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Application of a new polyester patch in arthroscopic massive rotator cuff repair—a prospective cohort study

Daniel Smolen, MD[a,b], Nicolas Haffner, MD[b,c], Rainer Mittermayr, MD[b,d,*], Florian Hess, MD[e], Christoph Sternberg, MD[a], Jan Leuzinger, MD[a]

[a]*Etzel Clinic, Pfaeffikon, Switzerland*
[b]*Ludwig Boltzmann Institute for Experimental and Clinical Traumatology, Vienna, Austria*
[c]*Orthopedic Hospital Gersthof, Vienna, Austria*
[d]*Trauma Center of the Workmen Compensation Board, Vienna, Austria*
[e]*Department of Orthopedic Surgery and Traumatology, Kantonsspital Frauenfeld, Frauenfeld, Switzerland*

Background: Massive rotator cuff (RC) tears still present a clinically challenging problem, with reported rerupture rates in up to 94%. The study objective was to determine the impact of synthetic patch augmentation for massive RC tears.
Methods: Between June 2012 and 2014, we performed 50 arthroscopic RC reconstructions augmented with a synthetic polyester patch. Pre- and postoperative imaging methods included arthrographic magnetic resonance imaging, arthrographic computed tomography, and ultrasound examination to determine tendon integrity or rerupture. Clinical outcome was evaluated using the Constant-Murley score and the subjective shoulder value. Mean clinical midterm and final follow-up was 22 months (9-35 months) and 52 months (25-74 months), respectively.
Results: The mean Constant-Murley score increased significantly from 36.5 (±16.4 standard deviation [SD]) preoperatively to a midterm value of 81.2 (±9.6 SD; $P < .0001$) and further improved to a mean of 83.4 (±10.8 SD) at final follow-up. The mean subjective shoulder value increased from 40.3 (±24.3 SD) to 89.2 (±12.9 SD; $P < .0001$) at midterm and to 89.6 (±15.2 SD) at final follow-up. We observed 7 complete reruptures (14%). However, reruptures did not correlate with revision surgery, which was performed in 8 patients. The main reason for revision was frozen shoulder or arthrofibrosis with an intact reconstruction and patch, which was performed in 6 cases.
Conclusions: The retear rate of 14% compared favorably with nonaugmented RC repairs in the literature. Therefore, we conclude that patch augmentation in massive RC tears is feasible to reduce retears and to improve clinical outcome.
Level of evidence: Level IV; Case Series; Treatment Study

Keywords: Massive rotator cuff tears; augmentation; patch; shoulder; arthroscopy

Investigation performed at Etzel Clinic, Pfaeffikon, Switzerland.
Approval of the Ethics Committee of Northwestern- and Central Switzerland was obtained, and the study was determined to be exempt before initiation.

*Reprint requests: Rainer Mittermayr, MD, Trauma Center of the Workmen Compensation Board, Meidling, Kundratstrasse 37, 1120 Vienna, Austria.
E-mail address: rainer.mittermayr@trauma.lbg.ac.at (R. Mittermayr).

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Shoulder pain and dysfunction are frequently caused by rotator cuff (RC) tears of either degenerative or traumatic origin. Advancing age is a major predisposing factor often leading to degenerative ruptures. In fact, almost 300,000 RC repairs are performed annually in the United States. Scandinavian databases show a 204% increase of incidence during a 14-year period.[10,24,37,44] Whereas a substantial number of RC tears are degenerative in nature and often asymptomatic, trauma or increase in tear size can lead to decompensation, impairing shoulder function and patients' quality of life.

Although most patients benefit from current techniques of RC repair, retears remain the biggest problem after surgery. Hence, in light of the high costs associated with surgical intervention followed by lengthy rehabilitation, there is a constant need to devise better ways to avoid construct failure and consecutive revision surgery.[23,30]

Patients with low physical demands, potential comorbidities, advanced age, or fatty infiltration beyond grade 3 according to Goutallier can be treated conservatively.[16] This approach also applies to patients with severely retracted tendons. Conservative measures include but are not limited to physical therapy, physiotherapy, nonsteroidal anti-inflammatory drugs, and acupuncture. Nonoperative treatment aims for pain relief and rehabilitation of shoulder function and does not necessarily imply poor outcome. However, if patients continue to be symptomatic, re-evaluation of potential surgery should be considered. On the contrary, in more active middle-aged patients, primary RC repair must at least be discussed with if not suggested to the patient because of potential tear size progression and deterioration of tendon quality.[45]

Depending on tear size, various treatment options exist. In small ruptures, a single-row repair seems to be an adequate measure, whereas larger or massive tears often require a double-row fixation.[45] If complete reinsertion to the footprint cannot be obtained, additional salvage procedures may be applied, including margin convergence technique, interval shift, superior capsular reconstruction, and tendon débridement with or without acromioplasty.[19,25,31,50] Should these approaches either fail or primarily not be indicated, a muscle transfer or a reverse prosthesis has to be taken into consideration, depending on the patient's age and clinical symptoms.

All-arthroscopic RC repair with various reconstruction procedures has been studied extensively and progressed in technique and materials in the past.[5,8,17,29,41] As indicated, despite all efforts, reruptures are still common, and failure rates range from 9% to 94%, depending on study population and the respective protocol.[3,6,14,19,39]

Innovative advances in surgical techniques with either biologic or synthetic augmentation of the RC have recently been applied and may be a promising alternative to the aforementioned salvage procedures. Especially synthetic patch augmentation showed good clinical results, with only a few complications and almost no foreign body reactions.[28] However, reports in the literature regarding the use of synthetic patches, specifically those focusing on radiographic and clinical outcome, are scarce, and study populations are often small.[13,38]

The purpose of this study was to assess the impact and potential advantage of a new synthetic polyester patch augmentation in repair of massive RC tears using clinical and radiologic follow-up.

