A New Anchor Augmentation Technique With a Cancellous Screw in Osteoporotic Rotator Cuff Repair: An In Vitro Biomechanical Study on Sheep Humerus Specimens

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Purpose: The aim of this study was to test a simple technique to augment the pullout resistance of an anchor in an over-drilled sheep humerus model. Methods: Sixty-four paired sheep humeri were harvested from 32 male sheep aged 18 months. Specimens were divided into an augmented group and non-augmented group. FASTIN RC 5-mm titanium screw anchors (DePuy Mitek, Raynham, MA) double loaded with suture material (braided polyester, nonabsorbable USP No. 2) were used in both groups. Osteoporosis was simulated by over-drilling with a 4.5-mm drill. Augmentation was performed by fixing 1 of the sutures 1.5 cm inferior to the anchor insertion site with a washer screw. This was followed by a pull-to-failure test at 50 mm/min. The ultimate load (the highest value of strength before anchor pullout) was recorded. A paired t test was used to compare the biomechanical properties of the augmented and non-augmented groups. Results: In all specimens the failure mode was pullout of the anchor. The ultimate failure loads were statistically significantly higher in the augmented group (P < .0001). The mean pullout strength was 121.1 ± 10.17 N in the non-augmented group and 176.1 ± 10.34 N in the augmented group. Conclusions: The described augmentation technique, which is achieved by inferior-lateral fixation of 1 of the sutures of the double-loaded anchor to a fully threaded 6.5-mm cancellous screw with a washer, significantly increases the ultimate failure loads in the over-drilled sheep humerus model. Clinical Relevance: Our technique is simple, safe, and inexpensive. It can be easily used in all osteoporotic patients and will contribute to the reduction of anchor failure. This technique might be difficult to apply arthroscopically. Cannulated smaller screws would probably be more practical for arthroscopic use. Further clinical studies are needed.

Most of the patients who have rotator cuff tears are aged older than 60 years, and osteoporosis is highly prevalent in these patients.1,2 Two main techniques have been used to reattach the ruptured rotator cuff tendon to its insertion site: transosseous suture and suture anchor. Recently, newer arthroscopic repair techniques including transosseous-equivalent repairs with anchors or arthroscopic transosseous suture passage have been developed.3 The stability of the anchor fixation is determined by the bone quality and the design and material of the anchor.1,2,4

The influence of bone density at the greater tuberosity (GT) and the ultimate failure load of suture anchors have been studied, but the results are conflicting. Kirchhoff et al.2 reported that bone quality within the GT increases from the anterior to the posterior aspect and from the lateral to the medial aspect. Barber et al.5 found higher pullout strength (approximately 40%) in the posterior area of the GT, whereas Tingart et al.1 reported higher pullout strength in the proximal, anterior, and middle area of the GT. X-treme CT (Scanco Medical, Brüttisellen, Switzerland) is a high-resolution quantitative computed tomography system that allows one to evaluate the trabecular structures of bone in detail. Recently, Kirchhoff et al.6 reported X-treme CT analysis of cancellous bone at the rotator cuff insertion in 36 human cadaveric humeral heads (75 ± 11 years) and concluded that the bone mineral density is decreasing in deeper portions. For this reason, screwing anchors to a deeper extent will not improve stability because the deeper bone stock is of worse quality.
Various anchors have been invented with different designs, materials, and sizes. The pullout strengths and failure patterns of these anchors have been previously investigated in experimental studies.\textsuperscript{1,7-10} Depending on the suture anchor material and design, different pullout strengths are reported in the literature.\textsuperscript{5,11,12} Tingart et al.\textsuperscript{1} found higher pullout strength for metal screw–type anchors than for biodegradable hook-type anchors. Pietschmann et al.\textsuperscript{5} found no differences between pullout strengths of absorbable suture anchors and metal anchors in osteoporotic bone.

Very few augmentation techniques have been reported previously to manage anchor pullout in osteoporotic bones.\textsuperscript{13-19} In this study we tested an anchor augmentation technique on over-drilled sheep humeral bones that has not been reported previously. The aim of this study was to test a simple technique to augment the pullout resistance of an anchor in an over-drilled sheep humerus model. The hypothesis of this study was that this augmentation technique would increase anchor pullout in osteoporotic bones.

**Methods**

Sixty-four paired sheep humerus specimens were harvested from 32 male sheep aged 18 months, frozen at $-20^\circ\text{C}$, and stored. All soft tissues were stripped from the bones. The specimens were thawed at room temperature for 24 hours before testing. FASTIN RC 5-mm titanium screw anchors with 2 No. 2 Orthocord sutures (DePuy Mitek, Raynham, MA) were used (Fig 1).

The paired specimens were divided into 2 groups. In the first group, the anchors were non-augmented and both sutures were attached to the testing machine (Fig 2); in the second group, the anchors were augmented (Fig 3). Normally, these anchors can be used without predrilling. To weaken the bone to simulate osteoporosis, we predrilled the bone with a 4.5-mm drill bit in the same direction and depth with anchor insertion.

