Evaluation of Healing Rates and Safety With a Bioinductive Collagen Patch for Large and Massive Rotator Cuff Tears

2-Year Safety and Clinical Outcomes

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Background: Failure of repair of large and massive rotator cuff tears is a challenging problem within orthopaedics. Poor tendon tissue and vascularity are known causes for failure of rotator cuff repairs.

Purpose: To assess the safety, outcomes, and healing rates when large and massive rotator cuff repairs are augmented with a bioinductive collagen scaffold patch in a proof-of-principle design.

Study Design: Case series; Level of evidence, 4.

Methods: Twenty-three patients undergoing repair of full-thickness large (2-tendon) or massive (3-tendon) rotator cuff tears augmented with a bioinductive collagen patch were enrolled in a prospective single-arm proof-of-principle study. No partial repairs were performed, and a complete rotator cuff repair was successfully achieved in each case. Sixteen patients underwent revision rotator cuff repairs versus 7 primary repairs. Safety was determined by any implant-related adverse event. A single magnetic resonance imaging (MRI) scan was utilized to confirm tendon healing and thickness at a minimum of 6 months postoperatively. Postoperative ultrasound (US) was used in office by the treating surgeon to assess tendon thickness at 3-, 6-, 12-, and 24-month intervals. American Shoulder and Elbow Surgeons (ASES) scores were collected at final follow-up.

Results: Overall, a 96% (22 of 23) healing rate was confirmed on US and MRI. However, incidence of treatment clinical failure was 9% (2 of 23), as 1 patient's tendon healed but eventually underwent additional surgery. There were no adverse events attributed to the implant reported. Final US rotator cuff thickness was 7.28 ± 0.85 mm (mean ± SD), and final MRI rotator cuff thickness was 5.13 ± 1.06 mm. The mean ASES score at final follow-up was 82.87 ± 16.68 (range, 53.33-100).

Conclusion: No complications attributed to the implant were reported, and new tendon formation was apparent on US and MRI, with relatively high healing rates at 2-year follow-up. Arthroscopic application of this bioinductive collagen scaffold when combined with rotator cuff repair is a safe and effective treatment for healing of large and massive rotator cuff repairs.

Keywords: shoulder; rotator cuff; collagen scaffold; bioinductive implant

Rotator cuff tears are a common problem, and the overall number of patients affected will rise as our population continues to age. As the number of rotator cuff tears rises, the incidence of large and massive rotator cuff tears requiring surgical intervention will also expand.[2,14,18] Despite a comprehensive understanding of the rotator cuff and biomechanically advanced surgical repair techniques, there is still a subset of rotator cuff tears that go on to failure.[2,14,18] Outcomes following repair of these rotator cuff tears depend on factors such as tear size, chronicity of the tear, patient age, and muscle atrophy.[11,12,14] Long-term data show that anatomic healing of rotator cuff tears produces better outcomes.[3,11,20,34]

Failure of anatomic repairs is reportedly 20% to 40% after primary rotator cuff repairs and is even higher in revision cases.[3,11,13,24,26] The inability to obtain high healing rates has spurred the investigation of biological options to augment rotator cuff repairs. Structural augmentation, such as periosteal patches, extracellular matrix, even freeze-dried rotator cuff, has been used with fair to poor results.[6-9,22,27,33]

It was shown that the mechanical properties of repaired rotator cuff tissue is significantly reduced as compared with the native tendon.[25] Instead of trying to compensate for poor tendon quality with structural support, newer technology has been developed to promote tendon

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vascularization and growth. The Rotation Medical bioinductive implant is a nonstructural, highly porous collagen scaffold made from highly purified type I bovine collagen. The scaffold has a weak tensile strength and provides no structural support. It is designed to induce collagen formation and remodeling of the damaged tissue, leading to an increased overall thickness of the healed tendon.[32] The patch provides the framework for the tendon to heal with increased thickness and strength. We believe that the added thickness decreases the strain and stress seen at the tendon during active use, decreasing the risk of failure and future tear propagation.

