



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

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Key Points



Reduces
re-tear rate



Significant
improvement
in CS and SSV



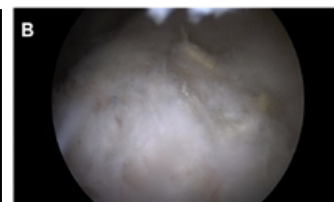
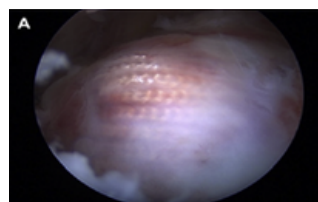
No observed
risk of rejection

Methods

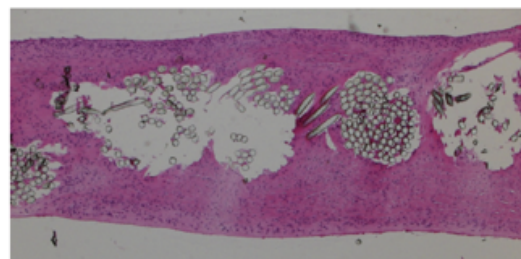
In this prospective study, 50 shoulders underwent augmented arthroscopic rotator cuff (RC) reconstruction using a synthetic polyester patch (**Pitch-Patch**). Clinical outcomes were evaluated pre- and postoperatively using the Constant-Murley Score (CS) and the Subjective Shoulder Value (SSV) at midterm (mean follow-up of 22 months, range 9-35) and final follow-up (mean follow-up of 52 months, range 25-74) assessments, respectively. Imaging modalities included arthrographic magnetic resonance imaging, arthrographic computed tomography, and ultrasound examination to assess tendon integrity and re-rupture.

Results

- At midterm radiologic follow-up (mean, 8 months; range, 1-35 months) after massive rotator cuff repair using Pitch-Patch, **86% of all tendons showed intact reconstruction** with complete footprint coverage, while only 14% exhibited re-rupture.
- Significant improvement in the Constant-Murley score (CS) and Subjective Shoulder Value (SSV)** from baseline was observed at midterm and final follow-up. All subcategories of the CS (pain, activities of daily living, range of motion and strength) revealed significant improvement at both timepoints.
- The significant changes in SSV also reflected **high patient satisfaction**.
- No adverse tissue reactions** i.e., allergic and inflammatory reactions, or tissue irritation observed through Post Market Surveillance activities or reports in clinical sources.²
- Six out of seven patients who experienced retears exhibited significant clinical improvement, leading them to decline any additional surgical interventions.¹



Intraoperative pictures showing the patch during revision surgery 6 months after primary surgery. Bursalike tissue can be seen growing on and over the patch.



Standard hematoxylin and eosin histology. Complete integration of the synthetic polyester patch is evident. No signs of foreign body reaction or tissue rejection are noticeable.

Conclusions

Comparatively the study concluded that augmenting with Pitch-Patch in extensive rotator cuff (RC) reconstruction significantly reduces the likelihood of retears that could vary between 20% and 57% for large and massive tears.² Furthermore, primary rotator cuff repair may yield re-tear rates of up to 94% as reported in the literature.²

Biocompatibility of the device is supported by pre-clinical data.² Allograft or xenograft rejection and the possibility of disease transmission are known risks associated with these types of grafts in any surgery. This risk has not been observed with Pitch-Patch to date. This is particularly noteworthy in cases of extensive RC tears, where both tendon quality and integrity are significantly compromised, demonstrating the efficacy of employing Pitch-Patch for improved outcomes.

1. 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.

2. Xiros data on file, Clinical Evaluation Report, Pitch-Patch.