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What is This?
Biomechanical Analysis of an Ovine Rotator Cuff Repair via Porous Patch Augmentation in a Chronic Rupture Model

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Background: Rotator cuff repair is a commonly performed procedure, but many of these repairs fail in the postoperative term. Despite advances in surgical methods to optimize the repair, failure rates still persist clinically, thereby suggesting the need for novel mechanical or biological augmentation strategies. Nonresorbable implants provide an appealing approach because patch materials may confer acute mechanical stability and act as a conductive scaffold for tissue ingrowth at the site of the tendon insertion.

Hypothesis: The polyurethane scaffold mesh will confer greater biomechanical function relative to a nonaugmented repair after 12 weeks in vivo using a chronic ovine model of rotator cuff repair.

Study Design: Controlled laboratory study.

Methods: After development of the chronic rupture model, the tensile failure properties of the nonresorbable mesh-augmented repair (n, 9) were compared with those of a surgical control in an ovine model (n, 8).

Results: Rotator cuff repair with the scaffold mesh in the chronic model resulted in a significant 74.2% increase in force at failure relative to the nonaugmented surgical control (P = .021). Apparent increases in stiffness (55.4%) and global displacement at failure (21.4%) in the mesh-augmented group relative to nonaugmented controls were not significant (P = .126 and P = .123, respectively). At the study endpoint, the augmented shoulders recovered 37.8% and 40.7% of the force at failure and stiffness, respectively, of intact, nonoperated controls.

Conclusion: Using the previously described chronic rupture model, this study demonstrated that repair of a chronic tendon tear with the polyurethane scaffold mesh provides greater mechanical strength in the critical healing period than that of traditional suture anchor repair.

Clinical Relevance: This device could be used to enhance the surgical repair of the rotator cuff and consequently improve long-term clinical outcome.

Keywords: rotator cuff repair; biomechanics; chronic model; polyurethane patch

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Rotator cuff repair is a commonly performed surgical procedure, with more than 150,000 surgical repairs reported in the United States alone in 2004. However, many of these repairs fail in the postoperative term. In primary repairs, retear rates of 25% in small to medium tears and up to 90% in large and massive tears have been reported 3 to 5 years postoperatively.10,15,22,35,41 These unacceptable failure rates can be attributed to a number of factors, including the relative hypovascularity of the rotator cuff,4,7,37 which inherently limits the reparative capacity of the tendon, as well as the incurrance of forces in the shoulder during the acute rehabilitation regimen that exceed the strength of the repair. Reilly and coworkers33 demonstrated that the supraspinatus muscle generates 300 N of axial traction force as the arm is moved from 0° to 30° of abduction. This finding is particularly of concern because biomechanical studies in ovine models have demonstrated that the pullout strength of rotator cuff repairs at 12 weeks is significantly lower than this value.14,33

Although considerable effort has been put forth in developing surgical methods to optimize the fixation of tendon to bone to achieve the highest possible initial strength of the repair,8,26,28,30,39 the aforementioned repair failure rates still persist clinically, thereby suggesting the need for novel mechanical or biological augmentation strategies. As a result, the current literature is replete with investigations evaluating the initial fixation and failure strength of various rotator cuff repair techniques in large and small animal acute healing models.24,27,29,34,37 Although these studies have made important contributions, they are not capable of addressing the in vivo healing sequelae of surgical repair techniques used to treat chronic rotator cuff tears, and to date, few studies have evaluated the effects of massive nonacuate rotator cuff repairs using a chronic in vivo healing model.5 This is a relevant concern given that most rotator cuff surgeries are performed on nonacute tendon disruptions that were likely initiated months to 5 years postoperatively.10,15,22,35,41 These unacceptable results. With regard to rotator cuff repair, enhancement of the tissue repair process at the tendon defect may be achieved by augmenting the repair with a patch material that theoretically provides acute stability and acts as a conductive scaffold for tissue ingrowth at the site of the tendon insertion. This conjecture is supported by the recent work of Cole and coworkers,5 who reported 80% tissue ingrowth into a polyurethane composite mesh used to augment rotator cuff repair in rats after 6 weeks in vivo. In humans, nonresorbable mesh implants have been demonstrated to confer excellent clinical success rates and offer a permanent adjunctive to construct stability.6

