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Arthroscopic repair of posterosuperior rotator cuff tears with bioabsorbable patch augmentation: a magnetic resonance–controlled case series with 1-year follow-up

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Background: Among many advances in the treatment of rotator cuff tears, arthroscopic augmentation techniques with patches of various biological and synthetic graft materials have been introduced to reinforce the repair. However, structural and functional outcomes after patch augmentation vary, and reinforcing the tendon healing remains a challenge. The aim of this study was to evaluate clinical and radiologic outcomes 1 year after arthroscopic posterosuperior (PS) rotator cuff repair with bioabsorbable patch augmentation.

Methods: From October 2014 to December 2017, all patients with PS rotator cuff tears undergoing arthroscopic repair with patch augmentation using a resorbable, biologically derived poly-4-hydroxybutyrate patch (Biofiber; Wright, Memphis, TN, USA) were enrolled in this study. Only full-thickness PS lesions with ≥ 1 of the following tear patterns were augmented with a patch and were the subject of this study: large U- and L-shaped tear, transtendinous tear, delamination, and fraying of the bursal layer. Patients were examined preoperatively and at 1 year postoperatively with a standardized examination protocol and magnetic resonance imaging (MRI).

Results: Sixteen patients were included in this study; 1 patient was lost to follow-up. One patient only underwent clinical follow-up. We detected 1 repair failure (6.7%) with dislocation of the lateral-row anchors on computed tomography scanning at 3 months postoperatively. MRI was performed in 14 patients after 1 year; in all of them, the cuff repair was intact. The Sugaya tendon integrity score was 1.7 ± 0.9 . The Constant-Murley score improved from 44 to 89 points ($P < .001$). Muscular strength improved in the supraspinatus (from 2.6 to 4.8), infraspinatus (from 3.2 to 4.9), and subscapularis (from 4 to 4.9) (all $P < .001$). Overall, patient satisfaction was high (3.6 ± 0.6).

Discussion: This small-sized case series is the first to prospectively assess clinical and radiologic outcomes after patch augmentation of PS rotator cuff tears using bioabsorbable poly-4-hydroxybutyrate patches. Good to excellent structural and functional outcomes were observed with a low retear rate (6.7%) and good tendon integrity on 1-year postoperative MRI, and the graft did not cause any complications. The use of bioabsorbable patches could be beneficial when unfavorable PS tear patterns are encountered in which a stable repair of the full tendon thickness at its insertion is otherwise difficult to reach.

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This study was approved by the cantonal ethics committee of Zurich (BASEC-Nr. 2019-01332).

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Rotator cuff tears commonly cause severe pain, reduced shoulder function, and decreased quality of life.⁴¹ Despite advances in the surgical treatment of rotator cuff tears, tendon healing after repair remains a challenge, and retear rates of up to 90% have been reported, depending on the tear size and morphology.^{5,13,32,35} Failure of repair depends on the patient's age, tear morphology and chronicity, and tendon and/or muscle quality.² Recurrence of tears often

occurs in the early healing phase and is associated with poorer postoperative rotator cuff strength results.^{9,15,27,31}

In recent years, augmentation techniques with biological and synthetic grafts have been introduced to increase the tensile strength of the reconstructed tendons and enhance tendon healing.^{1,36,37} Some studies have reported superior clinical outcomes and reduced retear rates in massive rotator cuff tears with patch augmentation,^{7,14,22,39,44} whereas other studies have reported no change in outcomes or even increased retear rates.¹⁶

Synthetic scaffolds have been developed for tissue engineering in plastic and orthopedic surgery, and these are biodegraded over a period of 3–18 months. Only a few studies have investigated these bioabsorbable patches, but they have shown promising results.^{4,29,34} However, evidence is limited, and no consensus has been established in terms of the occasions on which patients benefit from patch-augmented repair.

The aim of this study was to evaluate clinical and radiologic outcomes 1 year after arthroscopic posterolateral (PS) rotator cuff repair with bioabsorbable patch augmentation.

Materials and methods

This prospective case series was conducted at a single institution from October 2014 to January 2019. All patients who were treated with bioresorbable patch-augmented arthroscopic rotator cuff repair of a full-thickness PS tear (supraspinatus [SSP] and/or infraspinatus [ISP]) were included in this study. Patients with fatty infiltration > 50% in the torn rotator cuff muscle did not qualify for cuff repair and were excluded. Neither retraction of the torn tendon to the glenoid, grade 3 according to the Patte classification,³³ nor a concomitant subscapularis (SSC) tear was an exclusion criterion. PS tears were defined as eligible for patch reinforcement by

preoperative magnetic resonance imaging (MRI) and intraoperative findings whenever ≥ 1 of the following conditions was present: (1) large longitudinal U-shaped, L-shaped, or massive contracted PS tear (Fig. 1, A–C); (2) transtendinous SSP and/or ISP rupture (Fig. 1, D); and (3) SSP with significant delamination with extensive fraying and retraction of the bursal layer (Fig. 1, E). All patients were treated arthroscopically with patch augmentation by a single shoulder surgeon (Fig. 2) and were included in this case series. In all patients, a resorbable, biologically derived poly-4-hydroxybutyrate patch (Biofiber; Wright, Memphis, TN, USA) was used. Preoperatively and at 1 year postoperatively, patients underwent a standard clinical examination and MRI.

Clinical evaluation

The treating surgeon obtained a standard history and performed a clinical examination following a routine protocol preoperatively and at 6 weeks, 3 months, 6 months, and 1 year after surgery. The Constant-Murley score (CMS)¹⁰ was determined, and rotator cuff motor function tests were graded from 0 to 5, according to the classification of neurologic examination findings. The ISP was assessed with external rotation strength in a neutral position and in 0° of abduction and compared with the contralateral side. The Jobe test was performed for the SSP, and the modified belly-press test was performed for the SSC. At the final follow-up at 1 year, patients were asked to rate their satisfaction from 1 to 4 (poor, fair, good, or excellent).

Radiologic evaluation

All preoperative and postoperative MRI scans were assessed by a blinded musculoskeletal radiologist, who was unaware of the