The anchors were placed in the anterior one-third of the GT at an angle no greater than $45^\circ$. A goniometer was used to measure the insertion angles for the anchors. The depth of insertion was until the first demarcation line of the anchor.

In the augmented group, a hole was made with a 3.2-mm drill bit 1.5 cm inferior-lateral to the anchor insertion site perpendicular to the humeral shaft. The far cortex was not drilled. Subsequently, the suture attached to the superior hole of the anchor was fixed with a stainless steel 36-mm-long 6.5-mm fully threaded cancellous screw with a 13-mm plain washer (Ortopro, Izmir, Turkey) (Figs 3 and 4). The 2 legs of the sutures were crossed over each other before wrapping around the screw. Each leg of the sutures was turned around the screw for $360^\circ$ and tied on the inferior side of the screw with 5 simple knots: 2 plain, 1 reverse, and 2 plain, respectively. Finally, the screw was fastened (Fig 5). After specimen preparation and anchor insertion, the specimens were placed in a ZWICK/Z100 tensile testing machine (Zwick Roell AG, Ulm, Germany). Each humerus was clamped at the shaft by use of a custom-made clamp with the long axis of the humerus placed at $135^\circ$ to the load actuator. The sutures were grasped by a 20-cm surgical straight clamp (Bahadir, Samsun, Turkey) attached to the testing machine about 80 mm superior to the humeral head surface. In the augmented group, the suture at the inferior hole of the anchor was...
attached to the clamp. The adjustable angle fixture was positioned at a 45° angle to simulate the anatomic direction of the load applied to the rotator cuff (Fig 6). This was followed by a pull-to-failure test at 50 mm/min. The ultimate load (the highest value of strength before anchor pullout) was recorded. The final anchor position was evaluated to note whether the anchor pulled out totally and migrated medially or did not pull out totally and rotated in the bone.

This study was carried out in the mechanical laboratory of Tosyalı Holding Company (Iskenderun, Turkey). The biomechanical testing of specimens was realized with the participation of all authors. After being informed about the study, the staff of the laboratory provided help during the biomechanical testing and recording of the results. The augmented specimens were prepared by 2 authors (V.U. and R.O.), and the non-augmented specimens were prepared by 2 different authors (Y.D. and A.K.). Testing of all the specimens and recording of the results were realized in a blinded manner by 2 other authors (H.H. and F.K.).

Statistical Analysis
The statistical analysis was performed by use of GraphPad Prism (version 5.01; GraphPad Software, San Diego, CA). Normal distribution of the continuous variable (ultimate failure load [in newtons]) was tested with the Kolmogorov-Smirnov test. Results are reported as mean values and standard deviations. A paired t test was used to compare the biomechanical properties of the augmented and non-augmented groups. The level of statistical significance was set at $P < .05$.

Power Calculation
The mean ultimate failure load strength was 121.1 ± 10.17 N in the non-augmented group and 176.1 ± 10.34 N in the augmented group, and there were 32 specimens in each group. If $\alpha$ was accepted at .05, power of 100% would be achieved.

Results
In all specimens the failure mode was pullout of the anchor. No suture breakage was seen in either the
superiorly or inferiorly attached sutures. In addition, no anchor eyelet breakage was observed. In the non-augmented group, all anchors were totally pulled out from the bone and migrated medially. The failure mode in the augmented group was anchor pullout, but the final position of the anchor was a position of lateral rotation on the bone instead of undergoing total pullout and further medial migration (Fig 7). The ultimate failure loads were statistically significantly higher in the augmented group. The results are given in Table 1.

**Discussion**

The pullout strength of anchors depends on the anchor material, anchor design, and bone quality. In patients with poor bone quality, a failure rate of up to 68% has been reported after rotator cuff repair.\(^1\)\(^,\)\(^2\)\(^0\) For this reason, prophylactic augmentation of suture anchors would be useful.

In this study we found that anchor augmentation with cancellous screws results in better pullout strength. Furthermore, we found that screw augmentation prevents total pullout and further migration of the anchor medially.

Few techniques have been reported in the literature regarding the management of anchor loosening in poor-quality bone. Denard and Burkhart\(^1\)\(^4\) have reported a Level V study describing some techniques regarding anchor management in poor-quality bone: compaction bone grafting, the buddy anchor technique, rescue anchors, cortical fixation, fully threaded suture anchor fixation, and insertion of anchors at the dead-man angle. Postl et al.\(^2\)\(^1\) reported a case with a bone cyst in the GT filled with biocompatible bone void filler before anchor insertion. Kim et al.\(^1\)\(^6\) reported on impacted bone graft using with suture-bridge technique; they also reported a technique for revision of a pullout suture anchor in the lateral row during the suture-bridge technique. Nawab et al.\(^1\)\(^7\) described a technique using a Bio-Tenodesis screw (Arthrex, Naples, FL) to achieve effective fixation after suture anchors failed. However, there are no in vitro biomechanical studies supporting these augmentation techniques.