Methods

This prospective, noncontrolled clinical study was conducted in accordance with the Helsinki declaration (version 2013, Fortaleza) and the guidelines of the International Conference for Harmonisation.

Demographics

Inclusion criteria were age >40 years, RC tears involving at least 2 tendons, presentation with a massive RC tear as described by Gerber et al[15] and Davidson and Burkhart,[11] indication for primary surgery, and willingness of the patient to participate in this study. We excluded patients older than 75 years, fatty infiltration grade 4 according to Goutallier, revision operations (reruptures of former repairs), and cases with severe osteoarthritis. The patients were informed that patch augmentation was indicated if preoperative magnetic resonance imaging (MRI) suggested and intraoperative findings confirmed poor tendon or muscle quality, large or retracted tears, and unusual medial tear patterns.

Between June 2012 and June 2014, we performed 962 shoulder operations at our shoulder department, 383 of which were arthroscopic RC repairs. Of those, 264 were regular double-row or triple-row reconstructions and 24 were partial-thickness articular-sided supraspinatus tendon avulsion repairs. There were 95 patients who received augmented arthroscopic RC reconstructions with a synthetic polyester patch; 37 of these cases were revision operations after failed primary cuff repair and therefore were excluded from this study. Four patients refused participation initially, and another 4 were lost to follow-up. Thus, 50 shoulders (29 right and 21 left) in 50 patients (34 male and 16 female) were included in this study. Detailed description of the included patients and the RC status is shown in Table I. The dominant side was involved in 43 cases. All procedures were conducted by 2 senior surgeons (J.L. and C.S.). Mean age of the patients at the time of surgery was 64.8 years (range, 41-75 years).

Surgical technique

All patients were operated on by 2 experienced senior shoulder surgeons (J.L. and C.S.) under general anesthesia and a scalenus nerve block, followed by an overnight pain catheter, in a beach chair position with 80° of forward shoulder flexion and traction between 3 and 5 kg. After washing and draping, a standard viewing portal was placed at the dorsal soft spot. Further portals included but were not limited to a lateral, a dorsolateral, an anterolateral, and an anterior portal. If additional pathologic changes were present, they were treated simultaneously; these mostly

Table I Demographic data

	Age (yr)	Sex		Side		Follow-up (mo)	
		Female	Male	Right	Left	Midterm	Final
Patients (n = 50)	65 (± 8)	16	34	29	21	22 (± 7)	52 (± 10)

	SSP + ISP	SSP + SSC	SSP + ISP + SSC	Patte			Goutallier				Trauma	
RCs				1	2	3	0	1	2	3	Yes	No
	26	1	23	14	22	13	9	28	13	0	35	15

SSP, supraspinatus; *ISP*, infraspinatus; *SSC*, subscapularis; *RCs*, rotator cuffs.
Demographic data as recorded at the study inclusion. Categorical variables are presented as number. Continuous variables are presented as mean (± standard deviation).

involved the long head of the biceps tendon, treated with tenodesis or tenotomy as deemed appropriate by the surgeon. In addition, synovectomy and labral débridement were performed if considered necessary. After a thorough bursectomy, the rupture was fully visualized, and thereafter its size was estimated. After débridement of the footprint, we used a triple-row repair approach, as follows.

Two double-loaded Titan anchors (OrthoD 5.5-mm metallic suture screwed anchor; Orthomed, Gloucestershire, UK) were placed at the bone-cartilage interface into the previously débrided footprint. If a subscapularis tear was present, we used a third Titan anchor at the débrided lesser tuberosity for its repair.

All sutures were passed through the tendon using a suture passer and left in place to be knotted later. One double-armed PEEK suture anchor (Quattro X, 5.5 mm; Cayenne Medical Inc., Scottsdale, AZ, USA) was then inserted at the very lateral aspect of the greater tuberosity, serving as a primary reduction anchor. The PEEK anchor sutures were passed through the tendon's lateral edge and immediately tied to reduce the rupture to the footprint to allow tension-free tying of the medial row. Thereafter, the suture bridge was completed in a regular fashion using two Plug'n'Twist anchors (IST Innovative Shoulder Technology AG, Cham, Switzerland) at the lower facet of the greater tubercle (Fig. 1).

To insert the polyester patch (Pitch-Patch; IST Innovative Shoulder Technology AG), a flexible percutaneous cannula (PassPort Button Cannula; Arthrex, Naples, FL, USA) was inserted into the lateral portal. Two single stitches using a braided multifilament suture (Orthocord; Depuy Synthes, Raynham, MA, USA) were passed anteromedially through the supraspinatus and posteromedially through the infraspinatus muscle-tendon intersection. Two PEEK anchor sutures at the lateral edge of the footprint, not yet completed, were then knotted anterolaterally and posterolaterally. One end of each suture was individually shuttled through its respective portal. The corresponding end was gathered through the PassPort in the lateral portal. The Pitch-Patch provides 7 predefined holes. The 4 corner holes were armed with sutures shuttled through the PassPort. It is of paramount importance to avoid interfering soft tissue bridges to allow free passage of the sutures. After the patch was armed on all 4 corners, it was folded lengthwise in a "parachute" manner and inserted into the PassPort. Simultaneously, equal traction was applied on the 4 ends of the sutures at the respective portals (anteromedial, anterolateral, posteromedial, and posterolateral) to correctly place the patch, covering the tendon-bone intersection and most of the suture bridge repair. Thereafter, the 4 traction sutures were tied. Finally, a single suture was placed at the predefined mid-medial hole and on each middle hole at the side of the patch, using a suture passer (Fig. 2).

