Biomechanical Comparison of Intramedullary Cortical Button Fixation and Interference Screw Technique for Subpectoral Biceps Tenodesis

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Purpose: The purpose of this study was to biomechanically evaluate a new technique of intramedullary cortical button fixation for subpectoral biceps tenodesis and to compare it with the interference screw technique. **Methods:** We compared intramedullary unicortical button fixation (BicepsButton; Arthrex, Naples, FL) with interference screw fixation (Bio-Tenodesis screw; Arthrex) for subpectoral biceps tenodesis using 10 pairs of human cadaveric shoulders and ovine superficial digital flexor tendons. After computed tomography analysis, the specimens were mounted in a testing machine. Cyclic loading was performed (preload, 5 N; 5 to 70 N at 1.5 Hz for 500 cycles), recording the displacement of the tendon. Load to failure and stiffness were subsequently evaluated with a load-to-failure test (1 mm/s). **Results:** Cyclic loading showed a displacement of 11.3 $\pm$ 2.8 mm for intramedullary cortical button fixation and 9 $\pm$ 1.7 mm for interference screw fixation ($P = .112$). All specimens within the cortical button group passed the cyclic loading test, whereas 3 of 10 specimens within the interference screw group failed by tendon slippage at the screw-tendon-bone interface after a mean of 252 cycles ($P = .221$). Load-to-failure testing showed a mean load to failure of 218.8 $\pm$ 40 N and stiffness of 27.2 $\pm$ 7.2 N/mm for the intramedullary cortical button technique. For the interference screw, the mean load to failure was 212.1 $\pm$ 28.3 N ($P = .625$) and stiffness was 40.4 $\pm$ 13 N/mm ($P = .056$). **Conclusions:** We could not find any major differences in load to failure when comparing the tested techniques for subpectoral biceps tenodesis. Intramedullary cortical button fixation showed no failure during cyclic testing. However, we found a 30% failure rate (3 of 10) for the interference screw fixation. **Clinical Relevance:** Intramedullary cortical button fixation provides an alternative technique for subpectoral biceps tenodesis with comparable and, during cyclic loading, even superior biomechanical properties to interference screw fixation.

Pathologic changes of the long head of the biceps tendon (LHB) frequently cause shoulder pain, because the proximal third of the tendon has a high degree of innervation.[1,2] Biceps pathologies include tendinitis, fraying, instability, SLAP lesions, and partial or complete tears.[3-5] Isolated biceps pathologies are rare, because lesions are often associated with other pathologies, such as rotator cuff tears[6] or anterosuperior impingement syndromes.[3,7,8] Tenodesis of the LHB has been shown to be a reliable and effective therapy option for these pathologies.[4,9-12]

Numerous techniques for biceps tenodesis have been described, varying in terms of open versus mini-open or arthroscopic approach, proximal versus distal location of tenodesis, and fixation method. The tenodesis can be performed through a suprapectoral approach,[9,12-24] at the entrance of the bicipital groove, or through a subpectoral approach,[4,12,21,25-28] approximately 50 mm farther distal, under the tendon of the pectoralis major.[21] Fixation techniques include bone tunnel or soft-tissue tenodesis,[12,15,23] keyhole procedure,[29,30] and anchor[12,23,31] or screw[12,18] fixation.

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Several cadaveric studies have already reported on different techniques for biceps tendon refixation, showing the interference screw to provide the highest biomechanical stability.[12,21,27,32] There has been a trend toward subpectoral interference screw fixation because it is easy to perform, is reliable in relief of pain, and has been shown to improve function.[4,12] Moreover, any further sawing of the LHB through the rotator cuff tendons can be eliminated by using this technique.[4,33] The clinical results of subpectoral biceps tenodesis are good to excellent, with reliable pain relief and improvement of function.[4,12,26]

Despite these benefits, complications have been reported after subpectoral tenodesis with interference screw fixation, including implant failure, bioabsorbable screw reaction, persistent pain, neurovascular complications, and humeral fractures.[4,12,26,28] Nevertheless, the overall complication rate is reported to be as low as 2%.[26]

In a biomechanical study, Siebenlist et al.[34] tested a novel technique of intramedullary cortical button fixation for distal biceps tendon repair and found that there are no significant differences in the biomechanical properties between single intramedullary and single extramedullary cortical button fixation. However, for clinical use, the intramedullary positioning of the button may minimize the potential risk of nerve and vessel injury at the spiral groove as an iatrogenic complication.[35]

The purpose of this study was to biomechanically evaluate a new technique of intramedullary cortical button fixation for subpectoral biceps tenodesis and to compare it with the interference screw technique. Our hypothesis was that intramedullary cortical button fixation would provide superior fixation strength in static and cyclic loading when compared with the interference screw fixation.

