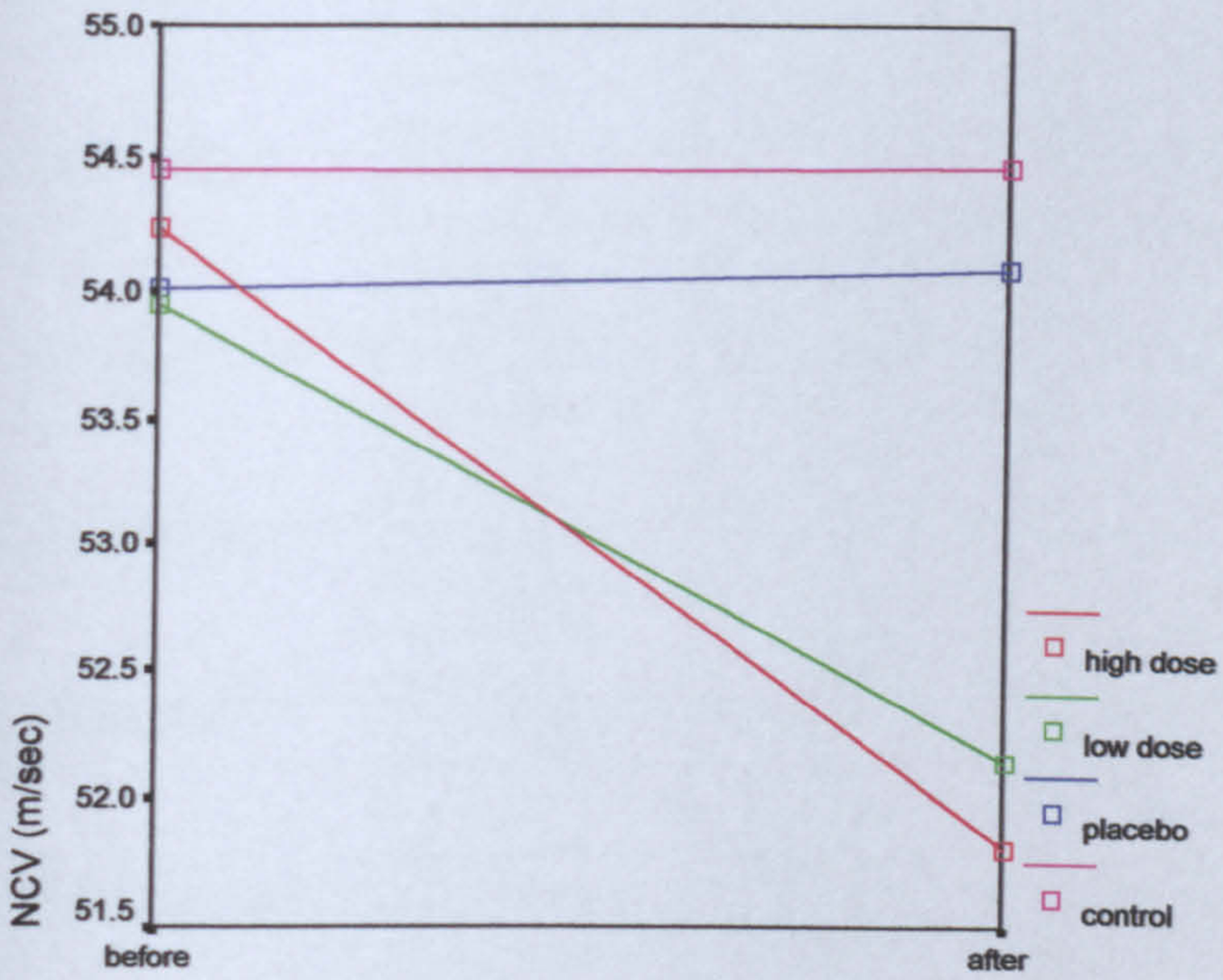
(I) COND	(J) COND	Mean Difference (I-J)	Std. Error	Sig.[a]	95% Confidence Interval for Difference[a]	
					Lower Bound	Upper Bound
high	low	-4.727E-02	.493	1.000	-1.471	1.376
	placebo	-.776	.439	.543	-2.042	.491
	control	-1.872*	.388	.000	-2.993	-.751
low	high	4.727E-02	.493	1.000	-1.376	1.471
	placebo	-.728	.643	1.000	-2.584	1.127
	control	-1.825*	.534	.014	-3.365	-.285
placebo	high	.776	.439	.543	-.491	2.042
	low	.728	.643	1.000	-1.127	2.584
	control	-1.097	.476	.184	-2.471	.277
control	high	1.872*	.388	.000	.751	2.993
	low	1.825*	.534	.014	.285	3.365
	placebo	1.097	.476	.184	-.277	2.471

Based on estimated marginal means

*. The mean difference is significant at the .05 level.

a. Adjustment for multiple comparisons: Bonferroni.

