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ORIGINAL ARTICLE

Radiologic and clinical evaluation of a bioabsorbable collagen implant to treat partial-thickness tears: a prospective multicenter study

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Background: Treatment of partial-thickness cuff tears remains controversial. Although conservative therapy may treat symptoms, these defects do not spontaneously heal and conversion to a full-thickness lesion with subsequent repair may alter the tendon footprint. The ability to induce new tissue formation and limit tear progression in intermediate- and high-grade partial-thickness tears without surgical repair may represent a significant advancement in the treatment paradigm for these lesions.

Methods: We prospectively enrolled 33 patients with chronic, degenerative, intermediate-grade (n = 12) or high-grade (n = 21) partial-thickness tears (11 articular, 10 bursal, 4 intrasubstance, and 8 hybrid) of the supraspinatus tendon in a multicenter study. Following arthroscopic subacromial decompression without repair, a bioinductive implant was attached over the bursal surface of the tendon. Clinical outcomes were assessed using American Shoulder and Elbow Surgeons and Constant-Murley scores preoperatively and at 3 and 12 months postoperatively. Magnetic resonance imaging was performed to assess postoperative tendon healing and thickness at the original tear site.

Results: At 1-year follow-up, clinical scores improved significantly ($P < .0001$) and the mean tendon thickness increased by 2.0 mm ($P < .0001$). Magnetic resonance imaging evidence of complete healing was found in 8 patients and a considerable reduction in defect size was shown in 23, whereas 1 lesion remained stable. In 1 noncompliant patient with a high-grade articular lesion, progression to a full-thickness tear occurred while shoveling snow 1 month after surgery. No serious adverse events related to the implant were reported.

This study was approved by Western Institutional Review Board (Puyallup, WA) (protocol No. 20141137). The common protocol of this study had institutional review board approval for each investigational site.

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Conclusions: Arthroscopic implantation of a bioinductive collagen scaffold is a safe and effective treatment for intermediate- to high-grade partial-thickness rotator cuff tears of the supraspinatus tendon.
Level of evidence: Level IV; Case Series; Treatment Study

Keywords: Arthroscopy; rotator cuff tear; partial-thickness; shoulder; biological augmentation; tissue induction; collagen implant; magnetic resonance imaging

Partial-thickness rotator cuff tears (PTRCTs) represent a relatively common shoulder pathology with a prevalence approximately twice that of full-thickness tears.[8] However, treatment of PTRCTs remains controversial. Although a number of surgical techniques have been used to treat PTRCTs,[5,6,9,12,19-21,24,25,27,33,36,40,43,46] prospective randomized trials comparing outcomes have not identified one technique to be superior over another.[12,36] Treatment of PTRCTs involving less than 50% of the tendon thickness ranges from nonoperative activity modification and rehabilitation to tear débridement with or without subacromial decompression.[4,11] However, because PTRCTs do not heal spontaneously,[4,13-15] they have a propensity to increase in size and may develop into full-thickness lesions.[23,28,48] A recent prospective evaluation of asymptomatic degenerative tears reported that 44% of partial-thickness tears with a median length of 6 mm increased in size over a 5-year follow-up.[23] Although some surgeons have advocated conversion of PTRCTs to full-thickness lesions that are then repaired by conventional methods,[9,12,20,21,24,25,33,37,38] these techniques can have a reported failure rate of up to 18%.[29] The ability to limit tear progression or induce healing of PTRCTs without the need to convert these to full-thickness repairs is an attractive treatment option because it would not only preserve the native footprint of the intact tendon but also potentially reduce the attendant increase in recovery time associated with such repairs.

