Prospective Study | Trauma International | 2023 January-June; 9(1): 01-04

Long-term Outcomes Following Synthetic Patch Augmentation to Treat Rotator Cuff Tears

Florian Hess[1], JoEllen Welter[1], Laurenz Jaberg[2]

Abstract

Background: Treatment of massive rotator cuff (RC) tears can result in re-rupture rates up to 94%, and some studies have detected re-ruptures occurring 3.5 years postoperatively. This study aimed to compare long-term clinical outcomes, measured at two time points, after massive RC tears with patch augmentation.

Methods: We performed 58 arthroscopic RC reconstructions augmented with a synthetic polyester patch between 2012 and 2014. 50 patients were available for long-term follow-up one and five years after surgery. We compared clinical outcomes (Constant-Murley score (CS) and subjective shoulder value (SSV)) to assess if the results were sustained over time.

Results: 86% (50/58) of the patients were assessed at the one- and five-year follow-up visits. The median CS one year postoperative reached 84 (interquartile range 76.5-90), and SSV was 95 (IQR 82.5-100). The median CS five years after surgery was 85 (IQR 81.5-91.5) and SSV was 95 (IQR 85-100). The clinical improvement between postoperative years one and five was statistically significant for CS (p=0.0013) and SSV (p<0.0001).

Conclusions: Rotator cuff repair with polyester patch augmentation achieved good clinical outcomes over the long term. Clinical improvement continued over time, with slightly more favorable results measured at the five-year follow-up visits.

Keywords: Massive rotator cuff tears, Augmentation, Patch, Shoulder, Arthroscopy

Introduction

Chronic and traumatic rotator cuff (RC) tears are relatively common [1-4]. Approximately 60% of all tears result from a traumatic event [1]. However, a substantial number of RC tears are degenerative and often asymptomatic. Frequently, degenerative rotator cuff tears can be treated conservatively [5]. On the contrary, tears resulting from trauma or those that are larger could lead to decompensation, pain, impaired shoulder function, and diminished quality of life. While small tears with persistent pain can be reliably repaired with a single or double-row [6], more complex cases involving larger and highly retracted tears are associated with an increased likelihood of failure [7, 8].

One viable alternative to surgery alone is all-arthroscopic rotator cuff repair with either biologic or synthetic tendon augmentation. These implantable devices, which reinforce the RC and function as a scaffold that incorporates the patient's own tissue, have been used to improve ingrowth in such tears. In particular, the non-absorbable synthetic patches have had favorable clinical results with few complications and almost no foreign body reaction to the patch two years after surgery [9, 10]. Nevertheless, complications such as re-ruptures can happen. Furthermore, some researchers have reported late-developing complications. For example, Proctor et al. [10] found that re-ruptures had occurred 3.5 years after the initial surgery.

Previously, we carried out a prospective study to assess the impact of a synthetic patch on RC repair [9]. While the findings were promising regarding clinical outcomes, our conclusions were based on comparisons between preoperative values and a range of mid and long-term follow-up points (mid-term mean of 22 +/-7 and long-term mean of 52 +/-10 months). For this current study, we assessed the same population but focused on comparing their one and five-year postoperative results. Our aim with this extended follow-up period was to detect potential changes in clinical outcomes and late-developing complications not normally tracked during routine care for this type of surgical treatment.

Materials and Methods

This prospective, single-center study was conducted in accordance with the Helsinki declaration and the guidelines of the International Conference for Harmonization. The local ethics committee approved this research investigation (ethics reference number: BASEC 2017-00159-L), and all patients provided written consent to participate in the study.

Of the 962 shoulder operations done at our institution between 2012 and 2014, 383 were arthroscopic RC repairs. From this group, 58 arthroscopic RC reconstructions augmented with a synthetic polyester patch were performed, but eight of the patients were excluded (refused participation or lost-to-follow-up). In a previous publication, we reported the preoperative clinical and radiological parameters and compared these to a range of mid- and long-term results of 50 patients [9]. For this current study, we continued to track

[1]Department of Orthopaedic Surgery and Traumatology, Cantonal Hospital Frauenfeld, Frauenfeld, Switzerland.
[2]Department of Orthopaedic Surgery, Clinica Ars Medica, Gravesano, Switzerland.

