Patient-Reported Outcomes After Use of a Bioabsorbable Collagen Implant to Treat Partial and Full-Thickness Rotator Cuff Tears

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Purpose: To collect outcomes data on patients treated with a bioinductive collagen implant designed to induce rotator cuff healing in partial- and full-thickness cuff tears and to assess the safety and efficacy of the device. **Methods:** Fifteen surgeons in 15 centers in the United States enrolled patients between April 2016 and August 2017 and collected standardized outcomes data. Patients 21 years of age and older, able to read and speak English, and with partial- or full-thickness tears of the rotator cuff documented by magnetic resonance imaging were included in the study. Patients were assessed preoperatively with visual analogue scale (VAS), single-assessment numeric evaluation (SANE), Veterans RAND 12-Item (VR-12), American Shoulder and Elbow Surgeons (ASES), and Western Ontario Rotator Cuff (WORC) outcomes measures. Postoperative assessment was made at 2, 6, and 12 weeks, 6 months, and 1 year. Patients underwent a standardized operative procedure with the implant. Patient demographics, comorbidities, tear types, and concomitant operative procedures were recorded. **Results:** Patients in both groups experienced statistically significant improvement in VAS, SANE, VR-12 PCS, ASES, and WORC scores (mean values 1.1, $P < .001$; 86.0, $P < .001$; 49.7, $P < .001$; 85.6, $P < .001$; and 84.4, $P < .001$ for partial tears and 1.2, $P < .001$; 80.7, $P < .001$; 45.7, $P < .001$; 83.8, $P < .0001$; and 80.1, $P < .001$ for full-thickness tears, respectively). For the partial tear group, average times for return to driving, work, and nonoverhead athletic activity were 14.6, 37.3, and 65.6 days, and for the full-thickness group, 24.5, 50.7, and 119.2 days, respectively. In the partial-thickness group, 84% and 83% of patients reported improvement in their VAS pain and ASES scores, respectively, that met or exceeded each measure's minimal clinically important difference. In the full-thickness group, 72% and 77% of the patients met or exceeded the minimal clinically important differences for VAS pain and ASES, respectively. **Conclusion:** Outcomes after repair of partial- and full-thickness rotator cuff tears using a bioinductive implant show safety and efficacy at 1-year follow-up. **Level of Evidence:** Retrospective case series, level IV evidence.

Rotator cuff pathology represents a significant disease burden for both individuals and society. Because cuff disease is degenerative in nature, an aging population such as currently exists in the United States will experience an increasing incidence of rotator cuff problems.[1-3] The spectrum of cuff disease ranges from simple inflammatory tendinitis to fibrosis, delamination, partial-thickness tearing, and full detachment of

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the cuff footprint. This process is affected by trauma, the local individual anatomic environment, and concomitant systemic disease. Although much rotator cuff pathology is asymptomatic and requires no treatment, visits to medical professionals for this condition in the United States number >3 million per year and result in direct costs alone of $7 billion.[4]

The focus of the surgical treatment of cuff pathology is to eliminate pain and restore function by reconstituting the degenerated and torn cuff tissue and footprint. These goals are hampered by the fact that tendon vascularity and tissue quality diminish in the disease state, making healing difficult. Partial tearing of tendon tissue increases the strain on the remaining fibers, increasing the likelihood of tissue failure.[5-10] In addition, tendon tissue that remains intact in partial tears may be of questionable quality.[11] Longitudinal studies have shown tear progression in partial- and full-thickness tears over time.[1-10,12-14] Despite these findings, in vitro studies have been used to advocate surgical repair only for partial-thickness tears involving 50% or more of the tendon thickness.[15] Unfortunately, it is well known that repairs of both partial- and full-thickness tears are not always successful.[16] Repair and restoration of the tendon footprint is the goal of surgical treatment, with caveats for muscle quality, patient age, and comorbidities. Repair integrity in both the short- and long-term postoperative periods remains a significant concern and represents the leading cause of failure in the surgical treatment of cuff pathology. The challenge in treating cuff pathology for surgeons remains the healing milieu and mechanics of repaired tissue.

