The biomechanical effects of polytetrafluoroethylene suture augmentations in lateral-row rotator cuff repairs in an ovine model

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Background: This study investigated the biomechanical effects of expanded polytetrafluoroethylene (ePTFE) suture augmentation patches in rotator cuff repair constructs.

Methods: The infraspinatus tendon in 24 cadaveric ovine shoulders was repaired using an inverted horizontal mattress suture with 2 knotless bone anchors (ArthroCare, Austin, TX, USA) in a lateral-row configuration. Four different repair groups (6 per group) were created: (1) standard repair using inverted horizontal mattress sutures, (2) repair with ePTFE suture augmentations on the bursal side of the tendon, (3) repair with ePTFE suture augmentations on the articular side, and, (4) repair with ePTFE suture augmentations on both sides of the tendon. Footprint contact pressure, stiffness, and the load to failure of the repair constructs were measured.

Results: Repairs with ePTFE suture augmentations on the bursal side exerted significantly more footprint contact pressure (0.40 \( \pm \) 0.01 MPa) than those on the articular side (0.34 \( \pm \) 0.02 MPa, \( P = .04 \)) and those on both sides (0.33 \( \pm \) 0.02 MPa, \( P = .01 \)). At 15 degrees of abduction, ePTFE-augmented repairs on the bursal side had higher footprint contact pressure (0.26 \( \pm \) 0.03 MPa) compared with standard repairs (0.15 \( \pm \) 0.02 MPa, \( P = .01 \)) and with ePTFE-augmented repairs on the articular side (0.18 \( \pm \) 0.02 MPa, \( P = .03 \)). The ePTFE-augmented repairs on the bursal side demonstrated significantly higher failure loads (178 \( \pm \) 18 N) than standard repairs (120 \( \pm \) 17 N, \( P = .04 \)).

Conclusions: Inverted horizontal mattress sutures augmented with ePTFE patches on the bursal side of the tendon enhanced footprint contact pressures and the ultimate load to failure of lateral-row rotator cuff repairs in an ovine model.

Level of evidence: Basic Science, Biomechanics.

Keywords: Rotator cuff repair; expanded polytetrafluoroethylene; patch augmentation; ovine model

Rotator cuff tears are a frequent cause of pain, weakness, and loss of motion of the shoulder. When conservative treatment of rotator cuff tears fails, surgical repair of the torn tendons can be an option to diminish pain and restore shoulder function. However, many rotator cuff repairs seem to be at risk, with failure rates ranging from 15% to more than 80% in primary cuff repairs.\(^{2,7,8,12-14,16,17,19,22,23}\)
Cadaveric studies and clinical observation have revealed that one of the main reasons for failure in rotator cuff repair is pulling of the suture through the tendon, in particular, with a diminished tendon tissue quality. To lower rates of cuff repair failure, the ability of the suture material and the suture anchor to firmly hold the tendon during the healing phase should be enhanced.

One possible strategy to prevent or delay the suture from pulling through could be augmentation of the suture strands. As a result, these sutures could provide better grip of the tendon in the repair construct. In our institution, arthroscopic lateral-row rotator cuff repairs using an inverted mattress suture in combination with the Opus Magnum 2 knotless suture anchor (ArthroCare, Austin, TX, USA) showed clinical success, with retear rates ranging from 16% to 29% using ultrasound assessment at 2 years of follow-up.

The aim of this study was to investigate the biomechanical effects of augmentation of the strands of the inverted mattress suture with small rectangular patches made from expanded polytetrafluoroethylene (ePTFE), a synthetic polymer of tetrafluoroethylene that has found numerous clinical applications for conditions in vascular and abdominal surgery, orthopedic surgery, and cosmetic surgery. The ePTFE is a strong material combined with a high degree of flexibility and is also biologically almost inert and therefore generally well tolerated when implanted. The 2 hypotheses of this study were that augmentation of the inverted mattress sutures with ePTFE patches would result in (1) an increased footprint contact pressure and (2) an increased load to failure of the repair construct when compared with standard nonaugmented repairs.

