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Two-year outcomes with a bioinductive collagen implant used in augmentation of arthroscopic repair of full-thickness rotator cuff tears: final results of a prospective multicenter study

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Background: Full-thickness rotator cuff tears (FTRCTs) represent a common shoulder injury that, if untreated, can progress in size, become increasingly painful, and inhibit function. These lesions are often surgically repaired, with double-row arthroscopic repair often preferred for larger tears. Biological augmentation technologies have been developed to improve rates of postoperative radiographic retear and enhance patient-reported outcomes after surgical FTRCT repair. This study sought to confirm that augmented repair with a bioinductive bovine collagen implant results in favorable retear rates and patient outcomes with follow-up to 2 years.

Methods: A prospective multicenter cohort study was undertaken to determine the efficacy and safety of augmenting single- or double-row arthroscopic repair of FTRCTs with a bioinductive bovine collagen implant. Of 115 adult patients participating, 66 (57.4%) had medium (1-3-cm) tears and 49 (42.6%) had large (3-5-cm) tears. Magnetic resonance imaging and patient-reported outcomes (American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form [ASES] and Constant-Murley Score [CMS]) were performed and recorded at baseline, 3 months, 1 year, and 2 years.

Results: Mean duration of follow-up was 2.1 years (range, 1.5-2.9 years). Between baseline and 2-year follow-up, mean total thickness of the supraspinatus tendon increased by 12.5% for medium tears and by 17.1% for large tears. Radiographic retear was noted in 7 of 61 available patients (11.5%) with medium tears, and in 14 of 40 patients (35.0%) with large tears. In both groups, these tears primarily occurred before the 3-month follow-up visit (13 of 21 [61.9%]). Radiographic retear with the supplemented double-row (DR) repair technique was 13.2% overall (12 of 91 DR patients; 11.3% for medium tears and 15.8% for large tears). The minimal clinically important difference was achieved by >90% of patients with both medium and large tears for both ASES and CMS. There were 2 serious adverse events classified by the treating surgeon as being possibly related to the device and/or procedure (1 case of swelling/drainage and 1 case of intermittent pain). Nine patients (7.8%; 4 medium tears and 5 large tears) required reoperation of the index rotator cuff surgery.

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

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Conclusion: Final 2-year data from this study confirm that using this implant in augmentation of arthroscopic double-row repair of FTRCTs provides favorable rates of radiographic retear and substantial functional recovery. The relative safety of the device is also further supported.

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

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

Full-thickness rotator cuff tears (FTRCTs) are a frequently encountered shoulder injury, which are more common in men, older patients, and those with predisposing risk factors such as muscle atrophy, metabolic disorders, and/or history of smoking.[1,2,22,32,51] FTRCTs can have an adverse clinical prognosis if left untreated, as they usually do not heal spontaneously and often increase in size over time.[32] Progression tends to occur in approximately half of symptomatic FTRCTs within 2 years, and at a faster rate in larger tears (>1-1.5 cm).[60] The risk of muscle degeneration and accompanying pain increases as these tears progress and enlarge.[34]

In recent years, arthroscopic-assisted repair has become the gold standard for treatment of FTRCTs.[26,35] Evidence suggests outcomes following arthroscopic repair are largely favorable,[28] and that surgical intervention in these tears may offer health care systems long-term benefits in the form of reduced costs.[49] As described in the American Academy of Orthopaedic Surgeons (AAOS) Clinical Practice Guidelines (CPG),[3] prospective randomized controlled trials[38,48] have shown clinically significant improvement in objective and subjective outcomes for both nonoperative intervention and surgical repair of FTRCTs. Although noting that strong evidence supports nonoperative management, the authors of the CPG also state that these tears often still increase in size and that substantial numbers of patients go on to experience muscle atrophy and fatty infiltration. The CPG offers a similar caveat in that although surgical repair resulted in superior outcomes compared to nonoperative therapy in symptomatic small-to-medium FTRCTs (strong evidence), the difference between groups did not meet the threshold considered to be of minimal clinically important difference (MCID).

Radiographic retear* following initial arthroscopic repair also remains a concern, although the heterogeneous nature of tear types and sizes, patient characteristics, and surgical interventions included in various clinical studies of arthroscopic repair makes it difficult to establish the expected risk for this adverse postoperative outcome. Radiographic retear rates following arthroscopic repair of medium to large FTRCTs have been reported to range from 10% to 53% at 1- to 2-year follow-up.[16,17,27,37,50] Such radiographic retears can ultimately prove also to be clinical retears and significantly affect postoperative clinical outcomes, patient satisfaction, and strength,[36,65] ultimately necessitating revision surgery.[39]

The continued difficulty in improving clinical outcomes and radiographic retear rates is thought to be due in large part to underlying structural issues present at the site of these tears, such as decreased blood flow, impaired tissue and tendon quality, and insufficient attachment.[39,52] To address these issues, surgeons and researchers have developed biologic technologies that aim to create an enhanced postoperative healing environment, thereby increasing the likelihood that arthroscopic rotator cuff repair will lead to successful outcomes.[7,8,12,15,47]