Brady et al.\(^1\)\(^3\) compared fixation with 5.0-mm, 5.5-mm fully threaded, 6.5-mm, and 5.0-mm dual Bio-Corkscrew anchors (Arthrex) in polyurethane foam. The highest pullout strength was reported in dual-anchor constructs. They reported better pullout strength with fully threaded 5.5-mm anchors than with 6.5-mm anchors. Oshtory et al.\(^1\)\(^8\) compared 10 matched pairs of cadaveric proximal humeri implanted with a metal screw—type suture anchor on 1 side and with tricalcium phosphate cement injected into the anchor holes before anchor placement on the other side. They concluded that suture anchor augmentation with tricalcium phosphate cement increased the final load to failure by 29%, whereas Giori et al.\(^1\)\(^5\) reported 71% additional pullout strength with anchor augmentation by polymethyl methacrylate.

The anchor can tilt medially under tension during knot tying, or the pulling strength of rotator cuff may cause medial movement of the anchor during post-operative rehabilitation. Our hypothesis was that if we fix 1 of the sutures of the double-loaded anchors to a screw inferior to the anchor insertion site, this will result in bypassing a part of the load to the lower cancellous screw and provide additional support to the anchor stability. This method has not been reported in the literature previously.

In our study the augmentation provided 44% (54 N) additional power to the suture anchor. This is higher than that achieved with tricalcium phosphate augmentation.\(^1\)\(^8\) On the other hand, augmentation with polymethyl methacrylate and dual-anchor fixation provided higher pullout strength than our technique; however, these techniques are much more expensive. In addition, there is a risk of cement extrusion and special needles are essential for cement-augmented techniques.\(^1\)\(^3\)\(^,\)\(^1\)\(^5\)\(^,\)\(^1\)\(^8\)

We used linear loading for biomechanical testing of the specimens. Most recent studies have used cyclic loading at the beginning of the test, followed by a pull

**Table 1. Ultimate Failure Results**

<table>
<thead>
<tr>
<th></th>
<th>Ultimate Failure Load (N)</th>
<th>Difference Between Mean Values (N)</th>
<th>95% Confidence Interval (N)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Augmented (n = 32)</td>
<td>176.1 ± 10.34</td>
<td>54.94 ± 7.547</td>
<td>172.3-179.8</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Non-augmented (n = 32)</td>
<td>121.1 ± 10.17</td>
<td>117.5-124.8</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*NOTE. Results are given as mean ± standard deviation.*
to failure with linear loading.\textsuperscript{5,15,22,23} Displacement distances at regular intervals can be measured and compared more easily and more accurately with cyclic loading. However, it has no superiority in measuring the ultimate failure load. The aim of this study was to measure the ultimate failure loads of augmented and non-augmented anchors. Therefore a linear loading test is sufficient for satisfactory results. Miller et al.,\textsuperscript{24} using single load-to-failure testing, reported that Orthocord suture had a load to failure of 218 N. In the augmented group, the highest value of pullout strength was 195 N, and this was not high enough for suture breakage.

In our study we tested a new augmentation technique for suture anchors using a simple, fully threaded cancellous screw with a plain washer, which is readily available and easy to apply. In Turkey the price of the screw and washer used is US $24 whereas the knotless anchors cost roughly US $395. Therefore the former is much more inexpensive and presumably more stable than knotless anchors, which can be alternatively used for lateral fixation similar to the suture-bridge technique.\textsuperscript{25} Our technique might be difficult to apply arthroscopically. Cannulated smaller screws would probably be more practical for arthroscopic use. Moreover, we think that cancellous screws can even be used alone in rotator cuff repair. Further clinical and biomechanical studies are needed.

Limitations

A limitation of this study is that we simulated osteoporosis by over-drilling the bone instead of using real specimens. Several osteoporotic sheep models have been reported in the literature.\textsuperscript{9,26,27} However, because of the high number of specimens, it would be very difficult to use these models, both technically and ethically. Grossterlinden et al.\textsuperscript{28} used an over-drilled sheep model for osteoporotic simulation in 12 sheep tibia. They tested the augmentation effect of a new bone adhesive on screws inserted into osteoporotic bone. Silva et al.\textsuperscript{29} biomechanically tested the influence of pilot hole diameter on insertion torque and pullout strength of pedicle screws inserted in 15 sheep L1-L3 pedicles and concluded that a pilot diameter smaller than the internal (core) diameter of the screw improved the insertion torque and pullout strength. We also used linear strength instead of cyclic loading because of the available laboratory setting.

Conclusions

The described augmentation technique, which is achieved by inferior-lateral fixation of 1 of the sutures of the double-loaded anchor to a fully threaded 6.5-mm cancellous screw with a washer, significantly increases the ultimate failure loads in the over-drilled sheep humerus model.

Acknowledgment

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References


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