Methods

Specimens

For this study, a total of 20 human cadaveric humeri preserved by the method of Thiel,[36] obtained from 10 paired shoulders, were used. The specimens had a mean age of 79 years (range, 65 to 96 years), and there were 12 female specimens. The soft tissue was removed, and the humeri were shortened to a consistent length of 15 cm from the proximal head. Instead of the human LHB, we used the superficial digital flexor tendon of the hind limb from sheep, which is anatomically comparable to the human biceps tendon[37] and was more readily available. Before use, the fresh-frozen ovine tendons were thawed at room temperature, the diameter of each tendon was measured by use of an electronic caliper, and the tendons were randomly assigned to fixation groups. The mean diameter of the ovine tendons was 6.4 ± 0.3 mm and therefore correlated with the mean diameter of human proximal biceps tendon measuring between 5 and 6 mm.[4] Because an 8×12—mm screw is recommended by the manufacturer (Arthrex, Naples, FL) for tendon diameters between 5.5 and 8 mm, this screw was used in all cases.

For evaluation of bone mineral density and the cortical thickness, all specimens were scanned on a clinical 256-slice multidetector computed tomography scanner (Brilliance iCT; Philips Healthcare, Hamburg, Germany). The bone mineral density was defined at the tuberculum majus simultaneously using a phantom provided by the manufacturer of the scanner and consisting of water- and bone-equivalent solid materials (0 and 200 mg/cm^3 calcium equivalent). The region of interest for the cortical thickness was the bicipital groove 50 mm distal from the entrance. This was used to validate the influence of bone quality and the measured failure strengths between repair groups. In addition, the intramedullary dimensions 50 mm distal from the entrance of the bicipital groove were defined by the anterior-posterior diameter and lateral-medial diameter.

In all specimens the subpectoral tenodesis was performed 50 mm distal from the entrance of the bicipital groove, distal to the inferior border of the insertion of the pectoralis major tendon.[12,21,25]

For each pair, 1 humerus was used to perform intramedullary cortical button fixation, and the contralateral humerus underwent tenodesis with the interference screw. The assignment of left and right was alternately changed.

Intramedullary Cortical Button Fixation

The cortical button that was used (BicepsButton; Arthrex) is an implantable titanium suture button that measures 2.6×12 mm and provides 2 suture holes, which is authorized for distal biceps repair. The subpectoral biceps tenodesis with the biceps button is an off-label use of the implant.

For intramedullary unicortical fixation, a 3.2-mm hole was drilled at the bicipital groove into the anterior cortex, approximately 50 mm distal from the entrance of the bicipital groove (Fig 1A). Next, a No. 2 nonabsorbable high-strength suture (FiberWire; Arthrex) was placed into the proximal 15 mm of the tendons with an interlocking Krackow stitch.[38] One strand was led through the suture holes of the button, whereas the other strand was left free. Then, the button was passed through the previously drilled hole in the anterior cortex with a Button Inserter (Arthrex), which held the button on a pin. The button was released in an intramedullary manner from the holder by pulling back the pin. The shuttled strand with the button was tensioned, allowing the button to be in contact with the anterior cortex while the tendon was pulled tight to the bone. Subsequently, the shuttled strand was passed through the tendon and tied to the free strand with 4 knots.