Summary of post hoc test for nerve conduction velocity



Line graph of changes in NCV across the experimental conditions in the non-treated side

DATA FOR NERVE ONSET LATENCY

Mauchly's Test of Sphericity[b]

Measure: MEASURE_1

Within Subjects Effect	Mauchly's W	Approx. Chi-Square	df	Sig.	Epsilon[a]		
					Greenhouse-Geisser	Huynh-Feldt	Lower-bound
condition	.664	8.911	5	.113	.780	.874	.333
phase	1.000	.000	0	.	1.000	1.000	1.000
side	1.000	.000	0	.	1.000	1.000	1.000
condition * phase	.723	7.031	5	.219	.840	.952	.333
condition * side	.880	2.778	5	.734	.918	1.000	.333
phase * side	1.000	.000	0	.	1.000	1.000	1.000
condition * phase * side	.282	27.525	5	.000	.622	.674	.333

Summary of Mauchly's test for sphericity

Tests of Within-Subjects Effects

Measure: MEASURE_1

Source		Type III Sum of Squares	df	Mean Square	F	Sig.
condition	Sphericity Assumed	1.491E-06	3	4.969E-07	4.619	.005
	Greenhouse-Geisser	1.491E-06	2.341	6.369E-07	4.619	.010
	Huynh-Feldt	1.491E-06	2.622	5.685E-07	4.619	.008
	Lower-bound	1.491E-06	1.000	1.491E-06	4.619	.042
Error(COND)	Sphericity Assumed	7.424E-06	69	1.076E-07		
	Greenhouse-Geisser	7.424E-06	53.832	1.379E-07		
	Huynh-Feldt	7.424E-06	60.309	1.231E-07		
	Lower-bound	7.424E-06	23.000	3.228E-07		
phase	Sphericity Assumed	1.905E-06	1	1.905E-06	55.323	.000
	Greenhouse-Geisser	1 905E-06	1.000	1.905E-06	55.323	.000
	Huynh-Feldt	1.905E-06	1.000	1.905E-06	55.323	.000
	Lower-bound	1.905E-06	1.000	1.905E-06	55.323	.000
Error(PHASE)	Sphericity Assumed	7.922E-07	23	3.444E-08		
	Greenhouse-Geisser	7.922E-07	23.000	3.444E-08		
	Huynh-Feldt	7.922E-07	23.000	3.444E-08		
	Lower-bound	7.922E-07	23.000	3.444E-08		
side	Sphericity Assumed	4.572E-07	1	4.572E-07	14.520	.001
	Greenhouse-Geisser	4.572E-07	1.000	4.572E-07	14.520	.001
	Huynh-Feldt	4.572E-07	1.000	4.572E-07	14.520	.001
	Lower-bound	4.572E-07	1.000	4.572E-07	14.520	.001
Error(SIDE)	Sphericity Assumed	7.242E-07	23	3.149E-08		
	Greenhouse-Geisser	7.242E-07	23.000	3.149E-08		
	Huynh-Feldt	7.242E-07	23.000	3.149E-08		
	Lower-bound	7.242E-07	23.000	3.149E-08		
condition * phase	Sphericity Assumed	8.565E-07	3	2.855E-07	9.062	.000
	Greenhouse-Geisser	8.565E-07	2.521	3.398E-07	9.062	.000
	Huynh-Feldt	8.565E-07	2.857	2.998E-07	9.062	.000
	Lower-bound	8.565E-07	1.000	8.565E-07	9.062	.006
Error(COND*PHASE)	Sphericity Assumed	2.174E-06	69	3.151E-08		
	Greenhouse-Geisser	2.174E-06	57.980	3.749E-08		
	Huynh-Feldt	2.174E-06	65.702	3.309E-08		
	Lower-bound	2.174E-06	23.000	9.452E-08		
condition *side	Sphericity Assumed	3.402E-07	3	1.134E-07	1.395	.252
	Greenhouse-Geisser	3.402E-07	2.755	1.235E-07	1.395	.254
	Huynh-Feldt	3.402E-07	3.000	1.134E-07	1.395	.252
	Lower-bound	3.402E-07	1.000	3.402E-07	1.395	.250
Error(COND*SIDE)	Sphericity Assumed	5.611E-06	69	8.133E-08		
	Greenhouse-Geisser	5.611E-06	63.363	8.856E-08		
	Huynh-Feldt	5.611E-06	69.000	8.133E-08		
	Lower-bound	5.611E-06	23.000	2.440E-07		
phase * side	Sphericity Assumed	7.178E-08	1	7.178E-08	2.322	.141
	Greenhouse-Geisser	7.178E-08	1.000	7.178E-08	2.322	.141
	Huynh-Feldt	7.178E-08	1.000	7.178E-08	2.322	.141
	Lower-bound	7.178E-08	1.000	7.178E-08	2.322	.141
Error(PHASE*SIDE)	Sphericity Assumed	7.109E-07	23	3.091E-08		
	Greenhouse-Geisser	7.109E-07	23.000	3.091E-08		
	Huynh-Feldt	7.109E-07	23.000	3.091E-08		
	Lower-bound	7.109E-07	23.000	3.091E-08		
condition *phase * side	Sphericity Assumed	6.960E-08	3	2.320E-08	.446	.721
	Greenhouse-Geisser	6.960E-08	1.865	3.732E-08	.446	.629
	Huynh-Feldt	6.960E-08	2.023	3.441E-08	.446	.645
	Lower-bound	6.960E-08	1.000	6.960E-08	.446	.511
Error(COND*PHASE*SIDE)	Sphericity Assumed	3.586E-06	69	5.197E-08		
	Greenhouse-Geisser	3.586E-06	42.890	8.361E-08		
	Huynh-Feldt	3.586E-06	46.527	7.707E-08		
	Lower-bound	3.586E-06	23.000	1.559E-07		