Although studies have demonstrated tissue ingrowth into various scaffolds in relevant models,5,7,24,27,37 no published studies have demonstrated meaningful biomechanical improvement in a chronic tendon repair model. Optimally, the implant has to confer acute biomechanical advantages and features that allow it to be used as a scaffold for tissue ingrowth and regeneration. Additionally, the material must be biocompatible so that it does not elicit a significant foreign body response beyond that typically observed for suture material. The objective of this study was to use an ovine animal model with a chronic rotator cuff tear to evaluate 2 repair techniques with respect to biomechanical function. Our hypothesis was that a polyurethane scaffold mesh (PSM) material would confer greater biomechanical function relative to a nontreated repair after 12 weeks in vivo.

MATERIALS AND METHODS

Power Analysis

This study was designed with the ability to detect a 30% difference in ultimate force at failure between the PSM (Biomerix RCR Mesh, Biomerix Corp, New York, New York) and the nonaugmented surgical control while ensuring a power of 0.80. From our preliminary power analysis, we determined that we needed a minimum of 8 sheep per experimental group.

Experimental Design

All animal procedures were performed at an accredited hospital for veterinary medicine under a protocol approved by the Institutional Animal Care and Use Committee. The novel chronic model used in this study was designed to simulate a chronic tear of the human rotator cuff. Coleman et al8 demonstrated that this chronic shoulder model is
reproducible and can be used to analyze both a direct repair of tendon to bone and an indirect repair requiring augmentation with a patch.

Seventeen skeletally mature Rambouillet-Columbia cross ewes (4 to 7 years old) weighing between 54 kg and 82 kg were used in this study. Nine sheep were randomly allocated to a group in which the tendon repair was augmented with the PSM, and 8 sheep underwent an identical tendon repair, but the construct was not augmented (surgical control). All repaired shoulders from the 2 experimental groups were allocated for biomechanical testing. An additional 9 shoulders from the contralateral limbs were harvested and tested to represent the intact mechanical behavior of the infraspinatus tendon. The ovine model was chosen because the geometry of the infraspinatus tendon is similar to the human supraspinatus tendon in width and thickness.9,13,37

Development of the Chronic Injury Model and Surgical Repair Technique

Generation of a chronic shoulder tendon rupture was initiated by detaching the infraspinatus tendon from the proximal humerus in the sheep. A 15-cm curved incision was made over the lateral aspect of the right shoulder joint. The incision was deepened, and the acromial head of the deltoideus muscle was identified. The muscle was elevated at its cranial edge to expose the tendinous insertion of the infraspinatus muscle and its insertion into the proximal aspect of the humerus. The infraspinatus tendon was transected from its humeral insertion site. Complete transection has been shown to approximate chronic disruption of the surrounding tissue.2 The tendon terminus was covered with a 5- × 3-cm sheet of Preclude dura substitute (WL Gore and Associates, Newark, Delaware) to prevent reattachment. The Preclude dura substitute has a pore size of less than 1 μm, allowing some nutrition to diffuse to the covered aspect of the tendon while inhibiting scarring of the tendon to the surrounding soft tissue.2 The incision site was closed in a standard fashion. All animals were allowed to walk unassisted upon recovery from anesthesia. This process inevitably produces a musculotendinous construct demonstrating chronic degeneration and fatty deposits similar to those observed clinically.6

A second procedure was performed 4 weeks postoperatively. The Preclude cover was identified and removed, and the tendon was mobilized with blunt dissection. The surface of the humeral tuberosity was roughened through the use of a curette to create a bleeding surface before anchor insertion. Four Biosuture tack anchors (Arthrex, Naples, Florida) were placed in a 1- × 1-cm square configuration in the tuberosity. The infraspinatus tendon was grasped and reattached to the proximal humerus with 2 suture anchors and a Mason-Allen pattern stitch. The PSM patch (3 × 6 cm) was placed on the top of the repaired site such that approximately 1 cm of overhang remained on the tuberosity side. The anchor sutures used for the tendon attachment were passed through the patch with vertical mattress pattern to securely fix the patch on the top of the repaired tendon, thus creating a layered construct consisting of patch and tendon (Figure 1). Laterally, the remaining 2 anchor sutures were passed through the patch to secure it to the humeral tuberosity. In control animals, infraspinatus reattachment was accomplished using an identical double-row repair and Mason-Allen stitch with the same 1- × 1-cm suture anchor configuration in the humeral tuberosity, with the only difference being the lack of PSM augmentation. The wound was subsequently closed in a standard fashion.

