Mechanical Design of an Auxiliary Fixation Technique to Make Single Bundle Graft for ACL Reconstruction

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Abstract
Purpose: The present study, introduced and mechanically tested an alternative method for graft preparation for ACL reconstruction surgery. The designed method aimed to offer a replacement for conventional suturing which reduces the chance of graft rupture and gradually increases the fixation strength. *Methods:* to validate the study a set of experiments was performed. Five bovine tendon samples were harvested and trimmed into identical sizes. Samples were passed through two endo buttons and looped in a manner that both ends share a common surface. Two custom straps were later applied around the graft. A three-stage mechanical test was performed, a cyclical preload of 10 to 50 N, 10 cycles, and 0.1 Hz. The major pullout test with a cyclical load of 50 to 200 N, 1 Hz for 200 cycles, and a pullout force with a loading rate of 20 mm/min determining the ultimate strength of the fixation. *Results:* No failure occurred on the overall structure during the cyclic stages. Also, no failure associated with tendon tissue damage was recorded. All samples experienced a fixation failure during the final pull-out test. The mean values for ultimate strength, cyclic elongation, and Average cyclic Stiffness were 287.66 ± 11.84 N, 2.08 ± 0.15 mm, and 14.52 ± 1.09 kN/mm respectively. *Conclusions:* The results indicate that using the proposed strapping method not only reduces any chance of tendon tearing but also presents acceptable major mechanical properties in comparison with the conventional suturing method. The study showed that the new design was mechanically sound.

Keywords: mechanical design, ACL reconstruction, experiment, pullout test, graft preparation

Introduction

Anterior Cruciate Ligament (ACL) ruptures hold a high occurrence rank among all orthopedic injuries. Recent research suggests that amid all ligamentous injuries that occur on the knee joint, over 40% of them are associated with ACL [1] knowing the vital role this ligament plays in the biomechanical function of the knee joint, commonly ACL tears are addressed surgically. among these treatment methods, ACL reconstruction is known to be the gold standard. Recent research states that more than 125,000 ACL reconstructive surgeries are performed annually in the US only [2].

ACL reconstruction surgery consists of the removal of the damaged ligament and the implantation of a new graft, there are various graft choices and fixation methods. Among graft fixation methods, Suspensory fixations with devices like Endobutton (Smith &Nephew Inc., US) have gained popularity as non-invasive fixations among orthopedic surgeons. in these methods, the graft is inserted inside two tunnels drilled into the tibia and femur bones. Then the graft gets fixed inside the tunnels using the Endobutton suspensory devices ”Figure 1”. In a suspensory fixation, the fixation must be rigid and stiff to withstand mechanical loading during daily activities allowed in current rehabilitation principles. Furthermore, the fixations have to facilitate biological incorporation by providing an extensive free contact area between the tendon and bone tunnel wall [3] to obtain a successful ACL reconstruction.

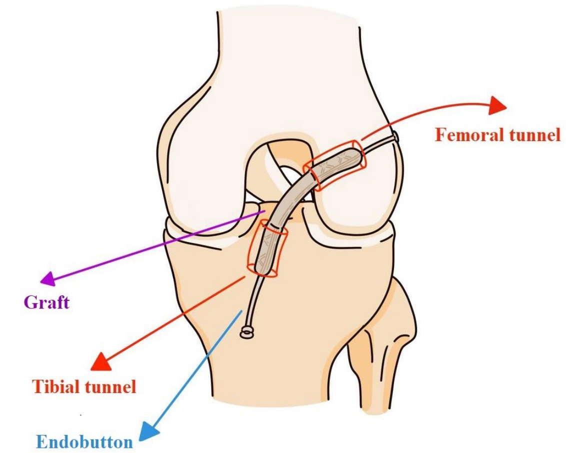

Figure 1. A tendon graft suspensory fixed inside the tibial and femoral tunnels for ACL reconstruction. Obtaining an extensive free contact area between the tendon and bone tunnel walls is necessary for a successful ACL reconstruction.