A preliminary study by Bokor et al[4] demonstrated magnetic resonance imaging (MRI) evidence of PTRCT healing following treatment with a highly porous collagen implant arthroscopically placed over the bursal surface of the supraspinatus tendon. Patients with intermediate- to high-grade bursal, articular, or intrasubstance partial-thickness tears of the supraspinatus tendon demonstrated no tear progression and showed progressive filling in of the defects coupled with improvement in tendon quality through 2-year follow-up. The mechanism of action for this healing response is thought to be related to the ability of the collagen implant to induce new host tissue formation and ingrowth over the bursal surface of the tendon.[4,45] This increase in tendon thickness is thought to improve the local biomechanical environment of the tear by reducing tendon strain, thus optimizing its healing potential.[4,45]

In an effort to validate initial findings, we conducted this study to further evaluate the safety and effectiveness of the same bioinductive implant in the arthroscopic treatment of intermediate- to high-grade PTRCTs in a larger patient population across multiple institutions. We hypothesized that when placed over the bursal surface of an injured tendon, the collagen implant would induce rapid host tissue ingrowth and create an environment that would either prevent tear enlargement or permit healing of the lesion as determined by MRI.

Materials and methods

A prospective, multicenter, open-label trial was conducted by 10 surgeons at 10 sites under a common protocol. All patients provided voluntary informed consent before enrollment.

Eligibility criteria

Patients were aged at least 21 years and had a diagnosis of a chronic, degenerative partial-thickness tear primarily of the supraspinatus tendon involving at least 25% of its thickness that was unresponsive to conservative treatment, such as pain medication, physical therapy, or injections, for a minimum of 3 months. A preoperative MRI scan was performed within 60 days prior to the procedure. Patients with full-thickness tears of the rotator cuff were excluded, as were those who presented with PTRCTs caused by acute injury or those who had undergone previous rotator cuff repair on the index shoulder. The exclusion criteria also included shoulder instability, chondromalacia of grade 3 or greater, cuff muscle fatty infiltration of grade 2 or greater, severe calcification within the index shoulder, and insulin-dependent diabetes. Patients with Workers' Compensation coverage; heavy smokers (>1 pack per day); those with a known hypersensitivity to bovine collagen; those with a genetic collagen disease; and those with a history of autoimmune, immunodeficiency, or chronic inflammatory disorders were excluded. To avoid potential inhibition of the healing process, oral steroid use within 2 months or a steroid injection within 1 month of enrollment was prohibited.

Patient evaluation

Prior to surgery, the medical history was recorded and each patient underwent a physical examination. In addition, the standardized American Shoulder and Elbow Surgeons (ASES) and Constant-Murley patient assessments were administered, and a noncontrast MRI scan of the affected shoulder was performed using a study-specific acquisition protocol. After eligibility was confirmed, the study procedure was performed within 60 days of this preoperative, or baseline, evaluation. At the time of surgery, intraoperative arthroscopic assessment of the rotator cuff pathology and visual confirmation of partial-thickness tear size were reviewed and recorded by the surgeon to confirm eligibility. Patients with a partial-thickness tear of less than 25% of the tendon thickness were not enrolled in the study.

Postoperative follow-up was performed 3 months and 1 year after the study procedure. At each follow-up, patients underwent a repeat

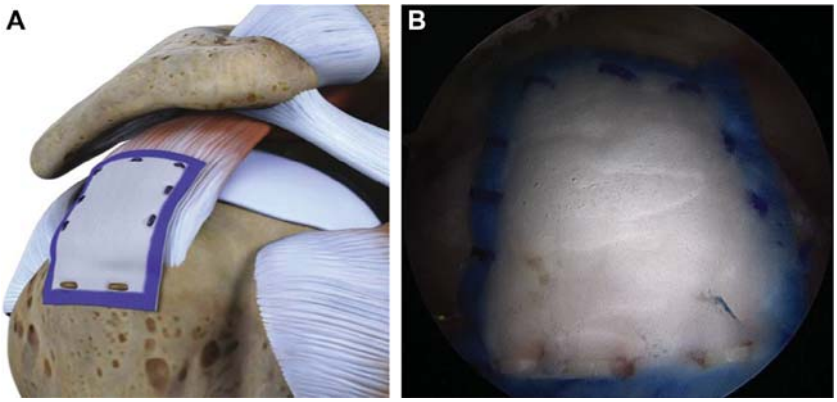

Figure 1 (**A**) Schema of the device placed over the width of the supraspinatus tendon extending laterally over the footprint and onto the humeral head. The device is fixed to the bursal surface of the tendon with 2 anterior, 3 medial, and 2 posterior polylactic acid tendon staples and anchored to bone with 2 polyetheretherketone bone staples. (**B**) Arthroscopic image of the bioinductive implant in the final position over a high-grade, articular-sided partial-thickness tear.