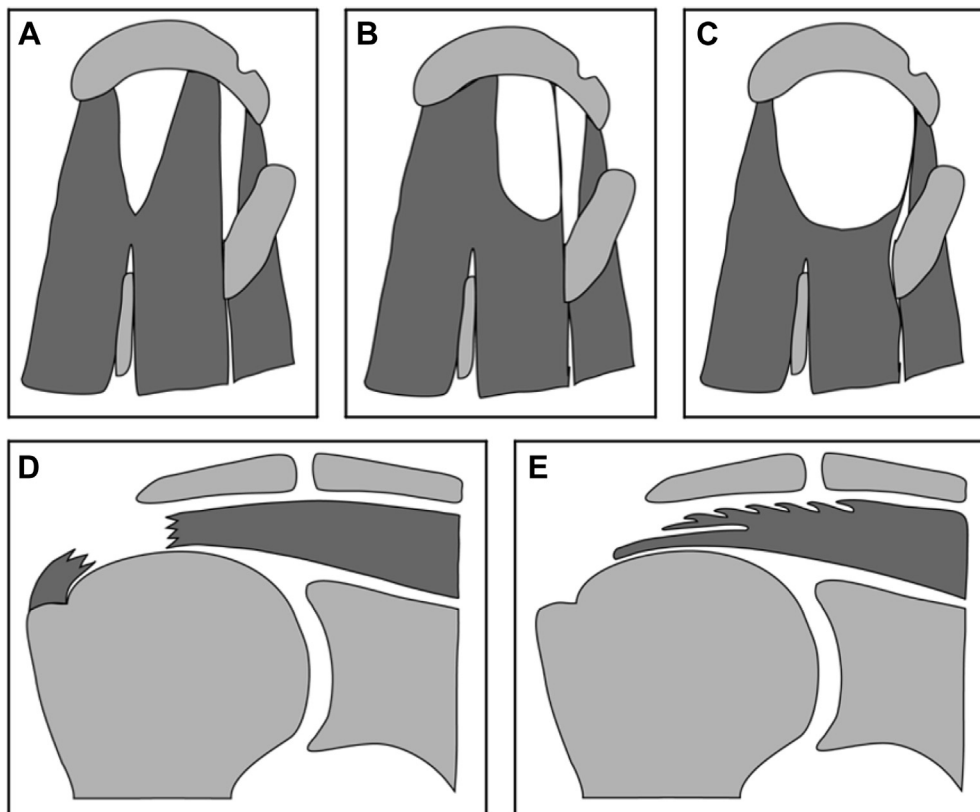


Figure 1 Rotator cuff tears eligible for patch augmentation. (A) Large U-shaped tear, Davidson type IIA. (B) Reversed-shape tear, Davidson type IIB. (C) Massive contracted posterolateral tear, Davidson type III. (D) Transtendinous posterolateral tear. (E) Supraspinatus with significant delamination with extensive fraying and retraction of the bursal layer.

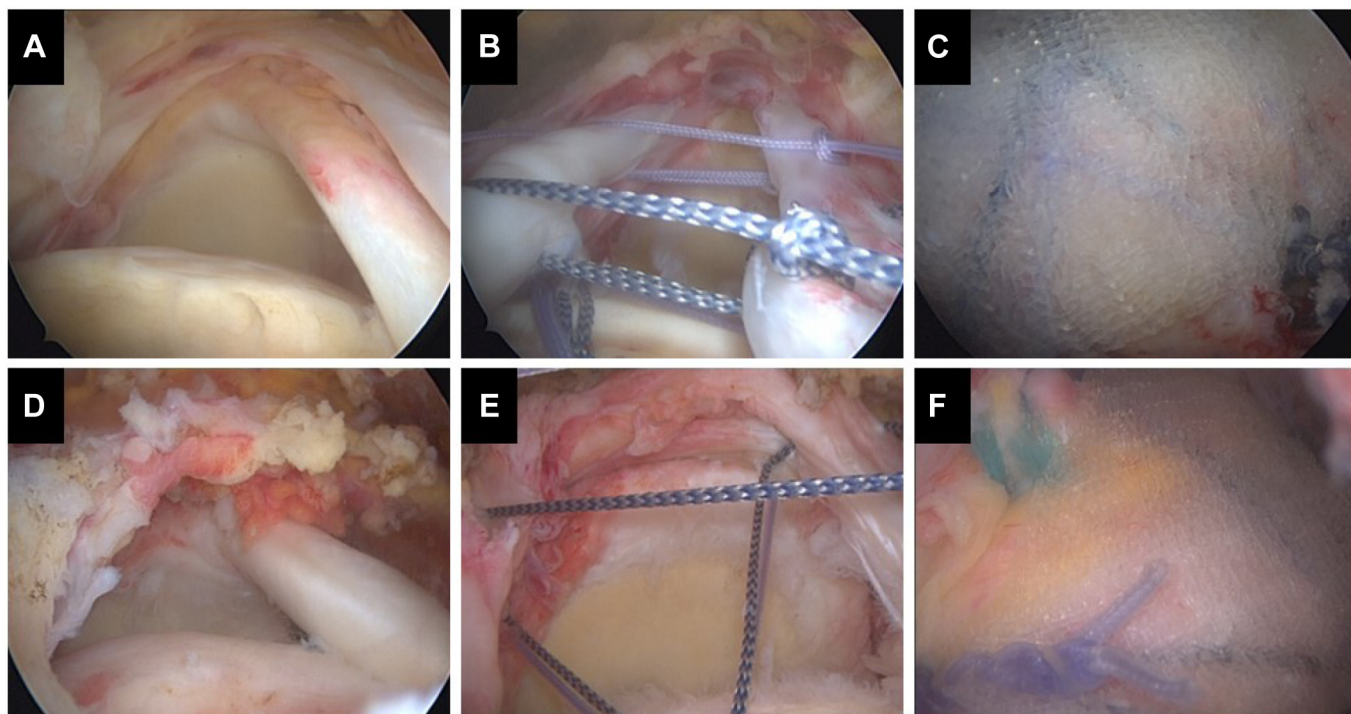


Figure 2 Arthroscopic images of patch-augmented rotator cuff repairs: large reversed-shape tear (A), side-to-side suture (B), and augmentation with patch (C) and large L-shaped tear with intensive fraying of superficial layer of supraspinatus tendon (D), side-to-side suture (E), and augmentation with patch (F).

patients' clinical outcomes. Rotator cuff tears were evaluated on contrast-enhanced MRI studies preoperatively. Magnetic resonance images were assessed for SSP and ISP tears; these tears were graded with a score of 1-3 according to the Patte classification.³³ Concomitant SSC tears were graded from 1 to 5 using the Lafosse classification.²⁸ Fatty infiltration was measured and graded from 0 to 4 according to the Goutallier classification,²³ modified by Fuchs et al.¹⁷ The muscle quantity of the ISP, SSP, and SSC was measured by the cross-sectional area as described by Zanetti et al.⁴⁵ At 1 year postoperatively, all patients were assessed with native MRI, and the same parameters were re-evaluated. Repair integrity was classified into 5 categories on T2-weighted images according to Sugaya et al.⁴⁰ (I, sufficient thickness and homogeneously low signal intensity; II, sufficient thickness with partial high-intensity signal; III, insufficient thickness without discontinuity; IV, minor discontinuity, suggesting a small tear; or V, major discontinuity, suggesting a large re-tear).

