



Biomechanical Analyses of Novel Techniques for Knee Meniscus Repair and Proximal Subpectoral Biceps Tenodesis

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Abstract (Meniscus Repair)

Background: Many all-inside suture-based devices are currently available, including the Meniscal Cinch, FasT-Fix, Ultra FasT-Fix, RapidLoc, MaxFire, and CrossFix System. These different devices have been compared in various configurations, but to our knowledge, the Sequent meniscal repair device, which applies running sutures, has not been compared with the Ultra FasT-Fix, nor has it been compared with its suture, No. 0 Hi-Fi, using an inside-out repair technique.

Purpose: To assess the quality of the meniscal repair, all new devices should be compared with the gold standard: the inside-out repair. To that end, this study aims to compare the biomechanical characteristics of running sutures delivered by the Sequent meniscal repair device with 2 vertical mattress sutures applied using the Ultra FasT-Fix device and with 2 vertical mattress sutures using an inside-out repair technique with No. 0 Hi-Fi suture.

Study Design: Controlled laboratory study.

Methods: Paired (medial and lateral), fresh-frozen porcine menisci were randomly assigned to 1 of 3 groups: Sequent (n = 17), Ultra FasT-Fix (n = 19), and No. 0 Hi-Fi inside-out repair (n = 20). Bucket-handle tears were created in all menisci and were subjected to repair according to their grouping. Once repaired, the specimens were subjected to cyclic loading (100, 300, and 500 cycles), followed by loading to failure.

Results: The Sequent and Ultra FasT-Fix device repairs and the suture repair exhibited low initial displacements. The Sequent meniscal repair device demonstrated the lowest displacement in response to cyclic loading. No. 0 Hi-Fi suture yielded the highest load to failure.

Conclusion: With the development of the next generation of all-inside meniscal repair devices, surgeons may use these findings to select the method best suited for their patients.

Clinical Relevance: The Sequent meniscal repair device displays the least amount of displacement during cyclic loading but has a similar failure load to other devices.

Abstract (Biceps Tenodesis)

Purpose: Proximal biceps tenodesis is one method for treating biceps-related pain. Tenodesis protects the length-tension relationship of the biceps muscle, maintains strength, and provides a better cosmetic appearance than tenotomy. The purpose of this investigation was to compare the mechanical properties of a unicortical metal button and an interference screw in proximal biceps tenodesis.

Methods: Six pairs of fresh-frozen shoulders were dissected, leaving the proximal biceps tendon as a free graft. On each pair of shoulders, a biceps tenodesis was performed using an interference screw or a unicortical metal button. The specimens were mounted and a cyclic load (10-60 N) was applied at 1 Hz for 200 cycles, followed by an axial load to failure. The displacement, ultimate load to failure, and mode of failure were recorded.

Results: Displacement in response to cyclic loading was 3.7 ± 2.2 mm for the interference screw and 1.9 ± 1.0 mm for the cortical button ($P = 0.03$). Load at failure for the interference screw was 191 ± 64 N (stiffness: 24 ± 11 N/mm) and 183 ± 61 N (stiffness: 24 ± 7 N/mm) for the unicortical button ($P = \text{n.s.}$ for both cases).

Conclusions: As a novel technique for subpectoral biceps tenodesis, a unicortical button demonstrated significantly less displacement in response to cyclic loading than the interference screw. The ultimate load to failure and stiffness for the two methods were not different. In this way, a unicortical button may provide a reliable alternative method of fixation with a potentially lower risk of post-operative humeral fracture and a construct that permits early mobilization following biceps tenodesis.

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Chapter I:

A Biomechanical Evaluation of All-Inside 2-Stitch Meniscal Repair Devices with Matched Inside-Out Suture Repair

I. INTRODUCTION

Meniscal tears are a significant source of knee pain and disability, and their treatment may result in premature osteoarthritis [10]. As a result, a concerted effort is made to preserve meniscal tissue whenever possible. Given its historical success and favorable mechanical profile (high load to failure), the inside-out suture repair is the gold standard of meniscal repair techniques [5, 15]. Since this technique depends on sutures passed from inside the knee to the outside, there is an increased risk of injury to neurovascular structures, when the suture limbs are tied. Moreover, this procedure is associated with increased perioperative morbidity [12, 16]. To minimize this risk, “all-inside” devices have been developed to repair the meniscus arthroscopically, without passing needles or suture through the skin [3, 5, 12, 16]. All-inside repair devices can be divided into two types: resorbable, rigid arrows (staples), which provide rigid fixation; and flexible, suture-based repair devices, which deploy anchors for stability. Rigid all-inside devices have demonstrated good outcomes, but their high failure rate has led to more frequent use of flexible, suture-based techniques [1, 2]. While previous all-inside devices such as the Ultra FasT-Fix (Smith & Nephew, Andover, MA, USA) complete a simple suture repair (a single vertical or horizontal stitch), newer devices, such as the Sequent Meniscal Repair device (ConMed Linvatec, Largo, FL, USA), allow for the application of multiple sutures with a single device.

Many all-inside, suture-based devices are currently available including the Meniscal Cinch (Arthrex, Naples, Florida), FasT-Fix (Smith & Nephew, Andover, Massachusetts), Ultra FasT-Fix (Smith & Nephew, Andover, Massachusetts), RapidLoc (Mitek, Westwood, Massachusetts), MaxFire (Biomet, Warsaw, Indiana), and CrossFix System (Cayenne Medical, Scottsdale, Arizona). These different devices have been compared in various configurations [5, 12, 20]; but to our knowledge, the Sequent Meniscal Repair device, which applies running sutures, has not been compared to its own suture, Hi-Fi No. 0, nor to the Ultra FasT-Fix device.

In order to assess the quality of the meniscal repair, these new devices should be compared to the gold standard, the inside-out repair. To that end, *we hypothesized that two running vertical mattress sutures performed with the Sequent Meniscal Repair device will have a higher load-to-failure and less displacement in response to cyclic loading than two vertical*

mattress sutures placed using the Ultra FasT-Fix (all-inside) system and the No. 0 Hi-Fi inside-out technique. Therefore, we aim to compare the biomechanical characteristics of the two running sutures applied using the Sequent Meniscal Repair device with the two vertical mattress sutures applied using the Ultra FasT-Fix device or using an inside-out repair technique with No. 0 Hi-Fi suture.

II. METHODS

Preparation and Repair

Paired (medial and lateral), fresh frozen porcine menisci, were randomly assigned to one of three groups: Sequent (ConMed Linvatec, Largo, FL) Meniscal Repair (n= 20), Ultra FasT-Fix (Smith & Nephew Endoscopy, Andover, MA) (n=18) and No. 0 Hi-Fi inside out repair (n=20). The menisci were thawed eight hours prior to testing. Using a No. 11 surgical blade, a vertical incision was created 3 mm from the peripheral rim starting at the midpoint of the pars intermedia and extending to the anterior and the posterior horns to create a bucket-handle tear [16] Using the Sequent Meniscal Repair device (**Figure 1a**), two vertical running stitches were deployed across the midpoint of the pars intermedia, by performing four passes in accordance with the manufacturer's instructions. Likewise, two vertical mattress sutures were placed using two Ultra FasT-Fix devices (**Figure 1a and 1b**) or with two strands of Hi-Fi No. 0 suture (**Figure 1c**) to simulate all-inside and inside-out repair techniques, respectively (**Figure 1**). Once repaired, the bucket-handle tear was completed with a No. 11 blade through the anterior and posterior horns. Tissue moisture was maintained during testing by consistent spraying of physiologic saline (0.9% by volume) on the specimens.

