

Investigation of Optimal Cue to Instruction for pelvic
Floor Muscle Contraction in Women, Using Ultrasound
Imaging

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List of Abbreviations

2-D RTUS	Two dimensional real time ultrasound
3-D	Three dimensional
AHP	Allied health professional
AMED	Allied and alternative medicine
ARA	Anorectal angle
ATFP	Arcus tendineus fascia pelvis
ATLA	Arcus tendineus levator ani
AUI	Angle of urethral inclination
Backstop	Supportive layer of pelvic floor muscle and fascia
BFLUTS	Bristol female lower urinary tract symptom questionnaire
CB	Professor Clive Bartram: study radiologist
CINHAL	Cumulative Index to Nursing and Allied Health Literature
CI's	Confidence intervals
CT	Computer tomography
DC	Dave Chattoor: second reader
DOH	Department of Health
DOH	Detrusor overactivity
EAS	External anal sphincter
EMBASE	Excerpta Medica Database
EMG	Electromyograph
ESP	Extended Scope Practitioner
EUS	External urethral sphincter
FI	Faecal Incontinence
GML ANOVA	General linear model
HREC	Harrow Research and Ethics Committee
IAP	Intra abdominal pressure
IAS	Internal anal sphincter
ICC	Intra class correlation
ICIQ-SF	International Continence Society Urinary Incontinence Short Form
ICS	International Continence Society
IUGA	International Urogynecology Association
IUS	Internal urethral sphincter
JP	Joan Pitkin Urogynaecology advisor
KC	Kay Crotty: author
MRI	Magnetic resonance imaging
MUI	Mixed urinary Incontinence
NHS	National Health Service
NICE	National Institute for Clinical Excellence
NPH	Northwick Park Hospital

PFM	Pelvic Floor Muscle
PIS	Participant Information Sheets
PPI	Patient and Public Involvement
POP	Pelvic organ prolapse
QoL	Quality of life
RCR	Royal College of Radiologists
RCTs	Randomised controlled trials
SIJ	Sacro iliac joint
SUI	Stress Urinary Incontinence
The Hammock	Supportive layer of fascia under the urethra
The Knack	Voluntary contraction of the pelvic floor muscle in preparation for a cough
TLF	Thoraco lumbar fascia
TLF	Thoraco lumbar fascia
TrA	Transversus abdominis muscle
TrA	Transversus abdominis muscle
UCP	Urethral closure pressure
UH	University of Hertfordshire
UI	Urinary incontinence
UK	United Kingdom
UC	Urinary Continence
USA	United States of America
UUI	Urge Urinary Incontinence
UVS	Urethrovesical structure

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Dedication

To my darling niece Ellen, whose breath-taking and immeasurable bravery eclipses a million-fold any courage required to start and finish this programme of work.

Abstract

Background

Pelvic floor muscle (PFM) training is recommended as first line conservative management for stress urinary incontinence (SUI). The fundamental issue of how to optimally contract the PFM has not previously been investigated. An effective voluntary PFM contraction is known to positively influence the bladder neck and urethra which are urethrovesical (UV) structures associated with continence. The PFM may be globally or selectively contracted according to cue to instruction. The main research question was to investigate which cue to instruction for a PFM contraction has the potential to optimise position of UVs following a brief period of practice in continent nulliparous pre-menopausal women (aiming to provide normative data) and parous menopausal women with previously unreported SUI.

Hypotheses

Posterior or combined cues for instruction of PFM contraction are more influential in optimising UV position (UVP) during PFMC following brief practice than an anterior cue. Posterior or combined cues are equally influential in altering UVP.

Aims

Preliminary aim was to investigate the reliability and suitability of 2-DRTUS and angle of urethral inclination (AUI) for imaging of selective contraction of the PFM and ease of reading images by a non diagnostic imaging researcher. Principal aim was to investigate if there is an optimal cue to instruction for a PFM contraction in two groups of women. Study 1: pre menopausal nulliparous continent women (to provide normative data) and Study 2: post menopausal parous stress incontinent women. Secondary aims were investigation of posture; ability to selectively contract the PFM contraction; and cue preference.

Method

Study 1: Twenty women who were able to effectively and selectively contract were taught the following cues: anterior; posterior; anterior and posterior combined. Following 4 weeks of practice, perineal 2-D RTUS images of three PFMC for each cue were captured in supine and

standing twice (for repeatability analysis) five minutes apart. Two raters measured AUI. Data analysis was undertaken using a Customized General Linear Model (GLM) ANOVA with Bonferroni correction for interactions between all variables; subject, cue, posture and test. Seventeen data sets were available for analysis.

Study 2: Methodology was based on Study 1. Twenty-one women were taught the study cues, followed the practice protocol and underwent data collection in the supine position. Twenty-one sets of data were available for analysis.

Results

Reliability: ICC [1,3] for intra rater reliability was 0.957 [CI 95%: 0.946 to 0.967 $p=0.000$], inter rater reliability [2,1] 0.820 [CI 95%: 0.768 to 0.861] and for repeatability [1,3] 0.781 [CI 95%: 0.690 to 0.849 $p=0.000$] (continent) and 0.954 [CI 95%:0.931 to 0.971 $p=0.000$] (incontinent).

Principal results Study 1: anterior vs posterior cues (difference) 3.979° (CI 95%: [0.503 to 7.455 $p=0.021$]); anterior vs combined 3.777° (CI 95%: [-0.099 to 6.853 $p=0.059$]) posterior vs combined cues -0.602° (CI 95%: [-2.874- 4.078 $p=1.00$]). Aggregated data from tests 1 and 2: anterior vs posterior 4.240° (CI 95%: [1.213 to 7.267 $p=0.003$]); anterior vs posterior 3.756° (95%CI: [0.729 to 6.783 $p=0.009$]); posterior vs combined -6.48° (95% CI: [-3.511 to 2.542 $p=1.000$]).

Principal results Study 2: anterior vs posterior 3.936° (95%CI: [0.863 to 7.008 $p=0.008$]; 4.946° anterior vs combined (95%CI: [1.873 to 8.018 $p=0.001$]); posterior vs combined 1.010° (95%CI: [-2.062 to 4.082 $p=1.000$]). Aggregated analysis was anterior vs posterior 3.703° (95%CI: [1.639 to 5.761 $p=0.000$]); anterior vs combined 5.089° (95%CI: [3.0287 to 7.1503 $p=0.000$]) and posterior and combined 1.389° (95%CI: [-0.672 to 3.450 $p=0.309$]).

Secondary results: 2-D RTUS and the AUI were found to be suitable for investigating selective PFM contraction. Posture: supine vs standing (difference) 9.496° ($p=0.000$); (posture did not affect absolute AUI). Three continent (13%) and 2 incontinent (7%) subjects were unable to selectively contract the PFM. Cue preference in both studies was posterior or combined.

Conclusions

AUI was significantly narrower/optimal when instruction for PFM contraction included a posterior cue, in both continent and stress incontinent women. This is proposed to be due to optimal recruitment of puborectalis. Puborectalis may be more important in urinary continence than widely recognized. This study has provided seminal information with respect to optimal cue to contraction for a PFM contraction and will change practice. Investigation of the potential impact of these findings clinically is required. It is proposed that further understanding will lead to standardisation of PFM instruction, ease of comparability between PFM research studies, and will clarify PFM instructions for the media and lay public.

Introduction

Stress urinary incontinence (SUI) is the most common single type of urinary incontinence (UI) in women (Hannested et al 2000; Shaw et al 2006; Minassian et al 2008). The standardised definition of SUI is “the complaint of involuntary loss of urine on either effort or physical exertion (e.g., sporting activities), or on sneezing or coughing” (Haylen et al 2010). It is widely accepted that patients with SUI should be informed of conservative therapeutic options including pelvic floor muscle (PFM) training as well as invasive options when discussing management (Abrams et al 2009; Department of Health [NICE] 2013). The aims of PFM training are to improve stabilisation of the bladder and urethrovesical structures by increasing strength, power, endurance and neuromuscular facilitation of the pelvic floor. Training programmes that incorporate elements of intensity, timing, repetition and duration are used although there is no consensus on optimal composition of a programme (Dumoulin and Hay-Smith 2010).

The development of the use of perineal 2-Dimensional real time ultrasound (2-D RTUS) has contributed to the understanding of how PFM contraction may influence urinary continence. The seminal finding in early ultrasound studies was the consistent observation of change of position in a cranioventral direction of the bladder neck during effective voluntary PFM contraction (Wijma et al 1991; Wise et al 1992; Schaer et al 1995; Dietz et al 1998). Change in bladder neck position has also been found to correlate with change in urethral position (Dietz et al 2002).

Following brief PFM training, a voluntary contraction of the PFM, so called “The Knack”, during a medium or deep cough was found to significantly reduce the volume of urine leaked in women with SUI (Miller et al 1998). This finding was corroborated by the observation on ultrasound of improved stabilisation of the bladder neck during The Knack (Miller et al 2002). Other studies have investigated bladder neck position following intensive training (Balmforth et al 2006; Braekken et al 2010a; Hung et al 2011). One of these studies reported significant improvement on maximal voluntary

contraction but not at rest, coughing or valsalva (Hung et al 2011). Another saw significant improvement in bladder neck position at rest, on pelvic floor muscle contraction and valsalva (Balmforth et al 2006) whilst another reported significant improvement in bladder neck position at rest (Braekken et al 2010a). Two of these studies found a positive correlation between improvement in bladder neck position and pelvic floor muscle strength (Balmforth et al 2006; Braekken et al 2010a). Each of these studies also reported significant improvement in either stress urinary incontinence (Balmforth et al 2006; Hung et al 2011) or pelvic organ prolapse (Braekken et al 2010a) although positive correlations between improvement in symptoms and bladder neck position were not reported. These studies have produced differing results, arguably due to differences in methodology as discussed in detail in Chapter 4, so that the clinical importance of a positive change in urethrovesical position and stability remains unknown. However, maintenance of continence is acknowledged as being multifactorial. Balmforth et al (2006) discuss that

“...it is perhaps naive to think that an improved bladder neck position after treatment should be directly correlated with improvements in clinical outcome measures, when it is known that bladder neck hypermobility alone correlates poorly with clinical measures of the severity of urinary incontinence”.

Improvement in bladder neck/urethral stability as observed following PFM training remains arguably useful. Bø (2004) suggested that an aim of PFM training should be to permanently alter position of the bladder neck in order to better resist increases of intra abdominal pressure (IAP). To date, there is insufficient evidence to reject this suggestion. Within this paradigm it may be fundamental for each pelvic floor muscle contraction to optimally influence position of urethrovesical structures (UVSs). Bø and Sherburn (2007) describe that the PFM normally contracts simultaneously as a mass contraction, although Shafik describes compartmental recruitment of the PFM (1998). It is the clinical experience of this author that a single voluntary PFM contraction may be facilitated using a generic or a selective cue to contraction and that different cues to selective contraction variously influence UVS position. To date there is no consensus for optimal cue to PFM

contraction nor has this been investigated. Some (published) professionals have advocated a mass contraction that may facilitate all regions of the PFM (Bump et al 1991; Bø 2004) whilst others have used cues that may not facilitate recruitment of all regions of the PFM (Thompson and O'Sullivan 2003; Constantini et al 2005; Raizada et al 2010) and rather concentrate the lift around the vagina or urethra. In media publications cues to instruction also vary widely and may be confusing for women. The clinical observation of the current author when using perineal 2-D RTUS is that a posterior cue to instruction produces a greater excursion of movement of UVS than an anterior cue in the majority of women. Additionally, women often report that they find a posterior PFM contraction more comfortable than an anterior contraction. Despite this, women are often encouraged to exercise anteriorly. This is probably due to the belief that an anterior contraction (by simple anatomical definition) will best influence the urethra.

Whilst studies have investigated various PFM exercise regimes and interventions as described by the Cochrane Collaboration (Neumann et al 2006), there are no studies that have addressed selective PFM contraction. This author identified a need to establish if there is an optimal cue for a single PFM contraction. The potential finding of an optimal cue may result in improvements in treatment outcomes due to optimal positioning of UVSs and improved self efficacy due to a more comfortable technique. Further, optimal cue may ultimately lead to standardisation of instruction resulting in enhanced ease of comparability of research studies. Finally, standardised instruction may result in more consistency and thereby less confusion in media publications.

The primary aim of this programme of study was to provide preliminary evidence with respect to the possible existence of an optimal cue for a single pelvic floor muscle contraction, in order to provide seminal information for clinicians, researchers and the lay public. The main research question was to investigate which cue to instruction for a PFM contraction has the potential to optimise position of UVSs following a brief period of practice in:

- a. continent nulliparous pre-menopausal women (aiming to provide normative data)
- b. parous menopausal women with previously unreported SUI

In order to attempt to answer the research question, two feasibility studies using a pragmatic approach were designed. A pragmatic approach was necessarily taken due to fiscal constraints. This researcher was independent and not affiliated to the NHS and/or a research facility and self funded the research programme other than sponsorship for electrodes, EMG and measurement software (see acknowledgements page viii).

A programme of work was undertaken which consisted of:

1. Investigation of whether perineal 2-D RTUS was a suitable method for measuring urethral change as influenced by selective PFM contraction, including investigation of intra and inter rater reliability.
2. Exploration of training required for a non diagnostic imaging Allied Health Professional (AHP) to read perineal 2-D RTUS images.
4. Objective confirmation of the ability of subjects to selectively contract the PFM.
5. A study of repeatability of selective PFM contraction.
6. Two pragmatic feasibility studies were undertaken to investigate which cue to instruction for a PFM contraction has the potential to optimise position of the urethra following a brief period of practice in:
 - a. Continent nulliparous pre-menopausal women (aiming to provide normative data).
 - b. Parous menopausal women with previously unreported SUI.
7. An investigation of the effect of postural position on selective cue to instruction.

The following chapters describe the background to, and the programme of work for, the process that was necessary to test the hypotheses formulated by this author. The first three chapters provide a critical overview of the extensive literature that broadly underpins the hypotheses. Chapter 4 provides a critical literature review of issues directly underpinning this programme of work and leads into the five remaining chapters concerned with the research programme, results and their extrapolation, clinical implications and suggested future research.

Chapter 1 Epidemiology and Conservative Management of Stress Urinary Incontinence

1. Introduction

Urinary incontinence (UI) is the complaint of involuntary loss of urine and is a common health problem in women, with wide ranging implications with respect to quality of life (QoL). Urinary incontinence is recognized as comprising sub-types; Stress Urinary Incontinence (SUI); Urge Urinary Incontinence (UII); and a combination of the two resulting in Mixed Urinary Incontinence (MUI). Recommendations from the Joint Standardisation Committee of the International Urogynecology Association (IUGA) and International Continence Society (ICS), with respect to terminology of UI are presented in Table 1.1 (Haylen et al 2010). This programme of work is concerned with female SUI. As a background to this programme of work, a critical overview of epidemiology, impact and conservative management of SUI follows.

Table 1. 1 Standardised Terminology for Urinary Incontinence Symptoms (Haylen et al 2010)

Urinary Incontinence	Complaint of involuntary loss of urine
Stress (urinary) Incontinence	Complaint of involuntary loss of urine on effort or physical exertion (e.g., sporting activities), or on sneezing or coughing
Urgency (urinary) Incontinence	Complaint of involuntary loss of urine associated with urgency
Urodynamic Detrusor Over Activity	A urodynamic observation characterized by involuntary detrusor contractions during the filling phase which may be spontaneous or provoked
Mixed (urinary) Incontinence	Complaint of involuntary leakage associated with urgency and also with exertion, effort, sneezing or coughing.

1.1 Critical Overview Design

1.1.1 Structure

Part I: Prevalence of SUI

Part II: Symptom severity, quality of life, self reporting and economic impact of SUI.

Part III: Risk factors for SUI

Part IV: Conservative management of SUI

1.1.2 Parts I-IV

Objective

The objective of parts I-IV was to provide a critical overview of epidemiology, impact of SUI and conservative management.

Search Strategy

Because of the significant breadth of the literature it was not possible to review all papers. Papers were therefore selected using a pragmatic approach, and searches narrowed as appropriate. Generalised searches were undertaken of the computerised databases Medline, AMED, CINHAL, EMBASE – Rehabilitation and Physical Medicine and The Cochrane Library of Systematic Reviews from 1980 to date. Key search terms were SUI; epidemiology; prevalence; through lifetime; worldwide; UK; risk factors; symptom severity; quality of life; self reporting; economic impact, vaginal delivery, levator ani, imaging, disruption; pelvic floor muscle, pelvic floor muscle training; musculoskeletal training; morphology; assessment; perineal ultrasound imaging; manometry; bio-feedback; cure; improvement; instruction; cue; maintenance. Hand searches of references, conference abstracts; textbooks in the library of the author and citation searches were also undertaken. Seminal studies already known to this author were also considered for inclusion.

Selection criteria

Papers were included where considered suitable by this author to contributing to a balanced overview. Papers were included if the following criteria were met:

1. The publication was in the English Language
2. Design and outcome measures were reliable and relevant to the area of investigation

1.2 Critical Overviews

1.2.1 Part I: Prevalence of SUI

The computerised searches revealed more than 1600 papers for SUI and prevalence and therefore the search was narrowed to source papers on prevalence of SUI through lifetime. This revealed the six key papers presented in Table 1.2. (Hannestad et al 2000; Shaw et al 2006; El Azab et al 2007; Minassian et al 2008; Dooley et al 2008; Garcia-Perez et al 2013). One study was found of world wide prevalence estimates for SUI (Irwin et al 2011) and one for UK estimates and these were both included (Imamura et al 2010). Other supporting studies from the library of this author were also selected (Viktrup et al 2006; Meyer et al 1998; Dolan et al 2003) and two sourced from hand searches of references (Viktrup et al 1992 and Viktrup and Lose 2001 [both identified from the reference list in Viktrup et al 2006]).

Stress urinary incontinence is undisputedly a common condition in women. It is estimated that SUI is the most common form of any UI at approximately 50% (Hannestad et al 2000; Shaw et al 2006; Minassian et al 2008). One study has provided a projected estimate of the worldwide number of women with SUI of 140,000,000 in 2013, rising to 153,000,000 in 2018 (Irwin et al 2011). These estimates were based on the findings from a robust population-based, cross sectional telephone survey of approximately 19,000 men and women across the UK, Canada, Germany, Italy and Sweden (Irwin et al 2006) and data from the US Census Bureau International database. The prevalence of female SUI in the UK has been estimated at 3.3 million (Imamura et al 2010). This estimation was based on an overall prevalence for SUI of 15% among women aged over 20 years, coupled with population statistics from the National Office of Statistics in mid-2007. It is arguable that a 15% prevalence for SUI is conservative and that the estimate might have been based on a higher prevalence rate, although regardless of this, it is clear that a large number of women in the UK are likely to experience SUI at some point in their lifetime.

Studies that provide information with respect to progression of prevalence of SUI through lifetime are presented in Table 1.2. (Hannestad et al 2000; Shaw et al 2006; El Azab et al 2007; Minassian et al 2008; Dooley et al 2008; Garcia-Perez et al 2013). The estimates vary between studies due to differences in survey design, setting and region. In broad terms prevalence increases during child bearing years, rises slightly around the perimenopausal years and then subsequently falls again. This is to be expected due to reduction and subsequent accommodation in oestrogen levels. Hannestad et al (2000), Shaw (2006) and Minassian (2008) discuss that this has historically been a consistent finding in studies. The reduction in the level of SUI reported in older age groups is also widely acknowledged to be due to the increasing incidence of MUI rather than SUI alone with increasing age. Two of the studies in Table 1.2 report lower prevalence rates across all age groups than the other cited studies (Hannestad et al 2000 and Garcia-Perez et al 2013). In the latter study, the authors discuss that urinary leakage very much remains a taboo subject in South America, and that subsequently women may be too embarrassed to report leakage, particularly given the face-face survey design. Hannestad et al (2000) state that embarrassment should not be responsible for the low prevalence rates in their study, although it is difficult to ascertain why these results were relatively low. Conversely, Shaw et al (2006) discuss that the relatively high rates in their survey may be due to the survey taking place in GP waiting rooms, although the results are broadly comparable with the studies of Minassian et al (2008) and Dooley et al (2008). Shaw et al (2006) discuss that women with urinary leakage may access primary care more often due to other co morbidities that are associated with UI. Minassian et al (2008) report higher prevalence rates for the 40-59 age bands than in other studies, and this may be due to the different threshold for collecting information. This study questioned if urinary leakage had occurred within the last 12 months rather than in the past month and this may have introduced recall bias. The highest prevalence of SUI at any age was seen in the Egyptian study at 40.5% in the 18-29 year age group (El Azab et al 2007). The authors discuss that higher rates may be due to young age at marriage, high parity rate and limited obstetric care in these subjects who were drawn from Egyptian villages. The variation in prevalence rates presented in Table 1.2, is likely to be representative of the

variation in estimates from the many epidemiological studies that are too numerous to discuss here. Regional, setting, and survey design differences must be taken into account on an individual basis, as these factors appear to be central to variation in prevalence rates between studies.

Transient SUI is estimated to occur in 32% to 85% of women during the pre and post natal period although incidence is seen to decline at three months post partum (Meyer et al 1998; Viktrup et al 1992 [cited in Viktrup 2006] and Viktrup and Lose 2001. Those with onset of symptoms in the antenatal period rather than following delivery are reported to be at greater risk of ongoing symptoms (Dolan et al 2003; Viktrup et al 2006) as are those with no remission of symptoms at three months postpartum (Viktrup et al 2006).

Table 1. 2 Prevalence of SUI in women by age band

	Number studied	18-29 (years)	30-39 (years)	40-49 (years)	50-59 (years)	60 (years)	70-79 (years)	80-89 (years)	90+ (years)
Hannestad et al 2000 Norway	28,000	7.6%	11.7%	16%	15%	13%	10.5%	12%	10%
Shaw et al 2006 UK	3,273	17.7%	24.7%	24.7%	22.7%	18.4%	13.8%	9.3%	—
El Azab et al 2007 Egypt	1,652	44.5%	26.1%	18.4%	9%	5%	—	—	—
Minassian et al 2008 USA	2,875	14.4%	22.7%	34.8%	35.7%	23.7%	21.5%	15%	—
Dooley et al 2008 USA	4,229	18.8% (20-39)	—	33.1% (40-59)	—	20.6% (60+)	—	—	—
Garcia-Perez et al 2013 Mexico	1307	10.4% (25-34)	11.07% (35-44)	9.83% (45-54)	—	—	—	—	—

1.2.2 Part II: Symptom severity, quality of life, self-reporting, and economic impact of female SUI

Computerised searches revealed more than 1500 papers and it was therefore considered reasonable to select five papers that were representative of the variation in setting and data collection methods in large community based surveys. The key papers identified were Monz et al 2005; Gasquet et al 2006; Shaw et al 2006; Lasserre et al 2009; Wallner et al 2009a). Two seminal papers were included (Norton 1998 and Rekers 1992), and one paper was identified that provided estimates for the economic burden of SUI in the UK (Turner et al 2004). Of the five key papers, all but one of the studies (Gasquet et al 2006) investigated any UI rather than SUI alone. The largest of the studies investigated across 14 countries (Monz et al 2005). Settings included: GP waiting rooms (Shaw et al 2006; Lasserre et al 2009); subjects randomly selected from the telephone directory (Gasquet et al 2006) or health directories (Monz et al 2005; Wallner et al 2009). Data collection was by self completed questionnaire (Monz et al 2005; Shaw et al 2006; Wallner et al 2009); face to face questionnaire (Lasserre et al 2009) or telephone interview (Gasquet et al 2006). All of the studies used validated questionnaires although only the 1-QOL (Wagner et al 2008) had been used in more than one paper (Monz et al 2005 and Shaw et al 2006).

It is widely acknowledged that that the majority of women with SUI self- report mild to moderate urine loss and quality of life (QoL) scores with a only a minority of women reporting severe symptoms/scores. Despite different settings and methodology the studies selected in this overview are broadly consistent with this phenomenon. Mild symptoms were reported in at least 75% of respondents with SUI; moderate symptoms in less than 20%, and severe in less than 6% (Gasquet et al 2006; Shaw et al 2006; Lasserre et al 2009). The study by Wallner et al (2009) was at variation in that the prevalence of either mild or moderate symptoms was similar at 40% and 50% respectively. This possible overestimation of moderate symptoms may be due temporal difference in questioning about leakage. Urinary leakage was ascertained for the past 12 months as well as

within the past 7 days (rather than within the past month as in the other studies cited here). It is possible that the 12 month time period may have resulted in recall bias.

It is acknowledged that in any UI, QoL scores may be affected. Commonly, as reported by Rekers (1992), women may experience depression and feelings of low self worth and may be embarrassed about the appearance of leakage on their outer clothing and odour, all of which may affect their social or intimate relationships. In SUI specifically, QoL scores have been reported as less negatively impacted (within the mild to moderate range) as compared with UUI or MUI (Monz et al 2005; Shaw et al 2006; Lasserre et al 2009). This is believed to be due to the unpredictability and greater urinary loss for MUI and UUI. Nonetheless SUI is reported as having an impact on avoidance behaviour, social embarrassment, functional limitations and psychosocial issues (Monz et al 2005; Shaw et al 2006) and that worsening of QoL is related to increasing severity (Monz et al 2005; Shaw et al 2006; Gasquet et al 2006; Wallner et al 2009). In women with SUI, Monz et al (2005) reported a negative impact on social embarrassment to a greater extent than for avoidance and limiting behaviour, or psychosocial impact, as are common in women with UUI or MUI. However, the authors discuss that QoL issues should be considered on a case by case basis, because differing lifestyles are likely to impact differently on QoL domains.

It has long been acknowledged that symptoms of any UI are under reported (Norton 1998). The consistent finding across studies is that a high percentage of women delay seeking help (Shaw et al 2006; Gasquet et al 2006; Lasserre et al 2009; Wallner et al 2009). Wallner et al (2009) reported that 70% of symptomatic women surveyed had unreported symptoms of more than one year, broadly supporting the finding of Lasserre et al (2009), that less than 40% of women with symptoms of five years or less had reported their symptoms. Shaw et al (2006) reported that only 15% of women in the UK with SUI several times per month had sought help from their GP, whilst in France, the help seeking rate was reported as more than double this figure (Gasquet et al 2006). This may be due to greater awareness of pelvic floor dysfunction in French women, as all are offered “perineal” education and training post partum and may therefore be more aware

of available help. Regardless of these differences, the consensus in these studies is that any UI is apparently under recognised by health professionals, that negative help seeking behaviour is driven by embarrassment and/or an acceptance of the inevitability of UI following child birth and/or ageing, and that greater education is required for both health professionals and the public.

The cost of SUI to the National Health Service (NHS) is high. An estimate based on the assumption that SUI comprises 50% of all UI cases, suggested an economic burden of £117 million per year in the UK and £90 million per year in individually borne costs such as containment products and laundry costs (Turner et al 2004).

1.2.3 Part III: Risk factors for Stress Urinary Incontinence

Computerised searches revealed more than 570 papers and therefore the search was narrowed to imaging studies of levator disruption that would also be discussed in Chapter 2. Ten papers were identified and included as key papers (DeLancey et al 2003; Dietz and Lanzarone 2005; Branham et al 2007; Abdool et al 2009; Valsky et al 2009; Kearney et al 2006; Krofta et al 2009; Margulies et al 2007; Heilbrun et al 2010; Miller et al 2010). Seminal studies were also selected (Madill and Mclean 2007; Ashton Miller and DeLancey 2007). For risk factors other than levator disruption, papers were selected where they were considered by this author to provide a balanced overview of risk of: increasing parity (Demerci et al 2001; Groutz et al 2007; Hermann et al 2009); instrumental delivery (Angioli et al 2000; Andrews et al 2006; Kearney et al 2004; Hudelist et al 2005) increasing age (Persson et al 2000; Dietz and Simpson 2007); high birth-weight Sultan et al (1994) and gestation (Viktrup et al 1992; Demerci et al 2001; Viktrup and Lose 2001). Other risk factors are cited in tabulated form only because risk of levator injury due to vaginal delivery is the principal paradigm of interest in this study. The tabulated citations (Table 1.3) were sourced from textbooks in the library of the author (Artibani et al 2005; Haslam and Laycock et al 2008; Bø 2007 et al; Abrams and et al 2009).

Vaginal delivery is the single most important risk for SUI and may result in trauma to muscle, connective tissue and nerve supply (Ashton Miller and DeLancey 2007). Miller et al (2010) describe that levator trauma may be caused by excessive stretching or tearing of the levator ani, fascia and ligaments; nerve injury; or ischaemia due to compression injury from the infant's head. Madill and Mclean (2007) describe that such defects may result in motor control deficits of the PFM i.e. inefficient and poorly timed contraction. To date, imaging of soft tissue trauma is restricted to observation of muscle. Disruption of the levator ani from the pubis may be observed on magnetic resonance imaging (MRI) or intra-cavity ultrasound imaging (DeLancey et al 2003; Dietz and Lanzarone 2005; Branham et al 2007; Abdool et al 2009; Valsky et al 2009; Kearney et al 2006; Krofta et al 2009; Margulies et al 2007; Heilbrun et al 2010; Miller et al 2010) (see also 2.2.3 and Table 2.2). One of these studies, investigated risk of levator trauma associated with size of infant head and length of second stage labour (Valsky et al 2009). The odds ratio of levator trauma as a result of delivery of an infant with a head circumference of greater than 35.5cm was estimated as 3.3; for second stage labour of longer than 110 minutes as 2.2; and with the two factors combined as 5.3. Two of these studies investigated and reported a strong association between levator disruption and SUI (DeLancey et al 2003; Dietz and Lanzarone 2005). One study investigated pelvic organ prolapse and found that women with major levator ani defects and pelvic organ prolapse were less likely to experience SUI than women with minor levator defects with no symptoms of pelvic organ prolapse (Morgan et al 2010). It is not known why this is the case. It is possibly due to altered anatomy that results in urethral obstruction during increases in intra abdominal pressure (IAP). Instrumental delivery using forceps or ventouse is widely acknowledged as a further risk factor during parturition (Angioli et al 2000; Andrews et al 2006; Kearney et al 2006; Hudelist et al 2005; Krofta et al 2009). Forceps delivery has been reported as being more injurious than ventouse delivery (Meyer et al 1998; Kearney et al 2006). It is widely acknowledged that the first vaginal delivery is reported as being the most traumatic to the PFM whilst second delivery moderately increases the risk of SUI until third delivery when a strong association with increased incidence of SUI has

been reported (Demerci et al 2001; Groutz et al 2007; Hermann et al 2009). Increasing age at delivery may also be a risk factor for levator trauma with one study reporting an estimated increase in the odds ratio of levator trauma of from 0.6 aged 19 or less at the time of delivery to 2.61 aged 35-39 at time of delivery (Persson et al 2000). This is supported by a retrospective study by Dietz and Simpson (2007) with multiple regression analysis that reported a 10% increase in odds for every year of delay in child-bearing. Birth weight of >4kg has been found to be associated with increased pudendal nerve trauma and SUI and is proposed to be due to sustained compression of the perineum (Sultan et al 1994), although it is probable that head circumference as discussed above, causing excessive levator ani stretching at delivery is also a factor. Gestation alone is also a risk factor for SUI regardless of mode of delivery as observed by comparisons of women delivering either by caesarian section or vaginally (Viktrup et al 1992; Demerci et al 2001; Viktrup and Lose 2001).

Non-pregnancy related risk factors for SUI are presented in Table 1.3.

Table 1.3 Risk Factors for SUI

Established Risk Factors	
The ageing process	Rud 1980; Klauser et al 2004; Perucchini et al 2002; Trowbridge et al 2007; Clobes et al 2008
Menopausal Status	Jolleys 1988; Mannonai et al 2006; Waetjen et al 2009
Obesity	Bump 1992; Brown et al 1996; Hunskaar 2008
Chronic Cough	Jackson et al 2004; Shariat et al 2009; Vella et al 2009
Smoking	Bump and M ^c Clish 1992; Hannestad et al 2003
Genetic factors	Mushkat et al 1996; Ertunc et al 2004; Dietz et al 2005; Altman et al 2007a
Ethnicity	Dooley et al 2008; Sears et al 2009; Townsend et al 2009
Constipation/chronic straining at stool	Spence-Jones et al 1992; Manning et al 2003
Non established riskfactors	Studies
Hysterectomy	Prior et al 1992; Altman et al 2007b; DeLancey 1997
Cancer surgery	Hample et al 2008; Lee and Tamimi 1986; M ^c Clurg and Hagen 2009; Daniels et al 2006
Female genital mutilation	Utz-Billing and Kentenich 2008; Griffith and Tengnah 2009
Hormone replacement therapy	Cody et al 2009; Townsend et al 2009
Oral Contraception	Townsend et al 2009

1.2.4 Part IV: Conservative management of SUI

Computerised searches revealed more than 950 papers and therefore the search process was narrowed to systematic reviews. One review was included as a key text because it reviewed PFM training alone without adjunctive training tools (Neumann et al 2006). International and national recommendations were included (Messelink et al 2005 [ICS]); Abrams et al 2009 [WHO Guideline]; UK NICE Guideline [DOH 2013]. Seminal papers were also included (DiNubile 1991; Bump et al 1991; Laycock 1994; Peschers et al 1997; Bernstein et al 1997; Bø 1988, 1990 and 2004; Dietz et al 1998 and 2002; Miller et al 2001; Thompson and O'Sullivan 2003; Folland and Williams 2010; Wijma 1991; Wise et al 1992; Schaer 1995; Dietz et al 2002; Thompson et al 2005). All papers identified in relation to reflex activity of the PFM were included (Hemborg et al 1985; Deindl et al 1993; Amerenco et al 2005; Bø and Sherburn 2007; Smith et al 2007). Other papers were sourced from hand searches of conference abstracts (Moran and Assassa 2010); hand reference searches (Morris 1936 cited in Dumoulin and Hay-Simth 2010) and publications in the library of the author (Bø and Sherburn 2008; Greer 2012).

Pelvic floor muscle training in the developed world has appeared in the modern literature for the past 80 years. In that time it has become rather more sophisticated than as delightfully described in 1936 by Morris, a women's health physiotherapist. Morris described that post partum PFM exercises were to be performed in time to Schubert's Waltzes opus 16 No.2, thus suggesting that PFM training was very much the remit of the middle classes. Pelvic floor muscle training is now widely available to women in developed countries. The World Health Organization-sponsored International Consultation on Incontinence recommends PFM training as a first line intervention in the treatment of SUI (Abrams et al 2009). The UK NICE Guideline on UI has recommended similarly (Department of Health [DOH] 2013). Expert PFM training is now widely available in the UK, delivered by Chartered Physiotherapists and Continence Nurses with post graduate specialist training. The British Society of Urogynaecology Database (BSUG.net) is an online audit tool for surgeons working in urogynaecology in the UK. Data presented at the Continence Society UK annual conference in April 2010

demonstrated that there were 148 centers registered of which 69 had entered data with respect to audit of care pathways and surgical episodes for SUI. Between January 2007 and January 2010 there were 14,977 surgical episodes. Of the women undergoing surgery, 78.6% had undergone previous PFM training, with 70% of these having received supervision from a physiotherapist (Moran and Assassa 2010).

The theoretical rationale for intensive PFM training is undisputed. Intensive training improves structural support within the pelvis by improving PFM muscle tone and stiffness of connective tissues. Such changes increase the ability to resist deformation and to elevate the PFM to a permanently higher location within the pelvis (Bø 2004). Physiologically these aims are met through:

- a. Increasing the number of activated motor units and motor unit firing rate of the PFM.
- b. Promoting muscular collagen synthesis and change in arrangement of intramuscular connective tissue to produce muscle hypertrophy and increased tendon stiffness.

The two principle constructs for PFM training are strength training and anticipatory training (Bø 2004).

Strength training is the main stay of most PFM training (Neumann et al 2006). Muscle strength is defined as the maximal force generated at a specified or determined velocity and is strongly proportional to cross sectional area and neuromuscular factors (DiNubile 1991). PFM training for SUI is based on the principals of high resistance general musculoskeletal (HRGMS) training although whilst HRGMS training broadly aims to enhance athletic performance, augment musculoskeletal health and alter body aesthetics (Folland and Williams 2010), PFM strength training aims to improve support and ultimately, closure of the urethra. High resistance general musculoskeletal training produces changes in whole-muscle size; muscle fibre hypertrophy; myofibrillar growth and proliferation; changes in fibre type and muscle architecture; neurological adaptations including firing frequency and synchronisation and cortical adaptations. Changes in

morphology have not been studied as extensively or in as great a depth in PFM, although it is known that muscle hypertrophy, change in fibre type and neural adaptations occur following PFM training (Bernstein et al 1997).

The healthy PFM has been observed to contract reflexly in anticipation of lifting (Hemborg et al 1985) and coughing (Deindl et al 1993; Amerenco et al 2005). Delay in this feed forward loop has been demonstrated during rapid arm movement in incontinent women (Smith et al 2007). Whilst all of these studies are small and require validation with larger studies, they provide some foundation for the rationale of including anticipatory training in a PFM training programme. It is believed that anticipatory training improves reflex pathways and acquisition of the voluntary skill to anticipate and prepare the PFM during sudden rises in intra abdominal pressure (IAP) (Bø 2004). Anticipatory training includes instruction for “The Knack” i.e. the ability to voluntarily contract the PFM prior to steep rises in IAP and is discussed in greater detail in Chapter 4.2.1.1 (Miller et al 2001).

There is no consensus for the composition of a PFM training regime (Neumann et al 2006; Dumoulin and Hay-Smith 2010). The studies presented in Table 1.4 by Neumann (2006) are representative of the wide difference in design of training programmes. Duration of training varies widely from four weeks (Berghmans 1996) to six months (Bø 1999; Morkved 2002 and Finkenhagen and Bø 1998). It is of particular interest in the context of this programme of work that there is no consensus on cue to instruction for a single PFM contraction, nor has this been discussed in the literature or previously investigated.

Digital vaginal assessment is the gold standard prior to the start of a PFM training programme (Bø et al 1988; Bump et al 1991; Laycock 1994; Peschers et al 1997). It provides subjective information with respect to ability to achieve an effective upward lift of the PFM. Persistent incorrect/downward movement of the PFM during a voluntary

contraction is counter-productive and may be potentially damaging (Thompson and O'Sullivan 2003). Expert digital assessment also provides further subjective information that will influence decision making for content of an individualised PFM training programme with respect to strength; endurance; resting muscle tone; the ability to relax after a contraction; coordination with the lower abdominal muscles; structural symmetry of right and left; scarring and adhesions; pain; speed and sequence of recruitment; and transverse and antero-posterior diameters of the urogenital hiatus (Bø and Sherburn 2007). Strength of the PFM may be assessed using a Modified Oxford Scale which grades strength on a six-point scale of 0-5, from "0=no discernable contraction" to "5=strong contraction that can withstand resistance" (Laycock 2004). There is however no evidence for responsiveness or reliability of measurement for this method. Two studies that compared the Modified Oxford Scale with perineometry found opposing results. Whilst Isherwood and Rane (2000) found a high kappa of 0.73, Bø and Finkenhagen (2001) found a kappa of only 0.37 (cited in: Bø & Sherburn [2007].) Nor is validity proven for the recommendation of ICS to grade as absent, weak, normal or strong (Messelink et al 2005).

Perineal 2-D RTUS is a useful tool for assessment of PFM function in clinical practice as described by Thompson et al (2005) although it is not yet widely available to pelvic floor physiotherapists in the UK. Conversations between this author and fellow pelvic floor physiotherapists working within the NHS across the UK, suggest that this is due to fiscal constraints. Pelvic floor muscle movement is viewed indirectly by observing movement of the bladder neck and urethra during imaging (Wijma 1991; Wise et al 1992; Schaer 1995; Dietz et al 1998). Either correct cranio-ventral movement or counter-productive dorso-caudal movement of UVSs are easily observed by clinician and patient alike. Direction of PFM movement as seen on ultrasound has been found to correlate with digital palpation and strength as measured by perineometry (Dietz et al 2002; Thompson et al 2005). Other phenomena that are easily visualized on perineal 2-D RTUS are quality of movement, muscular endurance and bladder neck and urethral displacement on coughing or valsalva. It is particularly useful in clinical practice for patients who are not suitable for digital examination per vagina. This may include children, women with

vaginismus or vaginal atrophy for whom digital examination may be painful, and for those women who chose to decline pelvic examination for any other reason.

Vaginal squeeze pressure may be used to assess strength using various commercially available instruments that involve an intra-vaginal probe against which the patient maximally squeezes. Due to lack of reported responsiveness and inconsistency in results for reliability, Bø and Sherburn (2008) advise that measurement of squeeze pressure should be used with caution as it is difficult to obtain valid and reliable results (because any rise in IAP may potentially contaminate the results). The authors recommend its use as a bio-feedback tool for the patient and therapist rather than for strength measurement. Trials and reviews of PFM training have largely investigated UI rather than individual subtypes of UI, although there is little evidence to support the use of PFM training for UUI (Greer 2012). Reporting of SUI alone is less common. A valuable review of PFM training studies identified 14 studies between 1995 and 2005 that reported outcomes of SUI following PFM training alone (without adjunctive therapy such as biofeedback) (Neumann et al 2006). The authors emphasize that comparison of studies is problematic due to issues of definition of “cure” and “improvement” and that results should be considered with some caution. However, the review found consistent evidence for the effectiveness of PFM training alone for SUI. Reported cures rates were from 2% to 69% and cure/improvement rates were from 41%-100% (Table 1.4). Maintenance training twice weekly has been shown as sufficient to maintain strength once expert supervision has ceased provided each contraction is of high intensity (Bø 1990).

Table 1. 4 Outcomes for 14 studies investigating PFMT alone for SUI. Neumann et al (2006)

Outcomes of studies of PFMT with percentage cure, cure/improvement and positive and statistically significant outcomes						
PFMT studies	Treatment time	N (subjects)	N (% lost to follow-up)	% cure	% cure/improved	N (%) positive & statistically significant outcomes
Bo (1999)	6 months	29	4 (14)	44 (1), 56 (4)	48 (4)	8/9 (89)
Morkved (2002)	6 months	50	4 (17)	46 (1), 30 (4) 57 (2)	93 (4)	6 (100)
Bo (2000)	6 months	24	4 (8)	6–44 (5)	NR	1 (100)
Berghmans (1996)	4 weeks	20	0 (0)	15 (2)	85 (2)	1 (100)
Miller (1998b)	1 week	27	0 (0)	23 (3)	NR	2 (100)
Hay-Smith (2002) ^a	20 weeks	64	2 (3)	7 (4)	47 (4)	NR
Hay-Smith (2002) ^b	20 weeks	64	3 (5)	2 (4)	41 (4)	NR
Arvonen (2001)	4 months	20	1 (5)	26 (1)	58 (4)	3 (100)
Glavind (1996)	NR (2–3 sessions)	20	5 (25)	20 (1)	NR	NR
Pages (2001)	3 months	27	0 (0)	69 (4)	100 (4)	3 (100)
Bidmead (2002)	14 weeks	40	NR	NR	NR	3 (100)
Sung (2000)	6 weeks	30	NR	NR	NR	3 (100)
Aksac (2003)	8 weeks	20	NR	75 (3)	100 (3)	10 (100)
Finkenhagen (1998)	6 months	38	2 (5)	35 (4)	71 (4)	NR

Hay-Smith ^a = motor learning protocol, Hay-Smith ^b = strength and motor learning protocol NR = not reported; (1) = pad test with standardised bladder volume; (2) = 48 hour pad test; (3) = other types of pad test; (4) = self-rated assessment of incontinence; (5) = self-reported quality of life/sexual function domains

Summary

Female SUI is a common problem that may affect women of all ages and which may have a negative impact on QoL. The most common risk factor is vaginal delivery. It is widely under reported due to embarrassment or the belief that the condition is inevitable. Pelvic floor muscle training is widely recommended as a first line treatment for SUI. Training programmes vary widely and there is no consensus on number of repetitions, sets of contractions per day, and length of training over time. Most PFM training programmes comprise strength and anticipatory training with the aim of improving support to and closure of the urethra. Studies have demonstrated a success rate from 41% to 100% for either improvement or cure and from 2% to 69% for cure alone. Maintenance of PFM exercise is required in order to maintain improvement. Consensus on instruction for a single PFM contraction does not exist nor does discussion appear in the literature.

Conclusion

Stress urinary incontinence is a common problem that may negatively impact on QoL. Pelvic floor muscle training is recommended as first line treatment in conservative management. To date there are no studies that have investigated cue to PFM contraction. Having introduced the paradigm of stress urinary incontinence and its conservative management, discussion of anatomy of the urinary continence system follows.

Chapter 2 Anatomy of the Lower Urinary Tract and Pelvic Floor Muscles

2 Introduction

The complex anatomy of the PFM and the relationships with viscera and connective tissue is inseparable from function in relation to urinary continence. Nonetheless separate chapters have been dedicated within this dissertation to anatomy and to function. This has been done for the sake of clarity although discussion of structure and function will necessarily be integrated throughout this dissertation. This programme of work is broadly concerned with storage of urine and therefore anatomy and function in this and the following chapter will be described in relation to the closure forces around the bladder base and urethra. The principal anatomist of the small pelvis in current time is acknowledged to be John O.L DeLancey MD, Professor of Obstetrics and Gynecology, University of Michigan, USA and it was considered reasonable to use his work as a foundation for this overview, although the work of other eminent anatomists is included where appropriate.

2.1 Critical Overview Design

2.1.1 Structure

Part I: Gross anatomy of the lower urinary tract

Part II: Anatomy of the pelvic floor muscles

Part III: Anatomical disruption of the pelvic floor muscles

2.1.2 Parts I – III

Objective

The objective of parts I-III was to provide a critical overview of the normal anatomy of the lower urinary tract, the PFM and support systems, and of anatomical disruption of the PFM that may lead to dysfunction.

Search Strategy

Because of the significant breadth of the literature it was not possible to review all papers. Papers were therefore selected using a pragmatic approach, and searches narrowed as appropriate. Generalised searches were undertaken of the computerised database Medline, from 1980 to date. Key search terms were: anatomy, DeLancey; small pelvis; bladder; urethra; external urethral sphincter; internal urethral sphincter; perineal membrane; ligaments; support; fascia; sphincter; vagina; rectum; anus; pelvic floor muscle; levator ani; puborectalis; pubovisceralis; iliococcygeus; nomenclature; nerve; supply; pudendal; MRI; ultrasound; imaging; disruption; dysfunction; avulsion; simulation; model. Hand searches of papers, conference abstracts and textbooks in the library of the author and citation searches were also undertaken. Seminal studies already known to this author were also considered for inclusion.

Selection criteria

Papers were included where this author considered they were suitable for contributing to a balanced overview. Papers were included if the following criteria were met:

1. The study was in the English Language
2. The study was confined to investigation of human tissue

2.2 Critical Overviews

2.2.1 Part 1: Gross anatomy of the lower urinary tract

The primary computerised search for the work of DeLancey produced more than 180 papers. This was narrowed by selecting key papers from hand searches of the library of this author (DeLancey 1989; 90; 94; Strohbehn and DeLancey 1997; Ashton Miller and DeLancey 2007; Stein and DeLancey 2008). A seminal paper was included (Rud 1980) and others identified as a result of reference searches of the key papers (Olerich 1983 cited in Stein and Delancey 2007; Yucel and Baskin 2004 and Nakajima et al 2007, both cited in Wallner et al 2009b). One paper was identified from a textbook in the library of the author (Cutner et al 1997).

The lower urinary tract comprises the bladder, its specialised bladder base and neck and the urethra. The function of the lower urinary tract is to store and ultimately eliminate urine. The female bladder/detrusor is a highly specialised muscular receptacle lying in relationship with the uterus and colon (Figure 2.1). There are several muscular layers to the detrusor. The two principal layers have an opposing configuration; the innermost layer is circular and extends distally to cover the ventral aspect of the bladder neck; the outer muscular layer is arranged longitudinally and extends to the bladder base and neck to envelop the ventral circular fibres of the proximal urethra. A further outer muscular layer provides two bands of muscle that form the U shaped detrusor loop on the anterior aspect in the region of the bladder base. The junction of the bladder neck and bladder base/trigone is known as the urethrovesical junction (DeLancey 1989; 1990). The various muscular layers of the detrusor assist in bladder neck closure at the region of the urethrovesical junction.

Figure 2. 1 Lateral view of urethral and pelvic floor muscular anatomy.

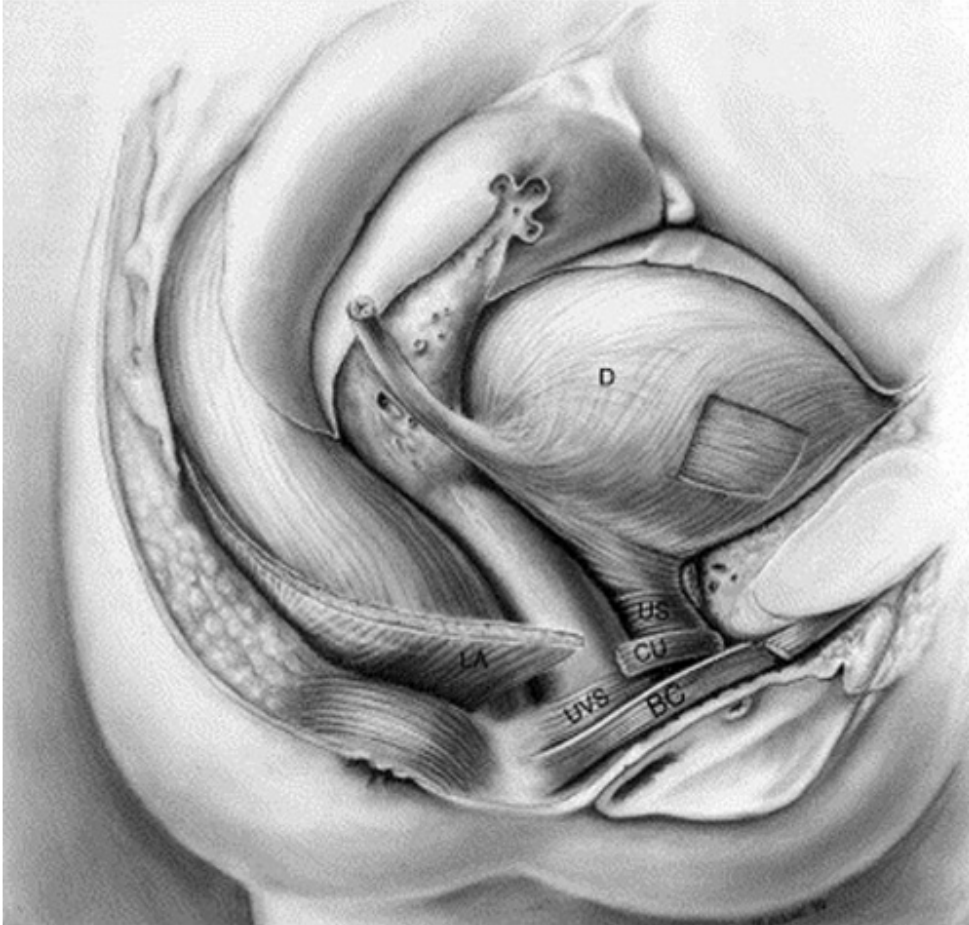


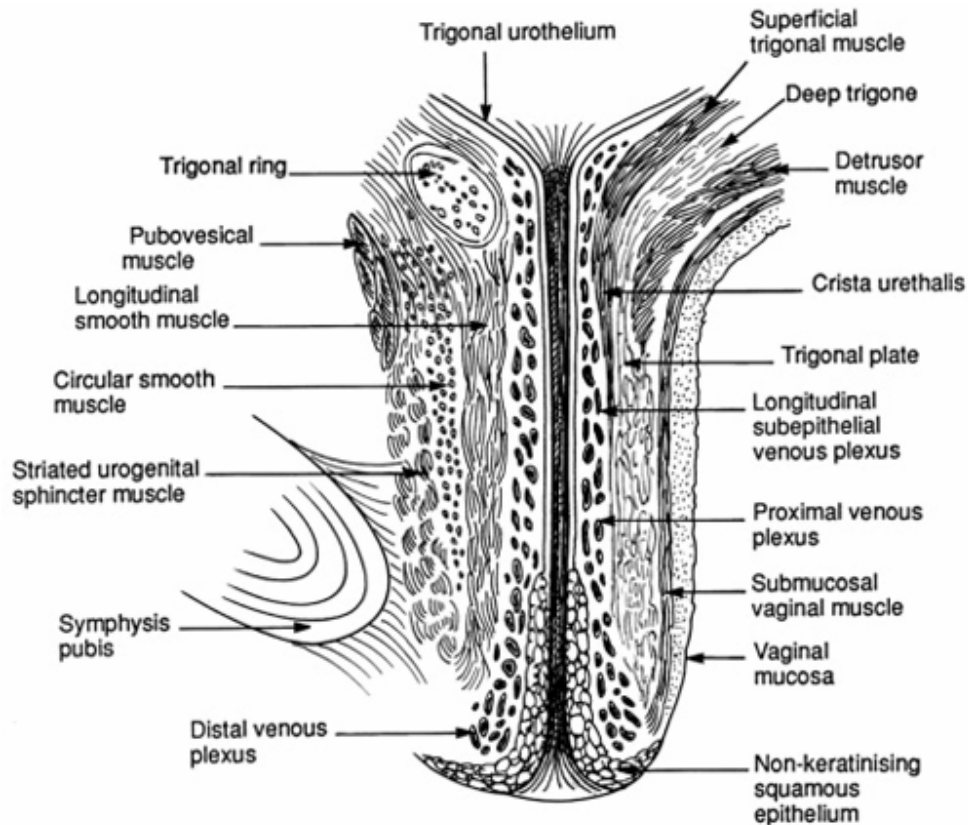
Figure 2.1. The bladder neck is seen immediately proximal to the urethral sphincter (US) and covered by the detrusor loop (US). BC: bulbocavernosus CU: compressor urethrae D: Detrusor LA: Levator ani UVS: urethra vaginal sphincter. Puborectalis is removed for clarity. In: DeLancey JOL and Ashton-Miller JA (2004) *Gastroenterology* 126[suppl1] S23-S32 *Reproduced with permission of Elsevier*

The urethra is the conduit through which urine is voided and which also functions to prevent escape of urine from the bladder other than during the condition of voluntary voiding. It is a complex tubular organ with its upper third separate from the vagina and the lower two-thirds intimately connected to the anterior vaginal wall (Ashton Miller and DeLancey 2007). Its anatomy is detailed in Figure 2.2. It has three layers, the deepest of

which is a vascular mucosa, believed to be an important contributor to continence by forming turgidity in the urethral walls and thereby enabling a watertight seal via coaption of the mucosal surfaces (Strohbehn and DeLancey 1997). The two smooth muscular layers comprise a deep longitudinal layer thought to be concerned with elimination of urine, and a smooth superficial circular layer thought to assist in closure. The circular layer, also known as the internal urethral sphincter (IUS) is present mainly at the superior part of the urethra where it is thicker dorsally to compensate for the absence of the external urethral sphincter (EUS) in this region. The EUS is superficial and slightly inferior to the IUS and is horse-shoe shaped in its upper and mid portions, it being absent on the dorsal aspect of the urethra. Its lower division spreads laterally to attach to the vagina, levator ani and the puborectalis muscle and the perineal body via its surrounding fascia known as the perineal membrane (Nakajima et al 2007; Stein and DeLancey 2008; Wallner et al 2009b; Cutner 1997). This division is described as being divided into the urethro-vaginal sphincter and the compressor urethrae muscle (Oelrich 1983; DeLancey 1986) although other authors do not recognise these divisions of the lower EUS and consider them to be one sphincteric structure (Yucel and Baskin 2004; Wallner et al 2009b).