Summary of within subjects effects for nerve onset latency

Tests of Within-Subjects Contrasts

Measure: MEASURE_1

Source	condition	phase	side	Type III Sum of Squares	df	Mean Square	F	Sig.
condition	high vs control			5.251E-07	1	5.251E-07	15.841	.001
	low vs control			5.104E-07	1	5.104E-07	12.960	.002
	placebo vs control			8.313E-08	1	8.313E-08	1.097	.306
Error(COND)	high vs control			7.624E-07	23	3 315E-08		
	low vs control			9.058E-07	23	3.938E-08		
	placebo vs control			1.743E-06	23	7.577E-08		
PHASE		before vs after		4.764E-07	1	4.764E-07	55.323	.000
Error(PHASE)		before vs after		1.980E-07	23	8.611E-09		
SIDE			treated vs non treated	1.143E-07	1	1.143E-07	14.520	.001
Error(SIDE)			treated vs non treated	1.811E-07	23	7.872E-09		
COND * PHASE	high vs control	before vs after		1.307E-06	1	1.307E-06	25.834	.000
	low vs control	before vs after		1.084E-06	1	1.084E-06	28.942	.000
	placebo vs control	before vs after		2.063E-07	1	2.063E-07	3.484	.075
Error(COND*PHASE)	high vs control	before vs after		1.163E-06	23	5 058E-08		
	low vs control	before vs after		8.612E-07	23	3.745E-08		
	placebo vs control	before vs after		1.362E-06	23	5.921E-08		
COND * SIDE	high vs control		treated vs non treated	1 204E-07	1	1.204E-07	772	.389
	low vs control		treated vs non treated	1.504E-07	1	1 504E-07	1.308	.264
	placebo vs control		treated vs non treated	6.750E-07	1	6.750E-07	4.088	.055
Error(COND*SIDE)	high vs control		treated vs non treated	3.590E-06	23	1.561E-07		
	low vs control		treated vs non treated	2.645E-06	23	1.150E-07		
	placebo vs control		treated vs non treated	3.798E-06	23	1.651E-07		
PHASE * SIDE		before vs after	treated vs non treated	7.178E-08	1	7.178E-08	2.322	.141
Error(PHASE*SIDE)		before vs after	treated vs non treated	7.109E-07	23	3.091E-08		
COND * PHASE * SIDE	high vs control	before vs after	treated vs non treated	1.067E-07	1	1.067E-07	.898	.353
	low vs control	before vs after	treated vs non treated	5.400E-07	1	5.400E-07	2.545	.124
	placebo vs control	before vs after	treated vs non treated	6.510E-08	1	6.510E-08	.150	.702
Error(COND*PHASE*SIDE)	high vs control	before vs after	treated vs non treated	2.733E-06	23	1.188E-07		
	low vs control	before vs after	treated vs non treated	4.880E-06	23	2.122E-07		
	placebo vs control	before vs after	treated vs non treated	9.967E-06	23	4.334E-07		

Summary of within subjects c

Pairwise Comparisons

Measure: MEASURE_1

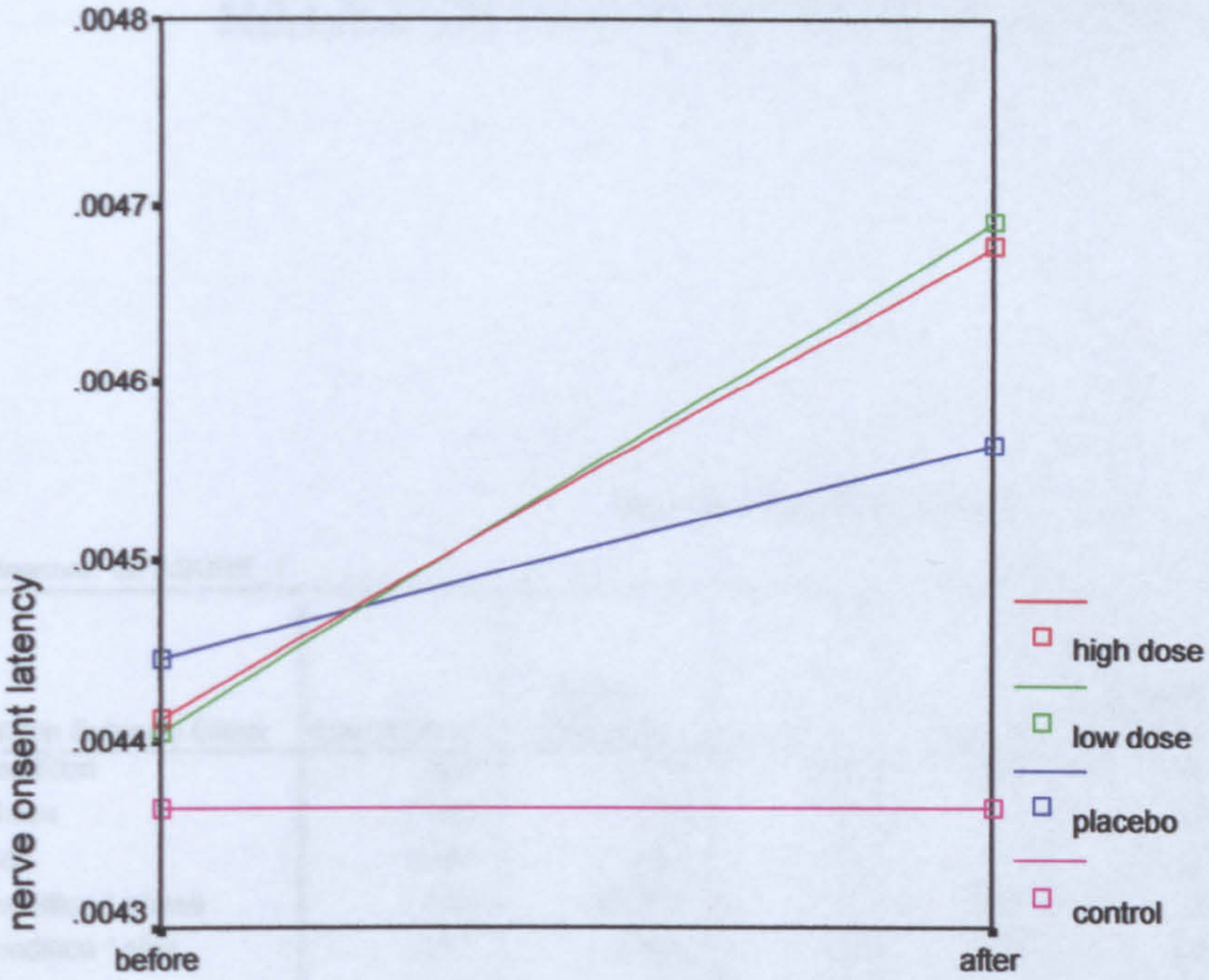
(I) COND	(J) COND	Mean Difference (I-J)	Std. Error	Sig.[a]	95% Confidence Interval for Difference[a]	
					Lower Bound	Upper Bound
high	low	2.083E-06	.000	1.000	-1.221E-04	1.262E-04
	placebo	8.906E-05	.000	.336	-3.870E-05	2.168E-04
	control	1.479E-04*	.000	.004	4.065E-05	2.552E-04
low	low	-2.083E-06	.000	1.000	-1.262E-04	1.221E-04
	placebo	8.698E-05	.000	.917	-8.279E-05	2.568E-04
	control	1.458E-04*	.000	.009	2.891E-05	2.628E-04
placebo	low	-8.906E-05	.000	.336	-2.168E-04	3.870E-05
	low	-8.698E-05	.000	.917	-2.568E-04	8.279E-05
	control	5.885E-05	.000	1.000	-1.033E-04	2.210E-04
control	low	-1.479E-04*	.000	.004	-2.552E-04	-4.065E-05
	low	-1.458E-04*	.000	.009	-2.628E-04	-2.891E-05
	placebo	-5.885E-05	.000	1.000	-2.210E-04	1.033E-04

