



All-Suture Suspensory Button Has Similar Biomechanical Performance to Metal Suspensory Button for Onlay Subpectoral Biceps Tenodesis

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Purpose: To evaluate the maximal load at failure, cyclic displacement, and stiffness of onlay subpectoral biceps tenodesis (BT) with an intramedullary unicortical metal button (MB) versus a unicortical all-suture button (ASB). **Methods:** Eighteen matched paired human cadaveric proximal humeri were randomly allocated for subpectoral BT with either ASB or MB using a high-strength suture. Specimens were tested on a servohydraulic mechanical testing apparatus under cyclic load for 1,000 cycles and then loaded to failure. The clamp was then adjusted to isolate the suture–anchor point interface and loaded to failure. Maximal load to failure, displacement, and stiffness were compared. **Results:** There was no significant difference between groups in stiffness, displacement, or yield load. The maximal load to failure for the MB was greater than the ASB ($347.6 \pm 74.1\text{N}$ vs $266.5 \pm 69.3\text{N}$, $P = .047$). Eight specimens in each group failed by suture pull-through on the tendon. When the suture–anchor point interface was isolated, there was no significant difference in maximal load at failure (MB $586.5 \pm 215.8\text{N}$ vs ASB $579.6 \pm 255.9\text{N}$, $P = .957$). **Conclusions:** This study demonstrates that the MB and ASB have similar biomechanical performance when used in subpectoral BT. Although the MB showed statistically significant greater maximal load to failure, there was no difference between the MB and ASB when the suture–tendon interface was eliminated. Suture pull-through was the most common mode of failure for both implants, underscoring the importance of the suture–tendon interface. **Clinical Relevance:** Fixation techniques for the treatment of long head of the biceps brachii tenodesis continue to evolve. The use of an all-suture suspensory button has advantages, but it is important to understand if this implant is a biomechanically suitable alternative to a metal suspensory button.

The proximal portion of the long head of the biceps brachii (LHB) is a common source of pain in patients presenting with anterior shoulder pain. LHB

tendinopathy frequently is associated with rotator cuff tears, SLAP tears, and subacromial impingement. Nonsurgical management is typically the first line of

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The authors report the following potential conflicts of interest or sources of funding: Funding was provided for portions of this project through the Inova Health System Seed Grant program and from a corporate grant from Arthrex. In addition, this research was supported in part by an appointment to the Department of Defense (DoD) Research Participation Program administered by the Oak Ridge Institute for Science and Education (ORISE) through an interagency agreement between the U.S. Department of Energy (DoE) and the DoD. ORISE is managed by ORAU under DoE contract number DE-20 SC0014664. The views expressed in this paper are those of the authors and

do not reflect the official policy of the DoE, ORAU/ORISE Department of the Army/Navy/Air Force, Uniformed Services University of the Health Sciences, DoD, or U.S. Government. Full ICMJE author disclosure forms are available for this article online, as [supplementary material](#).

This work has been presented as a poster at the AANA 2022 Annual Meeting in San Francisco, CA; May 19–21, 2022.

Received May 30, 2022; accepted September 13, 2022.

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2666-061X/22663

<https://doi.org/10.1016/j.asmr.2022.09.004>

treatment for patients exhibiting pain associated with the LHB tendon and, when symptoms persist, surgical intervention can be effective for resolving LHB-associated pain. While optimal surgical treatment remains a point of contention, LHB tenodesis and tenotomy are both viable options. LHB tenodesis has become a more popular alternative because it preserves the length–tension relationship of the LHB and eliminates the possibility of a “Popeye” deformity seen after tendon release in a tenotomy.^{1,2}