Surgical technique

A standardized treatment protocol for arthroscopic rotator cuff repair using a 30° arthroscope was performed.²⁴ Surgery was performed with the patient in the beach-chair position under general anesthesia and a brachial plexus block with an interscalene catheter. Intravenous cefuroxime or clindamycin for perioperative antibiotic prophylaxis was applied. Epinephrine, 1 mg, diluted in 20 mL of normal saline solution was injected into the glenohumeral joint. After diagnostic arthroscopy, the PS cuff was repaired from posterior to anterior. All lesions were repaired with a double-row suture bridge technique, knotted medially (4.5- or 5.5-mm Healix Advance BR or Healix TI; DePuy Synthes, Raynham, MA, USA) and knotless laterally (4.5- or 5.5-mm Healix Advance BR). For the medial suture row, 2-3 double-loaded threaded anchors were used, depending on the size of the tear. Depending on tear anatomy,

traction sutures, side-to-side stitches, and additional anchors, especially in U- and L-shaped tears, were used to reduce and close the lesions. In all cases, at least the deep layer of the SSP or ISP was reducible to the greater tuberosity with low tension; in some cases, a defect of the superficial layer was present. Until this point, the technique described was a standard published procedure.²⁴ Finally, the Biofiber patch was introduced by a parachute technique via a cannula (Arthrex, Naples, FL, USA) from the lateral portal and fixed at 4 points with Orthocord sutures (DePuy Synthes). Medially, the patch was fixed at the anterior border of the SSP and at the posterior border of the ISP, and laterally, the patch was sutured down over the reconstruction by using the 2 free threads of the lateral anchors (Healix Advance Knotless; DePuy Synthes). The intervention was completed with acromioplasty in all patients and with acromioclavicular joint resection in patients with acromioclavicular joint arthritis and tenderness.

Postoperative regimen

Postoperatively, shoulders were positioned in a 45° abduction pillow for 6 weeks. Passive physiotherapy in the pain-free range of motion was initiated on the first postoperative day. Active range-of-motion exercises started after 6 weeks, and cuff strengthening started after 12 weeks.

Statistical analysis

Statistical analysis was performed with IBM SPSS software (version 25; IBM, Armonk, NY, USA) and Stata software (version 13.1; StataCorp, College Station, TX, USA). Parametric data were tested for a normal distribution with the Shapiro-Wilk test. Statistical analysis of dependent groups was performed with the Wilcoxon signed rank test and the paired *t* test where applicable. Data are expressed as means and standard deviations,

Table 1
Patient characteristics, tear morphology, and surgical treatment

Variable	Data
No. of patients	16
Age, mean \pm SD (range), yr	61.2 \pm 9.7 (45–76)
Female sex, % (n)	25 (4)
PS tear pattern, % (n)	
Large U-shaped tear, Davidson type IIA	25.0 (4)
Large L-shaped tear, Davidson type IIB	12.5 (2)
Massive contracted PS tear, Davidson type III	18.8 (3)
Transtendinous SSP and/or ISP tear	31.6 (5)
SSP delamination with extensive superficial fraying	62.5 (10)
Tear morphology, % (n)	
SSP tear	93.8 (15)
Patte grade 1	31.3 (5)
Patte grade 2	43.8 (7)
Patte grade 3	18.8 (3)
ISP tear	68.8 (11)
Patte grade 1	43.8 (7)
Patte grade 2	25.0 (4)
Patte grade 3	0
SSC tear	43.8 (7)
Lafosse grade 1	6.3 (1)
Lafosse grade 2	25.0 (4)
Lafosse grade 3	0
Lafosse grade 4	12.5 (2)
Long biceps tendon luxation or subluxation	43.8 (7)
Tendinopathy of long biceps tendon	25.0 (4)
Surgical treatment, % (n)	
SSC treatment	43.8 (7)
Biceps treatment	
Tenodesis	87.5 (14)
Tenotomy	0
Acromioclavicular resection	62.5 (10)

SD, standard deviation; n, number of patients; PS, posterosuperior; SSP, supraspinatus; ISP, infraspinatus; SSC, subscapularis.

with ranges in parentheses. Statistical significance was set as $P < .05$.

Results

Patient characteristics

From October 2014 to December 2017, 17 patients (5 women and 12 men) were found to have unfavorable PS tear patterns defined by preoperative MRI and intraoperative findings and were treated with arthroscopic repair and poly-4-hydroxybutyrate patch augmentation. One patient was lost to follow-up. Sixteen patients underwent clinical follow-up at 1 year and were included in this study (Table 1). The mean age was 61 \pm 10 years (range, 45–76 years). Symptoms were present for 36 \pm 58 weeks (range, 0–210 weeks). One of the 16 patients refused MRI at 1 year postoperatively because of claustrophobia and only underwent clinical follow-up. Another patient only underwent a contrast-enhanced computed tomography (CT) scan at 3 months postoperatively, without further MRI follow-up, which is discussed in detail later. Therefore, in total, 14 of the 16 patients in this study were radiologically evaluated by MRI at 1 year after surgery.

Clinical outcome

Sixteen patients underwent clinical follow-up at 1 year postoperatively (Table II). The average overall patient satisfaction rating was between good and excellent (3.6 \pm 0.6). Only 1 patient rated his satisfaction as fair (score, 2). The CMS and muscular strength significantly improved from preoperatively to 1 year postoperatively. One patient refused to undergo MRI at 1 year postoperatively because of claustrophobia. This patient was clinically

doing excellently (satisfaction score, 4), with a preoperative to 1-year postoperative improvement in the CMS from 44 to 96 points and increases in strength from 3 to 5 for the SSP and ISP and from 4 to 5 for the SSC. A retear in this patient seemed unlikely. However, we defined retears on a radiologic basis, which is why the retear rate described later is based on only patients with postoperative radiologic follow-up.

Radiologic outcome

Of the 16 patients included in this study, 14 underwent radiologic follow-up at 1 year postoperatively with MRI (Table III). In all 14, the cuff repair was intact. The tendon integrity score according to the Sugaya classification was on average 1.9 \pm 0.7 (range, 1–3), with 2 patients being classified as Sugaya grade III (14%) and the remaining 12, as Sugaya grade II or less (grade I in 4 [29%] and grade II in 8 [57%]). Increases in the mean cross-sectional area (in square millimeters) were found in all examined muscles, but the change was not statistically significant. The Goutallier fatty infiltration grade did not change from preoperatively to 1 year postoperatively in the SSP and SSC. However, the Goutallier fatty infiltration grade did progress in the ISP, from 0.6 to 1.3 ($P = .011$).

One patient (63-year-old man) was found to have a dislocation of the lateral-row anchors, which was diagnosed on radiographs and a subsequent CT scan at 3 months postoperatively. Consecutively, this patient had a full-thickness ISP retear and a retear of the posterior half of the SSP tendon (Fig. 3). He was initially treated for a massive rotator cuff tear with an SSC tear of Lafosse grade 3, SSP of Patte grade 2, and transtendinous ISP of Patte grade 1 with significant delamination. The patient declined revision surgery. At the 1-year clinical follow-up, he reported only minor complaints but he had the lowest CMS (60 points) and rotator cuff strength of all patients. It should be noted that, if a 1-year postoperative MRI scan had been available for this patient, the PS tendon integrity would have been classified as Sugaya grade V.

The rate of repair failure among the 14 patients with 1-year postoperative MRI in our series was 0%. However, in the case described earlier, a repair failure was detected on the contrast-enhanced CT scan at 3 months postoperatively, and no further MRI was conducted at 1 year postoperatively in this patient. Therefore, in our case series, 1 of 15 patients showed a radiologically confirmed repair failure, corresponding to a retear rate of 6.7%.