Based on estimated marginal means

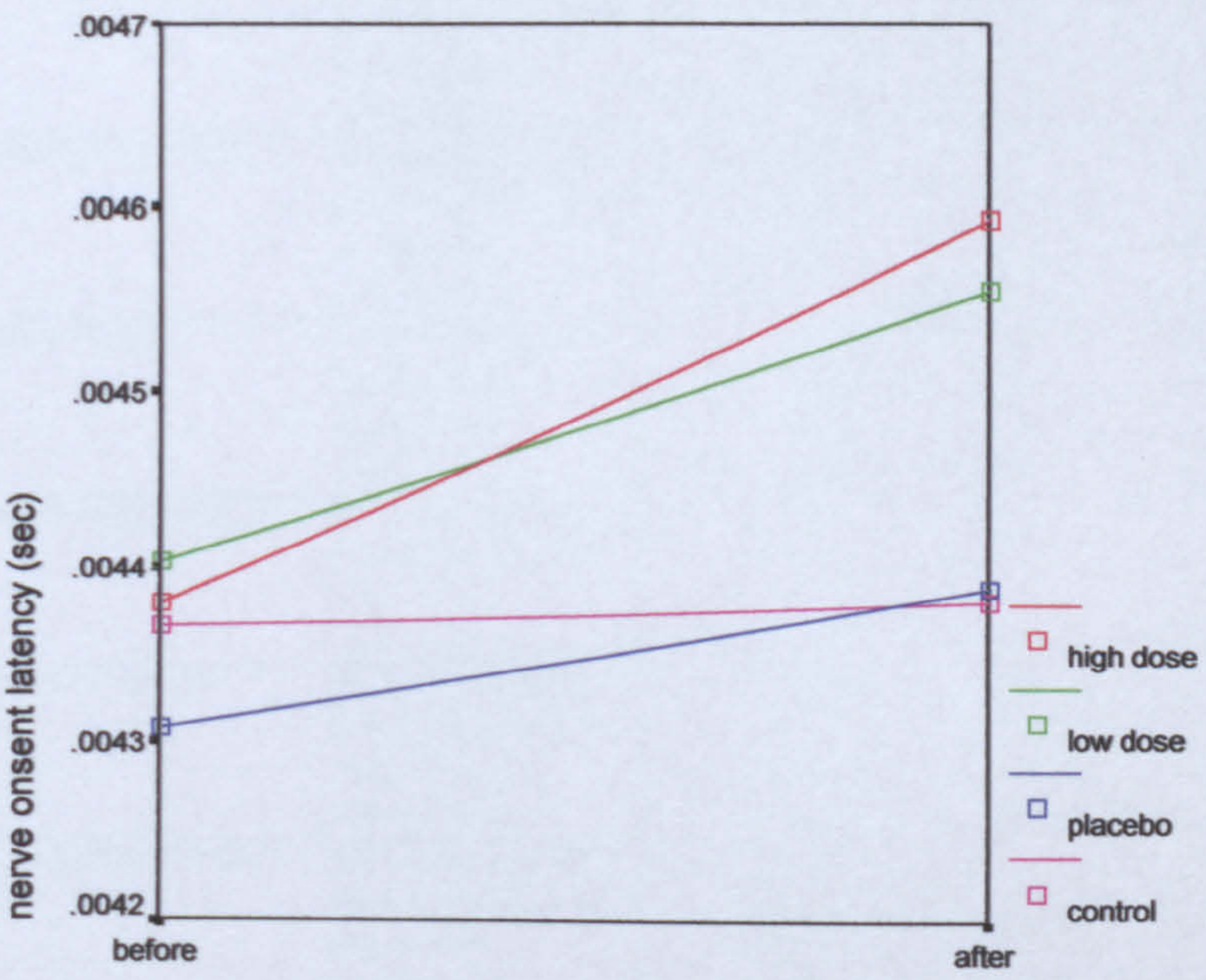
*. The mean difference is significant at the .05 level.

a. Adjustment for multiple comparisons: Bonferroni.