MRI scan using the study-specific acquisition protocol and completed a clinic visit during which the ASES and Constant-Murley surveys were administered. Duration of sling immobilization, time to return to work, time to return to activity considered by the patient to be "normal" (full, unrestricted activity), and cumulative number of physical therapy visits to a physical or rehabilitation therapist were self-reported by the patients to further assess recovery. Finally, all patients were monitored for adverse events related to the procedure or study device, and any revision or additional shoulder operations performed between discharge and 1-year follow-up were recorded.

Surgical technique

The arthroscopic surgical implant technique has been previously described.[4,35] Surgery was performed with the patient under general anesthesia in either the lateral decubitus or beach-chair position. The glenohumeral joint was assessed arthroscopically. Fraying of the labrum was débrided if necessary, and biceps tenotomy or tenodesis was performed if clinically indicated. With the arthroscope in the subacromial space, a bursectomy and acromioplasty were performed. If indicated, the coracoacromial ligament was released and minor fraying of the cuff tendon was débrided. Removal of the periosteum lateral to the footprint was performed to ensure adequate positioning and fixation of the collagen implant to bone.

The study system included the bioinductive collagen implant, polylactic acid (PLA) tendon staples, and polyetheretherketone bone staples (Rotation Medical, Plymouth, MN, USA). All devices had previously received 510(k) clearance by the US Food and Drug Administration. The bioinductive implant was made from highly purified type I bovine collagen and engineered into a highly oriented, highly porous (85%-90% porosity) scaffold that, once hydrated, was approximately 2 mm thick. The collagen implant was not designed to provide structural support immediately after surgery and absorbs within 6 months, whereas the PLA staples absorb within 12 months after implantation. Proprietary, single-use disposable instruments were used to arthroscopically deliver the implant into the subacromial space and position it over the bursal surface of the supraspinatus tendon with the lateral edge of the implant overlapping onto the humeral head approximately 5 mm beyond the lateral edge of the supraspinatus footprint. Two implant sizes (20 × 25 mm or 25 × 30 mm) were available, and the surgeon selected the size as necessary to cover the partial-thickness tear and the width of the supraspinatus tendon. PLA staples were used to attach the implant to the tendon, and PEEK bone staples anchored the lateral edge of the implant to the humeral head with the implant under slight tension. (Fig. 1). Standard methods were used for closure.

Rehabilitation

Patients followed a rehabilitation program that was accelerated compared with rehabilitation after full-thickness takedown rotator cuff repair.[18,44] Shoulder immobilization was discontinued as soon as comfortable, and patients were allowed to progress to motion as tolerated, moving from passive to active-assisted to active motion. For the first 4 weeks, forward flexion was limited to 100°. External rotation with the arm by the side was allowed, but abduction–external rotation was not allowed for the first 6 weeks. After 6 weeks, no restrictions were imposed on motion or arm use.

MRI assessment

All sites performed the same study-specific, noncontrast MRI examination protocol on the affected shoulder. MRI scans were obtained preoperatively and at 3 and 12 months after surgery. The scans were performed with the shoulder in slight external rotation using a dedicated shoulder coil. The field strength was 1.5 T at a minimum, the field of view was 12 cm, the slice thickness was 2 mm, and the interslice gap was 0.2 mm. Images including oblique coronal, sagittal, and axial images oriented to the shoulder were obtained with proton density, with and without fat saturation, and with non–fat saturation T2-weighted scans. All of the magnetic resonance images were read by a single musculoskeletal radiologist who was blinded to the clinical outcomes.

Tendon thickness measurements were made in the area of the tear from coronal images according to the method previously described by Bokor et al.[4] Measurements of the supraspinatus tendon were made at, and adjacent to, the partial-thickness tear. All postoperative MRI measurements were made as close as possible to the location of the original partial-thickness tear where the preoperative measurements were made.

On the basis of MRI assessment, defect tear size was categorized as no tear, low grade (<25% of the thickness of the tendon), intermediate grade (25%-50% of the tendon thickness), or high grade (>50% of the tendon thickness but less than full thickness). Determination of defect size was made by analyzing the entire sequence of images from the coronal, sagittal, and axial scans and characterizing the percent fill-in of the original defect.