Currently, multiple approaches and fixation techniques for LHB tenodesis exist. Compared with that of an arthroscopic suprapectoral approach, there is a lower tenodesis reoperation rate following a mini-open or open subpectoral approach.² As such, the techniques for subpectoral biceps tenodesis with either onlay or inlay fixation continue to evolve. While both modes of fixation confer no significant difference in functional outcomes,³ there is increasing evidence that inlay fixation, specifically the use of bioabsorbable interference screws, presents risks that include fracture at the humeral drill site, lingering pain, and adverse reaction to the bioabsorbable screw.^{1,4,5} Furthermore, in the modeling of inlay versus onlay tendon fixation in rabbits, tendon–bone healing within the bone tunnel was significantly less than healing at the cortical surface, providing evidence towards the efficacy of onlay repairs.⁶

Onlay fixation is commonly achieved using either a suture anchor or suture button. Recently, all-suture devices have gained traction⁷ due to their small drill hole, which minimizes both soft-tissue trauma and bone loss, and the absence of metal-induced artifacts upon postoperative imaging. Moreover, the biomechanical properties of all-suture anchor constructs have been shown to be similar to that of conventional solid anchors in regards to ultimate and torsional failure loads⁷. Lacheta et al.⁴ further demonstrated biomechanically that compared with unicortical button fixation, an all-suture anchor construct exhibited less displacement during cyclic loading. However, the difference in ultimate load and stiffness for both fixation groups was not significant. Recently, an all-suture device which functions as a suspensory button was developed and approved for use in subpectoral LHB tenodesis. This all-suture button (ASB) differs from an all-suture suture anchor in that the sutures used to fix the tendon are shuttled through the device following device insertion into the bone, more similar to a suspensory button than a suture anchor with the fixation sutures already attached to the anchor device. This ASB, with a drill size of 2.6 mm, reduces socket footprint by 19%⁸ compared with the metal button (MB) of the same manufacturer that has a drill size of 3.2 mm. With a reduced drill hole and a potentially robust construct profile, the ASB could reduce the risk of a

stress riser in the humerus without sacrificing fixation strength. However, there is a paucity of studies exploring the biomechanical properties of this type of all-suture suspensory device.

The purpose of this study was to evaluate the maximal load at failure, cyclic displacement, and stiffness of onlay subpectoral biceps tenodesis with an intramedullary unicortical MB versus a unicortical ASB. Our hypothesis was that both implants would perform similarly in regards to ultimate load to failure, displacement, and stiffness.

Methods

Ten matched pairs of fresh-frozen cadaveric proximal arms ($n = 20$; 7 male, 3 female, age = 56.5 ± 6.7 years old) were procured and stored at -20°C . Bone mineral density (BMD) of each specimen was measured at the surgical neck via dual-energy X-ray absorptiometry (Discovery-A System; Hologic Mississauga, Ontario, Canada). Specimens were thawed 12 hours before being dissected free of all soft tissue except for the pectoralis tendon. The biceps tendon was freed completely from the bicipital groove and wrapped in normal saline solution-soaked gauze and refrigerated prior to fixation. The bones were transected 14 cm proximal to the elbow joint. Specimens were then marked 50 mm below the palpable distal entrance of the bicipital groove, approximately at the midpoint of the pectoralis major insertion, to mark the device insertion point. This study was conducted following approval by the Walter Reed National Military Medical Center Institutional Review Board under protocol number WRNMMC-EDO-2020-0453 “Biomechanical Comparison of Fixation Techniques in the Upper Extremity.”

Experimental Design

Within each matched pair, humeri were randomly assigned to 1 of 2 treatments, onlay subpectoral biceps tenodesis using either an intramedullary unicortical MB (BicepsButton, Arthrex, Naples, FL; Fig 1A) or using an all-suture suspensory button device (FiberTak Button, Arthrex; Fig 1B). The biceps tendon was measured for width and thickness using a digital caliper. The tendon was then secured using a single high tensile-strength suture (No. 2 FiberLoop, Arthrex) in a whip stitch running 5 passes over 2 cm distal to the myotendinous junction. For the MB group, a unicortical drill hole was created at the marked location 50 mm distal to the bicipital groove with a 3.2-mm drill pin. The suture was then loaded onto the suture button with one end threaded in one direction and then the other in the opposite direction. The button was inserted and one strand of the suture was used to tension the tendon to the bone, passed through the tendon, and then tied with 6 surgical knots positioned on top of the tendon.