Address of Correspondence
Dr. Florian Hess,
Department of Orthopaedic Surgery and Traumatology Cantonal Hospital Frauenfeld Pfaffenholzstrasse 4 8501 Frauenfeld Switzerland.
E-mail: florian.hess@stgag.ch

Submitted: 29/04/2023; Reviewed: 20/05/2023; Accepted: 25/05/2023; Published: 10/06/2023

Trauma International ISSN 2455-538X | Available on www.traumainternational.co.in | ***DOI- https://doi.org/10.13107/ti.2023.v09.i01.031***

this same cohort to compare complete follow-up data measured 12 and 60 months (+/- 30 days) after surgery and assess any changes in clinical outcomes between these two postoperative time points. Included were patients aged 40 years and older, RC tears involving at least two tendons, presentation with a massive RC tear [11, 12], and complete clinical follow-up data one and five years after surgery. If complete reconstruction was not possible, the patient was excluded from the study. We excluded revision operations (re-ruptures of former repairs), patients older than 75, those with fatty infiltration grade 4 according to Goutallier [5], or anyone with osteoarthritis.

Operative technique and postoperative care

As reported in our previous publication [9], all patients were operated on by two experienced senior shoulder surgeons. The patch was always used as augmentation, not as interposition. Patients received general anesthesia and a scalenus nerve block, followed by an overnight pain catheter. They were placed in the beach chair position, and arm traction between three and five kilograms was applied. The RC reconstruction technique, patch placement, and fixation were done similarly for all patients [9]. We used the Pitch-Patch (Xiros, Leeds, UK), a polyester patch constructed to augment the RC tendons, with the chemical formula $(C_{10}H_8O_4)n$. Since the single polyethylene terephthalate fibers can be further processed, interwoven, and formed into the required shape, we adapted the shape to the anatomy and borders, and reinforced the prepared suture holes. This design's pull-out strength (300 N) was evaluated in advance to meet the particular requirements of massive RC tears.

Postoperatively, patients were placed in a shoulder sling in 30° of abduction for six weeks. During this rehabilitation phase, only continuous passive motion was allowed. During weeks 7-12, active range of motion without lifting any weight was permitted. The patients did not undergo physical therapy or physiotherapy during the first 12 weeks after surgery.

Clinical assessment

To evaluate the clinical outcomes, we used the Constant-Murley score (CS), which is used to assess subjective (35%) as well as objective (65%) parameters in the clinical follow-up of shoulder diseases and treatments. We also used the subjective shoulder value (SSV). This score is expressed as a percentage of the functioning of a healthy shoulder (100%). Both these tests are routinely done pre- and postoperatively (3 months). We used the preoperative data documented in the previous study as a reference for this current study, although it was not the primary endpoint. Clinical assessments gathered 12 months (+/-1 month) and 60 months (+/-1 month) after surgery were used to assess the primary endpoint (i.e., change in long-term clinical outcomes over time). This study was limited to clinical assessments; therefore, radiological evaluations with MRI were not performed. In addition, we tracked complications or adverse events associated with the procedure during the entire time under investigation.

Statistical analysis

This study included both descriptive and inferential statistical analyses. The Shapiro-Wilk test was used to determine if the data were normally distributed. Consequently, results were presented as median and interquartile range. The Wilcoxon signed-rank test was used to measure the difference between the clinical results measured at different time points. All analyses were conducted in Stata (version 15, StataCorp, College Station, TX). All tests were two-sided, and the alpha level was set at 0.05.