The motor units of the sphincters are continuously active at rest as well as during activity to constrict the urethral lumen. The striated muscles, smooth muscles and vascular submucosa are believed to contribute equally to resting urethral closure pressure (Rud et al 19).

Figure 2.2 Sagittal section of the female urethra

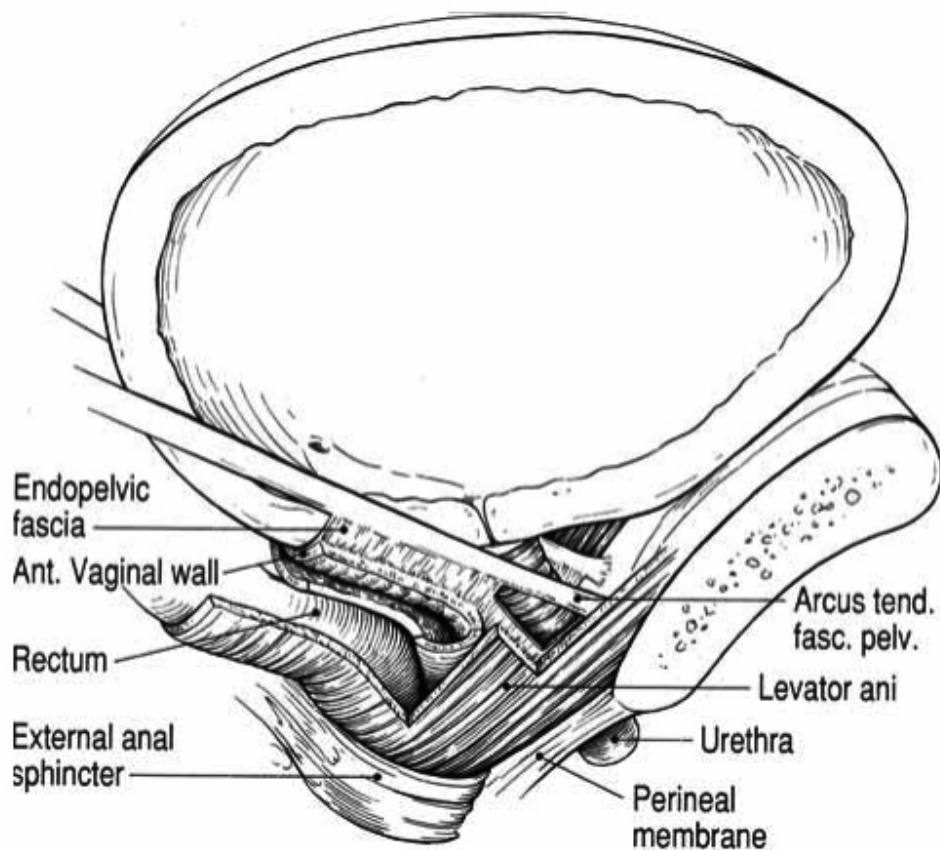


In: Strohbahn et al (1996) MRI anatomy of the female urethra: a direct histologic comparison. *Obstet Gynecol* 88 750-756 *Reproduced with permission of Wolters Kluwer Health*

The urethra and vesical neck depend on an intact support system and are supported by several intricately related structures: the vaginal walls; the endopelvic fascia; the perineal membrane; ligaments; the venous plexus of the urethra and the PFM. Disruption of any of these supporting systems may result in dysfunction. The tendinous arcs of the arcus tendineus fascia pelvis (ATFP) and arcus tendineus levator ani (ATLA) arise from the pubic rami and fuse in their latter half to insert into the ischial spine. Together they provide attachment for the endopelvic fascia and the PFM (Figures 2.3 and 2.4). The urethra is supported by the underlying sheet of endopelvic fascia slung between the two arcs of the ATFP in “the manner of a hammock” (DeLancey 1994). The anterior vaginal

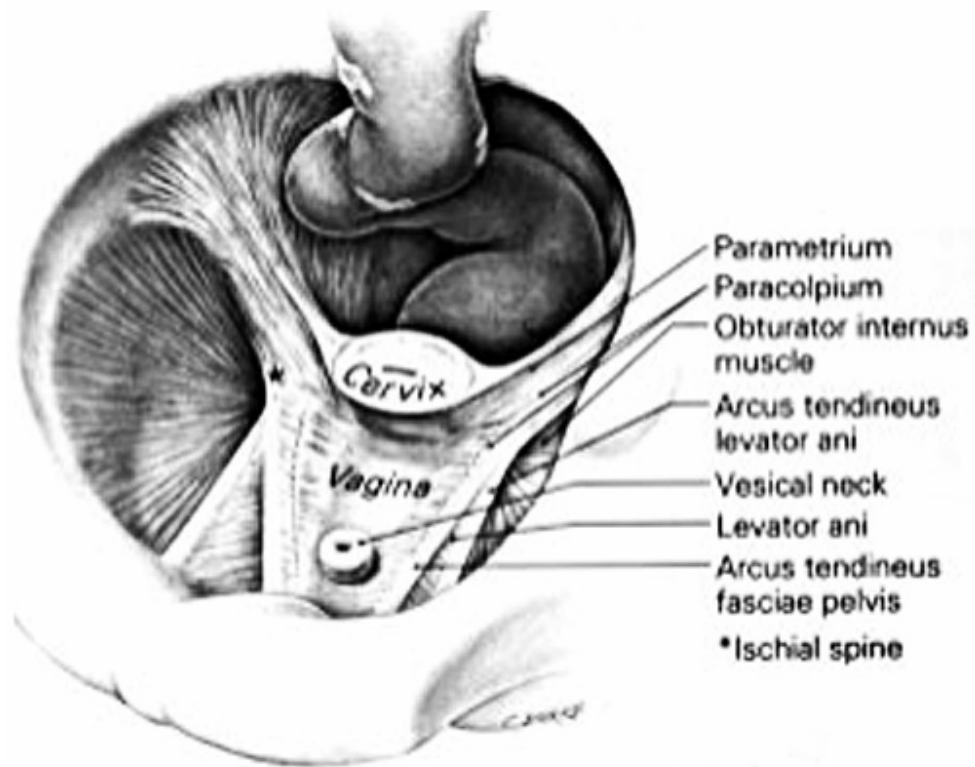
wall lies immediately below the hammock. The ATLA give rise to most of the levator ani including the iliococcygeus and the posterior section of the pubovisceralis.

Figure 2.3 Sagittal view of the bladder and urethra showing its support system and the endopelvic hammock



In: DeLancey JOL and Ashton-Miller JA (2004). 126[suppl1] *Gastroenterology* S23-S32 *Reproduced with permission of Elsevier*

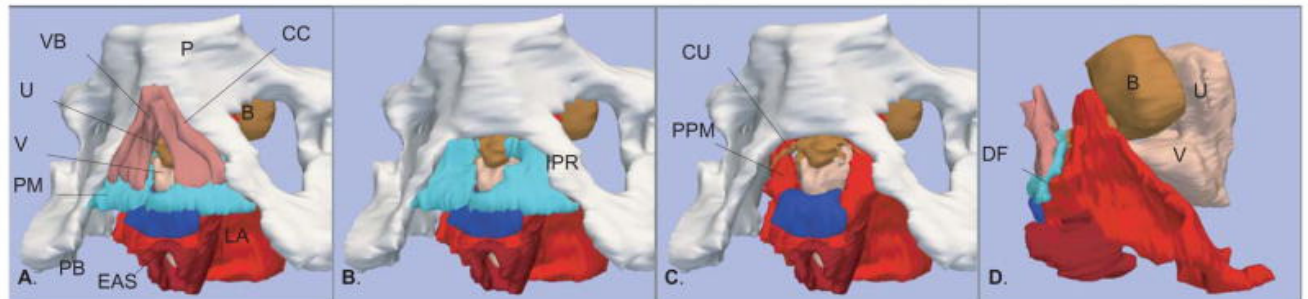
Figure 2.4 Anatomical supports of the cervix and vagina after removal of the bladder and uterine corpus



©DeLancey 2000 In: Herschorn (2004) Rev Urol 2004 : 6 [Suppl 5] S2-10
Reproduced with kind permission of DeLancey JOL

The lower urethra is firmly anchored by the perineal membrane which is a three-dimensional “complex apparatus that is connected to many structures” including the lateral vaginal walls, perineal body, ischiopubic rami ,vestibular bulb, clitoris crus and bulbocavernosus and ischiocavernosus muscles, the levator ani muscles, lower urethra and ATRP (Stein and DeLancey 2008). Its complexity is elegantly illustrated by 3-D MRI modelling as presented in Figure 2.5.

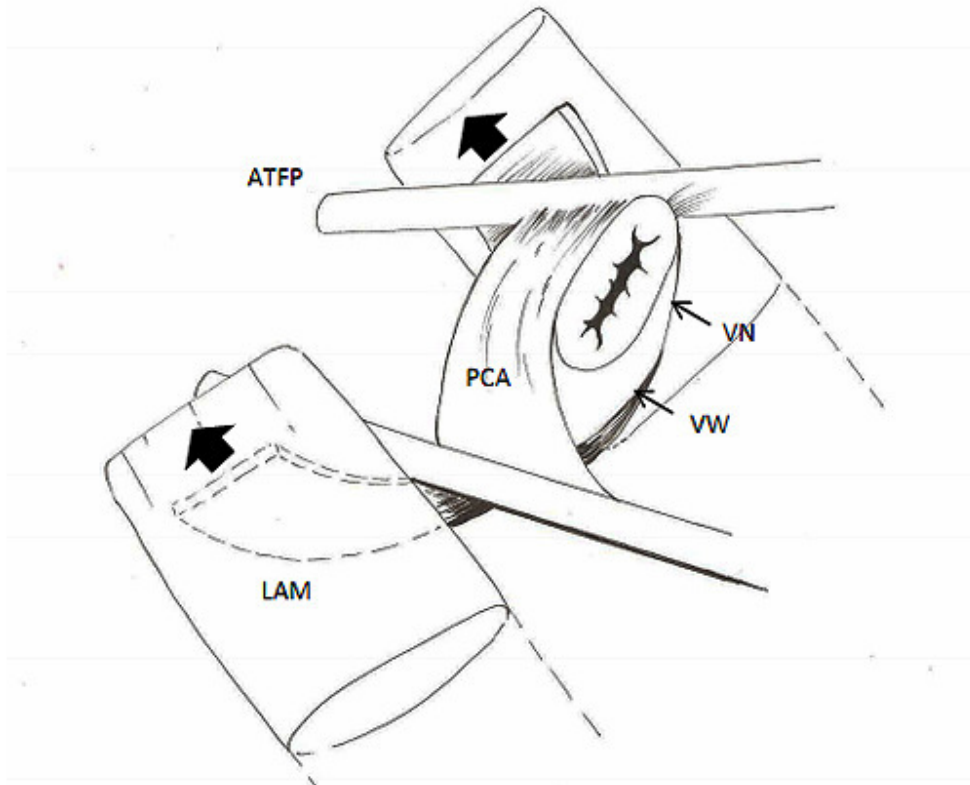
Figure 2.5 The perineal membrane



The three-dimensional relationships are best seen in the models generated from MR images of a 27 year old nullipara. **A.** Oblique left inferolateral view showing structures related to perineal membrane. **B.** Same view with clitoral crus and vestibular bulb removed to show the perineal membrane cephalad to these structures, extending bilaterally to the ischiopubic rami. **C.** Same view with the perineal membrane removed to illustrate its relation to the compressor urethra and anterior portion of the levator ani. **D.** Left lateral supine view of structures with pubic bone removed to illustrate parallel nature of levator ani to the ventral perineal membrane and the dorsal fusion (DF) of these structures. Pubic bone (PB) – white; Clitoral Crus (CC) and Vestibular Bulb (VB) – dark pink; Urethra (U), Compressor Urethra (CU), and Bladder (B)– brown; Vagina (V)– light pink; Perineal Membrane (PM) – turquoise; Puboperineal Muscle (PPM); Perineal Body (PB) – dark blue; External Anal Sphincter (EAS) – dark red; Levator Ani (LA) – red. ©DeLancey 2008. In Brandon et al Am J Obstet Gynecol 2009 (5) 583 e1-583 e6 *Reproduced with kind permission of DeLancey JOL*

Less dense fascial thickenings form supporting urethral ligaments around the bladder neck including the pubovesical ligament (from pubis to bladder). The Precervical arc is a further fascial structure that is believed to compress the urethra (Figure 2.6). The pubourethral ligament (from pubis to urethra) is proposed to be central to urethral closure (see Chapter 3.2.1 Figure 3.3).

Figure 2.6 The Precervical arc demonstrating compression of the urethra against the ligament



PCA=precervical arch ATFP=arcus tendineus fascia pelvis LAM=levator ani muscle VN=vesical neck VW=vaginal wall In: DeLancey JOL (1988) *Neurourology and Urodynamics* 7: 161-295 *Reproduced with permission of John Wiley and Sons*

2.2.2 Part II: Anatomy of the pelvic floor muscles

Computerised searches produced more than 2000 papers for pelvic floor muscle/levator ani anatomy. It was considered reasonable to narrow the search to seminal papers authored /co authored by DeLancey; and to Petros and Ulmsten (1990) as the work of these anatomists is discussed in the context of continence theories in Chapter 3. Other seminal papers by Shafik (1975) and Raizada and Mittal (2008) were also included. One paper was identified from the library of the author (Wallner 2009b) and two sourced from reference searches of the papers already included (Stoker et al 2001 cited in Raizada and

Mittal 2008; Bharucha 2006 cited in Wallner 2009b). One paper (Dickenson 1998) was sourced from a citation in a paper in the library of the author (Strohbehn 1998).

The PFM has a multidirectional and layered form and its complexity has long been noted:

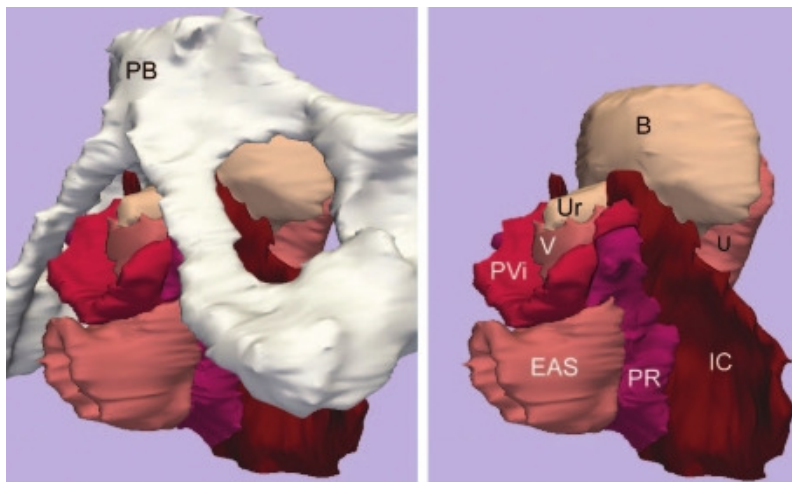
“I venture to affirm that there is no considerable muscle in the body whose form and function are more difficult to understand than those of the levator ani, and about which such nebulous impressions prevail” (Dickenson 1889).

To date, the nomenclature and grouping of the PFM remains nebulous. The various muscle components have been extensively grouped and named differently but terminology remains non-standardised. The term “pelvic floor muscle” is widely used interchangeably with the term “levator ani” despite the fact that the term levator ani refers only to the deep muscle layer of the small pelvis, whilst pelvic floor muscle incorporates superficial, middle and deep layers. The deep muscle layer comprises the pubovisceralis (also known as pubococcygeus), iliococcygeus and puborectalis muscles and most commonly these are considered as the levator ani. However, controversy exists as to whether the puborectalis should be considered as separate due to developmental evidence, innervation and histological studies (Bharucha 2006 cited in Wallner 2009b). An extensive review of 265 papers led by the surgical fellow of the prolific pelvic/urogynaecology anatomist John DeLancey, has contributed to clarification of terminology (Kearney et al 2004). The review consistently identified five origin-insertion pairs and recommended the nomenclature as described in Terminologia Anatomica (1998 cited in Kearney et al 2004). In this dissertation, nomenclature used will be as recommended by Kearney et al (2004) (Table 2.1a). The puborectalis will be considered one of five components of the levator ani (pubovisceralis [in three parts], iliococcygeus and puborectalis). The deep layer of the pelvic floor comprises the five components of the levator ani (Table 2.1a). It is a complicated structure in several planes and is the deepest muscle layer within the pelvis (Figures 2.7 to 2.9). The individual components are arranged in different orientations according to function and collectively produce a

cranioventral movement on voluntary contraction, assist in urethral closure and opening and provide visceral support

The muscles blend with sheets of fascia above and below to form the pelvic diaphragm. The ovoid space known as the levator/urogenital hiatus is bordered by the puborectalis and allows passage of the urethra, vagina and rectum (Figure 2.10). The components of the deep PFM or levator ani as described by Kearney are described in Table 2.1a. Description of a further deep muscle, the levator plate as described by Petros and Ulmsten (1990) is presented in Table 2.1b. A middle layer of the pelvic floor as proposed by Petros and Ulmsten (1990) comprising the long muscle of the anus is described in Table 2.1.c. The superficial PFM layer is described in Table 2.1d.

Figure 2.7 Three-dimensional model of levator ani subdivisions including the pubic bone and pelvic viscera

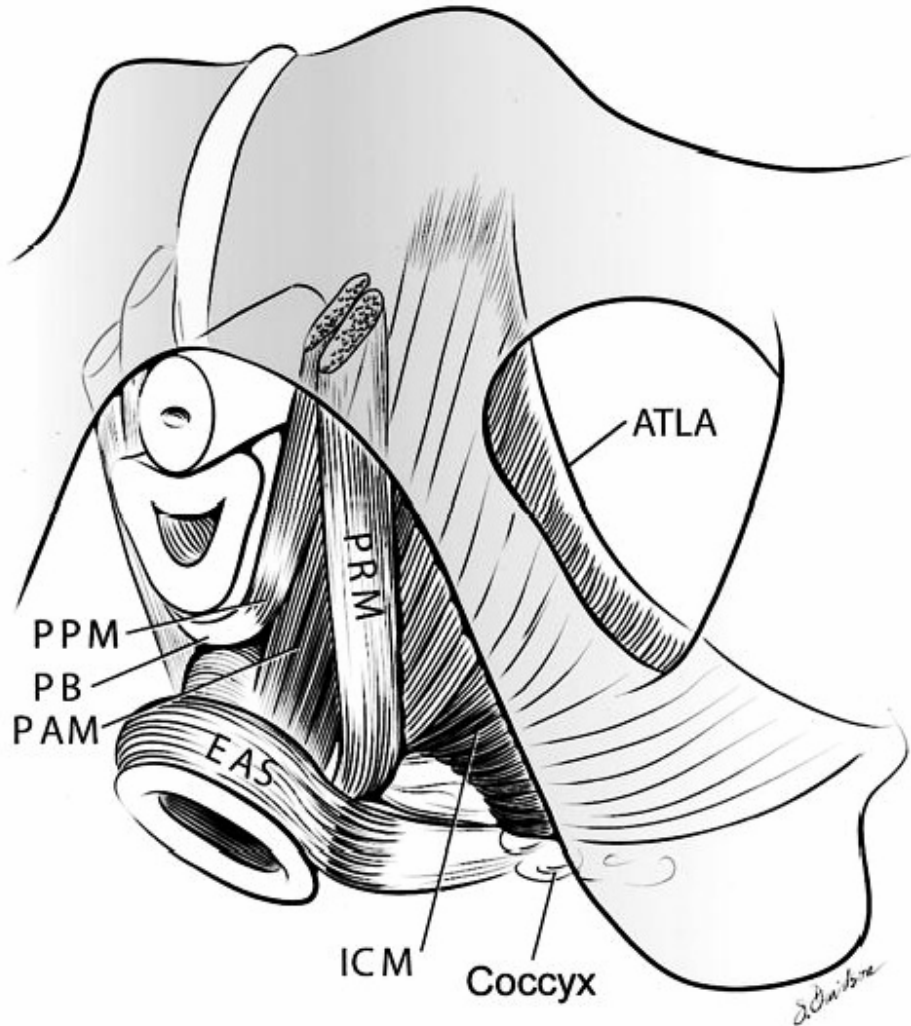


Left image : Inferior, left 3-quarter view. The pubovaginal, puboperineal and puboanal muscles are all combined into a single structure, the pubovisceral muscle
Right image: The same model without the pubic bone. PB=pubic bone; V=vagina; U=uterus; Ur=urethra; B=bladder; IC=iliococcygeus muscle; PR=puborectalis muscle; PVi=pubovisceral muscle; EAS=external anal sphincter.
©DeLancey 2006 In: Margulies et al (2006) Am J Obstet Gynecol 107 (5) 1064-1069 *Reproduced with kind permission of DeLancey JOL*

Table 2. 1a-c Descriptive Anatomy of the pelvic floor muscles

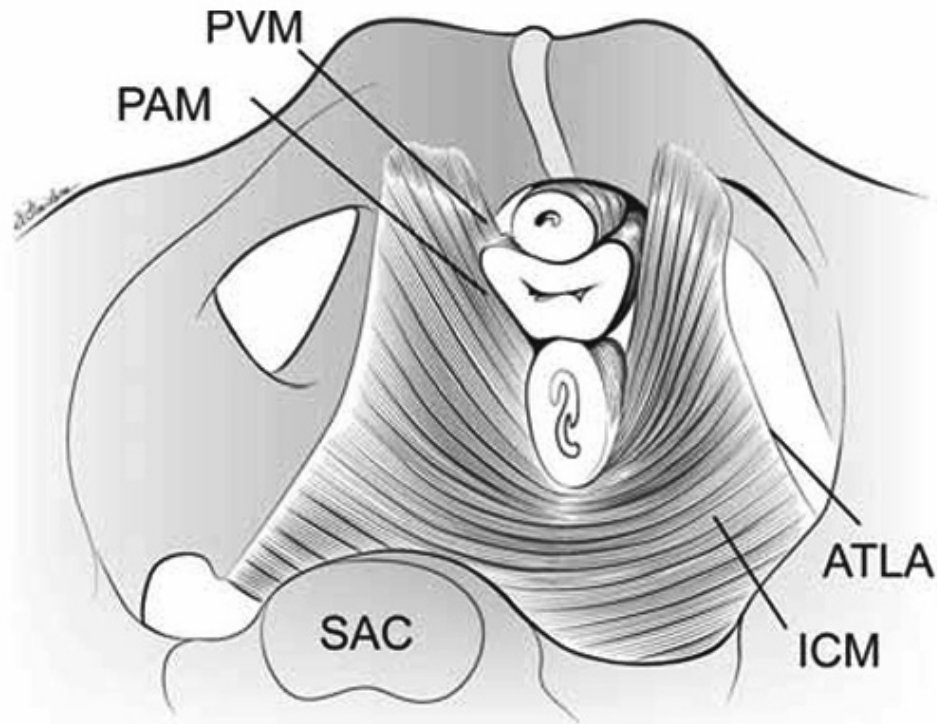
Table 2.1a Descriptive Anatomy of the deep pelvic floor muscles/levator ani (adapted from Kearney et al 2004)					
Nomenclature	Description/orientation	Origin	Insertion	Function	
Iliococcygeus	Relatively flat horizontal shelf Spans the potential gap from one sidewall of the pelvis to the other	ATFP bilaterally	The iliococcygeal raphe bilaterally	The two sides form a supportive diaphragm. Mid and dorsal fibres elevate the posterior pelvic floor. Visceral supportive role	
Its divisions:	Pubovisceralis	Slings like and more vertical	Arises 1.5cm above the lower border of the pubic symphysis bilaterally	Components insert variously into the walls of the urethra, vagina, perineal body, ATLA posteriorly, perineal membrane	Assists in compression of the urethra against the pubis. Visceral supportive role
	Puboperineal	Pubis	Perineal membrane	Tonic activity pulls perineal body ventrally towards pubis	
	Pubovaginal	Pubis	Vaginal wall at mid urethra	Elevates vagina in region of the mid urethra	
	Puboanalis	Pubis	Intersphincteric groove between internal and external anal sphincter	Elevates the anus	
Puborectalis	Large sling cephalad to the external anal sphincter . Almost vertical.	Pubis lateral to the pubovisceral muscle/around rectum to contralateral side of pubis		Forms a sling behind the rectum forming the anorectal angle	
ATFP=arcus tendineus fascia pelvis ATLA= arcus tendineus fascia levator ani					
Table 2.1.b Descriptive anatomy of the 6th component of the deep pelvic floor muscles/levator ani (Petros ad Ulmsten 1990)					
The levator plate	A flat plate comprising the most posterior portion of puborectalis where its two sides unite	Posterior fibres of puborectalis	Posterior wall of the rectum and sacrum	Creates an opposing force to the pubovisceralis to assist in opening and closure of the urethra	
Table 2.1.c Descriptive anatomy of the middle layer of the pelvic floor muscles (Petros and Ulmsten 1990)					
The long muscle of the anus	Short thin vertical muscle	Levator plate, pubovisceralis and puborectalis	External anal sphincter	Provides an opposing force to pubovisceralis in assisting opening and closing of the urethra	
Table 2.1.d Descriptive anatomy of the superficial layer of the pelvic floor muscles (Ashton-Miller and DeLancey 2007)					
Bulbocavernosus	Small sling like	Perineal body	Wraps around vestibular bulb	Sexual function	
Ischiocavernosus	Small sling like	The external surface of the pubis bilaterally	Surrounds the crus clitoris	Sexual function	

Figure 2. 8 Schematic view of the levator ani



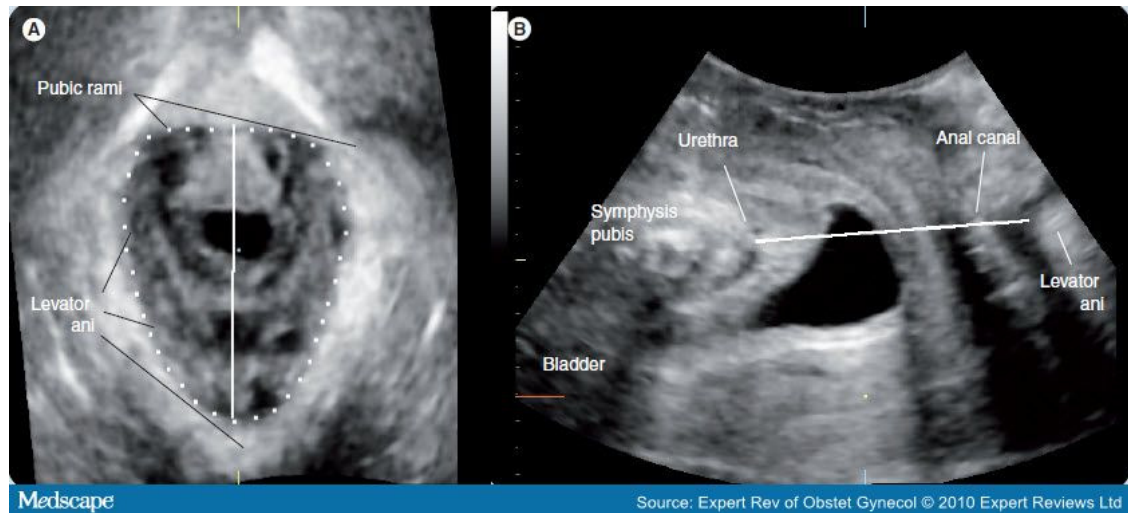
Schematic view of the levator ani muscles from below after the vulvar structures and perineal membrane have been removed showing the arcus tendineus levator ani (ATLA); external anal sphincter (EAS); puboanal muscle (PAM); perineal body (PB); uniting the two ends of the puboperineal muscles (PPM); iliococcygeal muscle (ICM); puborectal muscle (PRM). Note that the urethra and vagina have been transected just above the hymenal ring. ©2003 DeLancey JOL In Kearney *et al.* 2004. *Am Coll Obstet Gynecol* 104[1], 168-173 *Reproduced with kind permission of DeLancey JOL*

Figure 2. 9 The levator ani muscle seen from above



The levator ani muscle seen from above looking over the sacral promontory (SAC) showing the pubovaginal muscle (PVM). The urethra, vagina, and rectum have been transected just above the pelvic floor. PAM denotes puboanal muscle; ATLA: arcus tendineus levator ani; and ICM: iliococcygeal muscle (The internal obturator muscles have been removed to clarify levator muscle origins). ©DeLancey 2003 In: Kearney *et al.* (2004). *Am Coll Obstet Gynecol* 104[1], 168-173 Reproduced with kind permission of DeLancey JOL

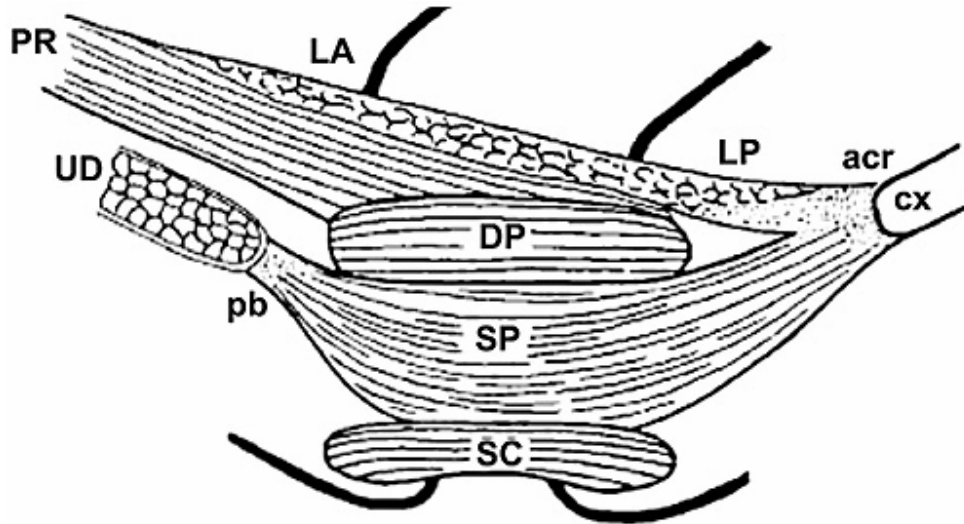
Figure 2. 10 The Levator hiatus



Transperineal ultrasound images of the levator hiatus showing (a) the plane of minimal dimensions (represented by the diagonal line) in the mid-sagittal section and (b) the corresponding axial image. The dotted line in (b) indicates area measurement of the hiatus at rest. In: Kruger et al (2010) *Ultrasound Obstet Gynecol*, 36(6):755-8 *Reproduced with permission of John Wiley and Sons Ltd*

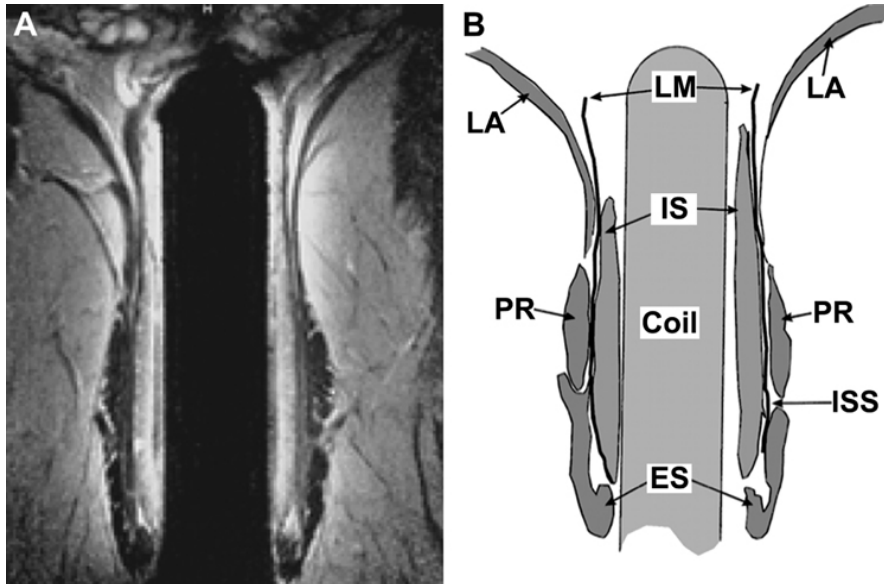
Special note of the relationship of the puborectalis with the external anal sphincter (EAS) is worthy of inclusion here. The puborectalis is in close structural relationship with the EAS. Historically the EAS was described as comprising subcutaneous, superficial and deep layers (Shafik 1975). These components are illustrated in Figure 2.11 as originally presented by Shafik (1975) with a later footnote by Raizada and Mittal (2008), describing that the deep portion of the EAS is actually puborectalis. Stoker et al (2001) also demonstrated the EAS as having only two layers comprising the EAS and internal anal sphincter (IAS) with puborectalis creating the third deep layer (Figure 2.12). For further discussion of the relationship of the EAS and puborectalis see Chapter 8.2.

Figure 2. 11 A sketch of the external anal sphincter from a lateral view, with three layers/loops, as described by Shafik (1975):, basal loop (BL), intermediate loop (IL) and deep loop (DP).



Foot note reproduced from Raizada and Mittal (2008) “ Note the relationship between the puborectalis muscle (PR) and (DP). We believe that DP is actually the posterior part of the puborectalis muscle (see text for explanation).” In: *Gastroenterol Clin North Am* 37[(3)], 493i-vii. *Reproduced with permission of Elsevier*

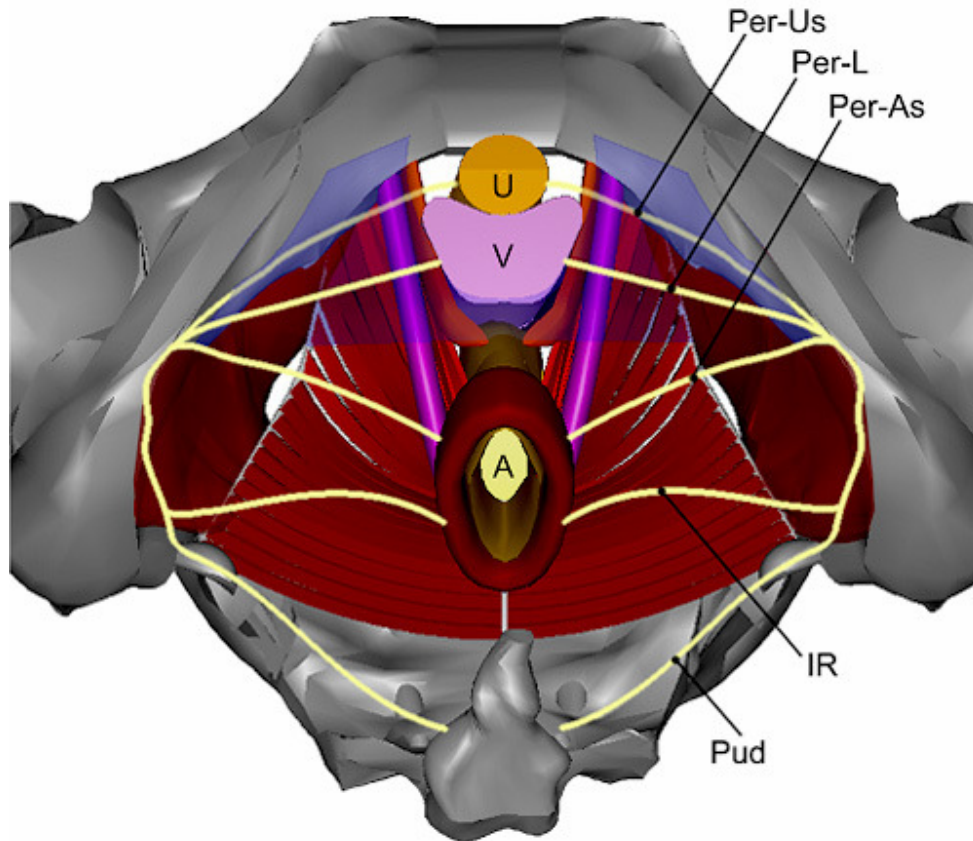
Figure 2.12 Relationship of puborectalis with the external anal sphincter



A: Coronal mid anal T2-weighted fast spin-echo (2,500/100) MR image obtained with an endoanal coil. B: Corresponding drawing demonstrates the internal sphincter (IS), intersphincteric space (ISS), longitudinal muscle (LM), external sphincter (ES), puborectalis muscle (PR), and levator ani muscle (LA) (Adapted from Stoker et al 2001). In: *Gastroenterol Clin North Am* 37(3), 493i-vii. *Reproduced with permission of Elsevier*

The pudendal nerve is known to supply muscles of the EAS, PFM and genitalia although controversy surrounds it with respect to innervation of puborectalis. An illustration of the nerve branches in relation to the pelvic basin is seen in Figure 2.13. For further discussion of controversy surrounding pudendal innervation see Chapter 8.2.

Figure 2.13 Pudendal nerve branches within the pelvis from a simulated 3-D model



Inferior view of the pudendal nerve branches and muscular structure of the female pelvic floor. The urethra (umber), vagina (pink), rectum (light brown), and external anal sphincter (maroon) are shown. Branches of the pudendal nerve (Pud) are shown: inferior rectal nerve (IR), the muscular branch of perineal nerve innervating external anal sphincter (Per-AS), the posterior labial branch (Per-L), and the muscular branch of perineal nerve innervating the urethral sphincter (Per-US). The red bandlike structures represent the levator ani muscle; the purple band, the puborectal muscle and the semitransparent blue structure represents the perineal membrane. In: Lien et al (2005) ©Biomechanics Lab University of Michigan Ann. *Reproduced with kind permission of Ashton Miller J © Biomechanics Research Lab*

2.2.3 Part III: Anatomical disruption of the pelvic floor

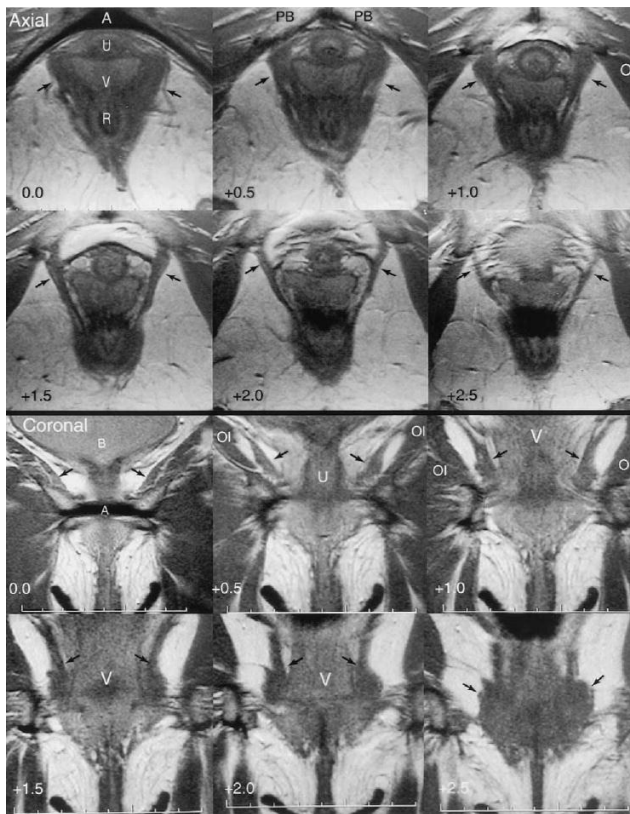
The process and results for searches with respect to anatomical disruption of the pelvic floor have been described in Chapter 1.2.3. Ten key papers were identified (DeLancey et al 2003; Dietz and Lanzarone 2005; Branham et al 2005; Abdool et al 2009; Valsky et al 2009; Kearney et al 2006; Krofta et al 2009; Margulies et al 2007; Heilbrun et al 2010; Miller et al 2010). A further computerised search for computer simulations of trauma to the pelvic floor during delivery identified three papers. Each is included here (Li et al 2010; Lien et al 2004; Parente et al 2009).

The most common cause of anatomic disruption of the PFM is parturition as discussed in Chapter 1.2.3. Ultrasound and MR imaging are used to identify common defects such as complete or partial avulsions from the pubic insertions, and neurological damage or tears manifesting as muscle atrophy, that occur as a result of vaginal delivery (Figures 2.14 to 2.16). Nomenclature in imaging is confusing with poor distinction in terminology between the pubovisceralis and puborectalis. Most studies have appeared to study only the pubovisceralis and may not cite the puborectalis specifically. As an example, in a study by DeLancey et al (2003), puborectalis was not considered separately but as part of the pubovisceralis. In a subsequent study by DeLancey's group, imaging technique for identification of specific levator divisions including puborectalis was described, thereby contributing to greater clarity for future studies (Margulies et al 2006). These authors describe that in the axial plane (although not the coronal plane) the puborectalis is easily distinguishable from the pubovisceralis. Conversely, Kruger et al (2007), report that pubovisceralis and puborectalis cannot be differentiated using US or MRI.

Three of the key studies in this overview specifically used the term puborectalis (Margulies et al 2007; Branham et al 2007; Abdool et al 2009). However, only the study of Margulies et al (2007) actually studied puborectalis in isolation as evidenced by description in the text. Email correspondence with the authors of Branham et al (2007) (Appendix 1a) and the authors of Abdool et al (2009) (Appendix 1b) confirmed that the pubovisceralis was considered part of puborectalis despite the term puborectalis being used throughout the publication. The one study to specifically study puborectalis reported no disruption (Margulies et al 2007). In the studies that group puborectalis and pubovisceralis together (DeLancey et al 2003; Dietz and Lanzarone 2005; Kearney et al 2006; Branham et al 2007; Krofta et al 2009; Valsky et al 2009; Heilbrun et al 2010; Miller et al 2010; Krofta et al 2009) (Table 2.2), levator defects are reported at 18% to 36%. One study excluded instrumental delivery and reported the incidence to reduce to 11% (Kearney et al 2006).

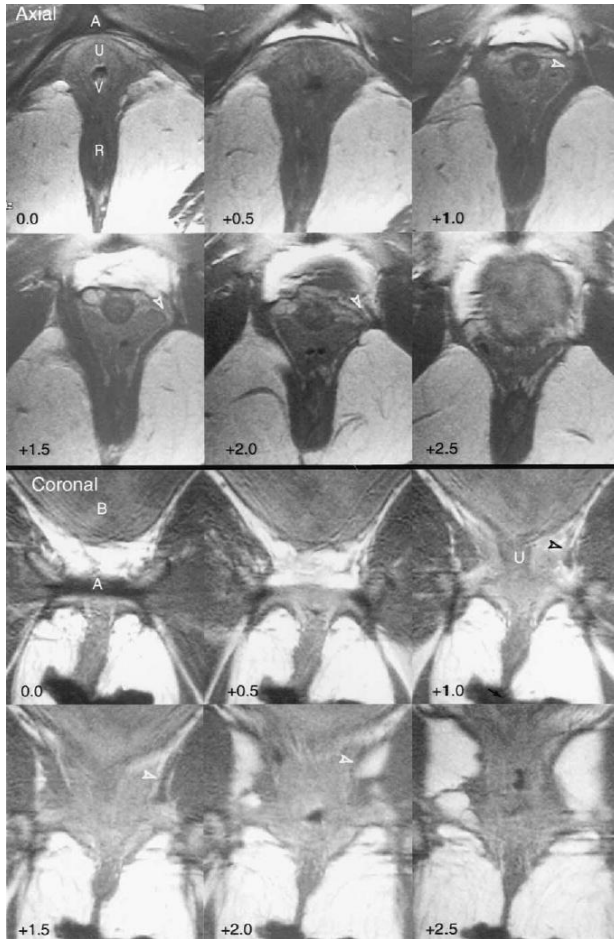
Iliococcygeus is reported as easily distinguishable on imaging and is also seen to be much less commonly avulsed than pubovisceralis at up to 8% (DeLancey et al 2003; Branham et al 2007; Margulies et al 2007).

Figure 2.14 Example of an intact levator ani



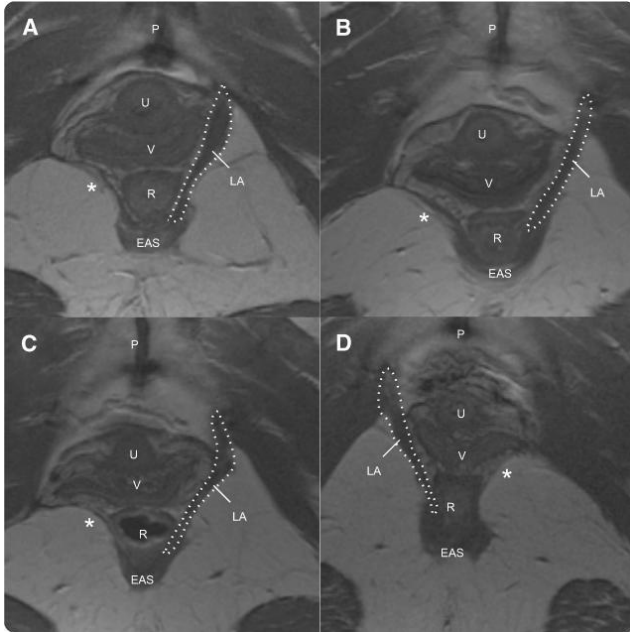
Axial and coronal images from a 45-year-old nulliparous woman. The urethra (U), vagina (V), rectum (R), arcuate pubic ligament (A), pubic bones (PB), and bladder (B) are shown. The arcuate pubic ligament is designated as zero for reference, and the distance from this reference plane is indicated in the lower left corner. Note the attachment of the levator muscle (*arrows*) to the pubic bone in axial +1.0, +1.5, and +2.0. Coronal images show the urethra, vagina, and muscles of levator ani and obturator internus (OI). © DeLancey 2002. In *Obstet Gynecol* (2003) 101(1) 46-53. Reproduced with kind permission of DeLancey JOL

Figure 2.15 Example of a unilateral levator defect



Axial and coronal images from a 34-year-old incontinent primiparous woman showing a unilateral defect in the left pubovisceral portion of the levator ani muscle. The arcuate pubic ligament (A), urethra (U), vagina (V), rectum (R), and bladder (B) are shown. The location normally occupied by the pubovisceral muscle is indicated by the *open arrowhead* in axial and coronal images +1.0, +1.5, and +2.0. © DeLancey 2002. In: *Obstet Gynecol* (2003) 101(1) 46-53 *Reproduced with kind permission of DeLancey JOL*

Figure 2.16 Examples of complete unilateral levator defects



Axial MR scans of 4 different women with complete unilateral levator defects are shown. Note the variations in morphology. The intact levator ani muscle is traced (*dashed line*) and labeled LA. The missing muscle is denoted (*asterisk*). **A**, **B**, and **C**, the defect is shown on the right side and **D**, on the left side. EAS, external anal sphincter; P, pubis; R, rectum; U, urethra; V, vagina. © DeLancey 2002 In: *Obstet Gynecol* (2003) 101(1) 46-53 *Reproduced with kind permission of DeLancey JOL*

Table 2.2 Imaging studies of levator trauma

Author	Imaging Tool	Nomenclature	Cohort	Avulsion %
16.2.a Mode of vaginal delivery not distinguished				
DeLancey et al 2003	MR 9-12 weeks post partum	Pubovisceralis complex Iliococcygeus	160 primiparas 80 controls	Pubovisceralis complex 18% Iliococcygeus 2%
Dietz and Lanzarone 2005	3D US Nullips seen at 36-40 weeks gestation and 2-6 months post partum	Levator ani	50 post partum primiparas Subjects acted as their own control	36%
Branham et al 2007	MR Six weeks and six months post partum	Puborectalis* Iliococcygeus	45 Primiparas 25 nulliparous controls	<u>Puborectalis</u> 6 weeks: 25%; 6 months: 12% <u>Iliococcygeus</u> 6 weeks: 8%; 6 months: 8%
Abdool et al 2009	3-4D US Retrospective screening of images	Puborectalis*	476 parous women. Number of deliveries not stated	21%
Valsky et al 2009	3-D US 24-72 hours post delivery	Levator ani	210 Primiparas Control=47	19%
16.2.b Instrumental vaginal delivery				
Kearney et al 2006	MR 9-12 months post partum	Pubovisceralis	160 parous women	Forceps delivery 66% Vacuum delivery 25% Normal delivery 11%
Krofta et al 2009	3-4D US 12 months	Pubococcygeus-puborectal complex	76 women delivered by forceps	64%
16.2 .c Complete unilateral tears only				
Margulies et al 2007	MR retrospective screen of 676 studies	Pubovisceralis Puborectalis Iliococcygeus	14 parous women with unilateral defect Control: the contralateral intact side	All 14 unilateral tears observed in the pubovisceralis only
16.2.d Studies of subjects at high risk of sustaining or having sustained avulsion				
Heilbrun et al 2010	MR 6-12 months post partum	Levator ani	89 women with anal sphincter tears	19%
Miller et al 2010	MR one month and seven months after delivery	Levator ani	19 women with risk factors: anal sphincter tear; lengthy second stage labour; precipitous delivery; shoulder dystocia	47%
*Personal correspondence with co author reveals that the nomenclature includes puborectalis with the pubovisceralis				

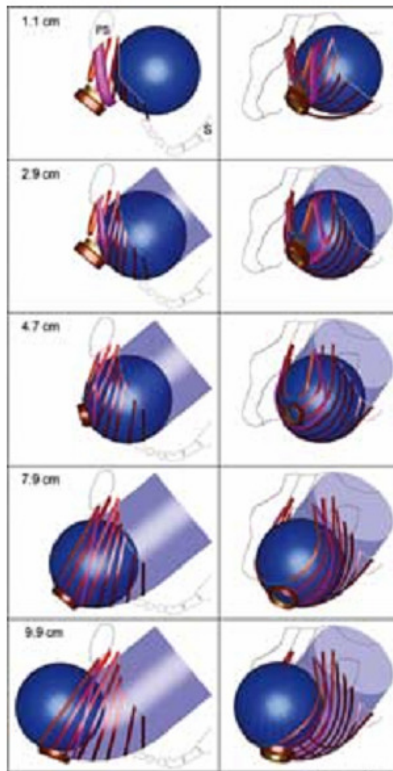
Computer simulated models of the head descending during the second stage of labour have been developed over the last decade to attempt to study PFM stretch. Lien et al (2004) divided the components of the levator ani into 24 bands (pubovisceralis, puborectalis, iliococcygeus) for the purposes of simulation (Figures 2.17 and 2.18). Only five of these bands, all within iliococcygeus, did not stretch a greater amount than would be required to cause damage in a normal muscle. The pubovisceralis reached a maximal stretch ratio of 3.26; the puborectalis 2.28; and the iliococcygeus 2.73. The largest stretch ratio seen in the pubovisceralis is reported as being due to its shorter innate length and medial placement whilst the longer initial length of the puborectalis resulted in relatively smaller maximal stretch. The puborectalis stretched maximally at crowning in the third stage of labour. The bands of the iliococcygeus that escaped over stretching are described as being due to their posterior and lateral position. Parente et al (2009) divided the sling of the levator ani into levels, medial to lateral. Lower stretch ratios were reported than in the study by Lien et al (2004) although the finding that the antero-medial muscles were more stretched is in agreement. Difficulties in computer modelling have been described by Li et al (2010) and Miller and Delancey (2007) and therefore these findings are considered preliminary. However both of these computer modelling studies suggest that it is the pubovisceralis that is the most commonly damaged muscle due to its medial position. Future studies may be able to produce a model capable of validation.

