Intramedullary Unicortical Button and All-Suture Anchors Provide Similar Maximum Strength for Onlay Distal Biceps Tendon Repair

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Purpose: To evaluate the biomechanical profile of onlay distal biceps repair with an intramedullary unicortical button versus all-suture anchors under cyclic loading and maximal load to failure. **Methods:** Twenty paired fresh-frozen human cadaveric elbows were randomized to onlay distal biceps repair with either a single intramedullary button or with two 1.35-mm all-suture anchors. A 1.3-mm high tensile strength tape was used in a Krackow stitch to suture the tendons in both groups. Specimens and repair constructs were loaded for 3,000 cycles and then loaded to failure. Maximum load to failure, mode of failure, and construct elongation were recorded. **Results:** Mean (± standard deviation) maximum load to failure for the unicortical intramedullary button and all-suture anchor repairs were 503.23 ± 141.77 N and 537.33 ± 262.13 N ($P = .696$), respectively. Mean maximum displacement after 3,000 cycles (± standard deviation) was 4.17 ± 2.05 mm in the button group and 2.06 ± 1.05 mm in the suture anchor group ($P = .014$). Mode of failure in the button group was suture tape rupture in 7 specimens, failure at the tendon−suture interface in 2 specimens, and button pullout in 1 specimen. Anchor pullout was the mode of failure in all suture anchor specimens. There were no tendon ruptures or radial tuberosity fractures in either group. **Conclusions:** This study demonstrates that onlay distal biceps repair with 2 all-suture anchors has similar maximum strength to repair with an intramedullary button and that both are viable options for fixation. **Clinical Relevance:** All-suture anchors and unicortical intramedullary button have similar maximum strength at time zero. Both constructs provide suitable fixation for onlay distal biceps repair.

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Distal biceps tendon rupture is a relatively rare injury that has garnered recent interest due to increasing incidence and a multitude of surgical fixation techniques.[1-12] Injury to the distal biceps tendon insertion most commonly occurs with an eccentric load to the elbow joint in the dominant arm of middle-aged male patients, with an incidence of 1.2 to 2.55 injuries per 100,000 person years.[1,13,14] These injuries are most frequently treated surgically, as nonoperative management leads to decreased supination and elbow flexion strength and comparative studies have demonstrated superior outcomes with surgery.[15-17] Despite the surgical

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nature of distal biceps tendon ruptures, there is a lack of consensus regarding the optimal repair technique.[1,18,19]

There have been multiple approaches and fixation techniques described in the surgical management of distal biceps ruptures.[1-12] While the advantages and disadvantages of single- or dual-incision approaches have been well described,[1,10,18,19] onlay and inlay repair techniques continue to evolve. With a single anterior incision approach, onlay tendon fixation is most commonly achieved using suture anchors or with an intra- or extramedullary cortical button. Cortical buttons were first described with an extramedullary inlay technique[20] and have since been adapted for intramedullary use in onlay repairs with good biomechanical and clinical results.[6-9,21,22] In biomechanical studies, cortical buttons have repeatedly demonstrated the greatest load to failure compared with other devices,[2,10,21,23] and an advantage of intramedullary button fixation is decreased risk of iatrogenic injury to the posterior interosseous nerve.[22,24]

There has been an increasing interest in all-suture anchors in soft-tissue repair.[12,25-32] All-suture anchors offer several advantages, including a small profile that allows for decreased risk of iatrogenic trauma. Creating smaller diameter drill holes for all-suture anchors reduces the amount of bone removed during repair which allows for a wider bone bridge between implants and provides surgeons greater flexibility in potential revision scenarios. In addition, all-suture implants allow for postoperative magnetic resonance imaging without metal induced artifacts.[5] Although all-suture anchors have been widely employed in shoulder and hip soft-tissue repair,[29,31,32] they have not yet been adopted for such use in distal biceps repairs. Recently, Otto et al.[5] compared the biomechanical profile of an all-suture anchor repair with traditional titanium suture anchors and found no significant difference in ultimate load to failure or construct stiffness.