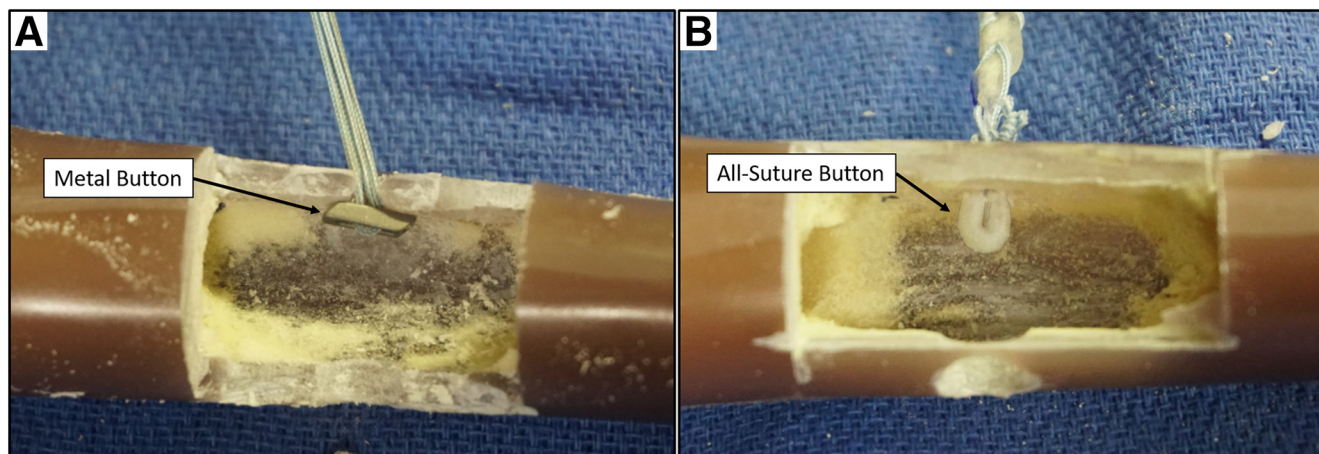


Fig 1. Example of intramedullary fixation on modified fourth-generation synthetic composite humeri of a metal suspensory button (A) and an all-suture suspensory button (B).

The ASB repair was performed in a similar manner in line with the manufacturer's instructions. The tendon was whip-stitched with a number 2 suture loop in the same fashion as the MB group. The manufacturer's drill guide was positioned at on the anterior aspect of the humerus, 50 mm distal to the bicipital groove, and a 2.4-mm drill pin was used to create a unicortical hole. The ASB was then passed through the drill guide until it cleared the anterior cortex. The drill guide was removed, and one limb of suture was passed through the ASB in one direction followed by the other limb in the other direction using the passing sutures imbedded with the device. The tendon was tensioned to the humerus by pulling one suture limb, which was then passed through the tendon and then secured with 6 surgical knots (Fig 2). All repairs were made by 2 investigators (E.S.C., C.J.T.) with orthopaedic sports medicine fellowship training.

Biomechanical Testing

The biomechanical testing protocol was modeled after previously published studies.^{4,7,9} Repaired specimens were tested using a servohydraulic mechanical testing system (MTS 858 Mini Bionix II; MTS Systems Corp., Eden Prairie, MN). The humeral head was secured into a custom mounting jig with pins in-line with the actuator. The biceps tendon was secured to the actuator and load cell through a custom sinusoidal clamp attached to the biceps tendon at the musculotendinous junction and in-line with the actuator (Fig 3). A pin was inserted just proximal to the repair site and a long-stroke linear variable differential transformer (LS-LVDT; LORD, Microstrain Sensing Systems, Cary, NC) was attached to the pin. Once mounted, the biceps tendon was preloaded to 5 N over 2 minutes, and the repairs were inspected to ensure there was no premature failure.