There are various graft choices available for ACL reconstruction, graft type is chosen depending on the patient's qualities and the doctor's discretion. Recently, the semitendinosus Hamstring tendons have been among the most commonly used tendons to prepare grafts in primary ACL reconstruction [4]. This popularity is due to their sufficient biomechanical qualities, low donor site morbidity, and cosmetic advantages [[2], [5]]. Also, a study of surgeons has revealed that hamstring grafts are their first preferred choice

The grafts are usually prepared by a step of suturing. Sutures are sterile surgical threads used to repair cuts. In this graft preparation process, sutures are used primarily to secure the free ends of the tendon graft and to attach the Endobuttons or any other alternative suspensory devices to the harvested graft.

Although sutures are widely used for graft preparation and various integrated threads have been introduced, Graft fixation is still known as the mechanically weak link within the entire system in the early postoperative period [6]. Certain outhouses including Yoo et al. [5] suggest that tendon rupture across sutures is the most frequent cause of single-bundle graft failure.

The objective of this study is to reduce the chance of graft failure by introducing and designing an implant device alongside a new graft preparation method as an alternative to the sutures used to prepare an ACL graft. The proposed design must provide enough direct tendon-bone contact surface in the femoral tunnel while enhancing the mechanical properties of the graft. This study hypothesized that a fixation device securing graft ends with belt-like nylon straps could not only improve the stiffness of the fixation and diminish graft elongation but also boost time conservation and repeatability.

The study uses an experimental method to investigate the mechanics of the designed fixation in a bovine model, in particular, to evaluate the strength of the graft prepared by the new method under mechanical loading. A two-step test consisting of cyclic loading followed by a tensile pullout test was carried out.

Materials and methods

Concept design

“Figure 2” illustrates this study's concept design. The design consists of two straps and a thin sheet of fiber, used to cover the contact surfaces of the graft, called a sheath. The straps are tightened around the sheathed graft loop.

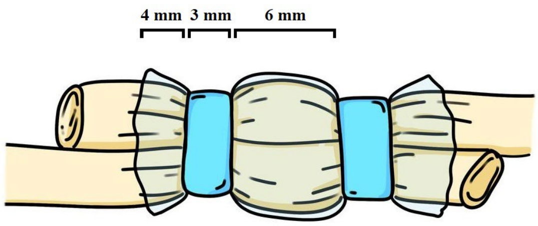

Figure 2. This study's concept design. Two straps (depicted in blue) are tightened around the two ends of the graft, securing them to each other. The tendons were initially covered with a thin sheath.

This study assumed that belt-like straps with wider surfaces can provide the same circumferential compression force on the graft as well as eliminate cutting edges compared to traditional graft suturing methods. The reduction of dense compression sites at contact surfaces resulted in the removal of any chance of tendon tearing under the fixation.

The crucial parameters of this design include inner diameter, the width of straps, and the number of strapped sites. To determine the proper inner diameter, tendon compression factor (TC) was introduced [7] which is defined using the following parametric equation:

$$TC = \frac{S_{tendon} - S_{strap}}{S_{tendon}} \quad (1)$$

TC is a unitless parameter to represent tendon compression. S_{tendon} and S_{strap} are respectively the cross-sectional areas of the tendon and the inner area of the straps. It was observed that a TC of 0.2 to 0.6 provides acceptable graft fixations. In addition, another research [8] demonstrated that circumferential compression of sutures on the graft significantly reduces its mean diameter by approximately one millimeter providing an acceptable TC of 0.205. We also captured data from our pilot tests that any cross-section reduction of 1.5 mm or more, causes evident tearing (gross tissue lacerations) on our 8 mm samples. On this basis, a mean inner cross-sectional diameter of 6.8 mm suppressing a desirable TC of 0.27, was designated for strapped parts in all tests.

A combination of the 3 mm straps apart with 6 mm in between was considered a proper choice ”Figure 2”. The two 3 mm straps suggested in this design, cover only 6 mm of the 20 mm long fixation providing enough 14 mm long tendon-bone contact surface to facilitate biological incorporation. Regarding the graft's covered area restriction and the rise of complications and technicalities with several straps, any other concept that employs wider or additional straps was abandoned. The idea of using straps with smaller sizes was also dropped due to their similarity to standard whip stitches.

