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Do double-row suture-locking anchors impact the biomechanical outcomes of rotator cuff surgery? A biomechanical study.

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Abstract:

Introduction: Several surgical techniques for arthroscopic repair of the rotator cuff have been described in the literature. The aim of this study was to determine whether the suture thread locking method in double-row anchors influences their biomechanical properties. We compared the pullout strength of two anchors with different locking mechanisms.

Methods: We performed 30 pullout tests at 135° using two different double-row anchors, an interference fit lock (5.5 mm SwiveLock) and a combination lock (5.5 mm MultiFix S). One anchor of each type was implanted on the tuberosity of a bovine humeral bone.

Results: Mean pullout strength was 239.29 ± 83.73 N for the SwiveLock anchors and 253.82 ± 87.65 N for the MultiFIX S anchors, mean displacement (in millimeters) was 28 ± 9 and 30 ± 12 , respectively which were not statistically significantly different.

Conclusion: The addition of an internal lock in the double-row suture-locking anchor did not improve the biomechanical properties in a pullout test of 135°.

Keywords : biomechanical, double row anchor, rotator cuff repair, pullout strength, SwiveLock, MultiFix

Word counts : 1892

Introduction

Surgical repair of the rotator cuff is performed to manage pain, reduce loss of functional impairment, and prevent the onset of rotator cuff arthroplasty^{8,14,17}. Several surgical techniques for arthroscopic repair have been described in the literature: single-row, double-row, conventional knot or knotless^{19,22}. Double-row repair appears to allow better healing of the tendon³. The particularity of the double-row technique lies in the capacity of the anchors to lock the suture thread without the need for a knot. Several suture locking methods have been developed based on the design of the anchor. The thread can be fixed between the anchor and the bone (interference fit), to the anchor itself (internal lock), or the two methods are used together (combined type). Several biomechanical studies have evaluated the pullout strength for different anchors and analyzed the causes of suture failure^{1,9,12,18,24,25}. In the majority of cases, tensile strength tests were performed along the axis of the anchor implant. Once the tensile axis reached an angle of 135° relative to the humeral shaft, this test was only performed for median anchors, i.e. of the first row. However the tensile axis modified the resistance properties of the implant pull-out, with a higher pull-out force for axial traction⁷. To our knowledge, there are no published biomechanical studies comparing anchors on the basis of their locking systems in a tensile assembly reproducing *in vivo* condition.

The primary objective of this study was to compare the pullout strength of two double-row anchors using different suture thread locking systems, one interference fit and the other combined type. The secondary objective was to analyze the causes of failure for each type. We hypothesized that the combined type locking anchor is not superior to the interference fit locking anchor.

Materials and Methods:

Fifteen bovine humeral bones from animals aged between 18 and 36 months were used in this biomechanical study. An excision of the soft part of the tuberosities was made prior to each insertion. Each humerus was first sectioned above the trochlea to conserve only the proximal part of the bone including the humeral head, the tuberosities and the shaft. The shaft was kept to facilitate fixation of the shoulder joint to the tensile testing machine, using a mold in a resin block (Axson Technologies®, F23 Fascast poluyurethane resin). The bovine humerus bones were frozen at -20°C until use. Bones were thawed only once to prepare the humerus bone, attach the anchors and perform the tensile tests. Two types of double-row knotless anchors were used, 1) an interference fit anchor (5.5 mm SwiveLock, Arthrex Inc, USA), and 2) a combination type fixation anchor (5.5 mm MultiFIX S, ArthroCare Corp, USA)(Figure 1). The anchors were tested using #2 FiberWire suture (Arthrex Inc).

Insertion of the anchors was performed in compliance with manufacturer's recommendations, using the arthroscopic ancillary dedicated to each anchor, for the MultiFIX S anchors as necessary. The anchors were implanted perpendicular to the lateral side of the lesser tuberosity, which has a large vertical surface plane allowing two anchors to be placed with at least 2 cm between each of them (Figure 2). The position of the implant (anterior or posterior) was attributed randomly to the two anchors. Each anchor had two suture stitches, located at the upper area of the implant, to best reproduce the *in vivo* conditions.