Healing of cuff tissue is considered important for successful surgical treatment, and there is a considerable and growing body of literature on novel grafting and biologic interventions to enhance the healing environment of torn cuff tissue.[17-20] An ideal implant would induce cuff healing with tendon tissue, resorb after the induction process, and be simple to introduce into the shoulder. Recent studies have shown that a highly porous, reconstituted collagen scaffold can induce the formation of new tendon-like tissue in a sheep model.[21] Magnetic resonance imaging studies of the same collagen scaffold in humans show healing of partial- and full-thickness cuff tears with new tendon-like tissue and increased thickness of the cuff tendon.[22-24] Biopsies of the collagen implant retrieved from human subjects showed biocompatibility, cellular incorporation, implant resorption, tissue formation, and maturation.[25]

The purposes of this study were (1) to collect outcomes data on patients treated with a bioinductive collagen implant designed to induce cuff healing and (2) to assess the safety and efficacy of the device. Our hypothesis was that the implant would produce short-term clinical results that were consistent with traditional methods of repair.

Methods

Using established survey instruments, 15 surgeons in 15 centers collected data through an insitutional review board–approved data registry study (REBUILD; Smith & Nephew, Andover, MA) that was created to collect outcomes on patients treated with the bioinductive implant between April 2016 and August 2017. Patients 21 years of age and older, able to read and speak English, and with partial- or full-thickness tears of the rotator cuff documented by magnetic resonance imaging were included in the study. Patients with a known hypersensitivity to bovine-derived products were excluded. Indication for surgery in the partial-thickness group was persistent intolerable shoulder pain despite conservative treatment including physical therapy and/or corticosteroid injection. For the full-thickness group, surgical indications were also failure of physical therapy and/or steroid injection for chronic cuff tears. Acute traumatic tears were indicated based on the age and activity level of the patient. Baseline data included medical history of diabetes, smoking status, worker's compensation status, and shoulder injury. Details including timing of injury, history of trauma, duration of symptoms, and previous treatments were recorded. Operative data included Ellman or Cofield grade, concomitant shoulder pathology, additional surgical procedures, and bioinductive implant size. Postoperative patient-reported outcomes including American Shoulder and Elbow Surgeons (ASES), single-assessment numeric evaluation (SANE), Veterans RAND 12-Item (VR-12), and Western Ontario Rotator Cuff (WORC) scores were collected at 2, 6, and 12 weeks, 6 months, and 1 year.

The reconstituted collagen implants were made from purified type I collagen from bovine tendons and processed to create a highly oriented, highly porous collagen scaffold (REGENETEN; Smith & Nephew).[20] The implant is cleared by the Food and Drug Administration for commercial use and is indicated for the management of tendon injuries in which there has been no substantial loss of tendon tissue. All uses of the implant in this study were on-label.

The standardized procedure involved the arthroscopic application of the bioinductive collagen implant to the bursal side of the rotator cuff, as has been previously described.[26] Patients underwent a diagnostic arthroscopy, and concomitant pathology was addressed. Once rotator cuff pathology was confirmed, a standard repair was undertaken for those patients with full-thickness tears with the technique, either double or single row, at the discretion of the treating surgeon. Partial tears were left in situ. The implant was delivered into the shoulder through a lateral subacromial portal with a proprietary deployment device. The graft was held in place and fixed to the rotator cuff tendon anteriorly, medially, and