Statistical analysis

Descriptive statistics were used to summarize patient demographic data, intraoperative surgical assessments, and patient recovery outcomes. Changes between baseline and postoperative clinical outcomes (ASES and Constant-Murley scores) and tendon thickness were compared using paired, 2-tailed Student *t* tests. All statistical calculations were made using SAS software (SAS Institute, Cary, NC, USA). All *P* values were considered significant at a 2-sided significance level of .05.

Results

We enrolled 33 patients in the study, 19 men and 14 women, with a mean age of 54.6 years (range, 34-75 years). The mean duration of preoperative pain in the affected shoulder was 21.6 months (range, 4-144 months).

On the basis of intraoperative arthroscopic visual assessment of partial-thickness tear size at the time of surgery, 12 patients had intermediate-grade tears (25%-50% of the tendon thickness) and 21 had high-grade tears (>50% of the tendon thickness but less than full thickness). Of the tears, 11 were articular sided, 10 were bursal sided, and 4 were intrasubstance. Eight patients presented with hybrid tears, in which partial tearing was observed in 2 distinct regions: articular and bursal sided (n = 4), bursal sided and intrasubstance (n = 3), or articular sided and intrasubstance (n = 1). A breakdown of tear size and location is presented in Table I. The biceps tendon was not surgically treated in 24 of 33 patients (73%), whereas 5 patients (15%) underwent a biceps tenodesis and 4 (12%) underwent a tenotomy.

Study MRI scans at 1-year follow-up were obtained for all 33 patients (100%). Of the patients, 32 (97%) completed the clinical examination and shoulder surveys at 1 year, whereas 1 patient failed to return to the clinic within the 1-year follow-up visit window despite multiple attempts to reach the patient to schedule the visit. The mean length of follow-up was 12.4 months (range, 10.8-13.5 months).

MRI assessment of tendon thickness and tear size

At 3 months following surgery, 6 tears (18%) had completely filled in (no tear), 25 (76%) showed a reduction in defect size of at least 1 grade, and 1 (3%) remained unchanged (Table I). One patient, with a high-grade, articular-sided tear

Table I Improvement and healing of partial-thickness defects by tear location and size over 12-month period

				Postoperatively	
Location of tear	n	Tear size	Preoperatively	3 mo	12 mo
Articular	11*	No tear	0	2	1
		Low grade	0	7	8
		Intermediate grade	6	1	1
		High grade	5	0	0
Bursal	10	No tear	0	2	5
		Low grade	0	8	4
		Intermediate grade	2	0	1
		High grade	8	0	0
Intrasubstance	4	No tear	0	1	0
		Low grade	0	2	3
		Intermediate grade	0	1	1
		High grade	4	0	0
Articular and bursal	4	No tear	0	1	1
		Low grade	0	3	3
		Intermediate grade	2	0	0
		High grade	2	0	0
Bursal and intrasubstance	3	No tear	0	0	0
		Low grade	0	2	2
		Intermediate grade	2	1	0
		High grade	1	0	1
Articular and Intrasubstance	1	No tear	0	0	1
		Low grade	0	1	0
		Intermediate grade	0	0	0
		High grade	1	0	0

* One patient did not comply with the rehabilitation protocol and reinjured the treated tendon while shoveling snow 1 month after surgery, resulting in a full-thickness tear.