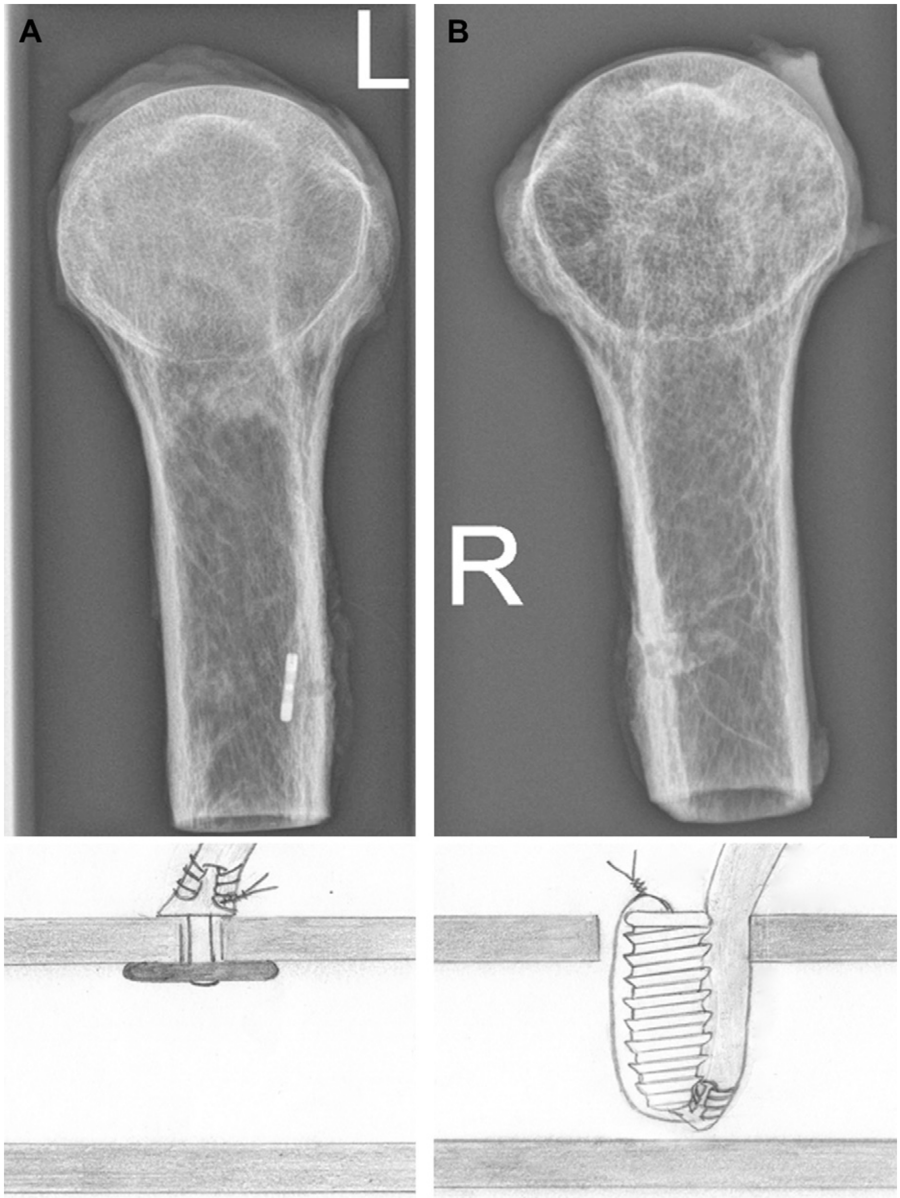

Fig 1. (A) Radiographic control and schema of both fixation techniques: intramedullary cortical button fixation and (B) interference screw technique.

Interference Screw Technique

According to the technique published by Mazzocca et al.,[12] an 8-mm drill was used to create a 15-mm-deep bone tunnel 50 mm distal from the entrance of the bicipital groove. The screwdriver and an 8 × 12−mm screw (Bio-Tenodesis screw) were used to perform the biceps tenodesis (Fig 1B). Again, a No. 2 nonabsorbable high-strength suture was inserted into 15 mm of the stump of the tendon with a Krackow stitch.[38] One thread was passed through the cannulated screw and screwdriver, and the other thread was left free. The shuttled thread was tensioned during insertion to ensure that the tendon was abutting the tip of the screw. After insertion of the screw-tendon construct, the 2 threads of No. 2 sutures were tied to each other with 4 pairs of surgical knots.

Biomechanical Testing

The specimens were securely fixed in a custom-built threaded jig that was mounted on the base of a material testing machine (Zwick 2.5 TN; Zwick/Roell, Ulm, Germany). The humerus and the tendon were mounted inverted. The cyclic loading forces and pullout strength forces were close to parallel to the longitudinal humeral axis. With this configuration, the in vivo direction of loading of the biceps muscle and tendon was simulated. The tendon was tightened in a clamp with a sinusoidal profile 50 mm distal of the tenodesis (Fig 2).