BIOLOGY OF THE IMPLANT

In a sheep model, this implant has induced the formation of new tendon that consisted of collagen fibers well organized in the direction of load.[32] The patch was found to completely incorporate by 6 months, and no foreign body reactions have been appreciated to date.[1,32] Approximately 2.5 mm of additional tissue was induced from the patch in those studies as compared with controls. The new tissue was well integrated into the native rotator cuff and showed a fibrocartilaginous transition from tendon to bone.

In human trials, the bioinductive collagen patch has been applied to the bursal side of the rotator cuff during repair. Initially, 9 patients with medium-sized tears underwent rotator cuff repair and augmentation with the patch. All were followed for 24 months with serial magnetic resonance imaging (MRI), with no failures occurring in that span. By 3 months, all patients had implant-induced tissue formation, with an additional 2 mm of new tissue reported at final follow-up.[5] In another study,[4] the same authors placed the nonstructural bioinductive collagen patch on 13 patients with intermediate- to high-grade partial-thickness rotator cuff tears without performing a repair. By 3 months, all patients showed new tissue formation averaging 2.2 mm of increased tendon thickness. Of 13 patients, 7 had complete healing, and the rest had no progression of the tears. The 2 mm of increased bursal cuff thickness has been proposed to reduce stress within the damaged tendon and provide an environment that allows for tendon-to-bone healing.[9,32] Most recently, Schlegel et al[30] performed a prospective multicenter trial using a similar protocol in the United States. They similarly reported improvements in outcome scores, no tear progressions, and 94% of patients with either no progression of tears or a reduction in defect size after 1 year.

Early results in small groups of patients have shown evidence of healing in partial-thickness rotator cuff tears and medium-sized rotator cuff tears with excellent healing rates and results.[4,5,30] Having seen the success of this implant in smaller tears,[4,5,30] we thought that it potentially had an appropriate application in the more difficult-to-heal large and massive rotator cuff tears. It is our hypothesis that the collagen patch may induce formation of functional tendon-like tissue at the site of the rotator cuff footprint in these tears as well. Therefore, the primary purpose of this prospective study was to first assess the safety of the collagen implant in this patient population and secondarily measure healing rates and complications associated with the implant's use.

METHODS

A prospective single-arm open-label trial was conducted by 2 surgeons (M.J.O., F.H.S.) at a single site under a common protocol as a proof-of-principle study to assess the safety and healing rates of using a bioinductive collagen patch for large and massive rotator cuff tears. All patients voluntarily consented to having the procedure done with the specified implant before enrollment. Each patient also agreed to undergo ultrasound (US) examination at each clinic visit and a single MRI scan postoperatively. Approval was granted from our institution's review board.

Eligibility Criteria

Patients with large (2-tendon) and massive (3-tendon) rotator cuff tears per the original Cofield classification[10] that required surgical repair were offered the addition of the nonstructural, highly porous collagen implant (Rotation Medical) to their rotator cuff repairs. Inclusion criteria for the study was any patient aged >30 years who underwent repair of a large or massive rotator cuff tear with the addition of the collagen scaffold implant. Any patient with a large or massive rotator cuff tear measuring >3 cm and with retraction of at least 3 cm as measured on preoperative MRI scan were considered for the study. Each patient meeting these criteria was offered placement of the collagen scaffold patch in addition to the repair. In each case, the patient was asked to agree to serial US examinations and to undergo single-study MRI performed 6 to 24 months postoperatively. The need for a revision rotator cuff repair did not exclude a patient from study consideration.

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Exclusion criteria included age <30 years, Hamada grade ≥3 preoperative rotator cuff arthropathy,[19] Goutallier grade ≥3 muscle atrophy,[17] <2-year clinical follow-up, and/or unwillingness to complete the study protocol, including postoperative MRI.