Table 1. Clinical evaluation of rotator cuff repair by patch augmentation at various time points (n=50)

Time point	Constant-Murley score	p-value	Subjective shoulder value score	p-value
Preoperative	32 (24-47)	**0.0001†**	40 (20-50)	**0.0001†**
Three months postoperative	80.5 (73.5-88.5)		90 (80-99)	
One-year postoperative	84 (76.5-90)	0.0515*	95 (82.5-100)	0.3441*
Five-year postoperative	85 (81.5-91.5)	0.0013**	95 (85-100)	0.0001**

Variables presented as median (interquartile range); Wilcoxon signed rank test used; † preoperative vs. three months postoperative; *comparison with measurement from three months postoperative assessment, **comparison with measurement from 12-month assessment

Results

Of the 58 patients who underwent rotator cuff reconstruction augmented with a polyester patch between 2012-2014, 50 (86%) had one-year and five-year follow-up visits and were included in this analysis. The median age at the five-year follow-up assessment was 72 years (IQR 67-75, range 46-80), and 68% (34) of the patients were male. The RC tear resulted from a traumatic event in 35 cases (70%). Table 1 presents the Constant-Murley scores and subjective shoulder value assessments measured at four different time points (preoperative, three months postoperative, and one- and five-year follow-up visits). Significant improvements were observed between the preoperative and the first postoperative measurements. Likewise, improvements continued over the long term, with more favorable results measured at one-year and five-year follow-up visits. The differences between the three-month postoperative and the one-year measurements were not statistically significant for either the CS or SSV. However, significant improvements in both scores were observed between the 12 and 60-month postoperative, which covered a more extended period.

Complications reported in the previous study included seven patients with a re-rupture detected at mid-term radiologic follow-up (mean eight months). Only one of the re-rupture cases needed revision surgery, and the others were treated conservatively. An additional seven patients had revision surgery to treat the following: frozen shoulder (3), arthrofibrosis (3), and crepitus (1). We did not detect any new or worsening of previously reported complications during the extended follow-up. All but two of the seven re-ruptures occurred within the first six postoperative months, and the remaining two occurred within nine months after surgery.

Discussion

This study expanded the follow-up period of a previously conducted investigation of patients with massive rotator cuff tears who underwent surgical treatment augmented with a synthetic polyester patch. We found similar shoulder function and scores at the one- and five-year postoperative assessments. More favorable results were observed at the longest follow-up visit, which indicates healing was achieved and sustained in most patients. In addition, there were no clinically relevant re-ruptures of the rotator cuff during the long-term- follow-up and no

worsening of previously reported complications.

Although both of our studies found that most patients had good outcomes and relatively few complications, the benefits of using patch augmentation are still not firmly established. There is a lack of evidence in the literature to demonstrate that this method leads to superior results. Furthermore, comparisons among the existing reports are limited by the heterogeneity of outcome scores being used. Nevertheless, trends in the current literature indicate support for its use [13-16]. Bailey et al. recently published a meta-analysis that reported better outcomes using patch augmentation and interpositional grafts [13]. When comparing RC reconstruction alone, some authors found significantly better ASES [17-19] and Constant-Murley Score [17, 20-24] after augmentation, but no change in the UCLA Score (The University of California and Los Angeles Score) [17, 19, 25]. Among the various types of grafts, the autograft showed the best ASES and UCLA scores. The lowest pain levels measured using Visual Analog Scale (VAS) were found with the allograft [13]. Synthetic grafts resulted in better Constant-Murley scores and favored anteflexion [13]. The xenograft had the worst outcomes based on the UCLA and Constant-Murley scores [15].

When considering the composition of the patches, the biological ones have the advantage of being degradable and more biocompatible [26]. Their main disadvantage is that they provide only short-term reinforcement. The relatively low mechanical properties, the unknown resorption rate, and the different biocompatibility depending on the graft material (autograft, allograft, or xenograft) often lead to uneven force distribution and, eventually, failure. Failure can also result from the foreign body reaction caused by the graft or its degeneration process. An inflammatory response is most often observed with xenogeneic patches, such as the SIS patch (Restore Orthobiologic Implant; DePuy, Warsaw, IN, USA) [27-31]. In the more recent literature, porcine patches did not show any benefit, which is why their use in augmentation is no longer recommended [29]. Since biological patches have poor mechanical properties, synthetic patches have been chosen to reinforce the construct permanently [26, 28]. In addition to better mechanical properties, such patches also have better chemical and physical properties. However, a synthetic patch can potentially cause the same type of complications as a foreign body, leading to a chronic immune response or infection [28].