Summary of post hoc test for nerve onset latency across the experimental conditions



Line graph for changes in onset latency across the experimental conditions in the treated side



Line graph for changes in onset latency across the experimental conditions in the Non-treated side

DATA FOR NERVE RESPONSE DURATION

Mauchly's Test of Sphericity[b]

Measure: MEASURE_1

Within Subjects Effect	Mauchly's W	Approx. Chi-Square	df	Sig.	Epsilon[a]		
					Greenhouse-Geisser	Huynh-Feldt	Lower-bound
condition	.939	1.356	5	.929	.962	1.000	.333
phase	1.000	.000	0	.	1.000	1.000	1.000
side	1.000	.000	0	.	1.000	1.000	1.000
condition * phase	.096	50.972	5	.000	.482	.506	.333
condition * side	.871	3.005	5	.700	.923	1.000	.333
phase * side	1.000	.000	0	.	1.000	1.000	1.000
condition *phase * side	.120	46.054	5	.000	.574	.616	.333

Summary of Mauchley's test of sphericity for nerve response duration

Tests of Within-Subjects Effects

Measure: MEASURE_1

Source		Type III Sum of Squares	df	Mean Square	F	Sig.
condition	Sphericity Assumed	17.867	3	5.956	1.429	.242
	Greenhouse-Geisser	17.867	2.885	6.192	1.429	.243
	Huynh-Feldt	17.867	3.000	5.956	1.429	.242
	Lower-bound	17.867	1.000	17.867	1.429	.244
Error(COND)	Sphericity Assumed	287.517	69	4.167		
	Greenhouse-Geisser	287.517	66.365	4.332		
	Huynh-Feldt	287.517	69.000	4.167		
	Lower-bound	287.517	23.000	12.501		
phase	Sphericity Assumed	.834	1	.834	1.895	.182
	Greenhouse-Geisser	.834	1.000	.834	1.895	.182
	Huynh-Feldt	.834	1.000	.834	1.895	.182
	Lower-bound	.834	1.000	.834	1.895	.182
Error(PHASE)	Sphericity Assumed	10.126	23	.440		
	Greenhouse-Geisser	10.126	23.000	.440		
	Huynh-Feldt	10.126	23.000	.440		
	Lower-bound	10.126	23.000	.440		
side	Sphericity Assumed	4.356	1	4.356	1.064	.313
	Greenhouse-Geisser	4.356	1.000	4.356	1.064	.313
	Huynh-Feldt	4.356	1.000	4.356	1.064	.313
	Lower-bound	4.356	1.000	4.356	1.064	.313
Error(SIDE)	Sphericity Assumed	94.154	23	4.094		
	Greenhouse-Geisser	94.154	23.000	4.094		
	Huynh-Feldt	94.154	23.000	4.094		
	Lower-bound	94.154	23.000	4.094		
condition * phase	Sphericity Assumed	2.964	3	988	1.971	.126
	Greenhouse-Geisser	2.964	1.446	2.050	1.971	.165
	Huynh-Feldt	2.964	1.517	1.954	1.971	.163
	Lower-bound	2 964	1.000	2.964	1.971	.174
Error(COND*PHASE)	Sphericity Assumed	34.583	69	.501		
	Greenhouse-Geisser	34.583	33.248	1.040		
	Huynh-Feldt	34.583	34.886	.991		
	Lower-bound	34.583	23.000	1.504		
condition * side	Sphericity Assumed	15.777	3	5.259	1.874	.142
	Greenhouse-Geisser	15.777	2.770	5.696	1.874	.147
	Huynh-Feldt	15.777	3.000	5.259	1.874	.142
	Lower-bound	15.777	1.000	15.777	1.874	.184
Error(COND*SIDE)	Sphericity Assumed	193.670	69	2.807		
	Greenhouse-Geisser	193.670	63.703	3.040		
	Huynh-Feldt	193.670	69.000	2.807		
	Lower-bound	193.670	23.000	8.420		
phase * side	Sphericity Assumed	.872	1	.872	2.639	.118
	Greenhouse-Geisser	.872	1.000	.872	2.639	.118
	Huynh-Feldt	.872	1.000	.872	2.639	.118
	Lower-bound	.872	1.000	.872	2.639	.118
Error(PHASE*SIDE)	Sphericity Assumed	7.601	23	.330		
	Greenhouse-Geisser	7.601	23.000	.330		
	Huynh-Feldt	7.601	23.000	.330		
	Lower-bound	7.601	23.000	.330		
condition * phase * side	Sphericity Assumed	1.615	3	.538	1.625	.191
	Greenhouse-Geisser	1.615	1.723	.938	1.625	.212
	Huynh-Feldt	1.615	1.849	.874	1.625	.210
	Lower-bound	1.615	1.000	1.615	1.625	.215
Error(COND*PHASE*SIDE)	Sphericity Assumed	22.859	69	.331		
	Greenhouse-Geisser	22.859	39.619	.577		
	Huynh-Feldt	22.859	42.527	.538		
	Lower-bound	22 859	23.000	.994		