Once the sensors and load were properly configured, the specimen was cycled from 5 to 70 N at 1 Hz for 1,000 cycles. After cyclic loading was completed, specimens were loaded to failure at a constant distraction rate of 1 mm/s until the construct failed. A specimen was deemed failed when the force across the construct dropped to 25% of the peak force achieved during testing. If the repair failed by suture–tendon pull-through, in which the suture material cut through the tendon along the axis of its collagen fibers, the clamp was adjusted to capture the just the remaining sutures and the repair was again loaded to failure at 1 mm/s in order to elicit the strength of the anchor point without the suture–tendon interface. Force and displacement were continuously measured (102 Hz) by the MTS actuator and in-line load cell (Model 1500; Interface, Inc., Scottsdale, AZ) in addition to the long-stroke linear variable differential transformer throughout the cyclic loading and loading to failure testing procedures. All testing was conducted at room temperature, and periodic saline spray was used to keep the biceps tendon hydrated throughout testing.

Data Reduction

Force and displacement data were filtered using a fourth-order zero-lag Butterworth filter with custom MATLAB scripts (version R2020a; MathWorks Inc., Natick, MA). Maximum displacement from cyclic loading, maximum load at failure, and mode of failure were recorded. Stiffness was calculated based on the slope of the linear region of the load-displacement data from load-to-failure testing. Modes of failure included (1) suture pull-through, (2) suture rupture, (3) fracture, and (4) implant pullout. Descriptive statistics (mean \pm standard deviation) were calculated for construct maximum displacement after 1,000 cycles, yield point displacement, yield load, maximum load at

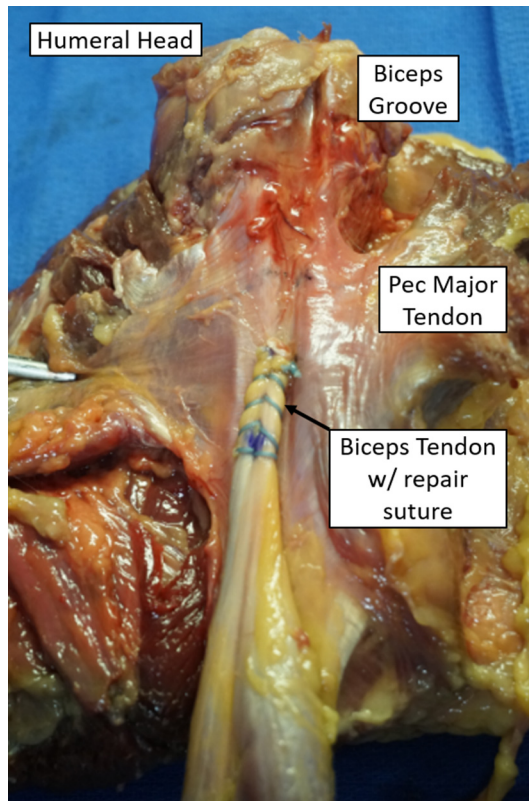


Fig 2. Example of a cadaveric proximal humerus specimen status post onlay subpectoral biceps tenodesis.

failure, and stiffness. Values less than the 25th percentile value minus 1.5 times the interquartile range [$Q1 - 1.5 \times \text{interquartile range}$] or greater than the 75th percentile value plus 1.5 times the interquartile range [$Q3 + 1.5 \times \text{interquartile range}$] were identified as outliers for exclusion.

Statistical Analysis

Two-way repeated-measures analysis of variance analyzed tendon–suture implant construct at the prescribed discrete cycles. Paired *t*-tests compared mean maximum displacement, mean maximum load at failure, stiffness, and cortical thickness between the MB and ASB groups. Pearson correlation coefficients were calculated to determine the relationship between BMD and tendon dimensions to maximum load at failure.