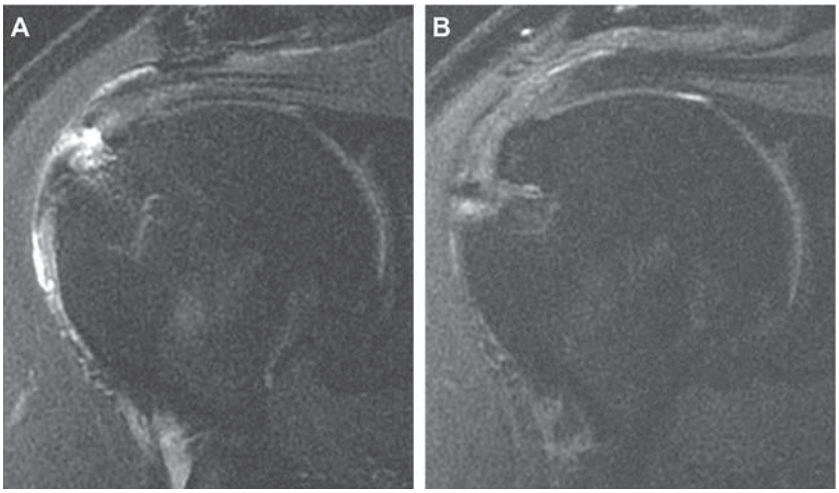

Figure 2 (**A**) Preoperative magnetic resonance image demonstrating a high-grade, bursal-sided partial-thickness defect of greater than 50% of the tendon thickness with less than 1 mm of the supraspinatus tendon intact at the lesion location. (**B**) One year after surgery, the thickness of the supraspinatus tendon at the defect location increased to 5.5 mm and the defect was completely healed (100% fill-in) with no visible boundary between the implant and underlying tendon.

preoperatively, did not comply with the rehabilitation protocol and reinjured the treated tendon while shoveling snow approximately 1 month after surgery, resulting in a full-thickness tear.

At 12 months after surgery, 8 patients (24%) showed no visible defect on MRI, 23 (70%) had a decrease in tear size by at least 1 grade from baseline, and 1 (3%) had a tear that remained unchanged (Table I). None of the partial-thickness tears progressed to full-thickness tears in the patients who followed the postoperative rehabilitation protocol, and no patients had undergone revision surgery through 1-year follow-up.

MRI evaluation showed that a layer of new tissue was consistently induced over the bursal surface of the supraspinatus tendon, as evidenced by a statistically significant increase ($P < .0001$) in tendon thickness. Before surgery, the mean tendon thickness at the defect location was 3.1 ± 0.3 mm (standard error of the mean [SEM]). At 3 months following surgery, the mean tendon thickness at the defect location was 5.4 ± 0.3 mm (SEM), for a mean increase of 2.2 ± 0.3 mm (SEM). This increase in thickness remained stable at 12 months after surgery, at which time the tendon thickness measured 5.2 ± 0.2 mm (SEM), for a mean thickness increase of 2.0 ± 0.3 mm (SEM) (Tables II and S1). When the postoperative rehabilitation protocol was followed, the tendon thickness at the defect location increased in 30 patients (94%). In 2 patients, the tendon thickness at the defect location at 12 months was slightly thinner than the preoperative thickness despite partial fill-in of the lesions and reduction in the degree of tear by 1 grade. The tendon thickness in 1 patient whose defect improved from a large- to intermediate-grade tear decreased by 0.5 mm, whereas in a second patient whose defect improved from an intermediate- to low-grade tear, it decreased by 0.2 mm. The MRI appearance of the new tissue in all patients showed a progressive maturation over time, such that by 1 year, the new tissue was indistinguishable from the underlying tendon (Fig. 2).

Subgroup analysis

The effect of the preoperative degree of tearing on the increase in tendon thickness was assessed. For intermediate-grade (25%-50% of the tendon thickness) partial-thickness tears (n = 12), the mean preoperative tendon thickness was 3.4 ± 0.4 mm (SEM), and the mean tendon thickness increased significantly by 1.4 mm ($P = .003$) at 1 year. For high-grade (>50% of the tendon thickness but less than full thickness) partial-thickness tears (n = 21), the mean preoperative tendon thickness was 3.0 ± 0.4 mm (SEM), and by 12 months, the mean tendon thickness increased significantly by 2.3 mm ($P < .0001$, Table II). Comparisons of tendon thickness increases between these subgroups at both 3 and 12 months were not statistically significant ($P > .15$).

To further assess the healing effect of the bioinductive implant, the changes in tendon thickness and defect size over time were analyzed according to the location of the partial-thickness tear. The mean tendon thickness in 11 patients with partial tearing on the articular surface of the supraspinatus tendon increased significantly by 1.8 mm ($P = .01$) at 3 months. This increase was sustained (1.7 mm, $P = .01$) through 12 months. The mean increase in tendon thickness at 3 and 12 months in 10 bursal-sided defects was 2.5 mm ($P < .01$) and 2.2 mm ($P < .01$), respectively. Comparison of the thickness increase between groups was nonsignificant ($P > .4$). The increase in tendon thickness for the other subgroups ranged from 0.7 to 2.5 mm (Table S1).