All testing was performed at room temperature. A spray bottle was used with a 0.9% sodium chloride solution to keep the biceps tendon graft moist and avoid desiccation. A preload of 5 N was applied to

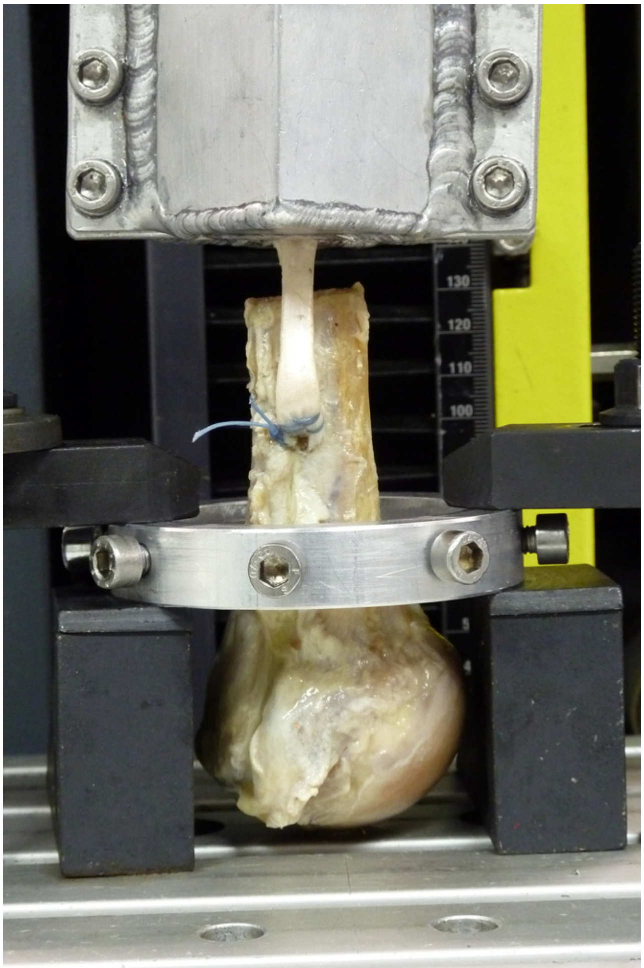

Fig 2. Setup for biomechanical testing.

precondition the construct and warrant a consistent starting point. Then, the specimens were loaded cyclically from 5 to 70 N for 500 load cycles at 1.5 Hz to evaluate the fixation displacement.[39] Afterward, all specimens in which failure did not occur during the cyclic loading were loaded to failure at a rate of 1 mm/s. Load to failure was considered to have occurred when the testing machine stopped at a drop in force of 50% from the applied maximum force (50%). The recorded maximum force was regarded as load to failure. A low-force load cell was used (2.5 kN) to monitor the tests.

The number of cycles and the clamping displacement were recorded continuously during cyclic loading with an accuracy of ±2 μm by use of data-acquisition software (testXpert; Zwick/Roell) interfaced with the material testing machine. Cyclic displacement was calculated according to the maximum clamping displacement of cycle 500 relative to that of cycle 1.[39] For load-to-failure testing, load-displacement graphs were generated for determination of load to failure. Furthermore, the slope of the linear portion of the graph was used to determine stiffness. In addition, the mode of tendon failure was recorded.

Statistical Analysis

The statistical power of the analysis was calculated according to a prior study.[34] In our study a 2-sided *t* test achieves a power of 80% on a 5% significance level to detect a mean difference of 280 to 380 N in load to failure with SDs of 45 N and 90 N when there are 10 specimens. This sample size was assessed for the unpaired *t* test and served as a conservative estimation for the paired data in this study. All analyses were performed with R for statistical computing. The distribution of measurements is presented by scatter plots. Accordingly, descriptive statistics about location and variability are given by mean and standard deviation. Comparisons of interference screw and intramedullary cortical button fixation are conducted by 2-sided paired samples *t* tests along with a presentation of mean differences and respective 95% confidence intervals. The Fisher exact test was used to compare failure rates of cyclic loading. All tests were performed in an explorative manner on a 5% significance level.

Results

Specimens

There were no statistically significant differences between the 2 repair groups in tendon diameter, bone mineral density, or cortical thickness ($P > .05$) (Table 1). The mean diameter of the used ovine tendons was 6.4 ± 0.3 mm. The intramedullary space 50 mm distal from the entrance of the bicipital groove was evaluated by measuring the anterior-posterior diameter (16.3 ± 2.6 mm) and the lateral-medial diameter (12.8 ± 1.7 mm). The data show that the intramedullary canal at the bicipital groove provides enough space to introduce the intramedullary cortical button vertically to the bone surface.