An a priori power analysis was conducted in line with similar previously published studies^{10,11} and determined that 10 pairs would achieve 80% power to detect a 100 N difference in load to failure with an estimated standard deviation of 100 N with an $\alpha = 0.05$ for a paired *t*-test. Clinically, 100 N is roughly the weight of the forearm holding a 1-kg load.¹⁰ A secondary power analysis revealed that 10 pairs would achieve 80% power to detect a 1 mm difference in displacement with an estimated standard deviation of 1 mm at 95%

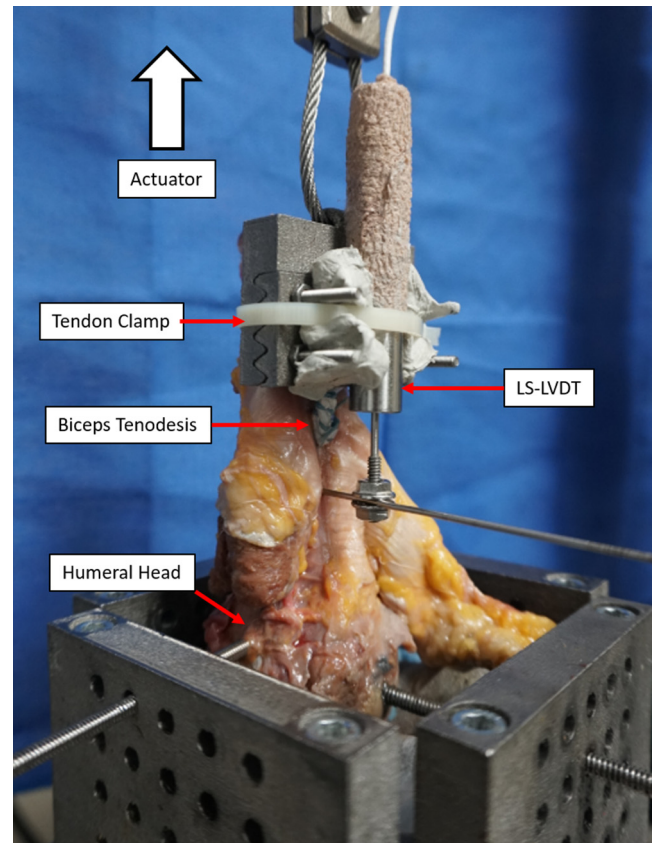


Fig 3. Proximal humerus specimen mounted to the servohydraulic testing system. The long head of the biceps was tenodesed 50 mm distal to the bicipital groove and the distal end was affixed to the load cell and actuator via a custom sinusoidal tendon clamp. The long-stroke-linear variable differential transformer (LS-LVDT) sensor pin was attached to a bone pin placed just proximal to the tenodesis site and the sensor body was secured to the tendon clamp using putty and zip tie.

confidence. All statistical analyses were performed using R (version, 4.0.2; R Foundation for Statistical Computing, Vienna, Austria) in RStudio (version 1.3, RStudio, Inc., Boston, MA) using the *rstatix* packages.

Results

Specimens

There were 7 male and 3 female specimens in each group, with a mean age of 56.5 ± 6.7 years old. The mean BMD was 0.665 ± 0.089 g/cm³, with no significant difference between groups (MB 0.659 ± 0.089 g/cm³ vs ASB 0.675 ± 0.086 g/cm³, $P = .895$). There was no significant difference in tendon width (MB 6.77 ± 1.10 mm vs ASB 6.65 ± 1.23 mm, $P = .727$) or tendon thickness (MB 2.19 ± 0.05 mm vs ASB 1.93 ± 0.44 mm, $P = .715$). There was no statistically significant correlation in maximal load or displacement with respect to tendon dimensions or BMD. The mean