Postoperatively, patients were placed in a shoulder sling in 30° of abduction for 6 weeks. During this rehabilitation phase, only continuous passive motion was used. In the following phase (weeks 7-12), active range of motion without weightlifting was allowed. No physical therapy or physiotherapy was applied in the first 12 weeks. Consequently, when tendon and patch integrity was radiologically confirmed (by MRI, computed tomography [CT], or ultrasound), patients started with coordination and loading exercises.

Pitch-Patch technical information

The Pitch-Patch is a polyester patch dedicated to augmentation of RC tendons. The shape is adapted to the anatomy and borders, and the prepared suture holes are reinforced. The pullout strength (300 N) of this specific design was evaluated in advance to meet the specific requirements in massive RC tears.

Polyethylene terephthalate, the most common thermoplastic polymer resin of the polyester family, is used in fibers for clothing, containers for liquids, and foods but also in medical devices, such as suture material. The chemical formula is $(C_{10}H_8O_4)_n$, and single polyethylene terephthalate fibers can be further processed and woven to shape.

Clinical evaluation

To evaluate clinical outcome, we used the Constant-Murley score (CS), which contains subjective (35%) as well as objective (65%) parameters in the clinical follow-up of shoulder diseases and associated treatments, and the subjective shoulder value (SSV), a patient's subjective shoulder assessment expressed as a percentage of a healthy shoulder, pre- and postoperatively. Mean midterm follow-up was 22 months (range, 9-35 months); mean final follow-up was 52 months (range, 25-74 months).

Radiologic evaluation

Preoperative imaging consisted mainly of arthrographic MRI (aMRI; n = 52). Two patients had to be diagnosed with arthrographic CT (aCT) because of contraindications to MRI. Postoperatively, 31 shoulders were evaluated with aMRI, 13 shoulders received aCT, and 6 shoulders were examined by ultrasound. The heterogeneity of the postoperative imaging techniques arose from

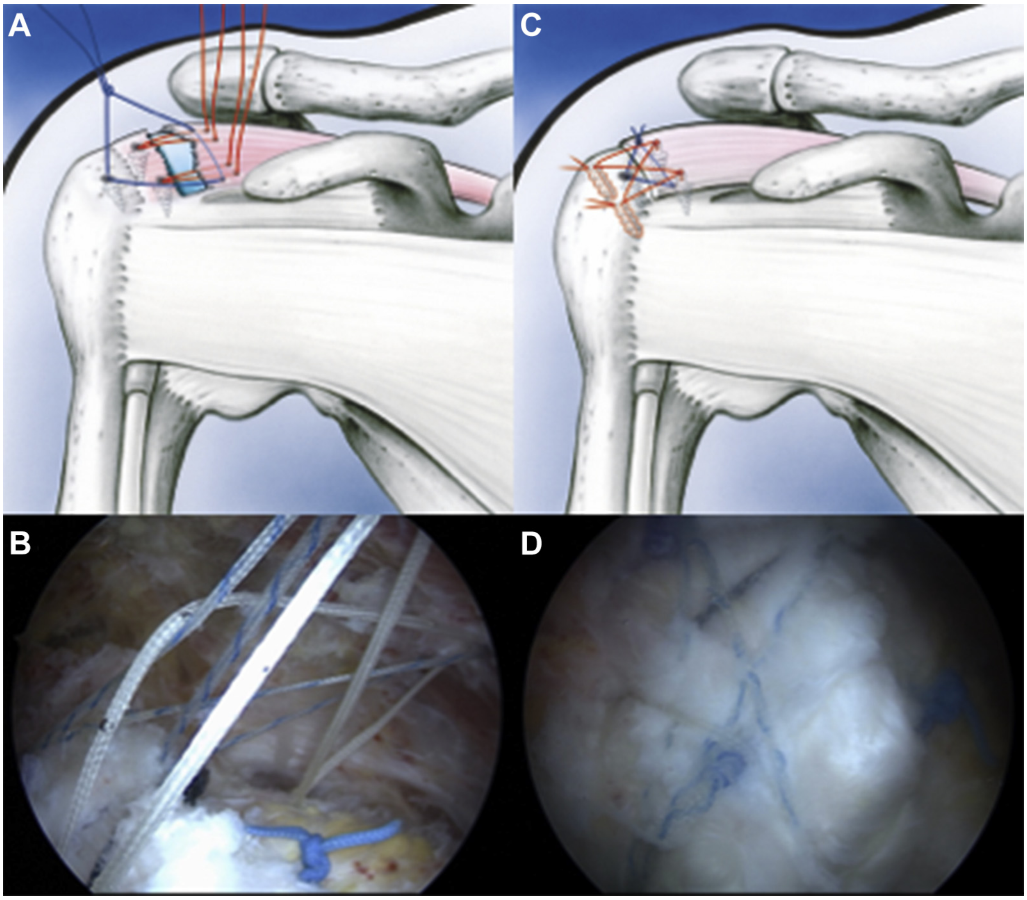

Figure 1 Graphics and intraoperative views of the triple-row rotator cuff repair. (**A** and **B**) Technical scheme showing suture placement before the rupture is reduced with the corresponding intraoperative view. (**C** and **D**) Technical scheme and arthroscopic view showing the completed triple-row reconstruction with tied sutures and a reconstructed rotator cuff.