Figure 2.17 Simulated 3-D model of levator bands



Inferior three-quarter view, seen from the left, of the pelvic structures appearing behind the ischiopubic rami (grey). That portion of the perineal membrane (blue) connecting the puboperineus muscles in the perineal body is shown. The lateral portions of the perineal membrane have been removed to show a close-up of the arrangement of the iliococcygeal, pubococcygeal and puborectalis muscles, as well as the urethra (umber), vagina (pink), and rectum (brown). Individual muscle bands are identified by a number inscribed near their origin on the arcus tendineus (white). The puboperineus muscle (2) is part of the pubococcygeal muscle. This figure appears in color online (From Lien et al 2004) *With kind permission of Ashton Miller J © Biomechanics Research Lab*

Figure 2.18 Simulated effect of fetal head descent on the PFM



Simulated effect of fetal head descent on pelvic floor muscles in the second stage of labor, a left lateral view shows the fetal head (blue) located posteriorly and inferiorly to the pubic symphysis (PS) in front of the sacrum (S). The sequence of five images at left, show the fetal head as it descends 0.6, 2.5, 6.4, 10.0, and 12.0cm below the ischial spines as the head passes along the Curve of Carus (indicated by the transparent, light blue, curved tube). The sequence of five images at right are front-left, three-quarter views corresponding to those shown at left. This figure appears on line (From Lien et al 2004) *With kind permission of Ashton Miller J © Biomechanics Research Lab*

Parturition trauma to the PFM is undisputed, but the levator ani component that is most damaged remains unclear. The only study in Table 2.2 to specifically study puborectalis found no incidence of trauma (Margulies et al 2007). Taken with the two computer simulations of vaginal delivery that have demonstrated the pubovisceralis to be more commonly damaged, it is possible that the puborectalis muscle is spared at parturition relative to the pubovisceralis. This paradigm is discussed further in Chapter 8.2.

Summary

The functional anatomy of the small pelvis with respect to urinary continence is complex. It comprises a muscular reservoir (the bladder), a conduit (the urethra) and sphincters (internal and external). Intimate to these structures are the superficial, middle and deep layers of pelvic floor muscles, as well as the supporting ligaments and fascia. This arrangement is intricately arranged to support the urethra and maintain closure at all times other than during micturition. Vaginal delivery is a major risk factor for disruption of the PFM. The puborectalis is possibly less subject to trauma at parturition than pubovisceralis although more research is required to confirm this.

Conclusion

The anatomy of the urinary continence system is complex. Having provided an overview of normal and disrupted PFM anatomy, an overview of variously proposed continence mechanisms follows.

Chapter 3 Continence Mechanisms

3 Introduction

The current understanding of the urinary continence mechanisms is incomplete. However it is acknowledged that SUI is multifactorial and is the end result of a continuum of dysfunction in several systems resulting in urethral hypermobility and/or sphincter dysfunction (Daneshgari and Moore 2006). The working party of IUGA describe it as “a variable combination of urethral hypermobility and urethral sphincter deficiency” (Ghoniem et al 2008). Slack (2006) describes the continence mechanism as “deceptively complex and elusive” and that a departure from one universal theory is to be welcomed. It is understood that the role of the PFM in urinary continence is to provide constant tonic support to urethrovesical structures (UVSs), and to augment this support as well as contribute to compression of the urethra during rises in IAP. In the broadest sense “the urethra and PFM work synchronously to produce a continent state” (Slack 2006).

An understanding of the evolution of urinary continence theories is both useful in interpreting current opinion, as well as being important with respect to results from this programme of work. A critical overview therefore follows.

3.1 Critical Overview Design

3.1.1 Structure

Part I: Evolution and presentation of continence theories

Part II: Current understanding of the role of the Pelvic Floor Muscles

3.1.2 Parts I - II

Objective

The objective of parts I-II was to provide a critical overview of continence theories and

how these have shaped current understanding of SUI.

Search Strategy

Because of the significant breadth of the literature it was not possible to review all papers. Papers were therefore selected using a pragmatic approach, and searches narrowed as appropriate. Computerised searches of Medline, AMED and CINAHL were undertaken dating back as far as possible (1968). Earlier publications were hand searched and subsequently sourced using reference and citation searches. Key search terms were stress urinary incontinence; continence mechanisms; continence theories; urinary; bladder neck; incontinence surgery. Hand searches of papers, seminal papers; conference abstracts and textbooks in the library of the author were also undertaken.

Selection Criteria

Papers were included where considered by this author to be suitable for contributing to a balanced overview. Papers were included if the following criteria were met:

1. The publication was in the English Language
2. The publication was confined to investigation of human anatomy

3.2 Critical Overviews

3.2.1 Part I: Evolution and presentation of continence theories

Computerised searches produced more than 450 papers. The searches were narrowed to the four currently widely accepted continence mechanisms (Enhorning 1961; McGuire 1977; DeLancey 1990; Petros and Ulmsten 1990). The computerised search was narrowed to reviews of continence theories and only one paper was identified (Daneshgari and Moore 2006). One seminal publication was identified from a hand search of references (Jeffcote and Roberts 1952 cited in Enhorning 1961) and others (Pawlick 1883; Giordano 1907; Kelly 1913; Bonney 1923) were identified in a textbook of surgical techniques that was not held at the British Library but was subsequently

sourced from a search of international web based book sellers (Ullery 1953).

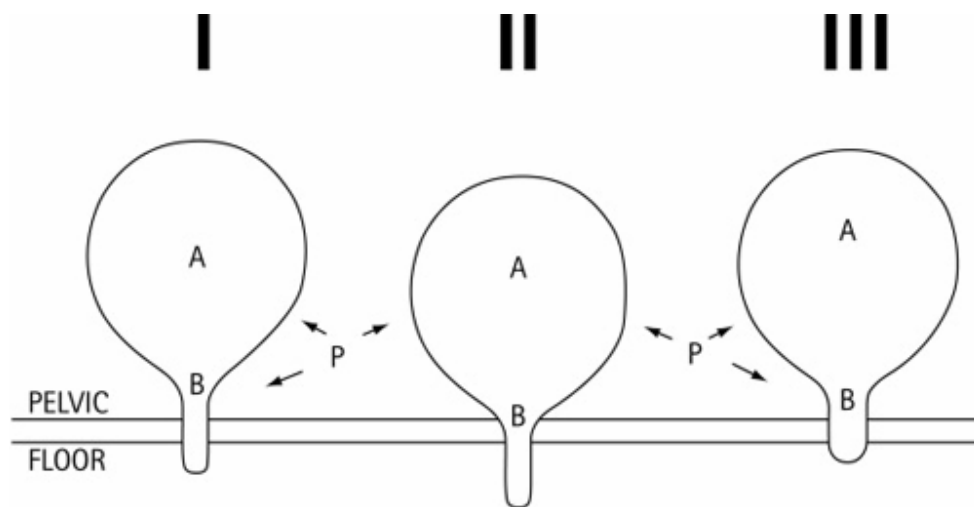
More than a century of trial and error with corrective surgery, enhanced imaging, cadaveric, histology and physiology studies as well as clinical trials have contributed to the current understanding of the urinary continence mechanism. Historically, surgical techniques of plication of the sphincter, suspension of the urethra and sling suspension of the urethra were based on mono-pathology. The earliest attempts to correct sphincter deficiency were by Pawlick (1883) who described surgery to shorten and twist the urethra; Giordano (1907) who introduced the concept of sling surgery using the gracilis muscle to compress the urethra and Kelly (1913) who described plication following his observations of “a gaping internal sphincter orifice that closes sluggishly”. Later Bonney (1923) reported that a dysfunctional urethra was due to loss of support and height of the bladder neck rather than inability to intrinsically close the urethral lumen. His surgical aim therefore was to either support the bladder neck from below using a buttress, or use suspension from above. These early surgical approaches did not always cure UI and therefore left many unanswered questions. In 1952 Jeffcote and Roberts were the first to depart from the mono-pathology that had dominated and clearly described several elements necessary for continence: a well functioning sphincter; support of the bladder neck and a secondary defence mechanism in the PFM. Despite this multifactorial stance, opposing singular theories existed until the 1990’s. Danseshgari and Moore (2006) discuss that four principal continence theories have been formulated that have shaped current management of SUI. The first two (Enhorning 1961; McGuire 1977) relate to single factor aetiology, whilst the third and fourth (DeLancey 1990; Petros and Ulmsten 1990) are multifactorial. These are described here:

Pressure transmission (Enhorning 1961)

Central to this theory is that continence relies on optimal position of the bladder neck. Enhorning (1961) proposed that a positive pressure gradient from the abdomen to the urethra automatically increases urethral closure pressure (UCP) in response to a rise in

IAP during times of physical stress, thereby maintaining urinary continence. This pressure gradient is likely to fail if the bladder neck is low so that IAP overcomes intra urethral pressure i.e. pressure transmission can no longer influence the urethra. Therefore a hypermobile urethra is implicated in this theory (Figure 3.1). This theory supported the paradigm of suspension surgery.

Figure 3. 1 The Pressure Transmission Theory (Enhorning 1961)



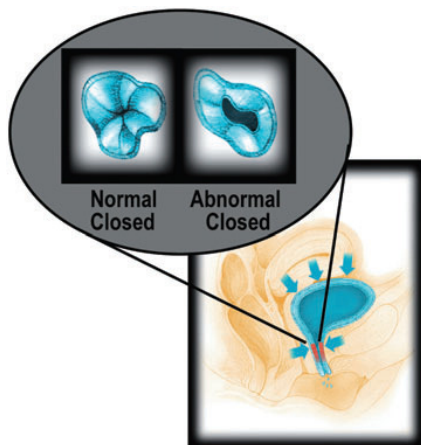
Increases in intra-abdominal pressure (**P**) are transmitted to the bladder neck and proximal urethra, **I, Normal female**. Increases in **P** are transmitted equally to the bladder neck/proximal urethra (**B**). **II, Urethral hypermobility**. During increases in **P**, the bladder neck/proximal urethra (**B**) descends abnormally to a position outside of the abdominal cavity. The pressure within the bladder (**A**) exceeds the pressure within the bladder neck/proximal urethra (**B**) and SUI ensues **III, ISD**. Here the bladder neck/proximal urethra (**B**) is adequately supported (there is no descent), but the bladder neck/proximal urethra is non-functional again resulting in SUI. From Gillenwater et al In: Daneshgari and Moore (2006) BJU Int 98, Suppl 1 8-14 *Reproduced with permission of John Wiley and Sons*

Intrinsic Sphincter Dysfunction Theory (McGuire 1977)

This theory developed in response to the question of why suspension operations failed in many women. McGuire (1977) proposed that if the bladder neck is in a well supported position but cannot close due to dysfunction of the sphincter, the patient will remain incontinent. Intrinsic sphincter dysfunction may be due to dysfunctional nerve supply, reduced blood supply to the vascular mucosa and poor soft tissue support (Figure 3.2).

This theory promoted the use of sling procedures to compress the urethra and the development of urethral bulking agents to improve the architecture of the urethra.

Figure 3.2 Intrinsic Sphincter Dysfunction (McGuire 1977)

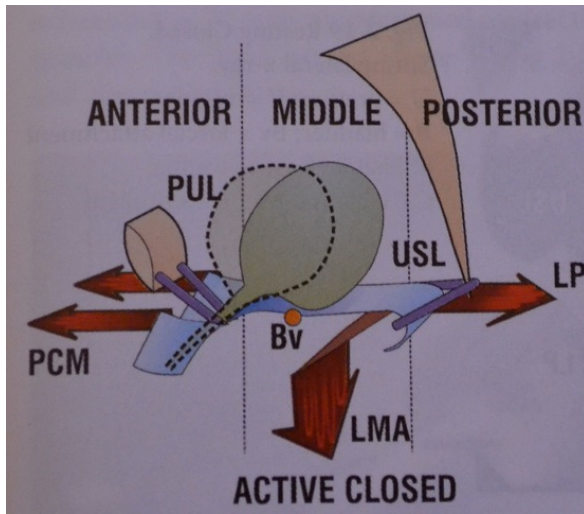


The urethra is unable to generate enough outlet resistance to retain urine in bladder © Daneshgari and Moore In: Daneshgari and Moore (2006) BJU Int [Suppl 1], 8-14 *Reproduced with permission of John Wiley and Sons*

Integral Theory (Petros and Ulmsten 1990)

This theory emphasizes the role of well supporting connective tissue and ligaments and introduced a new and more complex paradigm of stability for urethral closure. Petros and Ulmsten (1990) proposed that the levator plate and long muscle of the anus produce a dorso-caudal force in opposition to the cranio-ventral action of the pubovisceral muscle. This rotates the upper vagina and trigone around the precervical arc and pubourethral ligament insertion like a ball valve to assist in bladder neck closure (Figure 3.3).

Figure 3.3 The Integral Theory (Petros and Ulmsten 1990)

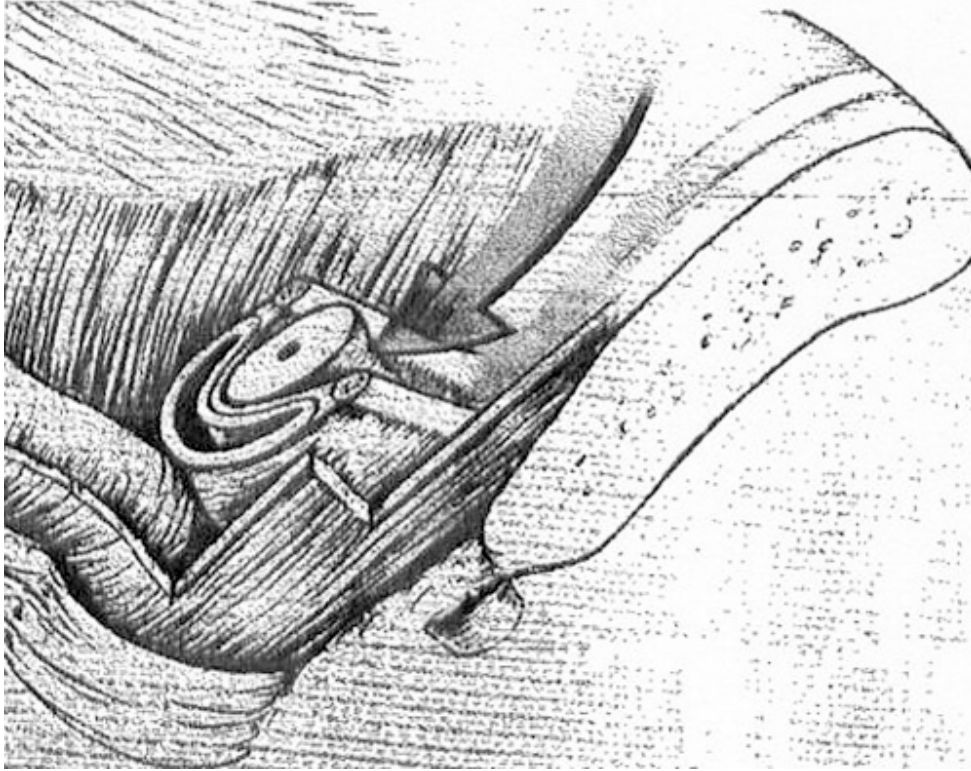


Bv=attachment of bladder base to vagina; PCM=pubococcygeal muscle; LMA=long muscle of the anus; LP=levator plate; PUL =pubourethral ligament; USL=uterosacral ligament. Petros PE: The Female Pelvic Floor. Chapter 2, page 27, Figure 2.17 © Springer Medizin Verlag Heidelberg 2007 *Reproduced with permission of Springer Science+BusinessMedia*

The Hammock Hypothesis (DeLancey 1990)

The “Hammock” as described by DeLancey (1990) is the supportive layer of endopelvic fascia slung between the ATRP on which the urethra sits (Figure 2.3). The stability of the hammock is influenced by the PFM acting through the ATRP and ATLA. As the PFM shorten on contraction, the hammock is lifted in a cranio-ventral direction, taking the urethra with it. This action stabilises and compresses the urethra against the precervical arc (Figure 2.6) and pubis during reflex or voluntary active contraction. The firm underlying hammock also acts as a backstop or brake with the PFM to halt the urethra as it travels in a dorso caudal direction during rises in IAP (DeLancey 1994; Lovegrove Jones et al 2009). In summary, the Hammock theory is therefore dependent on a well functioning and well supported urethra and an intact PFM and nerve supply.

Figure 3.4 DeLancey's Hammock Hypothesis



The active Hammock. Lateral view of the pelvic floor with urethra resting on the endopelvic hammock and vagina, at the level of the vesical neck drawn from three-dimensional reconstruction, indicating compression of urethra by downward force (arrow) against supportive tissues indicating influence of abdominal pressure. DeLancey 1994 In *Am J Obstet Gynecol* 170, 1713-172 *Reproduced with permission of Elsevier*

In a review of continence theories, Daneshgari and Moore discuss that none of these theories is capable of explaining the continence mechanism in its entirety and propose the “Trampoline Theory”. This likens the mechanism of a trampoline that has many springs, with the continence system that has many supporting structures. Each spring is necessary for function, and yet one or two broken springs will not cause the trampoline to fail. Over time as more springs fail, dysfunction will occur. This is similar to the support system for urinary continence. Urinary continence may be present despite one or more structures having been disrupted following parturition. Incontinence is maintained until additional components fail, such as a result of subsequent vaginal delivery, menopause or ageing, at which time compensatory mechanisms fail. Arguably the Trampoline Theory is a

metaphor and not a theory, because new scientific evidence is not presented. The authors acknowledge this although perhaps the word “theory” should be exchanged for “analogy” i.e. “The Trampoline Analogy of SUI”.

3.2.2 Part II: Current understanding of the role of the Pelvic Floor Muscles in the Continence mechanism

Computerised searches produced more than 650 papers. It was pragmatic to narrow this to include seminal papers (Atherton and Stanton 2000; Miller et al 2001) and papers that had been sourced for use elsewhere in the dissertation (Clark 1990; Howard et al 2000; Meyer et al 1998; Peschers et al 1996) or in the library of the author (Bø and Talseth 1997; Theofrastus et al 1997; Umek 2002; Baessler et al 2005 Schaer et al 1997; and Dietz and Clarke 2001; Di Pietro 2008; Ahtari 2008).

All of the continence theories that have been discussed in this chapter acknowledge the role of the PFM in urinary continence. The healthy PFM in the absence of pelvic trauma is constantly active in order to adequately tension the supporting sub-urethral fascia at rest and thereby provide optimal resting position of the bladder neck and urethra (as necessary for Enhorning’s theory of 1961); is capable of generating adequate force to lift and compress the urethra against the pre-cervical arch and the pubis (as acknowledged in the theories of DeLancey 1990; Petros and Ulmsten 1990 and McGuire et al 1997); and to act as a backstop for the urethra during rises in IAP as acknowledged in DeLancey’s Hammock (1990).

Various studies have explored PFM function within the context of stress urinary incontinence. Miller et al (2001) observed that a voluntary PFM contraction in preparation for a cough stabilised the urethra as compared with an unguarded cough. This study is central to this thesis and is reviewed in detail with other studies that have investigated the effect of PFM training on position of UVSs (see Chapter 4.1.1.).

In a study by Howard et al (2000), the efficacy of the PFM back stop was described as being related to PFM “stiffness” or its ability to resist deformation. In an observational study of 17 nulliparous continent women, 18 primiparous continent and 23 primiparous

incontinent women, muscle stiffness was calculated by dividing the IAP exerted during cough and valsalva manoeuvre, by urethral descent as seen on ultrasound. The nulliparous group were found to have significantly greater PFM stiffness during a cough as compared with the parous group ($p=0.001$). Continent parous women demonstrated approximately double the stiffness of the parous incontinent women. The reduced displacement of the urethra observed in the parous group on coughing implies that PFM stiffness equates to urethral stability.

As discussed in Chapter 2.2.1 the urethra has a vascular muscosa and a complex arrangement of sphincters that are constantly at work in the resting state to maintain closure. It is widely acknowledged that the PFM also contribute to UCP. A 3-D transrectal ultrasound study of 20 pre-menopausal women demonstrated that on voluntary PFM contraction, the IUS remains active whilst the EUS decreases in volume i.e. rests rather than co contracting with the IUS and PFM. This infers that the EUS is externally compressed by the PFM rather than actively contracted during voluntary PFM contraction and that the sphincter switches on again when not compressed by the PFM (Umek et al 2002). Several studies have correlated PFM contraction with a rise in UCP thus supporting the role of the PFM in compression of the urethra on contraction (Bø and Talseth 1997; Theofrastus et al 1997; Baessler et al 2005). Schaer et al (1997) and Dietz and Clarke (2001) also used ultrasound imaging and observed upward movement of the bladder neck during a simultaneous rise in UCP on PFM contraction. Urethral closure pressure is further discussed in relation to puborectalis in Chapter 8.2.

The issue of position of UVSs is controversial and is central to this thesis. It was proposed by Bø in 2004 that an aim of PFM training should be to restore bladder neck position by improving PFM support (see 1.2.1.1). Urethral hypermobility/altered urethral position following vaginal delivery is commonly associated with SUI as observed on imaging (Clark et al 1990; Meyer et al 1996; Miller et al 2001). However, urethral hypermobility is not diagnostic of SUI because women with a hypermobile urethra may not be incontinent (Peschers et al 1997; Di Pietro 2008). As discussed by Ahtari (2008) cut off values for urethral hypermobility have not been established. Whilst Dietz and

Wilson (1998) demonstrated bladder neck descent on valsalva of more than 25mm in women with SUI, Peschers et al (2001) found normal values of up to 32mm in continent women. With respect to surgical outcomes, colposuspension to elevate the bladder neck has a comparable cure rate with tension free vaginal tape that acts to support the mid urethra by acting as a backstop, but without effect on position of the bladder neck (Atherton and Stanton 2000). Pelvic floor muscle training studies have reported elevated bladder neck position at rest as well as on contraction post intervention. These studies are discussed in greater detail in Chapter 4.

Summary

Stability of the urethra and bladder neck provided by intact anatomical relationships, and a well functioning PFM and nervous system are central to the current understanding of the continence system. Four continence mechanisms continue to underpin the understanding of continence. These are pressure transmission (Enhorning 1961); Intrinsic Sphincter Deficiency (McGuire 1977); the Hammock Hypothesis (DeLancey 1990), and the Integral Theory (Petros and Ulmsten 1990). Together these mechanisms have led to the understanding that urinary continence is multifactorial. It is clear that a single theory is not adequate, nor would it be pragmatic for researchers or clinicians to base practice on a single theory or to seek a pan explanation for SUI.

Results from various studies indicate that the role of the PFM in urinary continence is to support the position of UVSs and to contribute to urethral closure.

Conclusion

The understanding of the mechanisms of continence remains incomplete. It is however acknowledged that maintenance of continence is dependent on several well functioning systems, including the PFM.

Because the stability of urethrovesical structures is central to this study, the evidence behind altered position of UVSs following PFM training was reviewed in the following chapter.

Chapter 4 Critical Review of Urethral Position in Relation to Pelvic Floor Muscle Training and Pelvic Floor Muscle Instructions

4 Introduction

Part of the theoretical rationale for intensive PFM training as discussed in 1.2.4 is to improve structural support and elevate the PFM to a permanently higher location in the pelvis (Bø 2004). The hypotheses of this study (see 5.2) suggest that within such a paradigm, a training aim should be for each PFM contraction to optimally influence urethral position. In clinical practice this investigator has subjectively observed that many women fail to maximally influence UVS position because of suboptimal PFM recruitment strategies at initial assessment as evidenced during perineal 2-Dimensional real-time ultrasound (2-D RTUS) imaging. Women often contract the PFM by squeezing around the urethra, although UVS position is improved following instruction to contract more globally. This anecdotal evidence suggests that an instruction to facilitate anterior regional recruitment i.e. “squeeze and lift from the front as if stopping the flow of urine” more often results in reduced magnitude of excursion of the urethra than a posterior cue to instruction such as “squeeze and lift from the back as if stopping the escape of wind”. Therefore differing cues to instruction may potentially produce either maximal or sub-maximal regional recruitment of the PFM and thereby variously influence UVS position. The clinical observations of this author, taken with the paradigm that PFM training should aim to improve UVS support raised certain questions at the outset of this programme of work:

1. Can PFM training influence position of UVSs?
2. If so, does this impact on incontinence outcomes in the physiotherapy management of SUI?

3. If position of UVSS as influenced by PFM training is important, is there any evidence to support the suggestion that certain instructions for a PFM contraction may produce sub-maximal regional recruitment of the levator ani and therefore suboptimal UVS positioning?
4. What are the instructions commonly used for a PFM contraction and how have they developed?

A critical review was undertaken in response to these questions.

4.1 Critical Review Design

4.1.1 Structure

Part I : Imaging studies relating to the influence of PFM training on UVS position.

Part II: Imaging studies relating to the influence of PFM training on UVS position as well as outcomes of UI.

Part III: Imaging studies investigating regional instruction of the PFM

Part IV: PFM instructions commonly used for a PFM contraction in:

1. Physiotherapist led research
2. Medical/surgical research
3. Physiotherapist led imaging research
4. Professional websites
5. The world wide web

4.1.2 Parts I-III

Objective

The objective of Parts I-III of this critical review was to examine the evidence base in order to answer questions raised above i.e. to establish if regional recruitment of the PFM as influenced by cue to instruction was worthy of further investigation.

Search strategy

Searches of the computerised databases Medline, AMED (Allied and Alternative Medicine), CINHAL (Cumulative Index to Nursing and Allied Health Literature),

EMBASE –Rehabilitation and Physical Medicine (Excerpta Medica Database) and The Cochrane Library Database were undertaken from 1980 to date. Key search terms were “pelvic floor muscle; dysfunction; training; exercise; bladder neck; urethra; position; stress urinary incontinence; ultrasound; physiotherapy; physical therapy”.

Selection Criteria

A study was included if the following criteria were met:

1. The trial was in the English language.
2. The trial reported the outcome of PFM training as it related to change in position of one or more UVSs.
3. Design and outcome measures were reliable and relevant to the area of investigation.

4.1.3 Part IV

Objective

The objective of part IV was to investigate what instructions are commonly used for a PFM contraction by continence researchers, professional groups and on the world wide web and how they have developed.

Search strategy

Searches were undertaken as follows:

1. The 12 randomised controlled trials (RCTs) selected for review by The Cochrane Collaboration Review of PFM training (Dumoulin and Hay-Smith 2010).
2. All bladder neck imaging studies referred to in the process of this programme of work.
3. The computerised databases Medline, AMED, CINAHL, EMBASE – Rehabilitation and Physical Medicine from 1980 to date. Key search terms were ultrasound imaging; pelvic floor muscle; bladder neck; position; voluntary contraction; and physiotherapy

4. The world wide web using the UK “Google” search engine for surgical and physiotherapy organisations most prolific in PFM research (Australia, Canada, New Zealand, UK, USA).
5. The world wide web using the UK “Google” search engine for PFM instructions used in public information sites. The search term was “how to do a pelvic floor exercise”. The first ten sites were reviewed.

4.2 Critical Reviews

4.2.1 Part I: Imaging studies of the bladder neck following PFM training

The literature search revealed two imaging studies relating to the influence of PFM training on UVS position (Miller et al 2001 and Braekken et al 2010a). There were no exclusions. Descriptions of each publication are seen in Table 4.1 and are described in greater detail in Appendix 2a. A summary of each is presented as follows:

Miller et al 2001

The objective of this prospective observational study was to test the hypothesis that “The Knack”, a voluntary PFM contraction initiated in preparation for a cough, (see 1.2.1.3 and 3.2) significantly reduces bladder neck displacement. A group of continent women ($n=11$) undertook 2-D RTUS examination of the bladder neck after brief Knack training whilst an incontinent group ($n=11$) practiced The Knack for six months prior to imaging. In both groups a cough without The Knack produced bladder neck displacement of 5.4mm, and with The Knack 2.9mm ($p=0.001$). This was an original study that despite some methodological flaws as described in Appendix 2a has provided seminal preliminary information about the stabilising function of the PFM. Despite lack of blinding in the ultrasound rater and lack of presentation of confidence intervals (CIs), the relatively robust methodology provides the reader with some confidence about the results. Preliminary information about PFM contraction and stabilisation of the bladder

neck during a cough is provided that obviates the need for further investigation.

Braekken et al 2010a

This RCT investigated morphological and functional changes of the PFM and positional changes of the bladder neck and rectum following PFM training in women with POP. It was a sub study of a parent RCT investigating improvement in symptoms of POP following PFM training (Braekken et al 2010b). The control group ($n=50$) were given advice and asked not to start PFM exercises, whilst the study group ($n=59$) undertook intensive PFM training. Perineal 3-D RTUS examination was performed prior to and following intervention in both groups. A highly significant elevation in bladder neck position at rest in the intervention group was seen of 4.3mm (CI 95% 2.1 to 6.5 $p<0.001$). A significant correlation between increased PFM strength/squeeze pressure and elevated bladder neck position was found ($\rho=0.25$, $p=0.017$). Outcomes of differences between groups for all other PFM indices studied reached levels of significance. This was a study of high quality, it being a RCT with robust methodology and statistical analysis. As a result the reader can be confident of the validity of the results. These demonstrated a significant change in bladder neck position following PFM training, and a positive correlation between change of bladder neck position and increased muscle strength.

4.2.2 Part II: Imaging studies relating to the influence of PFM training on position of urethrovesical structures as well as outcome of urinary incontinence

Five studies were identified that investigated bladder neck position as well as UI following PFM training intervention (Martan et al 1994; Meyer et al 2001; Reilly et al 2002; Balmforth et al 2006; Hung et al 2011). One study was excluded because it was in the Czech Language (Martan et al 1994), and two others due to poor methodology (Reilly et al 2002; Meyer et al 2001). In both of these studies, baseline ultrasound was undertaken pre delivery, but not prior to the start of intervention. In the interim subjects had undergone vaginal delivery. Vaginal delivery has been demonstrated to be associated with alteration of bladder neck position (Peschers et al 1997; Wijma et al 2003) and therefore may have negatively influenced the dependent variable of bladder neck

position. This potential confounder renders interpretation of the outcome of PFM training on bladder neck position problematic. For this reason, these studies were excluded.

A summary of exclusions and description of each included study is presented in Table 4.2 and in greater detail in Appendix 2b. A summary of included studies is presented as follows:

Balmforth et al 2006

This prospective observational study assessed the impact of PFM training on bladder neck mobility and improvement of SUI. Ninety-seven women with video-urodynamic proven mild to severe SUI were recruited. It is not clear if women with MUI were excluded. Subjects undertook ultrasound examination of the bladder neck prior to and following an intensive PFM training programme of 14 weeks. Significant changes in bladder neck position were seen at rest (7.3° [CI 95%: 51.7 to 59.1] $p=0.009$); on PFM contraction (10.4° [CI 95%: 29.1 to 41.4] $p=0.013$) and onValsalva (12.9° [CI 95%: 58.9 to 69.1] $p=0.002$). Urine loss reduced from 12.2g to 5.5g ($p<0.001$) although no correlation was found between change in bladder neck position and improvement in urine loss.

This original study provided preliminary information about changes in bladder neck position at rest, on PFM contraction and onValsalva following intensive PFM training. It was a large study, although there was no control group. There are some issues with non blinding of ultrasound raters and reliability tests, and there is no reference to adherence to the prescribed exercise diary. Due to the relatively weak correlation results, it is not easy to make inferences about the clinical significance of a change in bladder neck position and urinary loss. Despite these weaknesses, the study is of good size, the intervention is robust and the results are supported by strong CIs. It is reasonable to state that these results have provided a platform for further research.

Hung et al 2011

This prospective observational study investigated the effect of PFM strengthening on

bladder neck mobility in women with SUI or MUI using ultrasound imaging before and after PFM training intervention. It also investigated severity rating and self reported improvement. Twenty-three women who had reported either SUI or MUI in the previous month underwent a 16 week home training programme. Bladder neck position did not significantly change at rest post intervention: (3° [95% CI: 11 to 4] $p=0.335$); on coughing (3° 95%CI: -10 to 5, $p=0.436$) or valsalva (1° [95% CI: 13 to 1] $p=0.829$). A highly significant difference in bladder neck position on voluntary PFM contraction was seen (11° [95% CI: 4 to 14] $p=0.001$). Self reported severity index was significantly improved ($p=0.001$). No correlation was found (nor presented) between improved severity scores and improved bladder neck position. The methodology of this study is in general poor, in particular sample size, lack of randomization, lack of supervision during intervention and inclusion criteria of subjects with MUI. The negative findings are likely due to these shortcomings in design. The study is probably underpowered so that greater numbers may have influenced the results. There was no supervision in almost half of the subjects and no record of intervention compliance. The conclusion by the authors that PFM training does not alter bladder neck position should be considered with caution.

4.2.3 Part III: Studies investigating regional recruitment of the PFM

No imaging studies were found that investigated instruction for a PFM contraction or regional recruitment of the PFM.

Table 4.1 Summary of studies included in critical review Part 1: Bladder neck position following intervention.

Author/ design	Subjects	Method	Intervention	Outcomes
Miller et al 2001 USA Prospective Observational study CEBM evidence level 2c	$n=11$ continent nulliparous women, mean age 24.8 ± 7 $n=11$ stress incontinent parous women, Mean age 66.9 ± 3.9	<u>Pre and post intervention evaluation</u> Pre and post intervention ultrasound data collected of bladder neck at rest and on coughing with and without PFM contraction (The Knack) <u>Outcome measure</u> Bladder neck measured in mm at rest and with and without The Knack during coughing	Continent: Taught The Knack immediately before data collection Incontinent: Taught The Knack at the start of a 6 month programme of routine PFM training. Standardisation of exercise not stated over 6 month period prior to data collection	<u>Mean dorsocaudal shift of the bladder neck with and without the knack:</u> All subjects: 2.9mm with The Knack vs. 5.4mm without $p < 0.001$ Continent: 0.0 with The Knack vs. 4.6mm without $p = 0.007$ Incontinent: 3.5 with The Knack vs. 6.2 without $p = 0.003$
Braekken et al 2010a The Netherlands RCT CEBM evidence level 1b	$n=109$ women with POP $n=59$ (PFMT) mean age 49.4 ± 12.2 $n=50$ (control) mean age 48.3 ± 11.4	<u>Pre and post intervention evaluation</u> PFM strength measured using perineometry Bladder neck position at rest, using 4-D ultrasound PFM morphology using 3-D ultrasound	Control group: taught not strain. Asked not to start PFM training Study group: Individual strength training once weekly with physiotherapist for 3 months then fortnightly for 3 months plus daily home exercise three times per day: 8-12 close to maximal squeezes, length of hold not stated.	<u>Between group changes:</u> Bladder neck at rest 4.3mm (CI 95% 2.1 to 6.5 $p = 0.001$) Correlation between increased PFM strength/squeeze pressure and elevated bladder neck position ($\rho = 0.25$, $p = 0.017$).
SUI= stress urinary incontinence POP= pelvic organ prolapse RCT= randomised controlled trial PFMT= pelvic floor muscle training CEBM= Centre for evidence based medicine (Cambridge UK)				

Table 4. 2 Studies included in critical review Part II : Bladder neck position and UI following intervention.

<p>Balmforth et al 2006</p> <p>UK</p> <p>Prospective observational design</p> <p>CEBM evidence level:2c</p>	<p>n=84 women with SUI</p> <p>Mean age 49.5 ± 10.6</p>	<p><u>Pre and post intervention evaluation</u></p> <p>2-D ultrasound data collected of bladder neck angle at rest, on PFM contraction and valsalva</p> <p>Thirty minute pad test.</p> <p>QOL questionnaire</p>	<p>14 weeks intensive one-one strength and knack exercise programme designed for each subject individually x3 sets daily. Exercise diary, >4 visits to the physiotherapist and telephone support as necessary</p>	<p>Post intervention mean bladder neck angle change:</p> <p>at rest 7.3° (CI: 95% 51.7 to 59.1 p=0.009)</p> <p>at valsalva 12.9° (CI: 95% 58.9 to 69.1 p=0.002)</p> <p>at PFM contraction 10.4° (CI 95% 58.9 to 69.1 p=0.013)</p> <p>Urinary loss reduced by >50% =5.44g from 12.2 g (p=<0.001)</p> <p>No positive correlation between change in bladder neck angle and urinary loss</p> <p>QoL score improved significantly in 6 of 9 domains</p>
<p>Hung et al 2011</p> <p>Taiwan</p> <p>Prospective observational study</p> <p>CEBM evidence level: 2c with caution</p>	<p>n=23 women with SUI or MUI</p> <p>Mean age 51.9 ± 6.1</p>	<p><u>Pre and post intervention evaluation</u></p> <p>2-D ultrasound data collected of bladder neck rotation at rest, on PFM contraction and valsalva and cough</p> <p>Severity index score</p> <p>Self reported improvement</p> <p>Vaginal squeeze pressure</p>	<p>16 week home exercise programme. 6 maximal PFM contractions with the aim of holding for 10 seconds, and 10 fast contractions repeated 3-5 times per day. Supervision optional. Exercise diary optional</p>	<p>Post intervention mean bladder neck rotation change:</p> <p>at rest 3° (CI: 95% 11 to 4 p=0.335)</p> <p>at PFM contraction 11° (CI 95%: 4 to 14 p=0.001)</p> <p>at cough 3° (CI: 95% - 10-5 p=0.436)</p> <p>at valsalva 1°(CI 95% CI :13-1 p=0.829)</p> <p>Vaginal squeeze pressure improved 14cm H₂O (p=0.001)</p> <p>Severity index scoring improved (p=0.001)</p> <p>Self reported change: 4.3% cured 95.7% improved</p>
<p>SUI= stress urinary incontinence MUI=mixed urinary incontinence PFMT= pelvic floor muscle training QoL=quality of life CEBM= Centre for evidence based medicine (Cambridge UK)</p>				

4.2.4 Part IV: Review of PFM instruction

Instructions for a PFM contraction in physiotherapy PFM training studies

As previously described, studies reviewed in the Cochrane Review of PFM Training (Dumoulin and Hay-Smith 2010) were included for review of instructions used. These studies are detailed in Table 4.3.

Table 4.3 Instructions for a PFM contraction from the 12 RCTs analysed in the Cochrane Review. Dumoulin and Hay-Smith (2010)

Author	Country	Instruction
Aksak et al 2003	Turkey	Relax the abdomen and buttocks and contract the pelvic floor muscles as if interrupting micturition
Burns 1993	USA	Specific instruction not stated
Bidmead 2002	UK	Specific instruction not stated
Burgio 1998	USA	Specific instruction not stated
Bø 1999	Sweden	Specific instruction not stated
Castro 2008	Brazil	Specific instruction not stated `
Henalla et al 1989	UK	Place your index and middle finger held apart in the vagina and contract the pelvic floor by squeezing the fingers together
Henalla 1990	UK	Specific instruction not stated
Kim 2007	Japan	Specific instruction not stated
Lagro-Janssen 1991	Netherlands	Contract the pelvic floor muscles by attempting to hold back the flow of urine
Miller 1998	USA	Specific instruction not stated
Yoon 2003	South Korea	Contract and relax (the) pelvic muscles

Instructions for a PFM contraction in the medical/surgical imaging literature

All bladder neck imaging studies referred to in the process of this programme of work were reviewed for instruction for a PFM contraction. Results are presented in table 4.4.

Table 4.4 Instructions for a PFM contraction appearing in medical/surgical imaging studies sourced during this programme of work that investigated bladder neck position on voluntary contraction of the PFM

Researchers	Provenance	Instruction
Balmforth et al 2006	UK	Specific instruction not stated
Beer-Gabel et al 2002	Israel	Squeeze [rectal imaging probe] to prevent evacuation
Bump et al 1991	USA	Contract the muscles you would use if you were trying to keep from losing urine or if you are trying to stop the stream after you have started to urinate
Christensen et al 1995	USA	Specific instruction not stated
Constantini et al 2005	Italy	Mimic the interruption of urine
Deiz et al 2002; 2003	Australia	Specific instruction not stated
Gufler et al 2000	Germany	Squeeze your buttocks together
Hol et al 1995	Netherlands	Women were asked to squeeze her pelvic floor as if holding up urine
Hung et al 2011	Taiwan	Specific instruction not stated
Jung et al 2007	USA	Specific instruction not stated
Meyer et al 1998;2001	Switzerland	Specific instruction not stated
Miller et al 1998	USA	Specific instruction not stated
Pregazzi et al 2002	Italy	Ultrasound was performed during the withholding manoeuvre
Peschers et al 1996; 1997; 2001	Switzerland	Specific instruction not stated
Raizada et al 2010	USA	Squeeze as if you were trying to stop your stream of urine
Reddy et al 2001	USA	Women were instructed to perform a “Kegel” exercise
Schaer et al 1995	Germany	Specific instruction not stated
Wise et al 1992	UK	Tighten the vaginal muscles as if to interrupt their urinary stream during voiding
Wijma et al 1991	Netherlands	Specific instruction not stated
Weinstein et al 2007	USA	Specific instruction not stated
Umek et al 2002	Austria	Specific instruction not stated

Review of PFM instructions in the physiotherapist-led imaging literature

All physiotherapist led imaging studies that were identified during the programme of this work were included. Results are presented in Table 4.5.

Table 4.5 Instructions appearing in physiotherapist-led imaging studies that investigated position of the bladder neck on voluntary contraction of the PFM.

Authors	Provenance	Instruction
Avery et al 2000	Australia	Specific instruction not stated
Bernstein 1997	UK	Specific instruction not stated
Bø et al 2003	Sweden	Specific instruction not stated
Bø and Finkenhagen 2003	Sweden	Specific instruction not stated
Critchley et al 2002	UK	Imagine the pelvic floor as a hammock and lift the structure and tighten it gently as if stopping the flow of urine
Braekken et al 2010b	Netherlands	No specific instruction stated
Kelly et al 2007	Australia	Draw in through your pelvic floor muscles as best you can whilst breathing normally
Thompson and O'Sullivan 2003	Australia	Contract the muscles around the vagina and lift inwardly
Thompson et al 2005	Australia	Draw in and lift the pelvic floor muscles

Review of instructions appearing on international professional websites

Instructions from professional websites in the UK, southern hemisphere, and North America were reviewed. Results are presented in Table 4.6.

Table 4.6 Instructions for a PFM contraction from national surgical and physiotherapy Organisations

	UK	USA	Southern Hemisphere	Canada
National Surgical Colleges	<p>The Royal College of Obstetrics and Gynaecology</p> <p><i>No public information on pelvic floor muscle contraction instruction available</i></p> <p>www.rcog.org.uk</p>	<p>The American College of Obstetrics and Gynecology</p> <p><i>“squeeze the muscles that you use to stop the flow of urine”</i></p> <p>www.acog.org Gynecology Education pamphlet P166. Available as a download</p>	<p>The Royal Australian and New Zealand College of Obstetrics and Gynecology</p> <p><i>“These muscles are the ones you normally squeeze when you try to stop wind escaping”</i></p> <p>www.ranzcog.edu.org Urinary Incontinence A Guide for Women. Not available as a download. Paper order available</p>	<p>The Canadian Association of Obstetricians and Gynecologists</p> <p><i>“[pelvic floor exercises] are Kegels”</i></p> <p>www.sogc.org</p> <p>Women’s Health Information Urinary Incontinence</p>
National Physiotherapy Associations	<p>The Chartered Society of Physiotherapy</p> <p><i>“You should imagine that you are trying to stop yourself from passing urine and at the same time trying to stop yourself from passing wind”</i></p> <p>www.csp.org.uk “Pelvic Power Guide” available as a download</p>	<p>The American Physical therapy Association</p> <p><i>“Try stopping or slowing the flow of urine”</i></p> <p>www.apta.org “You can do something about incontinence. A Physical Therapists Prospective” available as a download</p>	<p>The Australian Physiotherapy Association</p> <p><i>“Tighten up and lift the muscles around the anus, vagina and urethra”</i></p> <p>www.physiotherapyasn.au “Feeling good looking good during pregnancy” Paper leaflet to order</p>	<p>Canadian Association of Physiotherapy</p> <p><i>“Tighten [the pelvic floor] as strongly as you can”</i></p> <p>www.physiotherapy.ca</p> <p>Download. Is your bladder ruining your life?</p>

Review of Instructions for a PFM contraction on the world wide web

The final World Wide Web search on May 30th 2013 revealed information sites too numerous to cite and therefore the findings of the first ten of these are presented (Table 4.7).

Table 4.6 Instructions for a PFM contraction appearing on the World Wide Web at May 30th 2013

Site	Country	Instruction
www.doctors.net.uk	UK	Try to tighten your muscles around your vagina and back passage and lift up, as if you're stopping yourself passing water and wind at the same time.
www.babycentre.co.uk	UK	Imagine that you are trying to stop yourself from passing wind and trying to stop your flow of urine mid-stream at the same time.
www.thewomesorg.au	Australia	Close your eyes, imagine what muscles you would tighten to stop yourself from passing wind or to 'hold on' from passing urine.
www.ehow.com	USA	You do this [locate the pelvic floor] by urinating and then stopping midway through the process.
www.themayoclinic.com	USA	Insert a finger inside your vagina and try to squeeze the surrounding muscles. You can also try to stop the flow of urine when you urinate.
www.sgsonline.org	Sweden	[locate the pelvic floor]by starting and stopping your urine flow while voiding
www.uptodate.com	USA	Tighten your pelvic muscles while you are urinating to stop the flow of urine.
www.themumszone.au	Australia	Tighten the muscles gently around your urine passage as if trying to stop the flow of urine.
www.oprah.com	USA	Squeeze the muscles around your vagina and anus
www.nhs.co.uk/choices	UK	You can feel your pelvic floor muscles if you try to stop the flow of urine when you go to the toilet.

4.3 Discussion: Parts I-III

Introduction

It is evident from this critical review that there is a paucity of evidence with respect to change in position of UVVs following PFM training and whether or not such change is related to clinical improvement. There are only four papers that were suitable for review here. Only one of these papers was a RCT and of high enough quality and sufficiently robust design that the reader may be very confident of the results (Braekken 2010a). Of the remaining three studies one had shortcomings that arguably render confidence in the results problematic (Hung et al 2011). The remaining two papers worthy of discussion were both original and seminal but were not without some limitations (Miller et al 2001; Balmforth et al 2006). The former was limited by small size and omission of CIs that may have assured the reader that the results may be repeatable in future studies. The latter contained some ambiguities for both data analysis and selection criteria.

The results from each study are broadly comparable as all used an x, y co-ordinate system for bladder neck measurement based on the description by Schaer et al (1995) and modified by Peschers et al (1997), although various indices of measurement were used between studies. These indices have been found to correlate well by Dietz and colleagues (2002) and are used per investigator preference (see 5.4). Most of the results in this review with respect to change in bladder neck position following PFM training reached levels of statistical significance. The one study in which outcomes were largely negative is probably due to poor study design (Hung et al 2011).

Based on the strong results of the study of Braekken et al (2010a) it is possible to confidently draw the preliminary conclusion that intensive PFM training results in a change in bladder neck position following PFM. This is supported by the study of Balmforth et al (2006). It is also possible to draw the preliminary conclusion that The Knack results in stabilisation of the bladder neck during a cough in both continent and incontinent women (Miller et al 2001).

The two studies that were suitably designed to provide information with respect to relationship between improvement in bladder neck position and UI failed to find positive correlations (Balmforth et al 2006; Hung et al 2011). Hung et al (2011) failed to exclude women with MUI in whom urinary loss was likely to be less dependent on urethral support than in women with SUI alone, and for which there is little evidence for the effectiveness of PFM training (Greer et al 2012). It is not stated if Balmforth et al (2006) excluded women with MUI although the inclusion of a bladder diary and behavioral advice (most usually used in MUI) infers that they were not excluded and this may have weakened the results. Braekken et al (2010a) reported a positive correlation between elevated bladder neck position and vaginal squeeze pressure ($r=0.25$ [$p=0.017$]). Hung et al (2011) did not report similarly but this is probably due to poor methodology as previously discussed. The study by Miller et al (2001) did not set out to investigate urinary loss but aimed to elucidate the mechanism of “The Knack” that had been previously shown to reduce urinary loss (Miller et al 1998). To contextualise, use of The Knack during a medium and deep cough was seen to reduce urine loss by 98.2% and 73.3% respectively as compared with an unguarded cough (Miller et al 1998). The inference of these two studies taken together is that a voluntary PFM contraction reduces urinary incontinence by lifting and stabilising the bladder neck and therefore may be clinically important.

The results of this review imply that bladder neck position may be important clinically although more studies are required to confirm this. The positive correlation between bladder neck position and vaginal squeeze pressure found by Braekken et al (2010) is important and supports a previous study that demonstrated a positive correlation between vaginal squeeze pressure and urethral closure pressure (Theofrastus et al 1997). Whilst failing to find a positive correlation between bladder neck position and urinary leakage, the work of Balmforth et al (2006) also suggests that bladder neck position is important in PFM training.

4.4 Discussion: Part IV

The results from this review clearly demonstrate that where instructions appear at all, they vary widely. This is particularly surprising for the physiotherapy literature as it might be expected that there would be broad consensus between leading physiotherapists about how to contract the PFM (Tables 4.3; 4.5 and 4.6). Despite discussing the difficulties associated with comparing PFM studies due to differing muscle training programmes; interventions; outcome measures; and data reporting methods, the Cochrane review of 2010 (Dumoulin and Hay-Smith) makes no reference to instruction used. Similarly, no reference is made to instruction in a recent review of the optimal way to train the PFM (Dumoulin et al 2011). It is disappointing that instructions from leading specialist PFM physiotherapists appear infrequently in the research literature. In Tables 4.3 and 4.5 the instructions are either to contract from around the urethra or the vagina, or less specific cues such as “contract the pelvic floor”. The instructions seen in Table 4.4 from medical and surgical publications overwhelmingly support contraction around the urethra. One study includes an instruction that omits any cue for a pelvic floor contraction altogether by asking subjects to squeeze the buttocks (Guffler et al 2000). This is not easily understandable given that this was a dynamic imaging study of the PFM.

UK and southern hemisphere physiotherapists and gynecologists recommend a global instruction where instructions appear at all (Table 4.6). In the USA and Canada as evidenced in Tables 4.6 and 4.7 the majority of instructions are directed around the urethra. The trend for women in North America to use an anterior cue for a PFM contraction probably developed as a result of the pioneering work of gynecologist Arnold Kegel, who published results from the first PFM training trial (1948), and whose name became synonymous with PFM exercise in the USA. In his original paper (1948), his instruction was “attempt to contract the muscles of the vagina” and later (1952) “Draw up, draw in, and retract the perineal muscles”, or if the instructions were not understood, “Contract as though to check a bowel movement or stop the flow of urine”. It is possible that given the choice, women opted for urethral contraction as this is likely more intuitive than contracting around the anus at some distance from the urethra where leakage occurs.

This may not be however, the global contraction that Kegel originally intended. Personal communication with a leading physiotherapy educator from the USA (Herman H) following presentation of this study at The World Congress of Physical Therapy (Vancouver 2007) revealed that trainee PFM physiotherapists in the USA at that time were being taught an anterior contraction alone.

Given the wide variations in the surgical and physiotherapy literature it is not surprising that instructions in the media vary widely (Table 4.7). Such wide variation is confusing not only for clinicians but also the public. It is the clinical experience of this author that women attending for initial PFM assessment, almost without exception, express that they are confused or unsure about how they should be executing a contraction. These wide variations also render comparison of PFM clinical trials problematic as differing instructions within studies and between studies may result in different outcomes.

Despite The ICS working towards standardised terminology for female PFM dysfunction (Haylen et al 2010) no standardised definition exists for the instruction to perform a PFM contraction. This is somewhat surprising, although less so when the lack of investigation in the literature about the possibility of the existence of an optimal cue to instruction is taken into consideration.