Among this class of new biological technologies is a highly porous collagen implant designed to be arthroscopically placed over the bursal surface of the supraspinatus tendon. Previous clinical studies have found that this implant produces favorable patient-reported outcomes and radiographic retear rates in a diverse group of patients with rotator cuff tears.[10,11,13,14,44,45,54,55,61] A report of the largest series of patients with FTRCTs treated with this implant noted that significantly improved outcomes occurred despite underlying tear size.[45] Nonetheless, these findings were derived from a real-world multicenter registry with only a 1-year final follow-up. This period overlaps, but does not fully align with, the average range by which many retears are thought to occur.[18] Furthermore, although most outcome scores are thought to stabilize within 1 year following rotator cuff repair surgery,[24] there is evidence to suggest improvements can continue beyond this point.[23] With these factors in mind, a prospective study was designed and conducted to assess the safety and efficacy of this bioinductive collagen implant in the arthroscopic treatment of FTRCTs in a large population across multiple centers with a final follow-up of 2 years.

The primary aim of this study was to evaluate change in tendon thickness, bioinduction of new tissue, and the rate of radiographic retear following the use of this implant as an adjunct to surgical repair in the treatment of supraspinatus tendon tears. Its secondary aim was to determine the functional improvements and safety associated with the use of this device. It was hypothesized that the favorable results observed at a 1-year interim analysis[14] would be maintained at final follow-up.

* "Radiographic retear" is a term commonly used in the literature to describe those tears uncovered on postoperative ultrasonography or magnetic resonance imaging. Such tears are not always considered a clinical failure, as the retears are often asymptomatic.[31]

Methods

Study design

Between October 2014 and January 2019, a total of 9 surgeons at 9 different centers in the United States prospectively enrolled patients in this study. Enrollment limit was determined by total enrollment between full-thickness and partial-thickness arms. The decision to indicate use of the implant was left to the discretion of the individual surgeon before enrollment. Patients were eligible for inclusion if they were ≥21 years of age, had medium (1-3 cm) or large (3-5 cm) FTRCTs often including the supraspinatus tendon planned for surgical repair, and chronic shoulder pain lasting longer than 3 months that was unresponsive to conservative therapy including—but not limited to—pain medication, physical therapy, and injections.

Conversely, patients were excluded if they had massive rotator cuff tears (≥5 cm), acute rotator cuff tears <12 months from injury, or if the index shoulder had undergone previous rotator cuff surgery or had evidence of instability, calcification, chondromalacia (≥grade 3), and fatty infiltration (≥grade 2). Patients were also excluded if they had a history of heavy smoking (>1 pack/day) within the last 6 months; genetic collagen disease; insulin-dependent diabetes; auto-immune, 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.

All patients provided voluntary informed consent before enrollment within the study, which was performed in compliance with the ethical principles of the Declaration of Helsinki.

Patients underwent a noncontrast magnetic resonance imaging (MRI) scan of the affected shoulder within 60 days prior to surgery to confirm they had FTRCTs, in line with the study's eligibility criteria. These MRI scans were performed using a standard protocol, and in addition to any previous nonprotocol MRI scans when necessary. During surgery, tear type was reconfirmed visually on arthroscopy with a calibrated probe, with only FTRCTs recorded by the investigators as meeting the Cofield grade[19] for medium or large included in the subsequent analysis.

All patients underwent arthroscopic repair of their FTRCTs augmented with the study implant (REGENETEN; Smith & Nephew, Andover, MA, USA), a bovine collagen implant made from highly purified reconstituted collagen fibers derived from bovine tendon designed to completely resorb usually within 6 months.[5] The surgical technique and rehabilitation program for this cohort has been previously described.[14]

Study outcomes

The primary efficacy outcomes for this analysis were all radiographic parameters and consisted of change in postoperative supraspinatus tendon thickness, integration of the newly induced tissue (as assessed by the presence or absence of a clear boundary between the device and the underlying tendon), and analysis of radiographic retear (defined as any new observable full-thickness discontinuity in the tendon). Tendon thickness was measured at the thinnest-appearing portion of the supraspinatus tendon on the MR images. This would obviate concern for partial volume averaging (which would exaggerate tendon thickness), and for the device, which was not apparent and could not be differentiated with no visible boundaries at follow-up. These radiographic outcomes were assessed using MRI scans at baseline and the 3-month, 1-year, and 2-year postoperative follow-up points. MRI scans were interpreted by a single board-certified, musculoskeletal radiologist for the official study results. The treating surgeon also reviewed the scans to determine implant boundaries, rotator cuff repair integrity, and other findings.

Secondary outcomes included change in the American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form (ASES) pain, function, and overall shoulder scores and the Constant-Murley shoulder (CMS) score, from baseline to each postoperative follow-up assessment. Patients provided self-reported assessments of their satisfaction with the outcome of index surgery on a 5-point Likert scale, as well as by responding to whether they would recommend the study procedure to a friend. Finally, the investigators assessed safety by evaluating and recording any serious adverse events considered possibly related to the device or procedure.