Table 1. Postoperative Rehabilitation Guidelines for Partial-Thickness Tears

Phase	Timing	Guideline
Phase I: Immediate postoperative	First 5-7 d after surgery, before starting physical therapy	1. Sling use for 24-48 h. Remove the sling 4 or 5 times a day to do pendulum exercises. Sleep with sling and pillow in place. 2. Use of the affected arm: Hand use on the affected arm is permissible as long as the hand remains in front of the body. It is all right to flex the arm at the elbow. Continue to move the elbow, wrist, and hand to help circulation and motion. Also, a. No lifting of objects >5 lbs b. No excessive shoulder extension c. No excessive stretching or sudden movements d. No supporting of body weight by hands 3. Continue to ice regularly for least 20 min 4-5 times/d.
Phase II: Intermediate phase	1-6 wks postoperative	Activities: 1. Patient is weaned out of sling use. 2. Continue to ice regularly for least 20 min 4-5 times/d. 3. Unless instructed otherwise, it should be okay to drive at this point. 4. Active use of the arm for daily living: bathing, dressing, driving, typing on a computer, eating, and drinking. Range of motion: 1. PROM (nonforceful flexion and abduction) 2. AAROM 3. AROM 4. Pendulums 5. Pulleys 6. Cane exercises 7. Self-stretchesStrengthening: 1. Isometrics: scapular musculature, deltoid, and rotator cuff as appropriate 2. Isotonic: theraband internal and external rotation in 0° abduction
Phase III: Active strengthening phase	6 weeks and beyond	Exercises: 1. Continue dumbbell strengthening (rotator cuff and deltoid) 2. Progress theraband exercises to 90/90 position for internal rotation and external rotation (slow/fast sets) 3. Theraband exercises for scapulothoracic musculature and biceps 4. Plyometrics for rotator cuff 5. PNF diagonal patterns 6. Isokinetics 7. Continue endurance exercises (UBE) 8. Diagonal patterns Return to sport: 12 weeks and beyond, once adequate strength achieved for sports-specific criteria

AAROM, active assistive range of motion; AROM, active range of motion; PNF, proprioceptive neuromuscular facilitation; PROM, passive range of motion; UBE, upper-body ergometer.

posteriorly with polylactic acid tendon staples through auxiliary portals made off the lateral acromion. The deployment device was then removed, and the graft was fixed to the greater tuberosity with PEEK bone staples.[26] A uniform postoperative rehabilitation protocol was used for those patients with a partial cuff tear (Table 1). The standardized physical therapy (PT) was modified as per surgeon preference for those patients (55.6%) who had biceps surgery in addition to the implant. For those patients with a full-thickness tear augmented with the implant, surgeon preference for rehabilitation for standard cuff repair was used.

Patient-reported outcomes were recorded and entered through an internet-based electronic data capture system. Electronic case report forms were configured to collect all outcomes data, and read/write protections were established to ensure that each study center could only enter and view data from their patients.

Patient medical history and clinical conditions were assessed with routine documentation and reviewed in the context of study eligibility criteria. Patient surveys were administered in accordance with the registry's study visit schedule and were completed by the patients either during their clinic visits or remotely using unique, secure electronic case report form account access information. The mean (± standard deviation) for each patient-reported primary outcome was calculated

Table 2. Demographics and Clinical Characteristics of the Patient Population

Variable	Value
Age (yr)	
Mean ± standard deviation (N)	54.2 ± 9.8 (173)
Median (range)	55.0 (24.0-74.0)
History of symptoms (mo)	
Mean ± standard deviation (N)	22.3 ± 35.1 (173)
Median (range)	10.0 (1.0-276.0)
Time of injury	
Acute	57 (32.9)
Acute-on-chronic	29 (16.8)
Chronic	87 (50.3)
Sex	
Female	75 (43.4)
Male	98 (56.7)
Diabetes	
No	155 (89.6)
Yes	18 (10.4)
Smoker	
No	148 (85.6)
Yes	25 (14.4)
Workers compensation	
No	152 (87.9)
Yes	21 (12.1)
Musculoskeletal disorders—other	
No	142 (82.1)
Yes	31 (17.9)
Chronic opioid use	
No	160 (92.5)
Yes	13 (7.5)
Shoulder treated	
Left	68 (39.3)
Right	105 (60.7)
Surgery type	
Primary	152 (87.9)
Revision	21 (12.1)

NOTE. Data are n (%) unless noted otherwise.