Summary of within subject effect for nerve response duration

Tests of Within-Subjects Contrasts

Measure. MEASURE_1

Source	COND	PHASE	SIDE	ype III Sum of Square	df	Mean Square	F	Sig.
condition	high vs control			4.084	1	4.084	1.891	.182
	low vs control			1.063	1	1.063	.458	.505
	placebo vs cont			.610	1	.610	.355	.557
Error(COND)	high vs control			49.659	23	2.159		
	low vs control			53.314	23	2.318		
	placebo vs cont			39.550	23	1.720		
PHASE		before vs after		.209	1	.209	1.895	.182
Error(PHASE)		before vs after		2.532	23	.110		
SIDE			treated vs non treated	1.089	1	1.089	1.064	.313
Error(SIDE)			treated vs non treated	23.539	23	1.023		
COND * PHASE	high vs control	before vs after		3.375	1	3.375	1.690	.207
	low vs control	before vs after		.120	1	.120	.074	.788
	placebo vs cont	before vs after		9.375E-04	1	9.375E-04	.001	.980
Error(COND*PHA E)	high vs control	before vs after		45.945	23	1 998		
	low vs control	before vs after		37.475	23	1.629		
	placebo vs cont	before vs after		34.927	23	1.519		
COND * SIDE	high vs control		treated vs non treated	20.350	1	20.350	3.120	.091
	low vs control		treated vs non treated	11.620	1	11.620	2.380	.137
	placebo vs cont		treated vs non treated	1.760E-02	1	1.760E-02	.003	.956
Error(COND*SIDE	high vs control		treated vs non treated	150.010	23	6.522		
	low vs control		treated vs non treated	112.295	23	4.882		
	placebo vs cont		treated vs non treated	132.190	23	5.747		
PHASE * SIDE		before vs after	treated vs non treated	.872	1	.872	2.639	.118
Error(PHASE*SID		before vs after	treated vs non treated	7.601	23	.330		
COND * PHASE * SIDE	high vs control	before vs after	treated vs non treated	2.282	1	2.282	.451	.508
	low vs control	before vs after	treated vs non treated	8.402	1	8.402	2.336	.140
	placebo vs cont	before vs after	treated vs non treated	10.270	1	10.270	2.797	.108
Error(COND*PHA *SIDE)	high vs control	before vs after	treated vs non treated	116.238	23	5.054		
	low vs control	before vs after	treated vs non treated	82.738	23	3.597		
	placebo vs cont	before vs after	treated vs non treated	84.440	23	3.671		

Summary of within subjects contrast for nerve response duration

DATA FOR PULSE RATE

Tests of Within-Subjects Contrasts

Measure: MEASURE_1

Source	condition	phase	Type III Sum of Squares	df	Mean Square	F	Sig.
condition	high vs control		112 278	1	112.278	.394	.536
	low vs control		7.272	1	7.272	.030	.865
	placebo vs control		38.592	1	38.592	.119	.734
Error(COND)	high vs control		6546 161	23	284.616		
	low vs control		5628.219	23	244.705		
	placebo vs control		7480 562	23	325.242		
phase		during vs before	17.217	1	17.217	7.650	.011
		after vs before	2.344E-02	1	2.344E-02	.012	.915
Error(PHASE)		during vs before	51.765	23	2.251		
		after vs before	45.789	23	1.991		
condition * phase	high vs control	during vs before	.103	1	.103	.005	.943
		after vs before	3.450	1	3.450	.101	.753
	low vs control	during vs before	83.004	1	83.004	2.850	.105
		after vs before	24.807	1	24.807	.929	.345
	placebo vs control	during vs before	.281	1	.281	.011	.918
		after vs before	5.134	1	5.134	.174	.680
Error(COND*PHASE)	high vs control	during vs before	456.517	23	19.849		
		after vs before	783 460	23	34.063		
	low vs control	during vs before	669.833	23	29.123		
		after vs before	614.153	23	26.702		
	placebo vs control	during vs before	604.618	23	26 288		
		after vs before	677.416	23	29.453		

Summary of within subjects contrast for pulse rate

DATA FOR CORE TEMPERATURE

Tests of Within-Subjects Contrasts

Measure: MEASURE_1

Source	COND	PHASE	Type III Sum of Squares	df	Mean Square	F	Sig.
condition	high vs control		.171	1	.171	.775	.388
	low vs control		.940	1	.940	3.978	.058
	placebo vs control		.108	1	.108	.464	.502
Error(COND)	high vs control		5.073	23	.221		
	low vs control		5.438	23	.236		
	placebo vs control		5.347	23	.232		
phase		before vs during	.146	1	.146	4.769	.039
		before vs after	4.690E-03	1	4.690E-03	.396	.535
Error(PHASE)		before vs during	.706	23	3.071E-02		
		before vs after	.272	23	1.185E-02		
condition *phase	high vs control	before vs during	.592	1	.592	1.827	.190
		before vs after	5.046E-03	1	5.046E-03	.050	.825
	low vs control	before vs during	3.511E-02	1	3.511E-02	.111	.743
		before vs after	2.407E-02	1	2 407E-02	.155	.698
	placebo vs control	before vs during	7.385E-03	1	7.385E-03	.026	.872
		before vs after	2.344E-02	1	2.344E-02	.206	.654
Error(COND*PHASE)	high vs control	before vs during	7.455	23	.324		
		before vs after	2.317	23	.101		
	low vs control	before vs during	7.305	23	.318		
		before vs after	3.581	23	.156		
	placebo vs control	before vs during	6.427	23	.279		
		before vs after	2.619	23	.114		