Postoperative Care

Upon recovery from anesthesia, all animals were allowed to walk unassisted. Postoperative analgesia, consisting of intravenous and percutaneous fentanyl and oral phenylbutazone, commenced immediately after surgery and for a minimum of 72 hours. Assessment of pain was recorded daily on a scale from 0 to 17 in all sheep using an Institutional Animal Care and Use Committee–approved scoring system based on animal alertness, movement, flock behavior, feeding behavior, and respiratory rate. The animals were placed in a small pen for the first 6 weeks to limit activity. After 6 weeks, the sheep were moved to a larger pen for the remainder of their convalescence and were allowed unrestricted activity.

Sample Preparation

Three months after the tendon reattachment surgery, all animals were humanely euthanized with an intravenous overdose of barbiturate. During necropsy, each infraspinatus muscle-tendon complex and the associated humerus were harvested from the operated and nonoperated limbs (Figure 2). Gross observations were made regarding the healing of the tendon in the repaired limbs and the condition of the surrounding tissue.

Biomechanical Testing

After harvest, all soft tissues (with the exception of the superficial head of the infraspinatus) were carefully dissected from the specimen. The humerus was subsequently potted in polyvinylchloride pipe (diameter = 2 in. [5 cm]) with high-strength polymethylmethacrylate. After polymerization, the potted specimens were wrapped in saline-soaked gauze sponges and frozen at –20°C until the time of biomechanical testing. On the day of testing, specimens were thawed and rehydrated in saline. The potted humerus was attached to a custom-designed testing fixture rigidly coupled to a servohydraulic testing system (MTS 809 Axial/Torsion Test System, Eden Prairie, Minnesota) and 5-kN load cell (Figure 3). A custom-designed brass cryo-clamp, implemented to preserve the natural cross section of the infraspinatus tendon and minimize soft tissue slippage, was used to apply a uniaxial traction force to the construct at an angle of approximately 135° to the potted...
This traction angle was chosen to mimic the physiological force vector of the tendon. Testing commenced when a thermocouple attached to the cryoclamp was below –22°C, a critical temperature that has been reported to be sufficient to ensure secure coupling between the tendon and clamp. Specimens were kept moist with a saline spray during the entire preparation and mechanical testing procedure.

Biomechanical testing consisted of 2 phases: preconditioning followed by quasi-static ramp to failure. All tendons were preconditioned to normalize viscoelastic effects and testing variability through application of a static, force-controlled 40-N preload for 2 minutes. The reference gauge length was measured from the tendon’s insertion into the cryoclamp to its insertion into the humerus under preload. To minimize the viscoelastic effects on the measured biomechanical response, 10 cyclic tensile loads ranging between 0% and 2% global strain were applied to the tendon. Actuator displacement data, standardized to the pretest gauge length, were used to characterize this global strain. After preconditioning, specimens were quasi-statically tensioned in a load-to-failure ramp at 0.5% per second. Digital photographs were taken of each specimen after failure, to document the location and mode of failure. Force-displacement data were used to characterize the structural properties of failure load, failure displacement, and stiffness. Failure was characterized as the first significant decrease in the monotonically increasing load-displacement profile. Stiffness was defined as the slope of the linear portion of the force-displacement curve.