Statistical analysis

Demographic data and intraoperative surgical assessments were summarized using descriptive statistics. Matched-pair analyses were performed to determine changes in radiographic retear rates and clinical outcomes (ASES and CMS scores) between baseline and successive follow-up visits. The MCID was calculated using the anchor method of 11.1 for ASES and 4.6 for CMS and assessed by the percentage of patients who met or exceeded it.[20] Resulting P values were quoted and 95% 2-sided confidence intervals (CIs) were generated where appropriate. Relevant subgroup analyses (tear size, repair technique) were performed with the same statistical methods. Although every effort was made to ensure capture of patients' clinical and MRI data at each time point, some patients were lost to follow-up and thus not included in the calculations for any missed time point. All statistical calculations were made using SAS software (SAS Institute, Cary, NC, USA). Statistical significance was set at $P < .05$.

Results

One hundred fifteen patients with FTRCTs were enrolled in this study (Table I), with data available for 114 (99.1%) at 1 year and 104 (90.4%) at 2 years. Mean duration of follow-up was 2.1 years (range, 1.5-2.9 years).

MRI assessments

Medium vs. large tears

Between baseline and final follow-up at 2 years, mean total thickness of the supraspinatus tendon increased by 12.5% from 4.0 mm (standard deviation [SD] = 1.424) to 4.5 mm (SD = 1.2) for medium tears ($P = .031$), and by 17.1% from 4.1 mm (SD = 1.578) to 4.8 mm (SD = 1.6) for large tears ($P = .127$).

Table I Patient demographics, clinical characteristics, and operative data

Variable	Medium (n = 66)	Large (n = 49)	Total (n = 115)
Age, yr			
Mean ± SD	59.9 ± 8.4	61.0 ± 7.5	60.4 ± 8.0
Median (range)	60.1 (42-73)	60.9 (44-81)	60.3 (42-81)
Sex			
Female	30 (45.5)	9 (18.4)	39 (33.9)
Male	36 (54.5)	40 (81.6)	76 (66.1)
Body mass index			
Mean ± SD	28.5 ± 4.8	27.5 ± 3.9	28.1 ± 4.5
Median (range)	27.9 (18.2-42.0)	26.8 (18.6-38.8)	27.4 (18.2-42.0)
Duration of experienced pain in affected shoulder, yr			
Mean ± SD	2.44 ± 3.73	2.57 ± 2.70	2.50 ± 3.32
Median (range)	1.25 (0.25-20.0)	1.25 (0.17-12.17)	1.25 (0.17-20.0)
Shoulder treated			
Left	25 (37.9)	12 (24.5)	37 (32.2)
Right	41 (62.1)	37 (75.5)	78 (67.8)
Biceps procedures, n	71	55	126
None/debridement	42 (59.2)	27 (49.1)	69 (54.8)
Tenodesis/tenotomy	29 (40.8)	28 (50.9)	57 (45.2)
Repair technique			
Single-row	13 (19.7)	11 (22.4)	24 (20.9)
Double-row	53 (80.3)	38 (77.6)	91 (79.1)

SD, standard deviation.
Unless otherwise noted, values are n (%).

At the 3-month follow-up visit, a visible boundary was identified between the device and the underlying supraspinatus tendon for only 8 patients (12.3%) with a medium tear and only 2 patients (4.3%) with a large tear. There were no visible boundaries identified at the final follow-up assessments for any patient in any tendon tear type group.

From baseline to 2-year follow-up, 7 of 61 available patients (11.5%) with medium tears and 14 of 40 patients (35.0%) with large tears experienced radiographic retears ($P = .0044$) (Table II).

Between the 1- and 2-year follow-up visits, there were only 2 new radiographic retears reported, both of which occurred in patients with large tears. The majority of radiographic retears in the large tear group occurred between baseline and 3 months (10 of 14), whereas 3 of 7 occurred during this time period in the medium tear group.

Single- vs. double-row repair

Rates of radiographic retear were higher in those undergoing rotator cuff repair with a single-row technique (9 of 24 [37.5%]) than a double-row technique (12 of 91 [13.2%]) ($P = .0061$) (Table II).

Clinical outcome scores

Significant improvements were observed for medium and large tears in ASES and CMS scores from baseline to 2 years. MCID was achieved by >90% of patients with both medium and large tears for both ASES and CMS (Table III).

Patient satisfaction survey results

At 2 years, 104 patients were available to respond to the satisfaction questionnaire. Of these patients, 98 (94.2%) strongly agreed to being satisfied with the outcome of the study procedure, 3 (2.9%) agreed, 1 (1.0%) neither agreed nor disagreed, and 2 (1.8%) strongly disagreed. All 104 patients (100%) asked if they would recommend the study procedure to a friend said "yes."

Safety

There were no notable changes in the safety results since the interim 1-year report. Two serious adverse events were classified as being possibly related to the device and/or procedure. One patient developed swelling and drainage in the surgically treated shoulder approximately 6 weeks after surgery. Biopsy and culture revealed a superficial, localized infection. Following intravenous antibiotics, the patient underwent extensive débridement where suture remnants and repair anchor were removed. The patient's 15-day cultures were negative and the patient symptomatically improved, with lessening pain and improved range of motion, marking the full resolution of this serious adverse event approximately 11 weeks after its onset. The patient's final clinical outcomes indicated a successful recovery, as they exceeded the MCID for both ASES (from 45 at baseline to 91.7 at 2 years) and CMS (from 41.6 at baseline to 77.8 at 2 years).