Biomechanical Testing

The menisci were fixed in custom made clamps aligned perpendicular to the tear and mounted in an Instron 8511 (Instron Inc., Norwood, MA, USA) mechanical testing system (**Figure 1d**). Cyclic loading was performed between 5 and 20 N at a frequency of 1 Hz, and recorded continuously using LabView 2011 (National Instruments, Austin, TX, USA). Displacement (gap formation) was recorded at a load of 5 N after cycles 1, 100, 300, and 500 using a calibrated, high-resolution digital camera (PixeLINK PL-B681C, PixeLINK, Ottawa, Ontario, Canada) and Labview 8.51 (National Instruments, Austin, Texas) at a sample rate of 50 Hz. Measurements to determine the gap formation were made from points adjacent to the suture repair so that possible slippage from the clamp would not affect the measurement. Displacement measurements were made using ImageJ (National Institutes of Health, Bethesda, Maryland) and were recorded as the vertical component of the measured distance. This

software has previously been validated [12]. Load-to-failure testing was then performed at a rate of 3.15 mm/s, and the stiffness was calculated as the slope of the linear segment (between 20% and 60% of yield load) for each load-displacement curve. Finally, the mode of failure was recorded for each specimen. The modes of failure were defined as: a sudden loss of fixation (suture failure), suture pull-through (tissue failure), anchor pull-through, or knot slippage.

Statistical Analysis

A previous study indicated load to failure results of 187 ± 42 N and 140 ± 30 N for the Ultra FasT-Fix and fiber wire suture repair techniques respectively [16]. Employing these values as a guide, a sample size of $n=18$ would result in 80% power to detect a 20% change in failure load based on analysis of variance (nQuery Advisor ver. 7.0, Statistical Solutions, Saugus, Massachusetts). The Shapiro-Wilk test for normality was used to evaluate the distribution of the data. A one-way analysis of variance (ANOVA) with Bonferroni post-hoc analysis was performed to assess changes in failure load and stiffness between the groups. A two-way analysis of variance was performed at a set number of cycles (1, 100, 300 and 500) using an estimated margin mean analysis to assess the differences between groups and differences between cycles across the groups. The SPSS software (version 19.0, Chicago, IL, USA) was used for data analysis. All comparisons were two-tailed, and a p value less than 0.05 was considered statistically significant.

III. RESULTS

All data (failure load, stiffness and displacement) were distributed normally ($P > 0.05$ for all cases). The No. 0 Hi-FI inside-out repair resulted in the highest load to failure ($P < 0.001$, **Figure 2, Table 1**). No difference in the load to failure was observed between the Sequent and Ultra FasT-Fix repair techniques ($P = 0.98$). No differences in stiffness were observed among the three repair groups ($P = 0.64$, **Figure 3, Table 1**).

Ultra FasT-Fix repair demonstrated the highest initial displacement ($P < 0.001$), while no difference in initial displacement was observed between the No. 0 Hi-FI inside-out and the Sequent repair techniques ($P = 0.82$, **Figure 4**). However, for cycles 100, 300 and 500, the Sequent repair method resulted in the lowest displacement value among the three repair groups ($P < 0.001$ for all three cycles, **Figure 4**). Over these values, the No. 0 Hi-FI inside-out repair and the Ultra FasT-Fix repair techniques were not statistically different ($P = 0.19, 0.15$ and 0.13 respectively). Estimated margin mean analysis indicated that displacement values were significantly different between the different testing intervals for each repair technique ($P < 0.001$ for all cases, **Figure 4**), with a higher number of cycles corresponding to greater displacement. All displacement results are outlined in **Table 1**.

There were differences in the modes of failure observed in the three repair groups. The No. 0 Hi-FI inside out repairs predominantly failed by suture breakage ($n=14, 70\%$), with suture pull through the tissue ($n=4, 20\%$) and knot slippage ($n=2, 10\%$) occurring at a lesser frequency. In the Sequent group, the most common mode of failure was loss of anchor fixation ($n=15, 88.2\%$) followed by the anchor pulling through specimens ($n= 2, 11.8\%$). Likewise, the Ultra FasT-Fix repair group mainly failed through loss of anchor fixation ($n=12, 63.2\%$), with suture breakage ($n=6, 31.6\%$) and tissue pull through occurring less commonly ($n=1, 5.26\%$).

IV. DISCUSSION

Over the past decade, meniscal repair techniques have improved significantly due to an enhanced understanding of the biomechanical properties of menisci, applied in conjunction with improvements in surgical technique, materials, and methods. The literature suggests that the meniscal repair failure rates range from 0% to 23% [13]. These failures are most commonly due to inadequate or suboptimal technique. While an “inside-out” meniscal repair is the golden standard, this technique is associated with increased neurovascular injury and perioperative morbidity [12, 16]. Consequently, these risks have led to an increased use of “all-inside” repair devices [5, 12, 16, 17]. All-inside meniscal repair techniques are less invasive, quicker to perform, and are associated with lower rates of morbidity and complication [12, 16, 17]. The process of wound healing after meniscal repair depends on many factors - including tear size, blood supply, location of tear, duration from injury, rehabilitation protocol, and surgical technique. Surgical technique plays a significant role in patient outcomes. For this reason, selection of the optimal repair technique should be considered carefully. Based on the pattern of meniscal injury, the biomechanical characteristics of the different repair devices and their application may facilitate decision making in a clinical setting [8, 19]. Repetitive stress during rehabilitation can lead to failure of a meniscus repair. However, failure may also occur suddenly in response to a single load beyond the repair’s load to failure. An ideal meniscal repair technique should provide stability of fixation. It should withstand the repetitive stresses associated with joint motion during rehabilitation as well as a large, sudden stress that can occur incidentally. Therefore, our biomechanical testing protocol aimed to address these issues by assessing both the displacement with cyclic loading and a load to failure. To the best of our knowledge, this study is the first of its kind to evaluate the strength of a two-suture repair.

In this study, the Ultra FasT-Fix repair demonstrated the highest initial displacement, while no difference in initial displacement was observed between the No. 0 Hi-FI inside-out and the Sequent repairs. Subsequently, after 100, 300 and 500 cycles, the Sequent repair method demonstrated the lowest displacement among the three repair groups. There were no significant differences between the inside-out suture group and the UltraFasT-Fix at 100, 300, and 500 cycles. In contrast, Barber et al [4] found that after 100 cycles, the Sequent repair had

a higher displacement (3.35 mm). This discrepancy may result from a difference in methodology, user variability, or applied load. While this study loaded the specimens to 20 N, Barber et al⁴ loaded their specimens to 50 N. The choice of a 20 N load and 500 cycles is consistent with previous studies [12, 16, 20]. It approximates the *in-vivo* loading forces associated with early rehabilitation after meniscal repair [2, 7, 9, 14, 16]. With respect to cyclic loading, the results suggest that patients undergoing Sequent Meniscal repair may benefit from an accelerated rehabilitation program to avoid the muscle atrophy associated with prolonged immobilization and to reduce the likelihood of knee stiffness and arthrofibrosis.

Prior investigations have identified the importance of initial displacement in meniscal repair testing [16]. Both Mehta and Terry [12] and Zantop et al [20] have supported the assertion that initial displacement may be inversely proportional to the healing rate. Clinically, initial displacement is difficult to observe. Repeat magnetic resonance imaging (MRI) provides a static evaluation of the unstressed repair. Second-look arthroscopy is conducted infrequently to assess meniscal healing. In this study, each of the 3 groups demonstrated very low initial displacements. The Ultra FasT-Fix group had the highest initial displacement: 0.460 mm versus 0.299 for the inside-out repair. However, the clinical impact of this difference is likely very small.