Statistical Analysis

Data are presented as mean ± standard error of the mean. Statistical differences in the biomechanical response between the PSM patch and the surgical control were determined with a 2-sample, 2-sided t test at a significance level of 5% (SigmaStat, Systat Software Inc, Richmond, California). Although reported, data from the intact contralateral controls were not included for statistical comparison.
RESULTS

The animal surgeries were uneventful, and vital signs were normal. By postoperative day 2, the pain scores were 0 to 1; by postoperative day 3, the scores were 0 in all animals. After day 3, provision of analgesics was no longer deemed necessary and was thus discontinued. During convalescence, there were no complications resulting from the surgical rotator cuff repair, no evidence of postoperative infection or drainage from the skin incisions, and no mortality in the 12-week survival period.

At necropsy, macroscopic examination of tissue adjacent to the PSM did not reveal any visible signs of adverse inflammatory reaction manifested as internal lesions to the polyurethane scaffold. Direct observation of the specimens before biomechanical testing revealed reparative scar tissue spanning a gap between tendon and bone, although it was difficult to discern scar tissue from normal tendon via gross observation, owing to the chronic model employed in this study. No gross failures of any of the PSM or surgical control specimens were noted before testing. Furthermore, the nonresorbable polyurethane mesh was not grossly visible in any of the specimens in this group, but it was completely encompassed by the fibrous reparative tissue at the repair site, which precluded any qualitative observation regarding the degree of tissue integration into the conductive mesh. However, a greater volume of new tissue formation was grossly observed at the repair site in the PSM-augmented repairs compared with the surgical controls. Finally, no gross evidence of any inflammatory response was noted in any of the treatment or surgical control specimens.

Table 1 provides raw biomechanical data from individual specimens. After the 12-week postrepair time point in vivo, rotator cuff repair with the PSM in the chronic model resulted, on average, in a 74.2% increase in force at failure (Figure 4) relative to the nonaugmented surgical control (PSM: 1327.65 ± 142.33 N; 95% confidence interval [CI], 1048.63 N, 1606.57 N; surgical control: 762.16 ± 167.50 N; 95% CI, 433.86 N, 1090.46 N)). This difference was statistically significant (P = .021). The PSM augmentation resulted in a 55.4% increase in global construct stiffness (99.23 ± 18.32 N/mm; 95% CI, 63.32 N/mm, 135.14 N/mm) and 21.4% increase in global displacement at failure (16.32 ± 1.16 mm; 95% CI, 14.05 mm, 18.59 mm) relative to the surgical control (respectively, 63.84 ± 10.45 N/mm;

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<th>Displacement at Failure (mm)</th>
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*PSM, polyurethane scaffold mesh.

**Figure 4.** Failure force (top) and stiffness (bottom) quantified during quasi-static ramp-to-failure testing, respectively. Calculated means shown with standard errors of the mean. RCR, rotator cuff repair.
95% CI, 43.36 N/mm, 84.32 N/mm; 13.72 ± 1.07 mm; 95% CI, 11.62 mm, 15.82 mm). These increases in stiffness and displacement were not statistically significant (P = .126 and P = .123, respectively). Force at failure, global construct stiffness, and global displacement at failure for the 9 intact contralateral infraspinatus tendons were 3516.39 ± 279.61 N, 243.60 ± 23.73 N/mm, and 13.44 ± 1.47 mm, respectively.

Construct failure for the augmented and surgical control groups primarily occurred in the proximal region of the tendon at the surgical site. Specifically, 89% of the PSM specimens (8 of 9) and 100% of the surgical controls (8 of 8) failed within this region. In the PSM group, failure was manifested as soft tissue rupture at the interface with the humeral tuberosity. One specimen in the PSM group failed via bone anchor pullout from the humeral tuberosity. No suture cutout was noted in any of the specimens in the PSM group, and no mesh failures were noted in this group. Conversely, mode of failure in the surgical controls was mixed and manifested as either tissue rupture at the bone interface or suture cutout from the repair tissue.

DISCUSSION

Rotator cuff repair failures are attributed to a number of factors associated with tendon healing, including poor tissue quality, defect size, and forces transmitted through the repair that approach and/or exceed the strength of the repair in the early rehabilitation process. As a result, retear rates have been reported in clinical studies, ranging from 25% to 90%, suggesting that augmentation strategies are necessary to reduce the frequency of rupture in the early postoperative period. Ideally, an augmentation device must be biocompatible; it must have an initial strength to act as a splint across the repair site; and it initially acts as an internal splint to confer immediate postoperative strength above and beyond that of the non-augmented repair. However, the PSM patch used in the current study is nonbiodegradable and resulted in a statistically significant 74.2% increase in force at failure after 12 weeks in vivo. Although speculative, extrapolation of this finding suggests the same result or a similar result in a cadaveric study.

