JSES International 5 (2021) 228–237

Contents lists available at ScienceDirect

JSES International

journal homepage: www.jsesinternational.org

Retear rates and clinical outcomes at 1 year after repair of full-thickness rotator cuff tears augmented with a bioinductive collagen implant: a prospective multicenter study

Brandon D. Bushnell, MD, MBA [a,*], Patrick M. Connor, MD [b], Howard W. Harris, MD [c], Charles P. Ho, MD [d], Scott W. Trenhaile, MD [e], Jeffrey S. Abrams, MD [f]

[a] *Department of Orthopedic Surgery, Harbin Clinic, Rome, GA, USA*
[b] *OrthoCarolina, Charlotte, NC, USA*
[c] *Texas Orthopedic Specialists, Dallas/Fort Worth, TX, USA*
[d] *The Steadman Philippon Research Institute, Vail, CO, USA*
[e] *OrthoIllinois, Rockford, IL, USA*
[f] *Princeton Orthopaedic Associates, Princeton, NJ, USA*

ARTICLE INFO

Keywords:
Rotator cuff
full-thickness
retears
bioinductive
implant
clinical outcomes
ASES
CMS

Level of evidence: Level IV; Case Series; Treatment Study

Background: Biologic technologies can potentially augment existing arthroscopic rotator cuff repair to improve retear rates and postoperative outcomes. The purpose of this study was to evaluate healing rates and clinical outcomes of full-thickness rotator cuff repairs augmented with a bioinductive bovine collagen implant.

Methods: In this prospective multicenter study, investigators enrolled 115 patients (mean age, 60.4 years) with full-thickness rotator cuff tears. There were 66 (57.4%) medium (1-3 cm) tears and 49 (42.6%) large (3-5 cm) tears. Eligible patients consisted of those ≥21 years of age with chronic shoulder pain lasting longer than 3 months and unresponsive to conservative therapy. Patients underwent single- or double-row repair augmented with a bioinductive bovine collagen implant. At the baseline, 3 months, and 1 year, magnetic resonance imaging was performed and patients were assessed for American Shoulder and Elbow Surgeons (ASES) Shoulder Score and Constant-Murley Score (CMS). The primary failure end point was retear, classified as any new full-thickness defect observed on magnetic resonance imaging.

Results: There were 13 retears (11.3%) at 3 months, with an additional 6 (19 total [16.5%]) found at 1 year. In large tears, double-row repair had a significantly lower rate of retear at 3 months ($P = .0004$) and 1 year ($P = .0001$) compared with single-row repair. ASES and CMS scores significantly improved between the baseline and 1 year for medium and large tears. At 1 year, the minimally clinically important difference for ASES and CMS was met by 91.7% (95% CI: 84.9-96.1) and 86.4% (95% CI: 78.2-92.4) of patients, respectively. Patients without retear and those <65 years of age had significantly better CMS scores at 1 year when compared with those with retear and those ≥65 years ($P < .05$). There was no statistically significant difference in outcomes based on treatment of the biceps tendon. Of 9 reported reoperations in the operative shoulder, only 2 were considered potentially related to the collagen implant.

Conclusion: Interim results from this prospective study indicate a favorable rate of retear relative to the literature and improvement in clinical function at 1 year after adjunctive treatment with the study implant augmenting standard arthroscopic repair techniques.

Despite the generally beneficial results observed with arthroscopic rotator cuff repair,[19] the continued risk of postoperative retears remains a challenge, especially as their presence can negatively affect clinical and functional outcomes.[23,28,38,47] Surgeons must consider the underlying biologic variables that might predispose a patient to significant risk of retear when deciding whether to proceed with arthroscopic rotator cuff repair or an alternative

Institutional Review Board approval was obtained from the Western Institutional Review Board (WIRB) (study no. 1147580).

* Corresponding author: Brandon D. Bushnell, MD, MBA, Department of Orthopedic Surgery, Harbin Clinic, LLC, 1825 Martha Berry Blvd NE, Rome, GA 30165 USA.
E-mail address: brad.bushnell.md@gmail.com (B.D. Bushnell).

https://doi.org/10.1016/j.jseint.2020.10.020

intervention for the symptomatic patient. Microvascular changes associated with patient age, chronicity and size of the tear, and chronic disease states affect the quality of biologic healing at the tendon-bone interface,[24,33,39] with suboptimal healing reducing the mechanical strength of the construct, thereby leading to potential retear. Retear rates can be impressively high, with a randomized study of 136 full-thickness tears reporting an overall 2-year retear rate of 46.4%[9] and another large study reporting up to a 53% retear rate.[46]

The need for an improved biologic environment for tendon healing led to the development of a bioinductive resorbable bovine collagen scaffold for rotator cuff repair augmentation, which has shown promising clinical performance to date.[2,5–7,34,41,46] In a 2013 analysis, a highly porous collagen implant induced the formation of mature tendon-like tissue and increased rotator cuff tendon thickness in a sheep model.[48] Further histology data obtained from biopsies of patients undergoing rotator cuff repair augmented with this implant indicated cellular incorporation, tissue formation and maturation, implant resorption, and no evidence of inflammatory response or foreign body reaction.[2] Magnetic resonance imaging (MRI) testing concluded that full-thickness tear repairs augmented with the implant had an increase in tendon thickness compared with published average normal values from 3 months postoperatively.[7] This increased tendon thickness persisted through follow-up at 6, 12, and 24 months ($P < .01$ vs published average normal values at all time points). Multiple clinical studies of augmented full-thickness tear repairs have reported that this collagen implant results in significant improvements in postoperative shoulder function and pain compared with the preoperative baseline.[7,34,46]

A prospective study was conducted to assess the safety and efficacy of this bioinductive collagen implant in the arthroscopic treatment of full-thickness rotator cuff tears in a large population across multiple centers. It was hypothesized that the use of this implant adjunctive to single- or double-row repair would lead to reduced retear rates as compared with traditional methods of repair. A secondary analysis of factors thought to influence retear rates was conducted to determine the potential efficacy of this implant in at-risk populations.

Methods

Study design

A prospective study was conducted by 9 surgeons at 9 centers in the United States between October 2014 and January 2019. Study patients will be followed up for 2 years. Interim results at 1 year are presented herein.

Patients met inclusion criteria if they were ≥21 years of age, spoke English, gave consent for participation in the study, had a medium or large full-thickness tear primarily of the supraspinatus tendon planned for surgical repair involving the implant, and chronic shoulder pain lasting longer than 3 months that was unresponsive to conservative therapy including pain medication, physical therapy, injections, and other treatments. The decision to indicate use of the implant was left to the discretion of the individual surgeon (ie, no criteria were used to direct “implant” vs. “no implant” before enrollment).

Patients were excluded if they had massive rotator cuff tears (> 5 cm), acute rotator cuff tears <12 months from known injury, or if the index shoulder had undergone previous rotator cuff surgery. Patients were also excluded if there was clinical or imaging evidence of instability, calcification, advanced chondromalacia (≥ grade 3), and/or fatty infiltration (≥ stage 2). Additional exclusion criteria included a history of heavy smoking (> 1 pack/day) within the last 6 months; genetic collagen disease; insulin-dependent diabetes; autoimmune, immunodeficiency, or chronic inflammatory disorders; an established hypersensitivity to bovine-derived materials; pregnancy or plans to become pregnant during the study; current involvement in any injury litigation or worker’s compensation claims relating to the index shoulder; cognitive or mental health status that interferes with study participation; and oral steroid and injectable steroid use within last 2 months or 1 month, respectively, of enrollment.

This study was performed in compliance with the ethical principles of the Declaration of Helsinki, and institutional review board approval was obtained for each investigational site. All patients provided voluntary informed consent before enrollment.