Table 1. Comparison of Displacement, Stiffness, Ultimate Load, and Failure Mode Between Metal and All-Suture Button Constructs

	Metal Button	All-Suture Button	P Value
Cyclic displacement, mm	2.69 ± 1.51	2.89 ± 0.89	.771
Yield load displacement, mm	7.93 ± 2.55	8.37 ± 3.39	.774
Ultimate load displacement, mm	13.31 ± 4.73	11.85 ± 8.43	.694
Stiffness, N/mm	30.86 ± 6.91	24.51 ± 4.87	.094
Ultimate load 1, N*	347.6 ± 74.1	266.5 ± 69.3	.047
Mode of failure			
Suture pull-through†	9	8	
Knot failure	0	1	
Ultimate load 2, N‡	586.5 ± 215.8	579.6 ± 255.9N	.957
Mode of failure			
Suture breakage	8	8	
Knot failure	0	1	
Implant pull-out	1	0	

*Ultimate load when the biceps tendon was secured in the tendon clamp and tensioned to construct failure.

†Suture pull-through defined as the suture material cutting through the tendon in-line with its collagen fibers during loading.

‡Ultimate load when the suture material attached to the suspensory device was secured directly in the clamp and tensioned to construct failure.

distance from the inferior aspect of the bicipital groove to the midpoint of the pectoralis major insertion was 55.48 ± 9.02 mm, and the mean length of the bicipital groove was 23.06 ± 3.63 mm.

Displacement

There was no significant difference in mean displacement during cyclic loading, at yield load, or at ultimate load (Table 1; Fig 4).

Ultimate Load and Failure Method

There was no significant difference in stiffness between constructs (Table 1; Fig 5). There was no significant difference in yield load (Fig 6A). The ultimate load at failure was greater for the MB group than the ASB (Table 1; Fig 6B). The MB cohort failed through suture–tendon pull-through in all constructs. In the ASB cohort, all but one (89%) failed through suture pull-through. There was one (11%) knot failure in this group.

After isolating the suture–tendon interface by adjusting the clamp to only pull the sutures attached to the suspensory mechanism, there was no significant difference in ultimate load to failure between the 2 groups (Table 1; Fig 6C). The most common method of failure after isolating the suture–anchor interface was suture rupture (89% in each cohort). There was one case of implant pullout in the MB group and one case of knot failure in the ASB group. There were no fractures in either group.

Discussion

The findings from this study support our hypothesis that fixation for an onlay subpectoral biceps tenodesis with an ASB exhibits similar biomechanical characteristics to a unicortical MB. Specifically, our results demonstrate no difference between the 2 methods of fixation in stiffness, displacement, or maximal load to failure when the anchor point is isolated. The similar load to failure and mode of failure between the 2

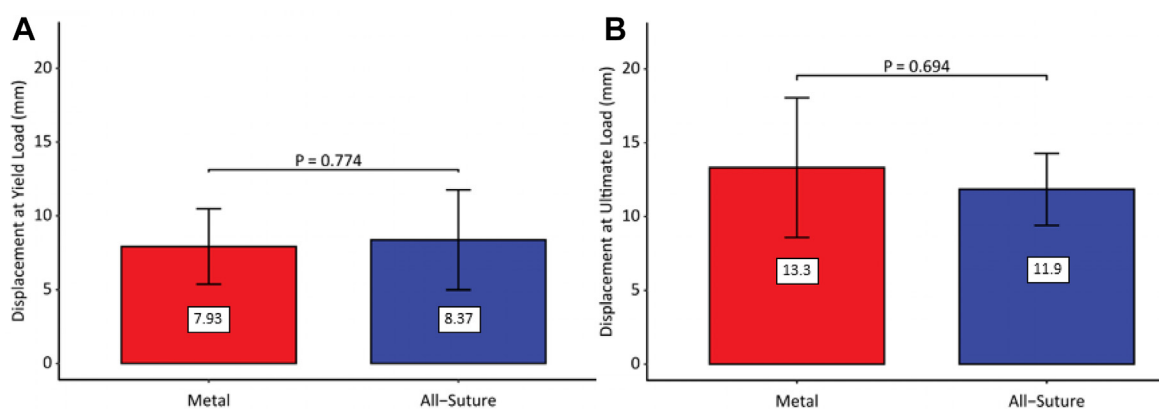


Fig 4. Mean (\pm standard deviation) maximum displacement in mm after 3,000 cycles for each group at yield load (A) and ultimate load (B).