Summary

A review of studies of bladder neck imaging and PFM training has revealed that two of the four trials reviewed here are considered sufficiently robust to draw the preliminary conclusion that bladder neck position improves following intensive PFM training (Balmforth et al 2006; Braekken et al 2010). A further study demonstrates that a voluntary PFM contraction stabilises the bladder neck during a cough after brief training (Miller et al 2001). A positive correlation between bladder neck position and PFM strength has been demonstrated (Braekken et al 2010a). It is possible that a positive correlation between bladder neck position and improvement in urinary leakage would also have been found with a more robust methodology (Balmforth et al 2006). When

contextualised with a previous study (Miller et al 1998), the results of Miller et al (2001) infer that improved bladder neck position when using The Knack is related to reduction in urinary loss.

A review of the physiotherapy and surgical literature, and public information on the World Wide Web, has revealed that instructions for a PFM contraction vary widely. This is confusing for clinicians and the lay public as well as rendering comparison of clinical PFM research studies problematic.

Conclusion

The findings of this review suggest that there is preliminary evidence to suggest that PFM training brings about positive change in bladder neck position. Such change may be clinically significant with respect to SUI.

The wide variation in instructions for a PFM contraction taught by professionals and appearing on the World Wide Web for the lay public suggests that there is a need to establish whether there is an optimal cue to instruction for a single PFM contraction that may further influence bladder neck position.

The next chapter discusses the aims, hypotheses, methodology and programme of work that was undertaken in order to begin to answer the questions discussed in this chapter.

Chapter 5 Methodology 1: Aims, Hypotheses, Ethics Approval, Study Design and Programme of Work

5 Introduction

This programme of work was to consider clinical practice questions which had not been adequately addressed in the literature to date (see Introduction to Chapter 4). The main research question was to investigate which cue to instruction for a PFM contraction has the potential to optimise position of UVSs following a brief period of practice in:

- a. continent nulliparous pre-menopausal women (aiming to provide normative data)
- b. parous menopausal women with previously unreported SUI

Because the studies within this programme of work were feasibility studies of pragmatic design, ongoing work was required which included exploration of suitability and reliability of 2-D RTUS for measuring selective PFM contraction; training requirements for acquisition of the skill to read UVS images in a non diagnostic imaging allied health professional (AHP); the ability of women to selectively contract the PFM and the ability to adequately repeat selective contraction.

5.1 Research question and aims

5.1.1 Research question

The research question was:

Which cue to instruction for a PFM contraction has the potential to optimise position of UVSs following a brief period of practice in:

1. Continent nulliparous pre-menopausal women (aiming to provide normative data)
2. Parous menopausal women with previously unreported SUI

5.1.2 Preliminary aims

The preliminary aims were:

- a. To confirm that 2-D RTUS, using angle of urethral inclination [AUI] as a measurement index, is suitable for the purpose of imaging selective contraction of the PFM by undertaking reliability tests.
- b. To investigate the training requirement for a non-diagnostic imaging professional to read ultrasound images of UVSs.

5.1.3 Principal aim

The principal aim was to investigate which cue/s to instruction for a PFM contraction has/have the potential to optimise UVS position during PFM contraction following a brief period of practice in continent nulliparous pre-menopausal women and in parous menopausal women with previously unreported SUI.

5.1.4 Secondary aims

The secondary aims were:

- a. To investigate the effect of postural position (supine and standing postures) on selective cue to instruction.
- b. To explore the ability in women to selectively contract the PFM and the ability to repeat selective contraction.
- c. To investigate cue preference post expert teaching and practice

5.2 Hypotheses

In continent nulliparous pre-menopausal women and parous menopausal women with previously unreported SUI, posterior or combined cue is more influential in optimising position of UVSs during a PFM contraction following a brief period of practice, than an anterior cue.

In continent nulliparous pre-menopausal women and in parous menopausal women with previously unreported SUI, a posterior or a combined cue are equally influential in optimising position of UVSs during a PFM contraction following a brief period of practice.

5.3 Study Design

The design was for two feasibility studies of pragmatic design based on a similar model. Study 1 comprised a continent nulliparous pre menopausal group and investigated reliability of 2-D-RTUS, repeatability of selective PFM contraction, the effect of posture on selective PFM contraction and the effect of cue to instruction on urethral position. Study 2 comprised an incontinent parous menopausal group and investigated repeatability of selective PFM contraction and the effect of cue to instruction on urethral position. Design for Study 1 is presented in Figure 5.1 and for Study 2 in Figure 5.2. Subjects were also questioned about cue preference at the beginning and end of the study (see Chapter 6.8.4). Throughout the studies, therapeutic advice was withheld from all subjects to minimise potential bias of the subject towards the opinion of the clinician/researcher that may have led to variation in effort whilst executing a PFM contraction using the different cues, or bias in answering cue preference questions. All women were however invited to attend for treatment at the end of the study (Appendix 3a and b).

5.3.1 Overview of design

An overview of the design is described below with greater detail presented in Methodology 2 (Chapter 6).

Definition

In order to attempt to answer the research question, two feasibility studies using a pragmatic approach were designed. A pragmatic approach was necessarily taken due to fiscal constraints (both studies may also be categorized as a quasi experimental measurement study as described by French [2003] because whilst the study undertook to manipulate the independent variable, randomisation of subjects was lacking).

Structure

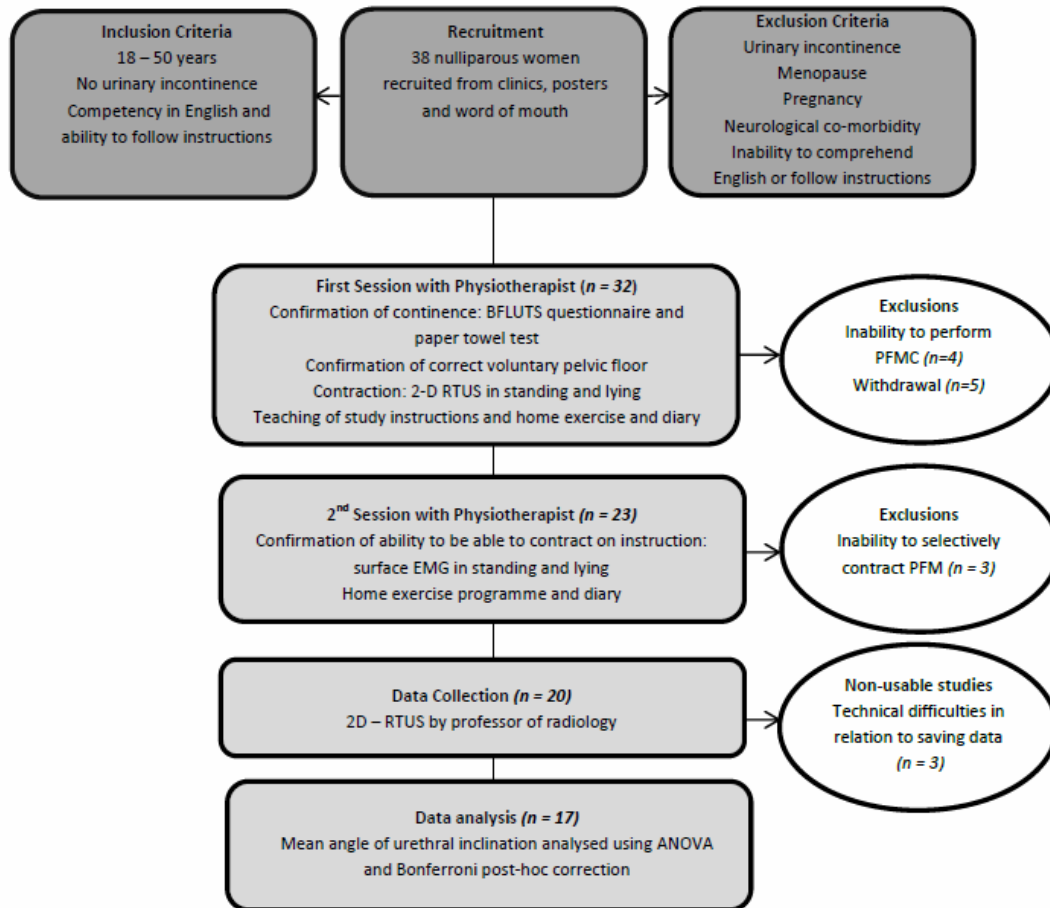
Study 1: Continent group (Figure 5.1)

Data was collected in pre-menopausal nulliparous continent women in order to gather normative information for proof of concept of selective contraction of the PFM and its influence on urethral position. Subjects were also questioned about cue preference prior to being taught the study cues, and following data collection (see Chapter 6.8.4). The age range 18-50 was chosen as it broadly reflects pre menopausal status. Confirmation of pre menstrual status was confirmed using a pragmatic approach (in the absence of blood tests to assess oestrogen levels) by asking about menstrual pattern. Inclusion was based on the existence of menstrual periods in a temporal pattern that was normal for the individual. The cut off point was irregularity/change of menstrual temporal pattern in the previous twelve months. None of the subjects reported irregular periods in the past twelve months and therefore all were included.

Study 2: Incontinent group (Figure 5.2)

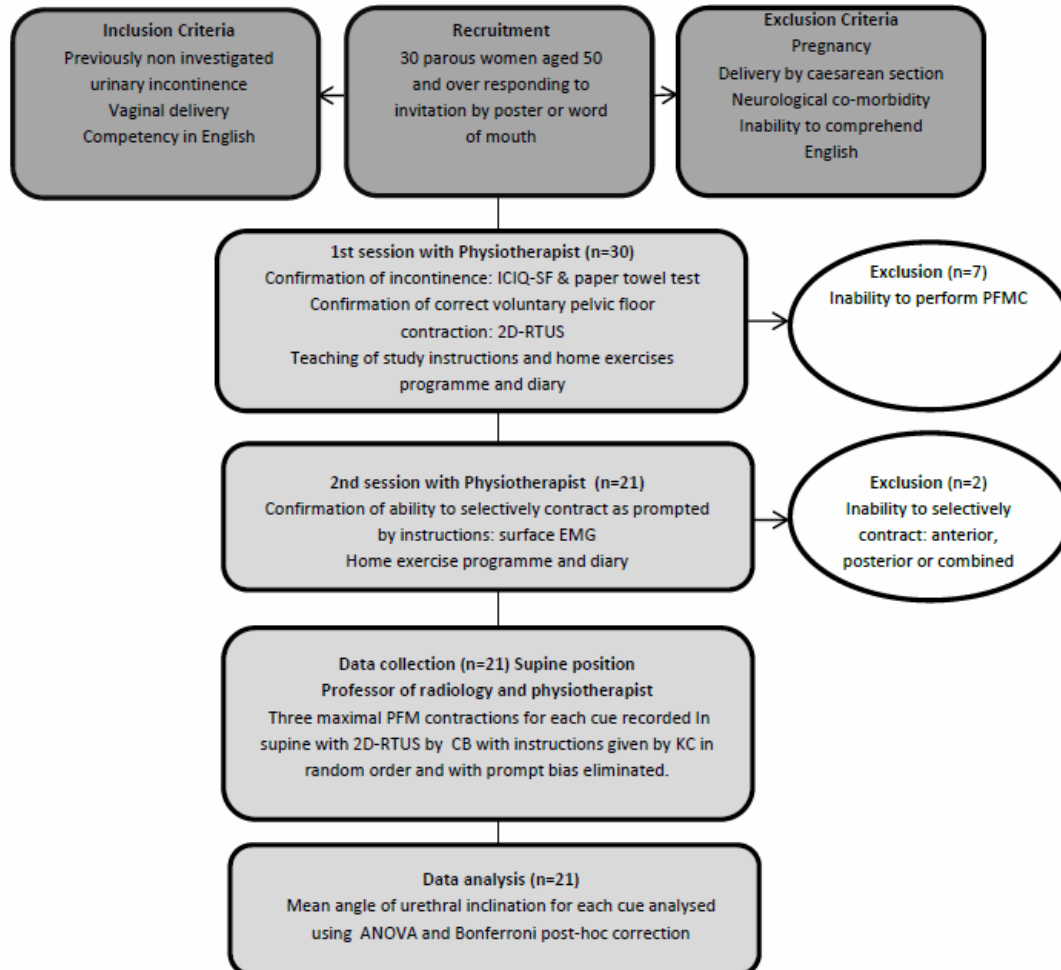
Data was collected in parous menopausal stress incontinent women for proof of concept of selective contraction of the PFM. Subjects were also questioned about cue preference prior to being taught the study cues, and following data collection (see Chapter 6.8.4). The age range in this cohort was chosen as menopausal because it was considered that the results from studies of oestrogen deficient and older women might be applied to pre-menopausal incontinent women more easily than applying results from a younger cohort to older women. The age range over 50 was chosen as it broadly reflects menopausal status. Confirmation of menstrual status was confirmed using a pragmatic approach (in the absence of blood tests to assess oestrogen levels) by asking the date of the last menstrual period. Inclusion was based on the absence of a menstrual period for at least the previous 12 months. All of the subjects reported the last menstrual period as more than twelve months previously and therefore all were included. Women with previously unreported symptoms were recruited in order that they were treatment naive.

Figure 5.1 Design for Study 1: Continent group



ICIQ-SF=International Continence Society Questionnaire Short Form; 2-D RTUS= 2-Dimensional real-time ultrasound imaging; KC= Kay Crotty; CB= Professor Clive Bartram

Figure 5. 2 Design for Study 2: Incontinent group



ICIQ-SF= International Continence Society Questionnaire Short Form; 2-D RTUS= 2-Dimensional real-time ultrasound imaging; KC= Kay Crotty; CB=Professor Clive Bartram

Sample size

Selective contraction of the PFM has not been previously studied and therefore it was not possible to undertake a power calculation based on published data. Sample size was therefore based on a previous observational trial of PFM contraction (Miller et al 2001).

These authors used a sample size of eleven continent and eleven incontinent subjects. It was considered reasonable to base the current study on this but to aim to approximately double the size. The aim therefore was to recruit twenty subjects to each cohort.

Informed consent

Each subject was required to give informed consent. It was a requirement that all subjects read and understood the Participant Information Sheets (PIS) (Appendix 3a and 3b), and that each had the opportunity to ask questions prior to agreeing to take part in the study and signing the consent form (Appendix 4). Informed consent was taken only if the researcher was satisfied that the subject was able to understand the conditions. Potential subjects were excluded if there was impairment of cognition or an inability to understand and/or speak the English language. For subjects recruited in a hospital setting a copy of the consent form was filed in the notes and a copy stored by the researcher. For those recruited in the community the original consent form was sent to the general practitioner of each subject with a letter at the start of the study (Appendix 5a and 5b). A letter was sent to each GP and each subject at the end of the study (Appendix 5c and 5d).

Cooling period

A cooling period between recruitment and start of the study process was set at seven days. This was included in the design in order that potential subjects would have time to reflect/ discuss the study with friends and/or family if they wished before committing to it, and to withdraw prior to the first session if they wished to do so, as described in The Research Governance Framework for health and Social Care (DOH, 2001).

5.4 Measurement Index Used

Urethrovesical structures of interest to this study are seen in Figure 5.3. The indices used to measure bladder neck position and angle of bladder neck rotation (AUI) are seen in Figures 5.4 and 5.5 whilst an example of the AUI is presented in Figure 5.6. The AUI was chosen for this study following preliminary investigation involving practice readings to investigate ease of identification of UVS landmarks.

5.4.1 Rationale for use of the angle of urethral inclination

In research studies, position of the bladder neck relative to the infero-posterior margin of the symphysis pubis and the γ angle between the symphyseal axis and a line from the symphyseal margin have been studied since the early 1990's (Wise 1992) (Figures 5.6 and 5.7). These indices have been found to be reliable (Schaer 1995; Peschers et al 1997). Bladder neck angle and position have been measured from the resting state of the PFM to maximal excursion. In the current study, comparisons were to be made between subtle differences in the end point of PFM contraction using different cues rather than from rest to maximal excursion. The differences between end points of the cues at maximal excursion were very small and easily subject to error and therefore accurate cursor placement was particularly critical. During practice readings, all images were first scanned through in an attempt to identify the margin of the bladder neck accurately. However, it was soon apparent that accurately identifying the superior ventral margin of the bladder neck was frequently problematic due to blurring. Such lack of clarity was likely to influence placement of the measurement cursor. By contrast, the urethral lumen was better defined and the AUI therefore easier to read.

The angle between urethral axis and pubic symphysis has been variously named the alpha angle (Sendag et al 2003); inclination of the urethra (Dietz et al 2002); the urethro-pelvic angle (Constantini et al 2005); or the angle of urethral inclination (Minardi et al 2007). The angle of urethral inclination (AUI) is in the opinion of this author the term that best describes this index because it is both explanatory and simple (rather than for example "the alpha angle" as described by Sendag [2003]) and therefore it was adopted for this study. Pregazzi et al (2002) discuss that bladder neck mobility relates to support of the proximal urethra, whilst mobility of the urethra relates to both proximal and distal urethral supports. The AUI may therefore be a more global measure of urethrovesical structures than measurement of the bladder neck alone. The AUI had been found to correlate strongly with bladder neck position and angle ($r=0.83-0.96$; $p<0.001$) (Dietz et al (2002). It has been used in observational studies (Sendag et al 2003; Constantini et al 2005; Minardi et al 2007) and is described as easily reproducible and identifiable (Constantini et al 2005).

Figure 5.3 Landmarks of Urethrovesical Structures

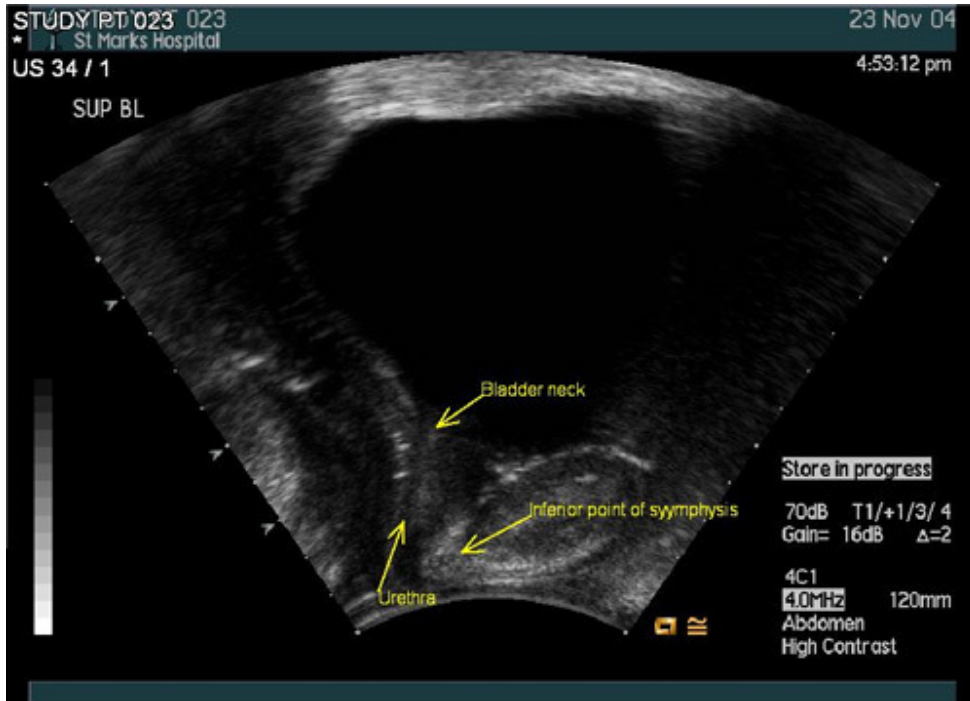
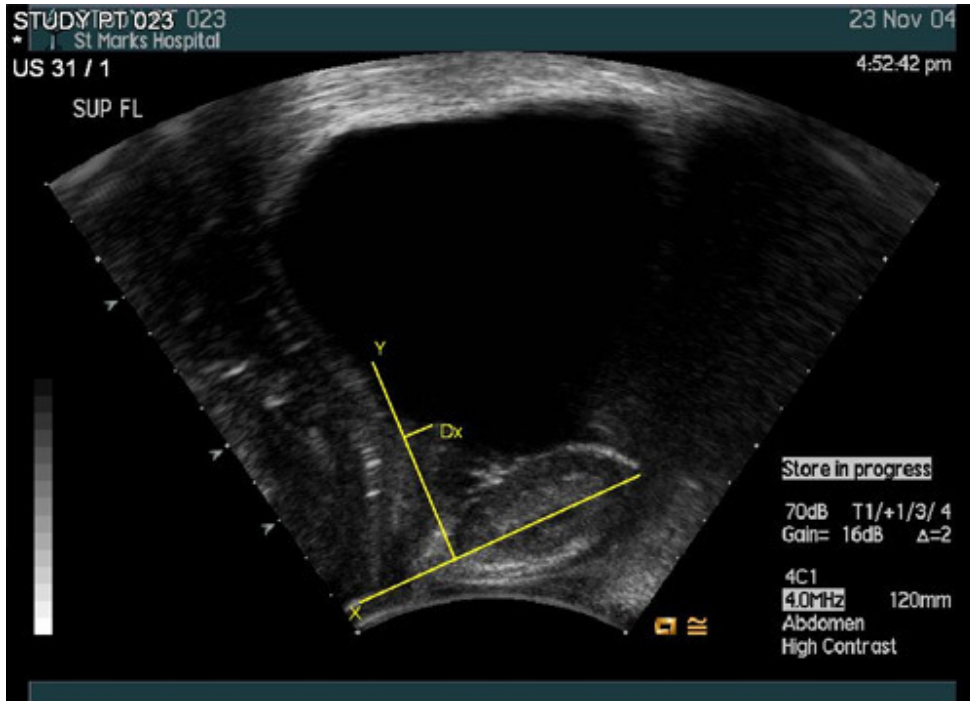


Figure 5.4 Bladder neck position

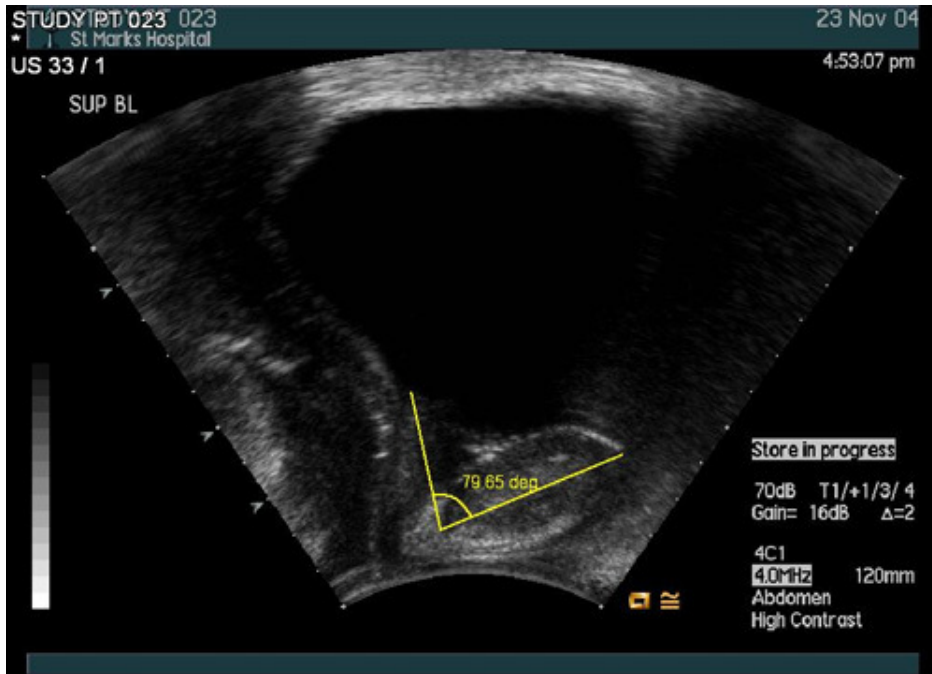


X represents axis through midline of the symphysis

Y represents axis intersecting the symphysis at 90° at the postero- inferior border of the symphysis

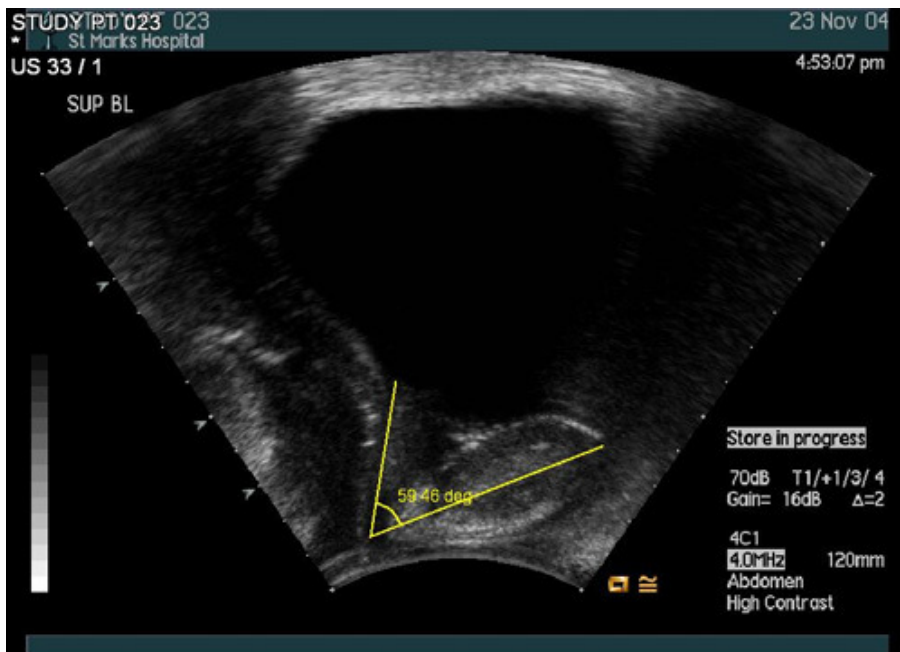
Dx represents the distance from the bladder neck to the y angle

Figure 5.5 Angle of bladder neck rotation



Angle between inferoposterior edge of the symphysis and bladder neck

Figure 5.6 Angle of urethral inclination (AUI)



Angle between mid axis of the symphysis and mid lumen of the urethra

5.5 Ethical Considerations

During study design, relevant ethical issues were given due consideration as documented in the Research Governance Framework for Health and Social Care (DOH: 2001). The programme of work was invasive and involved various intimate procedures. These issues are discussed here.

5.5.1 Intimate and invasive screening tests

Screening tests included paper towel test, vaginal digital examination, placement of electrodes on the anus, and perineal ultrasound in the standing as well as the supine posture. It is highly probable that many of these tests would not have been acceptable to a high proportion of women. Careful consideration was given to these at the planning stage with respect to issues of dignity such as allowing the subjects privacy to undress and dress; adequate covering of the lower body during the tests and ensuring a private assessment.

5.5.2 Coding for anonymity

Coding for anonymity was of the highest importance given the intimate nature of the procedures in this programme of work. Each subject was assigned a code number at the first session. This was stored with personal details in a file that was securely locked in a safe at the clinic of KC. The code appeared on investigator notes as well as on EMG and ultrasound output files. The investigator notes for each subject were stored in a locked cupboard that was inaccessible to the public in compliance with the Information Commission Office Regulations, incorporating the Data Protection Act (1998).

5.5.3 Informed Consent

Participant information sheets were prepared so that women would be fully informed prior to giving signed consent to the study (Appendix 3a and 3b). It was a pre requisite to signing a consent form (Appendix 4) that women could understand the content of the

PIS and be given the opportunity to ask questions. A cooling period of seven days was put in place to provide adequate time for women to withdraw after a period of consideration as previously discussed in 5.3.1.5. Subjects were advised that they were at liberty to withdraw at any stage during the study process without providing a reason for withdrawal and that withdrawal would not affect any ongoing treatment. At each screening session informed verbal consent was obtained.

5.5.4 Ethical approval

Ethical issues were approved by Harrow Local Research Ethics Committee (HREC) in April 2004 (04/Q0405/1) and the programme of work was approved by the UH research degrees committee in May 2004 (04/12/83).

5.5.5 Ethical developments

Developments with respect to some ethical issues arose during some of the screening tests. These are discussed in description of methodology for digital palpation (see 6.3.2.3); EMG electrode (see 6.3.3) and postural position (see 6.6.2.1).

5.6 Study Collaborators

The study was undertaken in collaboration with Northwick Park and St Marks Hospital Trust, Harrow. Miss Joan Pitkin BSc, FRCS, FRCOG Consultant Urogynaecologist at Northwick Park Hospital (NPH) contributed to study design and editing of manuscripts. Professor Clive Bartram FRCP, FRCS, FRCR, Consultant Radiologist at St Mark's Hospital (and latterly of The Princess Grace Hospital central London) contributed to study design, preliminary work, collected all of the data and edited manuscripts. Mr Dave Chatoor FRCS, Surgical Fellow at St Mark's hospital read the data for reliability purposes.

In addition to external collaborators, Dr Mindy Cairns PhD, MSc MCSP, MMACP, of the University of Hertfordshire was principal supervisor and contributed to design. Dr

Paul Taylor DipMathsStat (Cantab), BSc, FSS, also supervised and contributed to statistical design and statistical tutorials training. Professor Grace Dorey MBE PhD FCSP of the University of West of England contributed to study design and supervision of write up.

5.7 Programme of work

In preparation for the overall programme of work, preliminary planning was required such as contacting potential collaborators and organising relevant training. A summary of early work is presented in Table 5.1.

Table 5.1 Summary of early work

Spring 2003	Inception of study design	Study design evolved in response to a clinical question of KC with respect to selective contraction of the PFM
	Literature reviews	Early literature reviews were undertaken to inform the research proposal and study design
	Initial contact with University of Hertfordshire	Draft study design was presented to post graduate research team in the School of Physiotherapy. Enrolment agreed
	Initial contact with surgical/imaging collaborators	Study design was presented by KC to JP at NPH and CB at St Mark's Hospital
	Design of study	The design of the study with collaborators
	Permission to use existing screening tool	Permission was sought and gained to use selected questions from the BFLUTS questionnaire
	Trial of screening tests	This was undertaken as part of the programme of work in five subjects currently on treatment with KC. This included paper towel test, EMG, bladder filling, cues to instruction.
Autumn 2003	Trial of data collection process and analysis	Data collected by CB with KC observing (180 images)
	Training to read data	Training comprised a tutorial of approximately 45 minutes by CB on identifying UVSs on US images and using the measurement software
Winter 2003/4	Practice reading of images	The 180 training images were read repeatedly over several months using AUI, bladder neck position and angle of bladder neck rotation. It is estimated that Over 4000 measurements were made. A further 4000 were made during analysis
	Decision to use angle of urethral inclination	The decision to use AUI was made by KC and CB based on ease of measurement as found in practice measurements
	Contact with sponsors	KC sought sponsors to supply equipment for EMG and US measurement software
Spring 2004	Preparation and Ethics submission	KC prepared ethics submission documents and defended them before HREC and UH research degrees committee
	Spring 2004 Initial research methods training	Attendance at a two week M level research methods module (MTPY 0015)
<p>KC= Kay Crotty; PFM=pelvic floor muscle; JP=Joan Pitkin; NPH= Northwick Park Hospital; CB= Clive Bartram; EMG=Electromyograph HREC=Harrow Research and Ethics Committee; BFLUTS Bristol female lower urinary tract questionnaire; UVSs= urethrovesical structures; US= ultrasound AUI angle of urethral inclination UH=University of Hertfordshire</p>		

5.7.1 Literature reviews

Literature reviews started at the inception stage and continued through the length of the programme (Table 5.2). Searches of the computerised databases Medline; AMED (Allied and Alternative Medicine database); CINHAL (Cumulative Index to Nursing and Allied Health Literature), EMBASE (Excerpta Medica Database) and The Cochrane Library Database were undertaken periodically. Hand searches of references, citations, conference abstracts; and textbooks were also undertaken. Investigation into the earlier literature was facilitated by sourcing a textbook of surgical procedures (not held at the British Library but sourced by a search of international book sellers) (Ullery 1953). The programme of works for the literature review is presented in table 5.2.

Table 5.2 Programme of work for literature reviews

Literature reviews
Pelvic floor muscle/levator ani terminology
Epidemiology of SUI
Aetiology of SUI
History of management of SUI: conservative and surgical
Anatomy of the small pelvis
Current opinion of the anatomy, terminology and function of puborectalis muscle
Parturition trauma to the PFM
Outcomes in PFM training for SUI
Ability to effectively contract the PFM
Self report and subjective tests for continence status
EMG
Methodology for perineal ultrasound
Surgical literature for urinary continence
Continence mechanisms
Relevance of bladder neck position in urinary continence and current opinions
Medical/surgical studies of imaging of urethrovesical structures
Physiotherapist led studies of imaging of urethrovesical structures
Imaging studies investigating selective contraction of the PFM
Instructions commonly used for a PFM contraction in surgical/medical PFM research
Instructions commonly used for a PFM contraction in physiotherapy PFM research
World Wide Web search for instructions for a PFM contraction in surgical and physiotherapy organisations
World Wide Web Search of instructions in the media for a PFM contraction
Self efficacy
Pelvic organ prolapse and the pelvic floor
Low back pain and the pelvic floor

5.7.2 Training

Training for reading data

A training need was identified for KC to read UVSs on the US images. A training Session with CB took place and measurement software acquired for laptop use.

Pre preliminary work involved reading more than 4000 images (Table 5.1). At the end of this subjective analysis of intra rater reliability was considered sufficient to read the main data. The main continent data were read and re read twice amounting to a further 4000 measurements. Inter rater reliability was seen to improve when the second reading of KC was used for comparison with the readings of DC (7.1.2). This may have been due to practice effect and is discussed further in 8.1.

Generic training

Generic training at UH included Introduction to the Learning Resource Centre; Supervisor Relationships; Teaching for Research Students, PowerPoint XP; Excel XP; Getting Started with SPSS; Relationships in Data; Research: Science and Truth; Public Understanding of Science; Comparing Groups and Thesis Writing.

5.7.2 Progression

A conversion document of 11,500 words was prepared and subsequently defended by KC in October 2007 at UH in order to progress to PhD candidacy.

5.7.3 Suspension of Studies

Circumstances led to KC becoming a co-carer for a young family member firstly over two years from 2005 (as data collection from Study 1 was just being completed) and then from 2008 to date. These changes in circumstances led to suspension of studies for prolonged periods of time, hence the delay in submission of the dissertation.

5.7.4 Dissemination of work

Dissemination of various elements of the programme of work was ongoing as results began to emerge. Details are presented in Appendix 6.

5.7.5 Summary of work undertaken during write-up

Work undertaken during write up has been extensive and has included personal correspondence with authors for clarification of issues arising in literature reviews. Permissions to reproduce diagrams through the dissertation have been obtained directly from authors holding copyright and from publishing companies.

Summary

Two feasibility studies using a pragmatic approach were designed. The hypothesis was that posterior or combined cues are more effective in optimising UVS position than an anterior cue. Preliminary aims were to investigate the reliability of 2D-RTUS and training requirements for a non radiology AHP. The principal aim was to investigate the effect of selective voluntary contraction of the PFM on the urethra in women with and without SUI. Secondary aims were to investigate the effect of posture on AUI, ability to selectively contract the PFM and cue preference. Ethics approval was gained from the Harrow Research and Ethics Committee and approval gained from the Research degrees Committee at the University of Hertfordshire. Two-dimensional RTUS was used to investigate change in AUI on selective PFM contraction. An extensive programme of work underpinned the study.

Methodology for the study process leading to data collection is discussed in the following chapter.

Chapter 6 Methodology 2: Study process and Data Collection

6 Introduction

Methodology for the programme of work was developed with all study collaborators. The contributions by individual collaborators and supervisors are detailed in Chapter 5.6. All remaining methodological issues are discussed here.

6.1 Recruitment

6.1.1 Study 1

Invitation posters were displayed in Gynecology clinics at NPH (Appendix 7a). Kay Crotty attended 67 gynecology clinics. On arrival at clinic, KC identified potential subjects via patient notes. Nursing staff approached potential subjects, introduced the study briefly and offered participant information sheets (Appendix 3a). Interested potential subjects were directed to KC who explained the protocol and made an appointment for the first study session if the patient decided to participate.

Eighteen women were recruited from gynecology clinics, from which eight sets of data were ultimately collected. Amendment was granted from HREC to extend recruitment into the community and the recruitment poster was adapted appropriately and displayed at the workplace of KC. Further subjects were recruited by poster invitation and by word of mouth due to snowballing effect (Aitken et al 2003). This effect resulted in 13 health professionals being recruited to the study. Thirty eight continent women in total were recruited (Figure 5.1).

6.1.2 Study 2

Women responded to poster invitation (Appendix 7b) at the workplace of KC or by word of mouth as discussed in 6.1.1. Potential subjects were supplied with the

PIS prior to an appointment being booked (Appendix 3b). Thirty incontinent women in total were recruited (Figure 5.2).

6.2 Pre-session Requirements

6.2.1 Consent

All subjects gave informed written consent at the start of the first session and verbal consent at each remaining session as detailed in 5.4.4.

6.2.2 Bladder Filling Routine

Bladder volume at data collection was not fixed because this would have required invasive bladder filling via a urethral catheter and would have introduced the risk of infection. However, this was not considered problematic as a fixed volume has been described as unimportant unless looking for bladder neck funneling (Schaer 1996). A relatively full bladder however provides greater clarity for reading images and for this reason subjects were asked to follow a filling routine prior to 2-D RTUS. All subjects were therefore requested to arrive at the first session and at data collection having refrained from voiding for 2 hours prior to the scheduled appointment time and to have drunk 400mls of water one hour before the session (Miller et al 1998). This protocol was found to be inadequate during the hot summer months in three subjects and therefore all remaining subjects were asked to drink 500 mls one hour before the session.

6.2.3 Exercise Diaries

All subjects were asked to keep an exercise diary in order that practice effect was similar between subjects (Appendix 8). In recognition that it may not always have been possible for subjects to practice the regime twice per day or every day it was decided that subjects should have performed 80% of the prescribed exercise sessions in order to progress to the next stage, as evidenced in the diary. All subjects met the minimum requirement of 80% compliance.

6.3 Screening during the study process

6.3.1 Confirmation of continence/incontinence

Study 1

Confirmation of self-reported continence/incontinence was undertaken at Session 1. Written permission was acquired from the author of the Bristol Female Lower Urinary Tract Symptoms Questionnaire (BFLUTS) (Jackson 1996) to use three selected questions (Appendix 9a and 9b). All subjects self reported continence using this tool.

Study 2

In Study 2 a minor amendment was approved by HREC to use the ICS Urinary Short Form Questionnaire (ICIQ-SF) (Avery et al 2004). This is a shortened version of BFLUTS and was published after the start of Study 1. It was selected for Study 2 as it has three scored questions in its entirety and therefore it was not necessary to reduce it (Appendix 10). It also provides non scored questions relating to MUI which was of interest. Permission to use ICIQ-SF for research purposes is not required for academic institutions or clinicians:

(<http://www.iciq.net/userpolicy.html>). The aim of using ICIQ-SF was confirmation of incontinence. However collected total scores were subsequently found to be of interest. The results for severity scoring (Klovning et al 2009) are presented in Table 6.1 and are discussed further in 8.4.

Table 6.1 ICIQ-SF (Klovening et al 2009)

ICIQ-SF scores			
Range 4-14 Mean 7.95 (SD =3.05)			
Severity of SUI		n=21	% in group
Slight	1-5	4	20%
Moderate	6-12	15	70%
Severe	13-18	2	10%
Very severe	19-21	0	0%

ICIQ-SF= International Continence Society
Urinary Incontinence questionnaire-short form

Both studies

All subjects underwent paper towel test as described by Miller et al (1998). A tri-fold paper towel was self-placed in the gusset of the underclothing and self-held in place. The subject was then asked to cough deeply three times. Continence was confirmed by a dry pad and incontinence by leakage onto the towel. All continent subjects in Study 1 had a negative test and vice versa for all subjects in Study 2.

6.3.2 Assessment to confirm effective voluntary PFM contraction

Assessment of the ability to adequately contract the PFM was undertaken during the first session using perineal 2D-RTUS and/or digital vaginal examination in the supine position.

Method for digital palpation

Method used was that of Laycock (1994). A gloved and lubricated finger was introduced to the vagina to rest on the levator ani at the 5 o'clock and 7 o'clock positions. The subject was asked to "contract your pelvic floor muscles". An upward lift of the examining finger indicated a valid contraction (Laycock 1994).

In those who did not achieve lift, further varying instructions/imagery favoured by this author in clinical practice, were used to try and facilitate voluntary contraction i.e. “imagine you have swallowed a fishing hook and line and as it is being pulled out your pelvic floor is pulling up with it” or “imagine your back passage has a purse string around it and you are tightening the purse string” or “place your hand over your sacrum and imagine it is sliding upwards as you glide your hand upwards your head”.

Method for perineal 2-D RTUS

A Urosonic™ perineal 2-D RTUS unit used in the workplace of KC was used for imaging. A gloved curved array probe with gel was placed midline on the labia in a sagittal plane to obtain a view of the bladder, bladder neck, urethra and pubic symphysis in its entirety (Schaer et al 1995). Those subjects who did not achieve lift were invited to look at the screen for the purpose of biofeedback to try and facilitate upward lift on voluntary contraction. Those who were not able to effectively contract the PFM by the end of the session were excluded (Tables 6.3 and 6.4).

Digital vaginal examination: methodological development

After the first 20 subjects, use of vaginal digital examination was discontinued because although it is considered the gold standard for PFM assessment in clinical practice, it yielded no more information than perineal 2D-RTUS alone in assessing effective PFM contraction. This supports the literature that shows agreement between digital palpation and perineal 2-D RTUS assessment (Mouritsen et al 1999; Dietz et al 2002). A minor amendment to discontinue use of vaginal assessment was approved by HREC.

6.3.3 Indication of selective recruitment: EMG biofeedback

Surface electromyographic (EMG) bio-feedback was used to provide rudimentary intra-subject information with respect to regional recruitment of the PFM. It

provided subjective indication of whether instructions were being followed adequately when prompted by the various cues. It was undertaken in Session 2.

Electrodes used

A 3.2cm standard TNS electrode trimmed to quarter size, was placed on the anus by the operator. A square 5x5cm indifferent electrode was placed on the thigh.

Electrodes: methodological development

After the first 11 subjects this method was replaced by the self-placed Periform® Intra-Vaginal Probe electrode. Operator placed anal electrodes were initially used for EMG biofeedback because it was considered that this was the most suitable method for recording differences between the anterior and posterior pelvic floor compartments. However, migration of electrodes was found to be problematic and the subjects did not find the procedure completely acceptable due to the intimate nature of placement of the electrodes. Remaining subjects were offered the choice of operator placed anal electrode or self placed vaginal electrode and all selected the latter. The vaginal electrode demonstrated similar differences to the anal electrode and therefore discontinuation of use of the anal electrode was considered reasonable.

Recording

Recording was undertaken using the NeuroTrac 2.0.6 “work rest assessment” software which was programmed to record a five second contraction followed by a five second rest, repeated five times. There was a break of three minutes between tests. Subjects were blinded from the screen. A work/rest assessment was performed for each cue in random order. This was undertaken in the supine position in all subjects and also in standing in the continent cohort. Following a five minute break the entire process was repeated in order to provide indication that the subject was able to repeat adequately. The EMG tracings were observed in real-time and a consistently lower reading in peak power with the anterior cue

to instruction as compared to the posterior or the combined cue to instruction was taken to indicate that instructions were being followed adequately. An example of an EMG study that provides indication of the ability to adequately follow instruction is presented in Appendix 11a. EMG example of biofeedback in a subject unable to follow instruction adequately is presented in Appendix 11b. Examples of EMG values in the first ten subjects who were able to demonstrate the ability to follow instructions and in three subjects who were not are presented in Appendix 11c. These values are for intra subject observation only (see 8.5).

Observations during EMG biofeedback

EMG observation provided indication that 13% of the continent cohort and 7% of the incontinent cohort were unable to selectively contract the PFM. These subjects were excluded from data collection (Tables 6.3 and 6.4).

.

6.4 Teaching of Selective Cues to Instruction

All subjects were blinded to the study hypotheses throughout the study process. Cues to instruction were taught at the first study session. All Subjects were given verbal instruction to voluntarily maximally contract the PFM using three different cues to instruction as presented in Table 6.2. These instructions were included in the exercise sheet incorporating an exercise diary that was given to each subject (Appendix 8). Subjects were instructed to attempt to minimise accessory muscle recruitment during PFM contraction

Table 6.2 Differing cues to instruction used in this study

Anterior	Squeeze and lift from the front as if stopping the flow of urine
Posterior	Squeeze and lift from the back as if stopping the escape of wind
Combined	Squeeze and lift from the front and back together

6.5 Practice Period

The exercise regime was practiced for two weeks prior to each subsequent session. Miller et al (1998) used a practice period of seven days to allow for the acquisition of a new proprioceptive skill in The Knack (4.2.1.1). It was considered that a greater length of time may be necessary for subjects to become proprioceptively confident of the ability to selectively contract the PFM. Where 14 day scheduling was difficult for reasons of inconvenience for the subject, the subject was advised to practice for seven days following the first appointment and seven days before the second appointment in order that practice effect would be similar between subjects.

6.6 Posture

6.6.1 Supine

Supine examination posture was with knees bent and hips flexed at 60° with feet comfortably apart. Subjects were taught to find the neutral pelvic position with the spine maintained passively in a comfortable mid-range position between flexion and extension (Sapsford et al 2001).

6.6.2 Standing

Ultrasound assessment was performed in standing in Study 1 only, with feet comfortably apart and knees held comfortably straight.

6.6.3 Standing position: methodological development

A factor that strongly influenced the decision to discontinue investigation of the standing posture was that both operator and subjects found the standing posture less acceptable than the supine posture due to issues of dignity. This stance was supported by the results that demonstrated that posture does not affect absolute AUI (Table 7.5a). This is further discussed in Chapter 8.5.

6.7 Attrition

6.7.1 Withdrawals

There were 11 withdrawals in Study 1 (Table 6.3) but none in Study 2 (Table 6.4) (see 8.4).

6.7.2 Exclusions

In Study 1, 12.5% of the subjects were unable to effectively perform a voluntary PFM contraction. In Study 2 this figure rose to 23% (Tables 6.3 and 6.4). With respect to inability to selectively contract, in Study 1, 13% were unable to selectively contract and in Study 2 this figure was 7%. Exclusions are presented in Table 6.3 and Table 6.4. Description of the occupations of those excluded is presented in Table 6.5 (see also 8.4).

Table 6.3 Study 1: Attrition

Period	Numbers	Reason for Withdrawal/Unsuitability
Cooling	6 (19%)	Hospital admission following RTA <i>n</i> =1 Reasons unknown <i>n</i> =5
After 1 st session	9 (29%)	Unable to perform a correct upward going voluntary PFMC <i>n</i> =4 Developed unacceptable low abdominal ache during the home exercise programme <i>n</i> =1 Felt the study was too invasive <i>n</i> =1 Reasons unknown <i>n</i> =3
After 2 nd session	3 (13%)	<i>n</i> =3 Unable to selectively contract the PFM as indicated by EMG

RTA= road traffic accident PFMC= pelvic floor muscle contraction EMG=Electromyographic

Table 6.4 Study 2: Attrition

Period	Numbers	Reason for Withdrawal/Unsuitability
Cooling	<i>n</i> =0	N/A
After 1 st session	<i>n</i> =7 (23%)	Unable to perform a correct upward voluntary PFMC
After 2 nd session	<i>n</i> =2 (8%)	Unable to selectively contract the PFM as indicated by EMG

Table 6.5 Description of occupations in excluded subjects: Continent subjects

	Unsuitable for inclusion due to an inability to perform a correct PFMC	Unsuitable for inclusion due to an inability to distinguish between compartments
Non-health professionals <i>n</i> =19	<i>n</i> =2 (10%)	<i>n</i> =2 (10%)
Health Professionals <i>n</i> =13	<i>n</i> =2 (15%) (1 physiotherapist; 1 gynaecology nurse)	<i>n</i> =1 (8%) (1 midwife)

6.8 Data Collection

Introduction

Two-dimensional RTUS data was collected for Study 1 by CB at St Mark's Hospital Harrow. KC was present to lead instructions. CB retired from NHS practice after Study 1 and may not have collected the data for Study 2. However consistency of operator was desirable due to variation in pressure applied to the probe between operators which can be an issue (Schaer 1996). Whilst having time constraints due to retirement, CB kindly agreed to collect a further 20 data sets in supine for the study at The Princess Grace Hospital in central London. A substantial amendment for this change was approved by HREC. Descriptions of age and BMI for the final data sets are presented in Tables 6.6 and 6.7

Table 6.6 Characteristics: continent subjects

<i>n=17</i> Health professionals <i>n=9</i> Non health professionals <i>n=8</i>	Range	Mean (SD)	SD	Ethnicity
Age	24-47	34	5.39	Caucasian <i>n=15</i> Asian <i>n=1</i>
BMI	18-36	24.7	4.08	Black African <i>n=1</i>

Table 6.7 Characteristics: incontinent subjects

<i>n</i>=21 (all non health professionals)	Range	Mean (SD)	SD	Ethnicity
Age	51-69	55.61	5.10	Caucasian <i>n</i> =20
BMI	21-34	26.54	3.06	
*Parity	1-4	2.14	0.72	Asian <i>n</i> =1
Heaviest baby (kg)	2.6 - 4.2	3.6	0.43	
Years since delivery	6-35	19.19	8.06	
Months since onset of SUI	24-192	54.34	70.35	
Forceps	2			
Ventouse	1			
Episiotomy	5			
Tear only	8			
Third or fourth degree tear	0			
HRT	3			
SUI	11			
MUI	10			
Faecal incontinence	0			
Symptoms of POP	0			
*Total number of deliveries in cohort <i>n</i> =46				
BMI=body mass index HRT= hormone replacement therapy SUI= stress urinary incontinence MUI= mixed urinary incontinence POP= pelvic organ prolapse				

6.8.1 Bladder volume for data collection

Bladder volume was assessed immediately prior to data collection by CB using a trans abdominal approach. A minimum volume of 150 mls was the cut off point for scanning in order to clearly view the urethra and urethrovesical junction.

Bladder volume varied from 25mls to 507 mls (mean 308; SD: 133). Early on in the study, two subjects did not have sufficient volume for scanning. They were asked to drink a further 400mls and were imaged again after one hour at which time each had sufficient volume for data collection. It was after this development that the change to the filling protocol was made as discussed previously in 6.2.2.

6.8.2 Ultrasound data collection

In random order each subject was asked to perform three brief maximal PFM contractions using each of the study cues to instruction (Table 6.2). The specific

study instructions only were used, and were only given once in order to avoid instruction/prompt bias between subjects. The peak of each contraction was captured on-screen. There was a 5 second rest between contractions. This process was repeated after 5 minutes for reliability purposes. This was performed in supine in Studies 1 and 2 and also in standing in Study 1. There was a five minute break between postures and repetition. Following data collection, three subjects accepted the invitation to attend for pelvic floor physiotherapy (appendix 3a and 3b).

6.8.3 Cue preference

At the first session women were asked how they would normally perform a PFM contraction. The questions were asked (verbally): from around the front; from around the back; from the front and back together; from around the vagina and “other”. At the end of data collection (Session 3) the questions were repeated. Answers were recorded in the investigator notes for each subject. Results are presented in Table 7.9.

6.9 Data Management and Analysis

6.9.1 Data management

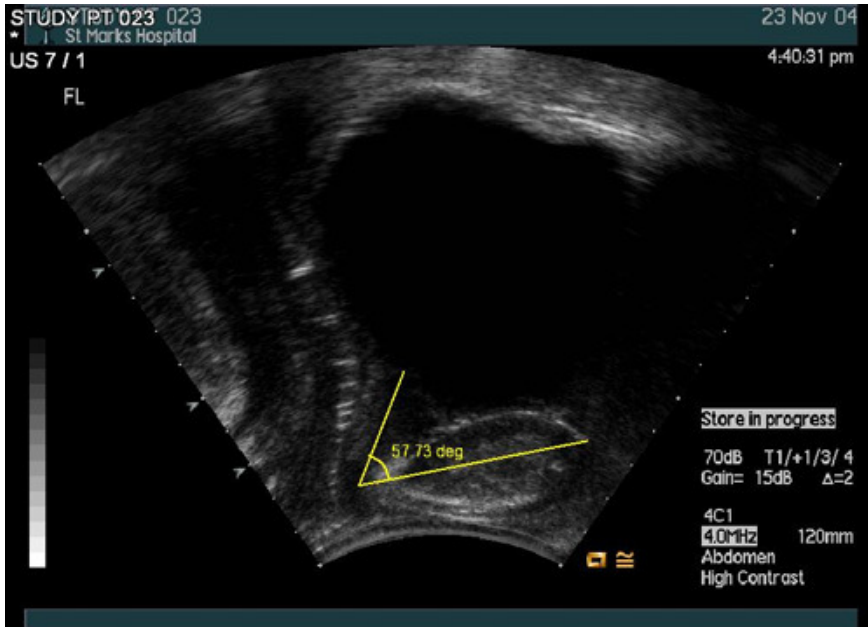
Ultrasound images were transferred to disc to be loaded onto personal computers. Images were read using an integral measurement software system: JiveX [dv] DICOM Viewer Version: 4.0.1 software (Bochum, Germany). Three sets of data were lost due to failure to save the data onto disc immediately so that they were wiped during routine clearing of the main frame by personnel unrelated to the research team. Future data sets were saved immediately.