This research also hypothesized that covering both tendon limbs with a sheath before the administration of the straps may enhance the major mechanical properties of the design. Sheaths have been used in plenty of surgical methods to decrease tissue lacerations, one of the most common causes of fixation failures. In a study done on ACL graft, the same graft as the one this paper is focused on, Saithna et.al [9] have shown that sheathing the contact surface between a graft and an interference screw not only increases stiffness and maximum load to failure but also prevents mal-rotation of the graft which reduces any undesired torsion. It was also concluded that the sheath protects the graft from undesired forces applied during the process of strap tightening. Moreover, it will add to the friction between the limbs.

Graft preparation

Five bovine digital flexor and extensor tendon samples were harvested from bovine hooves of the same race and age to model human hamstring semitendinosus, the bovine hooves were provided by a certified slaughterhouse and were delivered fresh to the lab under controlled conditions. The tendon harvesting procedure was performed in the Biomechanics Laboratory at Sharif University of Technology, and all procedures were certified by the Sharif ethical committee.

The tendons were trimmed into identical sizes with a length of 200 mm and a double-strand diameter of 8 mm which is known to be a desirable and effective graft choice. They were later looped and passed through the gauge template "Figure 3 (A)" to inspect the diameter. In some cases, the tendon was retrimmed to a lesser size "Figure 3 (b)".

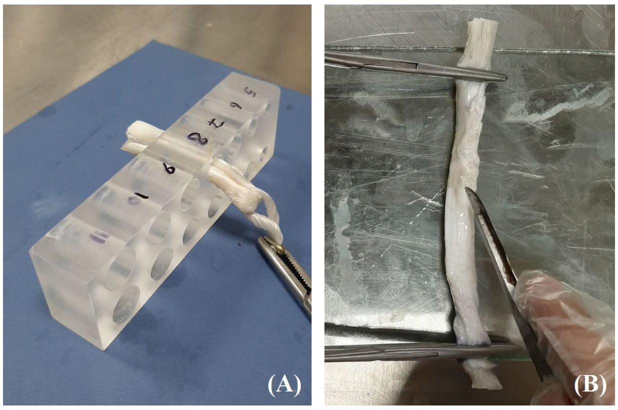

Figure 3. (A) Passing a looped tendon through the template's 8mm gauge to inspect the diameter of the graft.
(B)Trimming a harvested tendon graft to a desirable size with a surgical scalpel.

The trimming procedures were made by a surgical scalpel (knife) by keeping the tendon under a tension of less than 50 N demonstrating the load applied by the surgeon on the semitendinosus while harvesting. To maintain the mechanical qualities, the grafts were kept moist with normal saline during all preparation and testing procedures.

Following the trimming process, the samples were stored at a temperature of -20C for less than 48 hours, which was proven not to contain any considerable influence on the graft's mechanical properties [10], [11]. The tendons were thawed at room temperature at the time of testing.

The graft preparation procedure is illustrated in "Figure 4 (A)". (Cable tie wraps 3mm x 150mm) were designated to model the straps. Also, five 32mm x 20mm pieces of cotton pads were precisely cut and later soaked in normal saline as custom sheaths for the test. Each graft was passed through two endo buttons and then looped in a manner that both ends share a 20mm common surface. Then the graft's ends and the contact surfaces between them were covered by a sheath, each sheath folded like an English 8 fashion around the graft limbs. Two cable ties with the size of 3mm kept 6 mm apart from each other were then wrapped around the covered area. Each strap was fixed 4 mm apart from the sheath edges.

Both ends of the tendon were held under tension during all procedures above to simulate the pre-tensioning procedure done on sutured grafts during an ACL reconstruction surgery. The straps were initially tightened to some extent holding all the fixation parts together but not conveying all the designated circumferential compression to the graft. After certain controlling, the cable ties were retightened to reach the established inner diameter of 6.8mm "Figure 4 (B)". All prepared grafts were stored in normal saline and were tested shortly after their preparation.