Study outcomes

Patients underwent a noncontrast MRI scan of the affected shoulder within 60 days before surgery to determine whether they had full-thickness tears meeting the eligibility criteria. This was then reconfirmed intraoperatively during surgery. Only subjects with full-thickness tears visually confirmed on arthroscopy with a calibrated probe and recorded by the surgeons as meeting the Cofield grade[14] for medium (1-3 cm) or large (3-5 cm) tears were included in this analysis. The duration of implantation of the collagen implant, defined as the time from introduction of the guide wire instrument into the subacromial space to completion of last staple, was also recorded.

Formal postoperative data collection and imaging studies occurred at 3 months and 1 year. At both points, MRI scans were obtained to assess rotator cuff tendon integrity, with any observable full-thickness defect (ie, loss in supraspinatus tendon continuity) classified as a retear. It should be noted that the diagnostic reality and terminology around rotator cuff healing vs. retearing remains a controversial area due to the relative inability to determine whether a cuff has truly retorn, simply never healed, or some combination of both. In our study, we use the term ‘retear’ to include rotator cuffs that have actually retorn after healing as well as those that have not fully healed or failed to heal altogether postsurgery.

Follow-up MRIs were also used to assess the presence or absence of a visible boundary between the collagen scaffold/new tissue and the supraspinatus tendon, as well as to measure tendon thickness (Fig. 1). Patients were assessed for American Shoulder and Elbow Surgeons (ASES) Shoulder Score and Constant-Murley shoulder (CMS) score at the preoperative baseline, and again at each postoperative follow-up visit. The minimal clinically important difference was considered as 11.1 for ASES and 4.6 for CMS, based on the analysis from Cvetanovich et al.[15] Self-reported subject satisfaction with the outcome of the index surgery was recorded using a 5-point Likert scale at all follow-up points, including in those cases after revision surgery. Recovery was assessed by cumulative days the index shoulder was in a sling, completed rehabilitation visits, return to work (employed patients only), and return to normal daily activities. Surgeons monitored for and recorded adverse events classified as either device or procedure related, all serious adverse events, and the occurrence and timing of revisions and additional shoulder operations.

Study device and surgical technique

The study implant (REGENETEN; Smith + Nephew, Andover, MA, USA) consists of 3 components: a resorbable implant made from highly purified reconstituted collagen fibers derived from bovine tendon and designed to completely resorb within 6 to 12 months; polylactic acid (PLDLA) tendon anchors designed to

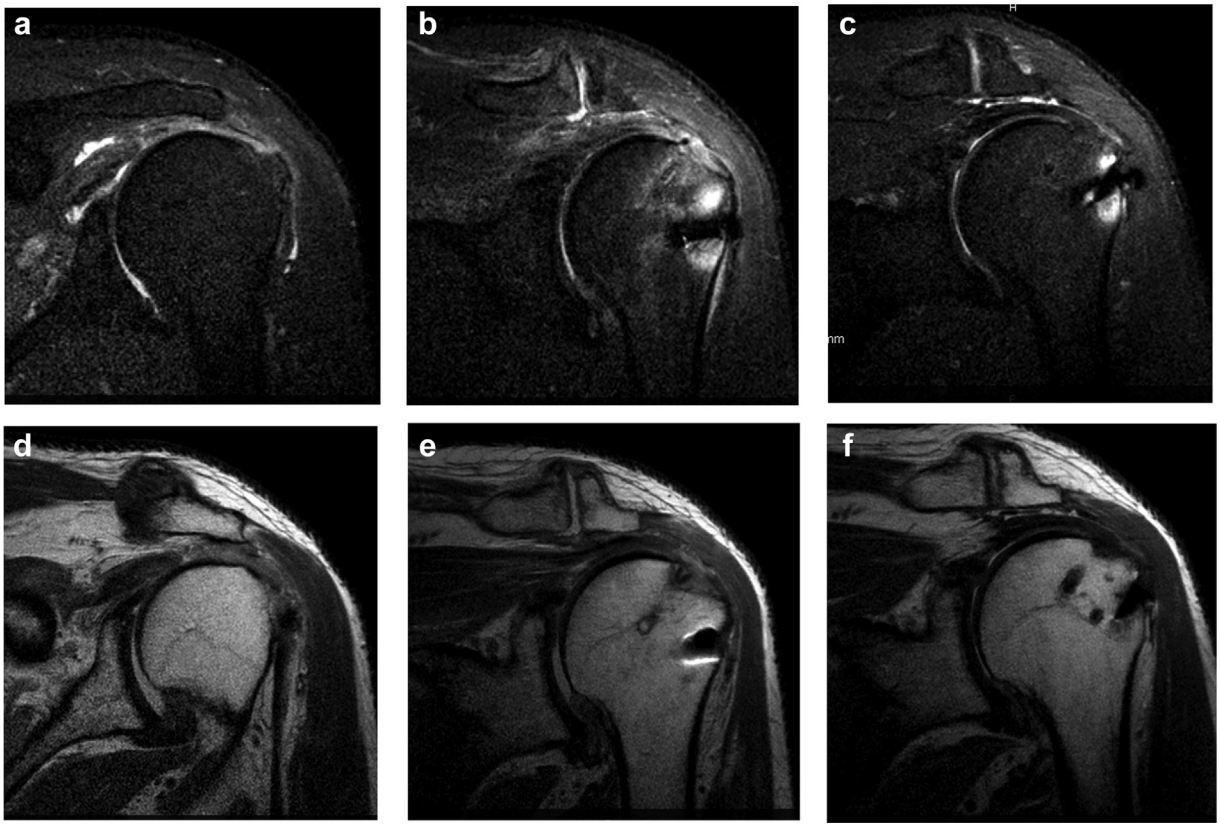

Figure 1 Respective magnetic resonance imaging (MRI) cuts at the baseline, 3 months, and 1 year from Spectral Attenuated Inversion Recovery (SPAIR) sequences (**a-c**) and transverse relaxation time (T2) sequences (**d-f**) of a study patient who had a 5-cm full thickness rotator cuff tear repaired with a double-row technique and a supplemental bioinductive implant.

completely resorb within 12 months; and polyetheretherketone bone anchors that are not resorbable.

Patients were placed under general anesthesia. The glenohumeral joint was arthroscopically assessed. If deemed clinically necessary, surgeons had the option to débride fraying of the labrum and perform biceps tenotomy or tenodesis, bursectomy and acromioplasty, and release of the coracoacromial ligament and débride minor fraying of the cuff tendon. Arthroscopic rotator cuff repair was performed by individual surgeon preference utilizing either a single- or double-row technique (Fig. 2). Removal of the periosteum lateral to the footprint was performed to ensure adequate positioning and fixation of the collagen implant to bone. The surgeon selected a collagen implant sized either 20 x 24 mm ("medium") or 25 x 30 mm ("large") to cover the repaired rotator cuff. Using proprietary, single-use disposable instruments, the surgeon then arthroscopically delivered the implant over the repaired tendon, secured the implant to the tendon with the PLDLA anchors and the implant to the greater tuberosity with the polyetheretherketone bone anchors. Standard methods were used for closure.

Patients followed a rehabilitation program at the discretion of the surgeon and consistent with standard practice for full-thickness rotator cuff repair.

MRI interpretation

All MRI results were interpreted by a single board-certified, musculoskeletal radiologist and also reviewed by the treating surgeon to determine implant boundaries, rotator cuff repair integrity, and other findings.

Statistical analysis

Descriptive statistics were used to summarize patient demographic data, intraoperative surgical assessments, and patient recovery outcomes. Matched-pair analyses were performed to determine changes in retear rates. A subgroup analysis was performed to determine the risk of retear among various cohorts: repair technique (single-row vs double-row repair), age (< 65 years vs ≥ 65 years), sling time (≤ 6 weeks vs > 6 weeks). Clinical outcome score (ASES and CMS scores) comparison between the baseline and successive follow-up visits was performed with Wilcoxon signed-rank analyses. A subgroup analysis was also performed to determine whether the aforementioned cohorts (repair technique, age, sling time), as well as those experiencing retear and undergoing biceps treatment or not at index surgery, influenced clinical ASES and CMS scores. Resulting P values were quoted and 95% two-sided confidence intervals (CIs) were generated where appropriate. All statistical calculations were made using SAS software (SAS Institute, Cary, NC, USA). Statistical significance was set at $P < .05$.