Table 3. Procedure Summary

	n	%
Tear Type		
Partial thickness	90	52.0
Grade 1 <25% (<3 mm)	15	16.7
Grade 2 25-50% (3-6 mm)	34	37.8
Grade 3 >50% (>6 mm)	41	45.5
Full thickness	83	48.0
Small (<1 cm)	4	4.8
Medium (1-3 cm)	42	50.6
Large (3-5 cm)	25	30.1
Massive (>5 cm)	12	14.5
Concomitant surgery		
Acromioplasty		
No	19	11.0
Yes	154	89.0
Acromioclavicular joint resection		
No	104	60.1
Yes	69	39.9
Labral repair		
No	162	93.6
Yes	8	4.6
Not specified	3	1.7
Capsular release		
No	150	86.7
Yes	21	12.1
Not specified	2	1.2
Debridement		
No	65	37.6
Yes	106	61.3
Not specified	2	1.2
Biceps		
No	77	44.5
Tenodesis	82	47.5
Tenotomy	14	8.1

at baseline and each subsequent follow-up visit. Statistical significance was set at $P < .05$. The overall number and percentage of patients who experienced a postoperative adverse event or revision surgery was documented. Means (± standard deviation) were also reported for postoperative recovery parameters such as time in a sling, narcotic use, and return to work, driving, and sport. Continuous variables were summarized with mean and standard deviations, and categorical variables were summarized with the number and percentage of subjects. Paired *t* tests were performed to test the difference between the means of the follow-up compared to the baseline measurements. Analyses were done with SAS version 9 (SAS Institute, Cary, NC).

Results

One-year follow-up was completed for 173 patients of a total of 203 eligible patients, for a 85% follow-up completion rate. The average age was 54.2 years (range 24-74), including 98 male and 75 female patients. The average duration of symptoms was 22.3 months (range 1-276). Approximately 10% of the patients had a history of diabetes, 14.4% were smokers, 12.1% were involved with a workers' compensation claim, and 7.5% reported chronic (>6-week) opioid use. Patient follow-up averaged 12.7 months (range 12.0-17.2) (Table 2).

Intraoperative arthroscopic visualization confirmed 90 partial-thickness tears and 83 full-thickness tears. Of the partial tear group, 16.7% were grade I tears, 37.8% grade II, and 45.5% grade III. Of the full-thickness tears, 4.8% were small, 50.6% medium, 30.1% large, and 14.5% massive. Concomitant surgical procedures included acromioplasty (89.0%), acromioclavicular joint resection (39.9%), capsular release (12.1%), and biceps surgery (55.6%) (Table 3).

Partial-Thickness Tears

Patients in the partial-thickness tear group exhibited statistically significant improvement in outcomes for VAS, SANE, VR12 physical component, ASES, and WORC over 12 months of study follow-up ($P < .05$). In the partial-thickness group, 84% and 83% of patients reported improvement in their VAS pain and ASES scores,

Table 4. Partial-Thickness Tear Patient-Reported Clinical Outcomes

Variable	Baseline		2 Weeks			6 Weeks			3 Months			6 Months			1 Year		
	n	Mean	n	Mean	*P* value (Δ)	n	Mean	*P* value (Δ)	n	Mean	*P* value (Δ)	n	Mean	*P* value (Δ)	n	Mean	*P* value (Δ)
VAS pain	89	5.3	85	3.3	<.001	89	2.7	<.001	90	1.8	<.001	85	1.4	<.001	89	1.1	<.001
ASES function	87	14.2	85	8.2	<.001	88	14.6	.415	90	19.3	<.001	85	22.4	<.001	87	24.8	<.001
ASES score	87	47.0	83	46.7	.750	88	60.6	<.001	90	73.2	<.001	84	80.5	<.001	87	85.6	<.001
SANE	88	42.5	86	37.3	.242	88	59.4	<.001	89	73.6	<.001	86	80.6	<.001	90	86.0	<.001
VR-12 PCS	90	35.8	86	33.5	.026	88	39.1	.001	90	45.3	<.001	86	47.7	<.001	90	49.7	<.001
VR-12 MCS	90	53.2	86	53.9	.427	88	54.3	.320	90	53.3	.922	86	53.1	.874	90	53.9	.499
WORC	85	38.2	81	40.1	.500	79	53.5	<.001	78	68.9	<.001	75	79.0	<.001	84	84.4	<.001