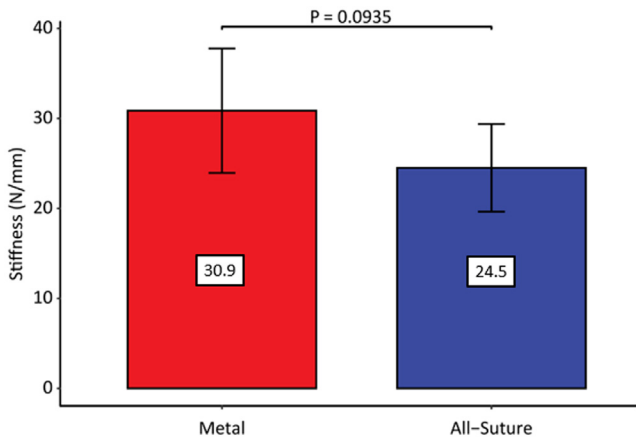


Fig 5. Mean (\pm standard deviation) stiffness during load-to-failure testing for each group.

methods of fixation suggests that the ASB is a viable alternative to a unicortical MB. In both groups, suture pull-through was the most common mode of failure and highlights the importance of adequately securing the suture-tendon interface. Despite a greater maximal load to failure in the MB group when the tendon was incorporated, isolation of the suture-anchor point interaction demonstrated no significant difference between the fixation methods.

Previous biomechanical studies have compared different implants and techniques for biceps tenodesis fixation.^{4,7,9,12-16} Despite the abundance of literature examining various implants, no consensus exists regarding the most optimal implant for tendon fixation. The introduction of ASB devices presents surgeons with yet another option to achieve fixation for biceps tenodesis. The ASB aims to provide a lower-profile implant while minimizing fracture risk and maintaining the biomechanical profile seen with other implants.^{4,7} In addition, all-suture implants eliminate metal artifact on magnetic resonance imaging when obtained in a revision situation. Furthermore, this ASB allows for similar fixation and surgical steps as using a metal unicortical button but allows for implant insertion through a drill guide.

Multiple previous studies have examined the biomechanical profile of all-suture device constructs relative to other modes of soft-tissue fixation.^{4,7,13,16-21} Frank et al.⁷ performed a biomechanical analysis of an all-suture anchor device compared with conventional suture anchors and interference screws for a mini-open subpectoral biceps tenodesis. Their results demonstrated similar peak loads during failure testing among the three implants. Similar to our results, the all-suture anchors failed at the tendon-suture interface in all specimens.⁷ Lacheta and et al.⁴ performed a biomechanical study comparing the same MB used in our study with a smaller all-suture anchor. The testing protocol used by Lacheta et al.⁴ and the present study is similar with the exception of the methods used to measure displacement. We measured displacement using a long-stroke linear variable differential transformer, whereas the previously mentioned study relied on displacement measurements from the actuator. Our method of displacement measurement may have allowed for more accurate measurements than those attainable with an actuator. While Lacheta et al.⁴ noted greater cyclic displacement in the MB relative to the all-suture anchor, we saw no significant difference. Furthermore, our displacement measurements overall were lower than those reported in the previous study.⁴ The present study further differs from results reported by Lacheta et al.⁴ in the stiffness and ultimate load at failure we report. While we also saw no significant difference between the 2 fixation techniques in stiffness or ultimate load, we found stiffness to be lower and ultimate load to be higher than the results reported by Lacheta et al.⁴