Results

Of 115 enrolled patients, 1-year data were available for 114. The one patient lost to follow-up had an established retear at 3 months, and was therefore included in the primary 3-month analysis. One subject missed an MRI at 3 months, but returned for the 1-year follow-up and did receive an MRI at that point. Demographic/clinical characteristics and operative details for this cohort of patients are provided in Tables I–III, respectively.

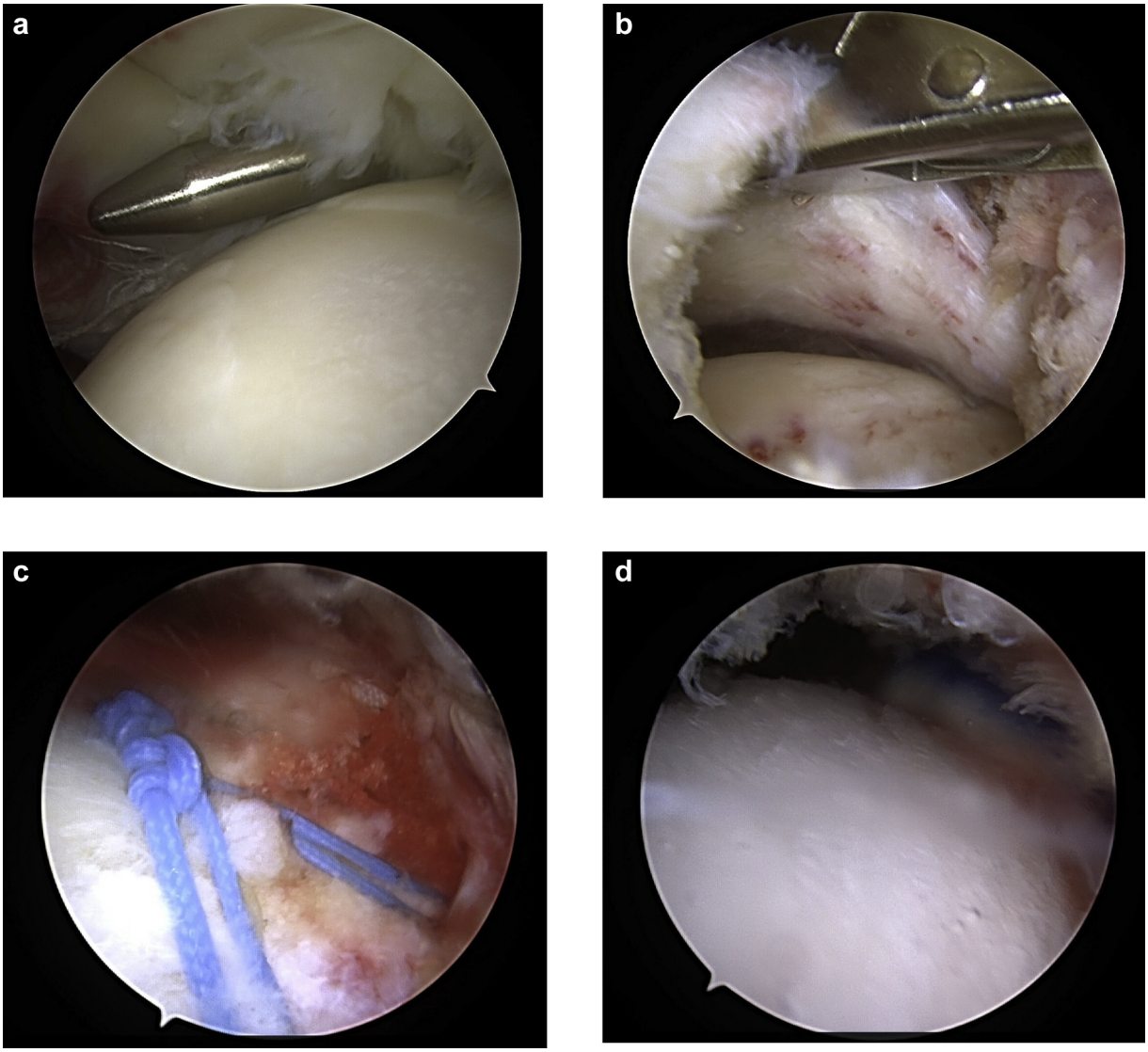

Figure 2 Arthroscopic images of a full-thickness rotator cuff tear from the articular (**a**) and bursal (**b**) sides that was repaired using a double-row technique (**c**) and a supplemental bioinductive implant (**d**).

Table I
Patient demographics and clinical characteristics (n = 115)

Variable	Value
Age (years)	
Mean ± standard deviation	60.4 ± 8.0
Median (range)	60.0 (42-80)
Sex, N (%)	
Female	39 (33.9%)
Male	76 (66.1%)
Body mass index, kg/m^2	
Mean ± standard deviation	28.1 ± 4.5
Median (range)	27.4 (18.2-42.0)
Duration of experienced pain in affected shoulder (years)	
Mean ± standard deviation (N)	2.50 ± 3.32
Median (range)	1.25 (0.17-20.0)
Shoulder treated, N (%)	
Left	37 (32.2%)
Right	78 (67.8%)

Retear

There were 13 retears (11.3%) at 3 months and 19 (16.5%) at 1 year. Retear rates for the various at-risk subgroups, classified by tear type, are provided in Table IV. Of the subgroups assessed, only surgical technique in large tears led to a significant difference, with double-row repair having a statistically lower rate of retear when compared with single-row repair at both 3 months (7.9% [3/38] vs 63.6% [7/11]; $P = .0004$) and 1 year (10.5% [4/38] vs 72.7% [8/11]; $P = .0001$).

MRI assessment—scaffold resorption

Scaffold resorption data were available for 112 patients at 3 months and 113 patients at 1 year based on MRI results. At 3 months, a visible boundary between the collagen scaffold/new tissue and the supraspinatus tendon was observed in 10 available

Table II
ASES scores by visit and revision status

Cofield classification	Revision	No revision	Total
ASES score baseline			
Medium			
Mean	74	36.7	63.3
Median	83.3	36.7	70
Std	24.5	23.6	28.7
Min	33.3	20	20
Max	95	53.3	95
N	5	2	7
P value			.1752
Large			
Mean	47.5	56.7	52.1
Median	40	51.7	46.7
Std	18.9	16.3	17.1
Min	35	43.3	35
Max	75	80	80
N	4	4	8
P value			.3094
Overall			
Mean	62.2	50	57.3
Median	70	50.8	53.3
Std	25.1	19.4	23.1
Min	33.3	20	20
Max	95	80	95
N	9	6	15
P value			.5165
ASES score month 3			
Medium			
Mean	58	75.8	63.1
Median	66.7	75.8	70
Std	23.3	5.9	21.0
Min	20	71.7	20
Max	80	80	80
N	5	2	7
P value			.2410
Large			
Mean	63.3	71.7	67.5
Median	60	72.5	63.3
Std	10.6	25.0	18.3
Min	55	41.7	41.7
Max	78.3	100	100
N	4	4	8
P value			.5614
Overall			
Mean	60.4	73.1	65.4
Median	63.3	75.8	66.7
Std	17.9	19.6	19.0
Min	20	41.7	20
Max	80	100	100
N	9	6	15
P value			.1746
ASES score year 1			
Medium			
Mean	79.6	98.3	85.8
Median	81.7	98.3	97.5
Std	23.0	2.4	20.3
Min	55	96.7	55
Max	100	100	100
N	4	2	6
P value			.6386
Large			
Mean	82.5	95	87.9
Median	95	100	98.3
Std	27.4	8.7	21.1
Min	41.7	85	41.7
Max	98.3	100	100
N	4	3	7
P value			.3681
Overall			
Mean	81.0	96.3	86.9
Median	95	100	98.3
Std	23.5	6.5	19.9
Min	41.7	85	41.7
Max	100	100	100
N	8	5	13
P value			.1791

(*continued on next page*)

Table II (*continued*)

Generated: 06/10/2020 16:49:23 by PROs by retear.sas

patients (8.9%) and was either not observed or could not be determined in the remaining patients (91.1%). At 1 year, no such boundary was observed or could not be determined in all available patients (100%).

