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SHOULDER

Biomechanical characterization of unicortical button fixation: a novel technique for proximal subpectoral biceps tenodesis

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Abstract

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 ($P =$ 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 postoperative humeral fracture and a construct that permits early mobilization following biceps tenodesis.

Keywords Biceps tenodesis · Interference screw · Cortical button · Load to failure · Displacement

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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 [3, 11, 14, 18, 20, 30, 36, 39].

Some surgeons recommend biceps tenodesis over biceps tenotomy in order to maintain the length–tension relationship of the biceps muscle and to prevent atrophy [1, 10, 16, 32]. 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 [21, 33, 35]. Because patients have reported ongoing muscle discomfort following tenotomy, biceps tenodesis is believed to decrease the incidence of biceps cramping and spasm [29].

Methods of tenodesis can be divided into open and arthroscopic techniques [1, 5, 8, 9, 11, 12, 14, 17, 20, 26, 31, 32, 43, 44, 46, 49, 52]. When comparing the biomechanical strength of these biceps tenodesis techniques, several authors have found comparable ultimate load to failure [23, 35]. 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) [19]. 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 [2, 6, 7, 36, 47, 48].

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 [35]. Therefore, the strength of this construct should support its use to tenodese 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 riser in the humerus is much smaller. In turn, the risk of post-operative humeral fracture should be lower than with the larger hole required for a keyhole or tenodesis screw [40, 45]. 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. [38], further increasing this technique's utility. Additionally, failure of a tenodesis screw can warrant re-operation [27].

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, *it is 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.*

Materials and 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 × 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 FiberLoop suture (Arthrex, Naples, FL, USA) was placed into the proximal biceps tendon using a modified whipstitch ("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 ("Appendix"). 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 [48]. 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. 1) 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 [4, 13, 41, 42, 50]. 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 $\pm$ 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 (Fig. 1). 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 [22, 25].

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.

Beth Israel Deaconess Medical Center does not require an Institutional Review Board (IRB) approval for studies involving cadaveric specimens.

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.

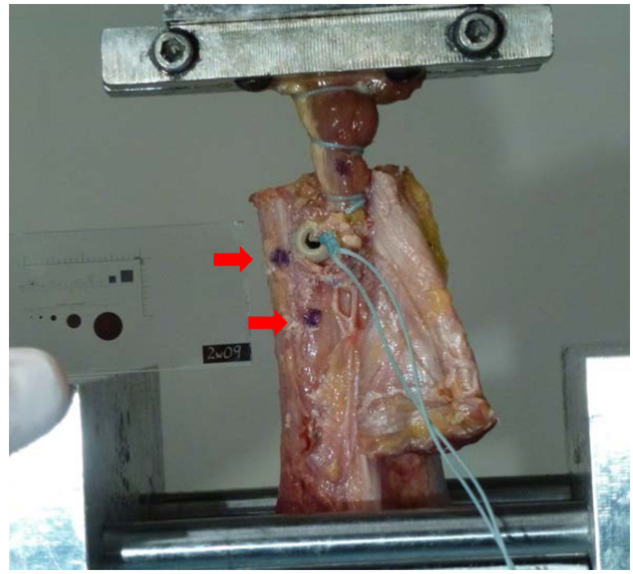

Fig. 1 An illustration of the test setup is present here. *Precise dots* were placed on each specimen using a permanent marker to measure displacement. The *dots* have been highlighted with *red arrows*. Calibration glass was used to calculate displacements between *dots*

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 then for the cortical button (1.9 ± 1.0 mm, $P = 0.03$, Fig. 2a). 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, $P =$ n.s., Fig. 2b). 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}, $P =$ n.s., Fig. 2c). None of the specimens failed during cyclic loading, and while all specimens were tested to failure, eleven specimens (92 %) failed at the tenodesis site.

Discussion

As a novel technique for subpectoral biceps tenodesis, a unicortical button demonstrated significantly less

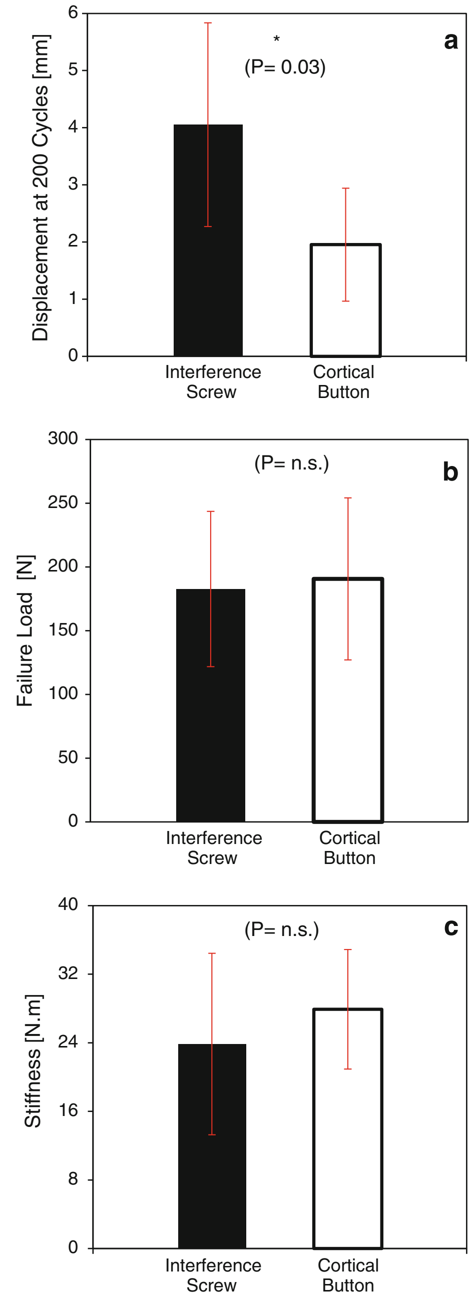

Fig. 2 Post-cyclic loading displacement **a** along with load to failure **b** and stiffness **c** results for the two methods

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 behaviour 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 post-operative 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 behaviour 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 post-operative 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 [48]. 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 [4, 13, 28, 41, 50].

