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Bioaugmentation demonstrates similar outcomes and failure rates for arthroscopic revision rotator cuff repair compared to revision without bioaugmentation

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Background: Arthroscopic revision rotator cuff repairs (RCRs) exhibit lower healing rates and inferior outcomes compared to primary repairs. There is limited evidence regarding the use of bioaugmentation in the setting of revision RCRs. Autologous conditioned plasma (ACP) is a promising adjunct that has been shown to improve healing rates and patient-reported outcomes (PROs) in the primary setting. In addition, bioinductive patches such as collagen bovine patches have become a popular adjunct for stimulating healing in the primary setting. The aim of this study is to assess the outcomes after use of ACP and collagen bovine patch augmentation for revision arthroscopic RCR. We hypothesized improved PROs and higher healing rates would be observed with bioaugmentation for revision repair compared to without.
Methods: This was an institutional review board–approved, retrospective case-control study from 2 fellowship-trained surgeons that included all consecutive patients undergoing arthroscopic revision RCR from 2010 to 2021. Reconstruction such as superior capsular reconstruction, partial revision repair, and less than 1-year follow-up were excluded. The bioaugmentation cohort received ACP and/or collagen bovine patch at the time of revision repair. PROs were collected from all patients including American Shoulder and Elbow Surgeons Standardized Assessment Form (ASES), visual analog scale for pain (VAS), Brophy score, and Patient-Reported Outcomes Measurement Information System (PROMIS) mental and physical scores. Failure of revision RCR was defined as an ASES postoperative total score less than 60 or a symptomatic retear confirmed on magnetic resonance imaging. Student's *t*-test was used for all comparisons of continuous variables. Chi-squared test used for comparison of all categorical variables. Statistical significance was set at <0.05.
Results: Thirty-eight patients met inclusion criteria with average follow-up of 3.5 ± 1.7 years. There was no significant difference in follow-up between patients with and without bioaugmentation. Of the 38 patients, 14 patients met failure criteria. There was no significant difference in the rate of failure between the bioaugmentation cohort (6/19, 31.6%) vs. patients who did not receive bioaugmentation (8/19, 42.1%) ($P = .74$). In addition, no significant differences were identified for ASES (64.6 ± 20.1 vs. 57.5 ± 17.2, $P = .32$), Brophy (6.4 ± 5.2 vs. 6.0 ± 4.1, $P = .84$), PROMIS Mental (13.4 ± 3.9 vs. 11.7 ± 3.2), or PROMIS Physical (12.8 ± 3.1 vs. 11.9 ± 3.2) scores between the bioaugmentation vs. no bioaugmentation groups.
Conclusion: Bioaugmentation with a bioinductive collagen patch or ACP demonstrated similar failure and PROs compared to without bioaugmentation in the setting of revision RCR.

Rotator cuff tears are one of the most common causes of shoulder pain and disability in adults, with an estimated prevalence of up to 30% in the general population.[17,26] While primary rotator cuff repair (RCR) can be successful in many cases, a significant proportion of patients will experience failure of the initial repair, with rates varying highly in the literature.[7,11,12] A recent

University of Pittsburgh Institutional Review Board approved this study - STUDY20030061.

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meta-analysis found long-term retear rates after RCR to be between 10% and 26%.[12] Multiple studies have shown that retearing of the RCR does not always correlate with clinical outcomes, with many patients having satisfactory patient-reported outcomes (PROs) despite failure of the repair seen on advanced imaging.[7,9,16] In the setting of a failed primary RCR, revision repair may be a viable option prior to considerations of reconstruction with arthroplasty.

Revision rotator cuff surgery is a challenging procedure ie, associated with lower success rates and higher complication rates compared to primary RCR.[16,19,23] Several factors have been identified as contributing to the high failure rates in revision rotator cuff surgery. These include lower bone mineral density (BMD), chronic tendinopathy, fatty infiltration of the rotator cuff muscles, tear size, advanced patient age, and technical errors during the initial surgery.[3,11,22] A retrospective review of revision RCRs in 203 patients with follow-up magnetic resonance imaging (MRIs) showed that patients had improved PROs if follow-up MRI showed a Sugaya I or II healing pattern.[24] They also found increased fatty infiltration with tendons that had Sugaya IV and V healing patterns.[24] Poor tissue quality, including muscle atrophy and fatty infiltration, is a common finding in patients who require revision rotator cuff surgery.[22] This can make it more difficult to achieve a successful repair, as the weakened tissue may not hold sutures or anchors securely.