Patients were enrolled on a volunteer basis for a consecutive 18-month period from July 2014 through December 2015. All patients who met the inclusion criteria were offered augmentation of their repairs with the patch and elected to undergo the procedure. Every patient had undergone extensive prior treatment that included physical therapy, injections, and/or anti-inflammatory medication for a minimum of 6 weeks before surgical intervention. All patients who had previous rotator cuff repairs had undergone the same nonoperative treatment either through our clinic or at the time of previous surgery. Twenty-three patients with full-thickness rotator cuff tears involving at least 2 tendons were voluntarily enrolled and followed prospectively. Each patient received preoperative MRI within 4 months of operative intervention confirming a large or massive rotator cuff tear. Preoperative MRI was read by a staff radiologist and the operative surgeon to determine if the patient met inclusion criteria for the study.

Outcomes

The primary outcome measure was safety with implant use. Failure was determined as any implant-related adverse event, any failure of the implant itself, noted complications attributed to the implant, or any implant-related tissue reaction during the study period. Patients were strictly monitored for adverse events throughout the length of the study period, which included but were not limited to hospitalization, medical or surgical intervention, further illness, worsening or permanent impairment, implant loosening, allergic reaction, or death.

Secondary outcome measures included tendon thickness at each US examination, change in tendon thickness on US (assessment of tissue induction), tendon thickness on MRI, MRI confirmation of tendon continuity, and American Shoulder and Elbow Surgeons (ASES) patient evaluations at final follow-up. Successful outcome on imaging was determined by healed rotator cuff tissue on the serial USs and the single MRI in the 2-year follow-up period. Secondary treatment failure was a lack of healing on either imaging modality (US and/or MRI) or the need for additional surgical procedures to be performed on the same shoulder during the study period, including conversion to reverse total shoulder arthroplasty.

Radiographic Assessment

US evaluations were performed by the operative surgeon at postoperative office visits at 3, 6, 12, and 24 months. The point of measurement was at the lateral edge of the articular cartilage and slightly posterior to the bicipital groove. This corresponds to the anterior cable of the supraspinatus and usually measures 8-mm thickness in normal rotator cuffs with our technique.

Every patient underwent MRI to assess the competency and tissue quality of the rotator cuff repair after at least 6 postoperative months with a target of postoperative 1 year for full maturation. In the animal model[32] and second-look human trials,[1] the implant was shown to be fully integrated into the native tissue by 6 months. MRI was ordered before the 1-year mark in the event of an issue in the postoperative period. This would include any complications, plateau of progress, onset of new symptoms, or suspected adverse reaction to the implant. All postoperative MRI scans were deidentified and read by the 2 senior authors of the study (M.J.O., F.H.S.). Final thickness measurements between the 2 surgeons were averaged and reported for each patient.

Surgical Technique

Each patient received a supraclavicular block preoperatively and was placed under general anesthesia. Patients were positioned in the lateral decubitus or beach-chair position (depending on surgeon preference). After standard arthroscopic glenohumeral assessment, capsular releases were performed to allow for appropriate humeral head positioning and rotator cuff mobility. In our practice, all patients with large, massive, or retracted cuff tears or those undergoing revision procedures have capsular releases performed during the procedure. In the current study, this consisted of a 360° capsular release, release of the coracohumeral ligament, and, in tears with significant retraction (greater than 3-5 cm), arthroscopic suprascapular nerve decompression. Each patient had a tear that measured >3 cm and included a minimum of 2 full tendons (large tear) or >2 full tendons (massive). Surgery included extensive debridement and releases with any additional bone work (subacromial or subcoracoid decompression, distal clavicle excision), biceps treatment, and suprascapular nerve decompression as indicated in each case.[29] Rotator cuff repair was performed with variable combinations of convergence sutures and suture anchor repair to the greater tuberosity, resulting in each patient's receiving a double-row transosseous equivalent repair. The complete capsular release and mobilization by advanced techniques allowed for a complete double-row repair over the greater tuberosity footprint. This allowed for the patch to be placed directly onto the repaired tendon with the lateral poly-L-lactide acid (PLLA) anchors, fixing the lateral aspect of the patch to the most lateral aspect of the repaired tendon, and avoiding the use of bone staples when stable fixation was achieved with the PLLA anchors.