ASES, American Shoulder and Elbow Surgeons; MCS, mental component score; PCS, physical component score; SANE, single-assessment numeric evaluation; VAS, visual analogue scale; VR-12, Veterans RAND 12-Item; WORC, Western Ontario Rotator Cuff.

respectively, that met or exceeded each measure's minimal clinically important difference (MCID).[27,28] The VR12 mental component was unchanged over the same time (Table 4).

The average time in a sling was 10.6 days for those without biceps surgery and 27.7 days for patients who underwent concomitant tenodesis. Patients returned to driving in an average of 14.6 days, and to work, in 37.3 days (9.4 days for sedentary jobs and 72.9 for physical jobs). Return to athletics averaged 65.6 days, with return to overhead athletics at 117.9 days. Patients used opioid medicines for pain control for an average of 18.3 days. The total number of PT visits averaged 20.6 (Table 5).

Full-Thickness Tears

Patients in the full-thickness tear group exhibited statistically significant improvement in outcomes for the VAS, SANE, VR12 physical component, ASES, and WORC over 12 months of study follow-up ($P < .05$). In the full-thickness group, 72% and 77% of the patients met or exceeded the MCIDs for VAS pain and ASES, respectively.[27,28] The VR12 mental component was unchanged over the same time (Table 6).

The average time in a sling was 34.0 days for those without biceps surgery and 39.4 days for patients who underwent concomitant tenodesis. Patients returned to driving in an average of 24.5 days, and to work, in 50.7 days (21.8 days for sedentary jobs and 62.5 for physical jobs). Return to athletics averaged 119.2 days, with return to overhead athletics at 143.7 days. Patients used opioid medicines for pain control for an average of 26.9 days. The total number of PT visits averaged 21.5 (Table 5).

Complications

Eight patients required revision surgery for complications. One patient with a full-thickness tear developed a postoperative infection requiring irrigation and debridement with removal of the implant. The patient eventually underwent a revision repair with success. One patient with a large full-thickness tear developed deep vein thrombosis and adhesive capsulitis. The patient was treated with an arthroscopic lysis of adhesions and manipulation with success. Another patient developed postoperative stiffness, and at arthroscopy 4 months after the index procedure, part of the graft was still present and loose in the bursa. After removal and debridement, the patient was asymptomatic. One patient experienced recurrent effusions requiring repeat arthroscopy and synovectomy for bursitis. Four patients had ongoing symptoms because of failure of cuff healing. One patient had a partial tear that failed to heal and was treated with a revision take-down and repair. Two patients with midsized (1- to 3-cm) full-thickness tears required revision repair, and 1 patient

Table 5. Postoperative Recovery Outcomes

Variable	Partial-Thickness Tears (N = 90)	Full-Thickness Tears (N = 83)
Sling time (d)		
No biceps surgery	10.6 ± 14.2 (49)	34.0 ± 17.1 (27)
Biceps surgery (tenodesis)	27.7 ± 16.8 (28)	39.4 ± 19.0 (43)
Return to driving (d)	14.6 ± 15.5 (76)	24.5 ± 32.2 (60)
Return to work (d)		
All work types	37.3 ± 77.4 (58)	50.7 ± 53.9 (52)
Sedentary	9.4 ± 6.3 (24)	21.8 ± 21.4 (17)
Physical	72.9 ± 113.3 (23)	62.5 ± 64.7 (26)
Return to nonoverhead sports (d)	65.6 ± 76.0 (33)	119.2 ± 91.2 (36)
Return to overhead sports (d)	117.9 ± 82.7 (24)	143.7 ± 95.7 (25)
Narcotics use (d)*	18.3 ± 38.6 (82)	26.9 ± 41.2 (78)
Total physical therapy visits (n)	20.6 ± 13.8 (63)	21.5 ± 15.4 (56)
Total injections (n)	1.2 ± 0.6 (29)	1.0 ± 0.0 (9)

NOTE. Data are mean ± standard deviation (n).
*Excludes patients with a history of chronic narcotic/opioid use.

with a large tear was revised with a reverse total shoulder replacement.