Due to the altered biological milieu encountered in the setting of revision RCR, multiple biological augments have been proposed to improve healing and patient function. The literature has mixed results. A recent review and meta-analysis found decreased rates of retear with the adjunct use of autologous conditioned plasma (ACP) or platelet-rich plasma (PRP) in the setting of primary rotator cuff tears.[25] Another meta-analysis of the use of ACP or PRP in the setting of primary RCR with single-row or double-row repair found that ACP or PRP reduced the rates of retears in small-to-medium tears, but did not statistically decrease the overall rates for retear or improve PROs.[10] A prospective, nonrandomized trial of the use of ACP in primary rotator cuffs showed no differences in the rates of rotator cuff healing at 6-month follow-up MRI.[1] Finally, a well-designed randomized control trial of concentrate bone marrow aspirate vs. sham during arthroscopic primary RCR was performed and found improved healing on MRI and PROs at 2-year follow-up.[4] The use of biological patches has also increased in recent years, with meta-analyses showing decreased rates for retears in patients undergoing primary RCR.[14] There are also data suggesting that augmentation of repair with human dermal allograft in the revision setting or in the setting of a massive rotator cuff tear results in successful patient outcomes,[2,18] but studies comparing augmentation with a patch to no augmentation are limited.

Despite improvements in surgical techniques and increased availability of biological augmentation, the failure rate of revision rotator cuff surgery remains a challenging clinical problem. The aim of this study, therefore, is to assess the use of ACP and collagen bovine patch augmentation for revision arthroscopic RCR. We hypothesized improved PROs and higher healing rates would be observed with bioaugmentation for revision repair compared to without.

Methods

A retrospective chart review of all consecutive patients undergoing arthroscopic revision RCR between January 1, 2010 and January 1, 2021 was performed after local Institutional Review Board approval. All patients underwent surgery with 1 of 2 sports-fellowship–trained surgeons with more than 10 years of experience (A.L. and B.L.). Operative reports containing the words “rotator cuff” and any of the following: “revision”, “failed”, “failure”, or “recurrent” were reviewed. Two authors reviewed all operative reports to confirm that the procedure performed was a revision RCR (R.T. and Z.H.). Patients were excluded if they underwent superior capsular reconstruction in the revision setting, if their tears were unacceptable for a formal repair or were only partial tears, if their clinical follow-up with orthopedic surgery was less than 1 year, or if a preoperative MRI was unavailable to review.

The electronic medical record was reviewed, and the following were retrieved on all patients where it was available: patient demographics at the time of revision surgery, preoperative PROs, preoperative physical examination, postoperative PROs at most recent follow-up, and postoperative physical examination at most recent follow-up. Demographics collected included patient sex, age at time of surgery, body mass index, number of prior procedures, hand dominance, and whether the retear was traumatic in nature. PROs collected included visual analog scale for pain (VAS), American Shoulder and Elbow Surgeons Standardized Assessment Form (ASES), Brophy score, and subjective shoulder value (SSV). Operative reports were reviewed to identify intraoperative findings including tendons involved, tear dimensions, number of anchors used, and the use of bioaugmentation with ACP or a bovine collagen patch.

The decision for bioaugmentation was made intraoperatively based on tissue quality and repairability. For patients who received a biological patch augmentation, a REGENETEN bovine-derived bioinductive patch (Smith & Nephew, Andover, MA, USA) was placed on the bursal side of the RCR and secured with soft tissue staples included in the REGENETEN system. In patients who received ACP, ACP was prepared per the protocol outlined in the ACP Kit (Arthrex, Naples, FL, USA) by centrifuging peripherally drawn blood at 1500 rpm for 5 minutes and drawing the concentrated plasma layer into a syringe. Tear size was measured intraoperatively using an arthroscopic ruler. The needle for ACP injection was placed under direct arthroscopic visualization into the rotator cuff footprint in the center of the anatomic footprint. The injection of ACP was performed after the arthroscope was removed and the shoulder was evacuated.

