Evidence in focus
Publication summary

Smith+Nephew

A randomised controlled trial (RCT) of medium and large full-thickness rotator cuff repairs augmented with the REGENETEN◊ Bioinductive Implant demonstrated significantly lower re-tear rates, compared with repair alone, at 2-year follow-up

Ruiz Ibán MA, Navlet MG, Moros SL, et al. Augmentation with a bovine bioinductive collagen implant of a posterosuperior cuff repair shows lower retear rates but similar outcomes compared to no augmentation: 2-year results of a randomized controlled trial. *Arthroscopy*. Published online April 11, 2025.

Available at: Arthroscopy

Key points

Significantly lower re-tear rate in repairs augmented with the REGENETEN Implant (p=0.004)

65% **Lower risk of re-tear** with the REGENETEN Implant

Patients with healed tendons had significantly better clinical outcomes, compared to those with re-tears (p≤0.015)

Overview

- Blinded, multi-centre, RCT assessing the clinical and radiological outcomes of rotator cuff tears repaired with and without augmentation of the REGENETEN Implant
- 124 patients with medium and large (1–4cm) full-thickness posterosuperior rotator cuff tears were randomised (1:1) after suture anchor repair to receive either:
  - Arthroscopic transosseous equivalent (TOE) double-row rotator cuff repair (control group; n=57)
  - Arthroscopic TOE double-row rotator cuff repair augmented with the REGENETEN Implant (REGENETEN Implant group; n=57)
- At 2-year follow-up, data were available for 114 patients
- There were no differences in pre-operative patient characteristics between groups
- Primary outcome was tendon integrity assessed on MRI using the Sugaya classification (grades ≤3 healed; ≥4 re-tears)
- Secondary outcomes were MRI characteristics, re-tear rate and patient-reported outcome measures (PROMs) including American Shoulder and Elbow Society (ASES) score and Constant-Murley score (CMS)
  - Post-hoc analysis of patients with healed tendons versus re-tears

Results

At 2-year follow-up, compared with repair alone, repair augmented with the REGENETEN Implant demonstrated:

- Significantly better tendon integrity (87.72% vs 64.91%; p=0.020)
- Significantly lower re-tear rate (12.3% vs 35.1%; p=0.004; Figure)
- A 65% lower relative risk (RR) of re-tear (RR=0.35; 95% confidence interval [CI]: 0.161–0.762; Figure)
  - The number of patients needed to treat with the REGENETEN Implant to avoid a re-tear was 4.4 (95% CI: 2.6–12.9)
- No difference in PROMs between the REGENETEN Implant and control group
  - Post-hoc analysis found patients with healed tendons (n=87) presented significantly better clinical outcomes, compared to those with re-tears (n=25)
  - Significantly higher ASES score (84.4 vs 71.7; p=0.015)
  - Significantly higher CMS score (80.2 vs 66.2; p=0.007)
- No additional complications or reinterventions

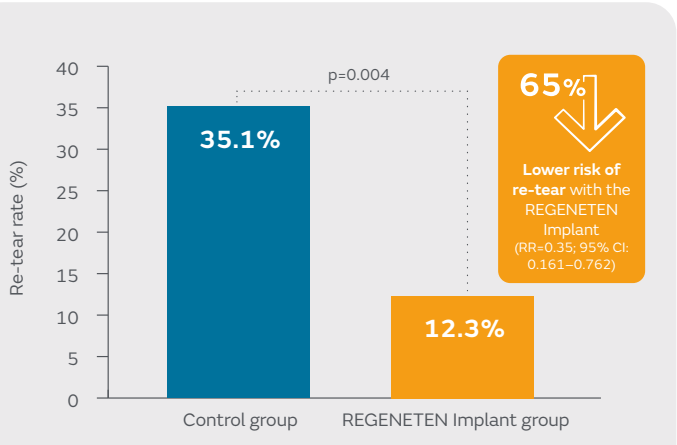

Figure. Re-tear rate (%) and risk of re-tear at 2-years post-operatively

Conclusions

In a randomised controlled trial, the repair of full-thickness rotator cuff tears augmented with the REGENETEN Bioinductive Implant demonstrated significantly lower re-tear rates and significantly lower risk of re-tear compared with repair alone at 2-year follow-up.Patients with healed tendons presented significantly better clinical outcomes compared to those with re-tears.

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