In the load to failure analysis, the No. 0 Hi-FI inside-out repair group had a significantly higher load to failure than the Sequent and Ultra FasT-Fix repair groups, whereas these two techniques were not different from one another. In contrast, Barber et al [4] reported that the Sequent repair device displayed a load to failure of 66 N, while their suture control had a load to failure of 73 N, with all experimental groups ranging between 54 and 88 N. The differences in the load to failure results between the current study and the work by Barber et al can be attributed to the differences in meniscus type (human vs porcine) and the gripping and failure mechanisms associated with the testing methods employed by the respective laboratories. A number of studies have shown that the vertical FasT-Fix suture has superior biomechanical characteristics for meniscal fixation during cyclic and load to failure testing compared with other devices [9, 16]. Another recent study has shown that the all-inside Sequent device

provided radial meniscus tear fixation that was comparable, but not superior, to conventional inside-out suturing [11].

The observed modes of failure varied among the three groups. The No. 0 Hi-Fi inside out repairs failed by suture breakage, while the Sequent and Ultra FasT-Fix repairs experienced anchor failure. Chang et al. found that FasT-Fix repairs failed at the knot of suture near the first anchor, while the RapidLoc meniscal repairs failed due to suture rupture [6, 7, 11, 20].

This investigation benefits from the testing techniques employed. Displacement was measured directly at the level of sample, using a high-resolution digital camera and markers adjacent to the tear. Previous studies have relied on calipers or actuator position to measure displacement [12, 20]. Unfortunately, these previously used methods cannot control for error due to compression, stretch of the tissue, and slippage within the clamp. To further improve the testing configuration, customized metal clamps were designed to hold each specimen away from the sutures and the repair site. This modification intended to improve the strength of the grip without affecting the load to failure or displacement. Previous biomechanical studies have employed a single implant or suture repair for longitudinal meniscal tears. Our study employed 2 vertical mattress sutures to repair a longitudinal meniscal repair. These repair configurations may more closely resemble what surgeons encounter clinically, as one implant/suture repairs are used less frequently than multiple implant/suture repairs.

As with all biomechanical investigations, this study has some limitations. Ideally, fresh menisci from young human cadaver donors would have been tested. However, given the scarcity and the cost associated with this tissue, porcine menisci were used. The porcine meniscus has the size, shape, and structure that resemble those of human meniscus. In testing their response to creep, porcine menisci demonstrate less deformation and equilibrium displacement when compared with bovine and human menisci [18]. This difference benefits the experimental design by minimizing specimen variability, but raises a question regarding the direct applicability of the results to human tissue. Given that meniscal tears frequently occur in degenerated menisci that do not have the same mechanical strength as healthy tissue, the load to failure and response to cyclic loading may correlate directly. Additionally, in this

investigation, a linear force was applied perpendicular to the tear. This approach does not recreate the complex, multidirectional forces encountered *in-vivo*.

In conclusion, the biomechanical characteristics of the two running sutures applied using the Sequent Meniscal Repair device demonstrated the lowest displacement in response to cyclic loading. Both devices and the inside-out suture technique demonstrated low initial displacements. The No. 0 Hi-Fi suture yielded the highest load to failure. With the development of the next generation of all-inside meniscal repair devices, surgeons may use these findings to select the method best suited for their patients.

Chapter II:

Biomechanical Characterization of Unicortical Button Fixation: A Novel Technique for Proximal Subpectoral Biceps Tenodesis

I. Introduction

The long head of the biceps is frequently cited as a cause of shoulder pain. While there have been conflicting reports on the function and importance of its pathology, the biceps tendon is implicated in a myriad of conditions ranging from impingement syndrome to arthritis. In addressing biceps-related pain, various approaches have been advocated, ranging from benign neglect to tenotomy and/or tenodesis [23, 31, 34, 38, 40, 50, 56, 59].

Some surgeons recommend biceps tenodesis over biceps tenotomy in order to maintain the length–tension relationship of the biceps muscle and to prevent atrophy [21, 30, 46, 52]. In this way, biceps tenodesis works to preserve elbow function by maintaining elbow flexion and forearm supination strength. It has been found to have a superior cosmetic appearance when compared with tenotomy [41, 53, 55]. Because patients have reported ongoing muscle discomfort following tenotomy, biceps tenodesis is believed to decrease the incidence of biceps cramping and spasm [49].

Methods of tenodesis can be divided into open and arthroscopic techniques [21, 25, 28, 29, 31, 32, 34, 37, 40, 46, 51, 52, 63, 64, 66, 69, 72]. When comparing the biomechanical strength of these biceps tenodesis techniques, several authors have found comparable ultimate load to failure [43, 55]. Others have demonstrated a significantly higher load to failure and stiffness when the Bio-Tenodesis screw (Arthrex, Naples, FL, USA) was compared with the Bio-Corkscrew suture anchor (Arthrex, Naples, FL, USA) [39]. While these methods demonstrate sound biomechanical properties, the use of a metal button (Endobutton, Smith & Nephew, Andover, MA, USA, and Biceps Button, Arthrex, Naples, FL, USA) has only recently been characterized as a technique for proximal biceps tenodesis [22, 26, 27, 56, 67, 68].

In the repair of the distal biceps tendon, the use of a metal button has been shown to have the highest ultimate load to failure [55]. Therefore, the strength of this construct should support its use to tenodesis the biceps proximally.

In addition to the strength of fixation, a cortical button also may offer additional benefits. Because a much smaller hole is required for deployment, the resulting stress increase in the humerus is much smaller. In turn, the risk of postoperative humeral fracture should be lower than with the larger hole required for a keyhole or tenodesis screw [60, 65]. Because this

technique advocates unicortical fixation, there is only one small cortical defect in the anterior humerus, rather than one anterior and one posterior as described by Mithoffer et al. [58], further increasing this technique's utility. Additionally, failure of a tenodesis screw can warrant re-operation [47]. To that end, the aim of this study was to characterize the mechanical properties (response to cyclic loading and load to failure) of a unicortical metal button in proximal biceps subpectoral tenodesis, and to compare them to a biceps tenodesis performed using an interference screw in a matched specimen. Given its effectiveness in distal biceps tendon repair, we hypothesized that a unicortical metal button would have less displacement after cyclic loading and a higher ultimate load to failure than a tenodesis using an interference screw.

II. Methods

Twelve fresh-frozen cadaveric shoulders (six paired upper extremities) were randomly divided into two groups for an open subpectoral biceps tenodesis using either an interference screw (Bio-Tenodesis Screw, Arthrex, Naples, FL, USA) or a unicortical button (Biceps Button, Arthrex, Naples, FL, USA). Paired extremities were used to minimize specimen variability. Left and right shoulders were evenly distributed among the groups.

The mean age of the donors was 72.1 ± 16.4 years. After thawing at room temperature for 24 h, each shoulder was dissected leaving the pectoralis major tendon attached to the proximal humerus and the long head of the biceps (tendon and muscle) as a free graft.