Therefore, the purpose of this study was to evaluate the maximal load at failure, cyclic displacement, and stiffness of onlay distal biceps repair with an intramedullary unicortical button versus all-suture anchors under cyclic loading and maximal load to failure. Our hypothesis was that both fixation methods would demonstrate similar performance in maximum load to failure and displacement under cyclic loading.

Methods

Specimens

Ten matched pairs of fresh-frozen cadaveric elbows ($n = 20$; 7 males, 3 females, age $= 56.5 \pm 6.7$ years old) were procured and stored at $-20°C$. Bone mineral density (BMD) of each specimen was measured at the radial 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 capsule. The biceps tendon was cut completely from the tuberosity and wrapped in normal saline solution-soaked gauze and refrigerated prior to fixation. The bones were transected 14 cm proximal and distal to the elbow joint. The humerus end was potted in 6.35-cm-long and 3.81-cm-diameter polyvinyl chloride pipes with fiberglass resin (Bondo; 3M Company, St. Paul, MN). Cortical thickness of the radius was measured using a digital caliper at volar aspect of the transected end. The radius and ulna were pinned together in forearm supination. An intramedullary threaded rod was securely inserted into the distal radius to allow for weights to be suspended from the radius (Fig 1). 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, elbows were randomly assigned to 1 of 2 treatments, distal biceps tendon fixation using one intramedullary unicortical button (Distal BicepsButton; Arthrex, Naples, FL) or using 2 all-suture anchors (1.35 mm FiberTak with 1.3-mm FiberTape; Arthrex) in an onlay technique (Fig 2 A and B). For the button group, the distal biceps tendon

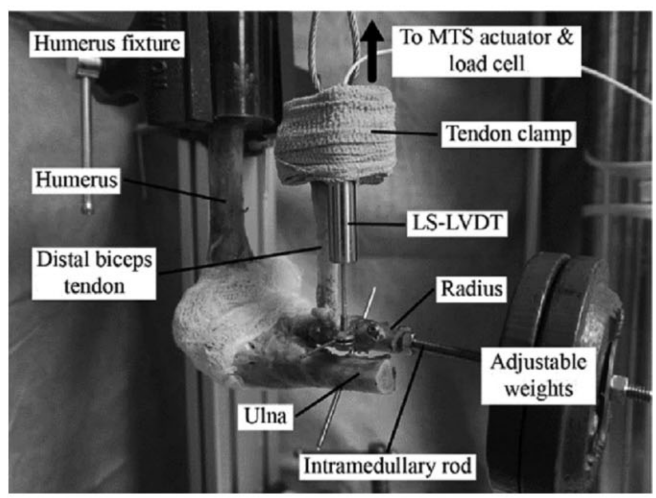

Fig 1. Left elbow specimen in 90° of flexion, mounted to the servohydraulic material testing system. Distal biceps tendon was repaired with all-suture anchors and proximal ended was attached to the load cell and actuator via a custom sinusoidal tendon clamp. The repair construct was loaded to 50 N by adjusting the moment arm of the weights on the threaded intramedullary rod. The long-stroke-linear variable differential transformer (LS-LVDT) sensor pin was attached to a bone pin placed just distally of the distal biceps tendon insertion and sensor body was secured to the tendon clamp using self-adherent wrap.