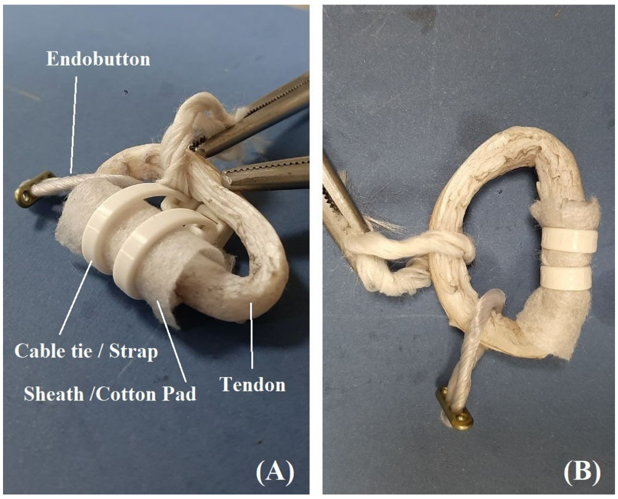

Figure 4. (A) The graft during preparation, the graft is passed through the Endobuttons, and cable ties are placed around the sheathed part. the cable ties are not fastened.
(B) A prepared graft with tightened straps. the depicted sample is ready for the testing stage.

Mechanical testing

Testing was performed at room temperature and specimens were kept moist by frequent application of normal saline spray. The mechanical test was completed using a servo-hydraulic testing machine (Amsler HCT 25–400; Zwick/Roell AG, Germany) The samples were cautiously mounted on the machine by passing two pins through the Endobuttons hanging them from the testing machine's crossheads "Figure 5".

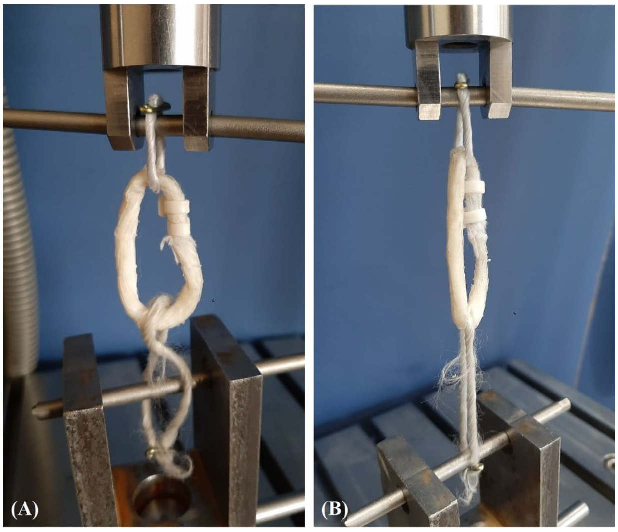

Figure 5. (A) The mechanical test setup. The samples were mounted on the machine by passing two pins through the Endobuttons hanging them from the testing machine's crossheads. (B) A graft undergoing cyclic tensile loading during the mechanical test.

Some Controlled processes were carried out to ensure the alignment of the graft structure. The closest Endobutton to the fixation site was hung to the actuator's crosshead and the other one was hung to the base of the testing machine.

The specimens were then subjected to a preconditioning test to align the tendon fibers, eliminate dead length, and remove fixture clearances. In this stage, a cyclical preload of 10 to 50 N was delivered to the graft for 10 cycles at a frequency of 0.1 Hz.

The major pullout test was done right after the preconditioning test, with a cyclical load of 50 to 200 N and a frequency of 1 Hz for 200 cycles. This step models early rehabilitation procedures of isokinetic loading in a rebuilt graft. Furthermore, it models the ACL load bearing in a passive gait extension. After the cyclic load was completed, If the sample survived the cyclical loading, a pullout force with a loading rate of 20 mm/min was imposed on the specimens to determine the ultimate strength of the fixation. For each test, the failure mode was monitored and recorded. "Table 1" illustrates the mechanical testing steps.

Table 1. Steps of mechanical testing.

steps	frequency /loading rate	load	No of cycles
preloading	0.1 Hz	10-50 N	10
main cyclic loading	1 Hz	50-200 N	200
final pullout	20 mm/s	200-failure	1

Average cyclic stiffness (ACS)

ACS was introduced to assess how well the graft functioned under daily cycle stresses, particularly in the early stages of recovery following ACL surgery. ACS is defined as follows:

$$ACS = \frac{Fc}{Dc \quad / Nc} \text{ (N/mm)} \qquad (2)$$

D_C is the pure displacement in the main cyclic loading (Cyclic elongation), N_C is the number of completed cycles in the second loading step (200 cycles), and F_C is the amount of main cycling loading (the difference between the upper and lower values in the cyclical loading from 50 to 200 N, which is 150 N).