Clinical outcomes

Significant improvements were observed for medium and large full-thickness tears in ASES and CMS scores from the baseline to 1 year ($P < .001$; Table V). The minimal clinically important difference for ASES and CMS was met at 1 year by 91.7% (95% CI: 84.9-96.1) and 86.4% (95% CI: 78.2-92.4) of patients, respectively.

Of the subgroups assessed for clinical outcomes, classified by tear type, age < 65 years and lack of retear both showed statistical significant improvements in CMS scores at 1 year compared with those ≥ 65 years and with retear, respectively (Table V). An additional subgroup analysis of patients undergoing biceps treatment or not at index surgery indicated no statistically significant difference between the groups in ASES ($P = .4582$) or CMS scores ($P = .38$) at 1 year.

Subject satisfaction

At 1 year, 110 of 114 patients (96.5%) reported that they "agreed/strongly agreed" that they were satisfied with surgery and 4 (3.5%) that they "disagreed/strongly disagreed." All 113 patients who responded said they would recommend the procedure to a friend.

Recovery

Patients reported a mean sling time of 38.7 days (SD, 18.3) and mean of 22 days (SD, 12.45) spent in physical therapy. After surgery, the mean time to return to work was 44.1 days (SD, 64.8) and to return to normal activities was 124.6 days (SD, 60.6).

Safety

There were 9 reoperations (7.8%) of the index shoulder, which occurred at a mean of 162.3 days (SD, 94.1) after surgery. Seven of the 9 reoperations consisted of revision rotator cuff repair for symptomatic recurrent or persistent rotator cuff tears: 1 in a patient with prior history of poor healing, 1 in a patient with traumatic injury, 3 in subjects who were postoperatively noncompliant, and 2 in subjects who had recurrent retears for unknown reasons (including one subject who also had an intratendinous failure of the cuff medial to the tear site). None of these cases were designated by the treating surgeon to be potentially related to the collagen implant.

Two additional reoperations occurred during the follow-up period, which were considered possibly related to the implant or the procedure, suture anchors, or tendon and bone fixation anchors. In the first, the patient developed swelling and drainage in the operated shoulder 6 weeks after surgery and was treated with intravenous antibiotics for suspected infection. The patient was

Table III
CMS scores by visit and revision status

Cofield classification	Revision	No revision	Total
CMS score baseline			
Medium			
Mean	69.6	44.1	61.1
Median	75.8	44.1	72.9
Std	19.3	41.2	27.1
Min	41.6	15	15
Max	85.0	73.2	85.0
N	4	2	6
P value			.4875
Large			
Mean	41.8	43.2	42.5
Median	38.1	38.9	38.1
Std	10.6	18.2	13.8
Min	34	27	27
Max	56.8	68	68
N	4	4	8
P value			.8852
Overall			
Mean	55.7	43.5	50.4
Median	49.2	38.9	43.3
Std	20.7	23.2	21.8
Min	34	15	15
Max	85.0	73.2	85.0
N	8	6	14
P value			.2720
CMS score month 3			
Medium			
Mean	66.3	52.0	56.8
Median	66.3	52.0	52.9
Std	.	1.2	8.3
Min	66.3	51.2	51.2
Max	66.3	52.9	66.3
N	1	2	3
P value			.5403
Large			
Mean	.	75	75
Median	.	75	75
Std	.	.	.
Min	.	75	75
Max	.	75	75
N	0	1	1
P value			N/A
Overall			
Mean	66.3	59.7	61.3
Median	66.3	52.9	59.6
Std	.	13.3	11.3
Min	66.3	51.2	51.2
Max	66.3	75	75
N	1	3	4
P value			1.000
CMS score year 1			
Medium			
Mean	62.6	77.0	67.4
Median	63.9	77.0	71.1
Std	14.8	6.5	14.0
Min	44.3	72.4	44.3
Max	78.2	81.6	81.6
N	4	2	6
P value			.2472
Large			
Mean	67.6	83.4	74.4
Median	71.6	81	78.5
Std	13.9	4.2	13.2
Min	48.8	81	48.8
Max	78.5	88.2	88.2
N	4	3	7
P value			.0497
Overall			
Mean	65.1	80.8	71.2
Median	67.6	81	77.8
Std	13.5	5.6	13.5
Min	44.3	72.4	44.3
Max	78.5	88.2	88.2
N	8	5	13
P value			.0156

(*continued on next page*)

Table III (*continued*)

Generated: 06/10/2020 16:49:56 by PROs by retear.sas.

Table IV
Cumulative rotator cuff retears at 3 months and 1 year for subgroups of interest

Subgroups	Medium tears (N = 66)		Large tears (N = 49)	
	3 months	1 year	3 months	1 year
Repair technique				
Single-row repair	0/13 (0%)	1/13 (7.7%)	7/11 (63.6%)	8/11 (72.7%)
Double-row repair	3/53 (5.7%)	6/53 (11.3%)	3/38 (7.9%)	4/38 (10.5%)
P value	1	1	.0004	.0001
Age				
< 65 years	1/46 (2.2%)	4/46 (8.7%)	5/36 (13.9%)	6/36 (16.7%)
≥ 65 years	2/20 (10%)	3/20 (15%)	5/13 (38.5%)	6/13 (46.2%)
P value	.2159	.425	.1039	.0577
Sling time				
≤ 6 weeks	3/42 (7.1%)	6/42 (14.3%)	9/33 (27.3%)	11/33 (33.3%)
> 6 weeks	0/24 (0%)	1/24 (4.2%)	1/16 (6.3%)	1/16 (6.3%)
P value	.2951	.4076	.1347	.0733

subsequently taken to the operating room where extensive débridement was performed. Suture remnants and a repair anchor were also removed out of an abundance of caution, and cultures and biopsies were obtained. Surgical cultures at 15 days were negative and the infection was determined by the treating surgeon to be isolated to superficial structures. In the second, the patient experienced intermittent pain in the treated shoulder. A 3-month MRI indicated inflammatory changes and subsequent x-rays showed osteopenia in the greater tuberosity region. Five and a half months after the index surgery, the patient underwent aspiration in the OR which yielded 3-4 ml of nonpurulent fluid. The patient then underwent arthroscopic débridement and lysis of adhesions was performed. All biopsies and cultures taken at the time of surgery yielded no growth. No additional procedures were performed, and follow-up of this patient was still ongoing at the time of this analysis.

Discussion

Symptomatic full-thickness rotator cuff tears are associated with a worse clinical prognosis if left untreated rather than surgically repaired.[29,36] Approximately half of symptomatic full-thickness tears increase in size within 2 years, with tears larger than 1-1.5 cm having a higher rate of progression.[45] A long-term study showed that over 8.8 years there was a mean increase of tear size by 8.3 mm in the anterior-posterior plane and 4.5 mm in the medial-lateral plane.[35] Natural history shows that nonoperative management can be associated with substantial muscle atrophy (49%) and fatty infiltration (41%).[35] Failed rotator cuff repair is also associated with decreased strength and poorer clinical outcomes as compared with intact or partially torn rotator cuffs.[47]

Several risk factors have been identified as contributing to postoperative retear, ranging from the well-established to those with comparatively less supportive evidence. As expected, the risk of retear increases in tandem with the initial size of the full-thickness tear, with separate studies reporting retear rates for medium and large tears of 32% and 53%, respectively, at 1 year[39] and of 22% and 50%, respectively, at 2 years.[12] Older patient age

Table V
Clinical outcome scores at all follow-up points for medium and large tears overall, and for the subgroups of interest