Our previously published findings [9], which included radiological (MRI, CT, and ultrasound) assessments after synthetic patch augmentation, showed improved healing when compared to other recently published studies [32, 33]. Specifically, only one of the seven re-rupture cases needed revision surgery, and many of the remaining revisions were due to shoulder stiffness (total revision rate 16%). Moreover, the study showed that a rupture was more likely to occur in advanced retraction (according to Patte) ($p< 0.001$) or in tendons whose muscle was affected by higher-grade fatty infiltration (according to Goutallier). Primary intact rotator cuffs had significantly better outcomes (SSV and Constant Murley Score); however, there was no statistically significant difference in pain level. The 14% re-rupture rate is comparable to some reports of non-augmented rotator cuff reconstructions, but this should be interpreted cautiously. Depending on the type and size of the tear, rates as high as 70% have been reported [26]. Kim et al. [27] used MRI to confirm a re-rupture rate of 42.4% measured over two years (n= 66) after RC reconstruction without augmentation. Similar results were published by Miller et al. [34], in which ultrasound verified the rotator cuff's integrity.

Conclusion

The primary aim of this current study was to track the clinical outcomes over the long term. Since other researchers have found late developing re-ruptures (up to 3.5 years postoperative), we extended the clinical follow-up beyond the previously conducted study to ensure we had complete data for the time points of interest. While we observed that, in general, the favorable outcomes were sustained over time, our study had some weaknesses. A longer follow-up could have been more informative with a radiographic assessment of potential retears. Moreover, the eight additional months may not have been long enough to detect long-term complications.

Given that factors such as patch type or surgical approach used may increase the likelihood of a re-rupture, further investigation is warranted. Prospective studies with a larger cohort are needed to compare augmented versus non-augmented surgeries and identifying the benefits of the different patch types over a prolonged follow-up period.

Clinical Relevance

Chronic and traumatic rotator cuff tears are relatively common. Various options are available to augment the tendon when surgical treatment is indicated. In this study, rotator cuff repair with polyester patch augmentation achieved good clinical outcomes over the long term. Clinical improvement continued over time, with slightly more favorable results measured at the five-year follow-up visits.

Abbreviations: CS- Constant-Murley score, CT- Computerized tomography, IQR- Interquartile range, MRI- Magnetic resonance imaging, RC- Rotator cuff, SSV- Subjective shoulder value, VAS- Visual Analog Scale, UCLA- University of California, Los Angeles, ASES- American Shoulder and Elbow Score.

Declaration of patient consent : The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient has given his/her consent for his/her images and other clinical information to be reported in the Journal. The patient understands that his/her name and initials will not be published, and due efforts will be made to conceal his/her identity, but anonymity cannot be guaranteed.