Group 1: Biceps tenodesis using a tenodesis screw

In this technique, an 8 x 23 mm polyether ether ketone (PEEK) tenodesis screw (Bio-Tenodesis Screw, Arthrex, Naples, FL, USA) was used to perform the tenodesis 1 cm proximal to inferior border of the pectoralis major tendon. The thickness of the biceps tendon was larger than the tunnel diameter for the screw in all cases. A No. 2 Fiber-Loop suture (Arthrex, Naples, FL, USA) was placed into the proximal biceps tendon using a modified whipstitch (**See Appendix**). Once the whipstitch was completed, a square knot was placed at the end of the suture–tendon interface. An 8-mm reamer was used to drill a unicortical hole 1 cm proximal to the inferior border of the pectoralis major tendon. Using the tenodesis screwdriver, the screw and tendon were advanced until the screw was level with the bone tunnel. The screwdriver was removed, and the limb of suture juxtaposed to the tendon was tied to the limb of the suture travelling through the screw.

Group 2: Biceps tenodesis using a unicortical button

In this technique, a cortical button (Biceps Button, Arthrex, Naples, FL, USA) was used to perform the tenodesis 1 cm proximal to inferior border of the pectoralis major tendon. A No. 2 FiberLoop suture (Arthrex, Naples, FL, USA) was placed into the proximal biceps tendon using a modified whipstitch. A 3.0-mm pin was drilled into the anterior humerus 1 cm proximal to the

inferior border of the pectoralis major tendon. Using the technique described by Sethi and Tibone, a cortical button was prepared for a tension slide [68]. One limb of the FiberLoop was passed through the right hole in the button and then back through the left. Next, the other limb was passed through the cortical button in the opposite direction (through the left hole then back down the right), such that both tails were towards the biceps tendon. A button inserter (Arthrex, Naples, FL, USA) was then used to push the button through the 3.0-mm hole in the anterior cortex of the proximal humerus. The button was deployed in the intramedullary canal, and retrograde traction was applied to the sutures to toggle the cortical button against the inner cortex of the proximal humerus. Tension was applied to the individual limbs to complete the tension slide and firmly opposed the biceps tendon to the anterior cortex of proximal humerus. One limb was then passed through the biceps tendon using a straight (Keith) needle, and the two limbs were tied to complete the tenodesis.

Biomechanical testing

Each specimen was mounted on an Instron 8511 load frame (Instron, Canton, MA, USA) using a custom clamp (Fig. 5) after the humeral head was embedded in polymethyl methacrylate (PMMA). The humerus and biceps tendon were aligned so that force applied to the biceps tendon was parallel to the longitudinal axis of the humerus, approximating the in vivo pull of the biceps muscle.

Testing was performed at room temperature, and desiccation was prevented by treating the specimens with 0.9 % saline. The tendons were preloaded to 10 N and then underwent cyclic loading between 10 and 60 N for 200 cycles at 1 Hz [24, 33, 61, 62, 70]. An axial load was then applied at 1 mm/s until failure. The mode of failure was recorded. The accuracy of the linear variable differential transformer (LVDT, displacement) and the load cell of the load frame is 0.5 % of the full scale. As a result, the accuracy of the LVDT and the load cell is ± 0.25 mm and 2.22 N, respectively.

Specimen motion was recorded using a high-resolution digital camera (Panasonic Lumix DMC-ZS10, Panasonic, Kadoma, Osaka, Japan) and Labview 2011 (National Instruments, Austin, TX, USA), at a sample rate of 20 Hz. Displacement was measured from a point on the tendon to two separate points on the proximal humerus in order to minimize the effect of hysteresis, tissue relaxation (stretch), and slippage (**Figure 5**). As a result, the displacement measurements were the average of the two separate distances, each from one point on the humerus to the one on the tendon. Measurements were taken using ImageJ software (National Institutes of Health, Bethesda, MD, USA) and were recorded as the absolute distance between two points [42, 45]. Stiffness was defined as the slope of the load–displacement curve. A linear regression was performed to find the best-fit line for the linear portion of the curve.

Statistical analysis

Using an a priori sample size analysis, six paired specimens in each group yielded a very large effect size (Cohen $d = 1.5$) for α and β values of 0.05 and 0.20, respectively. Data analysis was performed using SPSS software (version 19.0, SPSS, Inc, Chicago, IL, USA) to complete a paired Student's t test. P values < 0.05 were considered statistically significant. The SPSS software was used for the data analysis. All comparisons were two-tailed, and a P value < 0.05 was considered statistically significant.

III. Results

After 200 cycles, the mean displacement in response to cyclic loading was significantly higher (3.7 ± 2.2 mm) for the interference screw and than for the cortical button (1.9 ± 1.0 mm, $P = 0.03$, **Figure 6a**). No difference in ultimate load to failure was found when the unicortical button (191 ± 64 N) was compared to the interference screw (183 ± 61 N, $P = \text{n.s.}$, **Figure 6b**). Similarly, there was no difference in the calculated construct stiffness between the unicortical button (28 ± 7 N mm⁻¹) and interference screw (24 ± 11 N mm⁻¹, $P = \text{n.s.}$, **Figure 6c**). None of the specimens failed during cyclic loading, and while all specimens were tested to failure, eleven specimens (92 %) failed at the tenodesis site.

IV. Discussion

As a novel technique for subpectoral biceps tenodesis, a unicortical button demonstrated significantly less displacement in response to cyclic loading than the interference screw. The ultimate load to failure and stiffness for the two methods was not different.

In this study of a biceps tenodesis, the mechanical properties of two surgical techniques were compared. Because cyclic loading simulates the repetitive stress associated with arm motion, mechanical testing is designed to assess the integrity of the tenodesis construct in response to the routine range of motion and activity following surgery. Similarly, load to failure testing constitutes the best overall measure of the construct's mechanical strength in a worst-case scenario. In comparing the behavior of a unicortical button to the tenodesis screw, the established standard for subpectoral biceps tenodesis, this investigation sought to characterize the unicortical button as a potential method to improve upon the current standard of care.

Rehabilitation programs that do not limit post-operative motion are denoted as 'Early' or 'Accelerated'. These protocols are believed to benefit patients by preventing the stiffness that may result from a traditional period of postoperative immobilization following biceps tenodesis. While this approach has been found to be effective in a number of settings, concern remains because early motion can lead to failure at the tenodesis site and subtle differences in response to cyclic loading may predict a construct's behavior over time. In this study, after 200 cycles, the cortical button demonstrated less displacement than the tenodesis screw, suggesting that this technique may have an advantage for patients in whom early range of motion is indicated.

Based on these data, clinicians might adjust their postoperative instructions to patients and their physical therapists. If this in vitro decrease in displacement translates in the clinical setting, this technique would result in improved healing. The soft tissues that experience less strain during the post-operative recovery heal more effectively. Patients who are allowed to move their shoulder after surgery experience less post-operative stiffness. More effective healing and less stiffness are correlated with improved clinical outcomes.

In contrast, the load to failure and stiffness of the two constructs were not statistically different, suggesting that the unicortical button tenodesis construct does not demonstrate

superior mechanical integrity than the tenodesis screw. In a recent study, Sethi et al. found that biceps tenodesis using bicortical button fixation alone had a significantly lower load to failure and greater displacement following cyclic loading when compared with two techniques using an interference screw [68]. This disparity may result from difference in the mechanical testing protocols. In this study, cyclic loading was performed between 10 and 60 N for 200 cycles, while Sethi et al. cycled their specimens to 100 N for 5,000 cycles. However, the literature suggests that cyclic loading for fewer cycles using lower loads (under 70 N) better approximates the stress encountered during rehabilitation [24, 33, 48, 61, 70].