Discussion

The main findings of this study are that adding a bioresorbable patch did not cause any complications and a retear occurred in only 1 of 15 patients (6.7%) in a small patient cohort with large PS rotator cuff tears or tears with poor tendon quality. Clinical scores and shoulder function markedly increased from baseline to 1 year postoperatively after patch-augmented arthroscopic repair, and the tendon integrity was excellent on 1-year postoperative MRI. The cross-sectional areas did not significantly improve in all examined rotator cuff muscles. However, improvement in muscle volume could anyway be interpreted as the consequence of a reduction of the retracted muscles rather than due to a reactivation and recovery of muscular volume.¹⁸

The correlation of repair integrity with retears and clinical and functional outcomes has been previously described in the literature.^{9,15} The occurrence of repair failure in the first 3 months postoperatively in our series is in line with findings in previous studies.^{27,31} Kluger et al²⁷ reported a failure rate of 33% after rotator cuff repair; 74% of these failures occurred in the first 3 months.

A variety of classifications of rotator cuff tears have been described in the literature. Most of the classifications divide tears

Table II
Clinical evaluation

Variable	Preoperative	Follow-up	P value
No. of patients	16	16	
Strength			
Modified belly-press test (0-5)	4.0 ± 1.0 (2-5)	4.9 ± 0.5 (3-5)	.004*
Jobe abduction strength test (0-5)	2.7 ± 0.6 (1-3)	4.8 ± 0.5 (3-5)	<.001*
External rotation strength (0-5)	3.2 ± 0.5 (2-4)	4.9 ± 0.3 (4-5)	<.001*
CMS			
Total (maximum, 100 points)	44.3 ± 13.8 (19-72)	89.3 ± 11.1 (60-100)	<.001*
Pain (maximum, 15 points)	6.7 ± 3.9 (0-14)	14.3 ± 1.4 (10-15)	<.001*
Activity level (maximum, 10 points)	4.6 ± 2.5 (1-8)	9.4 ± 1.1 (6-10)	.001*
Painless activity (maximum, 10 points)	6.5 ± 1.9 (4-10)	9.6 ± 0.8 (8-10)	<.001*
ROM (maximum, 40 points)	23.8 ± 7.5 (8-34)	35.9 ± 4.9 (22-40)	<.001*
Strength (maximum, 25 points)	2.8 ± 2.4 (0-6)	20.1 ± 6.4 (4-25)	<.001*
Level of satisfaction	NA	3.6 ± 0.6 (2-4)	NA

CMS, Constant-Murley score; ROM, range of motion; NA, not available.
Data are given as mean ± standard deviation (range) unless otherwise indicated.
* Statistically significant.

Table III
MRI evaluation

Variable	Preoperative	1-yr follow-up	P value
No. of patients	14	14	
Rerupture, % (n)		6.7 (1 of 15)*	NA
Fatty infiltration grade (Goutallier classification)			
SSC	0.1 ± 0.4 (0-1)	0.2 ± 0.6 (0-2)	.317
SSP	1.6 ± 1.1 (0-3)	1.6 ± 0.7 (0-3)	>.999
ISP	0.6 ± 0.7 (0-2)	1.3 ± 0.9 (0-3)	.011†
CSA, mm ²			
SSC	2110 ± 531 (1474-3221)	2182 ± 586 (1494-3518)	.387
SSP	506 ± 170 (324-880)	545 ± 162 (351-945)	.155
ISP	864 ± 298 (294-1358)	885 ± 323 (315-1521)	.664
Tendon integrity (Sugaya classification)			
Mean	NA	1.9 ± 0.7 (1-3)	NA
Grade I, %		28.6	NA
Grade II, %		57.1	NA
Grade III, %		14.3	NA

MRI, magnetic resonance imaging; NA, not available; SSC, subscapularis; SSP, supraspinatus; ISP, infraspinatus; CSA, cross-sectional area.
Data are given as mean ± standard deviation (range) unless otherwise indicated. Data are presented for 14 patients; 1 patient refused to undergo postoperative MRI. Change in CSA was normally distributed, and significance was tested with the paired t test.
* A retear was diagnosed on a computed tomography scan postoperatively in 1 patient. This patient did not undergo any further MRI assessments after 1 year and is not included in the total of 14 patients who underwent MRI follow-up.
† Statistically significant.

according to the number of tendons involved and grade of retraction rather than the geometry of the tear itself.^{8,20,21,25} Davidson et al^{11,12} first described a geometric tear classification from 1 to 4, based on which a treatment algorithm was proposed. In our study, we prospectively assessed different tear patterns of the PS rotator cuff and defined them as suitable for patch augmentation whenever the following were present: large longitudinal U- or L-shaped tears; complete transtendinous PS tears; and full-thickness tears with delamination, extensive fraying, and retraction of the bursal layer (Fig. 1).

Repair of Davidson type II and III PS ruptures can lead to increased tensile stress in the middle of the repaired rotator cuff margin and may lead to ultimate failure.¹¹ Thus, patch augmentation at the tendon insertion site may reduce tensile stress through the tendon at the insertion site and play a protective mechanical role in these tears. Transtendinous rotator cuff tears are associated with higher complications with traditional repair (Fig. 4). Simple repair of the medial tendon to the anatomic footprint may lead to increased tension at the tendon-footprint interface, which has been linked to repair failure.³⁰ Patch augmentation has been shown to increase yield load and ultimate load to failure at the tendon-bone junction in such tears.¹

Similarly, full-thickness tears with poor tendon quality due to delamination and extensive fraying of the bursal-sided layer (Fig. 5, A) could profit from patch augmentation, as some studies have claimed increased tensile strength and enhanced tendon healing.^{1,36,37} Using resorbable patches may also be supportive in rotator cuff tears with poor tendon quality due to superficial fraying (Fig. 1, E, and Fig. 2). The patch may help restore the full tendon thickness and strength in these tears (Fig. 5, B). Previous studies have reported delamination as a negative prognostic factor for anatomic tendon repair integrity.^{3,6,15,38} However, the PS rotator cuff tear pattern defined as suitable for patch augmentation in this study is not an established form of rotator cuff tear and may need further investigation.