We performed the pullout tests using an Instron 5566A traction/compression Material Testing System with electronic data collection. Using a vertical pullout axis, the humeral shafts were positioned at 45° to the horizontal, with the humeral head oriented to the top. Thus at the anchor exit point, the suture thread ran along the length of the tuberosity, reproducing the tendon/double-row anchor trajectory, as occurs in rotator cuff repair surgery. The total angle formed by the tensile axis and the humeral shaft was 135° (Figure 3).

For each test, a 10 N pre-load was applied for 10 seconds to overcome loading artifacts of the test sample and to detect faulty fixtures²⁵. The pullout test was performed at a rate of 10 mm/min. The following parameters were measured: load to failure (breaking force in Newtons), displacement at rupture (mm), and reason for anchor failure. Anchors were tested sequentially.

Statistical tests were performed using JMP software (SAS Institute Inc). The Shapiro-Wilk test showed that the distribution of samples was not normal. We thus compared the mean pullout strengths and displacement using a Wilcoxon Rank-Sum test.

Results:

All planned anchors were implanted in the humerus bones: 15 SwiveLock and 15 MultiFIX S after pre-loads tests.

1- Pullout strength

Mean pullout strength (in Newton) was 239.29 ± 83.73 for the SwiveLock anchors and 253.82 ± 87.65 for the MultiFIX S anchors. Mean displacement (in millimeters) was 28 ± 9 and 30 ± 12 , respectively. Wilcoxon tests did not show a significant difference between the two anchor types in pullout strength or displacement (Table 1).

Figure 4 shows the distribution of the pullout strength for the two types of anchors (median and quartiles).

2- Reasons for failure (table 2)

Two reasons for failure were identified. Two suture thread breakages were reported in the SwiveLock group and one in the MultiFIX S group. All other reasons for failure were thread slippage across the anchor.

Discussion

Our study was designed to compare the pullout strengths of two types of double-row suture-locking anchors. We did not find a statistically significant difference comparing thread locked between the anchor and the bone versus when an internal lock was also present ($p < 0.05$). Many studies have compared the biomechanical properties of different anchors using force along the implantation axis. Deakin et al showed that the pullout strength of screw anchors was influenced by the suture pull angle⁷. Lower pullout strengths were needed when the tensile angle was 90° compared to tensile force along the axis, for all three anchors evaluated. Pietschmann employed this approach of a lower force along the bone axis as the best representation of the *in vivo* constraints¹⁸, following a study published by Schneeberger and Gerber²¹.

The main cause of failure we identified was the slippage of the suture thread across the anchor, irrespective of the interference or combination fixation. Thread breakage was only reported in three cases. FiberWire #2 thread was used in all cases. Woodmass reported similar results for double-row anchors implanted in dense bone²⁵. Wieser showed that the strength required for anchor pullout from the support was greater than that resulting in thread slippage²⁴. The use of an internal locking system did not reverse the strength relation. However the tensile force on the fixation was also along the axis of anchor implant. Our results confirm that in the anatomic setting, the weakness of the bone-anchor-suture assembly is located at the anchor-suture interface and not the bone-anchor interface. The addition of an internal locking system did not appear to improve this weakness.

The maximal force imposed on the supraspinatus muscle on the tuberosity during contraction is approximately 300 N^{4,23}. In our study, the mean pullout strengths for the two anchor types used were 239.29 N and 253.82 N, well short of the maximal strength used by the supraspinatus muscle. This confirms the importance of avoiding early rehabilitation after rotator cuff surgery, with a clear need for the tendon to heal before starting active rehabilitation. Repairing a torn rotator cuff with a double-row anchor does not provide adequate biomechanical properties for tolerating active mobilization. It is likely that the minimum resistance at the time of pullout or rupture that allows healing of the rotator cuff, is lower than when degenerative rupture of the rotator cuff insertion occurs. Although no specific rehabilitation program has been demonstrated as optimal, current practice involves strict immobilization or limited passive mobilization for four to six weeks^{11,16,20}, after which, recovery of joint amplitude using active muscle exercise can be initiated. When analyzing the displacement outcomes, the properties of the thread used should be taken into consideration. We thus performed the thread pullout tests using the same machine in order to study this parameter. The length of the thread between the two points of attachment was equal to that between the anchor and the upper point of attachment in our study. Failure of the fixture was seen with 322 N after a displacement of 8.06 mm. The mean force of displacement in the two groups was 28 and 30 mm. Taking into account the elasticity of the thread, we deduce that the mean displacement of the suture-anchor system was between 20 and 22 mm.