Conflict of Interest: None, **Source of Support:** None

References

1. Tan M, Lam PH, Le BT, Murrell GA (2016) Trauma versus no trauma: an analysis of the effect of tear mechanism on tendon healing in 1300 consecutive patients after arthroscopic rotator cuff repair. J Shoulder Elbow Surg 25 (1):12-21.
2. Colvin AC, Egorova N, Harrison AK, Moskowitz A, Flatow EL (2012) National trends in rotator cuff repair. J Bone Joint Surg [Am] 94 (3):227-233.
3. Jain NB, Higgins LD, Losina E, Collins J, Blazar PE, Katz JN (2014) Epidemiology of musculoskeletal upper extremity ambulatory surgery in the United States. BMC Musculoskelet Disord 15:4.
4. Paloneva J, Lepola V, Aarimaa V, Joukainen A, Ylinen J, Mattila VM (2015) Increasing incidence of rotator cuff repairs--A nationwide registry study in Finland. BMC Musculoskelet Disord 16:189.
5. Goutallier D, Postel JM, Bernageau J, Lavau L, Voisin MC (1994) Fatty muscle degeneration in cuff ruptures. Pre- and postoperative evaluation by CT scan. Clin Orthop Relat Res (304):78-83.
6. Davey MS, Hurley ET, Carroll PJ, Galbraith JG, Shannon F, Kaar K, Mullett H (2023) Arthroscopic Rotator Cuff Repair Results in Improved Clinical Outcomes and Low Revision Rates at 10-Year Follow-Up: A Systematic Review. Arthrosc - J Arthrosc Relat Surg 39 (2):452-458.
7. Meyer DC, Wieser K, Farshad M, Gerber C (2012) Retraction of supraspinatus muscle and tendon as predictors of success of rotator cuff repair. Am J Sports Med. 40 (10):2242-2247.
8. Shah NS, Suriel Peguero E, Umeda Y, Crawford ZT, Grawe BM (2022) Long-Term Outcomes of Massive Rotator Cuff Tear Repair: A Systematic Review. HSS J 18 (1):130-137.
9. Smolen D, Haffner N, Mittermayr R, Hess F, Sternberg C, Leuzinger J (2020) Application of a new polyester patch in arthroscopic massive rotator cuff repair-a prospective cohort study. J Shoulder Elbow Surg 29 (1):e11-e21.
10. Proctor CS (2014) Long-term successful arthroscopic repair of large and massive rotator cuff tears with a functional and degradable reinforcement device. J Shoulder Elbow Surg 23 (10):1508-1513.
11. Gerber C, Fuchs B, Hodler J (2000) The results of repair of massive tears of the rotator cuff. J Bone Joint Surg [Am] 82 (4):505-515.
12. Davidson J, Burkhart SS (2010) The geometric classification of rotator cuff tears: a system linking tear pattern to treatment and prognosis. Arthrosc - J Arthrosc Relat Surg 26 (3):417-424.
13. Bailey JR, Kim C, Alentorn-Geli E, Kirkendall DT, Ledbetter L, Taylor DC, Toth AP, Garrigues GE (2019) Rotator Cuff Matrix Augmentation and Interposition: A Systematic Review and Meta-analysis. Am J Sports Med 47 (6):1496-1506.
14. Ferguson DP, Lewington MR, Smith TD, Wong IH (2016) Graft Utilization in the Augmentation of Large-to-Massive Rotator Cuff Repairs: A Systematic Review. Am J Sports Med 44 (11):2984-2992.
15. Steinhaus ME, Makhni EC, Cole BJ, Romeo AA, Verma NN (2016) Outcomes After Patch Use in Rotator Cuff Repair. Arthroscopy 32 (8):1676-1690.
16. Smolen D, Haffner N, Mittermayr R, Hess F, Sternberg C, Leuzinger J (2019) Application of a new polyester patch in arthroscopic massive rotator cuff repair-a prospective cohort study. J Shoulder Elbow Surg. 2020 Jan;29(1):e11-e21.
17. Barber FA, Burns JP, Deutsch A, Labbe MR, Litchfield RB (2012) A prospective, randomized evaluation of acellular human dermal matrix augmentation for arthroscopic rotator cuff repair. Arthrosc - J Arthrosc Relat Surg 28 (1):8-15.
18. Gilot GJ, Alvarez-Pinzon AM, Barcksdale L, Westerdahl D, Krill M, Peck E (2015) Outcome of Large to Massive Rotator Cuff Tears Repaired With and Without Extracellular Matrix Augmentation: A Prospective Comparative Study. Arthroscopy 31 (8):1459-1465.
