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Leeds-Kuff Patch™ Clinical Summary

Compilation of publications for Rotator Cuff Repair using Leeds-Kuff Patch™

Introduction

Data from multiple publications suggest that Leeds-Kuff Patch can be used for large to massive tears to improve patient reported outcome scores.

Publications

Judhi et al (2018)

- A cohort study of consecutive patients with a massive cuff tear (>5 cm) undergoing open rotator cuff repair with Leeds-Kuff Patch augmentation.
- 17 patients.
- Average period between referral and surgery was 15 months (range 12-18 months).
- Rehabilitation included protection phase for 8 weeks followed by a strengthening phase.
- Patients were assessed for Visual Analogue Score (VAS) and Oxford Shoulder Score (OSS) pre-operatively and at least 12 months post-operatively (Table 1).
- Two complications were reported: One obvious re-tear at 4 months clinically, one evacuation of a haematoma at 10 days post op.
- Two patients were lost to follow up.

Table 1. Mean outcome scores from Judhi et al., 2018.

Functional Scores	Pre-operative mean	Post-operative mean
VAS	8	2
OSS	22	43

Cowling et al (2017) SPARC (Shoulder Patch for Rotator Cuff Tears) Study

Prospective study of patients with large and massive rotator cuff tears.

- Treatment decision was based on patient choice and intraoperative findings:
    - o Leeds-Kuff Patch group: Arthroscopically irreparable tears but mobile cuff, underwent open repair using Leeds-Kuff Patch (n=29).
- Median duration of symptoms in the Leeds-Kuff Patch group was 11.5 months.
- Rehabilitation consisted of 3 weeks in a sling with passive Range of Motion (ROM) and pendular exercises, active movements beginning at 3 weeks followed by strengthening at 8 weeks.
- Patients completed OSS, Shoulder Pain and Disability Index (SPADI), and Constant Score pre-operatively, and 6 months post-operatively (Table 2).
- The Leeds-Kuff Patch group demonstrated improvement in all outcomes from baseline to 6 months.
- The follow up period for this study is being extended to 2 years.

Table 2. SPARC study 6 month outcome scores for Leeds-Kuff Patch group.

Outcome Measure	Leeds-Kuff Patch group	
	Pre-operative mean (SD)	**6 month post-operative mean (SD)**
OSS (n=27)	27.6 (8.8)	39.9 (8.5)
SPADI (n=27)	49.9 (22.4)	21.6 (19.3)
Constant Score (n=28)	40.3 (16.4)	55.1 (13.7)

*Cowling et al (2017) SPARC study included a non-patch group where patients were treated with alternative therapy (arthroscopic repair, debridement, deltoid physiotherapy rehabilitation). This document is concerned with pre-operative and post-operative results with Leeds-Kuff Patch only.

Hackney (2019)

- This is a single surgeon series using a synthetic patch to bridge defects and augment repair of rotator cuff tendons which are not fully repairable, even using an open approach.
- 23 consecutive patients were followed.
- Every patient with a large to massive tear who had failed conservative treatment underwent an arthroscopy with mobilisation of the tendons and if achievable, an open repair augmented with a patch.
- Scores were taken pre-operatively and 6 months post-operatively.
- There were no recurrences of tear in this series. One required capsular release for stiffness.

Table 3. Mean Oxford Shoulder Scores from Hackney (2019).

Outcome Measure	Pre-operative mean	6 month post-operative mean
OSS	19	46

Study Citations

Juhdi, A, Abdulkarim, A and Harrington, P (2018). Synthetic augmentation for massive rotator cuff tears, presented at EORS, Galway, September.

Cowling, P, et al. (2017). The use of a synthetic shoulder patch for large and massive rotator cuff tears - a feasibility study. EFORT (European Federation of Orthopaedics and Traumatology) Congress.

Hackney, R,. Patches for Massive Tears of the Rotator Cuff. “British European Shoulder Associates, ESSKA 2019”.

Hackney, R, Lesniewski, P, and Cowling, P (2017). Options Before Reverse Total Shoulder Replacement, “Chapter 6” Advances in Shoulder Surgery.

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