No partial repairs were performed, and a complete rotator cuff repair was successfully achieved in each case. Likewise, no medialization of the footprint was performed. Our surgical techniques were previously reported and published extensively.[16,21,23,28,29]

After rotator cuff repair, the bioinductive patch was then implanted through a lateral or posterior portal. The bioinductive patches are available in 2 sizes: medium (20 × 24 mm) and large (25 × 30 mm). The appropriate patch was chosen according to the patient's size and repair

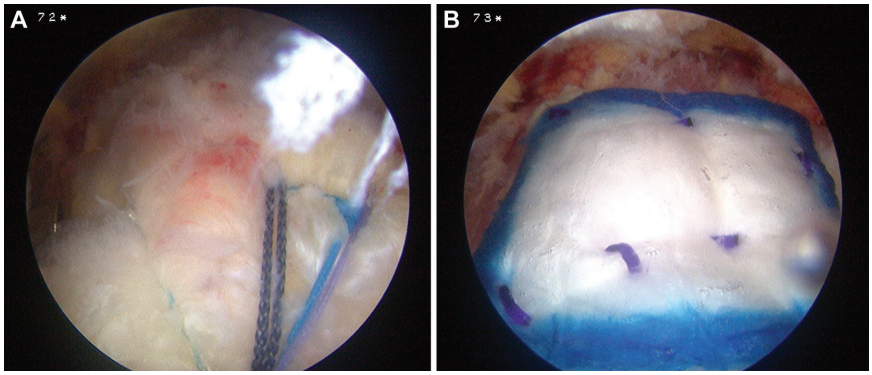

Figure 1. (A) Large rotator cuff tear repaired with double-row transosseous technique without patch applied. (B) Same repair with the patch and included PLLA staples to secure the patch to the repaired tendon on the medial and lateral margins of the repair. Optionally, the patch can be applied laterally and secured with the included PEEK bone staples (not pictured). PEEK, polyether ether ketone; PLLA, poly-L-lactide acid.

dimensions. An additional posterior lateral portal was made for visualization. Our preferred portal for implant introduction is via an anterior lateral portal, which allows the patch to be directly aligned with the anterior edge of the repaired supraspinatus tendon. This allows the patch to be inserted parallel to the repaired tendons and their footprints on the tuberosity. An 8.25 mm–diameter cannula was used for implant passage.

Once inserted through the desired cannula and viewed from an accessory portal, the implant was centered over the repaired supraspinatus and infraspinatus tendons. It was then deployed with the supplied delivery instrument and held in place over the repaired tendon, with the anterior edge set along the anterior edge of the supraspinatus tendon. A superior portal just lateral to the acromion was then established to implant the staples for patch fixation. The lateral, medial, anterior, and posterior edges were stapled with the supplied staple gun and bioabsorbable staples. Figure 1 demonstrates an intact repair before and after application of the implant.

Postoperative Rehabilitation Protocol

Postoperatively, each patient's arm was placed into an abduction pillow sling for 6 to 8 weeks. Cryotherapy was used immediately postoperatively and through the first 8 weeks as well. Our standard postoperative rehabilitation protocol for large/massive rotator cuff tears was followed, and no changes to our postoperative protocols were made in patients with the implant. Scapular retraction exercises were started postoperative day 1. The abduction pillow was worn at all times, including sleep, for 6 to 8 weeks. Only passive range of motion was allowed for the first 4 to 8 weeks. After 8 weeks, the patients began a progressive active range of motion protocol. Once active range of motion had returned to 85% to 90% of the unaffected extremity, the patients were allowed to start light strengthening exercises. This most commonly began at about 16 weeks postoperatively. We routinely counseled our patients that even with a successful repair, the affected extremity would in general reach only 80% of the function of the unaffected extremity.