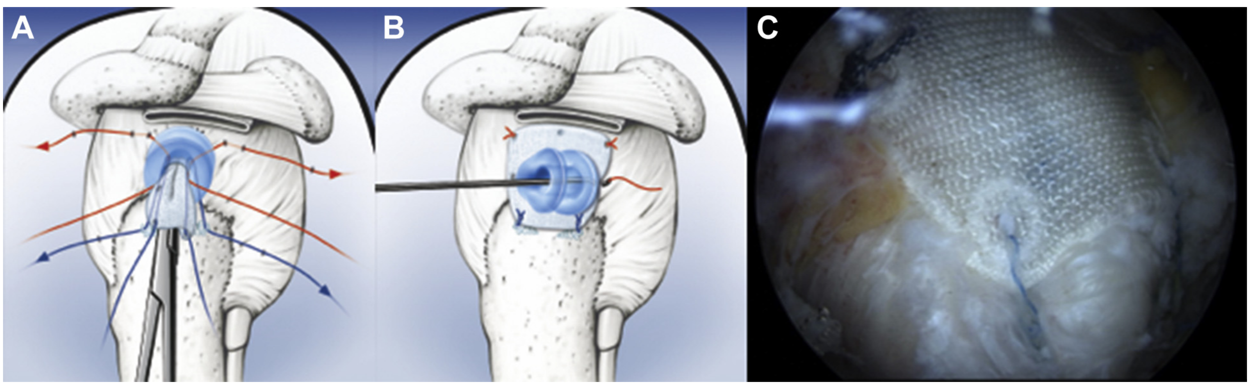

Figure 2 Technical illustration and arthroscopic view of patch implantation and placement. (**A**) The patch is inserted as augmentation onto the repaired rotator cuff through a cannula, using the preplaced sutures and the 4 predefined corner holes of the patch. (**B**) The predefined mid holes of the patch are secured to the tendon by additional sutures. (**C**) Arthroscopic view of the repaired rotator cuff and the patch in place.

patients' preference and costs. At final follow-up, tendon integrity was evaluated by ultrasound in all 50 cases.

In all imaging methods, tendon integrity was considered intact if full coverage of the débrided footprint was present when following the contour of the humeral head. In all cases, we specifically looked for the patch being in its original position.

Statistical analysis

Detailed statistical analysis was performed using SPSS (IBM Corp, Armonk, NY, USA). To assess normal data distribution, the Kolmogorov-Smirnov test was used. To reveal statistical differences between pre- and postoperative (midterm and final

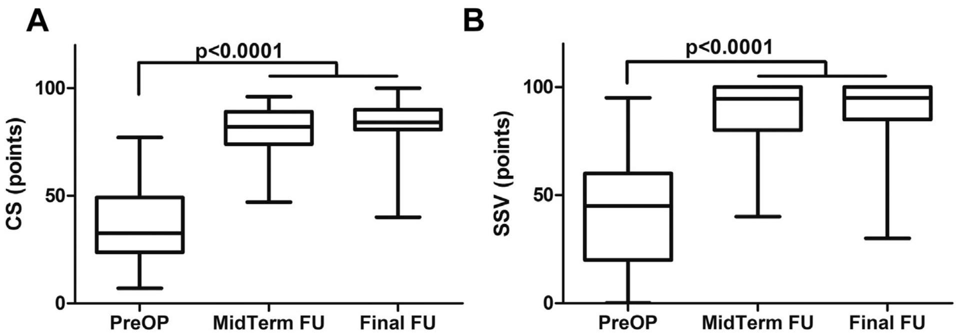

Figure 3 Constant-Murley score (*CS*) and subjective shoulder value (*SSV*). The mean Constant-Murley score (**A**) significantly increased from a baseline value of 36.5 points (± 16.4 standard deviation [SD]) to a mean postsurgical value at final follow-up (*FU*) of 83.4 points (± 10.8 SD; $P < .0001$). The subjective shoulder value (**B**) significantly improved from a mean presurgical value of 40.3 (± 24.3 SD) to 89.6 (±15.2 SD) at final follow-up, reflecting high patient satisfaction ($P < .0001$). Data are shown as box plots.

follow-up) CS and SSV, a repeated-measures test (Friedman) was used, followed by the Dunn post test. CS subcategories between preoperative evaluation and final follow-up were tested with a paired test (Wilcoxon matched pairs test). To assess statistical differences in traumatic vs. nontraumatic events in the medical history regarding CS and SSV, a two-tailed *t*-test was adopted.

To determine correlation between parameters, the Pearson χ^2 test or the Fisher exact test was performed. Finally, classification and regression tree analysis was performed to identify prognostic factors such as age, sex, and traumatic or degenerative etiology concerning reruptures and revisions. The level of significance was set below 5% ($P < .05$).

Results

Synthetic patches—healing and clinical outcome

To determine whether application of synthetic patches would influence healing, these were introduced into the shoulders after a triple-row RC repair (Figs. 1 and 2). A total of 50 shoulders (Table I) subjected to this surgery were included in this study and evaluated pre- and post-operatively for the parameters outlined earlier.

At a midterm follow-up of 22 months (range, 9-35 months), the mean CS significantly increased from a baseline value of 36.5 points (± 16.4 standard deviation [SD]) to a mean postsurgical value of 81.2 points (± 9.6 SD; $P < .0001$; Fig. 3, *A*). This value even further increased up to final follow-up, showing a mean CS of 83.4 (±10.8 SD; $P < .005$ vs. midterm follow-up).