The Rotator Cuff Healing Index (ROHI) score has previously been shown to predict failure in primary RCR (source) and was calculated for all subjects without the addition of osteoporosis as T-scores or dual energy X-ray absorptiometry scan results were not available for all patients. The patient acceptable symptom state (PASS) for ASES in the setting of revision RCR has not been well defined, but in the setting of superior capsular reconstruction has been found to be 68.[6] Failure of revision RCR was defined as a symptomatic retear confirm on postoperative MRI or an ASES score of < 60.

Statistics

Statistical comparisons were made between patients who underwent conventional revision RCR and revision RCR with bioaugmentation. Two-way comparisons between groups with categorical variable were performed using Chi-square comparisons. Two-way comparisons between continuous variables were performed using Student’s *t*-test if parametric or Mann-Whitney testing if nonparametric. Data are presented as mean ± standard deviation if they were found to be parametric using Shapiro-Wilk normality testing and median (interquartile range) if the variables were found to be nonparametric. Significance was set a priori at $P < .05$ for all statistical comparisons (Prism 8.0.1; GraphPad, San Diego, CA, USA).

Results

Thirty-eight patients met inclusion criteria over the study period (Fig. 1). Average follow-up was 3.5 ± 1.7 years and mean

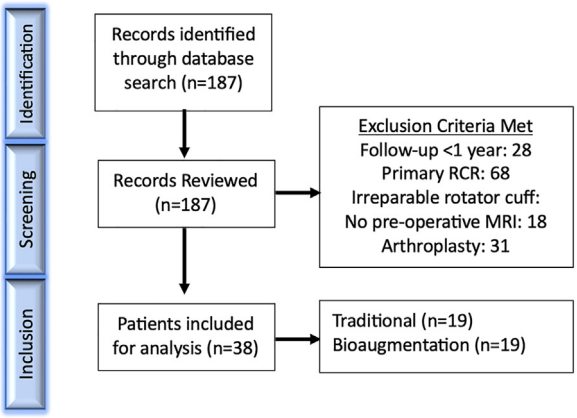

Figure 1 Inclusion-exclusion of patients within our electronic medical record which met search criteria for possible inclusion. *MRI*, magnetic resonance imaging.

patient age was 60.3 ± 8.4 years (range 41-74 years). The majority of patients had revision surgeries on their dominant arm (58%). Intraoperatively, the average tear size was 15.9 ± 9.3 mm in the anterior-posterior direction with 18.1 ± 11.0 mm of tendon retraction. Tears involved the supraspinatus in 37/38 (97.3%) patients, the infraspinatus in 6/38 (15.7%) patients, and the subscapularis in 11/38 (28.9%) patients. Releases were performed if needed and all tears were repairable without significant tension with a double-row fixation technique to restore the anatomic footprint. Tendons felt to qualitatively be unacceptable for a formal repair, partial repairs, or medialized nonanatomic repairs were all excluded from the study.

Nineteen patients (50.0%) had revision repair with bioaugmentation using either ACP injected at the repair site or a REGENETEN bovine-derived bioinductive patch (Smith & Nephew) placed over the repair site. Thirteen patients had augmentation with ACP only, while 6 patients had augmentation with ACP and bioindicutive patch. Nineteen patients underwent revision RCR without augmentation.

There were no significant differences in preoperative characteristics between patients who underwent revision surgery with and without bioaugmentation (Table 1). There were no significant differences in range of motion (ROM) or PROs before revision surgery between bioaugmentation and nonbioaugmentation group.

Postoperatively, patients had no statistically significant differences in VAS, SSV, ASES, Brophy, or PROMIS scores (Table 2). In comparing PROs overall between bioaugmented and nonbioaugmented groups, we found no differences in overall failure between groups. Failure rate among the augmented group was 31.6% (n = 6), while failure rate among the nonaugmented group was 42.1% (n = 8) ($P = .74$). All 14 patients meeting failure criteria had an ASES < 60. Of these 14 patients with ASES < 60, 3 had MRIs performed postoperatively for ongoing pain or dysfunction. There were no patients with ASES > 60 who had a repeat MRI for ongoing pain or a revision surgical intervention.

