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

Brett McKenzie¹, Chris Moore²
1 Smith & Nephew, Inc., Mansfield, MA, USA
2 Smith & Nephew, Inc., Memphis, TN, USA

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.

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.

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.

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.

*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.² 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

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.
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).

- 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).

- 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 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).

**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).

**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

References


**Disclaimer** Great care has been taken to maintain the accuracy of the information contained in the publication. However, neither Smith & Nephew, nor the authors can be held responsible for errors or any consequences arising from the use of the information contained in this publication. The statements or opinions contained in editorials and articles in this journal are solely those of the authors thereof and not of Smith & Nephew. The products, procedures, and therapies described are only to be applied by certified and trained medical professionals in environments specially designed for such procedures. No suggested test or procedure should be carried out unless, in the reader’s professional judgment, its risk is justified. Because of rapid advances in the medical sciences, we recommend that independent verification of diagnosis, drugs dosages, and operating methods should be made before any action is taken. Although all advertising material is expected to conform to ethical (medical) standards, inclusion in this publication does not constitute a guarantee or endorsement of the quality or value of such product or of the claims made of it by its manufacturer. Some of the products, names, instruments, treatments, logos, designs, etc. referred to in this journal are also protected by patents and trademarks or by other intellectual property protection laws even though specific reference to this fact is not always made in the text. Therefore, the appearance of a name, instrument, etc. without designation as proprietary is not to be construed as a representation by the publisher that it is in the public domain. This publication, including all parts thereof, is legally protected by copyright. Any use, exploitation or commercialization outside the narrow limits of copyright’s legislation, without the publisher’s consent, is illegal and liable to prosecution. This applies in particular to phototat reproduction, copying, scanning or duplication of any kind, translating, preparation of microfilms and electronic data processing and storage. Institutions’ subscriptions allow to reproduce tables of content or prepare lists of articles including abstracts for internal circulation within the institutions concerned. Permission of the publisher is required for resale or distribution outside the institutions. Permission of the publisher is required for all other derivative works, including compilations and translations. Permission of the publisher is required to store or use electronically any material contained in this journal, including any article or part of an article. For inquiries contact the publisher at the address indicated.