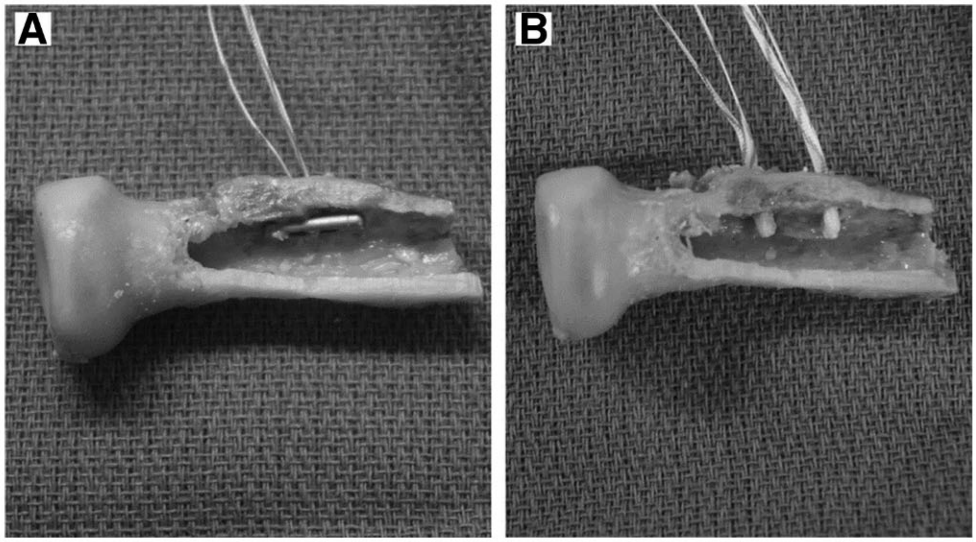

Fig 2. Example of intramedullary fixation on dissected proximal radius specimens of 1 intramedullary unicortical button (A) and 2 all-suture anchors (B).

was secured using a single high tensile-strength tape (1.3-mm FiberTape; Arthrex) in a Krackow stitch with 5 passes on each side of the tendon. A unicortical drill hole was created in the center of the anterior aspect of the radial tuberosity using a 3.2-mm drill pin directed distally at a 60° angle to allow for the button to flip inside the medullary canal. The tape was then loaded onto the suture button with one end of the tape threaded in one direction and then the other in the opposite direction. The button was inserted and one strand of the tape was sewn through the tendon in an interlocking Krackow stitch. The free strand of tape was used to tension the tendon to the radial tuberosity, passed through the tendon, and then tied with six surgical knots positioned on top of the tendon.

The all-suture anchor repair was performed as described by Otto et al.[5] A 1.6-mm pin was used to create 2 unicortical holes in the anterior cortex of the radial tuberosity according to manufacturer's instructions (Arthrex) and the drill holes were separated by 12 mm. The holes were drilled at approximately 45° angled distally to allow for deployment of the anchor without the inserter contacting the posterior cortex. The single-loaded anchors were implanted using the manufacturer's drill sleeve per instructions and the tendon was secured by using one end of each suture in an interlocking Krackow stitch. The tendon was tensioned to the radial tuberosity by pulling the free end of each suture. The free strand used for tensioning was then passed through the tendon and then secured with 6 surgical knots. All repairs were made by a single investigator (ESC) with Orthopaedic Sports Medicine fellowship training.

Biomechanical Testing

The biomechanical testing protocol was modeled after previously published studies.[2,3,5] Repaired specimens were tested using a servohydraulic mechanical testing system (MTS 858 Mini Bionix II; MTS Systems Corp., Eden Prairie, MN). The humerus pot was held with a rigid clamp in-line with the actuator and the biceps tendon was secured to the actuator through a custom sinusoidal clamp attached to the biceps tendon at the musculotendinous junction (Fig 1). Once mounted, the forearm was positioned at 90° of flexion and full supination, and the biceps tendon was preloaded with 50 N by loading the adjustable weights on the threaded rod inserted in the radius. A pin was inserted medially and just distal to the radial tuberosity to the distal biceps repair. A long-stroke linear variable differential transformer (LS-LVDT; LORD, Microstrain Sensing Systems, Cary, NC) was attached to the radial pin.

Once the sensors and load were properly configured, the specimen was cycled from 90° of flexion to full extension for 3000 cycles at 0.5 Hz. After cyclic loading was completed, specimens were restrained at 90° of flexion and loaded to failure at a constant distraction rate of 120 mm/min until the reconstruction failed. A specimen was deemed failed when the force across the construct dropped to 25% of the peak force achieved during testing. Force and displacement continuously measured (102 Hz) by the MTS actuator and in-line load cell (Model 1500; Interface, Inc., Scottsdale, AZ) 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, capsule, and ligament tissues moist throughout testing.