Additionally, it is also possible that the use of the metal button as a unicortical point of fixation may have a mechanical advantage. In the earlier work, the metal button (Biceps Button) was tested using a traditional bicortical technique as described by Mithoefer, in which the button is deployed on the posterior aspect of the humerus [58, 68]. However, in this protocol, the button was deployed within the intramedullary canal. As a result, the cortical button is very close to the biceps tendon. Positioned against the anterior cortex of the humerus, the button is rigidly opposed to the bone with no tissue interposition. In contrast, when the cortical button is deployed bicortically, it rests against the posterior cortex of the humerus, at a much greater distance from tenodesis site. The intervening soft tissue and suture material between the point of fixation (posterior cortex) and the biceps tendon may adversely affect the construct's mechanical integrity.

As a biomechanical investigation, this study did not evaluate healing of the tendon to the bone and cannot comment on potential outcomes or clinical performance. However, prior studies have demonstrated that both suture anchors and tenodesis screws produce good clinical outcomes [57]. Because a suture anchor secures the cut tendon against the anterior cortex of the humerus, it stands to reason that a cortical button that rigidly holds the tendon to the humerus would behave similarly. In this way, while the described technique does not secure the tissue to the bone with a screw, the 3-mm cortical defect required to deploy the button provides a surface area comparable to most suture anchors, and may have the advantage of allowing the medullary effluent direct access to the tendon during healing [71].

Like all tenodesis techniques, the proposed method creates a unicortical defect in the anterior humerus, which may place a patient at risk for post-operative fracture [60, 65]. However, in comparison with the tenodesis screw and keyhole techniques, the unicortical button requires a much smaller drill hole (3 mm). This difference in size may confer an advantage in the clinical setting, by decreasing the stress riser effect of the procedure and lowering the risk of humeral fracture. Additionally, because this study describes a unicortical method, the risks related to this technique may be lower than those associated with the bicortical method described by Mithoffer et al. [58].

One of the strengths of this investigation is that displacement was determined digitally using direct measurements at the tenodesis site (**Figure 5**). In similar studies, other investigators have relied on manual measurements using calipers or have recorded the actuator position as a surrogate for displacement [51, 53, 54]. These methods may introduce error inherent to manual measurement or changes in position that occur with compression or stretching of the soft tissue within the clamps or gripping devices. To improve accuracy, a high-resolution digital camera was used to capture images, and the analysis was performed using a validated technique [35, 42, 44, 45].

While the sample size was adequate to demonstrate a statistically significant difference in response to cyclic loading, it is possible that the groups in this investigation were too small to detect a difference in the load to failure. Furthermore, the load-to-failure values in this study are comparable to those previously published, lending credibility to this experimental design, despite the small sample size [61, 68, 70].

As a novel technique for subpectoral biceps tenodesis, a unicortical button demonstrated significantly less displacement in response to cyclic loading than the interference screw. The ultimate load to failure and stiffness for the two methods was not different. In this way, a unicortical button may provide a reliable alternative method of fixation with a potentially lower risk of post-operative humeral fracture and a construct that permits early mobilization following biceps tenodesis.

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Ramappa A.J., **Chen A.**, Hertz B., Wexler M., Grimaldi Bournissaint L., DeAngelis J.P., Nazarian A. A Biomechanical Evaluation of All-Inside 2-Stitch Meniscal Repair Devices with Matched Inside-Out Suture Repair. *American Journal of Sports Medicine*. **2014**, 42(1):194-9.

DeAngelis J.P., **Chen A.**, Wexler M., Hertz B., Grimaldi Bournissaint L., Nazarian A. & Ramappa A.J. Biomechanical Characterization of Unicortical Button Fixation: A Novel Technique for Proximal Subpectoral Biceps Tenodesis. *Knee Surgery Sports Traumatology Arthroscopy*. **2013**.

I designed and conducted the study, collected and analyzed the data and wrote the manuscript. MW and BH were Boston University undergraduate students who assisted me in collecting data. LGB was a researcher who also helped collect data and provided edits in the manuscript. JPD and AJR are orthopedic surgeons at Beth Israel Deaconess Medical Center who conceived of the project idea and performed the surgical techniques described in this thesis. AN is a Biomedical Engineer who served as my day-to-day advisor in the lab, and provided me with technical guidance and reviewed and edited the manuscripts prior to publication.

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Figures and Tables

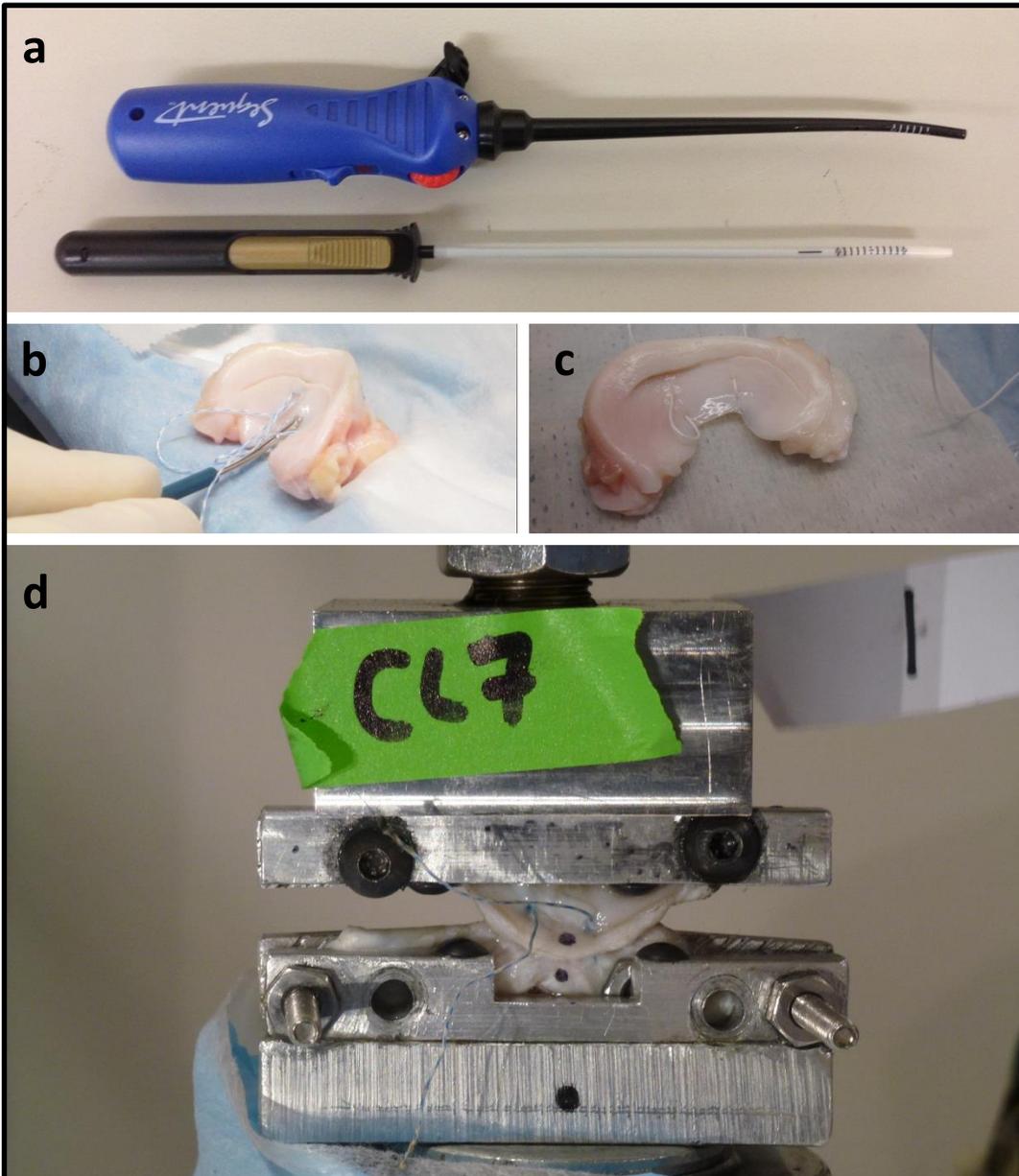


Figure 1 – **a)** Sequent (top) and Ultra FasT-Fix (bottom) meniscal repair devices used in the study; **b)** meniscal repair with Ultra FasT-Fix device; **c)** meniscal repair with the No. 0 Hi-Fi inside-out suture technique; and **d)** mechanical testing setup used in the study.