Summary of within subjects contrast for core temperature

DATA FOR ROOM TEMPERATURE AND HUMIDITY

Tests of Within-Subjects Effects

Measure: MEASURE_1

Source		Type III Sum of Squares	df	Mean Square	F	Sig.
room temperature	Sphericity Assumed	1.516	3	.505	.225	.879
	Greenhouse-Geisser	1.516	2.555	.593	.225	.849
	Huynh-Feldt	1.516	2.902	.522	.225	.873
	Lower-bound	1.516	1.000	1.516	.225	.640
Error(RT)	Sphericity Assumed	154.859	69	2.244		
	Greenhouse-Geisser	154.859	58.772	2.635		
	Huynh-Feldt	154.859	66.742	2.320		
	Lower-bound	154.859	23.000	6.733		
phase	Sphericity Assumed	5.208E-03	1	5.208E-03	1.000	.328
	Greenhouse-Geisser	5.208E-03	1.000	5.208E-03	1.000	.328
	Huynh-Feldt	5.208E-03	1.000	5.208E-03	1.000	.328
	Lower-bound	5.208E-03	1.000	5.208E-03	1.000	.328
Error(PHASE)	Sphericity Assumed	.120	23	5.208E-03		
	Greenhouse-Geisser	.120	23.000	5.208E-03		
	Huynh-Feldt	.120	23.000	5.208E-03		
	Lower-bound	.120	23.000	5.208E-03		
room temperature* phase	Sphericity Assumed	1.562E-02	3	5.208E-03	1.000	.398
	Greenhouse-Geisser	1.562E-02	1.000	1.562E-02	1.000	.328
	Huynh-Feldt	1 562E-02	1.000	1.562E-02	1.000	.328
	Lower-bound	1.562E-02	1.000	1.562E-02	1.000	.328
Error(room temperature*PHASE)	Sphericity Assumed	.359	69	5.208E-03		
	Greenhouse-Geisser	.359	23 000	1 562E-02		
	Huynh-Feldt	.359	23.000	1.562E-02		
	Lower-bound	.359	23.000	1 562E-02		

Summary of within subject effect for room temperature

Measure: MEASURE_1

Source	room temperature	phase	Type III Sum of Squares	df	Mean Square	F	Sig.
room temperature	high vs control		4.167E-02	1	4.167E-02	.017	.896
	low vs control		1.260	1	1.260	.829	.372
	placebo vs control		4.167E-02	1	4.167E-02	.027	.870
Error(RT)	high vs control		54.958	23	2.389		
	low vs control		34.990	23	1.521		
	placebo vs control		34.958	23	1.520		
phase		before vs after	2.604E-03	1	2.604E-03	1.000	.328
Error(PHASE)		before vs after	5.990E-02	23	2.604E-03		
room temperature * phase	high vs control	before vs after	.000	1	.000	.	.
	low vs control	before vs after	4.167E-02	1	4.167E-02	1.000	.328
	placebo vs control	before vs after	.000	1	.000	.	.
Error(RT*PHASE)	high vs control	before vs after	.000	23	.000		
	low vs control	before vs after	.958	23	4.167E-02		
	placebo vs control	before vs after	.000	23	.000		

Summary of within subject effect for room humidity

DATA FOR FUNCTIONAL STATUS

	Better	Worse	No changes	Did not have this symptom before
Changes in the level of pain since the last visit	21	-	3	-
Changes in standing after sitting	19	-	4	1
Changes in ascending stairs	18	-	5	1
Changes in descending the stairs	11	-	10	3
Changes in evening pain	16	-	5	3
In general are you better/ worse/ same	20	-	4	-

Summary of answers to functional questionnaire

Measure: MEASURE_1

Source	VAS	Type III Sum of Squares	df	Mean Square	F	Sig.
VAS	High vs baseline	106.682	1	106.682	36.965	.000
	Low vs baseline	66.334	1	66.334	20.214	.000
	Placebo vs baseline	20.258	1	20.258	19.023	.000
	Control vs baseline	12.615	1	12.615	7.667	.011
Error(VAS)	High vs baseline	66.378	23	2.886		
	Low vs baseline	75.476	23	3.282		
	Placebo vs baseline	24.494	23	1.065		
	Control vs baseline	37.845	23	1.645		

Summary of within subjects effects for VAS

Pairwise Comparisons

Measure: MEASURE_1

(I) VAS	(J) VAS	Mean Difference (I-J)	Std. Error	Sig.[a]	95% Confidence Interval for Difference[a]	
					Lower Bound	Upper Bound
intial	high	-.446	.458	.000	-1.867	.976
	low	-1.190*	.370	.038	-2.337	-4.246E-02
	placeb	-1.383*	.367	.010	-2.524	-.243
	control	-2.108*	.347	.000	-3.185	-1.032
high	intial	.446	.458	.000	-.976	1.867
	low	-.744	.421	.907	-2.051	.564
	placeb	-.938	.416	.339	-2.228	.353
	control	-1.663*	.370	.002	-2.810	-.515
low	intial	1.190*	.370	.038	4.246E-02	2.337
	high	.744	.421	.907	-.564	2.051
	placeb	-.194	.341	1.000	-1.252	.864
	control	-.919*	.211	.002	-1.573	-.265
placeb	intial	1.383*	.367	.010	.243	2.524
	high	.938	.416	.339	-.353	2.228
	low	.194	.341	1.000	-.864	1.252
	control	-.725	.262	.109	-1.538	8.775E-02
control	intial	2.108*	.347	.000	1.032	3.185
	high	1.663*	.370	.002	.515	2.810
	low	.919*	.211	.002	.265	1.573
	placeb	.725	.262	.109	-8.775E-02	1.538

Based on estimated marginal means

*. The mean difference is significant at the .05 level.

a. Adjustment for multiple comparisons: Bonferroni.

Summary of post hoc for VAS

Condition	Mean change (mm)
Baseline	5.438±1.661
High	3.446±1.755
Low	3.7115±2.271
Placebo	4.5135±1.623
Control	4.708±1.837

Change in pain level across the experimental conditions

Measure: MEASURE_1

Source	MUSCLE	Type III Sum of Squares	df	Mean Square	F	Sig.
MUSCLE	High vs baseline	2.042	1	2.042	9.548	.005
	Low vs baseline	.882	1	.882	3.220	.086
	Placebo vs baseline	.602	1	.602	2.996	.097
	Control vs baseline	1.170	1	1.170	7.520	.012
Error(MUSCLE)	High vs baseline	4.918	23	.214		
	Low vs baseline	6.298	23	.274		
	Placebo vs baseline	4.618	23	.201		
	Control vs baseline	3.580	23	.156		