The outcomes in our study were also dependent on the support used (bovine humerus bone). They are coherent with the values reported in other biomechanical studies using bovine humerus bones, with 265 to 325 N reported by Galland et al, 156 to 269 N by Wieser et al, and 350 N by Leek et al¹³. In a double-row setup using four anchors, Barber et al² found the assembly failed with a tensile force of 521 N. We chose to use bovine humerus bones in our study for several reasons including ease of use, reproducibility and availability. In addition, their bone density is close to that found in the human proximal humerus^{5,15}. The bovine model has been used in a number of studies, which have validated its use and provide reference data^{6,9,24}. The use of a single humeral sample for two different anchors allowed us to overcome

inter-sample variation. This was addressed by random selection of the positioning of the two anchors on the tuberosity. We were also careful to restrict the number of freeze-thaw cycles to a single cycle of 10 hours, allowing both assembly of the fixture and the pullout tests. It has been shown that this freeze-thaw approach does not affect the biomechanical properties of the bone ¹⁰. Human bone samples were not used as their bone characteristics can vary greatly ¹⁸.

Conclusion

In an assembly reproducing *in vivo* limitations imposed on the double-row anchors, the addition of internal locking mechanism to the suture did not improve the biomechanical properties of the implant. The cause of failure for double-row anchors was primarily due to thread slippage. The anchor-thread interface is thus the weak point of these devices. Our results confirm the need to avoid initiating early active rehabilitation after repairing a torn rotator cuff, in order to minimize the risk of failure of the rotator cuff repair surgery.

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Legends

Figure 1: MultiFIX S (left) and Swivelock (right)

Figure 2: Positioning of the anchors on the tuberosity

Figure 3: Tensile testing fixture

Figure 4: Distribution of pullout strength (left : SwiveLock, right : MultiFIX S)