Further analysis of the subcategories of the CS revealed that all single parameters significantly improved at midterm and final follow-up compared with preoperative values ($P < .0001$; Table II). Furthermore, pain as well as internal rotation even significantly improved from midterm to final follow-up ($P < .005$). Similarly, the SSVs significantly improved from a mean preoperative value of 40.3 (± 24.3 SD) to 89.2 (±12.9 SD) at midterm follow-up and 89.6 (±15.2 SD) at final follow-up, reflecting high patient satisfaction ($P < .0001$; Fig. 3, *B*).

Interestingly, patients who underwent reconstruction and augmentation for degenerative RC tears showed similar nonsignificant final follow-up CS and SSV scores compared with traumatic tears (Fig. 4). Trauma as the initial event for rupture, however, also did not show a correlation between the frequency of reruptures and surgical revision (data not shown).

Statistical and dependent or independent variable relations depicted that the postoperative CS was negatively dependent on the retraction grade 3 according to Patte ($P < .01$) and that male patients showed better final CS outcome ($P < .0005$). On the contrary, no correlation was found for the parameter fatty infiltration according to Goutallier grade, age, and whether the dominant side of the patient was operated on (data not shown). The final postoperative SSV also showed inferior outcome if the initial grade of retraction (Patte) was rated grade 3 ($P < .0001$). For all other parameters, no dependent or independent variable relations could be found.

Radiologic findings—retear rates

At midterm radiologic follow-up (mean, 8 months; range, 1-35 months), 86% (43 patients) of all tendons showed an intact reconstruction with complete footprint coverage. Only 7 of the 50 patients showed a rerupture (14%). In all but 1 of these cases, the patch remained at the bone interface, whereas the tendon detached from the footprint underneath. One rerupture included the patch, and in this case it was detached from its lateral anchorage.

Indication for revision surgery

Reruptures did not directly correlate with revision surgery, which was performed in 8 patients (16%), as only 1 rerupture had to be revised (Table III). This patient, presenting with a full-thickness retear, received a deltoid flap after patch removal. The remaining retears showed good

Table II Subcategories of the Constant-Murley score

Parameter	Subjective		Objective				
	Pain	ADLs (sleep, work, recreation/sport)	Flexion	Abduction	External rotation	Internal rotation	Strength
Preoperative	5.5 (3.1)	10.3 (3.6)	6.2 (2.8)	5.2 (2.9)	3.6 (3.8)	3.8 (2.2)	1.9 (3.1)
Midterm follow-up	13.6 (2.0)	19.4 (1.0)	9.9 (0.4)	9.6 (1.2)	9.8 (1.0)	7.1 (1.7)	11.9 (6.0)
Final follow-up	14.2* (1.7)	19.4 (1.4)	9.8 (1.0)	9.6 (1.3)	9.8 (1.2)	8.0* (1.8)	12.6 (6.4)

ADLs, activities of daily living.
Variables are presented as mean (standard deviation). All short-term and final follow-up values differ significantly from preoperative values with a $P <$ .0001.
* $P <$ .005 compared with short-term follow-up.

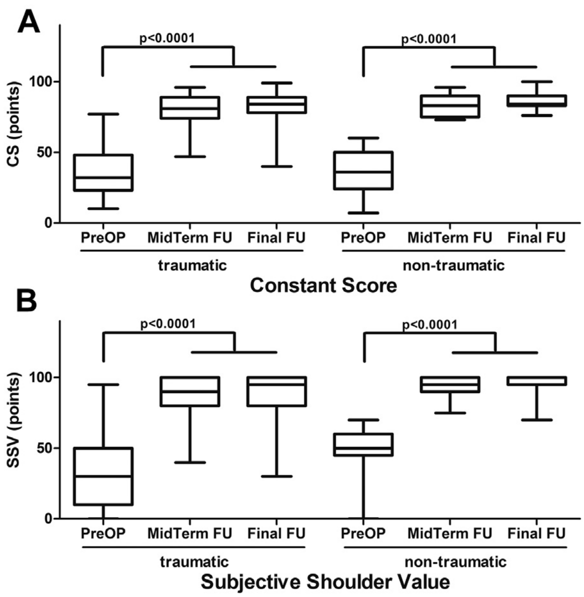

Figure 4 Relation of traumatic and nontraumatic causes to Constant-Murley score (*CS*) and subjective shoulder value (*SSV*). No differences were found regarding the Constant-Murley score (**A**). Patients who underwent reconstruction and augmentation for traumatic rotator cuff tears showed a similar nonsignificant final subjective shoulder value (**B**) compared with degenerative tears. The postsurgical Constant-Murley score and subjective shoulder value, however, were significantly better compared with baseline values, independent of etiology ($P <$ .0001). Data are shown as box plots.

clinical improvement, and therefore the patients declined further surgical interventions.

Six patients (12%) with intact reconstructions were revised for frozen shoulders or arthrofibrosis, receiving capsulotomies and arthrolysis, choosing operative over conservative treatment. However, after revision surgery, these patients at final study follow-up showed comparable good clinical results with the patch in situ as evidenced by CS (83.9 ± 10.9 SD intact tendons vs. 81.3 ± 11.6 SD revised tendons) as well as by SSV (90.4.9 ± 13.3 SD intact tendons vs. 93.3 ± 8.8 SD revised tendons).

In 1 patient with an intact repair, the patch had to be removed because of symptomatic crepitus. The explanted patch was analyzed histologically. The patch was fully integrated without signs of foreign body reaction (Fig. 5).