Data Reduction

Force and displacement data were filtered using a 4th-order zero-lag Butterworth filter with custom MATLAB scripts (vR2020a; MathWorks Inc., Natick, MA). Tendon-suture-implant construct displacement was analyzed at discrete cycles (1, 10, 100, 1,000, 2,000, and 3,000). 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, and (3) bone fracture. Descriptive statistics (mean ± standard deviation) were calculated for construct displacement at discrete cycles, maximum displacement after 3000 cycles, maximum load at failure, and stiffness. Maximum displacement and maximum load at failure values less than the 25th percentile value minus 1.5 times the interquartile range [Q1 − 1.5*IQR] or greater than the 75th percentile value plus 1.5 times the interquartile range [Q3 + 1.5*IQR] 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 button and FiberTak groups. A Shapiro−Wilk normality test demonstrated that BMD data was not normally distributed and therefore a Mann−Whitney *U* test was used to compare BMD between groups and medians (IQR) were reported. Pearson correlation coefficients were calculated to determine the relationship between BMD and cortical thickness to maximum load at failure.

An a priori power analysis was conducted in line with similar previously published studies[2,5] 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.[2] A standard deviation of 100 N was chosen, as it reflects the common range of reported standard deviations in similar studies.[2,5,7,21] 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% 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

There was no significant difference in BMD between the button and suture anchor group (0.45 g/cm^3 [IQR = 0.17] vs 0.60 g/cm^3]IQR = 0.08]). There was a positive correlation between BMD and maximal load to failure (r = 0.56, *P* = .032). There was no significant correlation between cortical thickness and maximal load to failure or difference between the button and suture anchor groups (2.73 ± 0.42 mm vs 2.82 ± 0.42 mm).

After 3,000 cycles, maximum displacement was greater in the button group compared with the all-suture anchor group (4.17 ± 2.06 mm vs 2.06 ± 1.05 mm; *P* = .014, Fig 3). However, there was no significant difference in maximum load at failure between the 2 groups (503.23 ± 141.77 N vs. 537.33 ± 262.13 N; *P* = .696, Fig 4). The button group demonstrated less stiffness than the all-suture anchor group during load-to-failure testing (15.30 ± 4.48 N/mm vs 24.40 ± 8.60 N/mm; *P* = .022, Fig 5). One specimen and its matched pair were excluded as an outlier based on maximum displacement. No outliers were identified based on maximum load at failure. Overall, anchor pull-out was the most common mode of failure (50%) and the only mode of failure for the all-suture anchor group. Suture tape rupture was the most common mode of failure in the button group, with 2 constructs failing by suture pull-through and one construct failing by button pull-out from the drill hole without fracture. Of note, the specimen that failed by button pullout required a second drill pass through the same drill hole during fixation due to inability to flip the intramedullary button along the initially drilled trajectory. Despite this mode of failure, this specimen achieved maximum load at failure of 494.19 N. Aside from this one specimen, there were no other issues inserting buttons or suture anchors unicortically at the angles previously described. No specimens failed due to fracture.

Discussion

The most important finding in this study is that onlay distal biceps repair with two all-suture anchors has similar maximum strength to repair with a unicortical intramedullary button at time zero. Furthermore, the double all-suture anchor repair demonstrated less displacement after cyclic loading, and no specimens failed during cyclic testing.

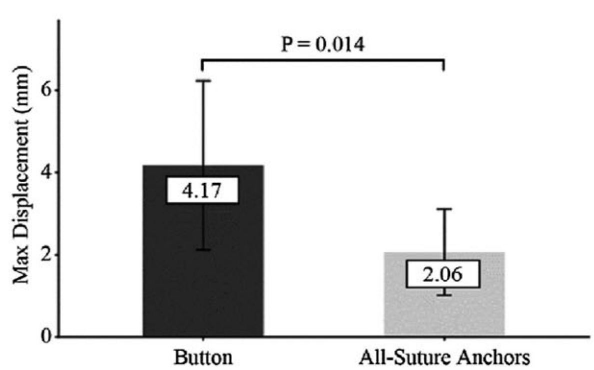

Fig 3. Mean (± standard deviation) maximum displacement in mm after 3,000 cycles for each group.

