

Pitch-Patch Clinical Summary

Compilation of publications for Rotator Cuff tears using the Pitch-Patch

Introduction

Data from recent publications suggest that the **Pitch-Patch** for augmentation of massive RC tears feasibly reduces the retear rate and significantly improves functional, structural, and clinical outcomes over the long term.

Publications

Smolen et al, 2020

- Data were collected prospectively on 50 patients with massive RC tears involving at least 2 tendons who underwent arthroscopic RC reconstruction using the **Pitch-Patch**.
- Mean clinical midterm and final follow-up was 22 months and 52 months respectively.
- Clinical outcomes at midterm and final follow-up including all subcategories of the CS and the SSV improved significantly from preoperative values.
- Radiologic midterm follow-up showed an intact reconstruction with complete footprint coverage in 86% of all tendons (43 patients).
- Only 14% (50 patients) experienced a rerupture, and only one of these cases involved patch detachment.
- Histologic analysis of one intact patch explanted due to symptomatic crepitus revealed no signs of foreign body rejection. Additionally, it was observed that the patch was covered in a fibrous, almost bursal-like mantle of tissue.
- Six patients (12%) with intact reconstructions were revised for frozen shoulders or arthrofibrosis, however after revision surgery, all of them showed comparable good clinical results with the patch in-situ. This rate is well within the range of up to 25% for this complication following arthroscopic rotator cuff repair.

Table 1. Results summary for Smolen et al (2020)

		Preoperative (mean, SD)	Midterm follow-up (mean, SD)	Final follow-up (mean, SD)
SSV		40.3 (24.3)	89.2 (12.9)	89.6 (15.2)
CS Subjective	Pain	5.5 (3.1)	13.6 (2.0)	14.2 (1.7)
	ADLs	10.3 (3.6)	19.4 (1.0)	19.4 (1.4)
CS Objective	Flexion	6.2 (2.8)	9.9 (0.4)	9.8 (1.0)
	Abduction	5.2 (2.9)	9.6 (1.2)	9.6 (1.3)
	External rotation	3.6 (3.8)	9.8 (1.0)	9.8 (1.2)
	Internal rotation	3.8 (2.2)	7.1 (1.7)	8.0 (1.8)
	Strength	1.9 (3.1)	11.9 (6.0)	12.6 (6.4)

Hess et al. 2023

- This prospective study continues tracking the same cohort of 50 patients published by Smolen (2020) to compare complete follow-up data measured at 3, 12, and 60 months after surgery.
- Clinical outcomes (CS and SSV) showed significant improvement from baseline at the 3-month follow-up, as well as between the 3-month and 60-month follow-ups, demonstrating continued clinical improvement over the long term.
- More favourable results were observed at the longest follow-up visit, which indicates healing was achieved and sustained in most patients.

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 No new or worsening of previous reported complications were detected during this extended follow up period.



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Table 2. Results summary for Hess et al (2023)

	Preoperative (mean, IR)	3 months follow-up (mean, IR)	1 year follow-up (mean, IR)	5 years follow-up (mean, IR)
SSV	32 (24-47)	80.5 (73.5-88.5)	84 (76.5-90)	85 (81.5-91.5)
CS	40 (20-50)	90 (80-99)	95 (82.5-100)	95 (85-100)

Dommer et al, 2023

- Data were collected retrospectively on 15 patients who underwent open or arthroscopic patch augmented RC repair using the **Pitch-Patch**.
- Good muscle quality (Goutallier grade ≤ II), high retraction (Patte grade ≥ 2) and short tendon length (< 15 mm) were required to include patients in the study.
- Mean follow-up was 43.8 months.
- Functionally the outcomes improved significantly.
- Overall satisfaction with surgery was 87%, with the same number stating they would have the surgery again.
- The structural failure rate or re-tear rate, described as Sugaya grade 4 and 5, was 53%, showing a favourable comparison to the previously reported rate of 92% for this population with short tendon length.
- Structural failures did not affect the functional outcome in terms of ROM or pain but only lead to a reduced abduction force. Preserved functionality may be attributed to the significantly reduced retear size compared to initial tear size with much worse functionality as well as a preserved muscle quality.
- Only 2 patients had any complaints about pain at the last follow-up with visual analog scale score of 2 and 1 of 10, respectively.
- Using the **Pitch-Patch** as a scaffold to strengthen the fixation gives the reconstruction more stability for an increased chance of healing and thus lowers the structural failure rate compared to nonaugmented repairs in presence of a good muscle quality and short tendon length.

Table 3. Results summary for Dommer et al (2023)

	Preoperative (mean, SD)	Follow-up (mean, SD)	P value
Constant-Murley score (relative)	36.1 (14.2)	84.3 (7.3)	< .01
Pain (visual analog score)	5.3 (3.3)	0.2 (0.6)	< .01
Subjective Shoulder Value	34.7 (20.2)	89.5 (12.1)	< .01
ROM (degrees) – Forward elevation	111.0 (40.2)	167.5 (6.2)	< .01
ROM (degrees) – Abduction	85.7 (28.8)	153.3 (22.7)	< .01
ROM (degrees) – External rotation	33.3 (21.9)	41.3 (20.9)	< .090
Abduction force (kg)	0.7 (0.4)	6.5 (2.9)	< .01
Tear size (mm)	33.3 (5.7)	17.3 (10.6)	< .01

Conclusions from the recent studies

- Patch augmented cuff repair using the Pitch-Patch leads to a significant improvement of functional and structural outcomes.
- Rotator cuff repair using the **Pitch-Patch** achieved good clinical outcomes over the long term.
- Data suggested that the retear rate of 14% compared favourably with nonaugmented RC repairs in the literature.
- The retear rate of 53% in patients with short tendon length is favourable compared to the previously reported rate of 92%. Functional outcome in terms of ROM or pain was not affected. Preserved functionality, may be attributed to the significantly reduced retear size compared to the initial tear with much worse functionality as well as preserved muscle quality, making the attempt of an anatomic reconstruction with the Pitch-Patch worthwhile.

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Abbreviations

ADL: Activities of Daily Living
CS: Constant-Murley score
IR: Interquartile Range

RC: Rotator cuff
ROM: Range of Motion
SD: Standard Deviation

SSV: Subjective Shoulder Value

Study Citations

Smolen, D., et al. (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.

Hess, F., et al. (2023). "Long-Term Outcomes Following Synthetic Patch Augmentation to Treat Rotator Cuff Tears." Trauma International 9(1).

Dommer, L. M., et al. (2023). "Massive rotator cuff tears with short tendon length can be successfully repaired using synthetic patch augmentation." J Shoulder Elbow Surg 32(10): 2089-2096.

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