Data Analysis

SPSS (v 25.0 for MacOS; IBM) was used for data analysis. Descriptive statistics were reported for mean and SD. Group proportions were reported with the chi-square test. Mann-Whitney U tests and analysis of variance are reported to compare groups of means for nonparametric and parametric data, respectively. Two-tailed P values with 95% CIs are reported, with $P < .05$ considered significant.

RESULTS

Demographics and Baseline Rotator Cuff Status

The 23 patients who completed the study protocol had a mean age of 57.9 years (range, 32-71 years); 15 were men and 8 were women (Table 1). No patients who enrolled in the study were lost to follow-up. Of the 23 patients, 16 were undergoing revision rotator cuff repairs versus 7 primary repairs. Eleven patients were classified as having large rotator cuff tears (2-tendon tears) and 12 patients with massive rotator cuff tears (3-tendon tears) per preoperative MRI. In addition to complete rotator cuff repair, 19 patients underwent subacromial decompression; 17, distal clavicle excision; 12, biceps tenodesis/tenotomy; and 5, suprascapular nerve release. There was no statistically significant difference in the number of primary versus revision repairs and large versus massive tears (Table 2). There was no difference in age or distribution of men and women between the primary and revision groups ($P = .48$ and $P = .68$, respectively) (Table 3). There was no difference in age found between the large and massive tear groups ($P = .52$) (Table 4). Of the patients with massive rotator cuff tears, 11 were men and 1 was a woman, which

TABLE 1
Descriptive Data of Included Patients: Mean Thickness of Rotator Cuff Tendon as Measured by US and MRI[a]

Mean age, y (range)	57.9 (32-71)
Sex, n	
Male	15
Female	8
Overall rate, n (%)	
Healing	22 of 23 (96)
Success	21 of 23 (91)
Mean thickness on postoperative US, mm	
3 mo	6.29
6 mo	6.75
12 mo	7.72
24 mo	7.28
Thickness on MRI, mm, mean ± SD (range)	5.13 ± 1.06 (3.97-6.84)
Final ASES score, mean ± SD (range)	82.87 ± 16.68 (53.33-100)

[a]ASES, American Shoulder and Elbow Surgeons; MRI, magnetic resonance imaging; US, ultrasound.

TABLE 2
Distribution of Primary and Revision Repairs and Large and Massive Tears[a]

Repairs	Large Tears	Massive Tears	Total	*P* Value (χ^2)
Primary	2	5	7	
Revision	9	7	16	
Total	11	12	23	.22

[a]No significant difference was found in the distribution of the included patients.

was significantly different when compared with patients with large tears ($P < .05$).

MRI Assessment

Mean time to postoperative MRI was 13 months (range, 7-16 months). Mean thickness on postoperative MRI was 5.13 ± 1.06 mm for all intact tendons. Figure 2 demonstrates intact tendon on postoperative MRI at 13 months with no evidence of the implant noted or seen.

Ultrasound Assessment

Mean initial postoperative US measurement for the rotator cuff at 3 months was 6.29 mm (range, 3.5-9 mm). The mean final US measurement was 7.72 ± 0.85 mm (range, 6.3-9 mm) at final follow-up at 24 months. There was no difference between the final rotator cuff thickness on US between primary and revision cases (7.18 mm vs 7.43 mm, respectively; $P = .82$) and between large and massive tears (7.78 mm vs 7.03 mm, respectively; $P = .20$). Figure 3 shows the mean thickness of the tendon on US at each follow-up.