The introduction of augmentation techniques with biological or synthetic patches have expanded the surgical options for challenging rotator cuff tears. However, the results are diverging throughout the literature, and neither a superiority to other techniques nor any clear indication for the use of a patch graft could be shown so far. Human and xenologous biological patches are resorbable, which may lead to faster tissue formation at the repair site, but they might cause antigenic reactions. Whereas synthetic patches lack antigenicity, they typically remain in the tissue and

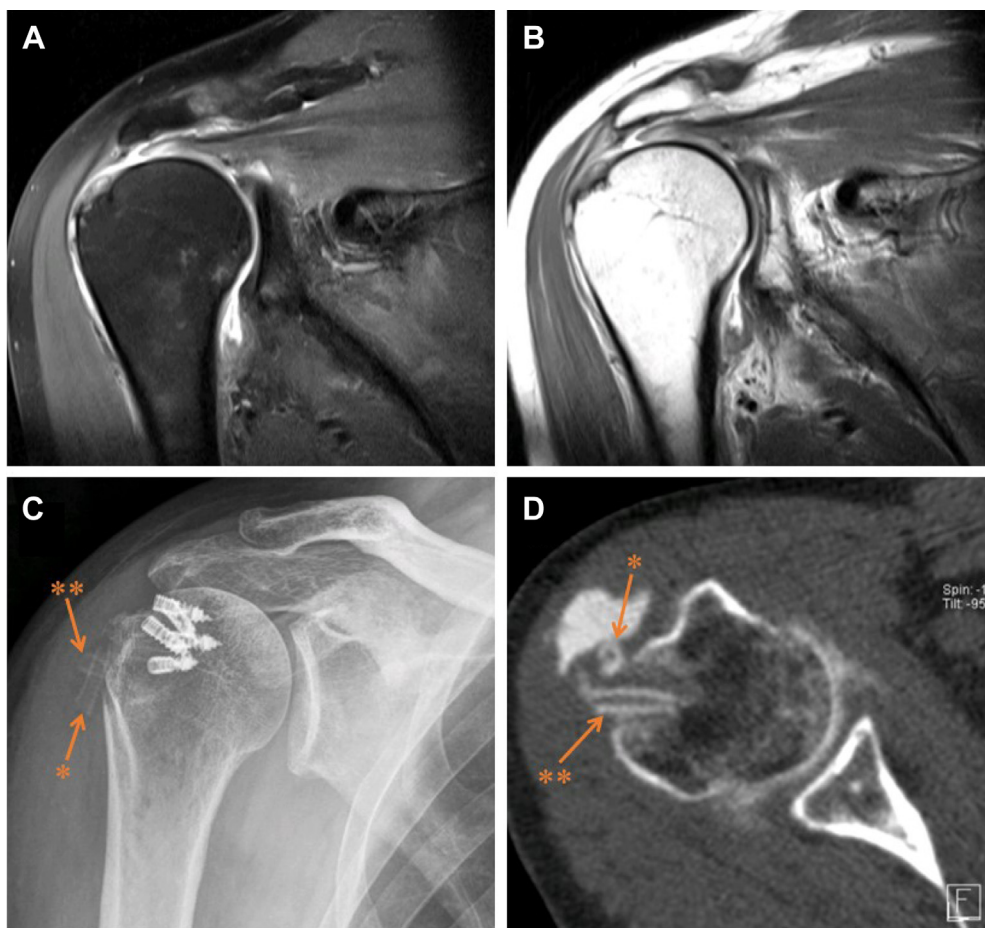


Figure 3 Rerupture of the rotator cuff repair occurred in 1 of 16 patients. (A, B) Preoperative paracoronal magnetic resonance imaging with transtendinous infraspinatus rupture and partial (superficial) supraspinatus rupture. (C, D) At 3 months postoperatively, a coronal radiograph and axial computed tomography scan show dislocation of 2 radiolucent lateral-row anchors with consecutive retears of the infraspinatus and posterior half of the supraspinatus tendon. *Fully dislocated anchor. **Partially dislocated anchor.

may cause foreign-body reactions. Biomechanical studies have shown increases in yield load and ultimate load to failure after patch-augmented repair.^{1,36,37} Bioabsorbable synthetic scaffolds have been developed for tissue engineering in plastic and orthopedic surgery. Over a period of several months, these aliphatic polyesters (polyhydroxybutyrate [PHB], poly-L-lactide, and polycaprolactone) are metabolized to nontoxic end products that are normally present in the body. The patch used consists of PHB, which retains 50%–70% of its mechanical stability after 3 months and is fully degraded after 18 months.^{42,43} In our study, the bioabsorbable patches were not definable on 1-year postoperative MRI in all patients (Figs. 4 and 5). No antigenic or antibody reaction to these bioabsorbable patches has been described.

The results of our case series are in line with those of other published studies that have investigated the use of bioabsorbable patches. In a small case series of 18 patients, Proctor³⁴ found a comparably low retear rate of 17% (3 cases) after 12 months and an additional retear (22%) after 42 months in patients with large to massive PS cuff tears, as well as substantial functional improvement. However, structural integrity was observed by ultrasound only. Lenart et al²⁹ reported a repair failure rate of 62% by MRI in 14 patients with massive rotator cuff tears involving ≥ 2 tendons who were treated with a resorbable poly-L-lactide patch-augmented repair. Reporting that similar published cohorts had even higher retear rates of up to 94%,¹⁹ Lenart et al concluded that patients did benefit from patch augmentation, which was also reflected in

significant clinical improvement. Buess et al⁴ illustrated the use of PHB patch augmentation in a standardized technique for arthroscopic revision of medial rotator cuff failure in their technical note. However, they did not provide any structural or functional outcomes of the technique.

A reduction in the rate of repair failure has been previously shown with human dermal extracellular matrix (ECM) grafts. Gilot et al²² reported a significant reduction in the rate of repair failure in large to massive rotator cuff tears using a dermal ECM patch (20 patients) from 26% to 10% in comparison to non-augmented repair (15 patients) in a prospective blinded study with a 2-year follow-up. However, tendon integrity was evaluated by ultrasound only. Similarly, Yoon et al⁴⁴ found a significant reduction in the rate of recurrent tears with a dermal ECM patch (21 patients) vs. without patch augmentation (54 patients), with retear rates of 19% vs. 46% based on 1-year postoperative MRI scans. In contrast, several studies reported higher rates of recurrent tears with xenograft patches than without patch augmentation. In a retrospective matched-cohort study, Flury et al¹⁶ compared patients who were treated with augmented rotator cuff repair with xenogeneic porcine patch augmentation vs. patients without patch augmentation. On the basis of 2-year postoperative MRI, they found a substantially higher retear rate in the patch-augmented group, with retear rates of 50% in the patch group and 20% in the control group. Ciampi et al⁷ found a higher 12-month rate of recurrent defects with a bovine pericardium xenograft (51%) than with a