During revisions with an intact reconstruction, it was noticed that the patch was covered in a fibrous, almost bursalike mantle of tissue (Fig. 6).

Tendon integrity grants better strength

Correlating the clinical outcome with the occurrence of radiologic reruptures, a significantly better CS could be observed in patients with intact repairs (n = 43) compared with patients showing a rerupture (n = 7) during follow-up (85.6 ± 8.1 SD vs. 70.1 ± 15.9 SD, respectively, at final follow-up; $P <$ .0005; Fig. 7, *A*). Interestingly, the subcategories "pain" and "rotation" of the CS were not statistically significantly different between intact and reruptured tendons at final follow-up, whereas the other parameters reached a significant difference between both groups (at least $P <$ .05; data not shown).

Similarly, the SSV also showed significantly better postsurgical values comparing patients with intact repairs with patients whose construct failed (93.8 ± 8.5 SD vs. 63.6 ± 21.6 SD, respectively; $P <$ .0001; Fig. 7, *B*).

To exclude preoperative confounding factors, the two groups were compared and deemed equal (37.3 ± 16.9 SD vs. 31.3 ± 12.0 SD; P = .3783) in respect to the CS. However, this did not apply for the SSV.

Tendon retraction is correlated with negative outcome

The predominant cause of RC tears in our study cohort was trauma related (n = 35), whereas ruptures based on pure degenerative alterations of the tendons accounted for one-third (n = 15). No correlation of the cause with rerupture rate or revision surgery was found in performing a Fisher exact test.

In contrast, a significant correlation between reruptures and a retraction grade 3 according to Patte could be seen (P < .001; Table IV). However, no significant differences

Table III Detailed description of revision surgery

ID	Sex	Age (yr)	Etiology	RC tear	Patte	Goutallier	CS		SSV		Rerupture	Revision surgery	
							Pre	Post	Pre	Post		Reason	Type
B.R.	Female	67	Traumatic	SSP + ISP	3	2	14	67	0	100	No	Frozen shoulder	Arthrolysis, capsulotomy
K.B.	Male	62	Traumatic	SSP + ISP	1	1	32	96	65	98	No	Frozen shoulder	Arthrolysis, capsulotomy
A.C.	Male	63	Traumatic	SSP + ISP	1	1	28	88	45	90	No	Crepitus	Patch removal, arthrolysis, capsulotomy
B.S.	Female	57	Traumatic	SSP + ISP	3	1	29	74	40	80	Yes	Rerupture	Patch removal, delta flap
E.W.	Female	66	Degenerative	SSP + ISP + SSC	2	1	53	85	50	100	No	Arthrofibrosis	Arthrolysis, capsulotomy
E.S.	Male	68	Traumatic	SSP + ISP + SSC	2	2	31	86	50	95	No	Arthrofibrosis	Arthrolysis, capsulotomy
E.R.	Female	69	Degenerative	SSP + ISP + SSC	2	2	24	75	50	90	No	Arthrofibrosis	Arthrolysis, capsulotomy
C.P.	Female	75	Traumatic	SSP + ISP + SSC	2	0	21	79	20	80	No	Frozen shoulder	Arthrolysis, capsulotomy

ID, patients' initials; *RC*, rotator cuff; *CS*, Constant-Murley score; *SSV*, subjective shoulder value; *SSP*, supraspinatus; *ISP*, infraspinatus; *SSC*, subscapularis.

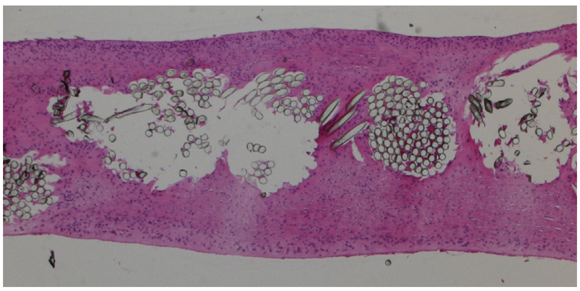

Figure 5 Standard hematoxylin and eosin histology of an explanted patch in a patient who underwent revision for symptomatic crepitus. At 100× magnification, complete integration of the synthetic polyester patch is evident (*white areas* around patch fibers are due to fixation artifacts). No signs of foreign body reaction or tissue rejection are noticeable.

could be found correlating surgical revisions and retraction grade (Patte). Fatty infiltration according to Goutallier showed no significant correlation with the presence of reruptures or with revision surgery.

The number of involved tendons (2 or 3) showed no correlation with revision or reruptures in applying the Pearson χ^2 test.

Looking at age, fatty infiltration, and retraction, no correlation could be observed.

Discussion

This study investigated the clinical application of a new synthetic polyester patch used to augment massive RC tears. Based on 50 shoulders, the use of this patch yielded good clinical results in this study. To our knowledge, this is the largest cohort study reporting on synthetic patches thus