Healing Rates and Clinical Outcomes

The tendon healing rate on both imaging modalities (US and MRI) was 96% (22 of 23). Of the 23 patients, 22 had a rotator cuff tear that healed in its entirety. Overall final ASES score was 82.87 ± 16.68 (range, 53.33-100) for all patients. Mean final ASES scores for primary repairs and revision repairs were 86.39 ± 14.20 and 82.22 ± 21.34, respectively. No difference was found between the final scores of these 2 groups ($P = .69$). Mean final ASES scores for large tears and massive tears were 83.66 ± 18.76 and 84.81 ± 17.91, respectively. No difference was found between the final scores of these 2 groups ($P = .92$). Tables 3 and 4 show comparison data of primary and revision repairs and large and massive tears, respectively. Table 5 shows comparisons of all final ASES scores.

Two failures were noted: 1 for a lack of healing and 1 attributed to progression of arthritis of the glenohumeral joint and worsening atrophy of the rotator cuff muscles. In the case that failed because of a lack of healing, the supraspinatus tendon failed to heal; however, the infraspinatus tendon did heal per MRI. Treatment failure was suspected at the patient's 3-month visit owing to limited progression with therapy, which was later confirmed on MRI. The additional failure was considered a clinical failure rather than a healing failure, given the progression of the patient's arthritis and further atrophy of her rotator cuff muscles. This patient underwent a reverse shoulder arthroplasty 25 months after her initial surgery. Overall, this yielded a 9% (2 of 23) failure rate between the 1 imaging failure and the 1 clinical failure. A detailed analysis of each failure is given in the Appendix (available in the online version of this article).

Complications

There were no postoperative infections or adverse events associated with the device. No patients were found to have any biologic reaction to the bioinductive patch. Of the 23 patients, 8 (35%) had postoperative scapular dyskinesia requiring prolonged therapy and bracing. All improved with treatment by the end of the study period. As stated earlier, 1 patient went on to reverse total shoulder arthroplasty owing to progression of pain and dysfunction.

DISCUSSION

The safety of any xenograft product has been justifiably questioned since the study by Iannotti et al,[22] in which a porcine product used to supplement rotator cuff repair demonstrated severe tissue reaction and rejection. The bioinductive patch used in this study is purified, very porous bovine collagen. Each initial study on the implant did not demonstrate any rejection or foreign body reaction.[4,5,30,32] The results of this study were consistent with those

TABLE 3
Primary vs Revision Repairs: Demographics, Healing Rates, and Final ASES Scores[a]

	Primary (n = 7)	Revision (n = 16)	*P* Value
Age, y, mean ± SD	61.0 ± 2.52	56.6 ± 2.91	.48
Sex, n			.68
Male	5	10	
Female	2	6	
Successful healing, n (%)			
Overall	7 of 7 (100)	14 of 16 (88)	.33
Large tears	2 of 2 (100)	8 of 9 (89)	.62
Massive tears	5 of 5 (100)	6 of 7 (86)	.38
Final ASES score, mean ± SD	86.39 ± 14.20	82.22 ± 21.34	.69

[a]*P* values reported are from chi-square or *t* test where appropriate. Successful outcome on imaging was determined by healed rotator cuff tissue on both the serial ultrasounds and the single magnetic resonance imaging in the 2-year follow-up period. ASES, American Shoulder and Elbow Surgeons.

TABLE 4
Large vs Massive Tears: Demographics, Healing Rates, and Final ASES Scores[a]

	Large (n = 11)	Massive (n = 12)	*P* Value
Age, y, mean ± SD	56.45 ± 3.76	59.25 ± 2.44	.52
Sex, n			.005[b]
Male	4	11	
Female	7	1	
Successful healing, n (%)			
Overall	10 of 11 (91)	11 of 12 (92)	.84
Primary repairs	2 of 2 (100)	5 of 5 (100)	.23
Revision repairs	8 of 9 (89)	6 of 7 (86)	.85
Final ASES score, mean ± SD	83.66 ± 18.76	84.81 ± 17.91	.92

[a]There was a statistically different proportion of men to women across the large and massive groups. *P* values reported are from chi-square or *t* test where appropriate. ASES, American Shoulder and Elbow Surgeons.
[b]$P < .05$.

