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Mechanical performance of the SUTUREFIX Ultra soft suture anchor for shoulder labral repair

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1 Research goal

To assess the mechanical performance of the newly designed SUTUREFIX Ultra soft anchor versus that of hard anchors currently used in shoulder labral repair.[1]

2 Type of evidence

3 Clinical relevance

- An estimated 178,000 shoulder labral tears in 2013 were diagnosed and repaired in the United States*. Each year this number is increasing, as more and more adults between the ages of 40 to 64 are staying active.
- The SUTUREFIX Ultra anchor **Figure 1** represents an easy to use, small, and soft solution for labral repair. It provides the mechanical performance expected from typical hard anchors, both with respect to fixation strength and post cyclic displacement.

4 Key result

- Mechanical performance tests showed higher fixation strength and lower displacement of SUTUREFIX Ultra following cyclic loading when compared to the two control hard anchors (SutureTak™, Arthrex Inc.; Gryphon™, DePuy Synthes. See **Figure 2**: results for hard bone simulation.

5 Important considerations

- Fixation and cyclic loading performance of the SUTUREFIX Ultra anchor exceeds that of hard anchors. Additional research would be necessary to confirm these benefits in clinical use.

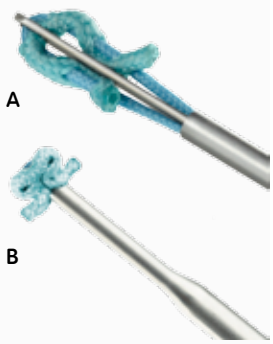

Figure 1: SUTUREFIX Ultra soft anchor (A) undeployed, and (B) deployed

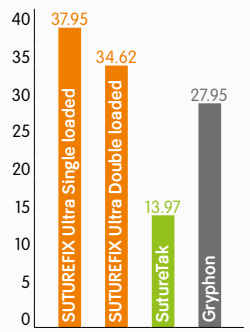

Figure 2: Anchor fixation strength (lbf) results for hard, cortical bone simulation.

*Worldwide procedural data for shoulder labral tears are not available.

Background

Arthroscopic repair of labrum tears is a successful alternative to open, more invasive surgical procedures.[2,3] This treatment often involves the use of hard suture anchors that enable firm bone fixation and closure of the tear.[3] These implants are designed to withstand the dynamic forces at the injury site, thereby re-stabilizing the joint and restoring function.[3] Standard hard anchors require significant preparation and bone removal at the insertion site.[4] In contrast, the utilization of soft anchors aids anchor placement due to less disruption of the native anatomy. This is especially helpful should subsequent revision be necessary.[4] However, there has been inherent doubt in the minds of some surgeons as to the performance of soft anchors, especially with respect to post-operative cyclic displacement. The purpose of the current study was to assess the mechanical performance of the newly developed SUTUREFIX Ultra (Smith & Nephew, Inc.) soft suture anchors (Figure 3) with respect to both fixation and cyclic performance, compared to two hard anchor designs currently marketed for labral repair.

Figure 3: SUTUREFIX Ultra soft anchor (A) undeployed, and (B) deployed (detailed views)

Methods

Test materials

SUTUREFIX Ultra single loaded (one size #2 suture; N = 10) and double loaded (two size #1 sutures; N = 10) were compared to two controls in all tests:

- Arthrex SutureTak™ hard anchor (N = 10)
- Mitek Gryphon™ hard anchor (N = 10)

Poor bone (15 lbs/ft³,**[240.3** kg/m³ **]):** Anchors were embedded into a 15 pounds per cubic foot (pcf) Sawbones™ polyurethane bone block, simulating the softest expected decorticated bone for both hip and shoulder repair procedures.

Cortical bone (30–15 lbs/ft³ ,**[480.5–240.3** kg/m³]): A Sawbones polyurethane bone block bone block with a laminated 30 lbs/ft³ [480.5 kg/m³] simulated cortical layer of 2mm thickness (representing moderate density) was also used. This was to test the optimization of fixation achieved by cortical engagement of the SUTUREFIX Ultra anchor versus traditional anchors.

Test set-up

- **To assess fixation strength**
  Anchors were embedded into the bone blocks both with and without simulated cortical bone and all anchors were pulled to failure at 19.3 in/min [490.2 mm/min] for direct comparison.

- **To assess cyclic displacement**
  Cyclic load was also applied to all anchors (in cortical bone), simulating post-operative clinical loading (**Figure 4**):
  - 3.37 lbf [15N] preload for 1 minute
  - Cyclic loading from 3.37 lbf [15N] – 13.49 lbf [60N] at 1 Hz for 500 cycles[5]

Statistical analyses

Appropriate parametric (ANOVA, Fisher comparison) and non-parametric (Wilcoxin Mann-Whitney) statistics were used to compare groups. A 0.05 level of significance was used in all tests.