There were no significant differences in preoperative demographics, PROs, or ROM between patients who failed and those who did not (Table 3). There was no difference in preoperative ROHI scores, between patients with clinical or radiographic failure (4.0 [0.0-8.0]) and those without failure (2.0 [1.0-3.0]) ($P = .15$). There was a weak trend toward larger tear size in patients who failed (19.3 ± 12.5 mm vs. 11.4 ± 9.1 mm, $P = .085$) but this was not statistically significant and may be limited by the small sample size of the present study.

Discussion

Overall, no significant differences were seen in PROs between bioaugmented and nonbioaugmented revision repair groups. In addition, there was also no significant difference in failure rates between the bioaugmentation and nonbioaugmentation cohorts. The rate of clinical failure, due to poor PROs, was 31.6% in the bioaugmentation group and 42.1% in the traditional group. Nonetheless, successful outcomes were observed at long-term follow-up for revision RCR with and without bioaugmentation.

The aim of the present study was to determine if bioaugmentation could improve healing rates and PROs in the revision setting. Revision repair represents a challenging problem and is influenced by tear morphology, soft tissue quality, and host factors that can result in a hostile healing environment. Biologic augmentation has been proposed as a potential useful adjunct in the revision scenario. The present study demonstrates at least noninferiority of ACP and collagen bovine patch augmentation in the setting of revision repair.

The average improvement in ASES for the bioaugmentation group of 24.9 exceeded the minimal clinically important difference (MCID) for ASES of 10.7[13] (75.0% pts meeting MCID), and is in line with previous literature showing 77% of bioinductive implant patients achieving MCID at 1-year follow-up.[15] The VAS also improved on average by 2.8 exceeding the MCID of 1.4[21] (74.2% pts meeting MCID), but failing to reach the 4.0 improvement in previous literature using bioinductive implants.[15] The PASS for VAS has also been established at 3 cm for patients with rotator cuff disease,[21] and at final follow-up 60.5% of patients in our study met PASS criteria for VAS. Importantly, the majority of patients were primary repairs (87.9%) in the study by McIntyre et al, and further breakdown of revision group was absent making comparison to this cohort difficult.[15] Additionally, a minority of the bioaugmentation group received a bioinductive patch which may account for the lower change in outcome scores. Of note, increased rates of postoperative stiffness in the bioaugmenation group, a subject of debate in current literature, were not observed in this study group.[27] One previous study found increased rates of stiffness in bioinductive patch augmentation of partial thickness rotator cuff tears, and noted significant synovitis and subacromial bursitis as a reaction to the patch.[27] As previously discussed, there is minimal literature on augmentation with ACP and/or bioinductive patches in revision RCR.

Failure was defined as an ASES less than 60 as a cutoff or a symptomatic retear confirmed with MRI. The rate of overall failure in the present study was found to be 36.8%, which is in line with previous studies.[16,23] Clinical failure in the setting of revision RCR has not been well defined for any single PRO. In the setting of primary RCR, the PASS for ASES has been found to be between 78.0 and 87.6.[5,8] There has historically been a high rate of failure in the setting of revision RCR, with decline in PROs between primary and revision surgeries.[16,19,23] In prior studies investigating long-term outcomes of 360 patients with primary or revision RCR, PROs were similar between primary and revision RCR at 1 year, but at 2 years, subjects who underwent revision RCR had lower PROs and ROM.[19] Bioaugmentation was used at the discretion of the surgeon and was often chosen when tissue quality was felt to be poor with concerns for failure. In line with our study, procedures performed with bioaugmentation in the revision setting showed a decrease in VAS scores, increase in ASES scores, and an increase in SSV scores postoperatively.[2]

The following limitations were acknowledged within the study. There is no Current Procedural Terminology code for revision RCR, which necessitated a manual search of operative reports to determine if a revision surgery was described. There may be patients excluded due to the search methodology. The decision to include

Table I
Patient preoperative characteristics.