6.9.2 Reading of images

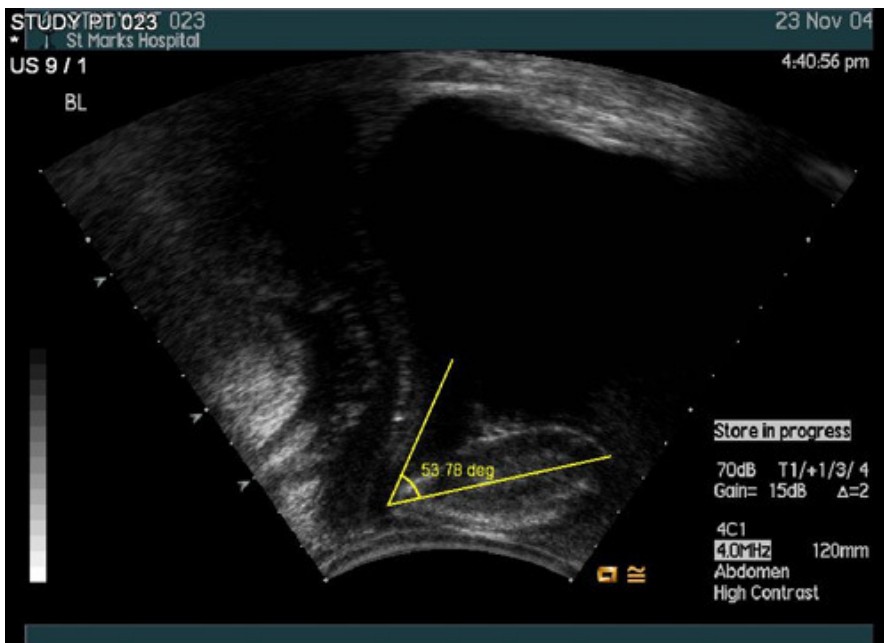
Throughout the process, the readers (either KC or DC) were blinded to the subject code and cue. An example of a set of images for one test is presented in Figure 6.1i-iii. All images were read twice by KC and once by DC.

Figure 6.1 i-iii Example of a set of images with measurement for one test

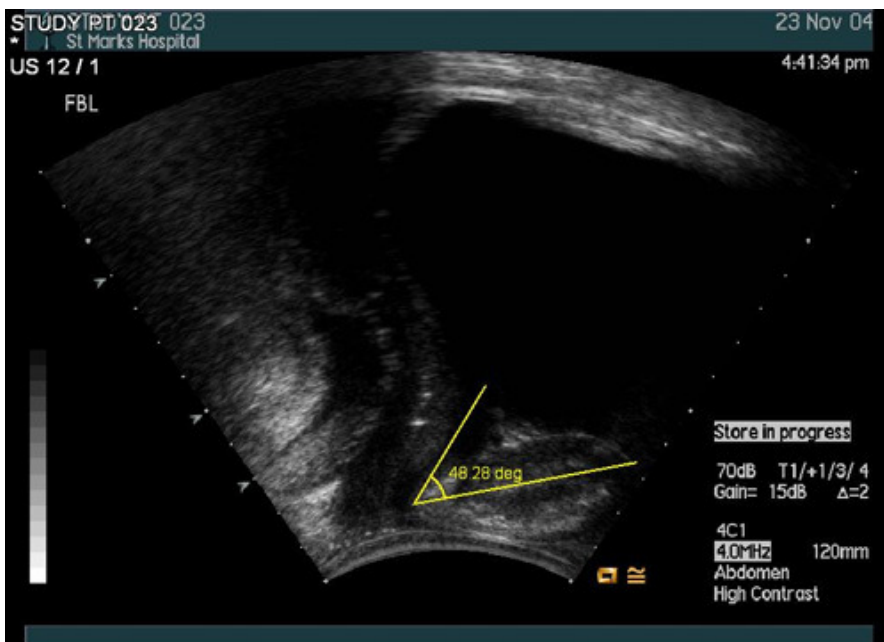
i. anterior cue



ii posterior cue



iii combined cue



6.9.3 Values for analysis

The mean measurement for each of the three PFM contractions for each cue to instruction was taken as the value to be used for analysis (Thompson et al 2005; Frawley et al 2006). Raw data is presented in Appendix 12.

6.9.4 Available data sets

In the continent group, 17 data sets were available for analysis in supine. Fourteen data sets were available for analysis in standing as three sets were found to have one or more image that was not of suitable clarity for analysis. In the incontinent group, 21 data sets were available for analysis in supine.

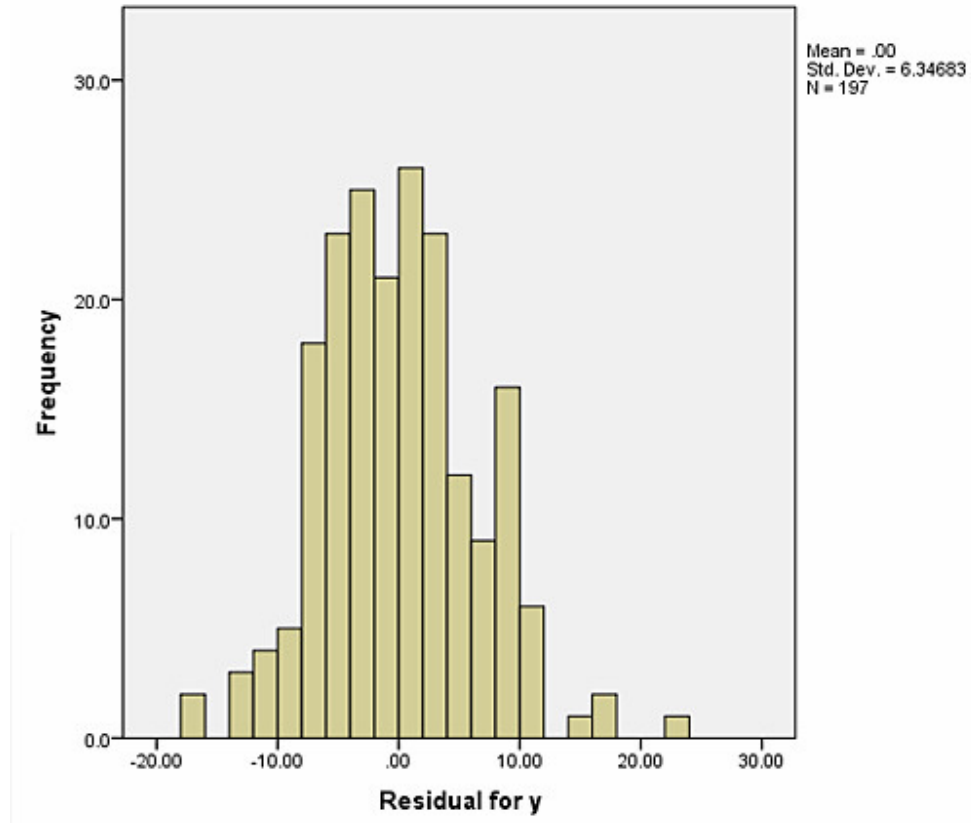
6.9.5 Statistical software

In both groups data sets were entered into SPSS versions 14.0 to 21.0 (Chicago).

6.10 Data Analysis: Distribution

Because data were normally distributed, parametric analysis was used (Figures 6.2 and 6.3).

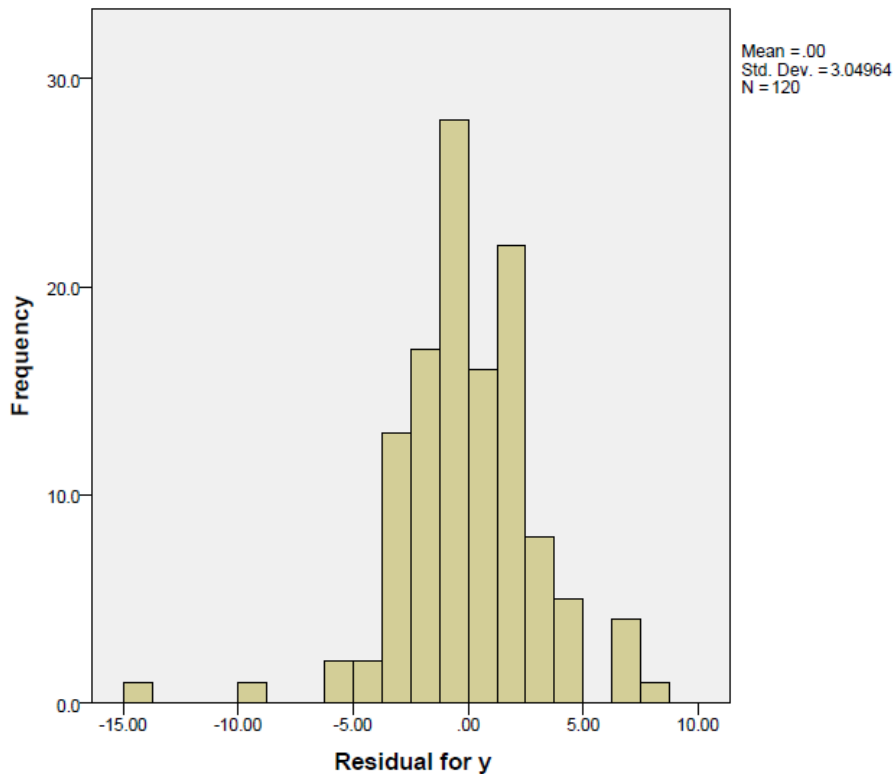
Figure 6.2 Distribution of data: continent group



x axis= degrees for residuals around the mean

y axis=frequency of observations

Figure 6.3 Distribution of data: incontinent group



x axis= degrees for residuals around the mean

y axis=frequency of observations

6.11 Data Analysis

6.11.1 Intra and inter rater reliability and subject repeatability

Intra class correlation (Shrout and Fleiss 1979)

Intra and inter rater reliability testing were undertaken in Study 1. Subject repeatability was undertaken in both studies. Each of these was analysed using Intraclass Correlation (ICC) (Shrout and Fleiss 1979), for which there are various equations as discussed by Rankin and Stokes (1998). Each equation may produce

different results, and therefore the method should be chosen carefully according to experimental design and potential use of the results. Each equation is indexed by two integers. The first relates to the situation and the second to the target being rated. For inter rater reliability, the aim was to be able to generalize the results to other raters within a similar population of professionals concerned with the small pelvis. This is possible using ICC [2,1]. The first integer relates to the situation, wherein the raters (KC and DC) are considered random effects so that the results are applicable to future random raters (Rankin and Stokes 1998). The second integer relates to the single target of analysis (each measurement). Intra rater reliability and subject repeatability are both investigations of repeatability. The former analyses repeatability of a rater, and the latter repeatability of a research subject. The results for repeatability in this study are less easily generalisable to future studies because of wider expected variations and therefore ICC [1,3] was ultimately selected (Rankin and Stokes 1998). The first integer refers to there being one area of interest i.e. one ultrasound rater or one subject. The second integer relates to the target being the mean of three measurements. In Study 1, ICC [2,1] was initially used for intra rater reliability (Crotty et al 2011). During subsequent discussions within the team it was agreed that ICC [1,3] was more appropriate. The results were very slightly stronger using ICC [1,3]. It was not considered necessary to contact the publisher of the journal: *Neurourology and Urodynamics* (in which the result using equation [2,1] had already been published [Crotty et al 2011]) with an addendum for this positive change (rather than a negative). Results for all of these tests are presented in Chapter 7.1.

Bland and Altman Analysis (1986)

Intraclass correlation gives no indication of actual measurement or ranges. Therefore where further investigation was considered of interest due to results being on the limits of acceptability, the method of Bland and Altman (1986) was used to produce difference versus means plots in order to easily observe how far differences were from the means, and plots of equality between means.

Intra rater Reliability

The results for intra rater reliability were robust using ICC [2,1] and [1,3] (Crotty et al 2011) (see 7.1.1).

Inter rater reliability

Analysis ICC [2,1] was performed using the data of KC's first reading versus DC's reading. Bland and Altman analysis (1986) was considered of interest as the results were on the limits of acceptability (see 7.1.2; Figures 7.1 and 7.2). Of interest was comparison of KC's second reading with DC's reading. Therefore ICC [2,1] and Bland and Altman analysis (1986) were also undertaken for KC's second reading vs DC (Crotty et al 2011) (see 7.1.2; Figures 7.3 and 7.4).

Repeatability

Study 1: Investigation for repeatability was undertaken using ICC [1,3]. Further investigation was of interest due to slightly weak results (see 7.1.3.1). Bland and Altman analysis (1986) subsequently demonstrated some outliers (Figures 7.5 and 7.6). This distortion suggested that a Type II error may have been present that was likely to be eliminated in a larger sample (investigation of a possible Type II error is further discussed in 6.11.4). To begin to test this suggestion, reduced analysis excluding the outliers was run (see 7.1.3.1; Figures 7.7 and 7.8).

Study 2: ICC [1,3] was run. The results were robust (see 7.1.3.2).

6.11.2 Selection of ANOVA method and post hoc contrast

Testing was undertaken in Study 1 in order to validate fundamental study design before moving to Study 2. Analysis of Variance (ANOVA) was used to assess if the means between independent variables/stimuli (cues) were or were not equal. A Customised General Linear Model (GLM) ANOVA was used as this is an overarching model that is convenient. Where ANOVA reveals that the variance ratio is statistically significant, post hoc contrast analysis is necessary because

ANOVA alone is not capable of indicating where the differences between variables lie. Post hoc tests enable this by grouping of means. There are various post hoc contrast methods but the Bonferroni is the most commonly used because it is highly flexible and simple to compute, and can be used with any type of statistical test (Newsom 2006). It is also important because it produces Confidence Intervals (CIs). Confidence Intervals are important in interpreting the results of a study because they show a range within which the true treatment effect is likely to lie. A probability (p) value alone cannot provide this information (Davies 2001).

6.11.3 Studies 1 and 2: Initial Customised GLM ANOVA

Customised GLM ANOVAs with post hoc Bonferroni correction with a significance level of 0.05 were used to test interactions between subjects, cues, postures and tests in Study 1. Four customised GLM ANOVA's, one for each posture and each test were produced (Table 7.1 i-iv). The results of the repeatability tests were reflected in these results (Table 7.2).

In Study 2, a customised GLM ANOVA with post hoc Bonferroni correction with a significance level of 0.05 was used to investigate interactions between subjects and cues using data from Test 1 (Table 7.6).

6.11.4 Study 1: Investigation of possible Type II error

Results for subject repeatability (see 7.1.3) were on the limits of acceptability and were reflected in the ANOVA results (Table 7.2). Further investigation was necessary to continue to explore the possibility of a Type II error as suggested by these findings.

Investigation of paired differences between postures

Investigation of paired differences between Test 1 and Test 2 for the supine and standing positions was undertaken using a paired t test to investigate why the results for re test in the supine posture failed to reach statistical significance as compared to the results in standing (Table 7.3). The strength of the t test results

for supine re-test compared with standing re-test provided reassurance that these results were probably a Type II error that would be eliminated in a larger sample. Confirmation with scatter plots for the t test (Figures 7.13 and 7.14) revealed a trend similar to tests of repeatability (see 7.1.3) in that a few outliers were likely to be responsible for the negative results.

Investigation of increased power using aggregated analysis

Testing of a sample with greater power was considered of interest to confirm whether or not the results seen for repeatability, differences between postures and ANOVA investigation were due to Type II error. However it was not feasible in this study to recruit more subjects (see 6.8), and therefore an alternative and efficient use of the available data was to increase power by aggregating the values from the first test and re-test. A customised GLM ANOVA with Bon Ferroni post hoc analysis and a significance level of 0.05 was run to analyse interactions between subject, cue and posture (Table 7.4). These results were also expressed as plots of estimated marginal means for cues and postures for ease of observation (Figures 7.15 and 7.16).

6.11.5 Study 1: Comparison of absolute AUI between postures

Comparison of effect of posture on AUI was of interest and therefore a customised GLM ANOVA with Bonferroni correction and a significance level of 0.05 was undertaken to investigate interactions between posture and cue (Table 7.5).

6.11.6 Study 2: Initial Customised GLM ANOVA

As per Study 1, initial Customised GLM ANOVA and Bonferroni post hoc correction with a significance level of 0.05 was run using data from Test 1 (Table 7.6).

6.11.7 Study 2: Aggregated Customised GLM ANOVA

The aggregated results for Study 1 (Table 7.4) suggested that aggregation was an efficient use of data and therefore an aggregated customised GLM ANOVA with post hoc Bonferroni correction with a significance level of 0.05 was also run to test interactions between subjects and cues (Table 7.7). Estimated marginal means for cues were also produced (Figure 7.17).

6.11.8 Comparison of AUI between cohorts

It was not an aim of the programme of work to compare cohorts. However it was of interest with respect to confirming whether the results of this work agreed with the observation of urethral hypermobility in incontinent women in the literature. Formal investigation was not therefore undertaken but simple comparison made (Table 7.8).

6.11.9 Cue preference

Cue preference pre and post expert teaching is presented in Table 7.9.

6.11.10 Power Calculation

A power calculation based on these results was undertaken in order to inform future studies of numbers needed for intention to treat analysis. The standard deviation for AUI were drawn from initial ANOVA tables of both studies and 2-sample *t* test comparison was calculated using a power of 80% at a significance level of 0.05 (Table 7.10a and 7.10b).

Summary

Continent and incontinent women were recruited to this programme and underwent two preparatory sessions before progressing to data collection. Exclusions were made of subjects who could not either effectively or selectively

voluntarily contract the PFM. The data for both cohorts were evenly distributed and therefore parametric analysis was used. Inter and intra rater reliability and repeatability were tested for correlation. Customized GLM Analysis of variance with post hoc Bonferroni correction was used to test for interactions between subjects, cues, tests and posture in Study 1, and for subjects and cues in Study 2. The question of a Type II error in Study 1 was raised as suggested by results of repeatability and ANOVA analysis. Analysis of paired differences suggested this error may be eliminated with increased power. The results from both tests were therefore aggregated to investigate this. Aggregated analysis in Study 1 was considered to be an efficient use of data and therefore was also undertaken in Study 2.

Having discussed methodology, results from this study are reported in the following chapter.

Chapter 7 Results

7 Introduction

Results are discussed here in chronological order so that preliminary investigation of reliability is discussed first, followed by the principal results.

7.1 Reliability

Preliminary work as detailed in 5.1.3 included investigation of whether 2-D RTUS was a suitable method for measuring urethral changes as influenced by selective PFM contraction; including intra and inter rater reliability studies and whether women were able to repeat selective contraction of the PFM. The choice of statistical tests to explore these issues is described in 6.11.1.

7.1.1 Intra rater reliability

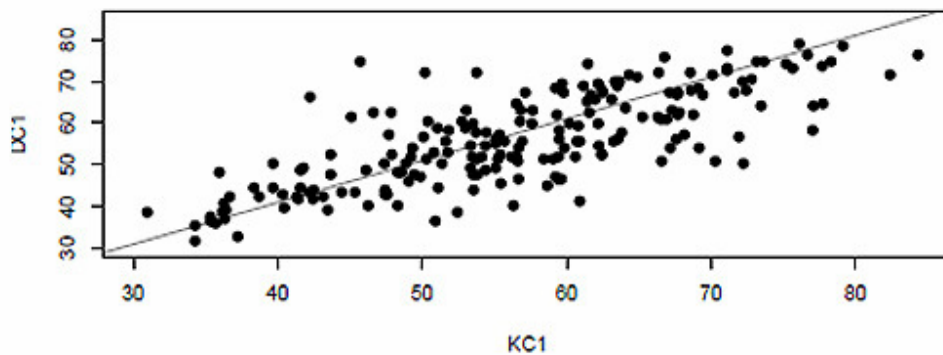
Initial analysis of ICC [2,1] (Shrout and Fleiss 1979) demonstrated intra-rater reliability to be excellent at 0.919 [CI 95%:0.8.94 to 0.938 $p=0.000$] (Crotty et al 2011). Subsequent analysis using the revised ICC [1,3] (see 6.11.1.2) strengthened the result to 0.957 [CI 95%: 0.946 to 0.967 $p=0.000$].

7.1.2 Inter rater reliability

Intra class correlation [2,1] (Shrout and Fleiss 1979) between the first read of KC versus DC's reading was 0.756 [CI 95%:0.689 to 0.81 $p=0.000$] (Crotty et al 2011). Whilst the results were considered within the boundary of acceptability they were slightly weak and therefore further investigation was undertaken (Bland and Altman 1986). The equality plot demonstrated differences between approximately 40° to 55° (Figure 7.1). Difference versus means plot demonstrated extreme outliers between approximately 55° and 65° (Figure 7.2). Intraclass correlation analysis [2,1] of KC's second reading versus DC's reading revealed an

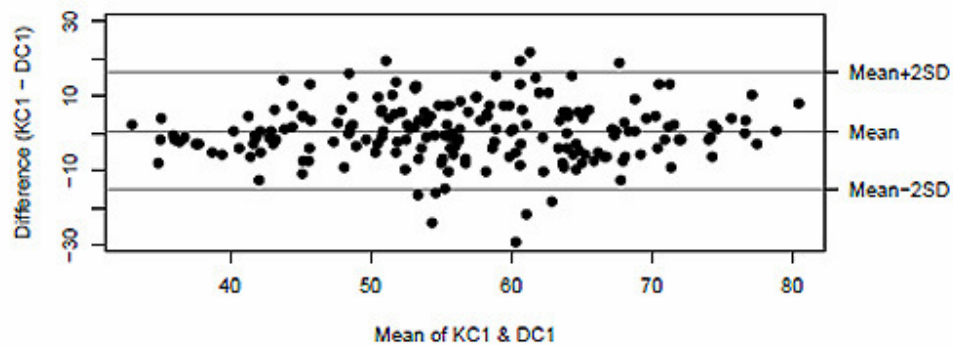
improved correlation of 0.820 [CI 95%: 0.768 to 0.861] (Crotty et al 2011). This improvement was also reflected in Bland and Altman Analysis (1986) (Figures 7.3 and 7.4).

Figure 7.1 Study 1 Equality plot: inter rater reliability (KC1 versus. DC) Bland and Altman (1986)



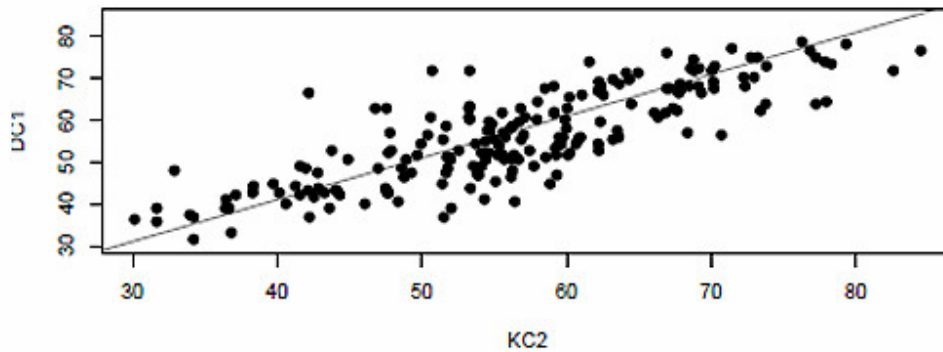
x axis= first rater: first reading (degrees)
y axis= second rater: reading (degrees)

Figure 7.2 Study 1 Difference versus mean plot: intra rater reliability (KC1 versus. DC) Bland and Altman (2006)



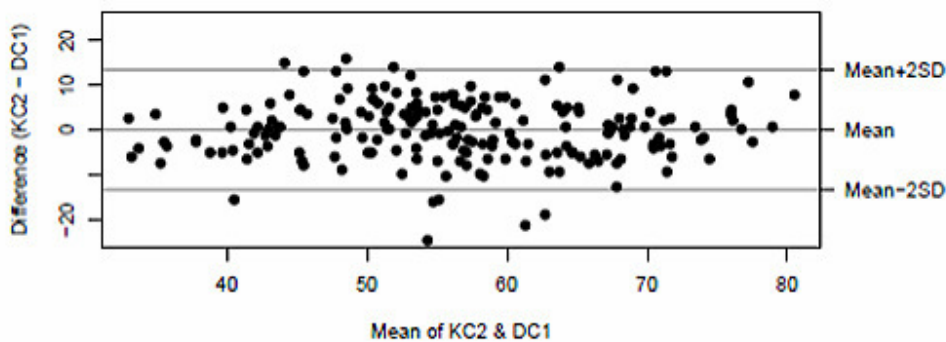
x axis= mean of first rater: first reading and second rater: reading (degrees)
y axis= Difference between means of first rater: first reading and second rater: reading (degrees)

Figure 7.3 Study 1 Equality plot: inter rater reliability (KC2 versus DC) Bland and Altman (2006)



x axis= first rater: second reading (degrees)
y axis= second rater: reading (degrees)

Figure 7.4 Study 1 Difference versus mean plot: inter rater reliability (KC2 versus DC) Bland and Altman (1986)



x axis= means of first rater: second reading and second rater: reading (degrees)
y axis= difference between means of first rater: second reading and second rater: reading (degrees)
0=mean

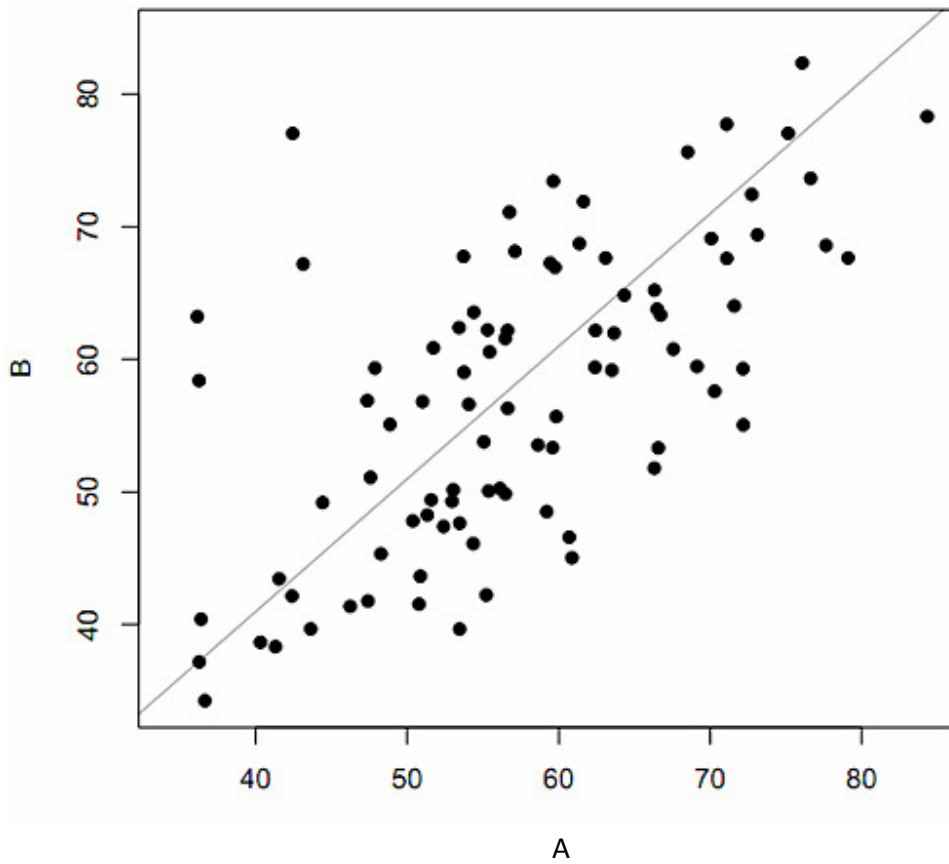
7.1.3 Repeatability of selective pelvic floor muscle contraction

Study 1

Intra class correlation [1,3] for repeatability of selective PFM contraction was on the limits of acceptability at 0.781 [CI 95%: 0.690 to 0.849 $p=0.000$]. Bland and Altman analysis (1986) demonstrated four outliers (2 subjects) at approximately 40° in Test 1 and between 60° and 80° in Test 2 (Figures 7.5 and 7.6). Reduced analysis to exclude outliers produced a more acceptable ICC of 0.876 [CI 95%:

0.820 to 0.917 $p=0.000$] (Figures 7.7 and 7.8). As discussed in 6.11.1.3, these results suggested the presence of a Type II error that may be eliminated in a larger sample.

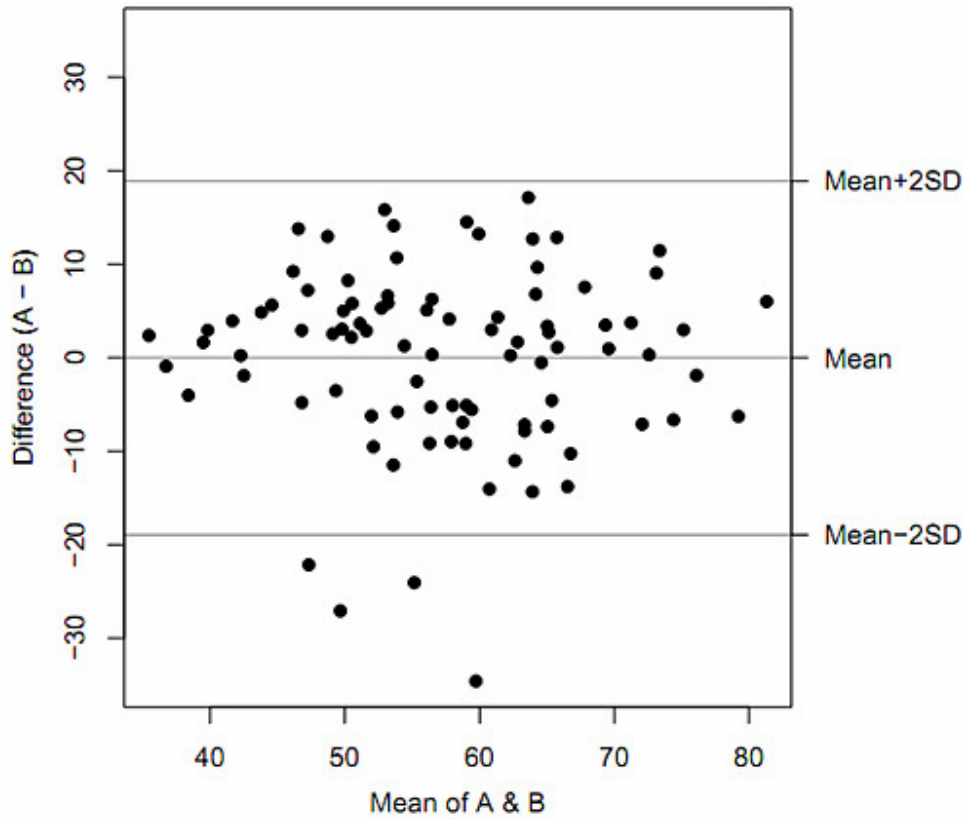
Figure 7.5 Study 1: Equality plot: repeatability: all subjects included Bland and Altman (2006)



x axis= A= Test 1 (degrees)

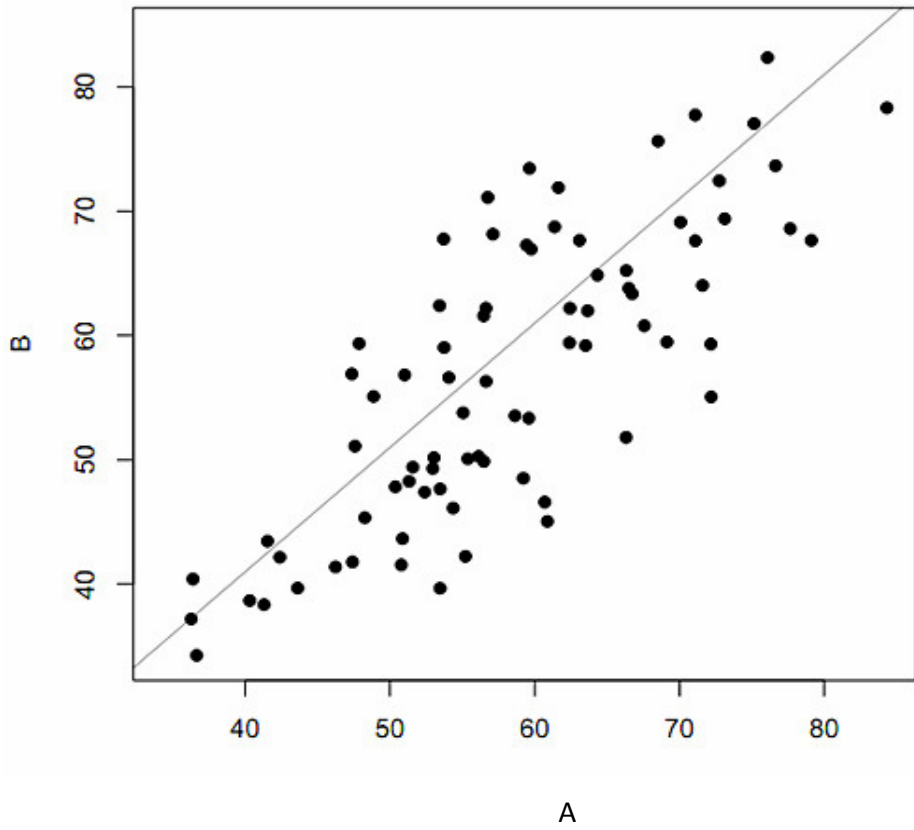
y axis= B=Test 2 (degrees)

Figure 7.6 Study 1 Difference versus means: repeatability: all subjects included Bland and Altman (2006)



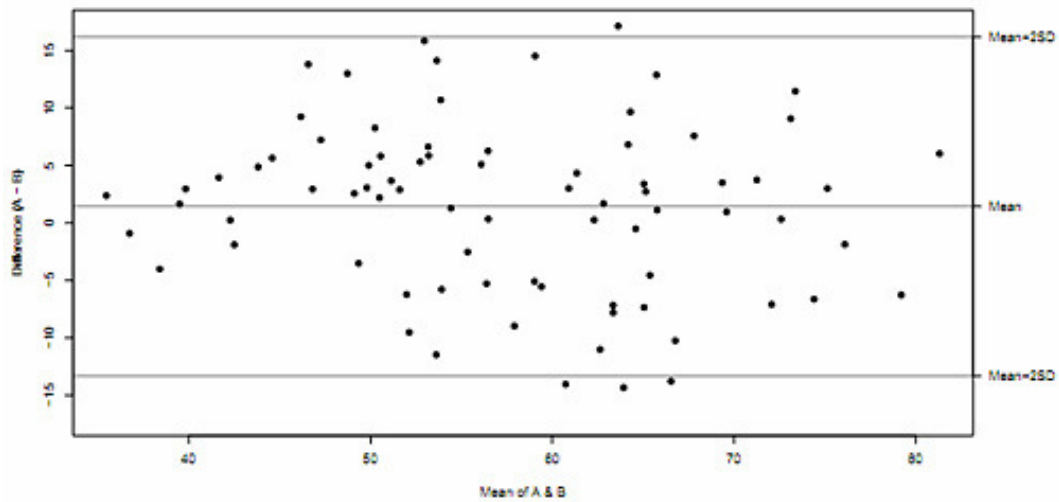
x axis= Mean of Test 1 and Test 2 (degrees)
y axis= Difference between means of Test 1 and test 2 (degrees)
0=mean

Figure 7.7 Study 1 Equality plot: repeatability: outliers excluded Bland and Altman (2006)



x axis= A=Mean Test 1 (degrees)
y axis= B=mean of Test 2 reading (degrees)

Figure 7.8 Study 1 Difference versus means: repeatability:
Outliers excluded Bland and Altman (2006)



axis= Mean of test 1 and Test 2 (degrees)
y axis= Difference between means of Test 1 and Test 2 (degrees)
0=mean

Study 2: Repeatability

Intra class correlation [1,3] for repeatability was robust with a high correlation of 0.954 [CI 95%:0.931 to 0.971 $p=0.000$].

7.2 Initial investigation Study 1: Results of investigations of differences between subjects, cues, tests and postures

7.2.1 Study 1: Initial Customized GLM ANOVA tests for cues

Customized GLM ANOVA tables for each cue posture and test are presented in Tables 7.1 i-iv whilst a summary of initial results for ease of comparison between cues, postures and tests is presented in Table 7.2.

Initial results for cues

The initial results are in agreement with the study hypothesis. Differences in AUI between anterior versus posterior or anterior versus combined cues either reached

statistical significance or a trend towards it. Also as hypothesised there was no statistical difference between posterior and combined cues (Table 7.1.i-iv).

As presented in the summary table (Table 7.2) post hoc analysis of each individual test and posture demonstrated that the mean difference in AUI in either posture or test was greater using a posterior or combined instruction compared with anterior instruction by approximately 4° Range: 3.37° [95%CI: 0.099 to 6.853: $p=0.059$] to 5.271° [2.012 to 8.529 $p=0.001$].

Table 7.1 i-iv Study 1. Initial ANOVA tables for each posture and test. Mean differences in angle of urethral inclination for different cues and postures (a); ANOVA main interactions (b); differences for cues Post-hoc Bonferroni Adjustment (c)

Table 7.1.i ANOVA main interactions Test 1 Supine					
Source	Type I Sum of Squares	df	Mean Square	F	P value
Subject	3929.128	16	245.570	18.286	0.000
Cue	263.800	2	131.900	9.822	0.000
Error	429.749	32	13.430		
Total	124671.831	51			
Corrected Total	4622.676	50			
R Squared =0.907 (Adjusted R Squared = 0.855)					
b. Mean angle of urethral inclination for different cues in supine					
Cue	Posture	Mean (degrees)	Std. Error	95% Confidence Interval	
Anterior	Supine	53.459	0.973	51.477	55.441
Posterior	Supine	49.480	0.973	47.498	51.462
Combined	Supine	50.082	0.973	48.100	52.064
c. Post-hoc Bonferroni Adjustment					
Comparison	Mean difference (degrees)	95% Confidence Interval		p value	
Anterior–Posterior cue	3.979	0.503	7.455	0.021*	
Anterior–combined cue	3.377	-0.099	6.853	0.059	
Posterior–combined cure	-0.602	-2.874	4.078	1.000	
Anterior cue: squeeze and lift from the front as if stopping the flow of urine. Posterior cue: squeeze and lift from the back as if stopping the escape of wind. Combined cue: squeeze and lift the front and back together *The mean difference is significant at the 0.05 level					

Table 7.1 ii ANOVA main interactions Test 2 Supine					
Source	Type I Sum of Squares	df	Mean Square	F	P value
Subject	5086.704	16	317.919	14.610	0.000
Cue	136.171	2	68.085	3.129	0.057
Error	696.310	32	21.760		
Total	138169.933	51			
Corrected Total	5919.185	50			
R Squared =0.882 (Adjusted R Squared = 0.816)					
b. Mean angle of urethral inclination for different cues in supine					
Cue	Posture	Mean (degrees)	Std. Error	95% Confidence Interval	
Anterior	Supine	53.233	1.131	50.928	55.537
Posterior	Supine	49.701	1.131	47.071	52.396
Combined	Supine	49.836	1.131	47.531	52.140
c. Post-hoc Bonferroni Adjustment					
Comparison		Mean difference (degrees)	95% Confidence Interval		p value
Anterior–Posterior cue		3.532	-0.510	7.757	0.104
Anterior–combined cue		3.397	-0.646	7.439	0.125
Posterior–combined cure		-0.135	-4.178	3.907	1.000
Anterior cue: squeeze and lift from the front as if stopping the flow of urine. Posterior cue: squeeze and lift from the back as if stopping the escape of wind. Combined cue: squeeze and lift the front and back together The mean difference is significant at the 0.05 level					

Table 7.1 iii ANOVA main interactions Test 1 Standing					
Source	Type I Sum of Squares	df	Mean Square	F	P value
Subject	4260.321	16	266.270	17.720	.000
Cue	249.126	2	124.563	13866.942	.000
Error	452.409	32	14.138		
Total	201009.576	51			
Corrected Total	4961.856	50			
R Squared = 0.909 (Adjusted R Squared = 0.858)					
b. Mean angle of urethral inclination for different cues in standing					
Cue	Posture	Mean (degrees)	Std. Error	95% Confidence Interval	
Anterior	Standing	64.993	0.912	63.135	66.851
Posterior	Standing	59.722	0.912	57.865	61.580
Combined	Standing	61.286	0.912	59.429	63.144
c. Post-hoc Bonferroni Adjustment					
Comparison		Mean difference (degrees)	95% Confidence Interval		p value
Anterior-Posterior cue		5.271	2.012	8.529	0.001*
Anterior-combined cue		3.706	0.448	6.965	0.021*
Posterior-combined cure		-1.564	-4.822	1.694	0.702
Anterior cue: squeeze and lift from the front as if stopping the flow of urine. Posterior cue: squeeze and lift from the back as if stopping the escape of wind. Combined cue: squeeze and lift the front and back together The mean difference is significant at the 0.05 level					

Table 7.1 iv ANOVA main interactions Test 2 Standing					
Source	Type I Sum of Squares	df	Mean Square	F	P value
Subject	14552.734	16	909.546	92.310	0.000
Cue	216.714	2	108.357	10.997	0.000
Error	315.301	32	9.853		
Total	192141.706	51			
Corrected Total	15084.749	50			
R Squared = 0.979 (Adjusted R Squared = 0.967)					
b. Mean angle of urethral inclination for different cues in standing					
Cue	Posture	Mean (degrees)	Std. Error	95% Confidence Interval	
Anterior	Standing	61.829	0.761	60.278	63.380
Posterior	Standing	57.649	0.761	56.099	59.200
Combined	Standing	57.285	0.761	55.735	58.836
c. Post-hoc Bonferroni Adjustment					
Comparison		Mean difference (degrees)	95% Confidence Interval		p value
Anterior-Posterior cue		4.179	1.459	6.900	0.001*
Anterior-combined cue		4.544	1.823	7.264	0.001*
Posterior-combined cure		0.364	-3.356	3.084	1.000
Anterior cue: squeeze and lift from the front as if stopping the flow of urine. Posterior cue: squeeze and lift from the back as if stopping the escape of wind. Combined cue: squeeze and lift the front and back together The mean difference is significant at the 0.05 level					

Table 7.2 Study 1. Summary of initial ANOVA results for each cue, posture and each test.

ANOVA Summary. All tests and postures				
	Test 1 Supine	Re-Test Supine	Test 1 Stand	Re-Test Stand
	Mean diff (95% CI)			
Anterior versus. Posterior	3.979° (0.503-7.455) <i>p</i> =0.021*	3.532° (-0.501-7.757) <i>p</i> =0.104	5.271° (2.012-8.529) <i>p</i> =0.001*	4.179° (1.459-6.900) <i>p</i> =0.001*
Anterior versus. Combined	3.377° (-0.099-6.853) <i>p</i> =0.059	3.397° (-0.646-7.439) <i>p</i> =0.125	3.706° (0.448-6.965) <i>p</i> =0.021*	4.544° (1.823-7.264) <i>p</i> =0.001*
Posterior versus. Combined	-0.602° (-2.874- 4.078) <i>p</i> = 1.000	-0.135° (-4.178-3.9070) <i>p</i> = 1.000	-1.564° (0.448-6.965) <i>p</i> =0.702	0.364° (-3.356-3.084) <i>p</i> =1.000
Anterior cue: squeeze and lift from the front as if stopping the flow of urine. Posterior cue: squeeze and lift from the back as if stopping the escape of wind. Combined cue: squeeze and lift the front and back together The mean difference is significant at the 0.05 level *indicates results have reached a level of statistical significance				

7.3 Study 1: Further investigation due to the suggestion of possible Type II error

Continued investigation of a Type II error was of interest as discussed in 6.11.4.

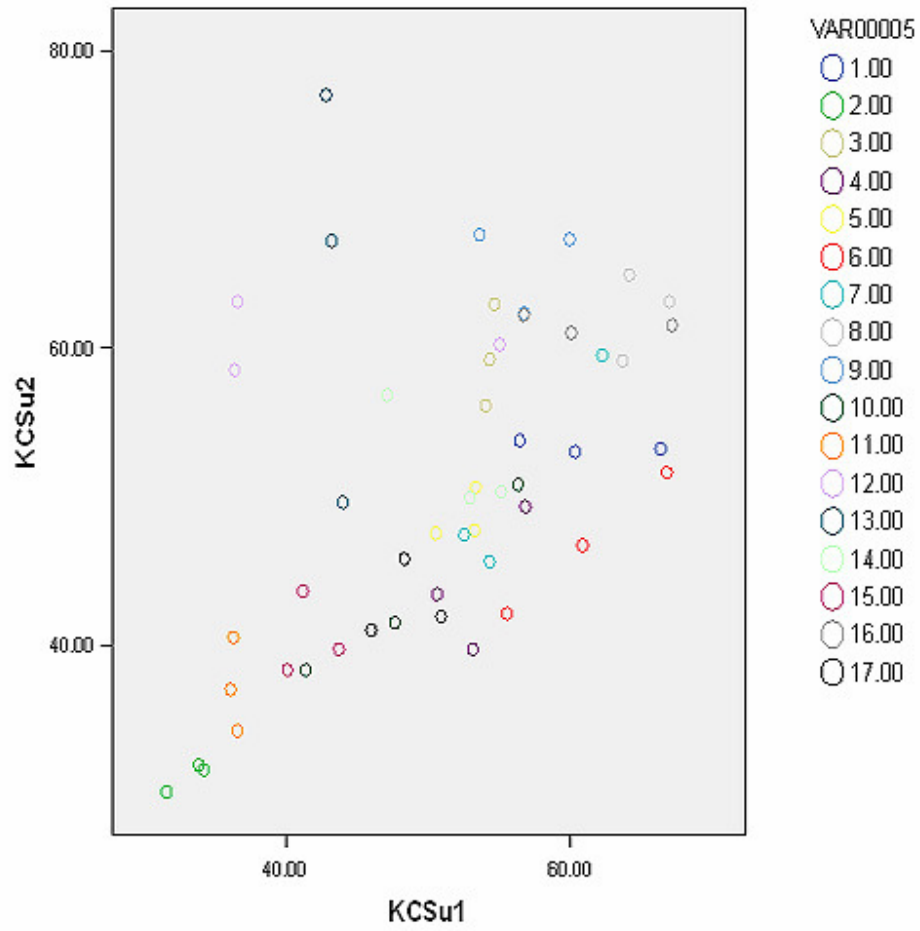
7.3.1 Analysis of paired differences between test and re test in supine and standing

Analysis of paired differences between test and re test for both postures was undertaken (Table 7.3). These results revealed that despite the weaker results in the supine tests, the *t*-value analysis of paired differences in supine was stronger ($t=0.059$) than the standing tests ($t=1.42$). The supine scatter plot revealed four outliers (2 subjects) (Figure 7.13). This was in contrast with the scatter plot for standing which demonstrated a more regular distribution (Figure 7.14). These results supported the suggestion that there may have been a Type II error that may be eliminated in a larger sample.

Table 7.3 Paired differences in supine and standing test re-test

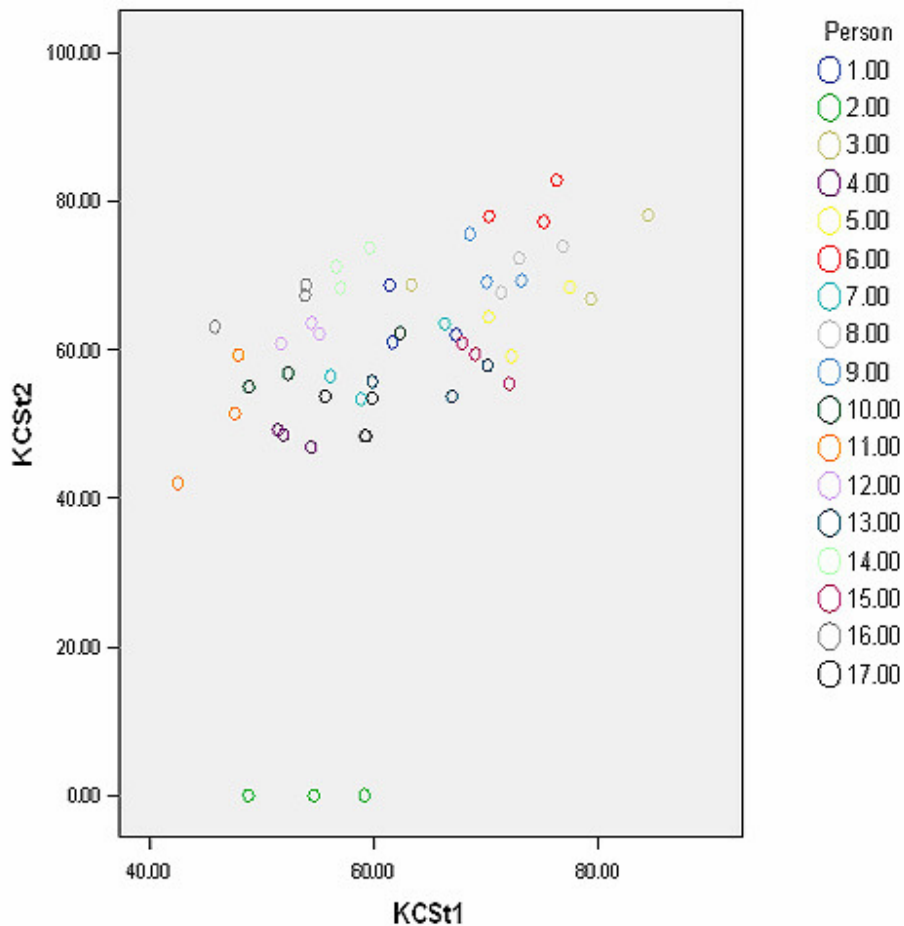
Difference between test and re test in each posture	Mean	Standard error	95% CI	<i>t</i> value	<i>P</i> value
Supine	0.08	1.41	-2.76 - -2.93	0.059	0.953
Standing	3.07	2.15	-1.24 – 7.40	1.42	0.159

Figure 7.9 Paired differences: supine



x axis= first test supine
y axis= second test supine

Figure 7. 10 Paired differences: standing



x axis= first test supine
y axis= second test supine

7.3.2 Study 1: Aggregated Customised GLM ANOVA Results

The aggregated results are presented in Table 7.4 (see 6.11.4.2 for rationale to aggregate the data). Due to increased power, the results reflected a strengthening of results presented in initial analysis (Table 7.1 i-iv). The mean difference in AUI between anterior versus posterior cue was 4.240° [95%CI: 1.213 to 7.267 $p=0.003$]; and between anterior and combined cue 3.756° [95%CI: 0.729 to 6.783 $p=0.009$]. There was no significant difference between posterior and combined cues -0.48° [-3.511 to 2.542 $p=1.000$] (Table 7.4.c). Cue is demonstrated to affect

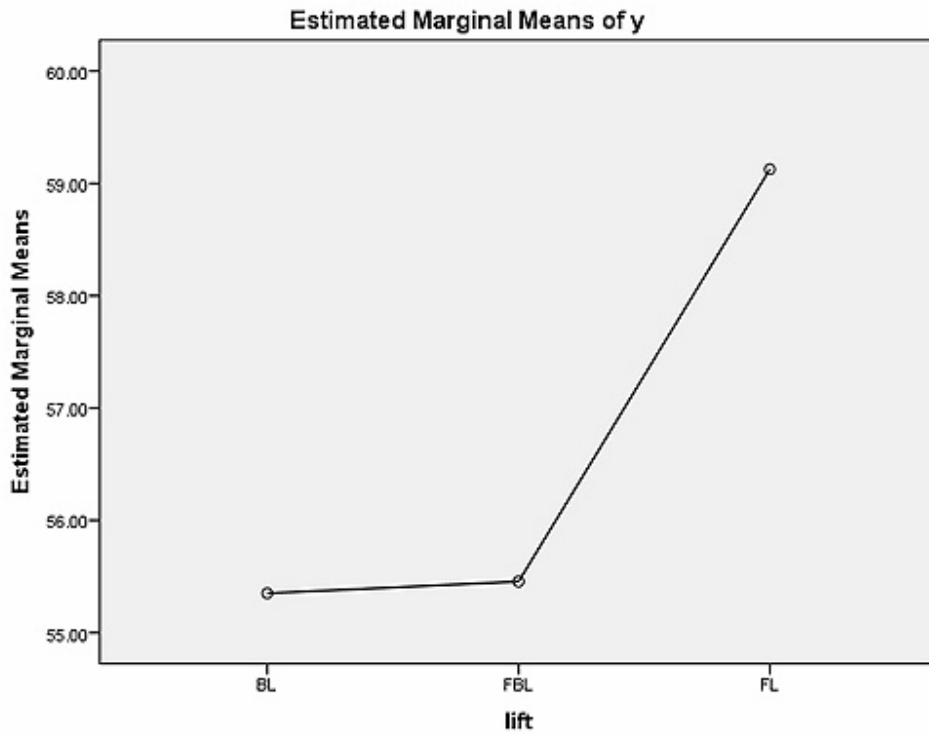
the AUI significantly [$F=6.882$ $p=0.001$] (Table 7.4.b and Figure 7.15). The ANOVA showed statistically significant differences between postures [$F=86.406$ $p=0.000$] (Table 7.4b and Figure 7.16). The absolute AUI measurement in supine was 9.496° more acute compared to standing: [95%CI: 7.478 to 11.513 $p=0.000$] (Table 7.4c). The ANOVA produced insufficient evidence to conclude that AUI is related to any interaction effects of posture and cue [$F=0.082$; $p= 0.921$] (Table 7.4a).