Mean ASES shoulder score (n; SD)	Medium tears			Large tears		
	Baseline	3 months	1 year	Baseline	3 months	1 year
Overall (n; SD)	52.4 (n = 66; SD, 18.3)	65.2 (n = 66; SD, 19.6)	94.3 (n = 64; SD, 11.6)	48.0 (n = 46; SD, 19.0)	67.9 (n = 45; SD, 16.9)	93.1 (n = 47; SD, 13.2)
P value*	–	<.001	<.001	–	<.001	<.001
Subgroups						
Repair technique						
Single-row repair	52.1 (n = 13; SD, 16.6)	67.9 (n = 13; SD, 23.1)	96.0 (n = 12; SD, 6.0)	55.0 (n = 8; SD, 11.6)	80.5 (n = 7; SD, 18.9)	88.5 (n = 9; SD, 18.5)
Double-row repair	52.5 (n = 53; SD, 18.8)	64.6 (n = 53; SD, 18.8)	93.9 (n = 52; SD, 12.6)	46.5 (n = 38; SD, 20.0)	65.6 (n = 38; SD, 15.8)	94.2 (n = 38; SD, 11.7)
P value†	.9308	.6304	.3982	.1222	.0879	.4038
Age						
< 65 years	48.8 (n = 46; SD, 15.8)	64.1 (n = 46; SD, 21.6)	94.2 (n = 44; SD, 12.0)	45.6 (n = 35; SD, 18.9)	68.4 (n = 35; SD, 17.4)	93.2 (n = 35; SD, 12.1)
≥ 65 years	60.8 (n = 20; SD, 21.1)	67.8 (n = 20; SD, 14.0)	94.5 (n = 20; SD, 11.0)	55.6 (n = 11; SD, 17.8)	66.2 (n = 10; SD, 16.1)	92.6 (n = 12; SD, 16.6)
P value†	.0293	.4068	.9134	.1267	.7056	.9101
Sling time						
≤ 6 weeks	54.5 (n = 40; SD, 20.6)	67.1 (n = 40; SD, 18.4)	94.9 (n = 39; SD, 10.0)	50.6 (n = 31; SD, 19.0)	69.2 (n = 31; SD, 17.3)	93.7 (n = 30; SD, 12.6)
> 6 weeks	49.3 (n = 26; SD, 13.7)	62.3 (n = 26; SD, 21.4)	93.3 (n = 25; SD, 13.9)	42.4 (n = 15; SD, 18.3)	65.1 (n = 14; SD, 16.3)	92.1 (n = 17; SD, 14.5)
P value†	.2265	.3501	.6338	.1700	.4534	.7051
Retear						
Retear	63.3 (n = 7; SD, 28.7)	63.1 (n = 7; SD, 21.0)	85.8 (n = 6; SD, 20.3)	52.1 (n = 8; SD, 17.1)	67.5 (n = 8; SD, 18.3)	87.9 (n = 7; SD, 21.1)
No retear	51.1 (n = 59; SD, 16.5)	65.5 (n = 59; SD, 19.6)	95.1 (n = 58; SD, 10.2)	47.1 (n = 38; SD, 19.5)	68.0 (n = 37; SD, 16.9)	94.0 (n = 40; SD, 11.5)
P value†	.1788	.8758	.2998	.5815	.7891	.3404
Mean CMS (n; SD)	Medium tears			Large tears		
	Baseline	3 months	1 year	Baseline	3 months	1 year
Overall	51.2 (n = 64; SD, 16.8)	63.2 (n = 21; SD, 16.8)	79.1 (n = 61; SD, 11.8)	48.5 (n = 46; SD, 18.1)	65.2 (n = 13; SD, 14.7)	85.3 (n = 46; SD, 9.6)
P value*	–	.002	<.001	–	.032	<.001
Subgroups						
Repair technique						
Single-row repair	49.9 (n = 12; SD, 12.9)	67.0 (n = 11; SD, 17.2)	82.5 (n = 10; SD, 5.5)	55.2 (n = 11; SD, 14.5)	67.7 (n = 8; SD, 13.1)	84.8 (n = 10; SD, 5.5)
Double-row repair	51.5 (n = 52; SD, 17.6)	59.0 (n = 10; SD, 16.3)	78.4 (n = 51; SD, 12.6)	46.4 (n = 35; SD, 18.8)	61.2 (n = 5; SD, 17.7)	85.4 (n = 36; SD, 10.6)
P value†	.1187	.5024	.8079	.7122	.2886	.1098
Age						
< 65 years	49.4 (n = 44; SD, 16.8)	61.7 (n = 17; SD, 18.1)	81.3 (n = 41; SD, 12.4)	45.3 (n = 33; SD, 16.6)	66.4 (n = 9; SD, 15.2)	87.6 (n = 34; SD, 7.7)
≥ 65 years	55.2 (n = 20; SD, 16.3)	69.2 (n = 4; SD, 9.0)	74.6 (n = 20; SD, 9.1)	56.6 (n = 13; SD, 20.0)	62.5 (n = 4; SD, 15.3)	78.8 (n = 12; SD, 11.8)
P value†	.0852	.6866	.0300	.2017	.2623	.0211
Sling time						
≤ 6 weeks	51.6 (n = 38; SD, 18.3)	62.2 (n = 12; SD, 18.8)	79.1 (n = 35; SD, 10.5)	49.9 (n = 29; SD, 18.7)	67.5 (n = 9; SD, 14.7)	84.9 (n = 31; SD, 10.2)
> 6 weeks	50.7 (n = 26; SD, 14.6)	64.5 (n = 9; SD, 14.7)	79.1 (n = 26; SD, 13.6)	46.1 (n = 17; SD, 17.4)	60.0 (n = 4; SD, 15.2)	86.1 (n = 15; SD, 8.6)
P value†	.4884	.4386	.6774	.8315	.7521	.9990
Retear						
Retear	61.1 (n = 6; SD, 27.1)	56.8 (n = 3; SD, 8.3)	67.4 (n = 6; SD, 14.0)	42.5 (n = 8; SD, 13.8)	75.0 (n = 1; SD, NA)	74.4 (n = 7; SD, 13.2)
No retear	50.2 (n = 58; SD, 15.3)	64.2 (n = 18; SD, 17.8)	80.3 (n = 55; SD, 11.0)	49.8 (n = 38; SD, 18.8)	64.4 (n = 12; SD, 15.0)	87.3 (n = 39; SD, 7.5)
P value†	.1314	.4031	.0272	.3174	.5167	.0067

ASES, American Shoulder and Elbow Surgeons Shoulder Score; *CMS*, Constant-Murley Score; *NA*, not applicable; *SD*, standard deviation.
* *P* value for difference since previous visit within each group.
† *P* value for difference with comparator group at this follow-up visit.

also increases the risk of retear.[30,37,39] In a systematic literature review, Hein et al noted that single-row repair had a significantly higher retear rate compared with double-row repair (33% vs 10%, $P < .001$) in large tears.[18] Rehabilitation after rotator cuff repair with early passive range of motion has also been thought to carry an increased risk of retear when compared with delayed range of motion, although this point remains debated.[3]

In patients with full-thickness tears, weak initial repair, inadequate healing, or structural failure of the repair increase the risk of retear,[27] which primarily occurs within 10 to 15 months after arthroscopic repair.[13] Biologic technologies can potentially augment existing arthroscopic repair during this initial repair and healing phase to reduce retear rates and improve postoperative outcomes.[7,46]

In the current analysis, the adjunctive use of this implant and arthroscopic repair led to a 16.5% rate of retear at 1 year in medium and large full-thickness tears. In this study, the term "retear" includes both rotator cuffs that have retorn after healing and those that have failed to heal after repair. A number of studies have reported retear at approximately 1 year using various fixation techniques, with rates ranging up to 76% for medium and large full-thickness tears.[4,21,39,43,44] To the authors' knowledge, the United Kingdom Rotator Cuff Trial (UKUFF) remains the largest prospective study of rotator cuff repair ever undertaken, making it an ideal population for comparison. In assessing UKUFF data, Rashid et al reported 1-year retear rates of 32% and 53% for medium and large full-thickness tears, respectively,[39] and Carr et al 2-year retear rates of 46.4% for small to massive full-thickness tears.[9]

Ten of 12 retears of large tears (83.3%) (and 13 of all 19 retears [68.4%]) occurred before 3-month follow-up, which is inconsistent with the findings of a meta-analysis on the timing of retear.[13] Chona et al found that medium and large full-thickness retear rates increased for roughly 15 months and 12 months, respectively, before leveling off. Conversely, most retears in the present study occurred before 3 months. Of 8 retears seen in the large tear/single-row group, 7 (87.5%) occurred before the 3-month MRI. Although our study was not designed to make conclusive determinations in this area, review of the data does suggest that the early failures herein could be due to the inability of the augmented repair to overcome the anatomical challenge of the tear—as the implant is admittedly nonstructural. Likewise, the rate of late failures may be reduced potentially as a result of the improved biology related to

the implant. These theories should be investigated further in future studies.