Partial to complete healing of the preoperative partial-thickness defects at 1-year follow-up occurred in 10 of 11

Table II Magnetic resonance imaging–based thickness of supraspinatus tendon by size of partial-thickness defect

Tear size	n	Baseline, mm		3 mo postoperatively, mm			12 mo postoperatively, mm		
		Mean	SEM	Mean	SEM	Change	Mean	SEM	Change
Intermediate grade (25%-50%)	12	3.4	0.4	5.1	0.2	+1.7	4.8	0.2	+1.4
High grade (>50%)	21	3.0	0.4	5.6	0.4	+2.6	5.4	0.3	+2.3

SEM, standard error of mean.

articular-sided tears (91%) and 9 of 10 bursal-sided tears (90%), as evidenced by a reduction in tear size from either an intermediate- or high-grade tear to either a low-grade defect or the absence of a visible tear (Table I). In the other 2 patients (1 articular and 1 bursal), the tear size decreased from high grade to intermediate grade. Similar healing trends were observed over sequential postoperative MRI assessments of intrasubstance and hybrid (ie, combined articular-bursal, bursal-intrasubstance, or articular-intrasubstance) partial-thickness defects. When compared with the preoperative tear size, none of the tears increased in size and all but 1 tear decreased in size at 1-year follow-up. The 1 tear that was not smaller in size at 1-year follow-up was a high-grade hybrid tear (bursal-intrasubstance) preoperatively, which had improved to an intermediate-grade tear at 3 months but returned to a high-grade tear at 1 year (Table I).

Clinical assessment, recovery, and satisfaction

Shoulder pain and function improved significantly over the 1-year postoperative period. The ASES pain score improved significantly from 4.2 ± 0.4 (SEM) at baseline to 0.6 ± 0.2 (SEM) at 1 year ($P < .0001$), and the ASES shoulder function score and ASES shoulder index score also improved significantly from 16.9 ± 1.3 (SEM) before surgery to 25.1 ± 1.5 (SEM) at 1 year ($P < .0001$) and from 57.0 ± 3.2 (SEM) before surgery to 89.1 ± 2.8 (SEM) at 1 year ($P < .0001$), respectively (Table S2). Improvements in both the ASES pain score and ASES shoulder index score were also approximately 2 times greater than the minimal clinically important differences (MCIDs) of 1.4 and 12.01-16.92, respectively.[41,42] The Constant-Murley shoulder score improved significantly from 57.1 ± 2.8 (SEM) at baseline to 81.4 ± 2.2 (SEM) at 1 year ($P < .0001$, Table S2), which was also greater than twice the MCID of 10.4.[26] In addition, ASES and Constant-Murley scores were compared between those patients with (n = 9) and without (n = 24) concomitant biceps surgery, and neither cohort saw significantly better improvement in pain or shoulder indexes compared with the other.

Shoulder immobilization in a sling averaged 23.3 ± 2.4 days (SEM). Return to work and full unrestricted activity averaged 30.5 ± 12.0 days (SEM) and 4.0 ± 0.7 months (SEM), respectively. Patients completed an average of 18 ± 1.6 physical therapy visits (SEM) over the duration of their shoulder rehabilitation. Patient satisfaction remained very high 1 year after surgery, with 30 patients (94%) either agreeing or strongly agreeing that they were satisfied with the results of their surgical procedure. Two patients were neutral about their results, and none reported dissatisfaction with the study procedure.