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 [38, 48]. 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 [37]. 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 [51].

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 [40, 45]. 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. [38].

One of the strengths of this investigation is that displacement was determined digitally using direct measurements at the tenodesis site (Fig. 1). In similar studies, other investigators have relied on manual measurements using callipers or have recorded the actuator position as a surrogate for displacement [31, 33, 34]. 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 [15, 22, 24, 25].

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 [41, 48, 50].

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 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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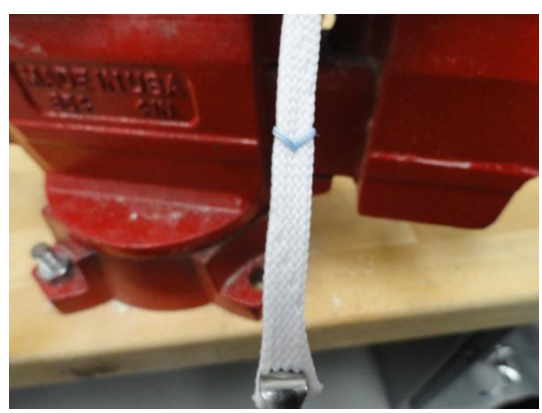
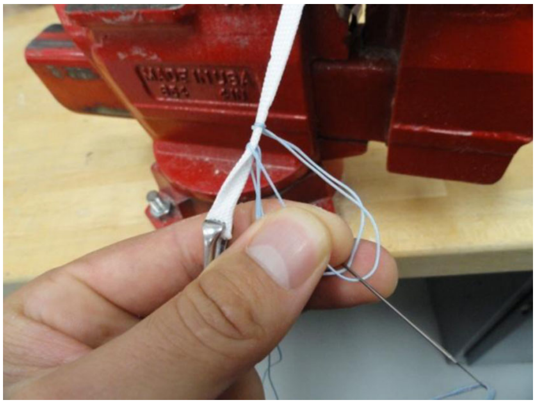
Appendix: Suture Configuration Instructions

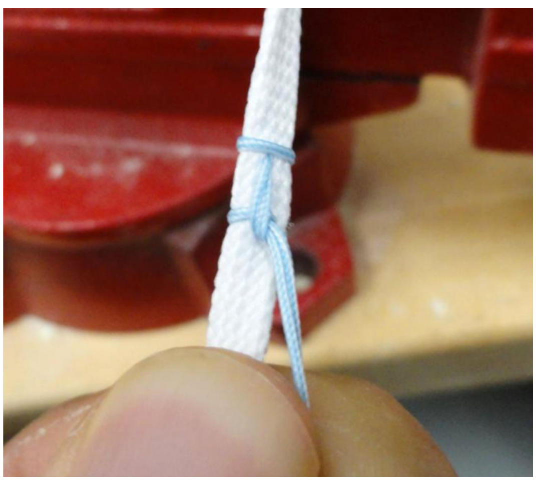
1. The first stitch is performed like normal stitch using FiberLoop.



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.

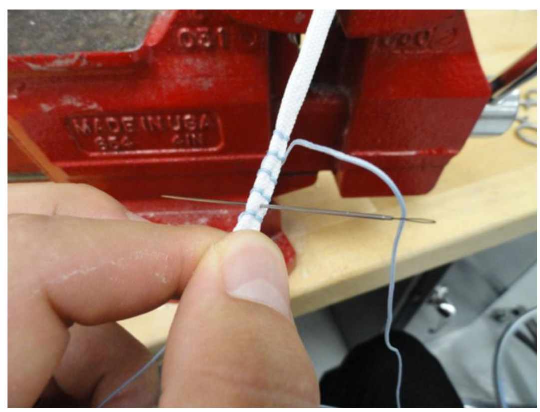


3. Once synched tight, the suture configuration on the backside should like below:

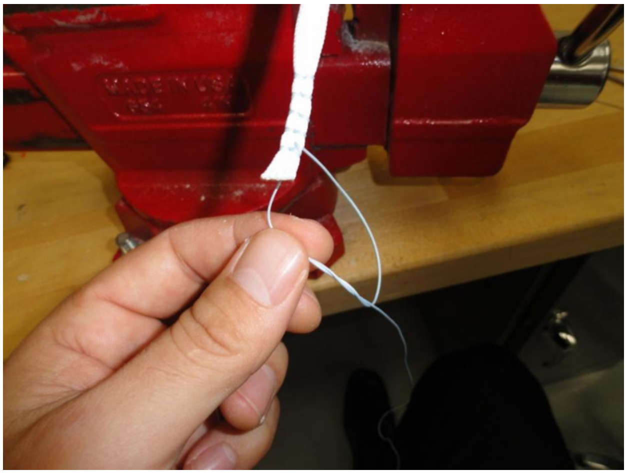


4. Repeat this process for the rest of the stitches. One side should look like a normal FiberLoop stitch. The opposing side should like the following:
5. After the last stitch, cut the loop (remember for passing suture through the button, the thicker splice junctions can be a nuisance, this is an opportunity 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.



8. Use the technique used for distal tension slide.

- Pass tails through button in an alternating manner.
- Fixate button.
- Terminate construct by passing one strand of suture back through the tendon and tying to free tail.

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