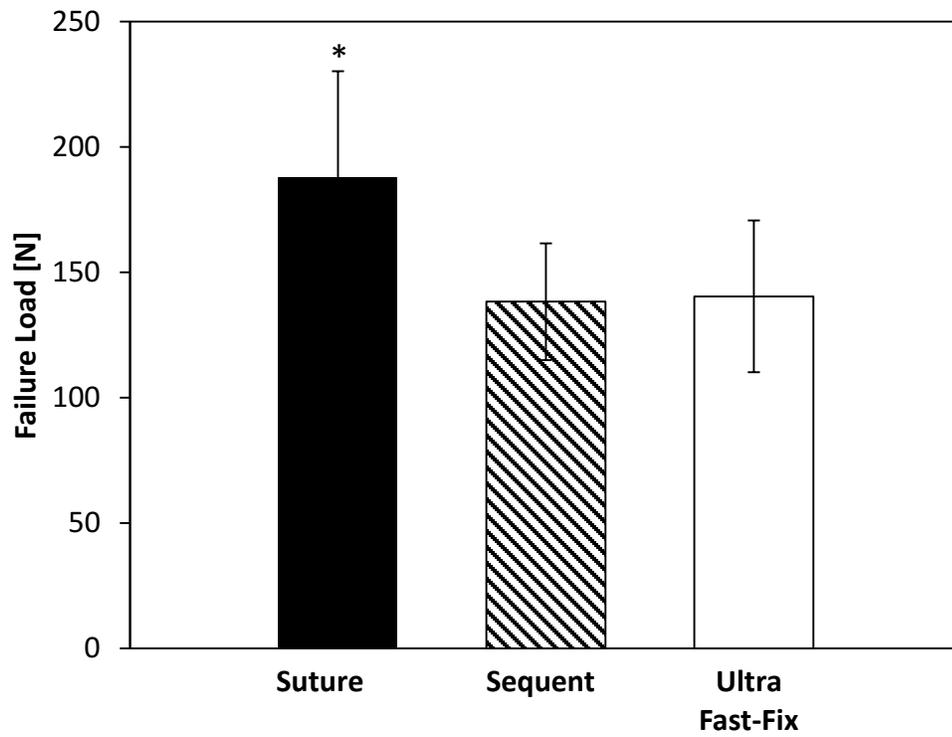


Figure 2 – Failure load depicted across the three repair groups

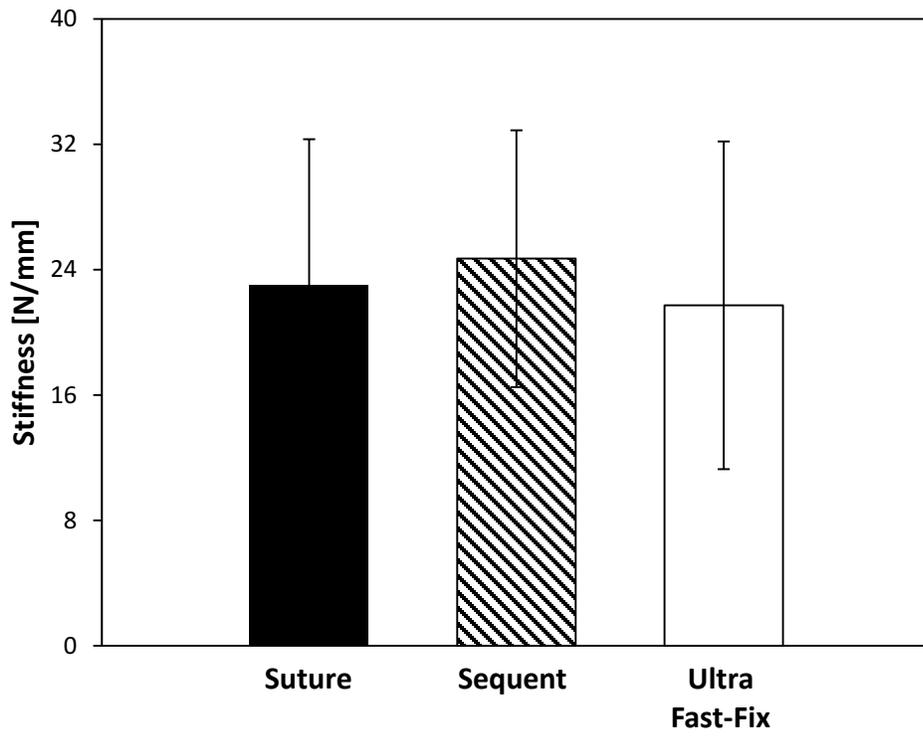


Figure 3 – Stiffness load depicted across the three repair groups

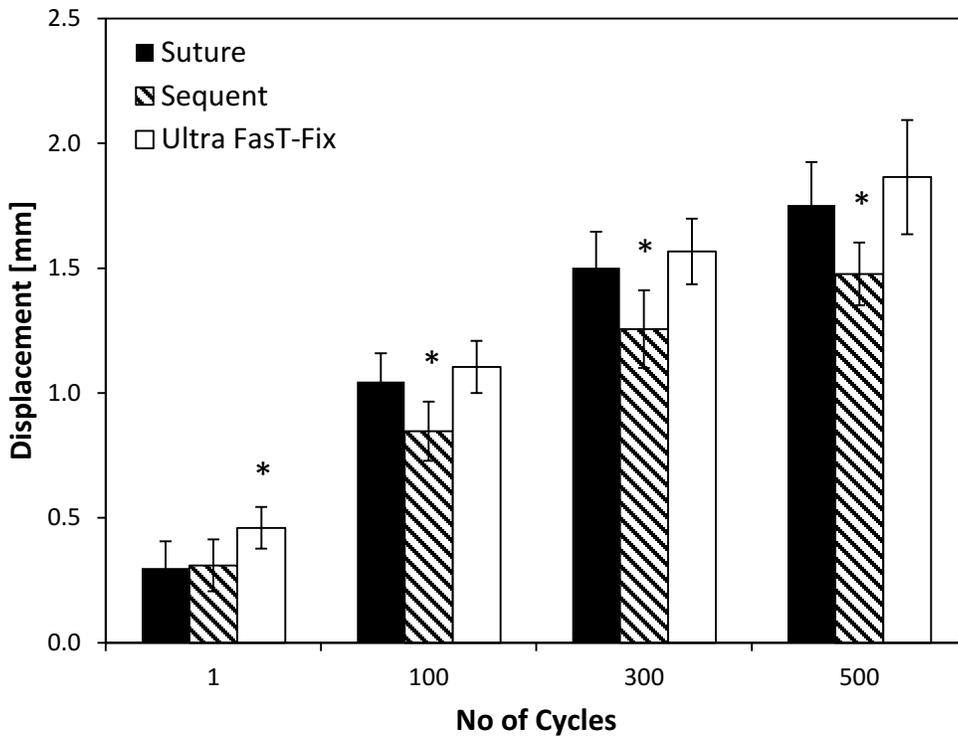


Figure 4 – Displacement values after 1, 100, 300 and 500 cycles across the three repair groups