Complications

In 1 patient, the 3-month study MRI scan showed increased accumulation of prominent subacromial fluid without clinical symptoms. Ultrasound-guided aspiration was performed, and a very small amount of normal physiological fluid was reported by the pathologist and considered nonreactive to the implant. The event spontaneously resolved without clinical sequelae, and the 1-year MRI scan confirmed resolution of fluid accumulation in the joint. One patient reported pain approximately 3 months after surgery that began shortly after the patient reached aggressively for a blanket using the treated shoulder to put out an electrical fire. A shoulder MRI scan was performed to rule out tendon injury, and the findings were negative. The pain was treated with a cortisone injection and subsequently resolved. Postoperative superficial skin issues were presented by 2 patients (1 with an allergic reaction to the skin preparation and 1 with wound drainage due to stitch abscess); both resolved. There was 1 serious, non–device-related adverse event in which a patient underwent cardiac ablation and overnight hospitalization. No other device- or procedure-related adverse events were reported.

Discussion

Management of PTRCTs remains controversial. Because of the lack of spontaneous healing in these lesions[15] and the propensity for partial-thickness tears to enlarge or progress to full-thickness tears,[48] arthroscopic treatment is commonly undertaken for tears that do not improve with nonoperative care. Studies attempting treatment of these tears with débridement without repair have shown highly variable results. Whereas some have reported good or excellent results in 85% of their patients,[2] others have reported satisfactory results in only half of the patients.[32] In 1 case series, failure of the tendon resulting in reoperation occurred in 25% of the cases.[10] Another study reported on patients a minimum of 5 years after débridement and acromioplasty without repair and found 35% of the tears had progressed to full-thickness tears, thus concluding that débridement with acromioplasty does not protect the cuff from further degeneration.[22]

An arthroscopic surgical technique that has been advocated by some authors for PTRCTs is the conversion of the tear to a full-thickness tear followed by repair.[9,21,24,25,33] Although satisfactory results have been reported in 83%-98% of cases,[9,21,33] a study using ultrasound imaging of the cuff revealed that the repaired tendon had developed into a full-thickness tear in 12% of patients.[21] In addition, an MRI study has reported an 11% retear rate for bursal-sided tears and an 8% retear rate for articular-sided tears.[24]

A potential disadvantage of tear conversion and repair is that this method requires intact tissue to be taken down to complete the tear, which can cause a length-tension mismatch of the repaired cuff and alter the normal footprint.[27] Not only does this introduce biomechanical challenges within the rotator cuff, but rehabilitation of surgically repaired shoulders may include up to 6 weeks of shoulder immobilization followed by gradual progression from passive to active motion and strengthening over a rehabilitation period of at least 6 months.[17,30] Postoperative rehabilitation and recovery observed in this study suggest that patients with intermediate- to high-grade partial-thickness lesions treated with the bioinductive implant in lieu of takedown and repair may have experienced a more rapid recovery than anticipated. Therefore, a surgical procedure that preserves the native cuff anatomy while biologically augmenting the degenerative tissue, mitigating increased strain within the tendon and potentially prompting quicker recovery, is of interest to physicians and their patients.

The bioinductive collagen implant used in this study was shown consistently to induce the formation of new tendinous tissue on the bursal surface of the supraspinatus tendon, as well as improve the quality (based on MRI) of the native tendon. In this study the mean increase in tendon thickness was 2.2 mm at 3 months following surgery, which is consistent with previous studies of this implant in sheep and in humans.[4,45] Similar to the results of these studies, the implant-generated host tissue in our study matured over time and remained stable at 12 months. A recent study examining postoperative biopsy specimens from clinical cases of rotator cuff repair has confirmed the ability of this implant-generated host tissue to rapidly mature into tendon-like tissue.[3]

Our study also demonstrated complete healing of the partial-thickness defects in 8 patients and reduction in defect size in 23 patients over the 12-month study period. Except for the 1 noncompliant patient with progression to a full-thickness tear while shoveling snow at 1 month, none of the defects increased in size. This finding is in agreement with a previous clinical study.[4] Although the mechanism by which the partial-thickness tears heal or decrease in size (especially those on the articular surface of the cuff) is not fully understood, the working hypothesis assumes that tissue induction on the bursal surface of the tendon increases tendon thickness and reduces local tendon strain, thereby improving the healing potential of the tendon. MRI analysis in our study, as well as in the previously published clinical study,[4] confirms that healing of these defects does occur. The working theory for this healing process is based on a finite element model that suggests that the addition of 2 mm of new host tissue on the bursal surface of PTRCTs could reduce strain in the tendon at the tear site by 47% for bursal tears and 40% for articular tears.[4,7] The ability to reduce tendon strain through the rapid, implant-mediated induction of new host tissue is thought to improve the biomechanical environment of the lesion, thus allowing for optimization of the healing process.[4] The absence of tear progression and the complete or partial healing observed in the current and previous clinical studies[4] appear to support this hypothesis.