Methods

Sample size calculation

A sample size calculation was performed by use of the standard deviation (0.02 MPa) from data collected previously for the lateral-row rotator cuff repair using an inverted mattress suture configuration in an ovine model. A difference in contact pressure of 0.06 MPa between 2 types of repair was considered relevant; this would indicate a 20% increase in footprint contact pressure between repair groups. With an α of 0.05 and power of 0.80, at least 4 specimens per group were needed based on a 1-way analysis of variance sample size calculation.

Complete full-thickness tear

Twenty-four fresh frozen ovine shoulders were thawed at room temperature and dissected free of soft tissue, with only the humerus, scapula, and the infraspinatus muscle and tendon being retained. The sheep infraspinatus tendon was used because of its similarity to the human supraspinatus tendon, its reproducible biomechanical properties, and our previous experience with this ovine model. In each specimen, surgical knives and blades were used to create a complete full-thickness tear by entirely releasing the infraspinatus tendon from the bony footprint of the humerus. The cuff repairs were performed by reattaching the fully detached infraspinatus tendon to the bony footprint using knotless bone anchors in a lateral-row configuration.

Infraspinatus tendon repair

The 24 specimens were randomly assigned to each of the 4 repair groups (with an equal distribution of left and right shoulders). In the first group of 6 shoulders, a standard rotator cuff repair was performed using an inverted horizontal mattress stitch with #2 MagnumWire sutures (ArthroCare) and bone fixation with 2.8-mm-diameter Opus Magnum 2 knotless suture anchors in a lateral-row configuration. The repair technique was essentially the surgical technique of the inverted horizontal mattress repair in humans that was described in detail previously.

To standardize suture delivery in the tendon, a SmartStitch device loaded with a PerfectPasser connector (ArthroCare) was used to deliver the suture strands through the already fully released infraspinatus tendon. The PerfectPasser connector was loaded with a SmartStich #2 MagnumWire suture cartridge. After the infraspinatus tendon was grasped in the jaw of the PerfectPasser connector, the 2 needles penetrate the tendon and pull both suture ends out of the suture cartridge through the tendon at a fixed distance of 18 mm from the lateral margin of the tendon. The spacing between both strands of the suture is a fixed distance of 4.5 mm. A configuration of 2 sutures and 2 bone anchors laterally was used in all specimens (Fig. 1). The tendon repair in the 3 augmentation groups (n = 6 per group) was performed with augmentation of the sutures with small (5-× 12-mm) rectangular patches made from the commercially available 2.0-mm-thick Gore-Tex soft-tissue patch (W.L. Gore & Associates, Newark, DE, USA). The ePTFE augmentation patches were placed between the suture strands and the tendon. To prevent the ePTFE augmentation patches from slipping away from between the suture strand and the tendon tissue, the suture was threaded through the ePTFE patches. The ePTFE patch augmentations were placed between the suture strands and the tendon on top of the tendon (bursal side), on the underside (articular side), or on both (bursal and articular) sides of the repaired tendon (Fig. 2).

After the ePTFE augmentation patches were placed, the suture ends were secured to the bone by using 2 knotless bone anchors in a lateral-row configuration. The location of the suture anchors was determined with a custom-made template using an 8-mm drill hole in the center of the footprint as a reference. The suture anchors were inserted 10 mm laterally from the center of the central footprint drill hole with 13-mm distance between the centers of the 2 anchors. After the anchor bone lock was activated, suture slack was taken up by rotating the suture ratchet knobs. The tendon was advanced completely toward the 2 suture anchors laterally, and the sutures were locked in the anchors. The anchor inserter handle was withdrawn and the suture trimmed to complete the repair.