Demographics	Overall (n = 38)	Traditional (n = 19)	Bioaugmentation (n = 19)	P*
Age, y (SD)	60.3 (8.4)	59.2 (6.6)	61.5 (9.8)	.41
Body Mass Index, kg/m^2 (SD)	32.0 (5.8)	32.7 (5.6)	31.4 (6.1)	.48
Active smoker, n (%)	6 (15.8)	5 (26.3)	1 (5.3)	.18
Dominant side affected, n (%)	23 (60.5)	13 (68.4)	10 (52.6)	.50
Number of prior surgeries, # [IQR]	1.0 [1.0-1.25]	1.0 [1.0-2.0]	1.0 [1.0-2.0]	.99
Length of clinical follow-up, y (SD)	3.5 (1.7)	3.5 (2.0)	3.5 (1.4)	.94
Traumatic reinjury, n (%)	15 (39.5)	9 (47.4)	6 (31.6)	.51
Tear size, mm (SD)	14.7 (11.1)	12.6 (5.5)	13.2 (9.1)	.84
Goutallier grade, grade [IQR]	1.0 [1.0-2.0]	1.0 [1.0-2.0]	1.0 [1.0-1.5]	.45
ROHI, score (SD)	2.8 (2.3)	3.1 (2.5)	2.5 (2.1)	.49
Preoperative range of motion				
Forward flexion, degrees [IQR]	160 [150-160]	160 [145-163]	160 [153-165]	.73
External rotation, degrees [IQR]	50 [45-60]	50 [38-53]	50 [48-60]	.36
Preoperative patient-reported outcomes				
VAS, score (SD)	6.8 (1.8)	7.2 (1.4)	6.4 (2.1)	.18
SSV, score (SD)	46.1 (22.2)	43.9 (25.3)	48.0 (19.8)	.63
ASES, score (SD)	44.1 (23.0)	50.2 (31.1)	39.7 (16.4)	.46
Brophy, score (SD)	8.6 (2.1)	7.6 (2.9)	9.2 (1.1)	.18
PROMIS Mental, score (SD)	12.3 (6.3)	14.7 (3.2)	10.0 (8.0)	.22
PROMIS Physical, score (SD)	13.2 (3.5)	14.2 (1.6)	12.2 (4.7)	.35

SD, standard deviation; *PROMIS*, Patient-Reported Outcomes Measurement Information System; *ASES*, American Shoulder and Elbow Surgeons Standardized Assessment Form; *SSV*, subjective shoulder value; *VAS*, visual analog scale; *IQR*, interquartile range; *ROHI*, Rotator Cuff Healing Index.
*Comparison between traditional repair and repair with bioaugmentation.

Table II
Patient postoperative characteristics.

Demographics	Overall (n = 38)	Traditional (n = 19)	Bioaugmentation (n = 19)	P*
Postoperative range of motion				
Forward flexion, degrees [IQR]	160 [150-170]	160 [140-160]	160 [160-170]	.29
External rotation, degrees [IQR]	50 [40-50]	50 [48-50]	50 [40-50]	.39
Postoperative patient-reported outcomes				
VAS, score (SD)	3.5 (3.1)	3.4 (3.2)	3.6 (3.0)	.90
SSV, score [IQR]	85.0 [60.0-95.0]	80 [68-100]	90 [50-91]	.78
ASES, score (SD)	61.9 (19.0)	57.5 (17.2)	64.6 (20.1)	.32
Brophy, score (SD)	6.2 (4.8)	6.0 (4.1)	6.4 (5.2)	.84
PROMIS mental, score (SD)	12.8 (3.7)	11.7 (3.2)	13.4 (3.9)	.24
PROMIS physical, score (SD)	12.5 (3.1)	11.9 (3.2)	12.8 (3.1)	.47
Postoperative failure*	14 (36.8)	8 (42.1)	6 (31.6)	.74

SD, standard deviation; *PROMIS*, Patient-Reported Outcomes Measurement Information System; *ASES*, American Shoulder and Elbow Surgeons Standardized Assessment Form; *SSV*, subjective shoulder value; *VAS*, visual analog scale; *IQR*, interquartile range.
*Defined as ASES < 60 or postoperative MRI, obtained for pain.

bioaugmentation in the revision setting was an intraoperative surgeon preference and thus subject to bias. Therefore, similar outcomes for the bioaugmentation vs. nonaugmentation cohorts may actually represent improved outcomes for high-risk patients vs. truly no difference between cohorts. A study assessing bioaugmentation and no bioaugmentation would be necessary to assess differences. Nonetheless, it is encouraging that patients who have poor tissue quality or a difficult repair can achieve similar outcomes to patients with better tissue quality in the setting of revision repair. By including only patients with minimum 1-year follow-up, we may have overestimated the rate of failure due to dropout from patients having excellent outcomes who did not follow-up in clinic. The bioaugmentation group also represents a heterogeneous population, receiving both patch augmentation and ACP. The population studied is small, and this combined with the heterogeneous population of the bioaugmentation group may underpower this study to find differences. For preoperative characteristics, we used a modified ROHI score as BMD was not available for 31 of 38 patients, but Spross et al showed that plain radiographic measurements of BMD have good correlation with microcomputed tomography BMD and might be a future substitute in the ROHI scoring system.[20] Future studies assessing these variables with a larger sample may be necessary to draw more definitive conclusions.