Both the Constant-Murley and ASES scores improved significantly over time, with postoperative improvement at 1 year well over the MCID thresholds reported in the literature.[26,41,42] However, previous studies have reported satisfactory results ranging from 45%-88% following treatment of PTRCTs with arthroscopic acromioplasty alone.[1,4,16,34,47] When compared with these previous studies, the 94% satisfaction result in our study coupled with the 92% satisfaction result in a previous study of this implant[4] suggests some clinical benefit from the induction of new host tissue (as well as the filling in of the partial-thickness defects) over acromioplasty alone.

Treatment of the biceps was at the clinical discretion of each surgeon on the basis of patient history and intraoperative arthroscopic assessment. Of the 11 patients with an isolated articular-sided tear (Table I), 45% underwent concomitant biceps treatment (tenodesis in 3 and tenotomy in 2). In one retrospective review, concomitant fraying or tearing of the biceps was observed in 35% of patients with articular-sided partial-thickness tears,[31] which is representative of our experience reported in this study. Although there is no evidence to suggest concomitant biceps treatment would bias the increase in tendon thickness or defect fill-in as reported in our study, biceps treatment may have contributed to improvement in patient clinical scores. Although stratification by tear location would have resulted in sample sizes too small for robust statistical analysis, clinical scores in patients with and without biceps surgery independent from tear location did not demonstrate significant differences in ASES and Constant-Murley scores between the 2 groups. In addition, comparison of changes in the ASES pain score, ASES shoulder score, and Constant-Murley shoulder score from baseline to 1-year follow-up between the 2 groups showed no significant difference. Further comparative studies are necessary to fully understand the impact concomitant biceps treatment may have on patient-reported clinical scores.

Finally, the lack of a case-matched control cohort does not permit a critical analysis of recovery time (shoulder immobilization, return to work, and so on) in our study population compared with that experienced by patients undergoing partial-thickness tear conversion and repair. Although such comparisons will require a prospective control cohort, anecdotal observations by two of us (T.F.S. and B.D.B.) tend to suggest a more rapid recovery in the patients treated in our study.

As previously noted, the primary limitation of this study is the lack of a prospective control group. However, there is

a substantial body of literature documenting conditional successes and variable failure rates of surgical interventions to treat medically refractory PTRCTs, and none of these methods, including techniques to structurally or biologically augment rotator cuff tendons, have shown the ability to increase tendon thickness or prevent tear enlargement.[2,22,34,39] Although surgical treatment of the partial tear was limited to débridement and arthroscopic onlay of the collagen implant at the defect site, thereby mitigating the likelihood that concomitant treatments biased tissue induction, acromioplasty and surgical treatment of the biceps, when indicated, may have contributed to clinical improvements reported in this study. Additional randomized studies are necessary to assess potential improvements in shoulder pain, strength, and function resulting from the study device alone.

Conclusions

Arthroscopic placement of a bioinductive collagen implant on the bursal surface of the supraspinatus tendon at the location of intermediate- and high-grade partial-thickness tears, including bursal, intrasubstance, and articular partial-thickness tears, has been shown to significantly increase the cross-sectional thickness of the tendon. In addition, the absorbable implant has consistently resulted in partial to complete fill-in of the original bursal, intrasubstance, and articular partial-thickness tear defects as early as 3 months postoperatively, with sustained efficacy through 12 months, without any evidence of adverse reactions or infection. Because the native tendon footprint remains intact around the location of the defect, postoperative rehabilitation and recovery may be accelerated as compared with more conservative postoperative management when partial-thickness lesions are taken down and repaired as full-thickness tears. Consistent healing and mitigation of tear progression suggest this bioinductive implant may be an alternative surgical treatment for intermediate- to high-grade partial-thickness tears.

Disclaimer

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Supplementary data

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