Cyclic Loading

The mean displacement during cyclic loading recorded was 11.3 ± 2.8 mm for the intramedullary cortical button fixation and 9 ± 1.7 mm ($P = .112$) for the interference screw technique (Fig 3). All 10 specimens in the intramedullary cortical biceps button fixation group completed the cyclical testing without failure. For interference screw fixation, 3 of 10 specimens (30%) failed by tendon slippage at the screw-tendon-bone

Table 1. Evaluation of Bone Quality and Tendon Diameter of 2 Repair Groups

	Tendon Diameter (mm)	Bone Mineral Density (mg/dL)	Cortical Thickness (mm)
Intramedullary cortical button	6.3 ± 0.2	112.2 ± 24.2	2.4 ± 0.6
Interference screw	6.4 ± 0.3	115.6 ± 23.6	2.5 ± 0.7
P value	.639	.138	.074

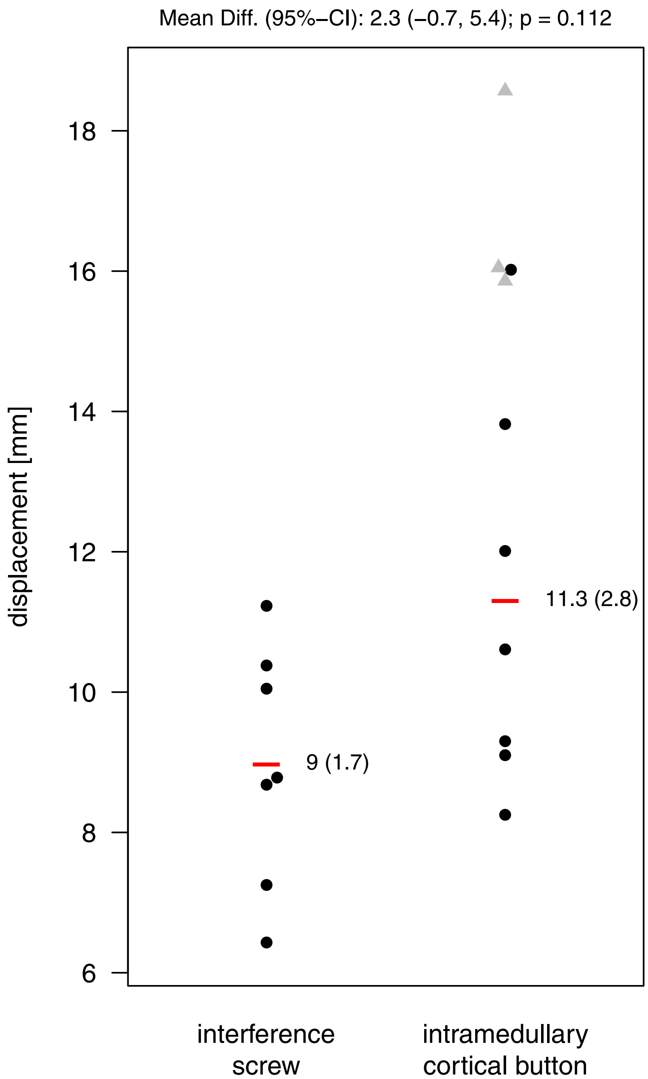

Fig 3. Scatter plot of displacement after cyclic loading with mean and standard deviation of each repair group. Mean difference (Diff), respective 95% confidence interval (CI), and *P* value are also presented. The measured values in the intramedullary cortical button group, which correspond to the 3 failures in the interference screw group, are presented (triangles) for the sake of completeness. They were not included in the analysis.