The other patient presented with intermittent pain in the treated shoulder at the 3-month postoperative visit. MRI

Table II Radiographic retear rates at all postoperative follow-up visits by tear size (medium and large) and repair technique (single-row and double-row)

	Medium, n (%) (n = 66)		Large, n (%) (n = 49)	
	Single-row (n = 13)	Double-row (n = 53)	Single-row (n = 11)	Double-row (n = 38)
3 mo	0 (0)	3 (5.7)	7 (63.6)	3 (7.9)
1 yr	1 (7.7)	6 (11.3)	8 (72.7)	4 (10.5)
2 yr	1 (7.7)	6 (11.3)	8 (72.7)	6 (15.8)

Table III Patient-reported clinical outcomes at baseline and all postoperative follow-up visits by tear size

	Medium (n = 66)				Large (n = 49)			
	Baseline	3 mo	1 yr	2 yr	Baseline	3 mo	1 yr	2 yr
ASES pain score (0-10)								
n	66	66	66	63	49	49	48	41
Mean ± SD	4.8 ± 2.3	1.8 ± 2.2	0.5 ± 1.2	0.2 ± 0.8	5.2 ± 2.6	1.7 ± 2.0	0.5 ± 1.4	0.5 ± 1.2
P value*	—	<.001	<.001	<.001	—	<.001	<.001	<.001
ASES shoulder function score (0-30)								
n	66	66	64	63	46	45	47	41
Mean ± SD	15.9 ± 5.7	14.6 ± 6.7	27.8 ± 4.2	27.9 ± 6.6	14.2 ± SD, 6.4	15.6 ± SD, 7.2	27.4 ± 5.8	29.2 ± 1.9
P value*	—	.197	<.001	<.001	—	.571	<.001	<.001
ASES shoulder score (0-100)								
n	66	66	64	63	46	45	47	41
Mean ± SD	52.4 ± 18.3	65.2 ± SD, 19.6	94.3 ± 11.6	95.6 ± 13.2	48.0 ± 19.0	67.9 ± 16.9	93.1 ± 13.2	96.3 ± 8.1
P value*	—	<.001	<.001	<.001	—	<.001	<.001	<.001
Patients meeting MCID for ASES shoulder score								
n/n	—	35/66	58/64	58/63	—	28/44	42/45	37/38
Percentage (95% CI)	—	53.0 (40.3-65.4)	90.6 (80.7-96.5)	92.1 (82.4-97.4)	—	63.6 (47.8-77.6)	93.3 (81.7-98.6)	97.4 (86.2-99.9)
P value	—	.712	<.001	<.001	—	.096	<.001	<.001
Constant-Murley Score								
n	64	21	61	58	46	13	46	37
Mean ± SD	51.2 ± 16.8	63.2 ± 16.8	79 ± 11.8	83.7 ± 9.5	48.5 ± 18.1	65.2 ± 14.7	85.3 ± 9.6	84.4 ± 9.5
P value*	—	.002	<.001	<.001	—	.032	<.001	<.001
Patients meeting MCID for Constant-Murley Score								
n	—	16/21	52/60	56/58	—	9/11	41/43	32/34
Percentage (95% CI)	—	76.2 (52.8-91.8)	86.7 (75.4-94.1)	96.6 (88.1-99.6)	—	81.8 (48.2-97.7)	95.4 (84.2-99.4)	94.1 (80.3-99.3)
P value	—	.027	<.001	<.001	—	.065	<.001	<.001

ASES, American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form; *SD*, standard deviation; *CI*, confidence interval; *MCID*, minimum clinically important difference.

* Change from baseline.

revealed some inflammatory changes and a subsequent radiograph suggested osteopenia in the region of the greater tuberosity. The patient underwent aspiration and the anterior half of the cuff appeared healed with good tissue approximation, whereas the posterior half appeared failed with a loose anchor. Adhesions were débrided and tissue was biopsied, revealing negative cultures. The patient was offered a superior capsular reconstruction, but had not undergone this procedure before being lost to follow-up between 1 and 2 years. Final follow-up data for ASES and

CMS scores for this patient were not available, and it was therefore not possible to determine whether they achieved the MCID.

At 2-year follow-up, 9 of 115 patients (7.8%; 4 with a medium tear and 5 with a large tear; 2 with single-row repair and 7 with double-row repair) required reoperation of the index rotator cuff surgery, which occurred at a mean of 162.3 days (SD = 94.1), with 195.8 days [SD = 101.8] for medium tears and 135.6 days [SD = 88.9] for large tears. The reasons for revision or additional surgery (multiple reasons/procedures possible) were new shoulder injury or defect (3 [27.3%]; all large tears), worsening of previous shoulder injury or defect (3 [27.3%]; 2 medium and 1 large tears), and other (5 [45.5%]; 3 medium and 2 large tears).