Conclusion

Bioaugmentation with a bioinductive collagen patch or ACP demonstrated similar rates of failure and PROs compared to without bioaugmentation in the setting of revision RCR. Further studies with larger numbers may be necessary to determine potential advantages of bioaugmentation in the setting of revision RCR.

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Table III
Comparison of patients meeting failure criteria.

Demographics	Success (n = 24)	Failure (n = 14)	P*
Age, y (SD)	60.3 (8.7)	60.3 (8.2)	.99
Body Mass Index, kg/m^2 (SD)	31.5 (5.8)	32.9 (5.9)	.49
Active smoker, n (%)	3 (12.5)	3 (21.4)	.65
Dominant side affected, n (%)	15 (62.5)	8 (57.1)	.99
Number of prior surgeries, # [IQR]	1.0 [1.0-2.0]	1.0 [1.0-1.25]	.49
Length of clinical follow-up, y (SD)	3.3 (1.5)	3.7 (2.0)	.43
Traumatic reinjury, n (%)	10 (41.7)	5 (35.7)	.99
Tear size, mm (SD)	11.4 (9.1)	19.3 (12.5)	.09
ROHI, score [IQR]	2.0 [1.0-3.0]	4.0 [0.0-8.0]	.15
Preoperative range of motion			
Forward flexion, degrees [IQR]	160 [145-163]	160 [150-165]	.49
External Rotation, degrees [IQR]	50 [49-60]	50 [38-50]	.23
Preoperative patient-reported outcomes			
VAS, score (SD)	6.7 (1.9)	6.8 (1.6)	.87
SSV, score (SD)	49.2 (24.2)	39.4 (16.3)	.28
ASES, score (SD)	46.6 (26.7)	41.6 (20.8)	.72
Brophy, score (SD)	8.5 (1.5)	8.7 (2.7)	.90
PROMIS Mental, score (SD)	14.1 (6.5)	9.8 (5.5)	.26
PROMIS Physical, score (SD)	14.3 (2.5)	11.6 (4.5)	.21
Postoperative range of motion			
Forward flexion, degrees [IQR]	160 [158-161]	160 [153-170]	.87
External rotation, degrees [IQR]	50 [40-53]	50 [40-50]	.15
Postoperative patient-reported outcomes			
VAS, score (SD)	2.2 (2.0)	5.4 (2.6)	**<.001**
SSV, score (SD)	80.4 (14.4)	51.3 (25.5)	**.003**
ASES, score [IQR]	80.0 [69.6-90.4]	46.7 [40.3-55.5]	**<.001**
Brophy, score (SD)	7.3 (5.2)	4.1 (3.4)	.06
PROMIS Mental, score (SD)	14.2 (3.3)	10.5 (3.2)	**.006**
PROMIS Physical, score (SD)	13.9 (2.6)	10.1 (2.3)	**<.001**

SD, standard deviation; *PROMIS*, Patient-Reported Outcomes Measurement Information System; *ASES*, American Shoulder and Elbow Surgeons Standardized Assessment Form; *SSV*, subjective shoulder value; *VAS*, visual analog scale; *IQR*, interquartile range; *ROHI*, Rotator Cuff Healing Index.
Bold values are statistically significant.
*Comparison between patients meeting failure criteria and those who did not.

Arthroscopy: Editorial or governing board; JISAKOS: Editorial or governing board; American Journal of Sports Medicine: Reviewer; Journal of American Academy of Orthopedic Surgeons: Reviewer; Knee Surgery, Sports Traumatology, Arthroscopy: Reviewer; Journal of Shoulder and Elbow Surgery: Reviewer; Journal of Bone and Joint Surgery: Reviewer. The other authors, their immediate families, and any research foundation with which they are affiliated have not received any financial payments or other benefits from any commercial entity related to the subject of this article.

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