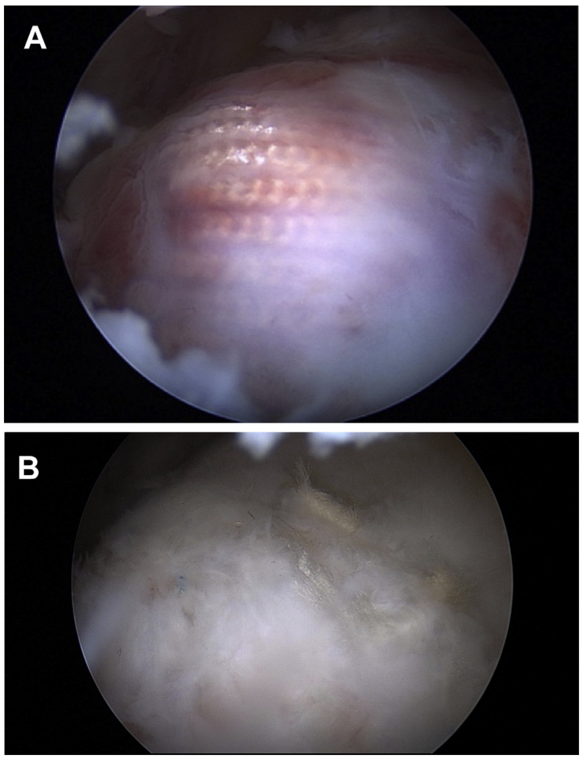

Figure 6 Intraoperative pictures showing the patch during revision surgery 6 months after primary surgery **(A, B)**. Bursalike tissue can be seen growing on and over the patch.

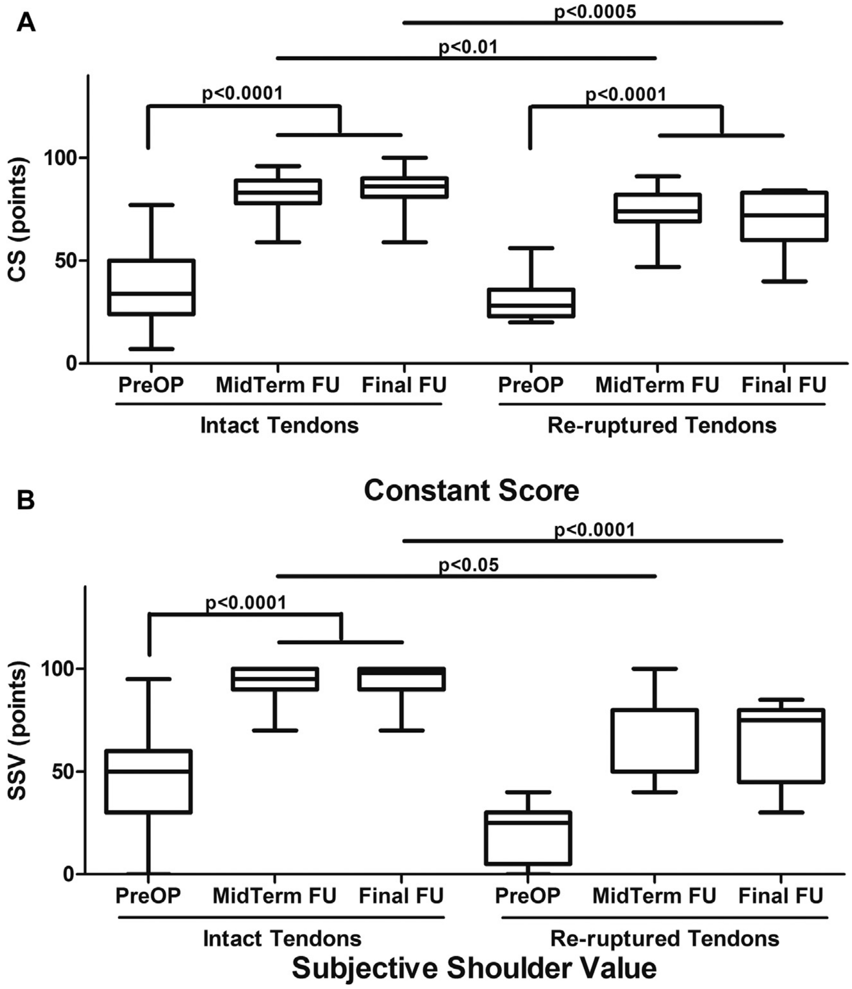

Figure 7 Correlation between intact reconstruction and reruptured tendons, preoperatively and postoperatively, regarding the Constant-Murley score (*CS*; **A**) and the subjective shoulder value (*SSV*; **B**). Both scores show significantly better postoperative values in the post-operative intact tendons in comparison to failed repairs ($P < .05$). Data are shown as box plots. *FU*, follow-up.

far. The integrity of tendons was analyzed using aMRI, aCT, and ultrasound, which revealed superior healing compared with recently published data.[19,47] Use of aMRI is rare in following up synthetic augmentation devices; to date, only a handful of such radiologic studies have been published.[28] Only 1 revision was performed because of a rerupture, whereas most revisions were for frozen shoulders and arthrofibrosis. Moreover, patients with intact tendons, as determined by MRI, had statistically significant greater levels of strength in the CS. Statistical analysis revealed that the greater the retraction grade (according to Patte), the more likely was rerupture to occur ($P < .001$). This was similarly true for tendons with increased fatty degeneration, according to Goutallier. Reruptures were increasingly seen the higher the grade of fatty infiltration, although this was statistically not significant.

All 50 patients benefited from the procedure, showing significant improvement in the CS and SSV ($P < .0001$). Looking more closely, comparing intact tendons with reruptures, patients with intact tendons presented with a significantly better SSV and CS, although interestingly, patients' pain was not significantly different. The inequality of the SSV in respect to preoperative confounding factors could be explained through the fact that 6 of 7 patients with failed constructs (reruptures) had a traumatic or at least in part traumatic event in addition to underlying degenerative changes in their medical history. The abrupt impairment due to trauma might add up to postsurgical dissatisfaction during rehabilitation.