Discussion

Biologic technologies have become quite popular recently, as the orthopedic community seeks to improve postoperative outcomes following rotator cuff repair by preventing mechanical failure and enhancing functional and subjective quality-of-life patient endpoints. Several biologic options exist that can augment cuff repair, although clinical data to support the efficacy of these interventions remains in its early stages.[47] The current prospective analysis represents an effort to determine whether the promise of preclinical data[63] with one such technology, a highly porous collagen implant, translates into clinical efficacy in patients undergoing arthroscopic repair for medium and large FTRCTs, as has been shown in other clinical studies.[10,14,44,45,61]

Results from the current analysis indicate the use of this implant increased tendon thickness in medium and large tears. This is in line with MRI results obtained in a series of patients with medium tears by Bokor et al,[10] who showed that tendon thickness increased by 3 months and did not decrease even up to 2 years. Furthermore, results from the current study support earlier histologic animal data,[63] which indicated that the implant achieves robust integration with the host tissue and bone interface and along the tendon. Taken together with findings from the current study, these data comprise a growing body of knowledge that consistent tendon thickening can be achieved with the use of this implant.

The attainment of timely integration and increased tendon thickness offers several theoretical advantages, including restoration of the natural tendon-bone interface and reduced strains on the rotator cuff.[4,10,42] In turn, this may provide enhanced healing conditions during the initial postoperative period that could reduce the incidence of mechanical failure (ie, radiographic retear) commonly observed following arthroscopic repair of FTRCTs.

Radiographic retear rates from this study obtained at 1 year[14] provided the initial indication that this implant does indeed provide such enhanced healing conditions. Thirteen (61.9%) of the radiographic retears noted in this cohort occurred in the immediate postoperative period leading up to the 3-month follow-up visit, more than half of which (53.8%) followed single-row repair in large FTRCTs. Human histology data obtained via biopsy[5] indicate that this implant exerts most of its biological effects within the period following the initial 3-month postoperative window up to around 6 months. At 3 months, the surface of the implant shows increased collagen formation, maturation, and organization. Remnants of the implant are still observed, but invading fibroblasts have begun the process of dissolution. At 6 months, comparatively, these remnants are no longer observed, replaced instead by newly generated tendonlike tissue. The dense, highly oriented collagen fibers observed at the 6-month stage denote functional loading of the new generated host tissue. Therefore, the timing of radiographic retears in the current analysis seems to indicate that the key contributor to failure in most cases was a failure to achieve adequate mechanical fixation during arthroscopic repair, and that the implant conferred its benefits during the period when it was expected to be active (3-6 months). In other words, the pattern of radiographic retear suggests that tears that were initially healed tended to remain so.

The hypothesis that the implant facilitates induction of tendon tissue, thereby enhancing the chances that the underlying mechanical repair will be successful, is further supported by the final results of this study. Only 2 of the 21 radiographic retears observed occurred between 1- and 2-year follow-up. This is in line with the optimal postoperative expectations reported in the published literature, which indicate that the majority of radiographic retears are thought to occur within 10-15 months of initial surgery[18] and become symptomatic before 1 year.[40] Radiographic retear rates at 2 years in our series for all medium tears and large tears treated with double-row repair ranged from 11.3% to 15.8%, which is well below the mean 26.6% rate of radiographic retear at 2 years reported in a meta-analysis of FTRCT studies by McElvany et al,[43] although their study did include single-row repairs. It is also consistent with or superior to rates reported elsewhere in the literature for nonaugmented repair in a similar follow-up period.[9,16,17,30,58,59] Issues of study design heterogeneity prevent an adequate comparison of meta-analysis data from similarly sized FTRCTs repaired only with double-row technique. Longo et al[41] recently reported a 12.7% retear rate for FTRCTs repaired with this method, yet they did not provide the follow-up period, which is a critical consideration when comparing this endpoint.

An exception to the otherwise successful results was the disproportionately high rate of radiographic retear (72.7%) occurring among patients with large FTRCTs repaired with a single-row technique. At the start of the previous decade, there was an active debate regarding the relative value of single-row and double-row techniques in the repair of FTRCTs.[21,53] In more-recent years, clinical results have indicated that double-row repair produces superior outcomes in large and massive FTRCTs.[25,57] This is especially true with regard to radiographic retears in FTRCTS, which have been noted in meta-

analyses to be significantly higher with single-row repair compared with double-row repair,[46,57] and in one study up to 5 times higher in the initial 6-month postoperative period.[64] The AAOS CPG note that there is limited data for FTRCTs alone.[3] Although there is still no consensus around whether single-row and double-row repair produce differing results in medium tears (1-3 cm), FTRCTs larger than 3 cm are now increasingly thought to benefit in repair quality and clinical function when treated with double-row techniques,[6] owing to the superior biomechanical properties imparted by this technique.[6,29] However, conducting sufficiently powered meta-analyses of the long-term outcomes of double-row repair in FTRCTs, including radiographic retear and reoperation, remains challenging given the lack of studies segmenting results based on tear size.[56] Results from the current study highlight the importance of securing adequate primary fixation at the time of surgery as a means of reducing the risk of early radiographic retear, even if these results do not solve the debate over double vs. single row. Further studies are warranted in the area of repair-row technique.