MacGillivray and coworkers used a goat model to evaluate the biomechanical and histological effect of a poly-L-lactic acid bioresorbable scaffold on rotator cuff repair temporally over the course of 6 months in vivo. At each time point, they found no significant biomechanical enhancement with the poly-L-lactic acid scaffold, despite histological evidence that the scaffold did serve as a 3-dimensional template for tissue ingrowth. Our findings differ on a number of levels. First, we used a nonresorbable polyurethane mesh. Our goal here was to use a material that would act as an internal splint immediately after the repair and that would continue to confer strength to the repair up to and beyond the acute healing phase. This vision was realized as returned biomechanical performance of the PSM-augmented shoulders that was significantly increased relative to the surgical control at our study endpoint. Second, the biomechanical findings of MacGillivray et al were conducted in parallel with robust histological analyses. Although this was not the case in our study, we have augmented our PSM biomechanical study with preliminary qualitative histological analyses on 4 specimens treated with the PSM patch to evaluate the biocompatibility of this device, scaffold/tissue integration with bone, and scaffold quality after 12 weeks in vivo. Our initial findings are encouraging and so indicate that (1) Sharpey fibers of the tendon and their interdigitation with bone collagen through a layer of fibrocortilage were observed in some regions of the bone-tendon interface, (2) the patch
material was intimately associated with scaffolding of fibrovascular collagenous tissue, and (3) the PSM did not elicit an adverse immunogenic response beyond that noted to suture. We anticipate that more robust, semiquantitative histological evaluations will confirm our early findings.

The sheep infraspinatus tendon displays similar geometry and mechanical properties to those of the human supraspinatus tendon. Thus, this model serves as a good approximation of the human anatomy, although several limitations should be noted. The sheep shoulder is a weightbearing joint. Therefore, it is likely that the acute, cyclic loads encountered in this model during convalescence are significantly greater than those in humans. This model thus serves as a worst-case model within which to evaluate the potential of various therapeutic adjuncts in rotator cuff repair. Like others, we considered immobilization of the sheep after the surgical repair, employing methods similar to those used by Lewis et al21 and Rodeo and coworkers.34 However, Lewis et al21 reported that there was no significant difference in rotator cuff repair load at failure or stiffness between immobilized and nonimmobilized sheep undergoing the same surgical procedure after 26 weeks in vivo. These results suggest that the degree of postoperative movement restriction is not a confounding factor when employing the ovine model; thus, we opted not to immobilize the sheep in the current study. Despite the aforementioned issues, we believe that the results of our current study are valid, given that the nonimmobilized, chronic sheep model allowed for a comparative investigation of 2 groups of sheep that underwent identical surgical reattachment of the rotator cuff and identical rehabilitation programs, with the PSM patch supplementing the infraspinatus repair in one of the groups.

In summary, we used our previously published chronic rupture model26 that more closely resembles the human clinical scenario25 to evaluate a nonabsorbable PSM in rotator cuff repair. Like others, we considered immobilization of the sheep after the surgical repair, employing methods similar to those used by Lewis et al21 and Rodeo and coworkers.34 However, Lewis et al21 reported that there was no significant difference in rotator cuff repair load at failure or stiffness between immobilized and nonimmobilized sheep undergoing the same surgical procedure after 26 weeks in vivo. These results suggest that the degree of postoperative movement restriction is not a confounding factor when employing the ovine model; thus, we opted not to immobilize the sheep in the current study. Despite the aforementioned issues, we believe that the results of our current study are valid, given that the nonimmobilized, chronic sheep model allowed for a comparative investigation of 2 groups of sheep that underwent identical surgical reattachment of the rotator cuff and identical rehabilitation programs, with the PSM patch supplementing the infraspinatus repair in one of the groups.

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