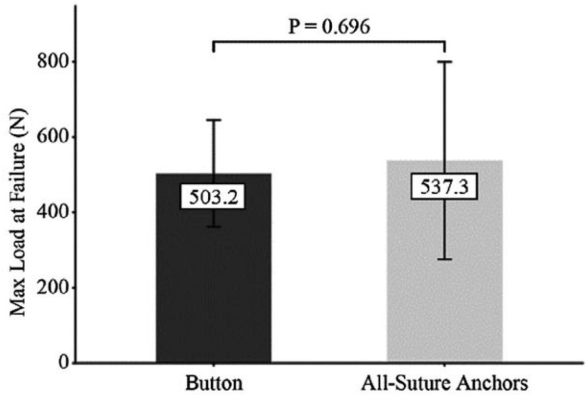

Fig 4. Mean (± standard deviation) maximum load at failure for each group.

Numerous biomechanical studies have evaluated the strength of various distal biceps repair constructs.[2,3,5,7,21-23,33-41] Mazzocca et al.[2] performed a biomechanical analysis of 4 types of distal biceps repair that included suture anchors and an inlay unicortical button technique. They found no statistically significant difference in displacement between groups however the unicortical button was significantly stronger in mean load to failure compared to suture anchors (440 N to 381 N, respectively). The cortical button repairs in the current study had a slightly greater displacement comparatively (4.17 mm in our study vs 3.42 mm in the Mazzocca study)[2]; however, the all-suture anchor repairs had slightly lower displacement (2.06 mm vs 2.33 mm respectively).[2] One possible explanation for the increased displacement in the unicortical button group seen in our study is the use of one high tensile-strength suture tape for the repair rather than the 2 high tensile-strength sutures used in the Mazzocca study for the EndoButton technique.[2,20] With the fixation device flush against the cortex, the majority of elongation was seen in the interaction between the tendon and the suture tape. The increased suture–tendon interaction gained by using additional suture material most likely leads to a stiffer construct, and this was likely the case when comparing the 2 groups in the current study as well as comparing these results to previous studies that examine the Bain extramedullary unicortical button technique.[2,3,20,38,40] In several instances, displacement also increased as the knot stack was pulled into the unicortical drill hole. With an inlay repair, some increased displacement is likely tolerable, as the tendon end is docked into the radial tuberosity; however, an onlay repair likely cannot tolerate as much displacement to achieve tendon–bone healing. Examining the biomechanical profile of a double-loaded intramedullary button is an area of potential future research, however the increased stiffness gained by additional suture material may lead to biologic implications at the tendon-bone interface.

Although the cortical button group demonstrated greater displacement than the suture anchor group (4.17 ± 2.06 mm vs 2.06 ± 1.05 mm), the clinical implications of this 2.09-mm difference are unclear.[2,3] Both groups achieved displacement less than the accepted 10-mm threshold for clinical failure.[5,37,40] Gap formation at the enthesis has been shown in animal studies to have detrimental effects on repair integrity, however clear thresholds have not been set and further research is required to fully understand this biological process.[42,43] While the clinical implications of displacement in distal biceps repair remain unclear, based on the results of this study clinicians may consider a more conservative postoperative protocol with an onlay intramedullary button repair to limit potential displacement.

Siebenlist et al.[7,21] performed 2 biomechanical studies examining intramedullary cortical buttons. The first examined the biomechanical profile of using 2 intramedullary buttons versus 1 intramedullary or 1 extramedullary button. They found that a double intramedullary cortical button had the greatest load to failure at 455 N compared with 275 N for the single intramedullary button. The peak load to failure for the single intramedullary button group in this study is much lower than in the present study likely due to several factors. First, the mode of failure in the study by Siebenlist et al. included 7 anterior cortex fractures compared with zero in our study. This is likely due to an average age of 79 years for the specimens in that study versus 56.5 years in the present study. In addition, that study did not incorporate the tendon into the repair construct and the remaining 5 specimens in the single button group failed due to suture rupture.[7] Although suture rupture was the main mode of failure for the intramedullary button group in the present study, load sharing at the suture–tendon interface likely allowed for increased overall construct strength.