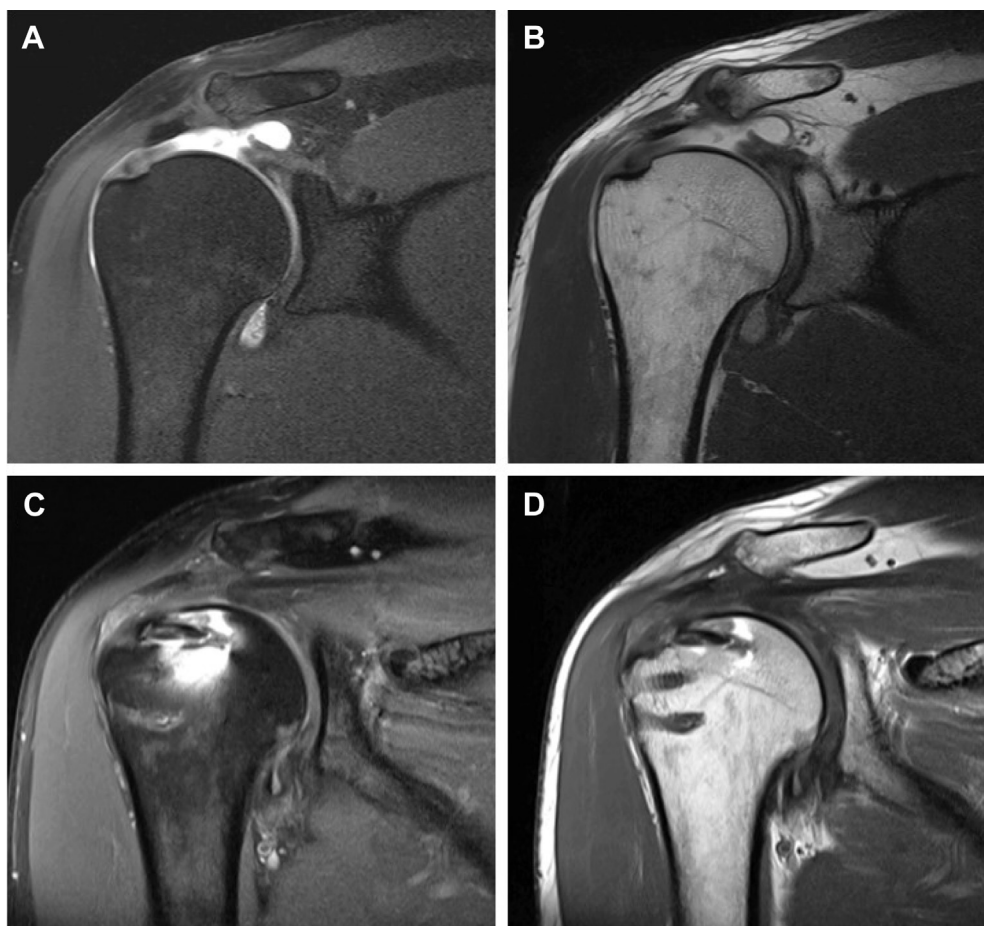


Figure 4 (A, B) Preoperative paracoronal preoperative magnetic resonance imaging of transtendinous supraspinatus tear with extensive retraction. (C, D) Corresponding 1-year postoperative magnetic resonance imaging slices show structural integrity with Sugaya grade II and a restored supraspinatus tendon thickness at the footprint.

synthetic (polypropylene) graft (17%), as well as without a graft (41%), but defects were assessed by ultrasound only. Another small randomized study investigated open rotator cuff repair with porcine dermal patch augmentation (15 patients) and without patch augmentation (15 patients) for the treatment of chronic large rotator cuff tears.²⁶ It reported an improved healing rate with xenograft patch augmentation, with healing rates of 27% (4 of 15 patients) and 60% (11 of 15 patients) in the patch and control groups, respectively, based on 1-year postoperative MRI.

To date, it has remained a challenge to decide whether a patient might benefit from patch augmentation and which patch material is ideal to reduce repair failure, as scientific evidence is yet weak. However, on the basis of our results and other currently published studies, we can only speculate that applying the proposed patch augmentation technique could decrease failure rates in large to massive PS tears or tears with poor tendon quality by promoting tendon healing and increasing tendon thickness and tensile strength (Fig. 4). Nevertheless, the benefit from PHB patch augmentation must be carefully weighed in relation to the additional operative time and possible adverse effects that may not have been described so far. Moreover, it is unclear whether the use of an additional implant, with the added expense, is cost-effective given that it is uncertain if these tears would have healed regardless without the patch. Current evidence shows that bioabsorbable patches and human dermal grafts appear to be more effective than xenogeneic grafts. Xenogeneic patches may trigger some negative biological interactions with the host, and this drawback would

outweigh the mechanical protective effects. However, only comparative, prospective randomized controlled trials with a high level of evidence can clarify the effects that can be attributed to patch augmentation. Synthetic, bioabsorbable, and biological patch augmentation should be comparatively assessed in a prospective randomized controlled trial.

This prospectively conducted case series has some limitations. First, this was a small-sized study without a comparison group. Of the 17 patients eligible for inclusion, only 16 were available for clinical follow-up and only 14 were available for radiologic analysis. Furthermore, this study only provides mid-term results, at 1 year after surgery; the long-term results remain unclear. Even though the tear patterns eligible for patch augmentation were defined by MRI and intraoperative observations, the clinical judgment of whether to use a patch was in the hands of the treating surgeon, which potentially introduces selection bias. Moreover, the clinical examination was performed by the treating surgeon and not by a third party, which is another potential source of bias. The PS tear patterns eligible for patch augmentation in this study included different tear types, making our patient group heterogeneous. The small sample size of this study did not allow any subgroup analysis of the different tear patterns. Further investigation of PS tears should focus on the tear morphology in association with clinical outcomes, tendon integrity, and retears. Finally, we cannot conclude that patients benefited from patch augmentation as no control group was available in this study; thus, the effect of patch augmentation per se remains unclear.