There is an ongoing debate in the literature whether early mobilization after rotator cuff repair may contribute to retear.[20,22,26] Although 9 of the 11 (81.8%) retears that occurred in subjects with mobilization $\leq$ 6 weeks in our series occurred before the 3-month MRI, there was no statistically significant difference in retear rates when compared with those mobilized > 6 weeks (1/16 [6.3%]; $P = .0733$). Owing to small sample sizes in this subgroup, the impact of early mobilization remains unclear.

Another noteworthy finding of the current analysis was the significantly lower retear rates observed for double-row over single-row repair for both medium and large tears ($P = .0004$ and $P = .0001$, respectively). Double-row rotator cuff repair augmented with a bioinductive graft led to an 11.3% and 10.5% retear rate at 1 year in patients with medium and large tears, respectively. Although this is in line with the 10% retear rates for medium tears in the systematic literature review of Hein et al,[18] it is notably below the 24% rate they reported for large tears.

Single-row repairs were once the standard of care for rotator cuff tears, but it is now believed that double-row repairs provide more contact area between the tendon and bone, allowing more fibers to engage in the healing process.[11] A systematic review of cadaveric and animal data reported that double row was associated with greater restoration of the anatomic rotator cuff footprint when compared with single-row repair.[50]

The clinical outcomes assessed in the present study also indicated a favorable postoperative prognosis for full-thickness tears repaired and augmented with the study implant, with significant improvements noted in both medium and large tears between the baseline and 1 year. ASES and CMS are the most commonly used patient-reported outcome scores in rotator cuff studies.[32] However, studies incorporating these outcomes understandably comprise a wide variety of indications, tear types, treatment modalities, and follow-up times—resulting in a heterogeneity of designs that complicates the ability to offer a direct comparison with the current findings. Nonetheless, a meta-analysis of 16 randomized controlled trials (1,221 shoulders) of nontraumatic full-thickness arthroscopic or miniopen rotator cuff repair by Gurnani et al[17] reported that at 1 year, mean ASES and CMS scores improved on average by 38.6 and 29.5 points, respectively. Between the baseline and 1 year in the current analysis, mean CMS improved by 27.9 and 36.8 for medium- and large-sized tears, respectively, and mean ASES by 41.9 and 45.1, respectively. These scores are therefore in range of or exceed the threshold established in that meta-analysis.

The mean postoperative ASES and CMS scores observed in our series are also consistent with those reported in prior studies of this implant in full-thickness tears. McIntyre[34] reported that the mean ASES score increased from 45.6 to 82.7 at 12 months of follow-up ($P < .001$). Bokor et al[7] showed that these benefits persisted at 24 months of follow-up, with an increase in ASES score from 44.6 to 87.8 ($P < .001$), and in the CMS from 50.7 to 78.0 ($P < .001$) compared with the preoperative baseline.

It is possible that the relatively low level of retear observed in the current series contributed to the improved clinical outcome scores at 1-year follow-up. There is ongoing debate on what impact postoperative retear after rotator cuff repair has on clinical outcomes.[16] Separate studies of arthroscopic repair techniques have noted comparable outcomes in those with and without retear,[25,49] whereas others have observed significant differences in postoperative clinical and functional assessments in those with retear.[9,23,28,38,47] The current results are aligned with the latter group of studies in reporting that patients with retear had significantly worse CMS scores at 1 year. Further comparative clinical trials and meta-analyses of existing data sets are warranted to better elucidate the role of postoperative retear on clinical outcomes and function.

Although there was a significant difference in retear between single- and double-row repair observed in the present study, this did not result in any clinically or statistically significant differences in ASES or CMS scores between the groups. The American Academy of Orthopaedic Surgeons recent Clinical Practice Guidelines on managing rotator cuff injuries includes a meta-analysis of randomized controlled trials using MRI to compare retear rates between single- and double-row repair. It concludes that strong evidence supports lower retear rates after double-row repair than after single-row repair for both partial- and full-thickness retears after primary repair.[1] Furthermore, double-row repair appears to have limited advantages over single-row when all sizes of full-thickness tears are taken together, and there is an apparent superiority in double-row repairs of large full-thickness tears in terms of select clinical outcomes (ASES and University of California, Los Angeles scores), muscle strength, and range of motion.[8,31]

Despite the clear role of advanced age in increasing retear and reducing function,[40] it has been suggested that arthroscopic repair still be considered a viable option for those > 65 years, specifically when the tear is limited to the supraspinatus.[10] Retrospective data indicate that consistent improvements in function and pain can be achieved in patients $\geq$ 75 years nearly 5 years after undergoing rotator cuff repair.[42] Although the present study found that CMS scores at 1 year did significantly favor those < 65 years, it also found that mean ASES and CMS score achieved greater than minimal clinically important difference in patients > 65 years, indicating no reason why relatively older patients with full-thickness tears would not benefit from rotator cuff repair augmented with the study implant.

Limitations

The present study has several limitations that should be considered. First, although it was prospectively designed, it lacks a control group by which to better measure its effects. Second, leaving the decision to indicate use of the implant up to the individual surgeon necessarily introduces some risk of selection bias. Third, the analysis of retear rates and clinical outcomes for various subgroups was not planned at the outset of this study. Power calculations have been performed retrospectively on the observed values, and for the single-row vs double-row subgroup analysis power was calculated to be less than 15%. Similar power levels were observed for the remaining subgroup analyses. Future studies should include prospectively designed subgroup analyses with appropriate power, potentially with randomized control groups, in order to report with greater confidence, the impact of these patient risk factors, demographic details, or surgical interventions. Finally, future research should consider the "value proposition" of this implant, with analysis of costs and risks vs. improved clinical outcomes and benefits.

Conclusion

Interim results from this ongoing prospective trial indicate that this bioinductive collagen implant may be an effective adjunctive treatment for reducing retear rates in full-thickness rotator cuff tear repairs, as compared with 1-year retear rates in the largest prospective series yet reported in the current literature.[39] In this study, most retears occurred in the early healing period (<3 months), which is before when histologic evidence shows maturation of the newly generated tissue provided by the implant, suggesting a component of early functional loading or inadequate repair technique contributing to early retear.[2] Patients with large tears treated

with double-row repair appeared to particularly benefit, with retear rates considerably lower than that previously reported in the literature for double-row repairs. That the rate of retear was comparable between medium and large tears treated with double-row repair (11.3% vs 10.5%, respectively) is also notable, given that large tears are usually associated with relatively inferior postoperative healing compared with medium and small tears. Clinical outcomes indicated a favorable postoperative improvement in pain and function at 1 year. The safety and efficacy of the study implant was evidenced by the low rate of reoperations attributable to the implant. Further follow-up of this study cohort will determine if these retear rates and clinical outcomes are maintained at 2 years, and additional prospective, randomized studies are necessary to determine the true efficacy of the study implant in augmenting rotator cuff repair as compared with standard of care.