Regarding the use of radiologic follow-up, this study showed that the retear rate of 14% compares favorably with the existing literature in standard nonaugmented RC repairs. Depending on tear type and size as well as study design, reruptures are reported in up to 79%.[14,19] In an MRI analysis of 66 patients with a nonaugmented RC repair, using a suture bridge technique, Kim et al[26] showed a retear rate of 42.4% after a 2-year follow-up. Similar results have been published by Miller et al[32] using ultrasound as their standard radiologic follow-up to evaluate repair integrity. However, these studies, including their radiologic follow-up, report outcomes of nonaugmented RC repairs only.

Table IV Dependence of retraction (Patte) and fatty infiltration (Goutallier) on rerupture

Patte	Rerupture		Goutallier	Rerupture	
	Yes	No		Yes	No
0			0		
Count	0	1	Count	1	8
% within category	0	100	% within category	11.1	88.9
1			1		
Count	0	14	Count	4	24
% within category	0	100	% within category	13.3	86.7
2			2		
Count	1	21	Count	2	11
% within category	4.5	95.5	% within category	50.0	50.0
3*			3		
Count	6	7	Count	0	0
% within category	46.2	53.8	% within category	0	0

The Pearson χ^2 test shows statistically significant correlation concerning Patte grade 3 and reruptures (*$P < .001$), whereas no correlation was found in analyzing the fatty infiltration according to Goutallier.

Acknowledging that, in general, a substantial number of RC tears are degenerative in nature and therefore already show intrinsic changes in the tendons, repair is prone to failure. Reruptures of RC repairs usually occur at the suture-tendon or tendon-bone interface. To reduce retear rates, different attempts have been made to reinforce the repair site. Augmentation most often consists of patches of either biologic or synthetic origin.[28,38] To date, there are only a few studies looking at radiologic follow-up of augmented repairs.[27,46]

Biologic patches have the inherent advantage of being degradable and therefore are thought to be more biocompatible.[28] However, their main disadvantage is that they provide only short-term reinforcement of the construct. The relatively low mechanical properties as well as the undefined degradation rate and the variations in biocompatibility depending on the source of the graft (autogeneic, allogeneic, or xenogeneic) have often led to uneven loading or complete failure of the construct. Whereas failure can be attributed to all of the reasons mentioned before, inflammation can be caused by either an immunologic response to the respective graft or the degradation process itself. Immunologic responses are mostly seen in xenogeneic patches such as the SIS patch (Restore Orthobiologic Implant; DePuy, Warsaw, IN, USA).[21,38,40,46,48]

The 12% rate of adhesive capsulitis and arthrofibrosis might be explained by implanting the patch. However, Desai et al[12] reported a rate of 3%-25% after regular arthroscopic RC repair with no augmentation, putting the data of this study well within this range.

Other autografts (eg, a periosteal flap, the transplanted long head of the biceps, or a free coracoacromial ligament graft) naturally do not cause adverse reactions, and to some extent they are able to positively influence retear rates. The autografts mentioned were used in only a small number of patients to treat large or massive RC tears, mostly as an interposition instead of an augmentation, lacking a control group, making comparisons difficult. However, in these difficult cases in which direct repair is impossible, this might be an alternative to palliative treatment, such as débridement, synovectomy, biceps tenotomy, tuberoplasty if needed, nonanatomic repair or partial repair, and tendon transfers (such as latissimus dorsi, pectoralis major, teres minor, deltoid, and trapezius transfer). Allografts such as freeze-dried RC allografts,[34,35] fascia lata allograft,[22] and human dermal matrix (GraftJacket; Wright Medical Group, Memphis, TN, USA)[2,4,18,43,49] overall showed good clinical and, if assessed, radiologic outcome. In addition, Bond et al[4] could radiologically assess full incorporation of the GraftJacket in >70% of the patients.

Mainly because of the low mechanical properties of biologic patches, synthetic patches have been successfully introduced owing to their ability to permanently reinforce the construct irrespective of tissue ingrowth.[28,38] Besides their superior mechanical strength, they also exhibit better control of chemical and physical properties. According to the literature, synthetic patches are effective in reconstructing large or massive RC tears and in restoring good functionality.[9,13,33,36] Unfortunately, because of the heterogeneity in their application as augmentation or interposition and the scarcity of studies, it is difficult to compare outcomes. Therefore, the evidence supporting this conclusion is existing yet still low.[1,20,42]

This makes our study a valuable, well-documented contribution with a high case load, demonstrating successful application of a third-generation polyester patch, with no complications regarding a host response. However, lack of a control group presents a limitation to our study.

Acknowledging intrinsic strengths and weaknesses of the respective materials—a potential disadvantage of synthetic patches may be the consistent presence of a foreign body, potentially leading to a chronic immune response or foreign body reaction, making them prone to infection[7]—other solutions to treat massive RC tears are constantly being proposed. The primary goal of all RC repairs remains to create a durable construct re-creating the footprint, with its distinct tendon-bone interface, and simultaneously to promote its healing. From a biologic and biomechanical standpoint, it is of paramount importance to enhance the contact area at the insertion site, not only to grant the biggest possible surface for the tendon-bone interface but also to distribute forces and to avoid peak loading and consequent failure of the construct. The authors believe that the Pitch-Patch even enhances this aspect because of the protection of the RC repair, including the biologic and surgical aspect of it, and because of force deflection, allowing the freshly repaired tendon to heal, avoiding peak loading.

Conclusion

We have shown that patch augmentation in massive RC reconstruction leads to a substantially lower retear rate compared with the recent literature. Especially in the context of massive RC tears, in which tendon quality as well as tendon integrity is highly affected, the use of this new patch yields positive results. Randomized controlled studies are needed in the future to further elucidate benefits of the patch.

Disclaimer

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