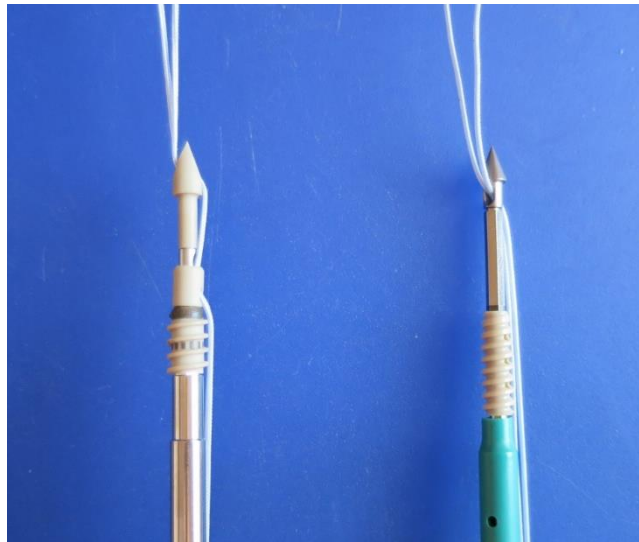


Figure 1

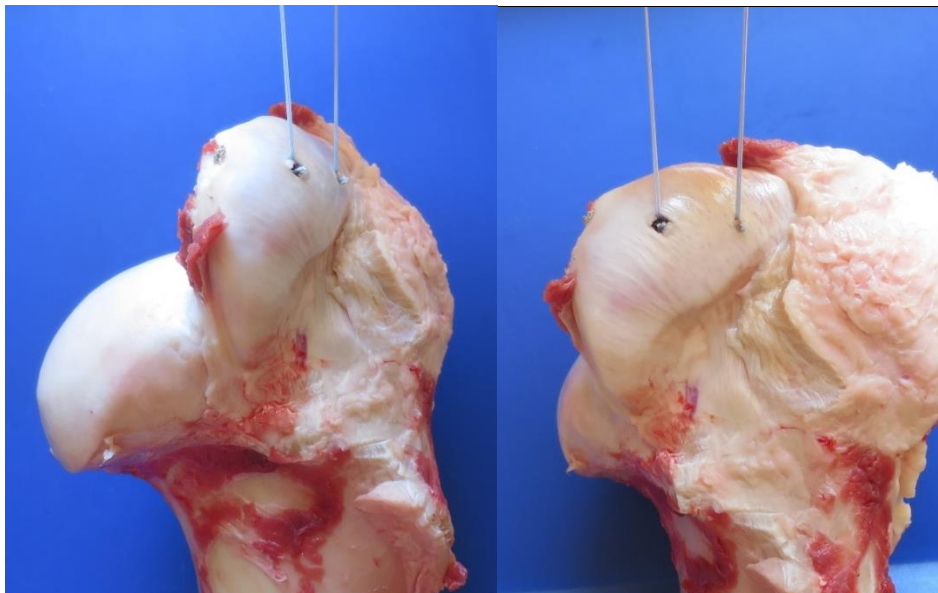


Figure 5

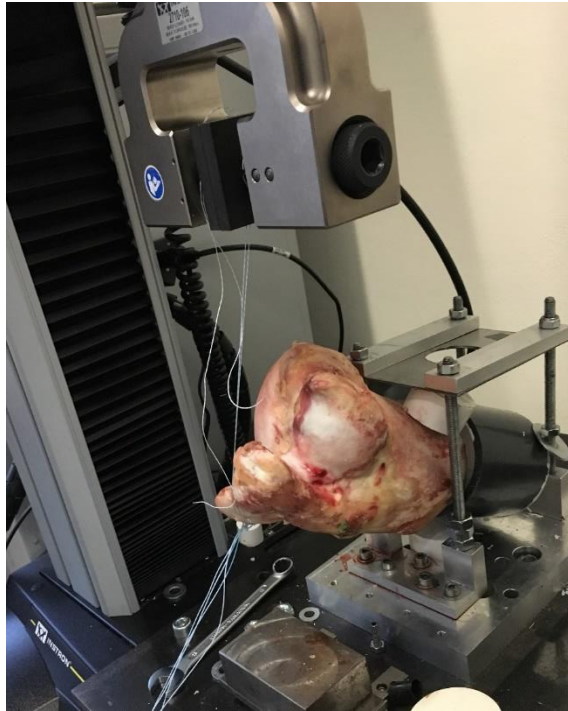


Figure 3

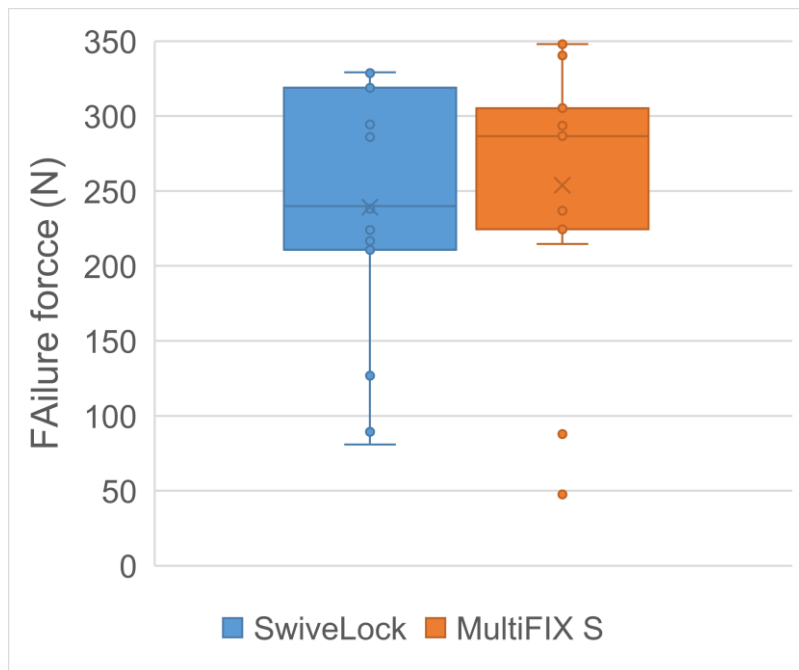


Figure 4