Otto et al.²¹ performed a similar cadaveric study using the same implants described in the study by Lacheta et al.⁴ Their study performed cyclic loading from 5 to 100 N for 5,000 cycles and used optical tracking to measure displacement. While limited by the use of unpaired specimens, the results demonstrated by Otto et al.²¹ showed no difference in displacement after cyclic loading or load to failure between the metal suture button and all-suture anchor.²¹ Their load to failure in

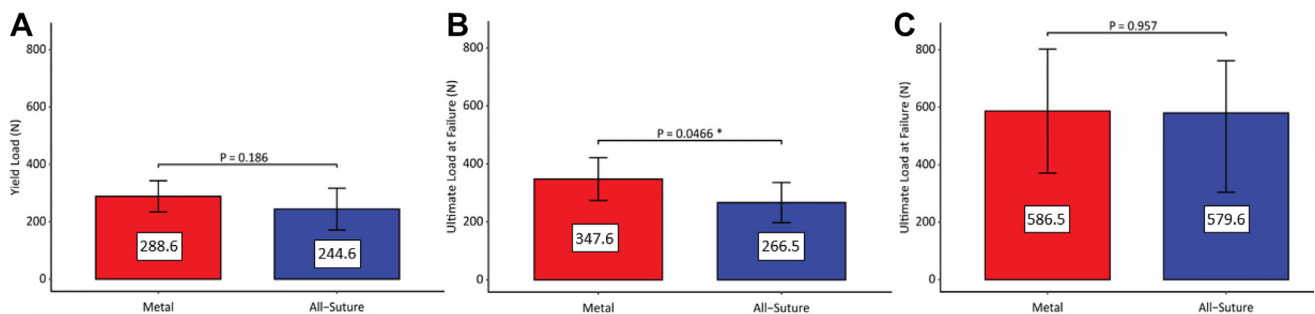


Fig 6. Mean (\pm standard deviation) maximum load at yield load (A), ultimate load (B), and ultimate load after the clamp was adjusted to eliminate the suture-tendon interface and isolate the button-cortex interaction (C).

the all-suture anchor group were similar to our results prior to isolating the suture-anchor interface (278 N vs 266.5 N). After isolating the suture-anchor point interface, we noted increased load to failure (579.6 N). Otto et al.²¹ reach the similar conclusion that all-suture anchors and unicortical MBs exhibit a similar biomechanical profile when used for onlay subpectoral biceps tenodesis. Variability in the results by Lacheta et al.⁴ and Otto et al.,²¹ despite similar protocols, illustrate the importance of our work further comparing the ASB and metal suture button. Despite the differences in stiffness, displacement, and ultimate load among three studies, similar conclusions are drawn. The ASB exhibits equivalent biomechanical characteristics to the metal suture button and is suitable for use in onlay subpectoral biceps tenodesis.

Limitations

There are some limitations to this study that must be addressed. In such a biomechanical study, we are limited to evaluating fixation techniques at time-zero. The results of this study do not account for any in vivo tendon healing that occurs. While it is possible there may be a difference in healing rates between the 2 fixation techniques, we demonstrated similar biomechanical properties at time-zero, when a construct is particularly vulnerable to failure. This study is also limited by the methods of failure that were observed. The most common method of failure was suture pull-through in initial testing and suture rupture when isolating the suture–anchor interface. These failure methods could suggest that the whip-stitch technique is being tested rather than the implants themselves. However, similar methods of failure have been observed in other studies.^{4,7,18,21}

Conclusions

This study demonstrates that the MB and ASB have similar biomechanical performance when used in subpectoral BT. Although the MB showed statistically significant greater maximal load to failure, there was no difference between the MB and ASB when the suture–tendon interface was eliminated. Suture pull-through was the most common mode of failure for both implants, underscoring the importance of the suture–tendon interface.

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