Perhaps a more clinically meaningful outcome for assessing the success of FTRCT repair is the rate of reoperation. Unlike radiographic retear, which may be clinically asymptomatic,[31] reoperation necessarily implies that postoperative performance was impaired enough to require a subsequent surgical intervention. In the current series, we observed a 7.8% rate of reoperation at 2-year follow-up. Although the heterogeneity of designs of studies assessing the surgical FTRCT also precludes a clear comparison, this rate is below the 10.4% reoperation rate reported at 2 years in a recently conducted large cross-sectional analysis of nearly 25,000 patients undergoing FTRCT repair.[62]

Final results from this analysis also confirm that patients undergoing arthroscopic repair of FTRCTs experience robust and sustained improvements in clinical outcomes, with more than 90% of patients achieving or exceeding the MCID for both ASES and CMS. MCID is considered the best reflection of patient improvement and satisfaction following orthopedic surgery.[33] Achieving improved functional outcomes is of increasing interest to health care systems, given the significant economic impact of productivity loss with FTRCTs.[49]

As with the 1-year interim analysis, there was no indication from the final 2-year results that use of the implant led to any noteworthy safety issues. With all novel surgical implants, it is necessary to confirm that there are no allergic reaction, inflammatory responses, or foreign body reactions. Evidence of the relative nonreactive nature of the implant was first suggested in a 2017 histologic analysis by Arnoczky et al[5] and has since been supported in many published clinical studies with this device to date.[10,11,13,14,44,45,54,55,61]

Limitations

Results from the current study should be considered alongside its potential limitations. First, the study was not designed with a control group, which would have allowed the isolation of and comparison with outcomes obtained with arthroscopic repair *without* the augmenting implant. Future studies should incorporate such comparative control groups to better gauge the safety and efficacy of this implant. Second, there is a risk of potential selection bias given that the decision to use the implant in this study fell to the discretion of the individual surgeons rather than by randomization, a decision that could have impacted the ultimate findings. Third, only 2 surgeons performed single-row repair of FTRCTs in this cohort, which presents a more limited range of clinical experience in comparison with that of double-row repairs. Given the substantially higher rate of radiographic retear following single-row repairs of FTRCTs,[46,57,64] this limitation is particularly relevant. Finally, there was a decrease of 10 patients with follow-up data available between 1 and 2 years, likely due to COVID-19 site restrictions blocking proper follow-up appointments during that phase of the pandemic. However, the overall follow-up rate for the cohort was 90% at 2 years, above the 85% threshold widely accepted as adequate for clinical studies.

Conclusion

Final 2-year follow-up data from this prospective, multicenter study indicate that the use of this bioinductive bovine collagen implant as an augmenting therapy for arthroscopic double-row repair of FTRCTs provides favorable rates of radiographic retear and substantial functional recovery, in line with or exceeding that observed with standard arthroscopic techniques for FTRCTs. These results add to the growing body of evidence in support of the clinical use of this implant.[10,11,13,14,44,45,54,55,61]