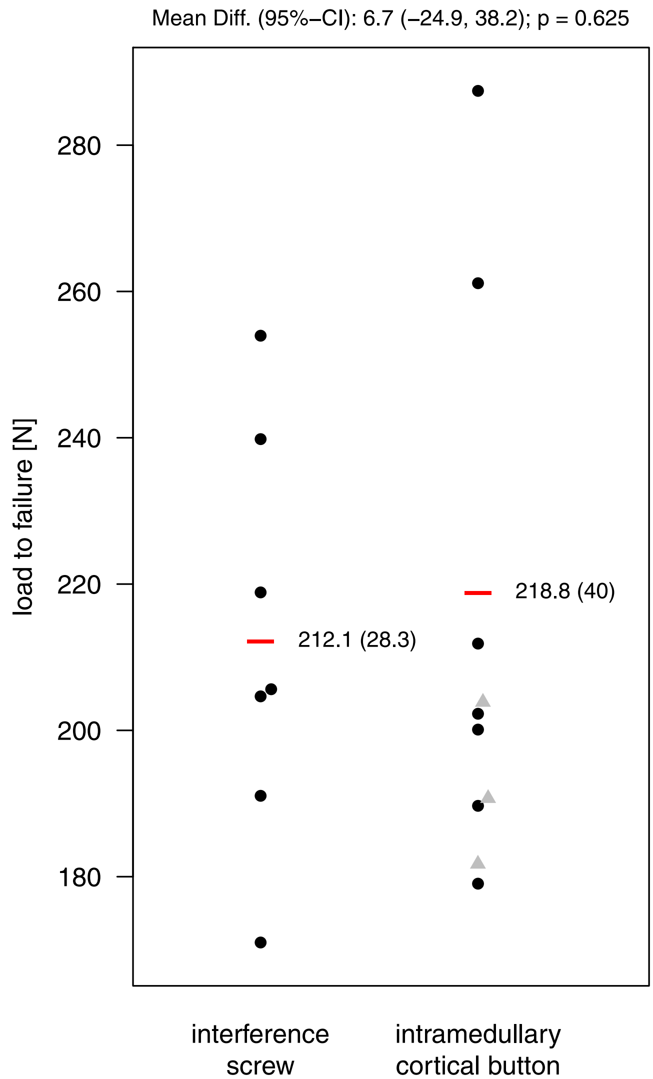

Fig 4. Scatter plot of load to failure with mean and standard deviation of each repair group. Mean difference (Diff), respective 95% confidence interval (CI), and *P* value are also presented. The measured values in the intramedullary cortical button group, which correspond to the 3 failures in the interference screw group, are presented (triangles) for the sake of completeness. They were not included in the analysis.

interface after a mean of 252 cycles (401, 299, and 56 cycles) (P = .211). Because these specimens failed during cyclic testing, data for load to failure and stiffness could not be reported.

Static Loading

For the cortical biceps button fixation, the mean load to failure was 218.8 ± 40 N and mean stiffness was 27.2 ± 7.2 N/mm. The interference screw constructs showed a mean load to failure of 212.1 ± 28.3 N and mean stiffness of 40.4 ± 13 N/mm. The difference in load to failure between both repair groups was not significant (P = .625); moreover, the difference in stiffness was not significant (P = .056) (Figs 4 and 5). In all specimens in the intramedullary cortical button fixation group, the constructs failed by the suture cutting or tearing through the tendon. The reason for failure in the interference screw group in all cases was tendon slippage from the bone tunnel and the consecutive breaking off of the screw from the bone socket. There was no failure of the bone itself (i.e., fracture).

Discussion

As hypothesized, our results did show that the intramedullary cortical button fixation performed better than the interference screw fixation, showing lower failure rates under cyclic loading, whereas there were no statistically significant differences under static