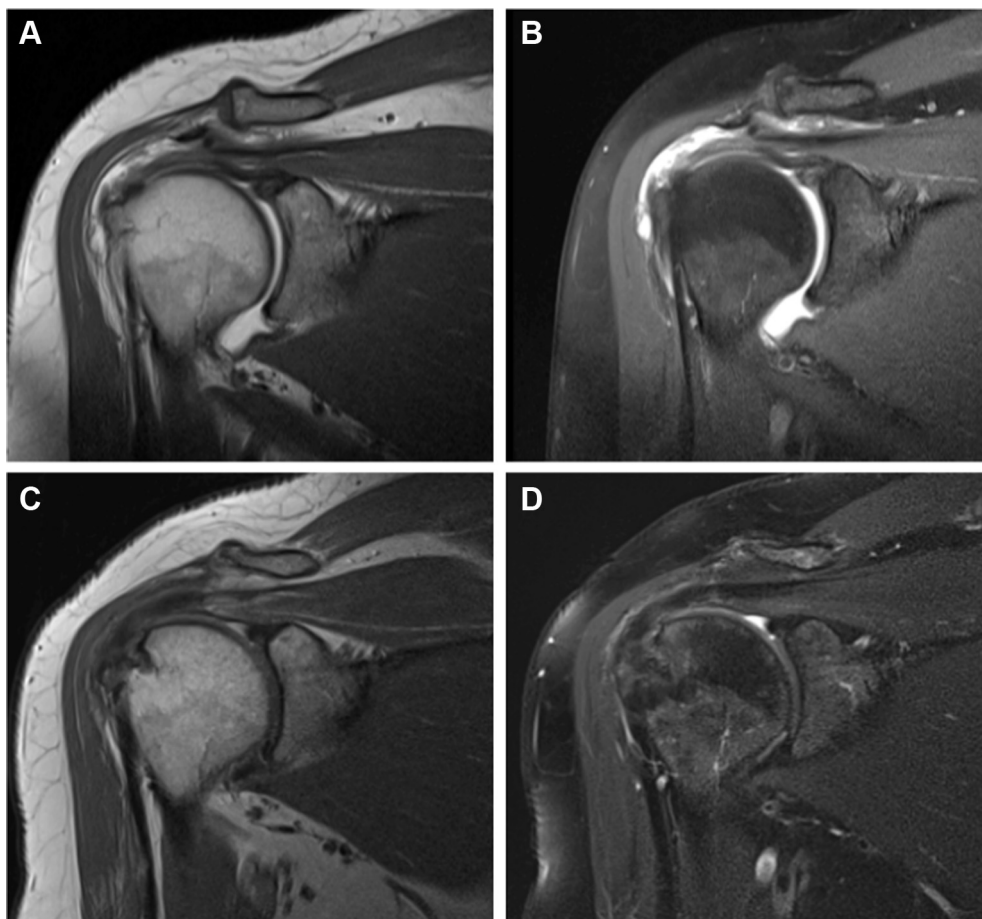


Figure 5 (A, B) Preoperative paracoronal magnetic resonance imaging preoperative with large L-shaped tear and significant fraying of superficial layer of supraspinatus. (C, D) Corresponding 1-year postoperative magnetic resonance imaging with full structural integrity Sugaya I. Note that the patch is radiographically indistinguishable, representing full resorption of the patch.

Conclusion

This small-sized case series is the first to prospectively assess clinical and radiologic outcomes after patch augmentation of PS rotator cuff tears using PHB bioabsorbable patches. The clinical and radiologic outcomes were good to excellent, with a low retear rate and good tendon integrity on 1-year postoperative MRI, and the graft did not cause any complications. The use of bioabsorbable patches could be beneficial when unfavorable PS tear patterns are encountered in which a stable repair of the full tendon thickness at its insertion is otherwise difficult to reach.

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References

- Barber FA, Herbert MA, Boothby MH. Ultimate tensile failure loads of a human dermal allograft rotator cuff augmentation. *Arthroscopy* 2008;24:20–4. <https://doi.org/10.1016/j.arthro.2007.07.013>.
- Bjornsson HC, Norlin R, Johansson K, Adolfsson LE. The influence of age, delay of repair, and tendon involvement in acute rotator cuff tears: structural and clinical outcomes after repair of 42 shoulders. *Acta Orthop* 2011;82:187–92. <https://doi.org/10.3109/17453674.2011.566144>.
- Boileau P, Brassart N, Watkinson DJ, Carles M, Hatzidakis AM, Krishnan SG. Arthroscopic repair of full-thickness tears of the supraspinatus: does the tendon really heal? *J Bone Joint Surg Am* 2005;87:1229–40. <https://doi.org/10.2106/jbjs.D.02035>.
- Buess E, Hackl M, Buxbaumer P. Arthroscopic revision of medial rotator cuff failure augmented with a bioabsorbable patch. *Arthrosc Tech* 2017;6:e1069–74. <https://doi.org/10.1016/j.eats.2017.03.009>.
- Burkhardt SS, Barth JR, Richards DP, Zlatkin MB, Larsen M. Arthroscopic repair of massive rotator cuff tears with stage 3 and 4 fatty degeneration. *Arthroscopy* 2007;23:347–54. <https://doi.org/10.1016/j.arthro.2006.12.012>.
- Choo HJ, Lee SJ, Kim JH, Kim DW, Park YM, Kim OH, et al. Delaminated tears of the rotator cuff: prevalence, characteristics, and diagnostic accuracy using indirect MR arthrography. *AJR Am J Roentgenol* 2015;204:360–6. <https://doi.org/10.2214/ajr.14.12555>.
- Ciampi P, Scotti C, Nonis A, Vitali M, Di Serio C, Peretti GM, et al. The benefit of synthetic versus biological patch augmentation in the repair of posterosuperior massive rotator cuff tears: a 3-year follow-up study. *Am J Sports Med* 2014;42:1169–75. <https://doi.org/10.1177/0363546514525592>.
- Cofield RH. Subscapular muscle transposition for repair of chronic rotator cuff tears. *Surg Gynecol Obstet* 1982;154:667–72.
- Cole BJ, McCarty LP III, Kang RW, Alford W, Lewis PB, Hayden JK. Arthroscopic rotator cuff repair: prospective functional outcome and repair integrity at minimum 2-year follow-up. *J Shoulder Elbow Surg* 2007;16:579–85. <https://doi.org/10.1016/j.jse.2006.12.011>.
- Constant CR, Murley AH. A clinical method of functional assessment of the shoulder. *Clin Orthop Relat Res* 1987;160–4.
- Davidson J, Burkhardt SS. The geometric classification of rotator cuff tears: a system linking tear pattern to treatment and prognosis. *Arthroscopy* 2010;26:417–24. <https://doi.org/10.1016/j.arthro.2009.07.009>.
- Davidson JF, Burkhardt SS, Richards DP, Campbell SE. Use of preoperative magnetic resonance imaging to predict rotator cuff tear pattern and method of repair. *Arthroscopy* 2005;21:1428. <https://doi.org/10.1016/j.arthro.2005.09.015>.
- Derwin KA, Badylak SF, Steinmann SP, Iannotti JP. Extracellular matrix scaffold devices for rotator cuff repair. *J Shoulder Elbow Surg* 2010;19:467–76. <https://doi.org/10.1016/j.jse.2009.10.020>.