Results

Fixation failure and tendon tearing was defined as the two expected failure modes. All failures that contained gross tendon tissue damages were categorized as tendon tearing failure. Fixation failure was also defined as a condition where the tendon graft slips out of the fixation without experiencing observable damage to the tendon tissue. Since the fixation would lose its functionality at a total graft elongation of 10mm or greater, this was regarded as a fixation failure. [7]. The testing results concluded that No failure occurred during the two primary stages of preloading and cyclic loading. Also, no failure associated with tendon tissue damage was recorded. All 5 samples used in this study, experienced a fixation failure during the final pull-out test. "table 2" represents the mean mechanical properties of the fixation

Table 2. The mean biomechanical properties of the fixation

Ultimate Strength (failure load)	287.6 ± 11.8 N
Cyclic Elongation (pure displacement in the main cyclic loading)	2.0 8 ± 0.15 mm
Average Cyclic Stiffness (ACS)	14.524 ± 1.1 kN/mm
Failure mode	100% fixation failure

the values were calculated from the load-displacement curve with a 95% confidence interval.

The mean ultimate strength at the final pullout was 287.6 ± 11.844 N and the results extracted from all five samples did not represent any significant difference and showed promising repeatability. Similarly, the values for cyclic elongation (indicating the difference in graft displacement between the final and first cycle valleys of the cyclic loading) provided promising repeatability. As a trivial consequence, the resulting ACS values were also considerably close. The mean values for cyclic elongation and ACS were 2.08 ± 0.151 mm and 14.524 ± 1.098 kN/mm respectively.

Discussion

The most important finding of the present study is that the introduced design successfully reduces the chance of tendon tearing under the fixation. This was concluded from the fact that no failure due to tendon tearing was recorded from the mechanical tests. In addition, no gross tissue laceration was observed on the tendon samples after the test. In contrast to the results of the present study, various studies containing similar mechanical tests on conventionally fixed grafts by suturing represented high rates of graft failure due to tendon tearing. There still exists controversy on what percentage of conventional graft failures are due to the tendon tearing under the sutures. The reported rates vary from 25% to 60% in different studies while there no tissue damage was observed in the current study.

The mean values of cyclic elongation after 200 cycles and average cyclic stiffness were also compelling. The current test represented significantly lower rates of cyclic elongation compared to both mechanical and clinical studies. The mean average cyclic stiffness of this method was also significantly better than the conventional interference screw method. In addition, the outcomes were even better when comparing our results with newly introduced methods like BASHTI fixation [12].

The ultimate strength of the current design is also compatible with the ones reported from other fixation methods. For instance [1] reported that the ultimate strength of BASHTI fixation, an organic implant-less technique for ACL reconstruction with 9 mm thick grafts was 278 ± 103N. Comparing these results with the 287.6 ± 11.844 N ultimate strength extracted from the current study, it can be concluded that the proposed method not only is feasible but also, presents better repeatability compared to the mentioned study.

As controversy still exists regarding the proper ultimate strength, and various papers have reported higher ultimate strengths for their tested graft, further modifications on the design of straps to increase ultimate strength are recommended.

Conclusions

The present study introduced and mechanically tested a new design along with a fixation method for graft preparation in ACL reconstruction surgery. The designed fixation consisted of two identical straps holding the tendon loop. The results showed that the proposed design successfully diminishes the chance of tendon tearing under the fixation. Moreover, it significantly reduces graft cyclic elongation and enhances graft cyclic stiffness. Despite the mentioned mechanical superiorities, the current design does not provide high levels of ultimate strength. Thus, further modifications to the design to advance ultimate strength are required.

Nomenclature

ACS	Average cyclic stiffness
Dc	Cyclic elongation
Fc	Amount of main cycling load
Nc	Number of completed cycles
S_{strap}	Inner area of the straps
S_{tendon}	Tendon cross-sectional areas
TC	Tendon compression

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