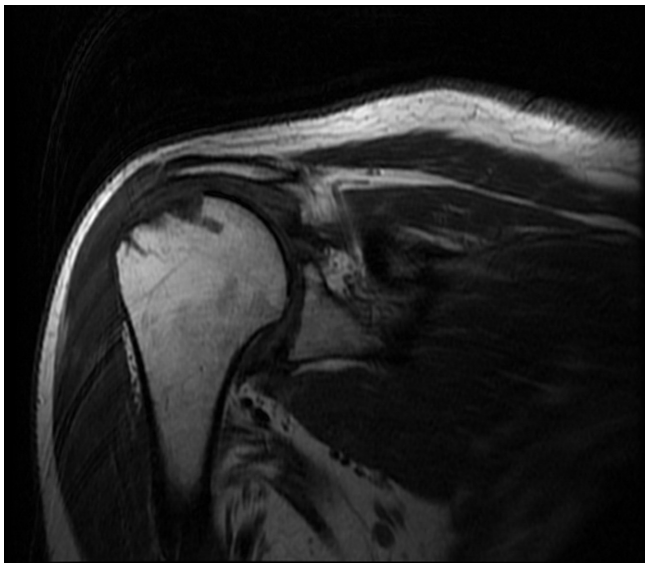

Figure 2. Confirmatory fat-suppressed T2 coronal magnetic resonance imaging cut shows intact tendon and no evidence of implant at 13 months after revision rotator cuff repair.

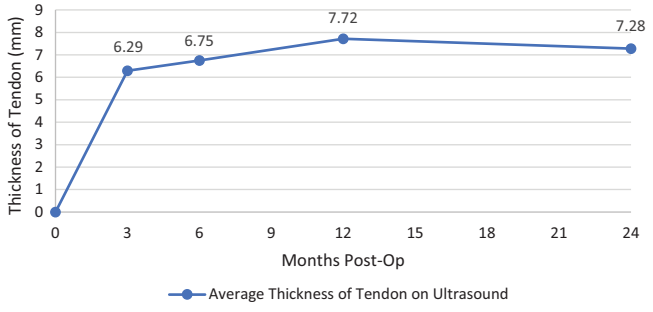

Figure 3. Mean thickness of tendon as measured on ultrasound at clinical follow-up visits of 3, 6, 12, and 24 months.

findings in that no foreign body reaction or evidence of tissue reaction was noted clinically, by US, or by MRI, thereby indicating a reasonable safety profile.

Initial human studies centered on the efficacy of this implant in partial rotator cuff tears. In the United States, a recently published multicenter study showed excellent results in stimulating a healing response in partial-thickness tears.[30] Imaging consistently showed formation

TABLE 5
Final ASES Scores With Comparison *P* Values of Primary and Revision Repairs and Large and Massive Tears[a]

	ASES Score, Mean ± SD (Range)	*P* Value
Overall (N = 23)	82.87 ± 16.68 (53.33-100)	
Repair		
Primary (n = 7)	86.39 ± 14.20 (63.33-100)	
Revision (n = 16)	82.22 ± 21.34 (53.33-100)	.69
Tear		
Large (n = 11)	83.66 ± 18.76 (53.33-100)	
Massive (n = 12)	84.81 ± 17.91 (63.33-100)	.92

[a]ASES, American Shoulder and Elbow Surgeons.