The results are in agreement with the study hypothesis. Differences in AUI between anterior versus posterior or combined cues all reached statistical significance. Also as hypothesised there was no statistical difference between posterior and combined cues (Table 7.4c). These results support the suggestion that results that did not reach levels of statistical significance in initial analysis were a result of a Type II error that may be eliminated in a larger sample.

Table 7.4 Study 1. Aggregated analysis:
Mean differences in angle of urethral inclination for different cues and postures;
test and re test aggregated:
(a) ANOVA main interactions; (b) differences for cues (c) Post-hoc Bonferroni Adjustment

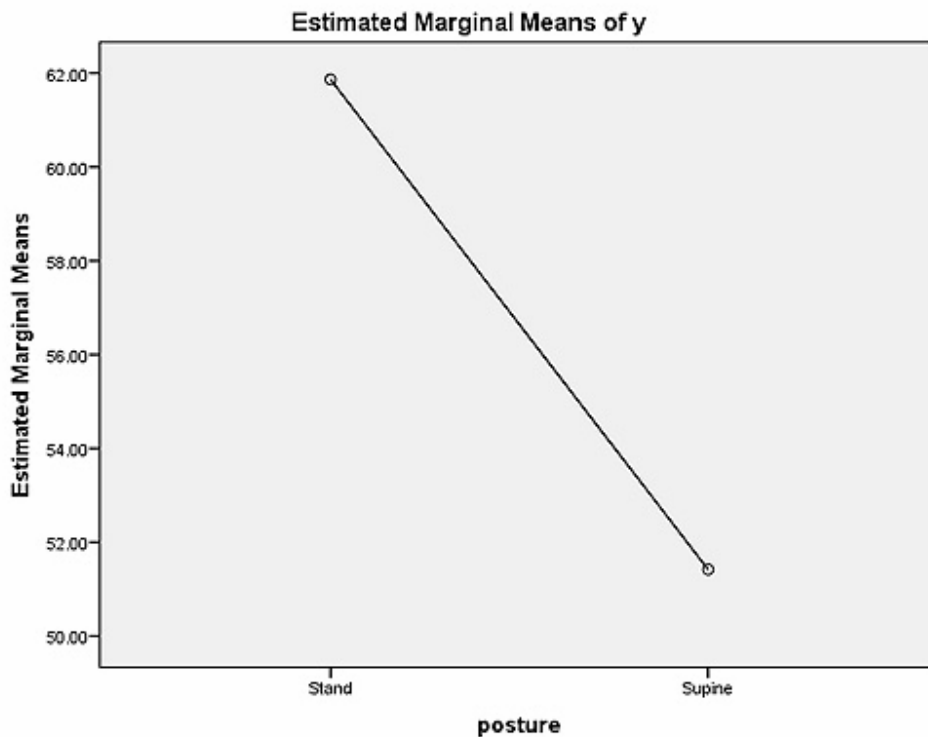
a. ANOVA main interactions					
Source	Type I Sum of Squares	df	Mean Square	F	P value
Subject	17443.529	16	1090.221	20.484	0.000
Test ^a	127.580	1	127.580	2.397	0.124
Subject * Test	3932.660	16	245.791	4.618	0.000
Posture ^b	4598.827	1	4598.827	86.406	0.000
Cue ^c	732.603	2	366.301	6.882	0.001
Posture * Cue	8.719	2	4.359	0.082	0.921
Posture * Test	114.410	1	114.410	2.150	0.145
Cue * Test	12.515	2	6.257	0.118	0.889
Posture * Cue * Test	4.562	2	2.281	0.043	0.958
Error	8515.757	160	53.223		
Corrected Total	35491.161	203			
R Squared = 0.760 (Adjusted R Squared =0.696)					
^a Test 1 or two (repeatability data) ^b Standing or supine ^c Anterior posterior or combined Anterior cue: squeeze and lift from the front as if stopping the flow of urine. Posterior cue: squeeze and lift from the back as if stopping the escape of wind. Combined cue: squeeze and lift the front and back together					
b. Mean angle of urethral inclination for different cues and postures					
Cue	Posture	Mean (degrees)	Std. Error	95% Confidence Interval	
Anterior	Supine	53.346	1.251	50.875	55.817
	Standing	63.411	1.251	60.940	65.882
Posterior	Supine	49.590	1.251	47.119	52.061
	Standing	58.686	1.251	56.215	61.157
Combined	Supine	49.959	1.251	47.488	52.430
	Standing	59.286	1.251	56.815	61.757
c. Post-hoc Bonferroni Adjustment					
Comparison	Mean difference (degrees)	95% Confidence Interval		p value	
Anterior–Posterior cue	4.240	1.213	7.267	0.003	
Anterior–combined cue	3.756	0.729	6.783	0.009	
Posterior–combined cure	-0.484	-3.511	2.543	1.000	
Standing-supine	9.496°	7.478	11.513	0.000	
Anterior cue: squeeze and lift from the front as if stopping the flow of urine. Posterior cue: squeeze and lift from the back as if stopping the escape of wind. Combined cue: squeeze and lift the front and back together The mean difference is significant at the 0.05 level					

Figure 7.11 Study 1. Aggregated results: estimated marginal means for cues



BL=back lift FBL=front and back lift FL=front lift

Figure 7.12 Study 1. Aggregated results: estimated marginal means for postures



7.4 Effect of posture on AUI

In order to compare potential differences between absolute values in the supine and standing postures a Customized GLM ANOVA with post hoc Bonferroni adjustment and a significance level of 0.05 was undertaken using supine and standing data from Test 1 alone. Results are presented in Table 7.5.

The ANOVA showed statistically significant differences between postures [$F=73.090$ $p=0.000$] (Table 7.5a). The absolute AUI measurement in supine was 10.797° more acute compared with standing: [95% CI: 9.392 to 13.741 $p=0.000$] (Table 7.5.c).

Whilst the ANOVA showed significant differences between posture, there was insufficient evidence to conclude that AUI is related to any interaction effects of posture and cue [$F=0.169$; $p=0.845$] (Table 7.5.a).

Table 7.5 Study 1. Test 1: Mean differences in angle of urethral inclination for different cues and postures (a) ANOVA main interactions; (b) differences for cues (c) Post-hoc Bonferroni adjustment

a. ANOVA main interactions					
Source	Type I Sum of Squares	df	Mean Square	F	P value
Subject	6118.304	16	382.394	9.403	0.000
Posture ^a	2972.304	1	2972.304	73.090	0.000
Cue ^b	312.284	2	156.142	3.840	0.000
Posture * Cue	13.733	2	6.867	0.169	0.845
Error	3253.327	80	40.667		
Total	338957.806	102			
Corrected Total	12669.953	101			
R Squared = 0.743 (Adjusted R Squared =0.676)					
^a Standing or supine					
^b Anterior posterior or combined					
Anterior cue: squeeze and lift from the front as if stopping the flow of urine.					
Posterior cue: squeeze and lift from the back as if stopping the escape of wind.					
Combined cue: squeeze and lift the front and back together					
b. Mean angle of urethral inclination for different cues and postures					
Cue	Posture	Mean (degrees)	Std. Error	95% Confidence Interval	
Anterior	Supine	53.504	1.547	50.426	56.582
	Standing	64.392	1.547	61.314	67.470
Posterior	Supine	49.878	1.547	46.800	52.956
	Standing	59.734	1.547	56.656	62.811
Combined	Supine	50.100	1.547	47.022	53.178
	Standing	61.746	1.547	56.668	64.824
c. Post-hoc Bonferroni Adjustment					
Comparison	Mean difference (degrees)	95% Confidence Interval		p value	
Anterior-Posterior cue	4.1420	0.3598	7.9241	0.027	
Anterior-combined cue	3.0251	-0.7570	6.8072	0.062	
Posterior-combined cure	-1.1169	-4.8990	2.6653	1.000	
Standing-supine	10.797	9.392	13.741	0.000	
Anterior cue: squeeze and lift from the front as if stopping the flow of urine.					
Posterior cue: squeeze and lift from the back as if stopping the escape of wind.					
Combined cue: squeeze and lift the front and back together					
The mean difference is significant at the 0.05 level					

7.5 Study 2: Initial investigation of differences between subjects and cues

7.5.1 Initial Customised GLM ANOVA tests

Results of the Customised GML ANOVA for cues are presented in Table 7.6.

The results are in agreement with the study hypotheses (see 5.2). Differences in AUI between anterior versus posterior or combined cues all reached statistical significance. There was no statistical difference between posterior and combined cues.

Post-hoc analysis demonstrated that the mean difference in AUI was greater using a posterior cue to instruction as compared with anterior cue by 3.936° [95%CI: 0.863 to 7.008 $p=0.008$] and combined cue compared with anterior by 4.946° [95%CI: 1.873 to 8.018 $p=0.001$]. There was no significant difference found between posterior and combined cues 1.010° [95%CI: -2.062 to 4.082 $p=1.000$] (Table 7.6c) (Crotty et al 2010).

Table 7.6 Study 2. Initial analysis.

Mean differences in angle of urethral inclination for different cues in supine (a) ANOVA main interactions; (b) differences for cues (c) Post-hoc Bonferroni Adjustment

a. ANOVA main interactions					
Source	Type I Sum of Squares	df	Mean Square	F	P value
Corrected model	16240.723 ^a	22	738.215	46.506	.000
Intercept	206589.500	1	206589.500	13014.773	.000
Subject	15953.932	20	797.697	50.243	0.000
Lift	286.790	2	143.395	9.034	.001
Error	634.938	40	15.873		
Corrected Total	16875.661	62			
R Squared =0.962 (Adjusted R Squared =0.942)					
^A Test 1 or two (repeatability data)					
^c Anterior posterior or combined					
Anterior cue: squeeze and lift from the front as if stopping the flow of urine.					
Posterior cue: squeeze and lift from the back as if stopping the escape of wind.					
Combined cue: squeeze and lift the front and back together					
b. Mean angle of urethral inclination for different cues					
Cue	Posture	Mean (degrees)	Std. Error	95% Confidence Interval	
Anterior	Supine	60.225	.869	58.468	61.982
Posterior	Supine	56.289	.869	54.532	58.046
Combined	Supine	55.279	.869	53.522	57.036
c. Post-hoc Bonferroni Adjustment					
Comparison	Mean difference (degrees)	95% Confidence Interval		p value	
Anterior–Posterior cue	3.936	0.863	7.008	0.008*	
Anterior–combined cue	4.946	1.873	8.018	0.001*	
Posterior–combined cue	1.010	-2.062	4.082	0.309	
Anterior cue: squeeze and lift from the front as if stopping the flow of urine.					
Posterior cue: squeeze and lift from the back as if stopping the escape of wind.					
Combined cue: squeeze and lift the front and back together					
The mean difference is significant at the 0.05 level*					

7.5.2 Study 2: Aggregated GLM ANOVA tests

Results of the aggregated Customized GML ANOVA for cues are presented in Table 7.7.

The results demonstrated that the mean difference in AUI was greater using an anterior cue to instruction compared to posterior cue by

3.703° [95%CI:1.639 to 5.761 $p=0.000$] and combined cue compared to anterior cue by 5.089° [95%CI: 3.028 to 7.150 $p=0.000$] (Table 7.7.c). There was no significant difference found between posterior and combined cues 1.389° [95%CI:-0.672 to 3.450 $p=0.309$] (Table 7.7c; Figure 7.17).

Table 7.7 Study 2. Aggregated analysis:

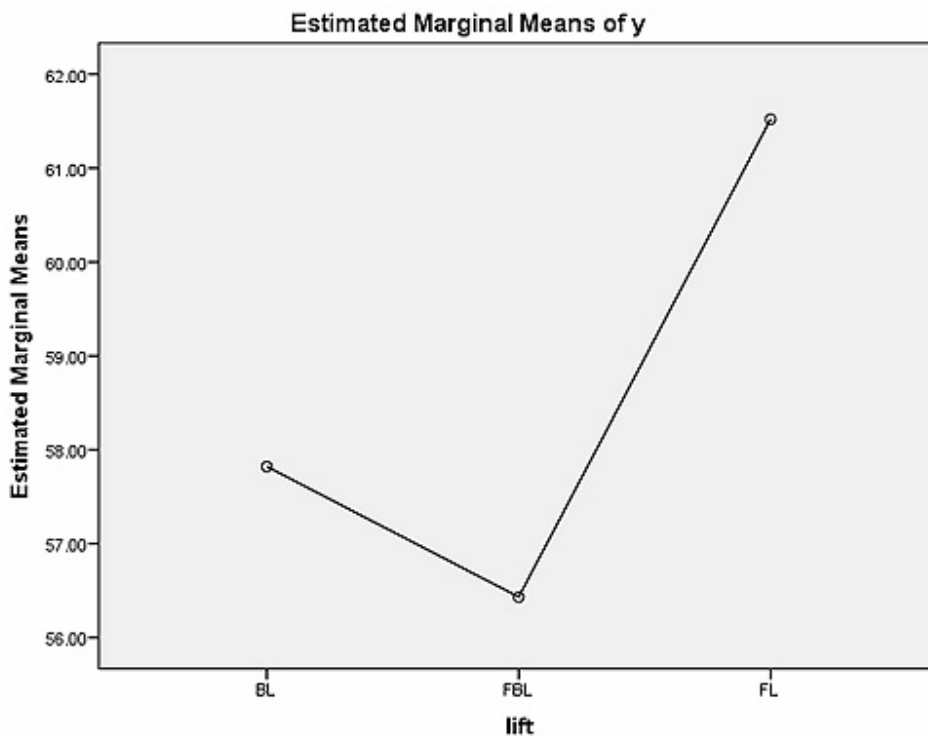
Mean differences in angle of urethral inclination for different cues in supine:

(a) ANOVA main interactions; (b) differences for cues (c) Post-hoc Bonferroni

Adjustment

a. ANOVA main interactions					
Source	Type I Sum of Squares	df	Mean Square	F	P value
Corrected model	2.9739.372	41	725.531	51.121	.000
Intercept	411956.837	1	411956.837	29033.629	.000
Subject	28376.423	20	1418.821	99.995	.000
Test	73.537	1	73.537	5.183	.026
Subject*test	735.747	18	40.875	2.881	.001
Lift	553.665	2	276.883	19.510	.000
Error	1106.738	78	14.189		
Corrected Total	30846.110	119			
R Squared = 0.964 (Adjusted R Squared =0.945)					
^A Test 1 or two (repeatability data)					
^c Anterior posterior or combined					
Anterior cue: squeeze and lift from the front as if stopping the flow of urine.					
Posterior cue: squeeze and lift from the back as if stopping the escape of wind.					
Combined cue: squeeze and lift the front and back together					
b. Mean angle of urethral inclination for different cues					
Cue	Posture	Mean (degrees)	Std. Error	95% Confidence Interval	
Anterior	Supine	61.521	.596	60.336	62.707
Posterior	Supine	57.821	.596	56.636	59.007
Combined	Supine	56.432	.596	55.246	57.618
c. Post-hoc Bonferroni Adjustment					
Comparison	Mean difference (degrees)	95% Confidence Interval		p value	
Anterior–Posterior cue	3.7003	1.6394	5.76611	.000	
Anterior–combined cue	5.0895	3.0287	7.1503	.000	
Posterior–combined cue	1.389	-0.672	3.450	0.957	
Anterior cue: squeeze and lift from the front as if stopping the flow of urine.					
Posterior cue: squeeze and lift from the back as if stopping the escape of wind.					
Combined cue: squeeze and lift the front and back together					
The mean difference is significant at the 0.05 level					

Figure 7. 13 Study 2: estimated marginal means for cues



BL=back lift; FBL=front and back lift; FL=front lift

7.6 Differences in AUI between cohorts

The difference in mean AUI in supine between Study 1 and Study 2 was 7.63°. Results taken from Table 7.4b and Table 7.7b are presented in Table 7.8 to demonstrate that no overlap exists in confidence intervals between the two studies i.e. the difference between cohorts in AUI is true.

Table 7.8 Differences in AUI between cohorts in supine

Mean angles for cues CI: 95% (from Tables 7.4b and 7.7b)				
	Anterior	Posterior	Combined	Mean
Continent supine	53.504 [50.426 to 56.582]	49.878 [46.800 to 52.956]	50.100 [47.022 to 53.178]	50.96
Incontinent supine	61.521 [60.336 to 62.707]	57.821 [56.636 to 59.007]	56.432 [55.246 to 57.618]	58.59
				7.63 (diff)

7.7 Cue preference

As described in 6.11.9 women were questioned about cue preference pre and post expert teaching. Results are presented in Table 7.9.

Table 7.9 Preferred cues pre and post expert teaching

Cue	Pre expert teaching	Post expert teaching%
Study 1: continent group		
Anterior	42% (n=11)	15% (n=3)
Posterior	8% (n=2)	45% (n=9)
Combined	0%	40% (n=8)
Vaginal	42% (n=11)	0%
Other technique	8% (n=2)	0%
Study 2: incontinent group		
Anterior	50% (n=10)	14% (n=3)
Posterior	0%	47% (n =10)
Combined	15% (=n 3)	38% (n =8)
Vaginal	35% (=n 7)	0%
Other	0%	0%

7.8 Power Calculation

In the present study, the power achieved in the continent group was 0.758 and in the incontinent group 0.991. The results of the power calculation undertaken to inform future studies indicated that in order to achieve a power of 80%, 35 continent and 14 incontinent subjects would be required to detect a difference of 4° on an analysis by intention to treat basis (Table 7.10).

Table 7.10 Power calculation to inform future studies

Table 7.10a Continent 2-sample <i>t</i> test $p=0.05$			
Degrees	Exclusion of those unable to effectively or selectively contract	Exclusion of those unable to selectively contract	Intention to treat
1	321.374	369.580	514.199
2	81.803	94.074	130.885
3	37.460	43.079	59.936
4*	21.963	25.258	35.141
5	14.812	17.034	23.700
6	10.947	12.589	17.516
7	8.632	9.927	13.811
8	7.140	8.211	11.425
9	6.125	7.044	9.800
10	5.403	6.213	8.645
Table 7.10b Incontinent 2-sample <i>t</i> test $p=0.05$			
Degrees			
1	126.731	138.800	181.044
2	33.171	36.330	47.837
3	15.893	17.407	22.705
4*	9.889	10.831	14.127
5	7.141	7.821	10.201
6	5.665	6.204	8.903
7	4.781	5.237	6.831
8	4.208	4.609	6.012
9	3.813	4.107	5.447
10	3.525	3.861	5.036
* mean differences observed in this programme of work			

Summary

Results for reliability testing were sound although in investigation of repeatability in Study 1, a Type II error was suggested in the supine tests. The primary results

prove the hypothesis that in both continent nulliparous pre-menopausal women and in parous menopausal women with previously unreported SUI, posterior or combined cue is more influential in optimising position of UVSs during a PFM contraction after a brief period of practice, than an anterior cue i.e. inclusion of a posterior cue has been demonstrated to produce a narrower AUI than an anterior cue alone. Further, either a posterior or a combined cue is equally influential in optimising position of UVSs during a PFM contraction after a brief period of practice. The results were strengthened when the data for test and re test were aggregated in both studies. The strengthened results in Study 1 confirmed the suggestion that the Type II error would be eliminated in a larger sample. The results also demonstrated that posture does not affect absolute values for AUI. The urethra was seen to be more mobile in the incontinent subjects (Study 2) than the continent subjects (Study 1). Subjects indicated that cue preference for a PFM contraction altered in favour of inclusion of posterior or combined cue following expert teaching. A power calculation indicated that Study 1 was slightly underpowered.

Conclusion

Results for reliability tests indicated that 2-D RTUS is a suitable method for imaging the AUI. Selective contraction of the PFM using various cues to instruction has been demonstrated to significantly influence urethral position in continent pre-menopausal nulliparous women and menopausal parous incontinent women who are able to effectively and selectively contract the PFM. Inclusion of a posterior cue to instruction is more influential in narrowing AUI than an anterior cue alone. Posture does not affect absolute AUI. The power calculation will inform future studies. Having presented the results of the study, a discussion of findings follows in the next chapter.

Chapter 8 Discussion

8 Introduction

The preliminary, principal and secondary aims of this investigation were met by a comprehensive programme of work as described in Chapter 5. Results of reliability tests demonstrated that 2-D RTUS was suitable for investigation of selective contraction of the PFM and that the AUI was a suitable measurement index. Further, it was demonstrated that a non diagnostic imaging AHP was able to acquire the skill of reading images from perineal 2-D RTUS with practice.

In both studies the principal aim was met and the study hypotheses were supported as it emerged that inclusion of a posterior cue to instruction resulted in greater narrowing of the AUI as compared with an anterior cue; and that no significant difference was found between posterior and combined cues (Crotty et al 2010; Crotty et al 2011).

With respect to secondary aims, it was found that posture did not affect absolute AUI (Crotty et al 2011); the skill to selectively contract the PFM was not complicit with the skill to effectively contract the PFM (Crotty et al 2011) whilst the overwhelming majority of those who had the ability to selectively contract demonstrated ability to repeat (Crotty et al 2011); and finally that subjects overwhelmingly reported a preference for inclusion of a posterior cue than an anterior cue following expert teaching. Incidental findings of interest also emerged throughout the study.

These results might be applied to pre menopausal nulliparous continent and menopausal parous incontinent women who are able to effectively and selectively contract the PFM. Discussion and extrapolation of findings follows.

8.1 Preliminary findings: reliability studies for 2-D RTUS

The suitability of 2-D RTUS using AUI as the measurement index for studying selective contraction of the PFM was proven by results of reliability studies. Results for both intra and inter rater reliability were robust (Crotty et al 2011) (see 7.1). The improvement in results for intra rater reliability when the test was re run using the second reading of KC is of interest. The initial results were just within the limits of acceptability at 0.756 [CI 95%:0.689 to 0.81 $p=0.000$] but improved with KC's second reading to 0.820 [CI 95%: 0.768 to 0.861 $p=0.000$] (Crotty et al 2011) (see 7.1.2). Rankin and Stokes (1998) discuss that reliability is relative and should be contrasted with the expected variation among the subjects (or raters) being tested. In this case the improvement in outcome suggested a positive practice effect as a result of KC having read a further 2000 images and infers that the results were relative to experience. This practice effect suggests that the training for a non diagnostic imaging AHP as used in this study was adequate but may have been improved with more practice reads. Training included a short tutorial and reading of 4000 images (Table 5.1). Based on these results it is reasonable to state that more than 4000 readings are required in order for a non diagnostic imaging AHP to be confident of reliability. These results are important because these issues had not been previously investigated.

8.2 Principal Results

Introduction

The principal aim of investigating optimal cue to instruction for a single PFM contraction was met and the study hypotheses were proven (see 5.1 and 5.2; Tables 7.2 and 7.6).

Initial analysis in Study 1 demonstrated that both the posterior and combined cues produced a narrowing of the AUI of approximately 4° as compared with an anterior cue alone in either supine or standing and that there was no significant

difference between the posterior and combined cues (Table 7.2). The suggestion of a Type II error in the initial results led to aggregation of data sets to investigate whether the error might be eliminated in a larger sample. This was considered an efficient use of data because there were time constraints with respect to the retirement of CB and it was not possible to extend the duration of the study (see 6.8). This investigation was found to be worthwhile as the error was eliminated. As expected, the point estimates for anterior versus posterior cue and anterior versus combined using aggregated data were more statistically significant than at initial analysis (Tables 7.2 and 7.4). These findings suggested that Study 1 was underpowered. This suggestion was supported by results of the power calculation that indicated that 22 subjects would be required for future studies if those who could not effectively or selectively contract the PFM were included (Table 7.10a). Unfortunately, as discussed in 6.9.1, 20 sets of data were collected although only 17 were available for analysis. It is probable that the Type II error would not have influenced the results as greatly had these data sets not been lost.

The results in Study 2 were broadly similar to those in Study 1 although reached greater levels of significance. Initial analysis demonstrated a 4° difference between anterior and posterior cues and a 5° difference between anterior and combined. As expected there was no significant difference between the posterior and combined cues (Table 7.6). Aggregation of tests in Study 2 was also seen to produce more statistically significant results (Table 7.7).

These results are important because selective contraction of the PFM has not been previously investigated. However, they might only be applied to pre-menopausal nulliparous continent women and menopausal parous incontinent women who are able to effectively and selectively contract the PFM.

Anatomical Extrapolation of Principal Findings

Pelvic floor muscle contraction is known to shift the ARA, vagina and urethra towards the pubis. It is proposed that in this study, optimal AUI (as reflected by narrower angle) when a posterior cue was included in instruction was due to

optimal recruitment of puborectalis. The puborectalis is not commonly discussed or acknowledged as having a role in UI. Traditionally, different disciplines have been interested in the anatomy of the anterior, middle or posterior compartment of the pelvis according to clinical specialty. Urology and gynaecology studies have mostly investigated pubovisceralis and management of UI whilst colorectal surgeons have mostly investigated the puborectalis and management of faecal incontinence. However, as described by Bharuca (2006)

“there is increasing enthusiasm for viewing the pelvic floor from a global perspective, discounting the traditional segregation into anterior, middle, and posterior compartments”.

Essentially, the puborectalis, like the pubovisceralis that has a universally acknowledged role in urinary continence, is a sling. It is therefore suited to the purpose of shifting the pelvic viscera forward, thereby contributing to urethral position and compression, as well as providing a firm backstop for the urethra. It is difficult to conceive that the puborectalis being the most posterior as well as the largest of the levator ani slings will not influence the vagina and urethra as well as the rectum during contraction. Within this paradigm, exploration of the literature with respect to puborectalis and its role in urinary continence is useful when attempting to interpret these results.

Controversy exists with respect to whether a shared nerve supply exists between the pubovisceralis (that is undisputedly supplied by the pudendal nerve) and the puborectalis. Shared pudendal nerve supply would infer shared function and thereby support the role of puborectalis in urinary continence. Findings from anatomic studies of cadavers, and in vivo nerve blockade or EMG studies of the puborectalis describe supply from either direct roots of the sacral nerves or the pudendal nerve (Percy et al 1981; Snooks and Swash 1986; Juenemann et al 1988; Barber et al 2002). A needle EMG study of 18 healthy volunteers investigating pudendal nerve supply demonstrated that electrical stimulation of the EAS

(undisputedly supplied by the pudendal nerve) effected an increase in activity in the urethral sphincters, the bulbocavernosus, the levator ani and the puborectalis thereby suggesting pudendal supply to puborectalis (Shafik 1998). More recently, pudendal nerve blockade in 11 women led to a significant reduction in EMG activity in the puborectalis both at rest and contraction ($p < 0.005$), also suggestive of innervation by the pudendal nerve (Guaderrama et al 2005). An elegant cadaveric study of the nerve supply to the pubovisceralis, iliococcygeus and puborectalis in 17 females, found that in most cadavers innervation for either muscle was from the perineal and inferior rectal nerve branches of the pudendal nerve and that most were also innervated by direct sacral nerves S2 and S3 (Grigorescu et al 2007). The table of findings from this publication is presented in Table 8.1 and demonstrates that the puborectalis is seen to share pudendal innervation with pubovisceralis via either the pudendal nerve or its branch, the inferior rectal nerve, in 82% (14 cadavers). In the 14 data sets for iliococcygeus in the same study, pudendal innervation is seen in 41% (7 cadavers). These studies arguably provide support to the suggestion that the puborectalis has shared nerve supply and function with pubovisceralis in urinary continence.

Table 8.1 Innervation of the levator ani muscles, the pubococcygeus (pubovisceralis), iliococcygeus and puborectalis from Grigorescu et al (1997)

Cadaver Number	PCM	ICM	PRM
1	Perineal N + IRN*	S3–S4	Perineal N + IRN*
2	S3–S4	–	Perineal N + IRN
3	Perineal N	–	Perineal N
4	Perineal N	–	Perineal N + IRN
5	Perineal N	S3–S4	Perineal N + IRN
6	Perineal N	S3–S4	IRN*
7	S3–S4 + IRN*	S3–S4	S3–S4
8	Perineal N + IRN	IRN	IRN
9	Perineal N + IRN*	Perineal N + IRN*	Perineal N + IRN*
10	–	S3–S4	S3–S4
11	Perineal N + IRN + S3–S4	IRN + S3–S4	Perineal N + IRN
12	Perineal N	S3–S4	Perineal N + IRN*
13	Perineal N + IRN* + S3–S4	IRN* + S3–S4	Perineal N + IRN*
14	Perineal N + S3–S4	S3–S4	S3–S4
15	Perineal N	Perineal N	IRN
16	Perineal N + S3–S4	S3–S4	Perineal N
17	IRN* + S3–S4	IRN* + S3–S4	Perineal N

PCM Pubococcygeus muscle, *ICM* iliococcygeus muscle, *PRM* puborectalis muscle, *S3, S4*, sacral nerves originating from sacral roots S3 and/or S4 (levator ani nerve), *Perineal N* perineal nerve, *IRN* “classical” inferior rectal nerve, *IRN** variant inferior rectal nerve, – no innervation was observed for the particular component muscle of Levator ani muscle *Reproduced with permission Springer Link*

The arrangement of pubovisceralis is of interest. It is commonly discussed as coursing around the rectum with the puborectalis (Peng et al 2006; Constantinou 2009). However, this stance is not in agreement with *Terminologia Anatomica* or with the MRI findings of a multinational team that describe the fibres of puborectalis as being exclusive in wrapping around the rectum and forming a “puborectal bump” (Margulies et al 2006). This finding is supported by an MRI

and 3-D anatomical modeling study ($n=20$) that has demonstrated that the puborectalis exclusively forms the boundary of the posterior compartment as it wraps around the rectum, with pubovisceralis present only on the lateral boundary (Hsu et al 2008). A study using high-definition manometry ($n=16$), demonstrated a high pressure zone in the mid vagina that was higher in the posterior to anterior direction than the lateral that could only have been generated by puborectalis (Raizada et al 2010). An earlier study of 11 nulliparous women also demonstrated puborectalis to be a generator of vaginal pressure. Following pudendal blockade of the puborectalis, EMG activity decreased significantly and a significant reduction in vaginal pressure was observed ($p<0.05$) (Guaderrama et al 2005). These studies collectively suggest that the puborectalis is a significant force in generating vaginal pressure and that this has implications for its role in the urinary continence mechanism.

Relative shortening of the puborectalis is also of interest. Movement of the urethra towards the pubis is acknowledged to be dependent on contraction and subsequent shortening of pubovisceralis. However, puborectalis is likely to have as much if not greater influence than pubovisceralis due to its morphology. In a 3-D ultrasound study of 27 nulliparous women, puborectalis length at rest and on voluntary contraction of the PFM was reported as 50.2mm and 40.6mm respectively i.e. voluntary contraction produced a shortening of approximately 20% (Weinstein et al 2007). In a CT defecography study of 30 healthy female and male volunteers the puborectalis was seen to shorten by 14% of its length to a mean of 63.5mm from 73.8mm, whilst the “levator ani” (pubovisceralis and iliococcygeus) shortened by only 3% to 89.4 from 92.4mm (Li and Guo 2007). The relative greater shortening of puborectalis supports its function in its sling-like role in the urinary continence system.

With respect to puborectalis and urethral stability, only one study has investigated the dynamic relationship of the ARA with the urethra (Lovegrove-Jones et

Al 2009). The authors used the term “levator ani” and not puborectalis specifically, as they take the stance that the pubovisceralis wraps around the rectum (Constantinou et al 2009). Nonetheless this study by Constantinou et al (2009) provides important information about puborectalis. Using 2-D RTUS and motion tracking in 23 continent and 9 urinary incontinent women, simultaneous displacement of the urethra and movement of the ARA were studied during a single cough. The ARA was observed to move forward in continent subjects, and backwards in those with UI. The urethra was displaced downwards in both groups, although the continent group moved only a third of the distance of incontinent subjects. These findings suggest that the puborectalis has a stabilising influence on the urethra that may be diminished in women with UI. A study of the levator hiatus also suggests a relationship between the puborectalis and stability of the urethra. The puborectalis forms the boundary of the levator hiatus and is considered to be the principal generator of muscle force in its closure. Braekken et al (2010a) observed an improvement in bladder neck position and a shortening of the hiatus following intensive PFM training thereby suggesting a role for puborectalis in urethral stability.

With respect to puborectalis and urethral compression, only one study has attempted to investigate relationship of UCP and puborectalis contraction. Using 10 female anaesthetised rabbits, the puborectalis and external urethral sphincter were electrically stimulated during simultaneous UCP measurement. Electrical stimulation of the puborectalis produced a significant increase in UCP compared to stimulation of the rhabdosphincter/external urethral sphincter alone ($p=0.05$) (Rajasekeran et al 2011). The study is limited by its use of an animal model but provides preliminary insight with respect to the contribution of puborectalis in the generation of urethral pressure.

The studies cited above all support the suggestion that puborectalis may be more important in urinary continence than is widely acknowledged although opinion

remains divided. Whilst some authors acknowledge the role of puborectalis as a constrictor that works beyond its role in faecal continence (Guaderrama et al 2005; Raizada and Mittal 2008; Ashton Miller and DeLancey 2007) others refute the role of puborectalis in UI. Following presentation by Mittal of work by his team (Rajasekeran et al 2011) at ICS Glasgow 2011, public debate ensued. Dietz argued with Mittal that it is not possible to distinguish between puborectalis and pubovisceralis during imaging. This was followed by KC briefly describing results of this study and the hypothesis that puborectalis is involved with UI. Dietz argued that the puborectalis is not involved in UI as evidenced by a lack of improvement in urinary symptoms when the avulsed puborectalis is repaired with mesh. This stance is arguable, as mesh is non contractile. Whilst it is likely to improve symptoms of POP by providing static support, it is not able to function as a contractile muscle unit in order to contribute to the functional constrictor action of the intact PFM in urinary continence. It was evident at this international meeting that there were two distinct “camps”. The American (including DeLancey and Mittal and their co workers), who are “pro-puborectalis” and the Australian (including Dietz and co workers) who are not. Personal email correspondence with Dietz confirmed that his opinion is that distinction between the components of the levator ani is unnecessary (Appendix 1b). This may not be the case in the context of selective contraction of the PFM. Bartram (of the current study) is recognized as a pre-eminent colorectal radiologist, and like DeLancey and Mittal, is of the opinion that puborectalis has a role beyond the remit of faecal incontinence.

Other posterior muscles; the iliococcygeus, levator plate and long muscle of the anus may also have contributed to the findings of this study indirectly. The iliococcygeus has an expansive arrangement and is not circumferential and therefore is not considered to contribute to compression of the urethra (Ashton-Miller and DeLancey 2007). It is however, in close relationship with the puborectalis structurally (Figure 2.7) although it does not share nerve supply as

frequently as puborectalis does with the pubovisceralis (Table 8.1). It is arguable that co contraction exists between iliococcygeus and puborectalis with a role of optimising tension of the endopelvic hammock and that it may be optimally recruited when a posterior cue is used. The muscle couple of the levator plate and long muscle of the anus may also have been optimally recruited when a posterior cue was used, thereby contributing to narrowing of the AUI by production of dorsal tension as an opposite to pubovisceralis force as described in the Integral Theory (Petros and Ulmsten 1990; see 3.1.2.3).

Of interest is the finding that the results in Studies 1 and 2 are broadly similar for differences between the anterior and posterior cue at approximately 4°. Taking the stance that the pubovisceralis is more commonly damaged than puborectalis (see 2.5), it may have been expected that results in Study 2 would have demonstrated a larger difference between anterior and posterior cues than in Study 1 (i.e. a relative weakness of pubovisceralis). This was not the case. However, the finding of a 5° difference in the parous group between anterior and combined cues as compared with 4° in the nulliparous cohort, reflects more conveniently the hypotheses that a relative weakness of pubovisceralis exists, although still does not explain the finding of only a 4° difference between the anterior and posterior cues, in agreement with the nulliparous cohort. These findings are difficult to explain although it is to be emphasised that this discussion is of interest only, because this study did not set out to make comparisons between groups. To do so would require parallel correlative MRI studies of levator trauma and multiple regression analysis. Further to attempt to formally make comparisons by analysing available data in this study would be inappropriate because the motivation to do so would be based on the incidental results that have arisen. Ultimately, the results for both cohorts support the inclusion of posterior cue in PFM instruction.

In summary, this is the first study that has attempted to investigate selective contraction of the PFM. It is proposed that narrowing of the AUI when a posterior

cue is used, is principally due to optimal recruitment of the puborectalis and infers a greater role of the puborectalis in urinary continence than has been widely recognised. The iliococcygeus and levator plate may also be optimally recruited when a posterior cue is included in instruction.

8.3 Secondary findings

Investigation of the effect of posture on AUI has not been previously investigated. The AUI was found to be more acute by 9.496° [CI 95%: 7.478 to 11.513 $p=0.000$] in supine compared to standing (Table 7.5c). This finding is in agreement with perineal ultrasound studies that have compared bladder neck position between these postures (Schaer et al 1996; Chen et al 1998). These studies demonstrated that whilst the bladder neck is lower in standing than supine, there are no statistically significant differences in absolute dynamic measurements between the two postures. The results of the current study may be used to assure practitioners that the subjective assessment findings of selective PFM contraction in supine for assessing optimal cue may be applied to the standing posture, which is a more functional posture than supine, and is preferred, by subjects and operators (see 6.6.2.1).

The ability to selectively contract the PFM is another paradigm investigated within this programme of work that had not been previously studied. The results were that three continent (13%) and two incontinent subjects (8%) lacked the ability to selectively contract (Tables 6.3 and 6.4). It may have been expected that a greater percentage of the incontinent subjects would be unable to selectively contract, given that incontinent women are known to have compromised motor control of the levator ani (Madill and McLean 2007). Studies are required in order to investigate this further.

A pre-requisite for selective contraction is the ability to effectively contract the PFM and the results here have contributed to the existing knowledge base in this

respect. It is known that up to 30% of incontinent women (Bump et al 1991; Wise et al 1992; Bø et al 1998) and 15% of continent women (Dietz et al 2003) are unable to effectively contract the PFM. The finding here that seven (23%) incontinent subjects and four continent subjects (12.5%) (Table 6.5) were unable to effectively contract the PFM is therefore in agreement with the literature. Wise et al (1992) suggested that in parous women, this may be due to neuromuscular dysfunction or detachment of the periurethral fascia post partum although this does not explain why a small percentage of nulliparous women do not have this skill either. Vodusek (2007) discusses that certain of the sensory input mechanisms that are found within the limb muscles are insufficient in the PFM and are poorer in women than men.

Repeatability of selective contraction of the PFM has not previously been studied. Analysis undertaken in Study 1 demonstrated results to be near the limit of acceptability at 0.78 [CI 95%: 0.690-0.849 $p=0.000$] (see 7.1.3.1). It is of interest to consider why these subjects could not repeat at data collection. Extrapolation is problematic because ability to selectively contract had been indicated subjectively on EMG. The probability is that it was due to random error.

Repeatability in Study 2 was better than in Study 1 at 0.95 [CI 95%:0.875-0.953 $p=0.000$] (see 7.1.3.2) and also supports the suggestion that the weakness in Study 1 may have been due to random error. It is possible however that a consistently small number of women may be unable to successfully repeat selective contraction of the PFM. Further studies of repeatability are required to investigate this suggestion.

Cue preference post expert teaching and practice is of interest (Table 7.9). Overwhelmingly women found inclusion of a posterior cue preferable. This finding supports the clinical experience of KC that inclusion of a posterior cue is usually preferred to an anterior cue. This is probably due to a posterior cue facilitating an anal squeeze similar to that voluntarily used when withholding

flatus. Such a squeeze is likely to be far more familiar than a urethral squeeze given that the social requirement to withhold flatus occurs frequently and will produce co-contraction of puborectalis. The close anatomical relationship of the puborectalis with the EAS is seen in Figures 2.11 and 2.12. Co-contraction of puborectalis and EAS has been evidenced using “maximal anal squeeze” during rectal dynamometry in subjects with FI. The squeeze produced increased rectal pressure deep to the EAS where only puborectalis could generate a voluntary increase in pressure (Fernandez-Fragas et al 2002). Cue preference is discussed further in Chapter 9.1.3 with respect to clinical applicability.

8.4 Incidental findings

Several incidental findings of interest emerged during the programme of work. These included difficulty with recruitment; the effect of inclusion of health professionals; symptom severity and delay in reporting symptoms; preferred assessment posture; and urethral hypermobility.

Recruitment proved more difficult than anticipated at the start of the study. Gul and Ali (2010) discuss that despite the serious implications of recruitment and attrition to a research study, this issue is not given due attention in publications and research. In particular these authors discuss that whilst researchers state the number of subjects recruited, the difficulties encountered during recruitment are rarely published. Difficulties in recruitment should not have been unexpected in this programme of work due to the invasive nature of the investigation and particularly in Study 1 where subjects were asymptomatic. Further, the high proportion of the population from ethnic minorities in Harrow at 41.2% at the time of recruitment (Census Survey 2001: UK), is reflected in the many women of ethnic origin who were approached in clinic but were found to be unsuitable for invitation due to language difficulties. Other women who did not have language difficulties may not have been suitable for inclusion due to cultural reasons. Recruitment in the incontinent group was probably easier because subjects were

symptomatic and possibly already in the contemplative stage of help seeking behaviour (Prochaska and Velicer 1997). The snowballing effect (word of mouth recruitment) as described by Goodman (1961) (see 6.1.1) was of particular value in this study with seven subjects across both cohorts being recruited in this way.

The five women in Study 1 who withdrew before Session 1 (Table 6.3), without giving a reason reflects the importance of providing a cooling period, particularly in an invasive study of asymptomatic subjects. These women were invited verbally to consider participating rather than responding to poster invitation only, as was the case in the incontinent group. With time to reflect they may have decided that the trial was inappropriate or too invasive considering that they were not seeking help. The 100% retention rate in the incontinent cohort after Session 1 as compared with 10% of continent subjects who withdrew after Session 1 without giving a reason (Table 6.3) is also likely to have been due to subjects being symptomatic.

It was of interest that in Study 1 health professionals who may be assumed to have an exercise and proprioceptive advantage over the general population were found to have no greater advantage over non health professionals (Table 6.5). Three previous observational studies of women have used physiotherapists exclusively (Sapsford and Hodges 2001; Bø et al 2003; Frawley et al 2006) although this is the first study to comment on the effect of inclusion of health professionals in the physiotherapy pelvic floor literature.

As previously discussed in Chapter 1.1.2 it is well known that many women delay reporting symptoms of urinary incontinence. In this study, the length of time before incontinent subjects came forward for intervention was 24 months-192 months [2-16 years] (mean 54.34 months, SD 70.35, 4.5 years) (Table 6.5). It may therefore have been expected that mild symptom profiles would have been seen. However ICIQ-SF (Avery et al 2004) scores demonstrated that 70% of subjects

had moderate symptoms (Table 6.1). As discussed in Chapter 1.1.2, women have been found to be reticent to report symptoms and may delay for many years (Norton et al 1988; Hannestad et al 2000; Perry et al 2001; Kinchen et al 2003; Hunskaar et al 2004; Hay-Smith et al 2007; Wallner et al 2009b). The current study supports these findings.

A finding in Study 1 was that women stated that they preferred the supine posture for reasons of dignity (6.6.3). The supine posture was also preferred by the operator (CB) for both reasons of dignity and steadiness of the probe. This concurs with a previous study that reported women to prefer the supine posture for reasons of dignity (Frawley et al 2006) and to another that reported assessment to be easier to undertake in the supine posture than in standing (Bø and Finckenhagen 2003). In a publication of reliability of examination techniques for 2-D RTUS Tunn et al (2005) suggest that posture of choice be selected according to operator and subject preference, providing that the posture is consistent throughout a given study.

The difference of 7.63% in AUI between cohorts as presented in table 7.8 reflects urethral hypermobility in the incontinent cohort which has long been known to be associated with SUI (Green 1975). These differences are in agreement with previous studies that have found similar differences in bladder neck position between continent and incontinent women (Clark et al 1990; Meyer et al 1998; Miller et al 2001).

8.5 Limitations

As with any research programme there are certain methodological issues that are recognised and require reflection. These are discussed here.

It is arguable that those subjects who could not perform an effective PFM contraction on initial assessment at Session 1 or selective contraction at Session 2

should not have been excluded (Tables 6.3 and 6.4). However this exclusion criterion was considered reasonable as the aim of these studies was to assess functional change rather than clinical effectiveness. It would have been problematic to investigate this in women who were unable to effectively or selectively contract the PFM. Exclusion of these subjects may be considered a constant error, although it was considered reasonable as this was an observational study rather than a clinical trial. In possible future clinical trials of selective PFM contraction, analysis by intention to treat will be necessary to include subjects who are unable to effectively or selectively contract the PFM. Based on the results of the power calculation, 35 continent subjects will be required for intention to treat analysis in order to detect a difference of 4° for continent subjects (Table 7.10a). For an incontinent group, the estimated number of subjects required for intention to treat analysis to detect a difference of 4° is 14. The disparity between power required for each group (35 for continent subjects and 14 for incontinent) is possibly due to the Type II error in Study 1 that is likely to have occurred randomly. Further the subjects in the incontinent group were “selected” to a greater degree than the continent group (due to pathology) which may have resulted in less variation in AUI compared with the continent group. It is suggested that equal numbers should be recruited to each group i.e. 35 per group.

The lack of randomisation between postures at data collection was recognised to be a potential weakness. However, the results clearly indicated no relationship between AUI and posture and therefore this is considered reasonable (Table 7.4b).

The use of surface EMG with respect to providing indication of ability to selectively contract the PFM was recognised as a weakness, but due to the pragmatic design, there was no other instrument available that was suitable. Surface EMG is not the gold standard for assessing neuro-muscular activity because it is subject to cross talk between neighboring muscle groups. Further, it cannot be used for inter subject comparisons due to variables such as muscle volume and amount of adipose tissue Basmajian (1985). For these reasons surface

EMG is not quantifiable. Needle EMG is the gold standard that eliminates these issues but was beyond the scope of this programme of work. Despite this limitation surface EMG was considered useful as a subjective biofeedback tool in order to provide rudimentary indication of the ability of a subject to follow cue to instruction for selective PFM contraction. The acquired surface EMG observations consistently agreed with reports from subjects that they were, or were not, proprioceptively confident in their ability to follow instructions. Further, the principal results showed significant differences between cues and thereby indicated that subjects had the ability to selectively contract. For these reasons the use of surface EMG was considered reasonable.

With respect to variables, the groups in Study 1 and Study 2 were deliberately not matched although within group subjects were deliberately broadly matched for age, parity and menopause status. This was so designed because the aim was not to compare groups but to observe changes in a group as close to “normal” (the nulliparous continent group) and another group that had been subject to the effects of parity and menopause. As discussed in 5.3.1, a menopausal age range was chosen because it was considered that it would be easier to apply results from menopausal women with SUI to a younger group of women with SUI than vice versa. BMI would arguably have been one of the biggest variable confounders, but this was well matched by chance (continent group: range 18-36, mean 24.7, SD 4.08; incontinent group: range 21-34, mean 26.54, SD 3.06). There were more variables in the incontinent group due to parity (Table 6.7) and this is recognised as a weakness. It was not possible to undertake logistic regression for these variables as it was considered that the study was too small to render them meaningful.

It is recognised that a limitation in this programme of work was lack of Patient and Public Involvement (PPI). Historically, at the time of development of this programme of work, PPI was not a necessary requirement in gaining ethical approval. It is now an essential element in study design as championed by the

United Kingdom Clinical Research Collaboration (www.ukcrs.org) partnered with the national advisory group INVOLVE (www.invo.org.uk). This partnership supports greater public involvement in NHS, public health and social care research. A review of seven papers that specifically investigated PPI at the design stage in primary care, identified and recommended improving the quality of information sheets; identifying additional outcome measures in clinical trials; ensuring data collection procedures are ethically acceptable; making recommendations as to the most appropriate time to approach potential participants and the best time and methods for follow-up (Boote et al 2009). It is now essential to have patient representation on any research team. Accordingly, the North West London Hospitals NHS Trust research hub currently details PPI as a requirement for any research project:

“patients or their representatives should be involved in the design of the project...”.

On reflection, the nature of this study was invasive and may not have been acceptable to many women. It is probable that inclusion of PPI may have resulted in increased recruitment and retention and greater acceptability of testing procedures for subjects. A greater understanding of attitudes towards intimate examination may have been gained so that the study design may have been more inclusive to women of all cultural groups. In any future study, PPI would be an essential component from the outset in order to inform design and to ensure that the research is patient focused and relevant.

It is also useful to reflect on the dual role of this clinician-researcher and the potential tension between these roles when conducting research. Brody and Miller (2003) discuss the paradigm of the "difference position" as recognition that clinical research and therapeutic medical practice are distinct activities that require different ethical rules and principles. The "similarity position" is that clinical investigators are bound by the same fundamental principles that govern

therapeutic medicine: specifically, a duty to provide the optimal therapeutic benefit to each patient or subject. The authors strongly recommend using the “difference stance”, and not the “similarity stance” in which the roles may become blurred due to the opportunity to offer therapeutic benefit to the subject (Brody and Miller 2003). In any research study it is necessary to be consciously mindful of the need to avoid taking advantage of any bias that the duality of the role may potentially introduce. Such consciousness is described by Clancy (2013) as “being crucial to becoming self-aware and thus able to see any influences that could affect data collection or analysis”. On reflection, it was on occasion difficult for this author not to offer therapeutic advice. However such difficulty was mitigated to a large extent by the knowledge that each subject had been invited in the PIS to attend for treatment following data collection (Appendix 3a and 3b). Other steps were consciously included in the design to avoid bias/tensions although these were not framed in the context of evidence based practice: subjects were informed in the patient information sheets that the purpose of the invitation to participate was for research purposes (Appendix 3a and b) and this was reiterated to the subject verbally; therapeutic advice was withheld in order that the subject was not biased towards the opinion of the clinician-researcher that may have led to variation in effort whilst executing a PFM contraction using the different cues (5.3); subjects were blinded to the hypotheses as well as any opinion that the clinician-researcher held about potential optimal cue so that bias in the form of favouring one cue over another either at ultrasound data collection or when answering questions about cue preference would be minimised (6.4); and one standardised prompt only was given for each cue at data collection (6.8.2) , rather than providing several as is usual when encouraging a patient in the clinical setting. Despite these conditions the potential existed in this study for the role between researcher and clinician to become blurred which may have affected the outcome, and this is difficult to entirely avoid. This issue was discussed during informal conversation with Clive Spence-Jones, urogynaecology surgeon/researcher (Whittington Hospital, London) at CSUK conference 2014.

His opinion was that it is almost inevitable that researchers investigating clinical issues will have a dual role and that providing the attitude of the clinician-researcher to each subject is impartial and that therapeutic advice is withheld appropriately, potential tension should be minimised. On reflection, these conditions were intuitively followed during this study but as stated previously, not within the framework of the evidence base. Nor was this issue acknowledged at the design stage. In future studies, mindful consciousness of the potential difficulties in this dual role, including reflective diaries, will be integral to design.

Summary

Reliability in this study was found to be robust. The weak results for repeatability in the supine position in Study 1 suggested a Type II error that was eliminated when power was increased by aggregating results from Tests 1 and 2. The narrower AUI seen when a posterior cue was included in instruction as compared to the anterior cue is proposed to be due to optimal recruitment of puborectalis. This suggests that puborectalis has a role in urinary continence. Certain anatomical and physiological phenomenon discussed here support this proposition, although professional opinion with respect to the role of puborectalis beyond the remit of its role in faecal continence is divided. This muscle is not widely discussed as part of the urinary continence mechanism, and deserves greater attention. Optimal recruitment of iliococcygeus, levator plate and long muscle of the anus when including a posterior cue may also have contributed to these findings. Standing posture did not affect absolute AUI as compared with the supine position. A wider difference in AUI between anterior and combined cues

was seen in the incontinent group. This may have been due to relative weakness of pubovisceralis as a result of parturition disruption. However, this study was not designed to formally address this issue and further exploratory studies would be required to confirm this. Of interest are the findings that practice effect influenced intra rater reliability for the non-diagnostic imaging AHP; that ability to selectively contract the PFM is not complicit with the ability to effectively contract the PFM; that operator and subjects preferred the supine position and that subjects preferred a posterior or combined cue post expert teaching. Exclusion of subjects unable to effectively or selectively contract the PFM; lack of randomisation of posture at data collection; use of surface EMG; lack of PPI and possible tension due to the dual role of this author as clinician and researcher are arguable weaknesses.