19. Mori D, Funakoshi N, Yamashita F (2013) Arthroscopic surgery of irreparable large or massive rotator cuff tears with low-grade fatty degeneration of the infraspinatus: patch autograft procedure versus partial repair procedure. Arthroscopy 29 (12):1911-1921.
20. Audenaert E, Van Nuffel J, Schepens A, Verhelst M, Verdonk R (2006) Reconstruction of massive rotator cuff lesions with a synthetic interposition graft: a prospective study of 41 patients. Knee Surg Sports Traumatol Arthrosc 14 (4):360-364.
21. Badhe SP, Lawrence TM, Smith FD, Lunn PG (2008) An assessment of porcine dermal xenograft as an augmentation graft in the treatment of extensive rotator cuff tears. J Shoulder Elbow Surg 17 (1 Suppl):35S-39S.
22. Giannotti S, Ghilardi M, Dell'osso G, Magistrelli L, Bugelli G, Di Rollo F, Ricci G, Calabrese R, Siciliano G, Guido G (2014) Study of the porcine dermal collagen repair patch in morpho-functional recovery of the rotator cuff after minimum follow-up of 2.5 years. Surg Technol Int 24:348-352.
23. Nada AN, Debnath UK, Robinson DA, Jordan C (2010) Treatment of massive rotator-cuff tears with a polyester ligament (Dacron) augmentation: clinical outcome. J Bone Joint Surg Br 92 (10):1397-1402.
24. Rotini R, Marinelli A, Guerra E, Bettelli G, Castagna A, Fini M, Bondioli E, Busacca M (2011) Human dermal matrix scaffold augmentation for large and massive rotator cuff repairs: preliminary clinical and MRI results at 1-year follow-up. Musculoskelet Surg 95 Suppl 1:S13-23.
25. Ciampi P, Scotti C, Nonis A, Vitali M, Di Serio C, Peretti GM, Fraschini G (2014) 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 42 (5):1169-1175.
26. Longo UG, Lamberti A, Maffulli N, Denaro V (2010) Tendon augmentation grafts: a systematic review. Br Med Bull 94:165-188.
27. Iannotti JP, Codsi MJ, Kwon YW, Derwin K, Ciccone J, Brems JJ (2006) Porcine small intestine submucosa augmentation of surgical repair of chronic two-tendon rotator cuff tears. A randomized, controlled trial. J Bone Joint Surg [Am] 88 (6):1238-1244.
28. Papalia R, Franceschi F, Zampogna B, D'Adamio S, Maffulli N, Denaro V (2013) Augmentation techniques for rotator cuff repair. Br Med Bull 105:107-138.
29. Phipatanakul WP, Petersen SA (2009) Porcine small intestine submucosa xenograft augmentation in repair of massive rotator cuff tears. Am J Orthop 38 (11):572-575.
30. Sclamberg SG, Tibone JE, Itamura JM, Kasraeian S (2004) Six-month magnetic resonance imaging follow-up of large and massive rotator cuff repairs reinforced with porcine small intestinal submucosa. J Shoulder Elbow Surg 13 (5):538-541.
31. Walton JR, Bowman NK, Khatib Y, Linklater J, Murrell GA (2007) Restore orthobiologic implant: not recommended for augmentation of rotator cuff repairs. J Bone Joint Surg [Am] 89 (4):786-791.
32. Henry P, Wasserstein D, Park S, Dwyer T, Chahal J, Slobogean G, Schemitsch E (2015) Arthroscopic Repair for Chronic Massive Rotator Cuff Tears: A Systematic Review. Arthroscopy 31 (12):2472-2480.
33. Shimokobe H, Gotoh M, Honda H, Nakamura H, Mitsui Y, Kakuma T, Okawa T, Shiba N (2017) Risk factors for retear of large/massive rotator cuff tears after arthroscopic surgery: an analysis of tearing patterns. J Orthop Surg Res 12 (1):140.
34. Miller BS, Downie BK, Kohen RB, Kijek T, Lesniak B, Jacobson JA, Hughes RE, Carpenter JE (2011) When do rotator cuff repairs fail? Serial ultrasound examination after arthroscopic repair of large and massive rotator cuff tears. Am J Sports Med 39 (10):2064-2070.

How to Cite this Article

Hess F, Welter J, Jaberg L | Long-term Outcomes Following Synthetic Patch Augmentation to Treat Rotator Cuff Tears | January-June 2023; 9(1): 01-04 | https://doi.org/10.13107/ti.2023.v09.i01.031