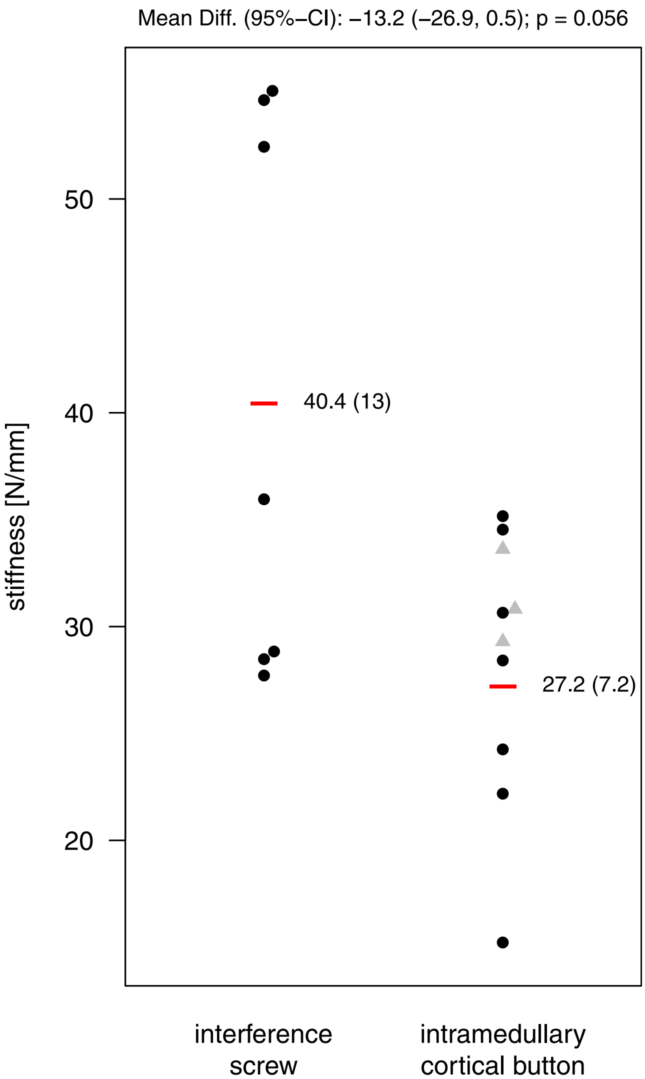

Fig 5. Scatter plot of stiffness with mean and standard deviation of each repair group. Mean difference (Diff), respective 95% confidence interval (CI), and *P* value are also presented. The measured values in the intramedullary cortical button group, which correspond to the 3 failures in the interference screw group, are presented (triangles) for the sake of completeness. They were not included in the analysis.

loading (mean load to failure, 218.8 N *v* 212.1 N; *P* = .625).

The findings of our study can be considered in the context of other biomechanical studies that tested different fixation techniques. Because these studies did not use the exact same models, the results are not directly comparable; however, the studies resemble each other in terms of setup and experimental design. Therefore the trends and conclusions of the studies can be considered coherently.

Golish et al.[25] found that subpectoral biceps tenodesis with tenodesis screws had a significantly higher mean load to failure (169.6 N) than tenodesis with suture anchors (68.5 N). Ozalay et al.[27] showed in a sheep model that interference screw fixation (243 N) was superior to a bone tunnel technique (229 N), suture anchor technique (129 N), and keyhole technique (101 N). Mazzocca et al.[12] tested the loads to failure of 4 fixation techniques—arthroscopic interference screws (237.6 N), subpectoral bone tunnels (242.4 N), open subpectoral tenodesis screws (252.4 N), and arthroscopic suture anchors (164.8 N)—and reported no significant differences regarding the mean loads to failure. Patzer et al.[21] compared different techniques for tenodesis in the suprapectoral and subpectoral position. They could show a biomechanical advantage of the interference screw techniques—suprapectoral tenodesis screw (218.3 N), subpectoral tenodesis screw (200.7 N), suprapectoral polyetheretherketone (PEEK) screw (173.9 N), and subpectoral PEEK screw (162.9 N)—over the suture anchor techniques without a significant difference for the position of the tenodesis—suprapectoral suture anchor (111.2 N) and subpectoral PEEK suture anchor (99.1 N).

Sethi et al.[40] found in a recent published study that cortical button fixation (99.4 N) provided significantly lower load to failure compared with interference screws for subpectoral biceps tenodesis: 7-mm interference screw and cortical button (237.8 N), 7-mm interference screw (275.5 N), and 8-mm interference screw (277.1 N). They assumed that the poor performance of the cortical button might be caused in some cases by the suture technique fixing the button to the tendon. Not passing the suture through the tendon before tying the knots may promote failure by the suture tearing through the tendon. In our study all specimens in the intramedullary cortical button fixation group failed by the same mode with suture tearing through the tendon; however, load to failure was comparable to the interference screw fixation (218.8 N *v* 212.1 N). Using a modified suture technique that includes passing the suture through the tendon before tying the knots may markedly improve the fixation strength of the intramedullary cortical button.

Although we found differences in stiffness between intramedullary cortical button fixation and interference screw fixation in our study, this difference was not significant (27.2 N/mm *v* 40.4 N/mm, *P* = .056). Compared with the literature, the button fixation showed a lower stiffness than the interference screw repair but higher stiffness than a suture anchor construct. Golish et al.[25] reported the mean stiffness of a suture anchor construct to be 19.3 N/mm compared with 34.1 N/mm for an interference screw fixation.