The fixed tendon fully covered the bony footprint after the repair. In all specimens, the repair was done manually by the same fellowship-trained orthopedic surgeon (L.B.). On the scapular side in each specimen, a constant 30-N pull was applied to provide tension in the repair construct (Fig. 3).
Footprint contact pressure

To measure contact pressure between the repaired tendon and the bony footprint, a 4.5-mm-diameter metal probe connected to an Instron 8874 load cell (Instron, Norwood, MA, USA) was passed through an 8-mm drill hole in the center of the bare humeral footprint of the infraspinatus tendon. This technique to measure footprint contact pressure was described in detail previously.1,21,28 The tip of the probe was positioned 1.7 mm proud to the footprint and was in full contact with the underside of the tendon. After visual verification that the probe did not contact the sides of the drill hole, the load cell was calibrated and zeroed. After infraspinatus tendon repair to the bony footprint, the footprint contact pressures were measured using the calibrated load cell at 0°, 15°, and 30° of abduction in each group with a 30 N load applied to the scapula (Fig. 3). Each specimen was preloaded for 1 minute with 10 N after the repair. The footprint pressure was dynamically measured using the probe and load cell for 30 seconds. The average recorded pressure of the middle 20 seconds was used for subsequent analysis. This series of 3 measurements with the increasing abduction angles was repeated 3 times for each specimen.

Repair stiffness and ultimate failure load

The repair stiffness and ultimate failure load of each specimen was measured with the Instron 8874 mechanical tensile testing machine. The humerus was secured to the baseplate with an 8-mm bolt. The baseplate was mounted to the tensile tester with an

Figure 1  This schematic overview shows the different infraspinatus tendon repair groups, with the tendon and its suture repair viewed from above: (A) the standard nonaugmented inverted horizontal mattress suture configuration, (B) the upper strands of the sutures on top of the tendon (bursal side) augmented with expanded polytetrafluoroethylene (ePTFE) patches, (C) the underside suture strands (articular side) augmented with ePTFE patches, and (D) the underside as well as the top side suture strands augmented with ePTFE patches.
The repaired infraspinatus tendon was dissected from the scapula and secured in a grasping clamp. The repair was tested in tension with the direction of pull perpendicular to the shaft of the humerus. The specimens were preloaded with 10 N for 30 seconds. The tendon was then pulled at 1.25 mm/s to failure, with the data captured at 100 Hz on a computer. The mode of failure was recorded with a digital camera system, and the footage was analyzed afterward.

**Figure 2**  (A) Schematic of the testing setup for measuring footprint contact pressure after infraspinatus tendon repair in an ovine shoulder at 0°, 15°, and 30° of abduction with a 30-N load across the tendon. The insert photograph shows the humeral head with its bare footprint and the probe tip positioned 1.7-mm proud with respect to the footprint. (B) Photograph shows the shaft of the humerus (S), the humeral head (HH), the infraspinatus muscle (IM), which is attached to the scapula, and a repaired tendon (T). The repair was performed with 2 inverted mattress sutures that were fixated using 2 knotless suture anchors laterally (a1 and a2), with a fixed distance between both suture anchors. Each of the 4 suture strands on top of the tendon was provided with small rectangular expanded polytetrafluoroethylene (ePTFE) suture augmentations. To prevent augmentations on the bursal side from slipping away from between the suture strand and the tendon tissue, the sutures were threaded through the rectangular ePTFE patches.

**Figure 3**  Footprint contact pressures (mean and standard error of the mean [error bars]) measured at (A) 0°, (B) 15°, and (C) 30° of shoulder abduction after infraspinatus tendon repair in the 4 different repair groups. From left to right, the vertical bars indicate tendon repair techniques using standard nonaugmented inverted horizontal mattress sutures or expanded polytetrafluoroethylene (ePTFE)-augmented sutures on the bursal side, articular side, or on both sides of the tendon. Comparisons between the repair groups were performed with 1-way analysis of variance. *P < .05 and **P < .01.

**Industrial vice.** The repaired infraspinatus tendon was dissected from the scapula and secured in a grasping clamp. The repair was tested in tension with the direction of pull perpendicular to the shaft of the humerus. The specimens were preloaded with 10 N for 30 seconds. The tendon was then pulled at 1.25 mm/s to failure, with the data captured at 100 Hz on a computer. The mode of failure was recorded with a digital camera system, and the footage was analyzed afterward.

