Biological augmentation in revision surgery: a matched-pair study of the effect of a a bioinductive collagen patch in patients with rotator cuff retear and a previous arthroscopic rotator cuff repair.

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Introduction: Biologic augmentation with a bioinductive collagen patch has been proposed as an alternative to improve the healing rate of rotator cuff tears. Several studies have reported promising results when treating partial and full thickness RCT and even massive tears ears[1, 2]. However, the effect of the patch on the repair of rotator cuff retears remains unclear. The aim of the study was to analyze the effect of the collagen patch on tendon integrity in patients with rotator cuff retear and a previous arthroscopic rotator cuff repair and to evaluate the effects of the bioinductive implant on functional outcomes and pain levels during the first 12-months postoperative.

Methods: Observational, prospective, randomized multicenter study of patients diagnosed with a rotator cuff retear after a previous arthroscopic rotator cuff repair, scheduled for a new arthroscopic rotator cuff repair. Patients were allocated to two groups: A, repair with an additional bioinductive collagen implant (REGENETEN, Smith&Nephew, Andover, MA) and B, repair without the bioinductive patch. The primary outcome measure was integrity of the repaired tendon evaluated at 12-months follow-up in an MRI study using Sugaya et al. classification. Repairs graded as IV and V according to Sugaya classification were defined as retear. Secondary outcome measures included pain levels measured with VAS score, functional outcomes, evaluated with the Constant Murley and ASES scores, and single Assessment Numeric Evaluation score (SANE).

Results: Forty-eight patients, 24 in each group, 56.2% male, mean age at surgery 58.2+7.8 years, with a mean follow-up of 14.9+5.15 months were included. No intraoperative or immediate postoperative complications occurred. MR imaging revealed a significantly lower retar rate in the REGENETEN group noted at 29.2% (7/24) compared with the control group noted at 54.2% (13/24) (p=0.04). Range of movement did not significantly differ from preoperative to postoperative and between groups. VAS score significantly decreased from preoperative, noted at 7.5 (range 2.5-10), to postoperative, noted at 4.8 (range 0-9) (p=0.001). Regarding functional outcomes, Constant and ASES scores significantly improved in the REGENETEN and control group, from 41.5/34.3 and 15/15, respectively, to 60/67.5 and 50/48.3 at 12 months follow-up (p=0.001), reaching 62.5%/75% of patients the minimal clinically important differences. No statistical differences were found in postoperative outcomes inclduing VAS, Constant, ASES and SANE score between the two groups (p=0.705, p=0.302, p=.462, p=0.52).

Conclusion: Biologic augmentation with a bioinductive collagen patch in revision rotator cuff tear repair reduces the rate at 12-month follow-up by 25%, yielding similar improvements in clinical outcomes and without any increased risk of complication.

Keywords: rotator cuff tear, revision surgery, collagen patch

References

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