Conclusion

The study hypotheses are proven by the principal results. Inclusion of a posterior cue to instruction resulted in narrower AUI than when using an anterior cue alone. These findings are proposed to be due to optimal recruitment of puborectalis when a posterior cue to PFM contraction is included in instruction. It is proposed that puborectalis may be more important in urinary continence than is widely acknowledged. Various issues of interest emerged through the course of the programme of work. There were arguably some limitations but these are recognised. These results may be applied to pre menopausal nulliparous continent and menopausal parous women with previously unreported SUI who are able to effectively and selectively contract the PFM.

The final chapter that follows discusses clinical importance of the results and suggestions for future studies.

Chapter 9 Clinical Importance of findings and Recommended Future Studies

9 Introduction

This programme of work has produced evidence to begin to answer the clinical question “What is the best way to teach a pelvic floor muscle contraction?”. Whilst preliminary to larger studies, the results from this programme of work are robust. Further studies are required to support these suggestions. These findings are potentially of significant clinical importance for several reasons:

1. A posterior cue to PFM instruction has been demonstrated to produce a significantly narrower AUI in these studies. This translates to an improvement in urethral stability simply by selecting a posterior cue compared with an anterior cue alone. This may result in improved outcomes for SUI in PFM training programmes.
2. The findings may be important in PFM training for women with SUI with respect to preferred cue and may improve exercise self-efficacy.
3. The findings are important in being able to assure women that the intervention of PFM contraction tuition is evidence based.
4. The finding that ability to selectively contract the PFM is not complicit with ability to effectively contract is useful clinically when counselling women who lack this skill.
5. The findings inform clinical practice with respect to posture for assessment of the PFM.
6. This preliminary evidence provides a platform from which to educate and simplify PFM instruction for patients, non specialist health professionals, and the media and lay public.
7. This work supports the need for international debate with respect to standardisation of instruction for a PFM contraction. Standardisation has implications for both clinical and research purposes.

8. Taken with the emerging evidence base, it may be tentatively suggested that inclusion of a posterior cue to instruction may also be useful in other arenas such as POP, core stability, low back pain and pelvic pain.
9. The confirmation that reading of US images is a skill that may be relatively easily acquired by a non-diagnostic imaging AHP is important for further research.

Discussion follows to support this reasoning.

9.1 Clinical importance of narrowed AUI

Introduction

The relevance of urethral stability has been discussed previously in Chapter 3.2. To summarise, the consensus of a working party of the International Urogynaecology Association is that “urethral hypermobility is an important aspect of the evaluation of SUI and requires further investigation” (Ghoniem et al 2008). The results of studies reviewed in Chapter 4 with respect to PFM training suggest that improvement in outcomes are related to urethral stability (Miller et al 2001; Braekken et al 2010a; Balmforth et al 2006; Hung et al 2011). It is not yet possible to definitively state that the difference in AUI of approximately 4° between anterior and posterior/combined cues seen across both studies is of clinical value because these results are preliminary to larger clinical trials. However, it is possible to make the suggestion that optimising urethral support by using a posterior cue and optimally narrowing the AUI may be of clinical value with respect to SUI.

9.1.1 Application of the results clinically: The Knack

The most obvious application of selective PFM contraction would be when using The Knack (see 1.2.1.3) (Miller et al 1998). These researchers demonstrated that voluntary contraction prior to increase in IAP significantly reduces urine loss following a brief period of training and that the urethra is stabilised when using

The Knack (Miller et al 2001). In women who are using a suboptimal recruitment strategy (anterior), improvement in urinary loss may be expected to be less than when an optimal cue (posterior or combined) is used during The Knack. This is observed in clinical practice in women who already use The Knack but have not previously included a posterior cue. Improvements in leakage are often seen within a week of change of technique.

9.1.2 Application of the results clinically: strength training of the puborectalis

As discussed previously, change in bladder neck position has been observed when the PFM is strengthened (Balmforth et al 2006; Braekken et al 2010a [see 4.2.1.2]). Because the puborectalis is implicated in the results of this study, optimal strengthening of the puborectalis by including a posterior cue may produce a greater difference in urethral support at the end of intervention than if puborectalis recruitment is sub-optimised. It is considered reasonable to suggest that optimising urethral stability by strengthening puborectalis may be important in clinical outcomes in women with urethral hypermobility although further research is required to support this suggestion.

9.1.3 Application of the results clinically: preferred cue and self efficacy

Poor self-efficacy in PFM training is arguably the biggest barrier to success (Hay-Smith et al 2007; Messer et al 2007). Confidence with respect to how to execute an exercise is a component of self efficacy. Messer et al (2007) have demonstrated improved adherence as confidence increases. This paradigm is reflected frequently in clinical practice. Women report greater confidence and subsequent improved self-efficacy having been taught to include a posterior cue, due to feeling more in control or more comfortable. Subjects in this programme of work overwhelmingly preferred the posterior or combined cue and this is likely to have impacted on confidence levels. It is therefore proposed that inclusion of a posterior cue may potentially have far reaching implications with respect to PFM training self efficacy although further studies are required to support this proposal.

9.1.4 Application of the results clinically: preferred cue and belief system

The belief that an intervention will work is a component of self-efficacy. Such beliefs are enhanced by learning about the mechanisms of how an intervention may work (Hay-Smith et al 2007). It is the clinical experience of KC that teaching an intervention is enhanced by reference to the evidence base. This contributes to engendering a belief system (for the patient) that an intervention will work. This has been reflected in clinical practice with teaching of selective cues whilst informing the patient of the results of this study. Relaying the principal findings of this programme of work to patients has been received well and described as useful with respect to improving belief and confidence. It is suggested that presenting the evidence from this study to patients contributes to improved exercise adherence and ultimately success of exercise programmes.

9.1.5 Application of the results clinically: ability to selectively contract

The finding that ability to selectively contract the PFM is not complicit with ability to effectively contract is useful clinically when counselling patients. The knowledge that 10% of women were unable to selectively contract the PFM in these studies is useful in reassuring women who lack this skill. Confidence that may otherwise have been compromised may be restored by referring to the evidence as produced here.

9.1.6 Application of the results clinically: posture for assessment

As discussed in 8.4 practitioners may be informed that the standing posture may not be absolutely necessary for assessing selective PFM contraction. The standing assessment was found to be a less acceptable for assessor and subjects than supine (see 6.6.3 and 8.5) and these factors should be taken into account in clinical practice.

9.1.7 Application of the results clinically: education for health professionals and the lay public

Although a proportion of specialist health professionals are likely to include a posterior cue to instruction for a PFM contraction, it is evident that many are not (see 4.2.4; Tables 4.3 to 4.8). The results of this study are important and infer that at least until further research emerges, physiotherapists and continence advisors should use clinical reasoning with respect to selective PFM contraction when planning a PFM training programme. A small number of women (16% in this study; Table 7.9) are likely to prefer the anterior cue and it is important that this choice is respected. However the inclusion of a posterior cue is easily understood and was preferred by the majority of subjects in this study. The simplicity of including a posterior cue is likely to diffuse the mystery surrounding PFM contraction. For those AHPs who do not have use of 2-D RTUS, digital palpation may be used to assess compartmental contraction using different cues.

The results therefore are not only potentially clinically important for pelvic floor AHPs but also for non specialist health professionals. Further, simple education of the lay public with respect to a posterior cue may improve confidence about technique and thus improve likelihood of adopting the habit of performing PFM exercises.

9.2 Debate with respect to standardisation of instruction

The literature review with respect to instruction for a single PFM contraction reveals many varying instructions across specialist and non specialist health professionals and professional bodies as well as the media (see 4.2.4). Such variation is confusing for all concerned, and may result in suboptimal recruitment of the PFM depending on technique used. In particular, it also renders comparison of research studies that use PFM contraction problematic. Whilst the results of the current study are preliminary, it is proposed that standardisation for instruction for

PFM contraction is worthy of debate at international level with the standardisation committee of ICS and IUGA.

9.3 Use of selective contraction of the PFM beyond continence

9.3.1 Pelvic organ prolapse

Pelvic floor muscle training has recently been evidenced in a UK multi centre RCT to be clinically and cost effective in the management of early stage pelvic organ prolapse (POP) (Hagen et al 2011). The authors of the study suggest that PFM exercises should be recommended as first line management for early stage POP. The understanding of the usefulness of PFM exercises in POP is reflected in the clinical practice of KC over the past three to five years. During this period, the ratio of female patients referred for UI and POP has increased from approximately 10:1 to 2:1 as the evidence base in support of PFM training in the management of pelvic organ prolapse has emerged. The exact mechanisms for improvement of POP following PFM training are not understood, although women with pelvic organ prolapse have a larger levator hiatus (Figure 2.10) than those without POP (Dietz et al 2001). Hiatal area has been seen to reduce significantly following PFM training (Braekken et al 2010a). The same trial demonstrated improvement in POP following PFM training although no correlation was seen between reduction in levator hiatus area and improvement in POP. Nonetheless, inclusion of a posterior cue may well be of use as the puborectalis acts to narrow the levator hiatus. Suboptimal recruitment of puborectalis if the posterior cue is excluded in a training programme may represent a missed opportunity for greater improvement in POP.

9.3.2 Core Stability and Low Back and Pelvic Pain

Control of IAP is important for lumbo-pelvic stability and has implications in the genesis of low back and pelvic pain. The PFM form the floor of the abdomino-pelvic cylinder, with the diaphragm forming the ceiling, and the transversus

abdominis (TrA) and thoracolumbar fascia (TLF) positioned circumferentially. The TrA is believed to be the greatest generator of IAP. Generation of IAP influences spinal segmental stiffness via its influence on the hoop like thoracolumbar fascia (Barker et al 2006). It is believed that the PFM contribute indirectly to development of spinal segmental stiffness by means of contribution to generation of IAP, thereby supplementing the pressure generated by the TrA (Tesh et al 1987). The PFM must reciprocally co-contract with TrA to meet the challenges imposed upon them from down coming pressure to assist with this control (Sapsford et al 2001; Bø et al 2003). A study of female cadaveric pelvises demonstrated that when PFM contraction was simulated, a significant increase in sacro-iliac joint (SIJ) force closure and backward rotation of the sacrum was seen (Pool-Goudzwaard et al 2004). In subjects with SIJ pain, the PFM was seen on 2-DRTUS to depress during active straight leg raise. The PFM depression was reversed when the SIJ's were stabilised using manual compression through the ilia (O'Sullivan et al 2002). Another study found that training of the PFM and TrA resulted in significant reduction in SIJ pain scores (O'Sullivan and Beales 2007). It is also evident that a relationship between back pain and UI exists. It is estimated that the risk of developing UI is >bi-fold in women with back pain (Eliasson et al 2008; Finklestein 2002). Similarly, women with UI have >bi-fold risk of developing back pain (Smith et al 2006). A survey of 30,000 women found that those with UI during pregnancy had an eightfold increase in risk of low back pain (Smith et al 2008). These studies infer the importance of PFM training in the management of low back and pelvic pain. The importance of a posterior cue to PFM contraction may be clinically significant in these patient groups.

9.4 Change in Clinical Practice

The above findings taken together should ultimately contribute to the biggest change in instruction for a PFM contraction since Kegel first published instruction in 1948. Dissemination of the results to date (Appendix 6) has resulted in many

verbal communications with practitioners nationally and worldwide. These communications are to the effect that inclusion of a posterior cue is found to be clinically useful and has already changed practice. Inclusion of a posterior cue has been adopted in PFM training programmes by the Women's Health Sector of the American Physical Therapy Association. This is particularly encouraging as instructions from the USA use anterior cue in isolation more commonly than in Europe or Australasia (Table 4.6). A pelvic floor educationalist in Ontario Canada has also adopted this strategy for physiotherapy training courses and the work is also being discussed in Australia as evidenced by verbal communication with colleagues.

It is evident therefore that change in practice has already begun. It is important that the work continues to be disseminated with the caveat that these results are preliminary and may be applied to pre-menopausal continent nulliparous women and menopausal parous incontinent women with previously unreported SUI who are able to effectively and selectively contract the PFM. Nonetheless the evidence to date of current change is encouraging with respect to the number of practitioners hearing of this work and making decisions to incorporate the results into teaching and practice. This trend should continue as the work is further disseminated (Appendix 6).

In a publication of when and how new therapies should become clinical practice, pre clinical studies are described as "the drivers of professional progress" (Bø and Herbison 2009). However, it is emphasized that such studies must be interpreted carefully, and cannot provide convincing evidence of the effectiveness of an intervention. It is suggested that absolute decisions of implementation be reserved until RCTs have been undertaken. It is arguable that such delay is not always practical.

9.5 Suggested Future Studies

This is the first study to have raised and explored the question of an optimal cue for a pelvic floor muscle contraction. The results have confirmed the validity of this question. Further studies are required to support this work:

9.5.1 Suggested pre clinical trials

Studies of the levator hiatus during selective PFM contraction

A study based on the current design using imaging of the levator hiatus that allows direct examination of PFM function may be useful to further investigate selective PFM contraction. Measurement of the hiatus may be easier than measuring an angle as used in the current study, although to date no publication has compared the two methods. Measurement of the levator hiatus was not an index that was widely in use at the start of this study and was not considered as it is not used in AHP clinical practice. The disadvantage of measuring the hiatus is that it requires a vaginal probe which is necessarily invasive.

Levator trauma

Further investigation of levator trauma would be of interest. It was not possible to investigate this in the current study and parallel correlative MRI imaging would be required to confirm whether levator trauma influences selective PFM contraction in parous women.

Urethral pressure studies during selective PFM contraction

This study was arguably limited by not being able to directly observe urethral sphincter function during selective PFM contraction. Urethral pressure studies are unlikely to receive ethical approval in the UK but may do so elsewhere in the world. Such studies may further support the results of the current study.

9.5.2 Clinical Trials

The Knack

An obvious application of these results would be with The Knack (Miller et al 1998 and 2001). Subjective reporting of improved urinary loss has been seen frequently by KC when selective contraction of the PFM has been used in women who have previously followed a generic instruction. Outcome measure potentially would be urine loss evidenced by paper towel test whilst using different cues to instruction during The Knack.

Strength training

Randomised controlled trials are of the utmost importance to investigate the effect of selective PFM contraction on outcomes of SUI following intensive strength training. A single centre trial is firstly required as a pilot for larger multi-centered trials. Such a trial may be based on the strength training protocols of Balmforth et al (2006; see appendix 2b) and Hoff Braekken et al (2010a) with MUI an exclusion criterion. It is anticipated that the trial would need to be of cross over design so that with respect to ethical considerations, those subjects randomised to the control group (anterior cue) would cross over to inclusion of a posterior cue at four months and be followed up in a further four months. The cross over design would be based on the PFM strength training design of Dorey et al (2004). Analysis would be on an intention to treat basis using the power calculation presented in Table 7.10. Logistic regression analysis would be interesting in such a trial to investigate the influence of instrumental delivery on selective contraction.

Summary

The results of this study may be clinically important with regard to outcomes of SUI; POP; low back pain and pelvic pain. They may also contribute to debate with respect to standardisation of instruction for PFM contraction. This is important in demystifying PFM contraction for health professionals and the lay public, as well as rendering comparison of research studies less problematic. There exists an urgent need for these results to be validated by further exploratory studies and RCTs. Observational trials of levator hiatus length, levator trauma and UCP with respect to selective contraction of the PFM would be of interest, although ethics restraints may be problematic in the UK for the latter. Single centre and multi-centered RCTs of The Knack and intensive PFM training using selective contraction are required.

Until further research emerges these results may only be applied to premenopausal nulliparous continent women and menopausal parous women with previously unreported SUI who are able to effectively and selectively contract the PFM.

Nonetheless, the results are already changing practice internationally. In the meanwhile, continued dissemination of the results will continue to challenge practitioners about their current practice. The results presented here provide preliminary information about previously un-investigated PFM contraction instruction, upon which to base clinical choices and with which to educate patients and the lay public.

Conclusion

This study is a “driver of professional progress” and change in clinical practice is taking place internationally based on its findings.

Conclusions

The preliminary; primary and secondary aims of this study have been met.

The primary results of this study support the hypotheses that a posterior cue to PFM contraction results in narrowing of the AUI compared to an anterior cue alone, in both continent and incontinent women. In this cohort of pre-menopausal continent nulliparous women who were able to both voluntarily and selectively contract the pelvic floor muscle after a brief period of practice, the AUI was approximately 4° more acute when either a posterior or combined cue to instruction was used as compared to an anterior cue alone. A similar result was seen in the cohort of menopausal and parous stress incontinent women. It is proposed that in both cohorts this difference was due to optimal recruitment of the posteriorly situated muscles, in particular puborectalis, when a posterior cue was included in instruction. This suggests that puborectalis may be more important in urinary continence than widely believed. Regardless of the anatomical basis for the principal findings in this study, the results demonstrate that inclusion of a posterior cue is more influential than an anterior cue alone in narrowing angle of urethral inclination in women who are able to selectively contract the PFM. These results however may only be applied to pre-menopausal continent nulliparous and menopausal parous women with previously unreported SUI, who are able to selectively contract the PFM.

The preliminary results validate the use of 2-D real-time ultrasound and the angle of urethral inclination to investigate optimal cue for PFM contraction. The skill of making measurements from 2-D real-time ultrasound images was relatively easily acquired by this investigator and therefore may be useful for future physiotherapy research studies. Investigation of repeatability for selective contraction of the pelvic floor muscle proved acceptable.

The secondary results have produced useful information with respect to posture, the ability for women to selectively contract the PFM and cue preference.

The standing posture as compared to supine produced a mean difference of approximately 10° between cohorts. However, posture did not influence absolute values for AUI. As expected the AUI was more obtuse in the incontinent cohort than the continent by 7.5° , but did not influence differences in AUI between cues. This is a reflection of urethral hypermobility in the incontinent group and supports the existing literature. Subjects and operator reported a preference for the supine posture as suggested in the literature. These findings support the discussion in the literature that examination posture should be one of operator and patient preference.

The number of subjects in this study who could not correctly contract the PFM was also similar to values reported in the literature. Selective contraction of the levator ani has not been previously studied although approximately 10% of subjects across the groups were unable to selectively contract the PFM.

In keeping with the literature, most of the incontinent women presented with moderate levels of urine loss although had not sought professional help previously. This is reflected in length of time since onset of symptoms to first report, with an average delay of four years.

The results of this study may be clinically important with respect to outcomes of urinary incontinence; pelvic organ prolapse; low back pain and pelvic pain. They may also contribute to debate with respect to standardisation of instruction for a pelvic floor muscle contraction. Dissemination of the results to date has already resulted in change of practice internationally.

This study is a driver of professional progress. It is the first study that has attempted to investigate optimal cue for a single PFM contraction and has

provided seminal information for the PFM evidence base. The findings support the suggestions made in the introduction to this dissertation that treatment if an optimal cue is proven, and that this may lead to standardisation of instruction. In turn this would render comparability of research studies less problematic and clarify instructions in the media and for the lay public.

Whilst this study represents only the start of investigation into an optimal cue to instruction for a PFM contraction, the results are both important and exciting. There exists an urgent need for these results to be validated by further exploratory and randomised controlled trials.

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Appendices

Appendix 1a: Email correspondence with Dr Alison Weidner

From: Dr Alison Weidner, M.D. [alison.weidner@duke.edu]

Sent: 31 August 2012 21:45

To: Kay Crotty

Subject: Re: Publication query: Levator ani abnormality six weeks after delivery persists at six months

Hello!

Thanks for your inquiry. In fact you are right while we did apply methods and some of the knowledge from Dr. DeLancey's paper we did not specifically distinguish between the various components of the levator ani as his team does. When I used the term puborectalis I would say it is most accurate to consider that as representing the muscle group they further subdivide into the puboanalis, visceralis, and vaginalis.

I hope this helps!

Best regards

Alison Weidner

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From: Kay Crotty <kcrotty@lineone.net>

Date: Sun, 26 Aug 2012 11:08:33 +0100

To: <Weidn001@mc.duke.edu>

Subject: Publication query: Levator ani abnormality six weeks after delivery persists at six months

Dear Dr Weidner

I am a PhD student in the UK and part of my work involves a literature review of levator ani abnormalities post partum. I have a query with respect to nomenclature in your study. I note that the study is of puborectalis and iliococcygeus but there is no mention of pubovisceralis. Please could you clarify that you specifically excluded trauma to the pubovisceralis? I am not able to see any mention of this muscle. I am wondering if you have grouped puborectalis and pubovisceralis together? This query is based on your incorporating methods from the work of DeLancey's 2003 paper, although this paper studied the pubovisceralis and did not discuss puborectalis specifically.

Many thanks indeed for clarifying this With kind regards Kay Crotty

Appendix 1 b: Email correspondence with Dr P Dietz

From: Hans Peter Dietz [hpdietz2@bigpond.com]
Sent: 23 November 2012 01:29
To: Kay Crotty
Subject: Re: Query re: nomenclature Abdool Shek and Dietz 2009
Hi,

thanks for the mail.

I agree there is confusion regarding nomenclature, but it's not caused by my unit.

We use the terms puborectalis and pubovisceral muscle as synonymous for these inferior or caudal components of the levator ani muscle that form the levator hiatus, originating on the os pubis and its rami, coursing around the anorectal junction to the os pubis on the opposite side. This structure defines the anorectal angle and the vaginal high pressure zone.

DeLancey sees the puborectalis as distinct from the pubovisceralis, which he defines as comprising the 'pubococcygeus' (a term that should not exist due to the fact that there is no muscle that runs from pubis to coccyx), pubovaginalis, puboperinealis and puboanalis. In fact, at times he has held that the puborectalis is not even part of the levator ani! This is where the confusion has originated from.

We try to simplify things, not to complicate them unnecessarily. It's hard enough to convince people that childbirth-related damage to the levator ani is real, not an artefact. Consequently, we use the term 'puborectalis' as defined above, which is in common usage clinically in Gynaecology, Colorectal Surgery, Gastroenterology, Radiology and Physiotherapy, and complies with basic anatomical conventions.

Kay, the main usage of the term is in describing maternal birth trauma and its consequences. Most clinically significant damage to the levator is avulsion of its inferior components from their insertion on the os pubis/ pubic rami. Whatever you call it- quite often everything is completely torn off. If you really want to understand the issue of childbirth-related levator trauma you need to learn to palpate. Once one understands what happens down there one can probably ignore squabbles over nomenclature.

"What's in a name? That which we call a rose
By any other name would smell as sweet."

Best wishes

Peter
Hans Peter Dietz
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On 22/11/2012, at 11:15 PM, Kay Crotty wrote:

Dear Dr Dietz

Query re: Abdool Z,Shek KL,Dietz HP, The effect of levator avulsion on hiatal dimension and function. Am J Obstet Gynecol 2009; 201:89.21-5

I am a PhD student in the UK and part of my work involves a literature review of levator ani abnormalities post partum. I have a query with respect to nomenclature in your study. I note that the study is of puborectalis. Please could you clarify that you specifically excluded trauma to the pubovisceralis? I note that in the paper that you co author with Kruger et al (2007) your team report that pubovisceralis and puborectalis cannot be differentiated using ultrasound (US) or MRI (magnetic resonance imaging).

With kind regards and thanks

Kay Crotty

Appendix 2a: Summaries of reviews of studies in Part 1 of the literature review: outcome of bladder neck position following PFM training

Miller et al 2001

Source: USA

Evidence level: 2c

Design: Prospective observational study

Objective: The objective of this cohort study was to test the hypothesis that a voluntary PFM contraction initiated in preparation for a cough significantly reduces bladder neck displacement.

Ethics approval : Ethics approval was obtained and informed consent received from each subject.

Recruitment: Subjects were recruited from advertisements in local papers and assigned to one of two groups as appropriate.

Inclusion criteria: The first group comprised young continent nulliparous women ($n=11$, aged 24.8 ± 7). The second comprised older women who were parous incontinent ($n=11$, aged 66.9 ± 3.9).

Exclusion Criteria: Prior bladder surgery, age less than 18 years, inability to refrain from valsalva manoeuvre on PFM contraction.

Attrition: No subjects withdrew

Primary Outcome measures: Bladder neck displacement during coughing with and without The Knack.

Secondary outcome measures: There were no secondary outcome measures.

Power calculation: The sample size selected was described as being appropriate for detecting a difference in bladder neck displacement of 4mm at a confidence level of 95% between coughs with and without The Knack.

Baseline tests: Continence status was confirmed in both groups by a paper towel stress test. A seven day diary was completed to note baseline frequency of urinary

leakage. Baseline ultrasound tests were taken at the same session as data collection.

Reliability: Test re-test reliability for cough pressure was tested within visit using a transducer placed in the upper vagina and described as acceptably consistent. Reliability issues for repeatability of The Knack in the younger cohort, with measures taken one week apart was undertaken and reported as sound. Inter reader reliability was discussed as being free of measurement error although data was not presented.

Intervention: In the younger group, intervention was brief teaching of “The Knack” i.e. avoluntary PFM contraction initiated in preparation for a cough immediately prior to data collection. In the older group subjects had already completed a six month intervention of PFM training that included practicing The Knack and data was collected at the last treatment session. The authors failed to report if one or more persons led the teaching sessions.

Instruction: not stated

Data Collection: Baseline ultrasound data collection of bladder neck at rest and voluntary contraction were collected followed by displacement of the bladder neck during a cough with and without The Knack. It is not reported if there was randomisation between contractions with the knack and without. Intra vaginal IAP measurements were taken during data collection in order to standardise cough pressures.

Reading of data: A single experienced evaluator read all of the images. The images were read by a second evaluator for the purposes of reliability. The authors fail to report if the images were read blinded from continence status or from labels for baseline or study images. The data were measured in millimetres for displacement of the bladder neck on the $x y$ co ordinate system using a modified version of the method described by Schaer et al (1996).

Data Analysis: The ultrasound data were found to be skewed and therefore the non parametric Wilcoxon signed-rank test for within group analysis and the Mann-Whitney U test for between-group analysis were used.

Results: Over both cohorts descriptive statistics demonstrated that a cough without The Knack produced bladder neck displacement of 5.4mm and with the knack 2.9mm ($p=0.001$).

In the continent group decrease in excursion was seen from 4.6mm without the knack to 0.0mm with The Knack ($p= 0.007$) and in the incontinent group from 6.2mm without The Knack to 3.5mm with The Knack ($p=0.003$).

Resting bladder neck position was significantly lower in the incontinent group than the younger ($p=0.001$).

Limitations: The authors acknowledge two limitations in this study. The first is lack of blinding for the rater that may have introduced bias, although this was due to technical restraints that did not allow for on screen labels to be removed, and was beyond the control of the researchers. The fact that data was read by a second rater and was found to be free from measurement is a reasonable compromise. The authors also discuss that a further limitation is lack of repeated measures in the older group. It is also to be noted that the study size is small.

Whilst the authors make no comment about the difference in training periods between groups, a previous study found that older women could acquire the skill within a week (Miller et al 1997). This however would not be obvious to the reader unfamiliar with previous work. It is not stated if the PFM contractions were randomised, although it appears that only three contractions were performed (maximal, a cough with the knack and a cough without The Knack) and so it is unlikely that lack of randomisation would have affected the results.

Finally, the reader would be more confident about whether these results would remain positive if the study were to be replicated if confidence intervals had been presented.

Strengths: This is the first study to investigate the stabilising influence that the PFM has on the urethra. Although small this study is well powered. Within-study reliability tests provide robust information with respect to methodology for future studies. Its usefulness is compounded by a previous paper by the same authors

(Miller et al 2007) in which urine loss was investigated with and without The Knack. The Knack was found to significantly reduce urine loss.

Braekken et al 2010a

Source: Norway

Evidence level: 1b

Design: randomised controlled trial.

Objective: This is a sub study of a parent RCT investigating improvement in symptoms of pelvic organ prolapse following PFM training (Braekken et al 2010b). The objective of this sub study was to investigate morphological and functional changes to the PFM and positional changes of the bladder neck and rectum after PFM training in women with pelvic organ prolapse (POP).

Ethics approval: Ethics approval was obtained before the start of the trial and informed consent received from each subject.

Recruitment: Subjects were recruited by community gynecologists

Inclusion Criteria: Women with POP ($n= 59$, aged 49.4 ± 12.2). Those randomised to control ($n=50$, aged 48.3 ± 11.4).

Exclusion criteria: Women without POP or those with greater than stage III; inability to contract the PFM; breastfeeding; previous POP surgery; radiating back pain; pelvic cancer; neurological disorders; psychiatric disorders; untreated UTI; planning pregnancy; planning to be away for more than 4 weeks of the intervention period.

Randomisation: Subjects all had a stage 1-III POP and were randomised by a computer generated system to a study group or to control group. Both groups were given advice to avoid straining, and were taught to contract the PFM before and during increases in IAP. The study group undertook a strength training intervention whilst the control group were requested not to start PFM exercises.

Attrition: Two subjects withdrew

Primary outcome measures: Morphologic changes as seen on perineal 3-D RTUS for PFM thickness and length; levator hiatus area; and bladder neck and rectal

position at rest. Functional outcome measures were changes in levator hiatus area and muscle length during valsalva.

Secondary outcome measures: Vaginal squeeze pressure.

Power calculation: A sample size of 45 per group was estimated using a power of 80% at the 5% level of significance selected.

Baseline tests: Degree of prolapse was identified using the Pelvic Organ Prolapse Quantification system (POP-Q) (Bump et al 1995); morphology of the PFM was studied using ultrasound for the primary outcome measures; strength of the PFM was assessed with perineometry

Reliability: Previously published reliability studies by the same authors were cited for inter and intra rater reliability and test and re-test (Brekken et al 2008; Majida et al 2009).

Intervention: The same physiotherapist throughout the study led the intervention. This consisted of six months of three sets of 8-12 close to maximal PFM contractions per day and an exercise diary. Visits to the physiotherapist were weekly for three months and fortnightly thereafter. An exercise diary was maintained with 80% compliance considered acceptable.

Instruction: not stated

Data Collection: It is not stated if the data were collected by a single sonographer/radiologist although this was confirmed in the original RCT (Hoff Brekken et al 2010b). The sonographer was blinded to group allocation and clinical and background data. Vaginal squeeze pressure data was collected by the same physiotherapist who had led the intervention.

Reading of data: It was not stated if one rater read all of the images or if the study was blinded although the parent study states that all ultrasound images were evaluated blinded by the study lead/physiotherapist. Bladder neck position was measured in millimetres using the system described by Peschers et al (1997). Vaginal squeeze pressure data were evaluated by the study lead.

Data Analysis: Analysis was not by per-protocol as the purpose was to obtain data on morphological change rather than clinical effectiveness. Pre and post intervention ultrasound data was analysed for normality. The data for bladder

neck position were not normally distributed and therefore was analysed using the non parametric Wilcoxon signed-rank test for within group analysis and the Mann-Whitney U test for between-group analysis. Relationship between vaginal squeeze pressure and the bladder neck position was analysed using Spearman *rho* (for abnormally distributed data).

Results: The results that are principally pertinent to this review are changes in bladder neck position following intervention and correlation of bladder neck position with vaginal squeeze pressure. Seventy-nine percent of subjects adhered to the exercise diary by 80%.

There was a highly significant elevation in bladder neck position at rest between groups at 4.3mm (CI 95% 2.1 to 6.5 $p < 0.001$).

Between group change (mean) in vaginal squeeze pressure was 13.1cm H₂O vs 1.1 mm H₂O (CI 95% 0.4 to 2.7 $p < 0.01$). This positively correlated with elevated bladder neck position ($r = 0.25$ $p = 0.017$).

Other changes between groups:

Increase in muscle thickness at rest: 1.9mm (CI 95%: 1.1 to 2.7 $p < 0.001$).

Muscle length at rest: 6.1 (CI 95% 1.5 to 10.7 $p = 0.07$)

Decreased hiatal area at rest: 1.8 (CI 95% 0.4 to 3.1 $p = 0.026$)

Elevation of rectal ampulla at rest: 6.7mm (95% C: 2.2 to 11.8 $p = 0.007$)

Muscle length at valsalva 11.0 mm (CI 95%: 3.4 to 18.5 $p = 0.001$)

Hiatal area decrease on valsalva 2.3 cm² (CI 95% -0.1 to 4.8 $p = 0.021$)

Significantly positive correlations were also seen between muscle strength gain and muscle thickness, muscle length on valsalva, and position of the rectal ampulla.

Limitations: There are few flaws in this study. One is that the physiotherapist could not be blinded to group allocation when evaluating vaginal squeeze pressure. This is because knowledge of group allocation would have been easily deducible due to contact with the study group during intervention. This may have introduced potential bias. Another is failure to state whether one sonographer/radiographer was used throughout the trial. Whilst this is discussed

in the primary publication of this study, it is an inconvenience for the reader to have to source a second publication.

Strengths: This is a study of high quality. It is well powered, well randomised to reduce potential bias and has an age and symptom matched control group. Its greatest strengths include length of intervention as recommended by The American College of Sports Science (Chapter 4.3.1) (Haskell et al 2007). Supervision was also intense, as well as 79% of subjects having met 80% compliance with the training protocol. Other strengths include robust reliability studies, these having been conducted for the primary study by the authors. Statistical analysis was also strong with no overlap in confidence intervals, and the results were well presented.

Appendix 2b: Literature Review Part II: studies relating to the influence of PFM training on position of urethrovesical structures as well as outcome of urinary incontinence

Exclusions

Reilly et al 2002

The aim of this UK study was to evaluate the influence of PFM training on the effect of post partum SUI in women with urethral hypermobility who had been imaged at 20 and 34 weeks gestation. Secondary aims were change in PFM strength and bladder neck position. Women were randomised into a study or control group. Intervention for the study group was supervised PFM training from 20 weeks until delivery. Post intervention ultrasound evaluation was undertaken at 3 months post delivery. The results demonstrated no difference between the cohorts when observing baseline and post intervention data. This is not surprising given that vaginal delivery negatively effects bladder neck position (Peschers et al 1997; Dietz et al 2002b) and therefore the dependent variable is likely to have been altered between the second and third evaluations. For the purposes of this review an additional and essential time point of interest would have been immediately post partum.

It was for this reason that the study was excluded from review.

Meyer et al 2001

The objective of this Swiss study was to assess the effect of PFM education after vaginal delivery on PFM characteristics in nulliparous women. The study was excluded because of poor design. Baseline ultrasound was undertaken pre delivery, but not prior to the start of intervention. In the interim subjects had undergone vaginal delivery that would have changed the baseline data. As discussed in 5.5.3.2 vaginal delivery negatively affects the dependent variable of bladder neck position. Pelvic floor muscle education started 9 weeks post delivery and further essential baseline data was not collected at the nine week time point. Further, intervention length was six weeks which is not long enough to

bring about sufficient morphologic change in the PFM that might influence bladder neck position. The study was therefore excluded from this review.

Inclusions

Balmforth et al 2006

Source: UK

Level of Evidence: 2c

Design: Prospective observational study

Objective: The study objective was to assess the impact of PFM training on bladder neck mobility and to investigate correlation of these with improvement in SUI.

Ethics Approval: Ethics approval was gained and written consent obtained from each subject.

Recruitment: Women were recruited prospectively from a urogynaecology clinic following video-urodynamic assessment. Ninety-seven women were recruited (mean age 49.5 years \pm 10.6).

Inclusion Criteria: Treatment naïve women with video-urodynamic proven mild to severe SUI.

Exclusion criteria: The authors fail to discuss exclusion criteria.

Attrition: Thirteen subjects withdrew due to lack of time required to commit to the programme.

Primary outcome measures: Primary outcome measures were bladder neck position at rest, PFM contraction andValsalva; standardised pad test and quality of life.

Secondary outcome measures: Secondary outcome measures were correlation studies of the primary outcome measures

Power Calculation: The authors failed to discuss a power calculation.

Baseline tests: Standardised thirty minute pad test was used for urinary leakage; QOL scoring was undertaken using the condition specific validated Kings Health Questionnaire (KHQ) (Kelleher et al 1997); bladder neck mobility using perineal ultrasound; PFM strength was tested using perineometry.

Reliability: Reliability issues (test re-test; inter and intra rater reliability) were not tested by the authors although the reliability studies of Peschers were cited that had previously been found to be reliable (Peschers et al 1997). No reference was made to source or reliability issues of the pad test.

Intervention: One physiotherapist led the intervention. The first one hour intervention session evaluated a three-day bladder diary, gave advice on lifestyle and behavioural modification and introduced PFM exercise verbally. The second session of one hour provided digital assessment with perineometry biofeedback to confirm correct PFM contraction. Subjects were asked to attend for at least three follow up sessions of thirty minutes. A 24-hour direct line answerphone was available for subjects to leave messages on with any queries. The training programme of 14 weeks was individualized and comprised fast and sustained maximal contractions. Repetitions and length of hold were dependent on ability and most subjects were instructed to perform the routine three times per day. A daily exercise diary was maintained.

Data collection: The authors failed to report how many evaluators collected and read the data.

Reading of data: Bladder neck angle was measured using the xy co-ordinate system described by Peschers et al (1997) that had been adapted from methodology of Schaer et al (1995). The issue of blinding was not raised and so it is not known if the evaluator was blinded to baseline and post intervention labels.

Data Analysis: Analysis was by intention to treat. Normality of data was presented and parametric analysis was undertaken. Pre and post intervention ultrasound data was analysed using paired t test. QOL data and urine loss was analysed using the non parametric equivalent Wilcoxon signed-rank test. Method of analysis for the correlation studies was not presented.

Results: Compliance with the intervention as evidenced by exercise diary results was not reported.

Mean bladder neck angle narrowed at rest by 7.3° (CI 95%: 51.7 to 59.1 $p=0.009$) and 10.4° on PFM contraction (CI 95%: 29.1 to 41.4 $p=0.013$) and reduced on valsalva by 12.9° (CI 95%: 58.9 to 69.1 $p=0.002$).

Urine loss was reduced from 12.2g to 5.5g ($p<0.001$). Three of nine domains of QOL (condition impact, role limitation and physical limitation) were highly significantly improved ($p<0.001$).

The authors reported that there was no significant correlation found between improvements in either urinary loss or QOL, and bladder neck position, although the results were not presented.

Limitations: The one major weakness in this study is in the reporting. The authors have not described exclusion criteria. The title of the article specifically states that it is SUI that is studied, although behavioural advice is included that is most usually associated with management of DO/ MUI. It is not clear if women with DO/MUI were excluded. There is little evidence for the effectiveness of PFM training in MUI (Greer et al 2012) and therefore possible inclusion may have weakened the results. Despite correlation between changes in bladder neck parameters and symptoms being a study objective there is scant reference of analysis of correlation in the results section. No data is presented with the following description only “There was no significant correlation between the improvements in the objective outcome measures (pad test and KHQ) and any of the ultrasound variables i.e. those women who showed greatest improvement in objective severity were not necessarily those with the most significant changes in bladder neck mobility.

It is the experience of this author that substantial improvement in urinary loss with behavioural and lifestyle advice is often established in the early weeks of physiotherapy intervention, long before morphological changes are established that would influence bladder neck position.

A further limitation is that there is no report with respect to adherence of the exercise diary. The fact that subjects were reasonably well supervised mitigates this to an extent. However, this remains a possible confounder that may have

weakened the results. Another potential weakness is lack of investigation of within-study reliability. Further it is not stated if the ultrasound rater was blinded to pre and post test labels and this may have introduced bias. This factor may potentially have falsely strengthened the results.

Strengths: This is the first study in the English language to have investigated bladder neck position and urinary loss following PFM training. Despite there being no discussion of power calculation, the greatest strength of this study is its size ($n=97$). The narrow confidence intervals suggest that the study was adequately powered to detect significant differences in change of bladder neck angle. The length of the trial was long enough for morphological change of PFM to have occurred. Intervention was moderately intense with individualized exercise programmes and regular supervision. Further, analysis by intention to treat renders the results more meaningful because of inclusion of withdrawal data in the analysis ($n=13$), although with respect to BNP it would be of interest to see if correlation would improve between bladder neck position and urine loss if analysis were on a non intention to treat basis, as 13 subjects (13.5%) withdrew. A further strength is the intensive intervention design.

Hung et al 2011

Source: Taiwan

Level of Evidence: 2c

Design: Prospective observational study

Objective: The study objective was to investigate the effect of PFM strengthening on bladder neck mobility in women with SUI or MUI.

Ethics approval: The authors fail to report if ethics approval was gained although women gave written consent.

Recruitment: Women were recruited from newspaper adverts and word of mouth ($n=23$ mean age 51.9 ± 6.1).

Inclusion criteria: Women who reported SUI or MUI and had at least one episode of UI in the previous month.

Exclusion criteria: Current pregnancy; being less than three months post partum; systemic neuromuscular disease; previous (pelvic) surgery or PFM training; other current treatment for UI and/or urinary tract infection.

Attrition: Number of withdrawals was not stated.

Primary outcome measures: Primary outcome measures were angle of bladder neck rotation at rest, on PFM contraction and during cough and valsalva.

Secondary outcome measures: Secondary outcome measures were collected by one physiotherapist throughout who also performed the intervention. These outcome measures were PFM vaginal squeeze pressure using manometry, severity index and self reported improvement.

Power calculation: Sample size was based on a power calculation for the secondary outcome measure of vaginal squeeze pressure.

Baseline tests: Severity index score (Sandvik et al 2000); self report of improvement on a 4 point Likert scale (worse, unchanged, improved, cured) vaginal squeeze pressure on perineometry; bladder neck position at rest, on PFM contraction and during cough and valsalva, pad test.

Reliability: Previous reliability studies were cited (Schaer et al 1995; Peschers et al 2001). There were no within study tests for reliability.

Intervention: Intervention consisted of 6 maximal PFM contractions with the aim of holding for 10 seconds, and 10 fast contractions repeated 3-5 times per day. Length of the intervention was four months. Maintaining an exercise diary was encouraged but not required. Interim follow up appointments of 30 minutes with a therapist to check the exercises was optional. Average number of sessions was 4.8.

Data Collection: The authors failed to discuss if ultrasound data was collected by one or more sonographers/radiologists.

Reading of data: The authors failed to discuss if ultrasound data was read by one or more evaluator, nor if the evaluator was blinded to baseline and post intervention labels. The x yco-ordinate system of Peschers et al (1997) was used and adapted according to the method of Balmforth et al (2006) to measure bladder neck angle.

Data Analysis: It was not stated if analysis was by intention to treat. Pre and post intervention ultrasound data was analysed and found to be normally distributed. The parametric two tailed paired *t* test was used for bladder neck angle and vaginal squeeze pressure. The Wilcoxon test was used for severity index score and PFM strength because covariance was found between variables and therefore the *t* test was considered unsuitable. To assess for clinical implications, effect size (ideal of 0.71) was based on previous studies of changes in vaginal squeeze pressure.

Results: Angle of bladder neck rotation narrowed at rest by 3° (95% CI :11 - 4, $p=0.335$); on cough by 3° (95%CI: -10 - 5, $p=0.436$) and on valsalva by 1° (95% CI: 13 - 1 $p=0.829$). A highly significant difference in bladder neck position on voluntary contraction was seen at 11° (95% CI: 4 - 14 $p=0.001$). Effect size for angle of bladder neck rotation on PFM was 0.84 but negligible effect sizes were seen for position of the bladder neck at rest, cough or valsalva following intervention (0.03 to 0.19).

For secondary outcomes, highly significant results were found for vaginal squeeze pressure: 14cm H₂O ($p=0.001$) with an effect size of 0.89, and severity index scoring ($p=0.001$). One subject reported cure (4.3%) and 22 (95.7%) reported improvement.

The correlation matrix was reported as contributing little and so was not presented, despite improvements in severity scoring, vaginal squeeze pressure and bladder neck parameters.

Limitations: Whilst it is important to replicate original studies to test for agreement in findings, this non original study has several flaws that result in lesser contribution to the literature than might otherwise have been the case with better design. The authors appear to be aiming to base the study on the original

work of Balmforth et al (2006) which is cited in the introduction, methodology and discussion sections. However, there were certain design short-comings with the result that this probable aim was not being met. These short-comings included small sample size, lack of mandatory interim supervision during the intervention, failure to include a mandatory exercise diary and possible unsuitability of a severity scoring tool. Sample size was based on a power calculation for the secondary outcome measure of vaginal squeeze pressure and not for excursion of the bladder neck. Why the authors did not base power calculation on the previous work of Balmforth et al (1996) is not known and must be considered a major flaw. The reasons for using vaginal squeeze for estimation of sample size were not stated although the inference was that the authors are assuming a relationship between vaginal squeeze pressure and resting bladder neck position. At the time of publication there was no evidence to support this assumption. Evidence has since emerged as discussed in this review although in this study the sample size was much larger ($n=59$) (Braekken et al 2010a). It is probable therefore that the study was too small to detect significant differences in resting bladder neck position following PFM training. Effect size was also based on vaginal squeeze pressure and therefore it is difficult to be confident of the effect size results for bladder neck position found in this study.

Almost half of the subjects opted out of supervision during the intervention. Whilst the authors discuss many variables that had been adjusted for during analysis, supervision was not one of them. It is suggested by a review group of the Cochrane Database that PFM programmes with regular supervision are more successful than those without (Hay-Smith et al 2011). This is likely to have influenced the results that did not reach statistical significance in this study. Because the use of an exercise diary was also optional and adherence not discussed, it is not possible to determine how many of the subjects complied with the intervention. This is a further confounder when interpreting the results. Attrition is not discussed and has to be deduced by the reader. The power calculation is stated as 18 subjects, with the final figure of 23 being decided upon to allow for withdrawals. It would appear that all 23 subjects have been included

in final analysis i.e. $n=23$ appears on results tables, although it is not clear if this is on an intention to treat basis and includes some withdrawals.

In common with Balmforth et al (1996), potential bias may have been introduced because there is no discussion of the ultrasound rater being blinded for pre and post test labels. Neither was the intervention physiotherapist blinded to vaginal squeeze pressures pre and post test.

The severity scoring instrument is also a possible issue as it is validated as a 48 hour pad test for epidemiological research, and not for clinical research.

Finally it is not clear if ethics approval was obtained as reference was made only to informed consent. It is somewhat surprising that this peer reviewed journal, Physical Therapy (the academic journal of the American Physical therapy Association) accepted the paper for publication without reference to ethics approval. As discussed by Greenhalgh (2010) research governance with reference to gaining ethics approval prior to the start of a study is an essential part of the research process.

Strengths: The strengths of this small study lie in the statistical analysis.

Normality of distribution of data is reported thus justifying use of the parametric t test, with confidence intervals further supporting the results. The length of intervention was also strong at 14 weeks.

Appendix 3a: Participant Information Sheets for Study 1

Participant information sheets

A study investigating the optimal (most effective) technique for a pelvic floor muscle exercise.

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Thank you for reading this.

What is a pelvic floor muscle exercise?

Pelvic floor muscle exercises have been used to help prevent and to treat urinary incontinence in women for many years. You may or not be aware of what a pelvic floor exercise is or indeed where and what the pelvic floor is. Some women will have been taught them by a health professional before or after having a baby, some may have read about them in the health pages of magazines or perhaps been encouraged to do them by a friend. Some women will not have heard about them at all. Imagine the pelvis as a basin made of bone containing the organs of your gut, bladder and reproductive systems. The bottom of the basin (floor) is made of the pelvic floor muscle. The muscle has three apertures, one each for the openings from the body to the outside world; the urethra (front passage), vagina (birth passage) and the anus (back passage). When the pelvic floor muscle is contracted (tightened up) it helps to close each of the apertures. This is particularly important in helping to maintain continence as the muscle assists in keeping the apertures closed.

Researchers in the UK have recently published results from a large survey of women and have found that one in four women over the age of forty will be incontinent of urine at least once per month. Severity may vary from being a minor nuisance to being completely disrupting. The first line of treatment for many women suffering with urinary incontinence will be pelvic floor exercises taught by a physiotherapist. It is also recommended that all women should be performing pelvic floor exercises regularly to help prevent the onset of urinary incontinence.

What is the purpose of the research study?

This study aims to investigate which is the best way to contract the pelvic floor so that in the first instance, women can be confident that they are performing exercises in the best possible and most effective way. Some women prefer to pull up from the front, some prefer to pull up from the back, and some in combination. Similarly, teachers of pelvic floor exercises use different techniques and have

their own theories about what works best. This can be confusing for women to such an extent that they simply stop doing their exercises.

The results of this research will be used to inform and reassure women and their teachers regarding how best a pelvic floor exercise should be performed. Importantly, pelvic floor exercises may become more effective, thus helping to better alleviate distressing urinary symptoms for many women.

Who is suitable for the study?

Women who have not reached menopause, have not delivered a baby and are not experiencing urinary incontinence are suitable for the study.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form at your next visit. If you decide to take part you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

What will happen to me if I take part?

You will be asked to attend for three sessions:

Your first and second visits will be with the physiotherapist at Pinner Road Physiotherapy (97 Pinner Road, Harrow, HA1 4ET). You will be asked to sign a consent form. You will undertake a simple vaginal examination and ultrasound scan (by using a probe placed on the perineum which is the area of skin between the back and front passages) whilst you are taught pelvic floor exercises. You will be given home exercises to perform twice daily and you will be asked to record your exercise sessions on paper. You should allow one hour for your first visit.

On your second visit (approximately two weeks later) you will be seen again by the physiotherapist who will check that you are performing the exercises correctly with a repeat ultrasound scan. She will also check the exercises with a specialised method called EMG. This involves using one electrode on the skin near to your back passage and one on your thigh. You should allow 45 minutes for this session.

Your third visit (approximately 2 weeks later) with the radiologist and physiotherapist will be at St Mark's Hospital (Harrow). The radiologist will perform ultrasound whilst the physiotherapist asks you to do the exercises you have been practising in a particular sequence. These are the scans that will be saved and used for analysis in the study. The study will end here but in recognition of your participation in the study the physiotherapist will advise you regarding ongoing exercises.

Will my travelling expenses be re-embursed?

You will be reimbursed £5 for each visit to cover public transport costs within the Harrow area or a car parking fee within the hospital campus.

Summary of your involvement

You will attend for three sessions, and do pelvic floor exercises at home between sessions. Before the third session you will be asked not to empty your bladder for 2 hours before and drink up to 400mls of water one hour before the study. Apart from this there are no lifestyle restrictions that you need to make.

Will my GP be contacted?

As a courtesy to your GP, and with your consent, a letter will be sent at the beginning of the study detailing your participation in the study, and at the end detailing the findings of the study.

What are the possible side effects if I take part?

Vaginal examination may cause discomfort

Perineal ultrasound scanning is not an internal examination and carries no known risks (no x-rays are involved).

Pelvic floor exercises carry no risk although a very few women may experience temporary low abdominal muscle ache when they first start them.

There is discomfort of a full bladder

What are the possible benefits of my taking part?

You will be offered an individualised pelvic floor exercise programme by a physiotherapist expert in this field, to include a follow up appointment to monitor your progress after the study has finished, if you so wish.

What happens about any gynaecology treatment that I am having?

At no point will there be any disruption in any treatment that you may be receiving from your gynaecologist at Northwick Park Hospital. Your treatment and follow up sessions will continue exactly as they would do if you were not participating in the study.

What happens at the end of the research study?

Both you and your GP will receive a letter when the results of the study become available detailing the findings of the study

What if something goes wrong?

If you are harmed by taking part in this research project, there are no special compensation arrangements. However, if you are harmed due to someone's negligence, you may have grounds for a legal action although you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms will be available to you.

Will my taking part in this research study be kept confidential?

All information which is collected about you during the course of the research will be kept strictly confidential. Any information about you which leaves the hospital/surgery will have your name and address removed so that you cannot be recognized from it.

What will happen to the results of the research study?

It is anticipated that the results of the study should be known by January 2006 and presented/published in the scientific arena following this. You will not be identified in any report or publication.

Who is organising and funding the research?

The study is being organised by Kay Crotty, Chartered Physiotherapist, in collaboration with Miss J Pitkin, Consultant Gynaecologist at Northwick Park Hospital and Professor Clive Bartram, Consultant Radiologist at St Mark's Hospital and the University of Hertfordshire. There is no external funding for the study.

Who has reviewed this study?

This study has been approved by the Harrow Local Research Ethics Committee (study number: 04/Q0405/1).

Who should I contact for further information?