**Statistical analysis**

Differences in footprint contact pressure, repair stiffness, and load to failure between the groups were processed by 1-way analysis of variance with correction for multiple comparisons by the Holm-Sidak method and with a significance level set at P = .05. Data in this study are reported as mean ± standard error of mean (SEM).
Results

Footprint contact pressure

The overall highest footprint contact pressure was measured for the bursal side ePTFE-augmented repairs with all of the 3 different angles of abduction (Fig. 3, A-C). Standard nonaugmented repairs recorded a footprint contact pressure of 0.36 MPa at 0° of abduction. With 15° of abduction, the footprint contact pressure decreased to less than half of the previous value. A further decline of footprint contact pressure was measured with 30° of abduction. The trend of a declining footprint contact pressure with an increasing abduction angle was also recognized in all other augmented repair groups. With 15° and 30° abduction, the bursal side ePTFE-augmented repairs exerted almost twice the footprint contact pressure compared with the standard nonaugmented repairs and the articular side ePTFE-augmented repairs. These measured differences reached statistical significance (P < .05).

Repair stiffness

Augmented ePTFE repairs on the bursal side demonstrated the highest stiffness values (Fig. 4), closely followed by the standard nonaugmented repairs and the articular side ePTFE-augmented repairs. The group with ePTFE-augmented repair on both sides showed the lowest stiffness values. No significant differences were found between the standard nonaugmented repairs and the augmented repairs.

Ultimate load to failure

Repairs with ePTFE augments on the bursal side of the tendon demonstrated the highest ultimate load to failure (Fig. 5), almost 50% more compared with the standard nonaugmented. The difference in load to failure between bursal side ePTFE-augmented and standard nonaugmented repairs showed a statistical significant difference (P < .05).

Mode of failure

In the standard nonaugmented group, the only mode of failure was by pulling of the suture through the tendon (Table 1). In the augmented repair groups, most repairs demonstrated the same mode of failure (mean of 72%). The other augmented repair constructs failed by the suture pulling from the suture anchor. The suture anchors neither failed nor were pulled out from the bony socket in any instance.

Discussion

This study showed that inverted horizontal mattress sutures augmented with small ePTFE patches had several positive effects.
biomechanical effects on the lateral-row rotator cuff repairs in an ovine model. The most important finding was that bursal side ePTFE-augmented sutures outperformed non-augmented sutures and sutures with articular side and both side ePTFE augments in footprint contact pressure after tendon repair. The contact pressure between the repaired tendon and the bony footprint is likely to be an important factor for healing after surgical repair.\textsuperscript{22} In our study, the repairs with ePTFE augmentations under the sutures on the bursal side of the tendon were able to push down the repaired tendon to the bony footprint of the humerus more firmly, resulting in higher footprint contact pressures. In contrast, when ePTFE patches were placed between the suture strands and the tendon on the articular side, the interpositioning of the small ePTFE patches somehow lifted the tendon from the bony footprint, resulting in decreased footprint contact pressures. When ePTFE patches were placed under the sutures on both sides of the tendon, the footprint contact pressure value was slightly higher, however, close to the articular side ePTFE-augmented repairs. Thus, additional bursal side ePTFE augmentations did not seem to help restore higher footprint contact pressures because the articular side ePTFE patches still had an impeding effect. In all 4 repair groups, the footprint contact pressure consistently decreased with an increasing angle of abduction of the shoulder. This finding was described previously.\textsuperscript{20}

The ePTFE-augmented repair groups also demonstrated the highest ultimate failure loads compared with standard nonaugmented repairs. We can conclude that the ePTFE patches postponed the process of cutting of the sutures through the tendon when pulled to failure. An explanation for this phenomenon is that the ePTFE patches may distribute the pressure of the suture on the tendon more evenly, thereby delaying the suture from cutting through the tendon when subjected to load.