of new tendon tissue. The present study differs from these earlier studies in the selection of patients with notably more difficult, large, complete, and relatively more avascular rotator cuff tears. The senior author's (F.H.S.) initial thoughts on the use of this bioinductive implant centered on these more difficult situations, where the enthesopathic environment is detrimental to tissue healing. These tears have been shown to have a less successful healing rate as compared with partial rotator cuff tears. Improving the local healing environment has been tried by various methods without success. The bioinductive implant was conceived as a porous nonstructural implant to improve local vascularity. We therefore set up a prospective study utilizing the patch to supplement the repair of large to massive primary or revision rotator cuff tears (2- to 3-tendon involvement with >3-cm retraction). As a bioinductive tissue, it was thought that the implant would stimulate improved blood flow and tissue healing. We measured this healing response by serial ultrasonography at regular intervals, and in each successful patient, the imaging did indeed seem to show better and more thick tendon in the area of measurement. Although only 1 patient underwent tissue biopsy, the formation of tendon tissue in the area of placement of the patch seems to indicate some efficacy of the bioinductive response.

The findings of our present study reveal that the arthroscopic application of a bioinductive collagen patch in the setting of large and massive rotator cuffs may provide benefits to healing these difficult repairs. The postoperative US scans demonstrated increases in tendon thickness as far out as 12 months. Tendon thickness was also shown to maintain throughout the study period. Most important, no complications or adverse reactions attributed to the implant were encountered, which was consistent with prior works.[4,5,30,32]

The implant is designed to stimulate collagen formation and tissue healing and to improve vascularity. As demonstrated in previous investigations,[4,5,30,32] it has been shown to provide excellent tissue formation and integration in the animal model, partial rotator cuff tears, and single-tendon tears. While large and massive rotator cuff tears continue to present a problem in regard to healing, we believe that this collagen scaffold implant helps to increase the tendon thickness and vascularity in these enthesopathic tendons. Additionally, the revision setting presents a uniquely difficult problem. with healing rates as low as 60% to 80%.[3,11,13,24] Our tendon healing rate of 96% is improved from these prior works and includes a majority of revision cuffs (16 of 23 patients), albeit in a small sample size. This increase in tendon healing rates is no doubt due to multiple factors; however, we achieved minimal conversion to arthroplasty despite the revision nature of the majority of patients after 2 years. We believe that improving the local biology by applying the patch improves the chances of successful healing in this difficult cohort of patients. Only long-term data will ultimately tell, but early results are promising in this initial cohort.

This study has several limitations, most notably a small sample size and a lack of control arm. A lack of a control arm prevents any direct comparison with any other technique in regard to strength, range of motion, functional outcomes, and so on. The patients were also not randomized or blinded to their treatment arm, as patient participation was voluntary, which may inadvertently lead to some sort of selection bias that cannot be controlled for in this type of study design. Another significant limitation of this study is the use of US by the treating surgeon as an imaging modality and measurement tool. US has been shown to be user dependent, and the treating surgeons were not blinded to the postoperative results. The in-office US was, however, consistently performed by the same operator at every visit, which would limit the variability in technique that can occur because of user interdependence. Despite these limitations, US does have significant benefits in that it is a validated diagnostic tool,[15,31] is readily accessible at all time points, has minimal to no extra cost to the facility or patient, requires little effort from the patient, and has virtually no risks to the patient.

Preoperative functional outcome scores (ASES scores) were not obtained for comparison pre- to postoperatively. However, the primary outcome and purpose of this proof-of-principle study was to determine the safety outcomes with the use of this implant in this unique population, with clinical outcome scores a secondary outcome. Randomized prospective future trials comparing multiple treatments would be beneficial to identify clear indications for the use of this bioinductive collagen scaffold. In addition, follow-up was only 2 years; longer follow-up would help assess the viability of the patch long term as well as its effect on modifying clinical outcomes. Our results show, however, that it may have utility in improving the healing rates of large and massive rotator cuff repairs, including revisions, and most important, we found no identifiable adverse events associated with its use in the procedures performed in this study.

CONCLUSION

Arthroscopic application of this bioinductive collagen scaffold when combined with rotator cuff repair is a safe and effective treatment for healing of large and massive rotator

cuff repairs. No complications attributed to the implant were reported, and new tendon formation was apparent on US and MRI with relatively high healing rates at 2 years.

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