Twenty-nine patients (32.2%) in the partial-thickness group required an average of 1.2 corticosteroid injections in the postoperative period for pain control. Nine of the patients (10.8%) in the full-thickness group required an average of 1.0 injection. Two centers administered steroid injections in 37% and 67% of their patients during the early postoperative period as a part of routine care. These 2 centers accounted for 29 of the 38 patients (76%) receiving 36 of 45 (80%) steroid injections. Nine sites did not administer any steroid injections across a combined population of 62 patients.

Discussion

Partial- and full-thickness rotator cuff tears treated arthroscopically with application of a bioinductive implant showed improved patient-reported outcomes at 1-year of follow-up. The healing environment for rotator cuff repair presents a challenge for treating surgeons. It is widely understood that cuff vascularity and tissue quality are compromised in the disease state, and that repair of cuff tissue back to bone does not occur in a certain percentage of operative reconstructive procedures.[29] Although many patients do well even if their tendons do not heal, the major cause of failure and poor outcome of cuff repair surgery is believed to be a lack of healing. This has led to a robust effort to improve the healing environment to ensure successful reconstruction of the cuff muscle tendon unit. This study reports the use of a bioinductive implant to promote healing and establish the formation of new tendon tissue in the surgical treatment of partial- and full-thickness rotator cuff tears. The implant proved safe and effective when used in multiple centers in treating both partial- and full-thickness tears.

The mechanism by which the implant can induce tendon healing throughout the entire cuff, even though it is placed on the bursal surface, is not completely understood at this time. The hypothesis is that tissue induction on the bursal surface reduces strain on the rest of the cuff tissue, improving the local mechanical environment.[24] Finite element analysis shows reduction of strain in partially torn cuffs when 2 mm of additional tissue is added to the construct.[22,30] There may also be a vascular response to ingrowth, with the implant improving the delivery of repair components to the area.[21,25]

Results of outcome metrics in full-thickness tears treated with the implant were consistent with published results in the literature for standard cuff procedures.[31-34] The use of the graft in full-thickness tears was at surgeon discretion, and as a result, little can be said concerning the indication for the implant in patients with full-thickness tears based on this study. Future studies comparing cuff healing and outcomes with and without the graft will be necessary to prove increased efficacy and indications for use in the treatment of full-thickness cuff tears. The potential for improving the local healing environment in chronic, large, massive tears, and especially in revision situations, is appealing and worthy of future investigation. Our present study included too few massive tears (12) to make definitive recommendations concerning use of the implant in this situation, but early results are promising.

Results of outcome metrics in partial-thickness tears treated with the implant were consistent with published results in the literature for standard cuff procedures.[31,32,35] There is no definitive indication for repair of partial-thickness tears of the cuff, but recognized treatment guidelines recommend that symptomatic tears that are >50% of the cuff width be repaired based on in vitro work.[15] The remaining intact fibers of a partially torn cuff experience an increase in strain based on both Mazzocca et al.[15] and

Table 6. Full-Thickness Tear Patient-Reported Clinical Outcomes

Variable	Baseline		2 Weeks			6 Weeks			3 Months			6 Months			1 Year		
	n	Mean	n	Mean	*P* value (Δ)	n	Mean	*P* value (Δ)	n	Mean	*P* value (Δ)	n	Mean	*P* value (Δ)	n	Mean	*P* value (Δ)
VAS pain	82	5.2	80	3.7	<.001	79	2.7	<.001	82	1.9	<.001	79	1.7	<.001	82	1.2	<.001
ASES function	74	13.1	80	4.6	<.001	76	8.6	<.001	82	16.7	<.001	80	21.6	<.001	81	24.0	<.001
ASES score	73	45.5	78	39.0	.01	88	60.6	.111	81	68.4	<.001	79	77.8	<.001	80	83.8	<.001
SANE	82	39.2	81	20.7	<.001	78	36.4	.306	82	63.3	<.001	80	74.6	<.001	83	80.7	<.001
VR-12 PCS	83	34.5	82	31.8	.025	79	35.4	.526	83	40.8	<.001	80	44.3	<.001	83	45.7	<.001
VR-12 MCS	83	48.8	82	47.9	.571	79	50.6	.246	83	51.7	.044	80	52.4	.008	82	53.0	.015
WORC	80	35.0	78	33.3	.157	75	41.1	<.001	76	57.6	<.001	72	72.5	<.001	67	80.1	<.001