Information regarding the use of synthetic graft materials for the bridging of massive rotator cuff defects is increasingly becoming available.\textsuperscript{9,11,15,18,24-28} An important question related to the use of synthetic graft materials is their safety. In a study by Kanbe et al,\textsuperscript{9} no major biological reaction was seen from a PTFE patch attached to cuff tissue and humeral bone in rotator cuff defect repair in 1 patient after 1 year. Kimura et al\textsuperscript{11} studied the PTFE felt–bone interface in dogs after reconstruction of a rotator cuff defect and found that fibrous tissue extended between the PTFE felt fibers. Some PTFE fibers were even incorporated into woven bone.

Ultrasound imaging was used to evaluate the short-term results of an ePTFE patch to bridge massive rotator cuff defects in 10 patients. We found excellent healing at the tendon–patch and bone–patch interfaces (with no retears) at 6 months after surgery.\textsuperscript{24} A clinical study of synthetic patch rotator cuff repair in 5 patients with long-term results was published recently.\textsuperscript{27} At a mean of 9.7 years postoperatively, all of the PTFE patches remained in situ, and no patient required further surgery. Ultrasound assessment showed that the repairs with the PTFE patches were intact in 4 of 5 patients. These studies indicate good tissue affinity of PTFE felt fibers to bone as well as to tendon. Kimura et al\textsuperscript{11} reported wear particles that were considered to have been produced as a result of fragmentation of the PTFE material. The wear particles were seen between 12 and 24 weeks and occurred in a limited area of the PTFE–bone interface in the dogs.

This study has several limitations. The tendons from the young sheep that were repaired in this study do not have the exact same anatomical measurements and might not demonstrate the same biomechanical properties as human tendons. However, the ovine model has a number of advantages that have also been recognized by other authors.\textsuperscript{5,29} By using tendons from healthy sheep, a clear comparison between the different repair groups could be made because the good tendon quality was considered to be evenly distributed in the different repair groups. Also, the sheep tendon is relatively easy to prepare for biomechanical testing owing to its size and provides a time-efficient way to investigate different cuff repairs and the influence of different repair designs with as few testing variables as possible.

Measurements of the footprint contact pressure were limited to a single location in the center of the bony footprint in this study. Whether the pressure readings in other footprint locations would show the same results would be interesting to know. However, the current design of the ovine model does not allow for more pressure readings because there is no space for additional sensors on the bony footprint. Also, due to the technical design of the ovine model, it was not possible to measure at the same time the contact pressure in combination with the contact area of the repaired tendon to the bony footprint in the repair constructs. However, it seems reasonable to expect that an increasing footprint contact pressure has a positive relation with the footprint contact area.

Many authors have recognized the high failure rate of rotator cuff repair constructs.\textsuperscript{2,7,8,16,17,19,22,23} Tendon quality and biology are among factors that cannot be controlled by the operating surgeon. However, the surgeon can choose from different suture configurations, suture materials, and suture anchors for the rotator cuff repair. Suture materials that provide more grip of the repaired tendon, preventing or delaying the failure of the repair construct, can provide improved clinical results and fewer retears. To our knowledge, no other study has studied the effects of reinforcing the suture strands of the rotator cuff repair constructs. This study found relatively small but significant differences between the different repair groups. The results indicate that there are opportunities for improvements in these repair constructs. Therefore, the effects of the ePTFE suture augmentations in human rotator cuff repairs seem to be worth studying. Before assessing the clinical relevance, the design of the patches should be further optimized to
minimize mechanical interference of the ePTFE augmentation patches with the surrounding anatomical structures (ie, coracoacromial arch).

Conclusions

In an ovine model, the bursal side ePTFE-augmented sutures achieved higher footprint contact pressures in rotator cuff repairs compared with standard non-augmented sutures or ePTFE-augmented sutures on the articular side or both sides. The ePTFE-augmented repairs also demonstrated the highest ultimate load to failure. By having a firmer grip on the repaired tendon, the bursal side suture augmentations might result in a better healing response of the torn tendon back on to the bony footprint after surgical repair. In clinical practice, a stronger repair construct might lead to a better healing response and lower retear rates in rotator cuff repairs.

Disclaimer

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