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References

1. Aagaard KE, Abu-Zidan F, Lunsjo K. High incidence of acute full-thickness rotator cuff tears. Acta Orthop 2015;86:558-62. https://doi.org/10.3109/17453674.2015.1022433
2. Abate M, Di Carlo L, Salini V, Schiavone C. Risk factors associated to bilateral rotator cuff tears. Orthop Traumatol Surg Res 2017;103:841-5. https://doi.org/10.1016/j.otsr.2017.03.027
3. American Academy of Orthopaedic Surgeons. Management of rotator cuff injuries clinical practice guideline. 2019. https://www.aaos.org/globalassets/quality-and-practice-resources/rotator-cuff/rotator-cuff-cpg-final-12-20-19.pdf. Accessed November 5, 2021
4. Angeline ME, Rodeo SA. Biologics in the management of rotator cuff surgery. Clin Sports Med 2012;31:645-63. https://doi.org/10.1016/j.csm.2012.07.003
5. 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
6. Aydin N, Karaismailoglu B, Gurcan M, Ozsahin MK. Arthroscopic double-row rotator cuff repair: a comprehensive review of the literature. SICOT J 2018;4:57. https://doi.org/10.1051/sicotj/2018048
7. Barber FA, Burns JP, Deutsch A, Labbé MR, Litchfield RB. A prospective, randomized evaluation of acellular human dermal matrix augmentation for arthroscopic rotator cuff repair. Arthroscopy 2012;28:8-15. https://doi.org/10.1016/j.arthro.2011.06.038
8. Barber FA, Hrnack SA, Snyder SJ, Hapa O. Rotator cuff repair healing influenced by platelet-rich plasma construct augmentation. Arthroscopy 2011;27:1029-35. https://doi.org/10.1016/j.arthro.2011.06.010
9. 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
10. 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
11. 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
12. Bond JL, Dopirak RM, Higgins J, Burns J, Snyder SJ. Arthroscopic replacement of massive, irreparable rotator cuff tears using a GraftJacket allograft: technique and preliminary results. Arthroscopy 2008;24:403-9. https://doi.org/10.1016/j.arthro.2007.07.033
13. Bushnell BD, Bishai SK, Krupp RJ, McMillan S, Schofield BA, Trenhaile SW, et al. Treatment of partial-thickness rotator cuff tears with a resorbable bioinductive bovine collagen implant: 1-year results from a prospective multicenter registry. Orthop J Sports Med 2021;9:23259671211027850. https://doi.org/10.1177/23259671211027850
14. Bushnell BD, Connor PM, Harris HW, Ho CP, Trenhaile SW, Abrams JS. 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. JSES Int 2020;5:228-37. https://doi.org/10.1016/j.jseint.2020.10.020
15. Cai YZ, Zhang C, Jin RL, Shen T, Gu PC, Lin XJ, et al. Arthroscopic rotator cuff repair with graft augmentation of 3-dimensional biological collagen for moderate to large tears: a randomized controlled study. Am J Sports Med 2018;46:1424-31. https://doi.org/10.1177/0363546518756978
16. 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
17. 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
18. 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
19. Cofield RH. Subscapular muscle transposition for repair of chronic rotator cuff tears. Surg Gynecol Obstet 1982;154:667-72.
20. 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
21. Duquin TR, Buyea C, Bisson LJ. Which method of rotator cuff repair leads to the highest rate of structural healing? A systematic review. Am J Sports Med 2010;38:835-41. https://doi.org/10.1177/0363546509359679
22. Fehringer EV, Sun J, VanOeveren LS, Keller BK, Matsen FA III. Full-thickness rotator cuff tear prevalence and correlation with function and co-morbidities in patients sixty-five years and older. J Shoulder Elbow Surg 2008;17:881-5. https://doi.org/10.1016/j.jse.2008.05.039
23. Gulotta LV, Nho SJ, Dodson CC, Adler RS, Altchek DW, MacGillivray JD; HSS Arthroscopic Rotator Cuff Registry. Prospective evaluation of arthroscopic rotator cuff repairs at 5 years: part I–functional outcomes and radiographic healing rates. J Shoulder Elbow Surg 2011;20:934-40. https://doi.org/10.1016/j.jse.2011.03.029
24. 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
25. Hantes ME, Ono Y, Raoulis VA, Doxariotis N, Venouziou A, Zibis A, et al. Arthroscopic single-row versus double-row suture bridge technique for rotator cuff tears in patients younger than 55 years: a prospective comparative study. Am J Sports Med 2018;46:116-21. https://doi.org/10.1177/0363546517728718
26. He HB, Wang T, Wang MC, Zhu HF, Meng Y, Pan CL, et al. Tendon-to-bone healing after repairing full-thickness rotator cuff tear with a triple-loaded single-row method in young patients. BMC Musculoskelet Disord 2021;22:305. https://doi.org/10.1186/s12891-021-04184-x
27. Hein J, Reilly JM, Chae J, Maerz T, Anderson K. Retear 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
28. 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
29. Hohmann E, König A, Kat CJ, Glatt V, Tetsworth K, Keough N. Single- versus double-row repair for full-thickness rotator cuff tears using suture anchors. A systematic review and meta-analysis of basic biomechanical studies. Eur J Orthop Surg Traumatol 2018;28:859-68. https://doi.org/10.1007/s00590-017-2114-6
30. 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
31. Jost B, Zumstein M, Pfirrmann CW, Gerber C. Long-term outcome after structural failure of rotator cuff repairs. J Bone Joint Surg Am 2006;88:472-9. https://doi.org/10.2106/JBJS.E.00003
32. Jung W, Lee S, Hoon Kim S. The natural course of and risk factors for tear progression in conservatively treated full-thickness rotator cuff tears. J Shoulder Elbow Surg 2020;29:1168-76. https://doi.org/10.1016/j.jse.2019.10.027
33. Katz NP, Paillard FC, Ekman E. Determining the clinical importance of treatment benefits for interventions for painful orthopedic conditions. J Orthop Surg Res 2015;10:24. https://doi.org/10.1186/s13018-014-0144-x