To simulate stress during the postoperative rehabilitation period, the specimens were initially tested during 500 cycles of repetitive loading between 5 and 70 N.[39] Within the interference screw group, 3 of 10 specimens (30%) failed during this testing, whereas all specimens in the cortical button group withstood the cyclic loading. Because cyclic testing, which should simulate forces during early rehabilitation, is more clinically relevant than the ultimate load testing, this is an important finding. The tendon fixation with an interference screw was performed as described by the manufacturer (Arthrex) using an 8-mm reamer and an interference screw size of 8 × 12 mm for tendon diameters between 5.5 and 8 mm. The tendon and the interference screw must be accommodated into the reamed hole to ensure adequate fixation strength, but as shown in our study, this seems to be a weakness of the interference screw fixation. By tightening the interference screw, the structure of the biceps tendon might be damaged, creating a weak point.[41] Whether the graft-screw diameter relation contributes to tendon slippage out of the hole also has to be investigated in further studies.

In contrast, these potential disadvantages associated with the interference screw fixation are not found with the button fixation technique. One potential disadvantage of the cortical button fixation may be a greater displacement compared with the interference screw fixation (11.3 mm *v* 9 mm, $P = .112$), because excessive tendon-bone detachment might compromise the repair and tendon-to-bone healing. However, greater displacement was only measured at load-to-failure testing, and we did not detect a displacement greater than 10 mm up to 180 N for either group. According to the literature, displacement greater than 10 mm corresponds to the clinical failure of a fixation method.[42] The force required to hold 1 kg at 90° of elbow flexion has been reported to be approximately 110 N, which is a good example for weights to be handled in daily activities.[43] Therefore the cortical button technique, as well as the interference screw method, should provide sufficient biomechanical properties for early motion and rehabilitation, without heavy weight bearing.

Both tenodesis techniques rely on different fixation characteristics. The interference screw technique represents an intraosseous fixation of the tendon, whereas the intramedullary cortical button technique fixes the tendon on the surface of the bone. The healing properties of the intramedullary cortical button fixation might be different from the interference screw technique because the tendon is attached to cortical bone instead of cancellous bone. However, several studies showed that there are no major differences in tendon healing to cortical bone compared with healing in cancellous bone.[44]

A potential advantage of the button fixation might be the smaller drill hole (3.2 mm) required for inserting the button. Reports exist in the literature describing postoperative fracture through the humeral drill hole, such as 1 recently published by Sears et al.[28] The large 8-mm drill hole that is necessary for insertion of the screw-tendon construct might account for this problem. However, the question of whether the drill hole size correlates with the risk of postoperative fracture stays speculative.

Limitations

This study has several limitations including the lack of exact measurement of the tendon-bone displacement (e.g., by an optical measurement device). In addition, the mean age of our cadaveric specimens, 79 years, was significantly older than the age of the typical patient in whom biceps tenodesis would be performed. However, it is comparable to the specimen age in other studies[12,25]; in addition, no significant differences in bone quality were detected among the 2 fixation groups, thus yielding the assumption that this parameter did not affect the test results. The tested human humeri were embalmed by the technique described by Thiel.[36] We already used Thiel-preserved human specimens in a previous study.[34] The mechanical properties of cortical bone are altered by this preservation technique comparable to other storage methods.[45] Unger et al.[46] reported that Thiel fixation increases the plastic energy absorption whereas formalin as well as alcohol-glycerin fixation decreases the plastic energy absorption. Furthermore, we used ovine tendons in combination with human cadaveric humeri. Although ovine tendons have been used to test biceps tenodesis before, this cadaveric model, as is the case with any biomechanical setup, cannot completely reproduce in vivo conditions.

However, our study protocol is rigorous, reproducible, and effective in providing additional information about the biomechanical qualities of both tenodesis techniques. In addition, we performed an analysis of paired samples from the left and right humeri alternated for each successive pair for the comparison between the intramedullary cortical button and interference screw to reduce intraindividual variability. Potential differences between groups regarding bone density, cortical thickness, or tendon diameter were also evaluated to reduce bias.

Conclusions

We could not find any major differences in load to failure when comparing the tested techniques for subpectoral biceps tenodesis. Intramedullary cortical button fixation showed no failure during cyclic testing. However, we found a 30% failure rate (3 of 10) for the interference screw fixation.

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