Disclaimer

Support for this study was provided by Rotation Medical, Inc., now a wholly owned subsidiary of Smith & Nephew Consolidated, Inc.

Dr. Bushnell reports research support and consulting fees from Smith & Nephew; Dr. Connor reports no conflicts; Dr. Harris reports no conflicts; Dr. Ho reports consulting fees from Smith & Nephew; Dr. Trenhaile reports research support, IP royalties, consulting fees, and speaker fees from Smith & Nephew, and JSES editorial board; Dr. Abrams reports IP royalties and consulting fees from Smith & Nephew and JSES editorial board.

Acknowledgments

The authors would like to acknowledge John Watson, Cristin Taylor, Amir Kamali, and Anasua Ganguly for technical assistance with the preparation of this article.

References

1. American Academy of Orthopaedic Surgeons. Management of Rotator Cuff Injuries Clinical Practice Guideline. Available at: https://www.aaos.org/globalassets/quality-and-practice-resources/rotator-cuff/rotator-cuff-cpg-final-12-20-19.pdf; 2019. Accessed June 25, 2020.
2. Arnoczky SP, Bishai SK, Schofield B, Sigman S, Bushnell BD, Hommen JP, et al. Histologic Evaluation of Biopsy Specimens Obtained After Rotator Cuff Repair Augmented With a Highly Porous Collagen Implant. Arthroscopy 2017;33:278-83. https://doi.org/10.1016/j.arthro.2016.06.047.
3. Bakti N, Antonios T, Phadke A, Singh B. Early versus delayed mobilization following rotator cuff repair. J Clin Orthop Trauma 2019;10:257-60. https://doi.org/10.1016/j.jcot.2019.01.016.
4. Bishop J, Klepps S, Lo IK, Bird J, Gladstone JN, Flatow EL. Cuff integrity after arthroscopic versus open rotator cuff repair: a prospective study. J Shoulder Elbow Surg 2006;15:290-9. https://doi.org/10.1016/j.jse.2005.09.017.
5. Bokor DJ, Sonnabend D, Deady L, Cass B, Young A, Kampen C, et al. Healing of partial-thickness rotator cuff tears following arthroscopic augmentation with a highly-porous collagen implant: a 5-year clinical and MRI follow-up. Muscle Ligaments Tendons J 2019;9:338-47. https://doi.org/10.32098/mltj.03.2019.07.
6. Bokor DJ, Sonnabend D, Deady L, Cass B, Young A, Van Kampen C, et al. Evidence of healing of partial-thickness rotator cuff tears following arthroscopic augmentation with a collagen implant: a 2-year MRI follow-up. Muscles Ligaments Tendons J 2016;6:16-25. https://doi.org/10.11138/mltj/2016.6.1.016.
7. Bokor DJ, Sonnabend D, Deady L, Cass B, Young A, Van Kampen C, et al. Preliminary investigation of a biological augmentation of rotator cuff repairs using a collagen implant: a 2-year MRI follow-up. Muscles Ligaments Tendons J 2015;5:144-50. https://doi.org/10.11138/mltj/2015.5.3.144.
8. Carbonel I, Martinez AA, Calvo A, Ripalda J, Herrera A. Single-row versus double-row arthroscopic repair in the treatment of rotator cuff tears: a prospective randomized clinical study. Int Orthop 2012;36:1877-83. https://doi.org/10.1007/s00264-012-1559-9.
9. Carr A, Cooper C, Campbell MK, Rees J, Moser J, Beard DJ, et al. Effectiveness of Open and Arthroscopic Rotator Cuff Repair (UKUFF): A Randomised Controlled Trial. Bone Joint J 2017;99-B:107-15. https://doi.org/10.1302/0301-620X.99B1.BJJ-2016-0424.R1.
10. Charousset C, Bellaïche L, Kalra K, Petrover D. Arthroscopic Repair of Full-Thickness Rotator Cuff Tears: Is There Tendon Healing in Patients Aged 65 Years or Older? Arthroscopy 2010;26:302-9. https://doi.org/10.1016/j.arthro.2009.08.027.
11. Chen M, Xu W, Dong Q, Huang Q, Xie Z, Mao Y. Outcomes of Single-Row Versus Double-Row Arthroscopic Rotator Cuff Repair: A Systematic Review and Meta-Analysis of Current Evidence. Arthroscopy 2013;29:1437-49. https://doi.org/10.1016/j.arthro.2013.03.076.
12. Cho NS, Lee BG, Rhee YG. Arthroscopic Rotator Cuff Repair Using a Suture Bridge Technique: Is the Repair Integrity Actually Maintained? Am J Sports Med 2011;39:2108-16. https://doi.org/10.1177/0363546510397171.
13. Chona DV, Lakomkin N, Lott A, Workman AD, Henry AC, Kuntz AF, et al. The timing of retears after arthroscopic rotator cuff repair. J Shoulder Elbow Surg 2017;26:2054-9. https://doi.org/10.1016/j.jse.2017.07.015.
14. Cofield RH. Subscapular Muscle Transposition for Repair of Chronic Rotator Cuff Tears. Surg Gynec Obstet Surg Gynecol Obstet 1982;154:667-72.
15. Cvetanovich GL, Gowd AK, Liu JN, Nwachukwu BU, Cabarcas BC, Cole BJ, et al. Establishing clinically significant outcome after arthroscopic rotator cuff repair. J Shoulder Elbow Surg 2019;28:939-48. https://doi.org/10.1016/j.jse.2018.10.013.
16. Galanopoulos I, Ilias A, Karliaftis K, Papadopoulos D, Ashwood N. The Impact of Re-tear on the Clinical Outcome after Rotator Cuff Repair Using Open or Arthroscopic Techniques - A Systematic Review. Open Orthop J 2017;11:95-107. https://doi.org/10.2174/1874325001711010095.
17. Gurnani N, van Deurzen DFP, van den Bekerom MPJ. Shoulder-specific outcomes 1 year after nontraumatic full-thickness rotator cuff repair: a systematic literature review and meta-analysis. Shoulder Elbow 2017;9:247-57. https://doi.org/10.1177/1758573217711903.
18. Hein J, Reilly JM, Chae J, Maerz T, Anderson K. Re-tear Rates After Arthroscopic Single-Row, Double-Row, and Suture Bridge Rotator Cuff Repair at a Minimum of 1 Year of Imaging Follow-up: A Systematic Review. Arthroscopy 2015;31:2274-81. https://doi.org/10.1016/j.arthro.2015.06.004.
19. Henry P, Wasserstein D, Park S, Dwyer T, Chahal J, Slobogean G, et al. Arthroscopic repair for chronic massive rotator cuff tears: a systematic review. Arthroscopy 2015;31:2472-80. https://doi.org/10.1016/j.arthro.2015.06.038.
20. Jancuska J, Matthews J, Miller T, Kluczynski MA, Bisson LJ. A Systematic Summary of Systematic Reviews on the Topic of the Rotator Cuff. Orthop J Sports Med 2018;6:2325967118797891. https://doi.org/10.1177/2325967118797891.
21. Jo CH, Park JW, Shin JS. Changes of Muscle Atrophy According to the Immediate Postoperative Time Point in Magnetic Resonance Imaging After Arthroscopic Rotator Cuff Repair. Arthroscopy 2016;32:2477-87. https://doi.org/10.1016/j.arthro.2016.04.032.
22. Keener JD, Galatz LM, Stobbs-Cucchi G, Patton R, Yamaguchi K. Rehabilitation following arthroscopic rotator cuff repair: a prospective randomized trial of immobilization compared with early motion. J Bone Joint Surg Am 2014;96:11-9. https://doi.org/10.2106/JBJS.M.00034.
23. Kim HM, Caldwell JME, Buza JA, Fink LA, Ahmad CS, Bigliani LU, et al. Factors affecting satisfaction and shoulder function in patients with a recurrent rotator cuff tear. J Bone Joint Surg Am 2014;96:106-12. https://doi.org/10.2106/JBJS.L.01649.
24. Kim YK, Jung KH, Kim JW, Kim US, Hwang DH. Factors affecting rotator cuff integrity after arthroscopic repair for medium-sized or larger cuff tears: a retrospective cohort study. J Shoulder Elbow Surg 2018;27:1012-20. https://doi.org/10.1016/j.jse.2017.11.016.
25. Kim KC, Shin HD, Lee WY. Repair integrity and functional outcomes after arthroscopic suture-bridge rotator cuff repair. J Bone Joint Surg Am 2012;94:e48. https://doi.org/10.2106/JBJS.K.00158.
26. Kluczynski MA, Isenburg MM, Marzo JM, Bisson LJ. Does early versus delayed active range of motion affect rotator cuff healing after surgical repair? A systematic review and meta-analysis. Am J Sports Med 2016;44:785-91. https://doi.org/10.1177/0363546515582032.
27. Lädermann A, Denard PJ, Burkhart SS. Management of failed rotator cuff repair: a systematic review. J Isakos 2016;1:32-7. https://doi.org/10.1136/jisakos-2015-000027.
28. Lafosse L, Brozska R, Toussaint B, Gobezie R. The outcome and structural integrity of arthroscopic rotator cuff repair with use of the double-row suture anchor technique. J Bone Joint Surg Am 2007;89:1533-41. https://doi.org/10.2106/JBJS.F.00305.
29. Lambers Heerspink FO, van Raay JJ, Koorevaar RC, van Eerden PJ, Westerbeek RE, van 't Riet E, et al. Comparing surgical repair with conservative treatment for degenerative rotator cuff tears: a randomized controlled trial. J Shoulder Elbow Surg 2015;8:1274-81. https://doi.org/10.1016/j.jse.2015.05.040.
30. Lee YS, Jeong JY, Park CD, Kang SG, Yoo JC. Evaluation of the risk factors for a rotator cuff re-tear after repair surgery. Am J Sports Med 2017;45:1755-61. https://doi.org/10.1177/0363546517695234.
31. Ma HL, Chiang ER, Wu HT, Hung SC, Wang ST, Liu CL, et al. Clinical outcome and imaging of arthroscopic single-row and double-row rotator cuff repair: a prospective randomized trial. Arthroscopy 2012;28:16-24. https://doi.org/10.1016/j.arthro.2011.07.003.
32. Makhni EC, Steinhaus ME, Morrow ZS, Jobin CM, Verma NN, Cole BJ, et al. Outcomes assessment in rotator cuff pathology: what are we measuring? J Shoulder Elbow Surg 2015;24:2008-15. https://doi.org/10.1016/j.jse.2015.08.007.
33. Matthews TJ, Hand GC, Rees JL, Athanasou NA, Carr AJ. Pathology of the torn rotator cuff tendon. Reduction in potential for repair as tear size increases. J Bone Joint Surg Br 2006;88:489-95. https://doi.org/10.1302/0301-620X.88B4.16845.
34. McIntyre LF, Bishai SK, Brown PB 3rd, Bushnell BD, Trenhaile SW. Patient-Reported Outcomes After Use of a Bioabsorbable Collagen Implant to Treat Partial