34. Keener JD, Galatz LM, Teefey SA, Middleton WD, Steger-May K, Stobbs-Cucchi G, et al. A prospective evaluation of survivorship of asymptomatic degenerative rotator cuff tears. J Bone Joint Surg Am 2015;97:89-98. https://doi.org/10.2106/JBJS.N.00099
35. Kelly BC, Constantinescu DS, Vap AR. Arthroscopic and open or mini-open rotator cuff repair trends and complication rates among American Board of Orthopaedic Surgeons Part II examinees (2007-2017). Arthroscopy 2019;35:3019-24. https://doi.org/10.1016/j.arthro.2019.06.022
36. Kim HM, Caldwell JM, 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;2:106-12. https://doi.org/10.2106/JBJS.L.01649
37. 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
38. Kukkonen J, Joukainen A, Lehtinen J, Mattila KT, Tuominen EK, Kauko T, et al. Treatment of nontraumatic rotator cuff tears: a randomized controlled trial with two years of clinical and imaging follow-up. J Bone Joint Surg Am 2015;97:1729-37. https://doi.org/10.2106/JBJS.N.01051
39. 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
40. Lobo-Escolar L, Ramazzini-Castro R, Codina-Grañó D, Lobo E, Minguell-Monyart J, Ardèvol J. Risk factors for symptomatic retears after arthroscopic repair of full-thickness rotator cuff tears. J Shoulder Elbow Surg 2021;30:27-33. https://doi.org/10.1016/j.jse.2020.05.010
41. Longo UG, Carnevale A, Piergentili I, Berton A, Candela V, Schena E, et al. Retear rates after rotator cuff surgery: a systematic review and meta-analysis. BMC Musculoskelet Disord 2021;22:749. https://doi.org/10.1186/s12891-021-04634-6
42. Lui P, Zhang P, Chan K, Qin L. Biology and augmentation of tendon-bone insertion repair. J Orthop Surg Res 2010;5:59. https://doi.org/10.1186/1749-799X-5-59
43. McElvany MD, McGoldrick E, Gee AO, Neradilek MB, Matsen FA III. Rotator cuff repair: published evidence on factors associated with repair integrity and clinical outcome. Am J Sports Med 2015;43:491-500. https://doi.org/10.1177/0363546514529644
44. McIntyre LF, Bishai SK, Brown PB III, 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
45. McIntyre LF, McMillan S, Trenhaile SW, Bishai SK, Bushnell BD. Full-thickness rotator cuff tears can be safely treated with a resorbable bioinductive bovine collagen implant: one-year results of a prospective, multicenter registry. Arthrosc Sports Med Rehabil 2021;3:e1473-9. https://doi.org/10.1016/j.asmr.2021.07.009
46. Millett PJ, Warth RJ, Dornan GJ, Lee JT, Spiegl UJ. Clinical and structural outcomes after arthroscopic single-row versus double-row rotator cuff repair: a systematic review and meta-analysis of level I randomized clinical trials. J Shoulder Elbow Surg 2014;23:586-97. https://doi.org/10.1016/j.jse.2013.10.006
47. Mirzayan R, Weber AE, Petrigliano FA, Chahla J. Rationale for biologic augmentation of rotator cuff repairs. J Am Acad Orthop Surg 2019;27:468-78. https://doi.org/10.5435/JAAOS-D-18-00281
48. 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;96:1504-14. https://doi.org/10.2106/JBJS.M.01393
49. Parikh N, Martinez DJ, Winer I, Costa L, Dua D, Trueman P. Direct and indirect economic burden associated with rotator cuff tears and repairs in the US. Curr Med Res Opin 2021;37:1119-211. https://doi.org/10.1080/03007995.2021.1918074
50. 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
51. Reilly P, Macleod I, Macfarlane R, Windley J, Emery RJ. Dead men and radiologists don't lie: a review of cadaveric and radiological studies of rotator cuff tear prevalence. Ann R Coll Surg Engl 2006;88:116-21. https://doi.org/10.1308/003588406X94968
52. Rothrauff BB, Pauyo T, Debski RE, Rodosky MW, Tuan RS, Musahl V. The rotator cuff organ: integrating developmental biology, tissue engineering, and surgical considerations to treat chronic massive rotator cuff tears. Tissue Eng B Rev 2017;23:318-35. https://doi.org/10.1089/ten.TEB.2016.0446
53. Saridakis P, Jones G. Outcomes of single-row and double-row arthroscopic rotator cuff repair: a systematic review. J Bone Joint Surg Am 2010;92:732-42. https://doi.org/10.2106/JBJS.I.01295
54. Schlegel TF, Abrams JS, Angelo RL, Getelman MH, Ho CP, Bushnell BD. Isolated bioinductive repair of partial-thickness rotator cuff tears using a resorbable bovine collagen implant: two-year radiologic and clinical outcomes from a prospective multicenter study. J Shoulder Elbow Surg 2021;30:1938-48. https://doi.org/10.1016/j.jse.2020.10.022
55. 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
56. Sobhy MH, Khater AH, Hassan MR, El Shazly O. Do functional outcomes and cuff integrity correlate after single- versus double-row

rotator cuff repair? A systematic review and meta-analysis study. Eur J Orthop Surg Traumatol 2018;28:593-605. https://doi.org/10.1007/s00590-018-2145-7
57. Spiegl UJ, Euler SA, Millett PJ, Hepp P. Summary of meta-analyses dealing with single-row versus double-row repair techniques for rotator cuff tears. Open Orthop J 2016;10:330-8. https://doi.org/10.2174/1874325001610010330
58. 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
59. Taniguchi N, Suenaga N, Oizumi N, Miyoshi N, Yamaguchi H, Inoue K. 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
60. 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
61. 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
62. Truong NM, Cevallos N, Lansdown DA, Ma CB, Feeley BT, Zhang AL. Arthroscopic rotator cuff repair results in lower two-year reoperation rates compared with open rotator cuff repair in a large cross-sectional cohort. Arthrosc Sports Med Rehabil 2021;3:e2015-23. https://doi.org/10.1016/j.asmr.2021.10.008
63. 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.
64. Wade R, Salgar S. Clinico-radiological evaluation of retear rate in arthroscopic double row versus single row repair technique in full thickness rotator cuff tear. J Orthop 2017;14:313-8. https://doi.org/10.1016/j.jor.2017.01.001
65. 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