Summary of within subjects contrasts for muscle strength

Measure: MEASURE_1

(I) MUSCLE	(J) MUSCLE	Mean Difference (I-J)	Std. Error	Sig.[a]	95% Confidence Interval for Difference[a]	
					Lower Bound	Upper Bound
intial	high	.483	.156	.051	-8.877E-04	.968
	low	.450*	.104	.238	.129	.771
	placebo	.513*	.098	.725	.208	.817
	control	.292	.094	.517	-1.329E-03	.585
high	intial	-.483	.156	.051	-.968	8.877E-04
	low	-3.333E-02	.138	1.000	-.461	.394
	placebo	2.917E-02	.130	1.000	-.374	.432
	control	-.192	.107	.859	-.523	.140
low	intial	-.450*	.104	.238	-.771	-.129
	high	3.333E-02	.138	1.000	-.394	.461
	placebo	6.250E-02	.053	1.000	-.103	.228
	control	-.158	.091	.968	-.442	.126
placebo	intial	-.513*	.098	.725	-.817	-.208
	high	-2.917E-02	.130	1.000	-.432	.374
	low	-6.250E-02	.053	1.000	-.228	.103
	control	-.221	.081	.116	-.471	2.913E-02
control	intial	-.292	.094	.517	-.585	1.329E-03
	high	.192	.107	.859	-.140	.523
	low	.158	.091	.968	-.126	.442
	placebo	.221	.081	.116	-2.913E-02	.471

Based on estimated marginal means

*. The mean difference is significant at the .05 level.

a. Adjustment for multiple comparisons: Bonferroni.

Summary of post hoc test for muscle strength

Measure: MEASURE_1

Source	ROM	Type III Sum of Squares	df	Mean Square	F	Sig.
ROM	High vs baseline	459.375	1	459.375	6.971	.015
	Low vs baseline	4.167	1	4.167	.060	.809
	Placebo vs basline	9.375	1	9.375	.223	.641
	Control vs baseline	234.375	1	234.375	3.616	.070
Error(ROM)	High vs baseline	1515.625	23	65.897		
	Low vs baseline	1595.833	23	69.384		
	Placebo vs basline	965.625	23	41.984		
	Control vs baseline	1490.625	23	64.810		

Summary of within subjects contrast for ROM

Pairwise Comparisons

Measure: MEASURE_1

(I) ROM	(J) ROM	Mean Difference (I-J)	Std. Error	Sig.[a]	95% Confidence Interval for Difference[a]	
					Lower Bound	Upper Bound
intial	high	4.792	1.915	.020	-1.152	10.735
	low	5.000	2.107	.264	-1.539	11.539
	placebo	7.500*	1.831	.442	1.818	13.182
	control	4.375	1.657	.146	-.768	9.518
high	intial	-4.792	1.915	.020	-10.735	1.152
	low	.208	1.915	1.000	-5.735	6.152
	placebo	2.708	1.728	1.000	-2.657	8.073
	control	-.417	1.700	1.000	-5.694	4.861
low	intial	-5.000	2.107	.264	-11.539	1.539
	high	-.208	1.915	1.000	-6.152	5.735
	placebo	2.500	1.806	1.000	-3.105	8.105
	control	-.625	1.323	1.000	-4.730	3.480
placeb	intial	-7.500*	1.831	.442	-13.182	-1.818
	high	-2.708	1.728	1.000	-8.073	2.657
	low	-2.500	1.806	1.000	-8.105	3.105
	control	-3.125	1.643	.698	-8.226	1.976
high	intial	-4.375	1.657	.146	-9.518	.768
	high	.417	1.700	1.000	-4.861	5.694
	low	.625	1.323	1.000	-3.480	4.730
	placebo	3.125	1.643	.698	-1.976	8.226

Based on estimated marginal means

*. The mean difference is significant at the .05 level.

a. Adjustment for multiple comparisons: Bonferroni.

Summary of post hoc test of ROM

APPENDIX G

SEARCH STRATEGY FOR LITERATURE REVIEW

In conducting the literature review in Chapter 3 and 4 several databases were searched. A systematic computerised search of CINHAL (Cumulative Index to Nursing and Allied Health Literature) was done and this covered literature published from 1982 to present. AMED (Allied and Complementary Medicine) covered literature from 1960 to 2004, PeDRO (Physiotherapy Evidence Database) and PubMed (Medline) using the most appropriate Medical Subject Headings (MeSH) were also included in the search. The search also included publication in non physiotherapy literature in in Embase (Biomedical and Pharmacentical Database) and other physiology and engineering data bases.

The search terms used were short wave, short wave diathermy, electromagnetic field. The terms used for initial search were broad due to the limited in number of papers on PSWT.

A general internet search was conducted. Web sites search engines were reviewed to identify gray literature relevant to PSWT that was not covered by the above mentioned databases.

A hand search was also undertaken to references and conference abstracts

The literature identified was later refined to trials that used pulsed and not the continuous short wave for the reasons mentioned in Chapter 1. Studies retrieved ranged from single to double blinded controlled to non-controlled.

Summary of papers identified for Chapter 3 is described in Table 1, and papers identified for Chapter 4 is described in Table 2.

PSWT and Temperature (skin and muscle)	PSWT and Blood perfusion	PSWT and nerve conduction
6 human trials	2 human trials and 1 conference abstract	2 trials human trials 4 animal studies

Table (1) Result of literature review on physiological effects of PSWT

Condition		No of papers identified
Rheumatology		6
Musculoskeletal	Subdeltoid	2 reports
	Hand injuries	1
	Ankle sprain	5
	Laboratory	2
	Post operative wound healing	6
	Skin graft	1
	Skin ulcer	4
	Pressure sore	1
	Others	1
	Fractures	2
	Animal studies	1
Pain		5

Table (2) Results of literature review on the effect of PSWT on the pathological conditions