14. Ferguson DP, Lewington MR, Smith TD, Wong IH. Graft utilization in the augmentation of large-to-massive rotator cuff repairs: a systematic review. *Am J Sports Med* 2016;44:2984–92. <https://doi.org/10.1177/0363546515624463>.
15. Flurin PH, Landreau P, Gregory T, Boileau P, Brassart N, Courage O, et al. Réparation arthroscopique des ruptures transfixiantes de la coiffe des rotateurs: étude rétrospective multicentrique de 576 cas avec contrôle de la cicatrisation. [Arthroscopic repair of full-thickness cuff tears: a multicentric retrospective study of 576 cases with anatomical assessment]. *Rev Chir Orthop Reparatrice Appar Mot* 2005;91:31–42. [https://doi.org/10.1016/s0035-1040\(05\)84503-9](https://doi.org/10.1016/s0035-1040(05)84503-9) [in French].
16. Flury M, Rickenbacher D, Jung C, Schneider MM, Endell D, Audige L. Porcine dermis patch augmentation of supraspinatus tendon repairs: a pilot study assessing tendon integrity and shoulder function 2 years after arthroscopic repair in patients aged 60 years or older. *Arthroscopy* 2018;34:24–37. <https://doi.org/10.1016/j.arthro.2017.06.024>.
17. Fuchs B, Weishaupt D, Zanetti M, Hodler J, Gerber C. Fatty degeneration of the muscles of the rotator cuff: assessment by computed tomography versus magnetic resonance imaging. *J Shoulder Elbow Surg* 1999;8:599–605.
18. Fukuta S, Tsutsui T, Amari R, Wada K, Sairyo K. Tendon retraction with rotator cuff tear causes a decrease in cross-sectional area of the supraspinatus muscle on magnetic resonance imaging. *J Shoulder Elbow Surg* 2016;25:1069–75. <https://doi.org/10.1016/j.jse.2015.11.008>.
19. Galatz LM, Ball CM, Teefey SA, Middleton WD, Yamaguchi K. The outcome and repair integrity of completely arthroscopically repaired large and massive rotator cuff tears. *J Bone Joint Surg Am* 2004;86:219–24. <https://doi.org/10.2106/00004623-200402000-00002>.
20. Gerber C, Fuchs B, Hodler J. The results of repair of massive tears of the rotator cuff. *J Bone Joint Surg Am* 2000;82:505–15.
21. Gerber C, Wirth SH, Farshad M. Treatment options for massive rotator cuff tears. *J Shoulder Elbow Surg* 2011;20:S20–9. <https://doi.org/10.1016/j.jse.2010.11.028>.
22. Gilot GJ, Alvarez-Pinzon AM, Barcksdale L, Westerdahl D, Krill M, Peck E. Outcome of large to massive rotator cuff tears repaired with and without extracellular matrix augmentation: a prospective comparative study. *Arthroscopy* 2015;31:1459–65. <https://doi.org/10.1016/j.arthro.2015.02.032>.
23. Goutallier D, Postel JM, Bernageau J, Lavau L, Voisin MC. Fatty muscle degeneration in cuff ruptures. Pre- and postoperative evaluation by CT scan. *Clin Orthop Relat Res* 1994;78–83.
24. Grueninger P, Nikolic N, Schneider J, Lattmann T, Platz A, Chmiel C, et al. Arthroscopic repair of massive cuff tears with large subscapularis tendon ruptures (Lafosse III/IV): a prospective magnetic resonance imaging-controlled case series of 26 cases with a minimum follow-up of 1 year. *Arthroscopy* 2015;31:2173–82. <https://doi.org/10.1016/j.arthro.2015.05.012>.
25. Hamada K, Fukuda H, Mikasa M, Kobayashi Y. Roentgenographic findings in massive rotator cuff tears. A long-term observation. *Clin Orthop Relat Res* 1990;92–6.
26. Iannotti JP, Codsí MJ, Kwon YW, Derwin K, Ciccone J, Brems JJ. Porcine small intestine submucosa augmentation of surgical repair of chronic two-tendon rotator cuff tears. A randomized, controlled trial. *J Bone Joint Surg Am* 2006;88:1238–44. <https://doi.org/10.2106/jbjs.E.00524>.
27. Kluger R, Bock P, Mittlbock M, Krampla W, Engel A. Long-term survivorship of rotator cuff repairs using ultrasound and magnetic resonance imaging analysis. *Am J Sports Med* 2011;39:2071–81. <https://doi.org/10.1177/0363546511406395>.
28. Lafosse L, Jost B, Reiland Y, Audebert S, Toussaint B, Gobezie R. Structural integrity and clinical outcomes after arthroscopic repair of isolated subscapularis tears. *J Bone Joint Surg Am* 2007;89:1184–93. <https://doi.org/10.2106/jbjs.F.00007>.
29. Lenart BA, Martens KA, Kearns KA, Gillespie RJ, Zoga AC, Williams GR. Treatment of massive and recurrent rotator cuff tears augmented with a poly-l-lactide graft, a preliminary study. *J Shoulder Elbow Surg* 2015;24:915–21. <https://doi.org/10.1016/j.jse.2014.09.044>.
30. Meyer DC, Wieser K, Farshad M, Gerber C. Retraction of supraspinatus muscle and tendon as predictors of success of rotator cuff repair. *Am J Sports Med* 2012;40:2242–7. <https://doi.org/10.1177/0363546512457587>.
31. Miller BS, Downie BK, Kohen RB, Kijek T, Lesniak B, Jacobson JA, et al. When do rotator cuff repairs fail? Serial ultrasound examination after arthroscopic repair of large and massive rotator cuff tears. *Am J Sports Med* 2011;39:2064–70. <https://doi.org/10.1177/0363546511413372>.
32. Parnes N, DeFranco M, Wells JH, Higgins LD, Warner JJ. Complications after arthroscopic revision rotator cuff repair. *Arthroscopy* 2013;29:1479–86. <https://doi.org/10.1016/j.arthro.2013.06.015>.
33. Patte D. Classification of rotator cuff lesions. *Clin Orthop Relat Res* 1990;81–6.
34. Proctor CS. Long-term successful arthroscopic repair of large and massive rotator cuff tears with a functional and degradable reinforcement device. *J Shoulder Elbow Surg* 2014;23:1508–13. <https://doi.org/10.1016/j.jse.2014.01.010>.
35. Rhee YG, Cho NS, Yoo JH. Clinical outcome and repair integrity after rotator cuff repair in patients older than 70 years versus patients younger than 70 years. *Arthroscopy* 2014;30:546–54. <https://doi.org/10.1016/j.arthro.2014.02.006>.
36. Ricchetti ET, Aurora A, Iannotti JP, Derwin KA. Scaffold devices for rotator cuff repair. *J Shoulder Elbow Surg* 2012;21:251–65. <https://doi.org/10.1016/j.jse.2011.10.003>.
37. Santoni BG, McGilvray KC, Lyons AS, Bansal M, Turner AS, Macgillivray JD, et al. Biomechanical analysis of an ovine rotator cuff repair via porous patch augmentation in a chronic rupture model. *Am J Sports Med* 2010;38:679–86. <https://doi.org/10.1177/0363546510366866>.
38. Sonnabend DH, Watson EM. Structural factors affecting the outcome of rotator cuff repair. *J Shoulder Elbow Surg* 2002;11:212–8. <https://doi.org/10.1067/mse.2002.122272>.
39. Steinhaus ME, Makhni EC, Cole BJ, Romeo AA, Verma NN. Outcomes after patch use in rotator cuff repair. *Arthroscopy* 2016;32:1676–90. <https://doi.org/10.1016/j.arthro.2016.02.009>.
40. 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>.
41. Vitale MA, Vitale MG, Zivin JG, Braman JP, Bigliani LU, Flatow EL. Rotator cuff repair: an analysis of utility scores and cost-effectiveness. *J Shoulder Elbow Surg* 2007;16:181–7. <https://doi.org/10.1016/j.jse.2006.06.013>.
42. Williams SF, Martin DP, Moses AC. The history of GalaFLEX P4HB scaffold. *Aesthet Surg J* 2016;36:S33–42. <https://doi.org/10.1093/asj/sjw141>.
43. Williams SF, Rizk S, Martin DP. Poly-4-hydroxybutyrate (P4HB): a new generation of resorbable medical devices for tissue repair and regeneration. *Biomed Tech (Berl)* 2013;58:439–52. <https://doi.org/10.1515/bmt-2013-0009>.
44. Yoon JP, Chung SW, Kim JY, Lee BJ, Kim HS, Kim JE, et al. Outcomes of combined bone marrow stimulation and patch augmentation for massive rotator cuff tears. *Am J Sports Med* 2016;44:963–71. <https://doi.org/10.1177/0363546515625044>.
45. Zanetti M, Gerber C, Hodler J. Quantitative assessment of the muscles of the rotator cuff with magnetic resonance imaging. *Invest Radiol* 1998;33:163–70.