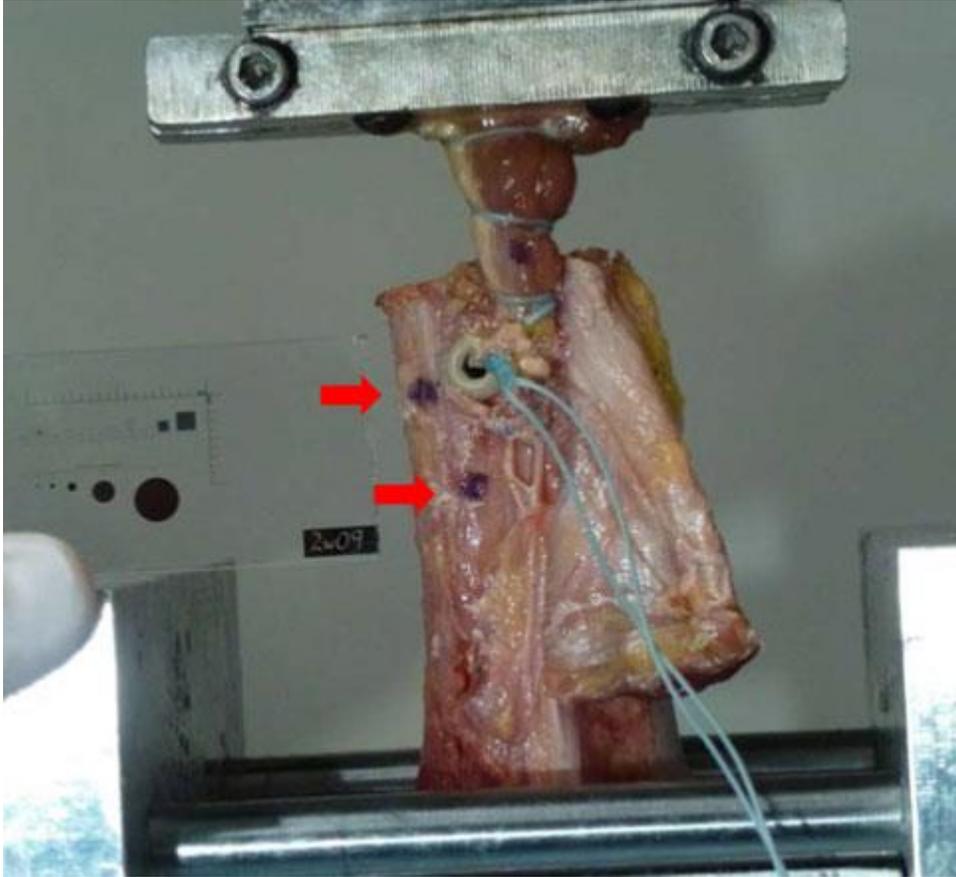


Figure 5 – An illustration of the test setup is present here. Precise dots were placed on each specimen using a permanent marker to measure displacement. The dots have been highlighted with red arrows. Calibration glass was used to calculate displacements between dots.

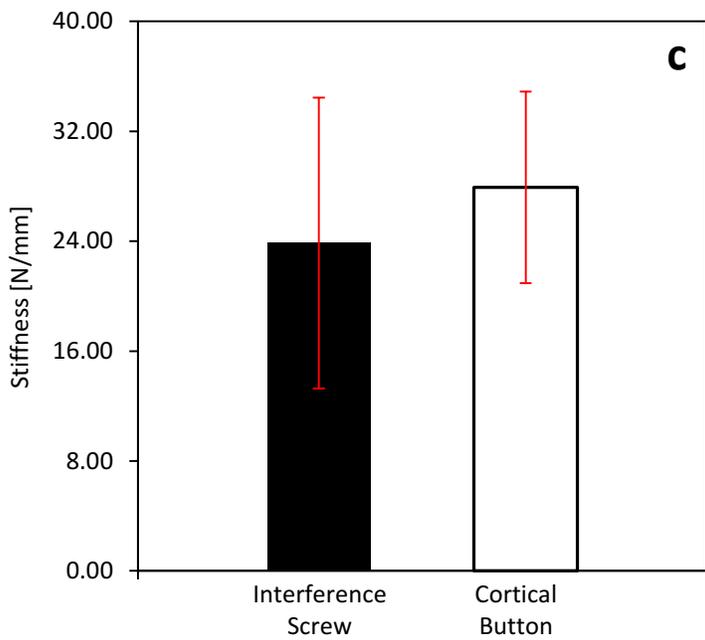
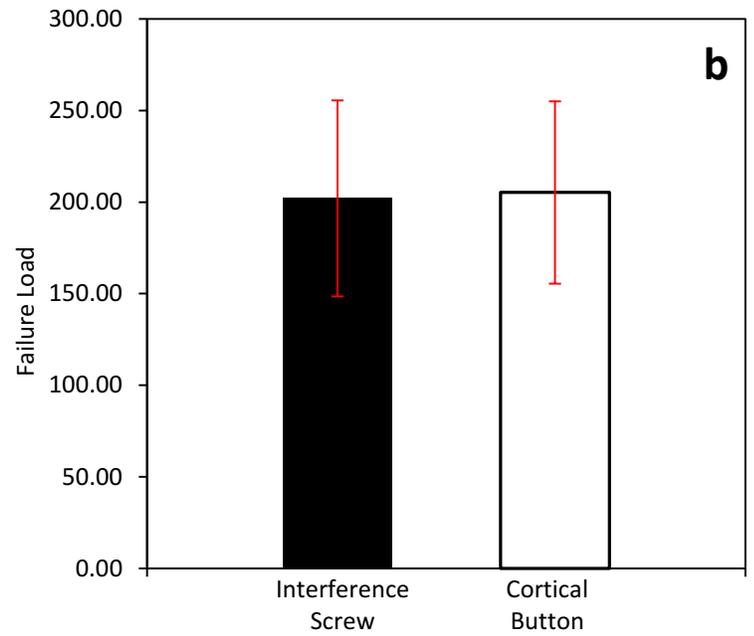
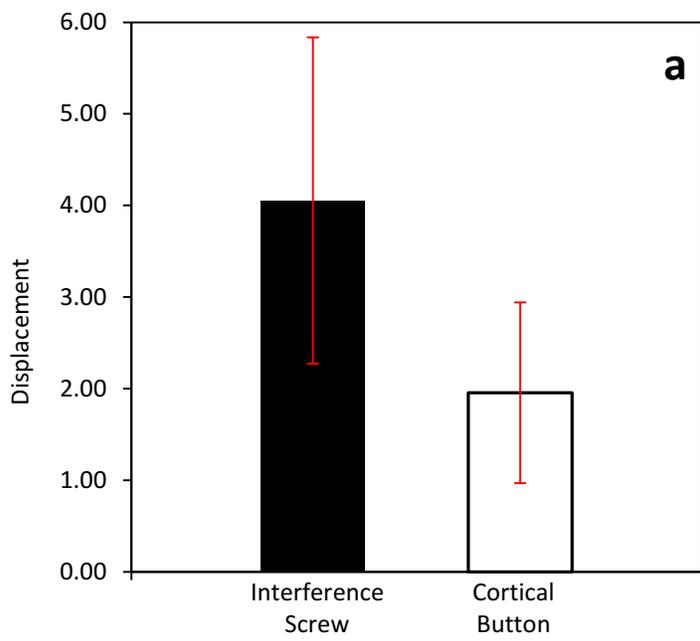