and Full-Thickness Rotator Cuff Tears. Arthroscopy 2019;35:2262-71. https://doi.org/10.1016/j.arthro.2019.02.019.
35. Moosmayer S, Gartner AV, Tariq R. The natural course of nonoperatively treated rotator cuff tears: an 8.8-year follow-up of tear anatomy and clinical outcome in 49 patients. J Shoulder Elbow Surg 2017;4:627-34. https://doi.org/10.1016/j.jse.2016.10.002.
36. Moosmayer S, Lund G, Seljom US, Haldorsen B, Svege IC, Hennig T, et al. Tendon repair compared with physiotherapy in the treatment of rotator cuff tears: a randomized controlled study in 103 cases with a five-year follow-up. J Bone Joint Surg Am 2014;18:1504-14. https://doi.org/10.2106/JBJS.M.01393.
37. Oh JH, Kim SH, Kang JY, Oh CH, Gong HS. Effect of age on functional and structural outcome after rotator cuff repair. Am J Sports Med 2010;38:672-8. https://doi.org/10.1177/0363546509352460.
38. Park JY, Lhee SH, Oh KS, Moon SG, Hwang JT. Clinical and ultrasonographic outcomes of arthroscopic suture bridge repair for massive rotator cuff tear. Arthroscopy 2013;29:280-9. https://doi.org/10.1016/j.arthro.2012.09.008.
39. Rashid MS, Cooper C, Cook J, Cooper D, Dakin SG, Snelling S, et al. Increasing age and tear size reduce rotator cuff repair healing rate at 1 year. Acta Orthop 2017;88:606-11. https://doi.org/10.1080/17453674.2017.1370844.
40. Saccomanno MF, Sircana G, Cazzato G, Donati F, Randelli P, Milano G. Prognostic factors influencing the outcome of rotator cuff repair: a systematic review. Knee Surg Sports Traumatol Arthrosc 2016;24:3809-19. https://doi.org/10.1007/s00167-015-3700-y.
41. Schlegel TF, Abrams JS, Bushnell BD, Brock JL, Ho CP. Radiologic and clinical evaluation of a bioabsorbable collagen implant to treat partial-thickness tears: a prospective multicenter study. J Shoulder Elbow Surg 2018;27:242-51. https://doi.org/10.1016/j.jse.2017.08.023.
42. Stone MA, Ho JC, Kane L, Lazarus M, Namdari S. Midterm outcomes of arthroscopic rotator cuff repair in patients aged 75 years and older. J Shoulder Elbow Surg 2020;29:S17-22. https://doi.org/10.1016/j.jse.2019.11.022.
43. Sugaya H, Maeda K, Matsuki K, Moriishi J. Repair integrity and functional outcome after arthroscopic double-row rotator cuff repair. A prospective outcome study. J Bone Joint Surg Am 2007;89:953-60. https://doi.org/10.2106/JBJS.F.00512.
44. Taniguchi N, Suenaga N, Oizumi N, Miyoshi N, Yamaguchi H, Inoue K, et al. Bone marrow stimulation at the footprint of arthroscopic surface-holding repair advances cuff repair integrity. J Shoulder Elbow Surg 2015;24:860-6. https://doi.org/10.1016/j.jse.2014.09.031.
45. Tashjian RZ. Epidemiology, Natural History, and Indications for Treatment of Rotator Cuff Tears. Clin Sports Med 2012;31:589-604. https://doi.org/10.1016/j.csm.2012.07.001.
46. Thon SG, O'Malley L, O'Brien MJ, Savoie FH III. Evaluation of healing rates and safety with a bioinductive collagen patch for large and massive rotator cuff tears: 2-year safety and clinical outcomes. Am J Sports Med 2019;47:1901-8. https://doi.org/10.1177/0363546519850795.
47. Yang J Jr, Robbins M, Reilly J, Maerz T, Anderson K. The Clinical Effect of a Rotator Cuff Re-tear: A Meta-analysis of Arthroscopic Single-Row and Double-Row Repairs. Am J Sports Med 2017;45:733-41. https://doi.org/10.1177/0363546516652900.
48. Van Kampen C, Arnoczky S, Parks P, Hackett E, Ruehlman D, Turner A, et al. Tissue-engineered augmentation of a rotator cuff tendon using a reconstituted collagen scaffold: a histological evaluation in sheep. Muscles Ligaments Tendons J 2013;3:229-35.
49. Voigt C, Bosse C, Vosshenrich R, Schulz AP, Lill H. Arthroscopic supraspinatus tendon repair with suture-bridging technique: functional outcome and magnetic resonance imaging. Am J Sports Med 2010;38:983-91. https://doi.org/10.1177/0363546509359063.
50. Wall LB, Keener JD, Brophy RH. Double-row vs single-row rotator cuff repair: a review of the biomechanical evidence. J Shoulder Elbow Surg 2009;18:933-41. https://doi.org/10.1016/j.jse.2009.07.002.