If you have questions before you decide to take part in the study, you can contact Kay Crotty (physiotherapist) on **020 8861 6001**

What happens next?

If you think you would like to take part in the study, appointments will be made for you. There will be an interval of at least one week so that you can have time to think further, perhaps discuss it with family or friends and raise any questions that may arise.

With your permission we will telephone you approximately 48 hours ahead of the first appointment to answer any questions and confirm the appointment. As discussed earlier in this document you will be free to withdraw from the study at any time.

This information is yours to keep and if you decide to take part you will also be given a copy of the consent form that you will be asked to sign at your first appointment.

Many thanks for taking time to read about the study

Appendix 3b: Participant Information Sheets for Study 2

Participant Information Sheets

A study investigating the optimal (most effective) technique for a pelvic floor muscle exercise.

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Thank you for reading this.

What is a pelvic floor muscle exercise?

Pelvic floor muscle exercises have been used to help prevent and to treat urinary incontinence in women for many years. You may or not be aware of what a pelvic floor exercise is or indeed where and what the pelvic floor is. Some women will have been taught them by a health professional before or after having a baby, some may have read about them in the health pages of magazines or perhaps been encouraged to do them by a friend. Some women will not have heard about them at all. Imagine the pelvis as a basin made of bone containing the organs of your gut, bladder and reproductive systems. The bottom of the basin (floor) is made of the pelvic floor muscle. The muscle has three apertures, one each for the openings from the body to the outside world; the urethra (front passage), vagina (birth passage) and the anus (back passage). When the pelvic floor muscle is contracted (tightened up) it helps to close each of the apertures. This is particularly important in helping to maintain continence as the muscle assists in keeping the apertures closed.

Researchers in the UK have recently published results from a large survey of women and have found that one in four women over the age of forty will be incontinent of urine at least once per month. Severity may vary from being a minor nuisance to being completely disrupting. The first line of treatment for many women suffering with urinary incontinence will be pelvic floor exercises taught by a physiotherapist. It is also recommended that all women should be performing pelvic floor exercises regularly to help prevent the onset of urinary incontinence.

What is the purpose of the research study?

This study aims to investigate which is the best way to contract the pelvic floor so that in the first instance, women can be confident that they are performing exercises in the best possible and most effective way. Some women prefer to pull up from the front, some prefer to pull up from the back, and some in combination. Similarly, teachers of pelvic floor exercises use different techniques and have

their own theories about what works best. This can be confusing for women to such an extent that they simply stop doing their exercises.

The results of this research will be used to inform and reassure women and their teachers regarding how best a pelvic floor exercise should be performed. Importantly, pelvic floor exercises may become more effective, thus helping to better alleviate distressing urinary symptoms for many women.

Who is suitable for the study?

Women who have reached menopause, have delivered a baby, and are experiencing urinary incontinence that they have not yet reported to a doctor are suitable for the study.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form at your next visit. If you decide to take part you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

What will happen to me if I take part?

You will be asked to attend for three sessions:

Your first and second visits will be with the physiotherapist at Pinner Road Physiotherapy (97 Pinner Road, Harrow, HA1 4ET). You will be asked to sign a consent form. You will undertake ultrasound scan (by using a probe placed on the perineum which is the area of skin between the back and front passages) whilst you are taught pelvic floor exercises. You will be given home exercises to perform twice daily and you will be asked to record your exercise sessions on paper. You should allow one hour for your first visit.

On your second visit (approximately two weeks later) you will be seen again by the physiotherapist who will check that you are performing the exercises correctly with a repeat ultrasound scan. She will also check the exercises with a specialised method called EMG. This involves using one electrode on the skin near to your back passage and one on your thigh. You should allow 45 minutes for this session.

Your third visit (approximately 2 weeks later) with the radiologist and physiotherapist will be at The Princess Grace Hospital (central London). The radiologist will perform ultrasound whilst the physiotherapist asks you to do the exercises you have been practising in a particular sequence. These are the scans that will be saved and used for analysis in the study. The study will end here but in recognition of your participation in the study the physiotherapist will advise you regarding ongoing exercises.

Will my travelling expenses be re-embursed?

You will be reimbursed £5 for each visit in Harrow to cover public transport costs and £10 for the visit to The Princess Grace Hospital to cover public transport costs to central London.

Summary of your involvement

You will attend for three sessions, and do pelvic floor exercises at home between sessions. Before the third session you will be asked not to empty your bladder for 2 hours before and drink up to 400mls of water one hour before the study. Apart from this there are no lifestyle restrictions that you need to make.

Will my GP be contacted?

As a courtesy to your GP, and with your consent, a letter will be sent at the beginning of the study detailing your participation in the study, and at the end detailing the findings of the study

What are the possible side effects if I take part?

Vaginal examination may cause discomfort

Perineal ultrasound scanning is not an internal examination and carries no known risks (no x-rays are involved).

Pelvic floor exercises carry no risk although a very few women may experience temporary low abdominal muscle ache when they first start them.

There is discomfort of a full bladder

What are the possible benefits of my taking part?

You will be offered an individualised pelvic floor exercise programme by a physiotherapist expert in this field, to include a follow up appointment to monitor your progress after the study has finished, if you so wish.

What happens at the end of the research study?

Both you and your GP will receive a letter when the results of the study become available detailing the findings of the study.

What if something goes wrong?

If you are harmed by taking part in this research project, there are no special compensation arrangements. However, if you are harmed due to someone's negligence, you may have grounds for a legal action although you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms will be available to you.

Will my taking part in this research study be kept confidential?

All information which is collected about you during the course of the research will be kept strictly confidential. Any information about you which leaves the hospital/surgery will have your name and address removed so that you cannot be recognized from it.

What will happen to the results of the research study?

It is anticipated that the results of the study should be known by January 2008 and presented/published in the scientific arena following this. You will not be identified in any report or publication.

Who is organising and funding the research?

The study is being organised by Kay Crotty, Chartered Physiotherapist, in collaboration with Miss J Pitkin, Consultant Gynaecologist at Northwick Park Hospital and Professor Clive Bartram, Consultant Radiologist at The Princess Grace Hospital, and the University of Hertfordshire. There is no external funding for the study.

Who has reviewed this study?

This study has been approved by the Harrow Local Research Ethics Committee (study number : 04/Q0405/1).

Who should I contact for further information?

If you have questions before you decide to take part in the study, you can contact Kay Crotty (physiotherapist) on **020 861 6001**

What happens next?

If you think you would like to take part in the study, appointments will be made for you. There will be an interval of at least one week so that you can have time to think further, perhaps discuss it with family or friends and raise any questions that may arise.

With your permission we will telephone you approximately 48 hours ahead of the first appointment to answer any questions and confirm the appointment. As discussed earlier in this document you will be free to withdraw from the study at any time.

This information is yours to keep and if you decide to take part you will also be given a copy of the consent form that you will be asked to sign at your first appointment.

Many thanks for taking time to read about the study

Appendix 4: Consent form

**RESEARCH PROJECT
CONSENT FORM**

Hospital Number:

Name:

Date of Birth:

Title of Project: *A Pilot Study Investigating the Clinical Usefulness of Standardising Technique for a Single Pelvic Floor Muscle Contraction*

Ethics Committee (EC) No.: 04/Q0405/1

Principal Investigator: Kay Crotty

PART A: TO BE COMPLETED BY THE INVESTIGATOR:

I confirm that I have explained this research project to the patient in terms which, in my judgement, are suited to the understanding of the patient and/or one of the parents or guardians of the patient.

<i>Name of Researcher</i>	<i>Signature</i>	<i>Date</i>
---------------------------	------------------	-------------

<i>Name of Person taking consent (if different from researcher)</i>	<i>Signature</i>	<i>Date</i>
---	------------------	-------------

PART B: TO BE COMPLETED BY THE PATIENT AND/OR PARENT OR GUARDIAN:

Please tick

1. I confirm that I have read and understand the information sheet dated.....
for the above study and have had the opportunity to ask questions.
2. I understand that my participation is voluntary and that I am free to withdraw at any
time, without giving any reason, without my medical care or legal rights being
affected.
3. I understand that my identity will not be disclosed in any published or written data
resulting from this study.

4. I understand the above information and agree to take part in the above research project.

*Name of Patient
(and/or Parent/Guardian)*

Signature

Date

On completion, one copy of this form (the original) is to be inserted into the patient's case notes.

A copy must also be sent to the patient's General Practitioner and a copy handed to the patient to keep.

Appendix 5a: Initial GP letter Study 1

Dear Dr

Your Patient:

Re: "A pilot study investigating the possibility of standardising pelvic floor muscle contraction technique" *in collaboration with Miss J Pitkin Consultant Gynaecologist Northwick Park Hospital, Professor C Bartram Consultant Radiologist St Mark's Hospital, and The University of Hertfordshire.*

This is to inform you that your patient has agreed to take part in this study. There will be three study sessions. The first two will be with the myself in order to teach pelvic floor exercise techniques using digital vaginal palpation, perineal ultrasound and EMG for biofeedback purposes. Simple home exercises will be performed between sessions. At the third session your participant will be asked to perform these exercise techniques during perineal ultrasound scanning by the project radiologist in order that data may be collected regarding bladder neck movement and urethral closure. All participants will be offered an individualized exercise programme at the final session and be invited to return for follow up and progression of exercises should they so wish.

It is hoped that the 20 urinary continent participants recruited from Miss Pitkins gynaecology clinic will benefit from participating in the study by being given prescriptive exercises, and follow up should they wish. This service is not routinely available to continent women within the HPCT. Those women who start the study but wish to withdraw at any stage will also be offered a specialised exercise programme and follow up appointment.

Information extrapolated from the study may help us to standardise technique in order to improve both efficacy of and compliance with pelvic floor muscle exercises.

If there is any reason why you would not like your participant to take part, or if you have any questions regarding the study, please telephone me on 020 8861 6001.

I will inform you of the results of the study in due course.

Yours sincerely,

Kay Crotty,
Honorary Research Physiotherapist, NWLH Trust

Appendix 5b: Initial GP letter Study 2

Dr

Re:

DOB:

Dear

Re: "A pilot study investigating the possibility of standardising pelvic floor muscle contraction technique" *in collaboration with Miss J Pitkin Consultant Gynaecologist Northwick Park Hospital, Prof C Bartram, Honorary Consultant Radiologist St Mark's Hospital, and The University of Hertfordshire.*

This is to inform you that your patient has agreed to take part in this study. There will be three study sessions. The first two will be with myself in order to teach pelvic floor exercise techniques using digital vaginal palpation (optional), ultrasound and surface EMG using a vaginal electrode. Simple home exercises will be performed between sessions. At the third session your participant will be asked to perform these exercise techniques during perineal ultrasound scanning by the professor of radiology in order that data may be collected with respect to urethral movement. Studies will be undertaken with a comfortably full bladder in supine. Your patient will be fast tracked to a treatment programme at the end of the study if necessary. It is hoped that approximately 20 menopausal parous women with previously unreported stress urinary incontinence will be recruited. Participants recruited from GP clinics in HPCT and from Pinner Road Physiotherapy will benefit from participating in the study by having expert pelvic floor muscle teaching with the option of being fast tracked for treatment that they would otherwise be on a waiting list for, and by having an ultrasound scan of pelvic floor muscle activity that would not be routinely available to them. Those women who start the study but wish to withdraw at any stage will also be offered a specialised exercise programme and follow up appointment. Information extrapolated from the study may help us to standardise technique in order to improve both efficacy of and compliance with pelvic floor muscle exercises.

If there is any reason why you would not like your patient to take part, or if you have any questions regarding the study, please telephone me on 020 8861 6001. I will inform you of the results of the study in due course.

Yours sincerely,

Kay Crotty,
Honorary Research Physiotherapist, NWLH Trust

Appendix 5c: Outcome letter to GP both studies

Dear Dr

Your Patient:

I wrote to you sometime ago to inform you that your patient had agreed to take part in a research study to investigate optimal instruction for a pelvic floor muscle contraction. The study investigated pre menopausal continent nulliparous women, and menopausal parous women with previously unreported stress urinary incontinence. The results are now available. These demonstrate that a cue to facilitate the posterior pelvic floor i.e. pull up as if trying to stop the escape of wind, results in greater change in the angle of the urethra (more optimal) than a cue that facilitates the anterior pelvic floor i.e. contract around the front as if trying to stop the flow of urine.

This was the first study to have investigated optimal instruction for a pelvic floor muscle contraction. These results are preliminary to clinical studies and have provided seminal information about pelvic floor muscle behaviour. It is hoped that ultimately results from the study may contribute to standardisation of instruction and may result in improvement in compliance and outcomes of pelvic floor muscle training for stress urinary incontinence. The results will be published in due course.

Please do not hesitate to contact me if you would like more information

Yours Sincerely

Kay Crotty,
Honorary Research Physiotherapist. NWLH's Trust

Appendix 5d: Outcome letter to subjects both studies

Dear

I am delighted to inform you that the results of the pelvic floor research study that you took part in some while ago are now available.

The results show that including an instruction to use the back of your pelvic floor i.e. “pull up from the back as if stopping the escape of wind” is more effective in changing position of the bladder than pulling up from the front i.e “pull up from the front as if stopping yourself from passing urine”. Pulling up from the front and back is also more effective than pulling up from the front on its own. Although more research is needed, we would recommend that you include the instruction to pull up from the back each time you do a pelvic floor muscle exercise. We recognise that some women will not feel comfortable using this technique and therefore should continue with the method that they are most comfortable with. The results will be published in due course. Meanwhile please do not hesitate to contact me if you would like more information.

Finally, I would like to take this opportunity to thank you again for your participation in this important study.

With kind regards

Yours Sincerely

Kay Crotty,
Honorary Research Physiotherapist. NWLH's Trust

Appendix 6: Dissemination of findings

Award

Presentation of results of Part 1 of the study won the award for best scientific platform presentation at the annual conference of Continence Society UK (Hampshire 2008)

Peer Reviewed Publication

Crotty K, Bartram C, Pitkin J, Cairns M, Taylor P, Dorey G, Chatoor D (2011). Investigation of optimal cues to instruction for pelvic floor muscle contraction: a pilot study using 2D Ultrasound Imaging in pre-menopausal, nulliparous, continent women. *Neurourol Urodyn*. Nov;30(8):1620-6 (impact factor 2.958)

Pending Publication: under review

Ultrasound imaging in menopausal parous women with stress urinary incontinence to investigate optimal cues to instruction for pelvic floor muscle contraction. *European Journal of Obstetrics and Gynaecology*

Peer Reviewed Abstract Published Online

Crotty K, Bartram C, Cairns M, Dorey G, Pitkin J, Taylor P (2010). An investigation of optimal cues to instruction for a pelvic floor muscle contraction: a 2-D dynamic ultrasound imaging study of mildly stress incontinent parous women. Abstract 594 Proceedings of ICS/IUGA Toronto. available at: <http://www.ics.org/publications/abstracts>

Peer Review Abstract Available on CD

Crotty K, Bartram CI, Cairns M, Dorey G, Taylor P & Chatoor DR (2007). An ultrasound imaging study of young nulliparous continent women investigating optimal cue to pelvic floor instruction. Proceedings of 15th International WCPT Congress, Vancouver. Abstract RR-PL 2264. Available on CD from <http://www.wcpt.org/abstracts2007/WCPT2007.html>

Citation

Botelho S, Pereira L, Marques J, Lanza A, Amorim C, Palma P, Riccetto C (2013). Is there correlation between electromyography and digital palpation as means of measuring pelvic floor muscle contractility in nulliparous, pregnant, and postpartum women? *Neurourology and Urodynamics*, 2013, 32 (5) 420-423

Non peer reviewed articles that include dissemination

Crotty K (2013). Athletes at London 2012: too elite to leak? Journal of the Association of Chartered Physiotherapists in Women's Health. Spring 2013 112-23-6

Crotty K (2007). The Pelvic Floor: the Phoenix of the Musculoskeletal System. Journal of Physiofirst: The Organization of Chartered Physiotherapists in Private Practice UK. Autumn Edition

Crotty K (2005). The uses of dynamic perineal ultrasound imaging in pelvic floor muscle training. Journal of The Association of Continence Advisors. 25(1) 6-9. 2005

Platform presentations

Crotty K, Bartram C, Pitkin J, Cairns M, Taylor P, Dorey G Investigation of optimal facilitation of the levator ani. A pilot study of post menopausal, parous incontinent women. Chartered Physiotherapists Promoting Continence. November 2010 Manchester.

Crotty K, Bartram C, Pitkin J, Cairns M, Taylor P, Dorey G An investigation of optimal instruction for pelvic floor muscle contraction using ultrasound imaging: a pilot study. Platform presentation. Annual conference of the Association of Women's Chartered Physiotherapists in Women's Health. Hinckley. 2008

Crotty K, Bartram C, Pitkin J, Cairns M, Taylor P, Dorey G An investigation of optimal instruction for pelvic floor muscle contraction using ultrasound imaging: a pilot study. Continence Society UK Annual Conference. April 2008 Hampshire Award for best scientific platform presentation

Crotty K, Bartram C, Pitkin J, Cairns M, Taylor P, Dorey G, Chatoor D. Effect of compartmental pelvic floor muscle contraction on urethrovesical structures using real time ultrasound: a pilot study. International Continence Society Round Table Physiotherapy meeting Rotterdam Netherlands August 2007

Crotty K, Bartram C, Pitkin J, Cairns M, Taylor P, Dorey G Effect of compartmental pelvic floor muscle contraction on urethrovesical structures using real time ultrasound: a pilot study. Platform presentation. The World Congress of Physical Therapists Vancouver Canada June 2007

Crotty K. A pilot study investigating the clinical usefulness of standardising technique for a single pelvic floor muscle contraction. Annual research forum,

School of Health and Emergency Professions, University of HertfordshireUK
September 2006

Poster presentation

Crotty K, Bartram C, Pitkin J, Cairns M, Taylor P, Dorey G. An investigation of optimal cues to instruction for a pelvic floor muscle contraction: a 2-D dynamic ultrasound imaging study of mildly stress incontinent parous women. Annual Conference of ICS/IUGA Continence Society. August 2010. Toronto.

Dissemination of findings within other platform presentations

Crotty K. Too Elite to Leak? Experience in running a survey of incidence and felt need in female Paralympians at London 2012. Annual conference of the Association of Women's Chartered Physiotherapists in Women's Health. September 2012

Crotty K. The Olympic Pelvic Floor. Royal College of Nursing. Annual Continence Forum Manchester December 2011

Crotty K. The Olympic Pelvic Floor. Annual Study Day. Chartered Physiotherapists Promoting Continence Bury November 2011

Crotty K. Continence and the Athlete. Presentation to members of the Medical Organizing Committee of the London 2012 Olympic Games August 2010. London

Crotty K. The Pelvic Floor: the Phoenix of the Musculoskeletal System. Annual Conference. Physiofirst, the Organization of Chartered Physiotherapists in private Practice. Leicester March 2011

Crotty K. Teaching pelvic floor muscle exercises. Chartered Physiotherapists in Care of the Elderly. Collaborative Study Day. The Chartered Society of Physiotherapy. London. April 2010

Crotty K. Pelvic floor and long term conditions –teaching pelvic floor exercises. Royal College of Nursing Annual Continence Forum. York. October 2009

Crotty K. Stress Urinary Incontinence: management for the Respiratory Physiotherapist. Department of Physiotherapy, The Royal Brompton Hospital, London. December 2009.

Crotty K. Reciprocal Spino-pelvic Health. The BMI Group Physiotherapists in Women's Health Special Interest Group. Annual seminar May 2008.

Crotty K. The Lift to the Crow's Nest: Elevating the Bladder Neck. Chartered Physiotherapists Promoting Continence Spring meeting. Platform Presentation. BristolUKMay 2007

Crotty K. Teaching Pelvic Floor Muscle Exercises. Harrow Primary Care Trust. GP Forum. Harrow. January 2007

Crotty K. Teaching Pelvic Floor Muscle Exercises. The Institute of Urology. Urodynamics Course for Trainee Urologists. January 2007

Crotty K. A Pilot Study Investigating the Clinical Usefulness of Standardising Technique for a Single Pelvic Floor Muscle Contraction
Platform presentation, Annual Clinical Research Forum, School of Health and Emergency Professions, University of Hertfordshire September 2006

Planned Publications

The ability to effectively and selectively contract the pelvic floor muscle in parous and nulliparous women

Secondary findings of interest from a pilot study of pelvic floor muscle contraction using 2-dimensional ultrasound as applicable to physiotherapy practice and research

How should we be teaching pelvic floor muscle exercises?

The puborectalis muscle: is it important in urinary continence?

Planned Presentations

The Royal College of midwives
Association of Chartered Physiotherapists in Sports Medicine
The British Association of Sport and Exercise Medicine
The Musculoskeletal Association of Chartered Physiotherapists
National Pelvic Floor Society

Further dissemination

This author is on a sub committee of the Chartered Society of Physiotherapy that is currently collaborating with the Royal College of Midwives to develop undergraduate and post graduate training to midwives with respect to teaching PFM exercises in the peri, intra and post partum phases. This represents an enormous opportunity to disseminate this work.

Having completed this course of study and compilation of the related dissertation, this author plans to accept invitations as they arise in order to exploit every possible opportunity to disseminate this work.

This author intends to continue with future studies in order to continue dissemination of importance of selective contraction and ultimately standardisation of instruction.

Appendix 7a: Poster for recruitment Study 1

Pelvic Floor Research Project

Researchers at Northwick Park Hospital and St Marks Hospital Harrow, in collaboration with the University of Hertfordshire, are currently undertaking a study looking at the best way for women to perform pelvic floor muscle exercises. Pelvic floor exercises are used in the treatment of urinary incontinence. One in four women suffer with this condition so it is important that we find the best form of treatment for this group of women, as well as being able to confidently inform the public of the best and easiest way to contract the pelvic floor.

We are recruiting pre-menopausal women who have not delivered a baby, between the ages of 20 and 50 and who do not have a history of urinary incontinence to take part in our study. Involvement in the study will mean a commitment of 2 visits to our physiotherapist to include a vaginal examination, an EMG test (a simple test using electrodes placed on or near the back passage), expert pelvic floor exercise teaching, and a visit with our radiologist and physiotherapist for ultrasound scanning. The process will take place over a period of 7 weeks, and appointments will be at your convenience. A simple home exercise programme will be given to perform during this time. Travelling expenses will be paid and you will receive a personalised pelvic floor training programme from our physiotherapist.

If you think you may be suitable to be included in the study, and would be interested in finding out more:

Please telephone Kay Crotty (Research Lead)

020 88616001

Thank you for taking time to read this

Appendix 7b: Recruitment poster Study 2

Pelvic Floor Research Project

In collaboration with the University of Hertfordshire and NorthwickPark and St Marks Hospitals, we are currently undertaking a study looking at the best way for women to perform pelvic floor exercises. Pelvic floor exercises are used for the treatment of urinary incontinence. One in four women suffer with this condition and so it is important that we find the best form of treatment.

We are recruiting menopausal women who have had one or more vaginal deliveries, and who leak urine during moments of physical stress (such as during coughing, sneezing, laughing, or exercising) and who have not reported this to their GP. Involvement in the study will mean a commitment of 2 appointments with our physiotherapist (at Pinner Road Physiotherapy 97 Pinner Road, Harrow) for expert pelvic floor exercise teaching, muscle testing and ultrasound scan. The third appointment will be with our Professor of Radiology and physiotherapist at The Princess Grace Hospital, London W1 (6 minute walk from Baker Street tube) for ultrasound scanning. The process will take place over a period of up to 7 weeks. A simple home exercise programme will be given to perform during this time. Travelling expenses will be paid and you will receive a personalised pelvic floor training programme from our physiotherapist.

If you think you may be suitable to be included in the study, and would be interested in finding out more:

Please make enquiries with your physiotherapist, GP, practice nurse or call our lead researcher, Kay Crotty on 020 8861 6001

Appendix 8 : Exercise Diary

Subject code.....

Session number.....

Home exercises and exercise diary

Please perform these exercises twice daily. Put a tick in the diary on each occasion you do them. In order that all women in the study have done the same amount of exercise it is important that you are honest when reporting the exercise sessions. Please do not be tempted to tick the box if you haven't done them and do not fear that you will be reprimanded if you don't.

On one of the sessions do the exercises lying on your back with your knees bent (as you were positioned for your assessment). On the other session, do the exercises standing up. Make each pull as strong as possible, aiming to make each one even stronger than the last one.

1. Pull up from the back as if stopping the passage of wind. Hold for 5 seconds. Rest for 5 seconds. Repeat 3 times

2. Pull up from the front as if stopping the flow of urine. Hold for 5 seconds. Rest for 5 seconds. Repeat 3 times


3. Pull up from the back and front combined. Hold for 5 seconds. Rest for 5 seconds. Repeat 3 times

NB Please do not be tempted to perform the exercises more than twice daily

Exercise Diary: Place a tick in the appropriate box each time you do the exercises (ie ideally there should be 2 ticks in each box)

	Mon	Tues	Wed	Thurs	Fri	Sat	Sun
Week1							
Week2							
Week3							
Week4							

Appendix 9a: Permission to use BFLUTS


PINNER ROAD PHYSIOTHERAPY

Mr S Jackson
Dept of Obstetrics and Gynaecology
John Radcliffe Hospital
Oxford
OX3 7DU
September 25th 2003

- 1 OCT 2003


Dear Mr Jackson

Re: The Bristol Female Lower Urinary Tract Symptoms Questionnaire

I am currently designing a pelvic floor research project in collaboration with Professor Bartram (St Marks Hospital Harrow), Miss Joan Pitkin (Northwick Park Hospital Harrow) and The University of Hertfordshire.

With your permission I would like to use selected questions from the BFLUTS questionnaire (nos 1,2,3,4,6,7,8,9,13) as an assessment tool to contribute towards confirming continence status in a cohort of continent women.

I look forward to hearing from you

Yours sincerely


Kay Crotty

Kay Crotty
Yes thank you
Good luck!
Sue Jackson

KAY CROTTY & LICENCEES, CHARTERED PHYSIOTHERAPISTS
97 PINNER ROAD, HARROW, MIDDLESEX, HA1 4ET

**Appendix 9b: Selected Questions from the validated Bristol
Female Lower Urinary Tract Symptoms questionnaire (BFLUTS)
(Jackson et al 1996)**

Code.....

Date.....

URINARY SYMPTOMS QUESTIONNAIRE

We are trying to find out if you have a problem with urinary leakage. We would be grateful if you could help us by filling out this questionnaire.

When answering the questions think about the **symptoms you have experienced in the past month.**

You will see that some questions ask if you have a problem occasionally, sometimes or most of the time.

Occasionally = less than one third of the time

Sometimes = between one third and two thirds of the time

Most of the time = more than two thirds of the time

Does urine leak when you are physically active, exert yourself, cough or sneeze

never

occasionally

sometimes

most of the time

all of the time

How often do you leak urine?

never

once or less per week

once per day

several times per day

How much urinary leakage occurs?

none

drops/pants damp

dribble/pants wet

floods soaking outer clothing

floods running down legs /to the floor

Thank you for completing this questionnaire

Appendix 10 : ICIQ-SF questionnaire of continence status

ICIQ

CONFIDENTIAL

Year

□□□□□□

day Month

Many people leak urine some of the time. We are trying to find out how many people leak urine, and how much this bothers them. We would be grateful if you could answer the following questions, thinking how you have been, on average, over the PAST FOUR WEEKS.

1. Please write in your date of birth

□□□□□□

2. Are you (*tick one*):

Female

Male

3. How often do you leak urine? (*tick one*)

- Never 0
 About once a week or less often
 1
 Two or three times a week
 2
 About once a day
 3
 Several times a day
 4
 All the time
 5

4. We would like to know how much urine you think leaks.

How much urine do you usually leak (whether you wear protection or not)?
 (*tick one box*)

- None 0
 A small amount 2
 A moderate amount 4
 A large amount 6

5. Overall, how much does leaking urine interfere with your everyday life? (please ring a number between 0 (not at all) and 10 (a great deal))

0 1 2 3 4 5 6 7 8 9 10

Not at all

A great deal

ICI-Q score: sum scores 3 +4+5

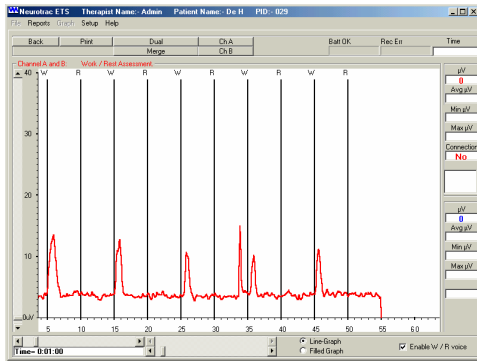
6. When does the urine leak? (*please tick all that applies to you*)

- Never – urine does not leak
 Leaks before you can get to the toilet
 Leaks when you cough or sneeze
 Leaks as you sleep
 Leaks when you are physically active or/ exercising
 Leaks when you have finished urinating and are dressed
 Leaks for no obvious reason
 Leaks all the time

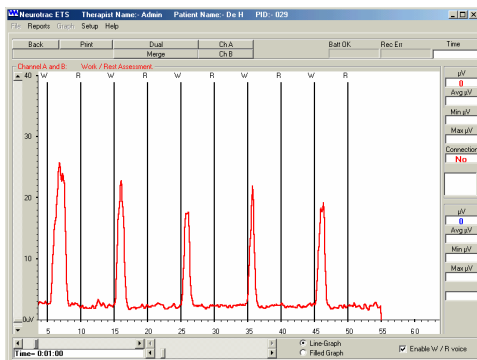
Thank-you for answering these questions Copyright © “ICI-Q Group

Appendix 11a: Example of an EMG study indicating subject ability to selectively contract the PFM Note lower EMG recording when anterior is used alone

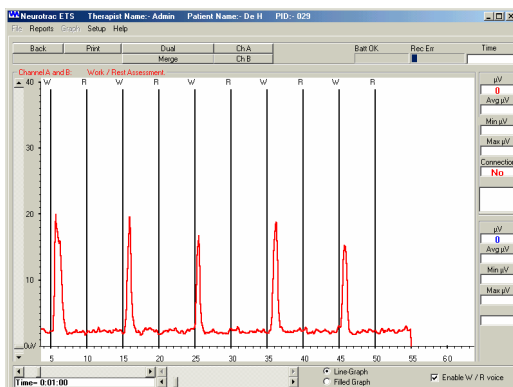
i. anterior instruction



ii. posterior instruction

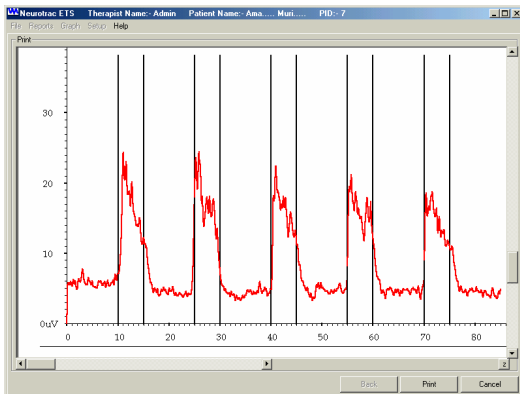


iii. combined instruction

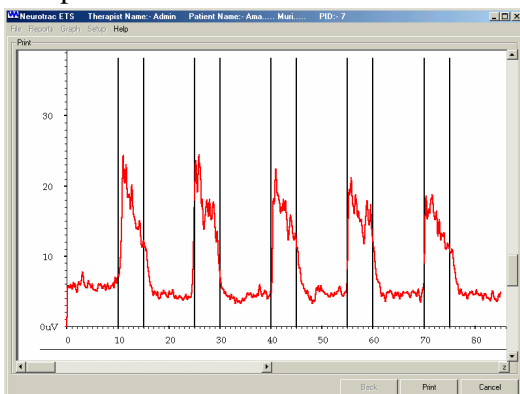


Appendix 11b: Example of a single subject EMG indicating subject inability to selectively contract the PFM. Note similar readings for each instruction

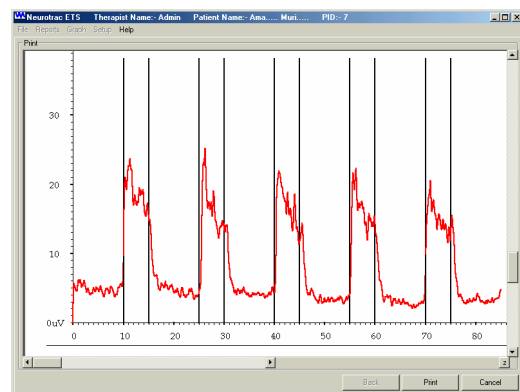
i. anterior instruction



ii. posterior instruction



iii. combined instruction



Appendix 11c: EMG mean peak values

- a. Studies indicating the ability to follow cues
- b. Studies indicating inability to follow cues

Example number	Test Number	Anterior Cue (µV)	Posterior Cue (µV)	Combined Cue (µV)
a. note lower values for anterior cue as compared with posterior or combined				
1	Test	5.5	13.45	27
	Re test	8.8	14.8	36.2
2	Test	27.1	33.5	33.6
	Re test	33.9	96.6	67.2
3	Test	16.7	22.6	29.5
	Re test	5.5	22.8	23.9
4	Test	11.1	19.9	19.1
	Re test	21.9	32.6	31.9
5	Test	9.8	26.3	43.9
	Re test	7.7	12.1	39.9
6	Test	26.4	33.6	39.5
	Re test	10.8	24	47.3
7	Test	31.8	45.2	62.3
	Re test	24.7	29.5	35.5
8	Test	8.2	13.8	16.4
	Re test	31.6	53.7	54.8
9	Test	48	56.8	56.1
	Re test	11.2	17.4	17.7
10	Test	17.1	38.8	42.8
	Re test	28.2	37.9	33.4
b. note higher or similar values for anterior cue as compared with posterior or combined				
1	Test	17.4	4.7	16.5
	Re test	20.8	22.5	16.5
2	Test	13.4	13.6	12.8
	Re test	11	10.9	15.4
3	Test	6.9	4.2	5.3
	Re test	3.1	7.6	3.6
µV Microvolts Mean peak value				

NB Data is presented for the three work/rest assessments in supine for test and re-test for the first 10 subjects in whom EMG provided indication that they were able to follow instructions, and in three who could not.

Appendix 12 a: Raw data Study 1 First read KC

KC	Read 1	Study 1																
Supine 1	FL	54.2	37.39	53.34	58.67	54.67	63.67	62.89	69.55	54.89	56.34	38.17	54.03	43.89	54.78	41.77	67.27	50.01
	FL	57.17	34.97	55.2	56.24	52.93	67.5	61	63.32	51.15	56.01	35.32	55.39	41.02	52.9	43	67.51	51.96
	FL	58.06	33.59	53.7	54.55	51.55	67.79	63.34	67.33	55.12	56.04	35.71	56.95	42.44	51.23	46.14	66.61	50.41
	BL	56.88	32.15	55.24	48.2	49.56	61.77	61.12	65.08	56.86	47.89	36.2	37	42.33	46.71	42.8	58.9	50.12
	BL	64.8	28.79	52.81	52.9	51.2	59.83	60.7	64	58.53	47.01	34.88	35.38	47.38	46.8	40.63	62.64	46.71
	BL	57.61	31.96	53.2	51.54	50.4	60.52	60.83	63.92	54.52	47.35	38.9	36.44	43.57	48.61	41.25	51.36	48.01
	FBL	58.14	37.29	50.33	56.32	56.32	55.72	53.75	64.63	59.71	43.66	36.7	39.43	43.83	55	40.59	59.08	46.65
	FBL	70.52	37.21	52.5	53.88	53.88	54.83	52.73	63.26	59.41	40.24	36.23	34.65	42.54	55.97	40.17	58.02	44.11
	FBL	70.34	31.51	57.47	50.21	50.21	55.12	50.75	62.66	59.22	40.04	35.94	34.4	43.05	55.2	40.23	63.45	47.99
	Stand 1	FL	57.61	52.09	85.92	51.06	78.06	77.82	62.43	88.04	71.48	61.4	49.83	53.02	72.81	58.06	70.04	0
FL		66.05	52.34	82.96	51.58	79.32	75.04	69.32	70.74	66.15	63.8	49.36	53.85	69.43	57.87	69.05	0	58.43
FL		67.33	53.81	84.1	51.36	75.59	75.38	67.77	71.13	67.95	62.11	44.45	56.35	68.66	63.02	68.31	0	58.01
BL		57.21	51.23	59.91	51.51	71.51	71.41	58.1	69.4	71.01	51.38	49.66	55.3	61.01	55.01	74.33	43.07	56.32
BL		65.89	48.06	63.78	54.72	72.72	79.47	59.9	73.3	69.14	50.83	45.41	55.4	59.42	56.98	71.69	45.42	53.59
BL		61.84	47.9	65.6	48.55	70.55	74.59	57.93	70.6	70.08	50.86	47.7	55.24	59.1	58.31	70.56	48.63	55.28
FBL		60.48	58.83	0	55.28	73.28	71.85	56.72	72.5	72.7	50.14	40.42	52.63	69.43	60.04	66.93	61.37	61.79
FBL		63.47	51.96	0	53.36	71.24	71.78	57.1	74.13	73.26	49.64	43.79	48.82	67.09	56.02	69.47	60.86	60.12
FBL		60.19	52.3	0	54.48	71.99	69.63	56.13	71.63	73.42	46.85	43.01	53.76	63.21	55.32	66.34	61.21	55.74
Supine 2		FL	62.63	36.16	57.03	51.46	51.64	52.33	61.020	64.01	68.35	50.16	40.78	60.49	74.9	48.32	37.93	61
	FL	62.65	36.97	55.9	47.91	48.05	52.58	59.660	63.7	65.01	50.01	40.04	61.22	79.4	50.41	38.69	61.5	42.11
	FL	59.46	34.7	56.91	50.24	50.81	50.5	57.540	62.34	69.92	50.66	40.43	59.99	76.79	49.19	42.45	61.89	40.48
	BL	70.44	33.62	58.54	45.91	48.91	42.66	43.16	69.22	60.11	41.42	35.99	56.05	48.03	56.34	45.47	60.54	46.25
	BL	66.78	32.79	60.05	43.86	48.36	46.39	43.78	62.45	62.26	40.32	33.85	59.01	50.38	58.24	42.95	65.98	43.83
	BL	63.58	40.67	58.51	41.21	46.23	50.73	48.21	62.9	64.19	43.6	33	60.17	49.23	56.11	41.98	60.85	45.95
	FBL	68.27	35.41	66.36	41.46	46.97	40.88	44.05	59.32	68.67	37.85	36.63	65.64	64.23	53.01	38.42	61.72	44.2
	FBL	64.79	34.84	65.54	39.66	46.68	39.24	46.07	59.09	63.45	37.21	37.33	62.16	69.43	47.2	37.6	61.02	39.57
	FBL	62.61	32.55	55.3	37.91	49.32	46.61	52.1	59.16	69.67	40.02	37.65	61.87	67.9	50.05	40.02	60.96	40.39
	Stand 2	FL	64.57	0	96.54	48.12	68.64	82.12	63.55	78.4	75.76	62	61.78	64.67	57.67	73.25	57.85	68.4
FL		58.87	0	70.47	47.37	67.71	84.2	65.7	71.59	75.67	63.16	58.63	62.41	57.21	72.64	59.08	70.98	54.43
FL		62.51	0	67.91	49.31	69.42	80.72	62.11	70.95	75.46	61.38	57.64	63.62	57.92	74.4	61.5	67.03	53
BL		73.03	0	68.04	49.94	66.27	78.13	53.44	68.01	69.21	55.55	54.32	62.87	57.31	63.9	59.23	62.4	53.38
BL		75.09	0	63.43	46.97	63.39	75.81	53.37	67.44	69	56.01	50.87	62.81	52.88	72.97	53.06	66.01	53.8
BL		67.56	0	71.49	51.32	62.43	77.19	53.83	67.39	69.13	58.9	48.13	60.99	56.91	76.43	52.9	61.43	54.18
FBL		68.29	0	68.04	44.64	59.79	77.89	56.19	71.22	71.29	55.07	42.31	60.92	53.02	69.63	59.9	68.21	48.38
FBL		67.03	0	63.43	43.78	59.12	77.34	56.12	73.24	68.98	56.2	42.92	59.08	54.67	68.39	61.89	68.55	48.66
FBL		70.89	0	71.49	49.94	59.01	77.95	56.63	72.85	67.9	54.03	41.27	62.63	52.28	66.41	60.55	65.83	48.53

Appendix 12b: Raw data Study 1 Second Read KC

KC	Read 2	Study 1																
Supine 1	FL	58.51	35.55	52.34	56.81	52.21	72.58	59.57	67.98	52.77	58.52	36.76	55.37	43.86	56.28	42.81	67.99	55.24
	FL	57.57	34.41	54.12	66.06	54.61	66.73	62.61	66.03	56.22	55.65	37.93	55.15	43.64	53.72	47.25	68.11	48.88
	FL	57.9	31.88	55.8	57.34	53.1	61.06	64.42	66.69	55.15	54.89	34.48	54.7	40.97	58.8	41.23	65.31	53.45
	BL	57.03	33.2	56.570	50.23	50.54	62.98	62.06	66.11	57.4	45.37	38.2	36.1	45.89	57.88	41.75	59.2	48.8
	BL	65.07	28.8	54.740	52.46	51.15	58.67	49.84	63.82	57.82	47.9	35.73	38.37	42.82	48.68	43.02	61.29	48.98
	BL	53.33	33.0	51.830	51.89	50.03	57.53	51.05	62.42	66.7	49.74	37.48	34.86	43.37	60.55	39.02	59.64	47.29
	FBL	50.03	34.19	52.76	59.88	49.81	53.71	51.03	61.57	58.74	42.28	34.76	33.54	38.72	49.63	40.42	58.5	46.31
	FBL	58.32	33.46	55.49	55.77	53.46	54.64	49.85	63.02	63.04	42.99	37.51	37.63	45.38	44.61	40.94	56.28	44.93
	FBL	51.59	34.98	55.56	53.11	56.53	58.44	55.11	66.37	58.18	39.35	54.41	38.78	45.59	48.8	39.03	55.37	46.93
	Stand 1	FL	63.05	53.85	81.82	51.3	79.48	79.76	61.73	90.26	68.86	58.07	51.48	59.23	53.91	70.09	61.34	0
FL		64.01	64.46	82.65	51.32	78.49	74.07	68.62	72.42	67.77	63.71	49.34	49.82	57.05	71.12	60.15	0	54.86
FL		65.89	53.1	88.87	53.28	76.91	74.86	68.49	67.77	68.96	65.29	42.79	54.42	52.28	69.23	57.33	0	56.5
BL		60.69	42.46	61.95	50.76	69.66	79.17	60.25	67.66	60.11	44.33	44.19	56.32	67.78	58.15	54.96	74.42	58.68
BL		67.14	55.41	59.39	49.78	67.2	75.35	57.99	75	72.69	49.92	43.41	54.08	59.36	67.95	58.11	70.35	57.97
BL		58.64	48.41	61.83	53.83	73.68	78.9	58.29	71.52	77.26	70.17	55.2	56.4	50.89	53.5	56.9	73.34	56.49
FBL		58.49	57.2	0	55.13	69.51	72.09	52.82	69.68	70.89	49.65	42	55.57	53.25	64.71	51.1	67.36	56.1
FBL		57.23	52.09	0	52.13	76.18	68.41	58.29	69.47	75.95	51.55	41.21	59.2	50.49	67.99	60.47	68.78	54.19
FBL		64.77	53.01	0	55.82	70.96	70.18	57.36	79.65	72.67	45.44	44.3	62.83	51.38	68.03	59.53	67.42	51.2
Supine 2		FL	49.93	34.7	51.48	52.48	48.97	55.94	47.46	62.92	66.59	51.42	46.44	60.34	49.36	52.21	39.13	60.01
	FL	57.8	31.32	59.85	53.09	52	50.9	59.44	63.72	66.98	50.11	38.3	58.52	50.26	49.21	41.1	60.77	42.27
	FL	52.06	32.6	57.19	49.39	51.12	48.08	58.78	62.94	69.37	54	36.97	61.75	68.66	48.36	38.94	63.81	41.82
	BL	53.35	30.04	55.97	39.75	50.54	47.4	59.67	63.26	58.25	44.62	34.8	61.35	50.34	56.77	43.1	60.92	45.43
	BL	49.31	29.59	62.24	42.41	46.23	46.17	52.3	63.89	62.71	39.65	32.41	59.18	49.06	56.17	41.38	62.72	44.74
	BL	57.01	30.82	59.51	46.12	45.83	46.71	54.7	67.58	65.99	40.36	35.46	55.16	49.58	57.67	46.35	62.96	42.22
	FBL	61.19	31.83	58.32	47.16	49.23	40.81	49.45	54.17	66.18	37.27	34.97	68.29	55.58	53.87	35.84	61.69	38.2
	FBL	57.89	32.27	53.5	43.92	48.24	41.77	47.65	60.08	65.94	36.6	38.38	59.96	48.78	47.53	36.84	0	42.71
	FBL	58.18	30.95	60.39	43.49	45.8	43.95	45.3	63.12	69.83	41.19	37.04	61.34	61.6	49.73	42.25	0	52.03
	Stand 2	FL	64.45	0	93.21	49.29	65.29	77.78	62.48	70.12	69.11	60.54	61.31	71.63	60.9	84	56.66	69.02
FL		63.1	0	71.38	48.39	69.64	85.71	64.04	66.22	82.17	59.82	58.59	59.79	59.73	65.49	58.56	68.24	53.72
FL		59.97	0	67.1	48.08	70.37	84.16	64	69.96	70.04	66.26	58.05	59.35	53.12	71.7	63.18	68.95	54.16
BL		69.96	0	67.03	48.29	65.35	76.06	57.91	68.23	66.13	56.55	51.3	62.69	50.16	62.12	59.42	65.64	55.52
BL		73.76	0	62.14	53.08	61.82	75.65	53	69.5	71.27	55.24	56.37	64.76	59.36	68.24	59.14	67.71	55.36
BL		68.41	0	69	46.37	66.22	79.95	49.14	65.51	69.96	58.64	46.56	59	57.73	77.11	64.25	68.74	50.5
FBL		72.41	0	67.78	45.68	61.46	76.33	56.16	72.02	63.32	56.15	44.01	62.6	60.06	68.1	54.49	63.28	50.43
FBL		72.94	0	65.43	49.16	53.76	79.57	55.58	75.81	71.57	53.02	41.44	58.33	50.65	68.57	53.95	63.88	51.55
FBL		74.81	0	70.26	46	62.27	77.95	57.49	69.17	73.06	55.78	40.83	61.48	50.44	68.37	55.463	62.15	53.35

Appendix 12c: Raw data Study 1 Study 1 DC

	DC	DC	Study 1															
Supine 1	FL	63.98	35.77	61.58	49.29	65.45	68.87	50.32	80.22	51.68	56.91	39.21	44.44	44.38	59.69	49.95	70.39	56.94
	FL	64.67	38.73	47.44	56.14	64.09	57.9	53.6	75.37	59.89	50.93	39.81	43.38	42.23	56.61	54.27	69.2	48.22
	FL	65.56	38	47.66	50.55	60.47	58.69	53.94	72.3	61.39	48.21	38.46	49.1	45.51	59.98	53.62	63.02	53.82
	BL	69.41	44.77	51.76	50.85	53.96	54.26	45.78	70.03	51.4	44.19	47.07	39.85	44.52	50.27	47.22	63.29	41.76
	BL	62.01	39.95	53.27	29.82	64.12	58.34	40.65	71.67	54.48	41.96	32.69	43.5	41.9	49.47	43.06	64.12	41.49
	BL	71.18	31.73	49.17	29.41	63.97	55.17	37.49	73.02	56.75	42.46	46.93	40.07	43.5	52.05	43.47	61.49	38.4
	FBL	68.79	37.75	53.79	49.79	56.5	49.19	39.33	69.51	56.62	43.5	38.44	43.16	45.11	54.86	45.77	60.08	43.96
	FBL	78.18	35.23	49.42	50.21	62.22	53.48	36.94	68.17	58.49	41.93	34.33	33.24	41.29	52.93	41.84	62.12	37.27
	FBL	69.33	37.42	53.09	43.97	61.41	52.23	40.71	68.91	59.88	41.71	38.74	40.34	41.71	49.73	41.41	57.15	39.08
Stand 1	FL	69.37	71.02	70.73	42.26	76.1	78.04	56.18	81.43	68.91	65.88	51.97	52.77	53.76	69.7	51.11	67.51	47.47
	FL	65.04	61.57	77.06	52.59	80.7	81.37	62.98	75.44	71.55	70.66	57.64	63.69	47.98	70.83	56.25	68.8	50.46
	FL	75.22	49.45	81.94	56.58	64.29	77.14	63.52	72.92	76.49	67.77	48.69	56.52	51.08	68.09	55.71	79.84	42.77
	BL	60.76	50	67.96	50.89	63.67	70.35	43.22	79.09	65.87	65.5	42.47	56.82	54.78	62.18	52.42	72.93	45.24
	BL	72.38	38.76	64.38	57.25	68.98	76.85	44.26	75.02	69.58	55.47	43.71	57.45	52.49	57.49	44.16	76.69	49.36
	BL	68.24	50.11	65.92	58.61	70.04	75.23	47.25	78.43	79.69	56.13	42.31	57.32	54.87	61.86	54.92	75.19	53.41
	FBL	65.84	50.67	96.29	56.54	71.46	72.71	49.24	65.59	73.14	48.89	39.82	53.5	51.25	63.78	63.51	62.24	46
	FBL	64.61	50.69	69.79	54.81	69.2	73.33	43.94	70.76	74.53	53.87	44.24	54.2	51.76	66.92	59.15	0	49.13
	FBL	65.57	45.81	69.5	53.04	69.86	73.08	46.21	74.94	77.14	48.68	41.66	52.13	50.6	71.76	46.56	72.21	46.11
Supine 2	FL	68.89	60.92	46.44	50.49	70.87	67.36	38.57	69.76	65.68	49.97	42.88	51.37	53.49	57.95	45.27	78.32	51.26
	FL	58.94	43	56.44	47.17	71.95	50.1	55.55	69.99	61.19	50.9	35.91	50.25	51.51	53.35	43.57	75.14	46.21
	FL	60.81	40.65	50.05	44.87	73	57.85	61.51	69.72	60.79	53.09	41.23	54.92	69.93	51.47	45.15	68.9	48.94
	BL	60.18	35.24	51.49	52.61	63.01	62.69	58.4	74.73	61.4	53.41	28.7	52.43	54.87	56.54	38.8	66.89	48.05
	BL	58.39	35.94	51.1	45.54	65.74	61.62	65.15	68.66	58.53	45.52	33.04	51.29	48.93	56.87	39.51	68.82	37.08
	BL	64.3	37.53	52.47	44.62	59.43	63.74	61.5	70.52	59.86	49.18	33.61	49.98	51.55	53.78	39.01	65.75	45.22
	FBL	60.34	34.71	48.33	49.02	60.07	67.6	44.65	67.41	59.78	47.1	32.3	56.99	55.93	58.53	46.42	65.48	36.45
	FBL	60.19	35.96	51.51	53.69	53.52	70.6	44.95	67.52	62.39	42.35	29.55	52.42	54.52	53.51	39.44	68.8	41.53
	FBL	64.4	36.61	57.99	48.98	58.16	61.26	42.52	70.07	66.77	44.12	37.21	57.6	51.6	58.16	41.78	67.91	48.42
Stand 2	FL	64.06	0	78.01	46.53	64.88	76.41	53.85	84.92	70.65	70.64	46.53	59.37	61.17	59.44	51.06	49.2	48.84
	FL	66.86	0	77.16	50.91	72.57	73.33	58.49	71.51	75.45	70.61	47.72	55.25	59.78	65.23	57.54	0	52.45
	FL	66.82	0	69.95	48.11	66.75	65.98	60.82	67.91	73.09	67.26	46.56	53.95	59.12	67.93	59.66	0	46.5
	BL	48.06	0	65.7	45.2	54.95	59.19	47.87	64.45	68.25	58.87	47.26	54.23	49.61	61.56	55.29	47.7	52.35
	BL	69.65	0	60.46	50.19	67.38	64.17	41.84	66.87	70.55	62.24	45.96	55.22	56.98	85.76	58.66	0	45.89
	BL	52.42	0	59.41	47.59	69.31	68.57	41.84	68.83	66.53	67.69	40.82	54.65	60.94	70.82	54.6	0	44.96
	FBL	66.92	0	63.99	49.25	59.02	63.56	39.63	70.03	63.35	58.41	42.11	55.08	55.8	53.43	61.95	48.4	53.18
	FBL	72.8	0	67.01	49.88	63.48	60.67	40.7	68.03	68.63	55.55	41.69	56.35	54.87	61.15	57.32	0	43.44
	FBL	47.24	0	70.72	46.71	63.56	70.08	41.36	66.25	68.1	52.32	46.38	55.5	53.25	56.77	59.46	0	48.69