ASES, American Shoulder and Elbow Surgeons; MCS, mental component score; PCS, physical component score; SANE, single-assessment numeric evaluation; VAS, visual analogue scale; VR-12, Veterans RAND 12-Item; WORC, Western Ontario Rotator Cuff.

finite element analysis.[8] In addition, those remaining fibers may be of questionable quality, adding to the propensity for failure.[11] It is known that symptomatic, painful shoulders with both partial- and full-thickness tears are more likely to experience progression of tearing.[12] The natural history of symptomatic shoulders then is one of progression of disease. This may present an opportunity for treatment options that affect this trend with new tissue formation, especially in younger, more active patients. The promising results of this study in conjunction with previous reports indicating that the implant induces new tendon tissue warrant further comparative studies to re-evaluate repair treatment guidelines based on percentage tearing to better elucidate how newer regenerative technologies can affect the natural history of cuff disease.[22-25]

The perioperative morbidity associated with cuff repair surgery can be significant, with the inconvenience of sling immobilization, inability to drive and perform work functions, sleep interruption, and time away from recreational activities. The move from open to arthroscopic surgery has decreased surgical morbidity, and adjunct treatments such as peripheral nerve blocks have facilitated the migration of cuff repair from an inpatient to outpatient site of service. Any treatment options that further allow for the more rapid resumption of activities of daily living and recreation have tremendous value for patients and surgeons alike. Some studies indicate postoperative morbidity for partial repair, especially with in situ techniques.[35,36] Documenting earlier return to work, driving, and other activities of daily living may prove valuable. Future higher-level comparison studies analyzing newer regenerative techniques will be necessary to prove the value of innovative procedures and devices. In the current study, average time in a sling for patients with partial-thickness tears was 10.6 days without biceps surgery and 27.7 days with tenodesis. The literature indicates 4-6 weeks for patients treated with more traditional methods.[35-38] Decreased time in a sling presents the opportunity to resume activities of daily living, including driving and work, sooner. Our return to driving also compared favorably for both partial- and full-thickness repairs. Patients with full-thickness tears treated with the implant returned to driving in an average of 24.5 days, and with partial-thickness tears, 14.6 days. Both compare favorably to the literature, which shows an average return of 8 weeks.[39] Return to sport was also improved at 65.6 days for partial tear patients compared with between 12 and 24 months in the literature for partial tears.[37,38] Return to sport averaged 119.2 days for full-thickness tears, which compares favorably to an average return of 6.9 months in the literature.[40] Overhead athletes returned at 143.7 days for full-thickness tears and 117.9 days for

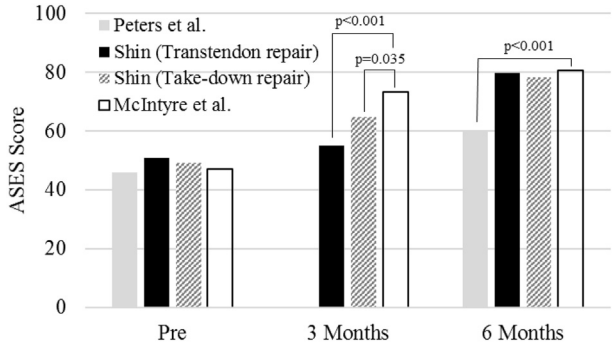

Fig 1. Comparison of American Shoulder and Elbow Surgeons scores in patients with partial-thickness tendon tears treated with standard surgical repair versus treatment with the bioinductive implant.

partial tears. There were no high-level throwers in this group.