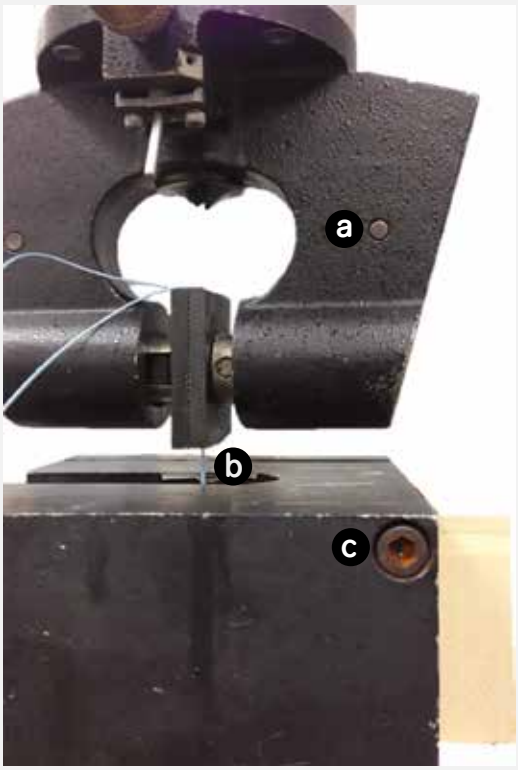

Figure 4: Anchor test set-up. A pneumatic suture grasper (a) pulls on the suture of anchors embedded in bone block with a 2cm gage length (b). The bone block is housed in a fixture to protect the simulated cortical layer (c).

Results

- In the poor bone model without a simulated cortical layer, SUTUREFIX Ultra single and double loaded anchors demonstrated statistically significantly higher fixation strength than both the SutureTak™ and Gryphon™ hard anchors ($p < 0.05$; Figure 5).

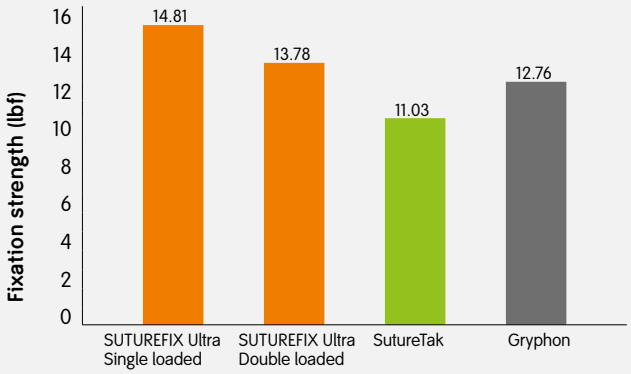

Figure 5: Anchor fixation results for poor bone simulation. (15 pcf bone block)
Fixation strength metric unit equivalents: SUTUREFIX Ultra single loaded (65.88N); SUTUREFIX Ultra double loaded (61.30N); SutureTak (49.06N); Gryphon (56.76N).

- Furthermore, there was a large increase in fixation strength for the SUTUREFIX Ultra anchors with the added laminate cortical layer. It achieved statistically significantly higher fixation strength than both control anchors ($p < 0.05$; Figure 6).

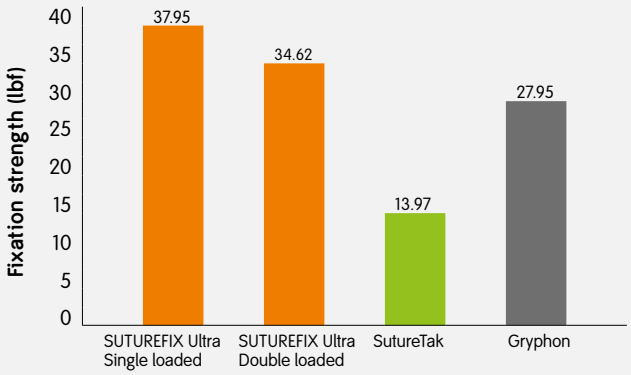

Figure 6: Anchor fixation results for bone with a cortical layer of moderate density. (30-15 pcf bone block)
Fixation strength metric unit equivalents: SUTUREFIX Ultra single loaded (168.81N); SUTUREFIX Ultra double loaded (154.0N); SutureTak (62.14N); Gryphon (124.33N).

- SUTUREFIX Ultra demonstrated the least amount of displacement following cyclic loading, statistically significantly lower than the control devices. ($p < 0.05$; Figure 7).
  - No failures were observed for SUTUREFIX Ultra.
  - A total of six* and three** anchors (Figure 7) failed to reach 500 cycles before losing fixation for the Suture-Tak and Gryphon suture anchors, respectively.

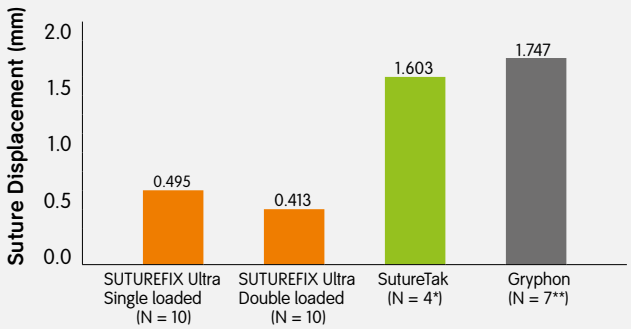

Figure 7: Displacement results after 500 cycles in cortical bone. (30-15 pcf bone block)
Suture displacement imperial unit equivalents: SUTUREFIX Ultra single loaded (0.019in); SUTUREFIX Ultra double loaded (0.016in); SutureTak (0.063in); Gryphon (0.069in).

Conclusion

Study results show that the SUTUREFIX Ultra soft anchor demonstrates significantly increased fixation strength and displacement performance when compared to two standard, hard suture anchors. These results are clinically promising, as soft anchors may be used during shoulder labral repair to reduce bone removal and aid anchor placement, attributes that could improve the likelihood of surgical success.[4]

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