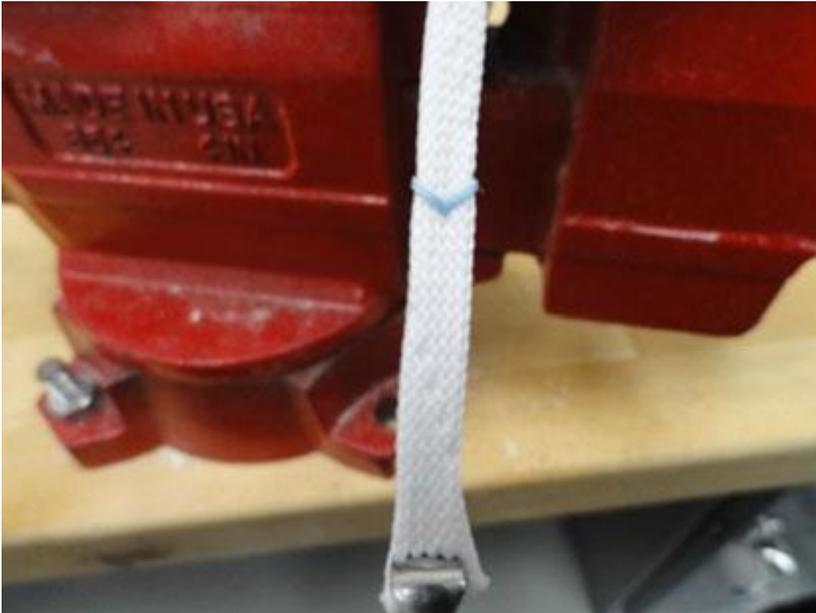
Figure 6 – **a.** Post-cyclic loading displacement at 200 cycles, **b.** load to failure, and **c.** stiffness for the interference screw vs. cortical button.

	Load to Failure (N)	Stiffness (N/mm)	Cycles of Displacement (mm)			
			1	100	300	500
Suture	187.750	22.984	0.299	1.046	1.503	1.753
<i>Std Dev</i>	42.427	9.350	0.107	0.113	0.144	0.173
Sequent	138.298	24.704	0.310	0.847	1.257	1.477
<i>Std Dev</i>	23.326	8.184	0.104	0.119	0.155	0.125
Ultra FasT-Fix	140.436	21.735	0.460	1.105	1.567	1.865
<i>Std Dev</i>	30.282	10.458	0.084	0.105	0.131	0.229

Table 1 – load, stiffness and displacement results for three repair techniques

Appendix: Suture Configuration Instructions

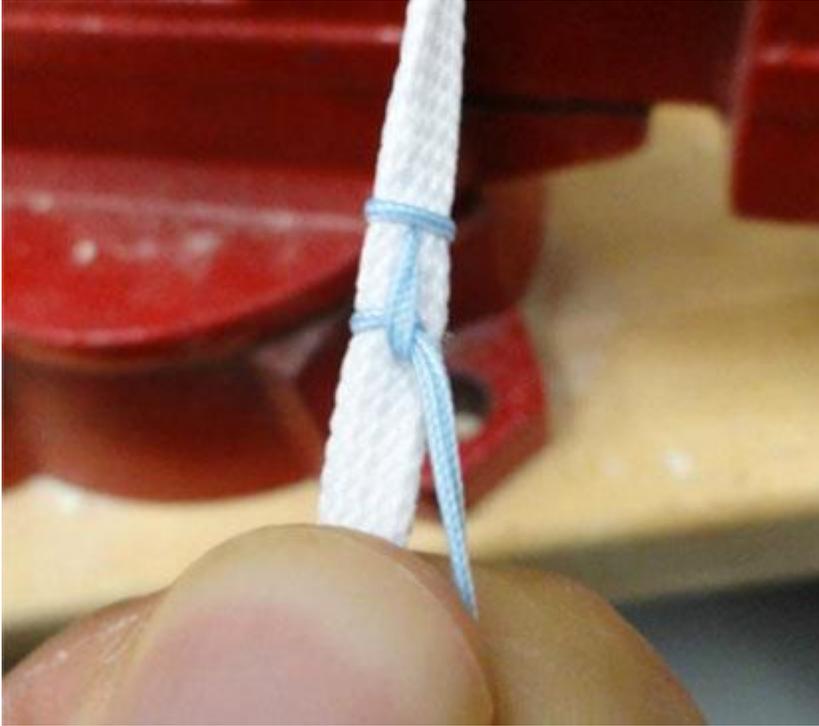
1. The first stitch is performed like normal stitch using FiberLoop.



2. The second stitch is also placed through the tendon as would normally be done for a FiberLoop stitch. Tighten the sutures as normal, but stop before leaving approximately 1" to 2" of slack. This should leave two loops as seen below. Pass the needle through both loops and synch tight.



3. Once synched tight, the suture configuration on the backside should like below:

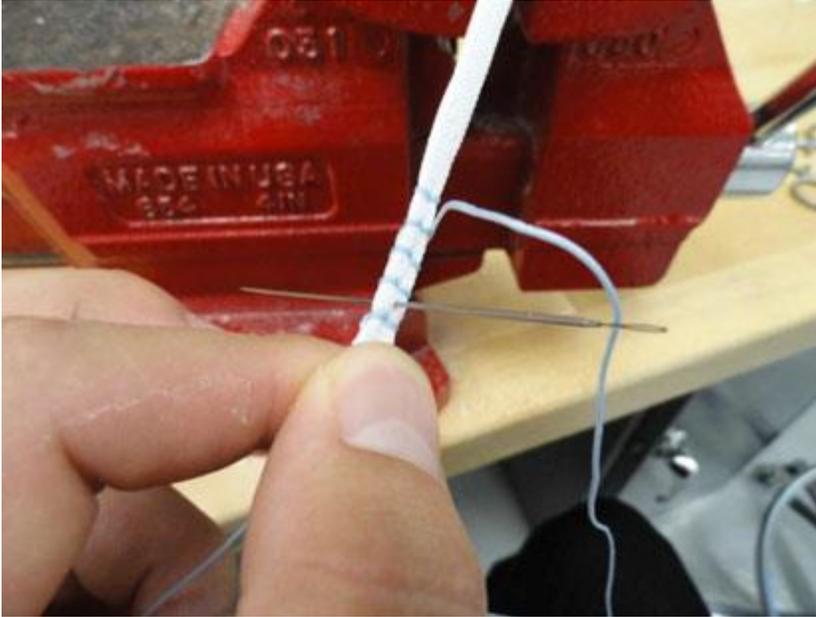


4. Repeat this process for the rest of the stitches. One side should look like a normal FiberLoop stitch. The opposing side should look like the following:



5. After the last stitch, cut the loop (remember for passing suture through the button, the thicker splice junctions can be a nuisance, this is an opportunity to get rid of the thick splice section).

6. Using the needle, pass one strand of suture on the backside of the last stitch as seen below. The needle should be going from the 'clean' side to the 'locked' side.



7. Tie the suture two tails of the suture together (surgeon knot) to terminate the stitch.