Pain relief and ASES scores 6 months after surgery for patients treated with the bioinductive implant for partial-thickness tears compare favorably to patients treated with standard surgical techniques.[35,36] The mean scores reported in this study within the first 6 month after surgery are statistically significantly better ($P < .001$) than those reported in Shin[36] (Figs 1 and 2). Part of the value of the implant therefore may be more rapid pain relief and resumption of function in addition to facilitating new tissue formation. There were no other studies in the literature that assessed outcomes before 3 months, so comparison in the early postoperative period cannot be performed.

Strengths of the study include attention to patient activity milestones such as time in a sling, time to return to driving and work, and return to athletics as outcomes metrics. Measuring outcomes in the immediate postoperative period at 2, 6, and 12 weeks also adds value in assessing patient return to activities of daily living and perioperative morbidity. The study had a high rate of follow-up, decreasing the chance of selection bias based on patients lost to follow-up.

Limitations

Limitations of this study include the selection bias associated with a level IV study design and nonconsecutive patient inclusion. As such, the added value of the implant will require future higher-level comparative analysis. Lack of a control group makes analysis of results comparing the implant to more traditional methods of repair without augmentation difficult. In addition, there is considerable heterogeneity in both the partial- and full-thickness tear groups involving extent of cuff disease, history of trauma, duration of symptoms, and concomitant pathology. Cuff repair techniques were at the discretion of the treating surgeon and were not standardized, introducing additional bias. Drawing specific conclusions concerning application of the implant in any specific patient can be based only on the overall improvement of the groups. We did not separate the partial-thickness group according to tear location, which limits delineation of results between partial tear locations. There is evidence in the literature that partial-thickness bursal-sided tears do not respond as well to surgical treatment as articular-sided tears.[41,42] However, Van Kampen et al.[21] reported similarly good healing rates between patients with bursal-sided and articular-sided partial-thickness tears after arthroscopic placement of the bioinductive implant. There is a considerable body of literature documenting the results of in situ repair, take-down and repair, and comparison of the two,[36,43,44] but there are only 2 studies that show increase in tendon thickness in partial-thickness tears treated surgically without instrumentation of the partially torn cuff. Both the studies used the bioinductive implant used in this report.[22,24] Younger, active patients with partial cuff tears might be better managed with early surgical intervention with biologics to disrupt the natural history of their disease progression. The value in full-thickness tears, especially in environments where healing is problematic, is promising and worthy of further study.

Conclusions

Outcomes after repair of partial- and full-thickness rotator cuff tears using a bioinductive implant show safety and efficacy at 1-year of follow-up. In the partial-thickness group, 84% and 83% of patients reported improvement in their VAS pain and ASES scores, respectively, that met or exceeded each measure's MCID and that was also clinically meaningful. In the full-thickness group, 72% and 77% of the patients met or exceeded the MCIDs for VAS pain and ASES scores, respectively.

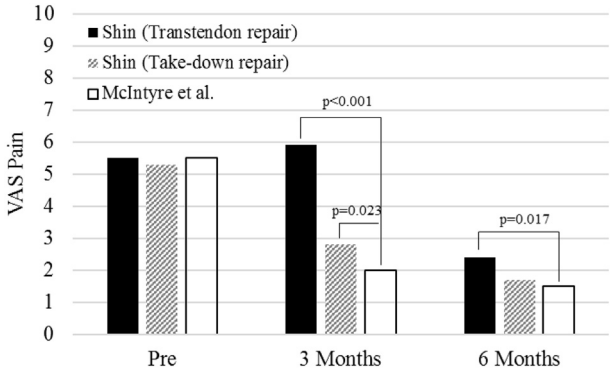

Fig 2. Comparison of visual analogue scale pain scores in patients with partial-thickness tendon tears treated with standard surgical repair versus treatment with the bioinductive implant.

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