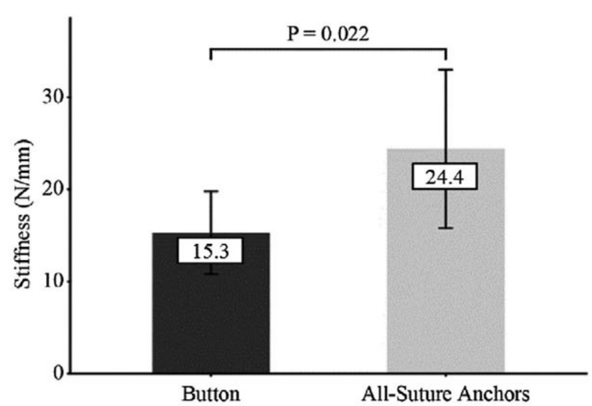

Fig 5. Mean (± standard deviation) stiffness during load-to-failure testing for each group.

In another study, Siebenlist et al.[21] compared a double intramedullary button repair with a double suture anchor repair. They found decreased displacement after cyclic loading and greater maximum load to failure in the intramedullary button group (0.6 mm vs 1.4 mm and 312 N vs 200 N, respectively). The lower maximum load to failure in this study compared with both the suture anchor and intramedullary button groups in our study is likely due to significantly older specimens in the previous study as the mode of failure again was predominantly anterior cortex fracture in the button group and anchor pullout in the anchor group.

Otto et al.[5] were the first to evaluate all-suture anchors compared with a traditional metal suture anchor in distal biceps tendon repairs and found that there was no difference in peak load to failure or stiffness between the repairs. They found a mean peak load to failure of 293.53 ± 122.15 N in the dual all-suture anchor repairs, which is less than what we found in this study. The methods of this study and the current study are similar in that they had a comparable specimen age, specimen BMD (0.58 g/cm^3), similar biomechanical testing protocol, and the same anchors; however, 1 methodologic element that may explain this difference is suture material.[5] The current study used high tensile-strength tape (1.3-mm SutureTape; Arthrex), whereas the Otto study used high tensile strength suture (No. 2 FiberWire; Arthrex).[5] Despite evidence that high tensile-strength tape has greater ultimate load to failure than high tensile-strength suture in tendon repairs,[44,45] this may not explain the difference in load to failure between this study and the study by Otto et al., as the mode of failure for all-suture anchor repairs in both studies was anchor pull-out from the bone.[5] Additionally, all-suture anchor pull-out strength has shown a positive correlation with BMD[5,29,46] and was again demonstrated in our study.

Limitations

This study has several limitations. Although anatomically accurate, our methods did not allow for rotational movement of the radius during flexion and extension. This was largely due to the need to ensure simultaneous movement of the radius and ulna through the flexion cycle without the surrounding soft tissues but also to allow for accurate displacement monitoring the LVDT sensor. The LVDT is the standard for measuring displacement in this biomechanical model[2,3,5] but does not allow for rotation. Also, we did not use a standard angle drill guide, as seen in previous studies[5,7]; however, all repairs were performed in a standard setting by the same investigator which more closely approximates performing these repairs clinically. Third, we used 2 all-suture implants as compared with a single intramedullary cortical button. We chose a single intramedullary button, as this surgical technique has been described and performed clinically.[9,47] Furthermore, these results represent the biomechanical profile of each construct at time-zero and do not necessarily represent the clinical results in vivo.

Conclusions

This study demonstrates that onlay distal biceps repair with 2 all-suture anchors has similar maximum strength to repair with an intramedullary button and that both are viable options for fixation.

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