+ Evidence in focus
Publication summary

Smith+Nephew

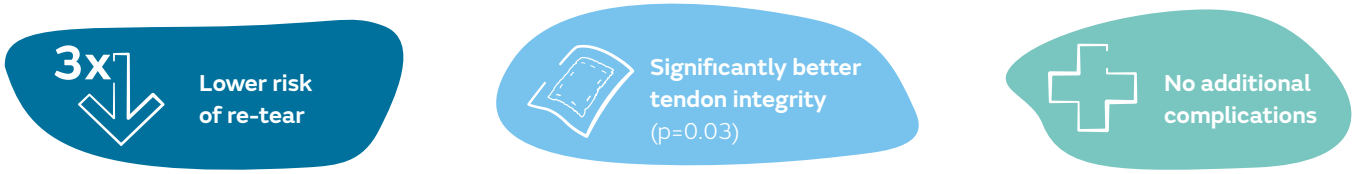
A randomised controlled trial (RCT) of medium and large full-thickness rotator cuff repairs augmented with the REGENETEN◊ Bioinductive Implant demonstrated significantly lower re-tear rates, compared with repair alone

Ruiz Ibán MA, Navlet MG, Marco SM, et al. Augmentation of a transosseous equivalent repair in posterosuperior non-acute rotator cuff tears with a bioinductive collagen implant decreases the re-tear rate at one year. A randomised controlled trial. *Arthroscopy.* Published online December 27, 2023.

To read the full publication go to: https://doi.org/10.1016/j.arthro.2023.12.014

Key points

Compared with repair alone, repair augmented with the REGENETEN Implant at 12-months follow-up demonstrated:



Overview

- Blinded, multi-centre, RCT comparing the healing rate of full-thickness rotator cuff tears repaired with and without the augmentation of the REGENETEN Implant
- 124* patients with reparable† 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 double-row rotator cuff repair (control group; n=62)
  - arthroscopic transosseous equivalent double-row rotator cuff repair augmented with the REGENETEN Implant (REGENETEN Implant group; n=60)
- No differences in pre-operative patient characteristics
- Primary outcome re-tear rate assessed on MRI at 12 months using the Sugaya classification
  - re-tear defined as Sugaya grades 4–5
- Secondary outcomes were characteristics of the healed tear (healed tear defined as Sugaya grades 1–3) and clinical outcomes including Brief Pain Inventory, EQ-5D-5L questionnaire, Constant-Murley score, American Shoulder and Elbow Society score and time to return to work

Results

At 12-months follow-up, compared with repair alone, repair augmented with the REGENETEN Implant demonstrated:

- Significantly lower re-tear rate (8.3 vs 25.8%; p=0.01; Figure)
- Significantly better tendon integrity (91.7 vs 74.2%; p=0.03)
- A three times lower risk of re-tear (RR=0.32; 95% CI: 0.13–0.83; Figure)
- No differences in clinical outcome measures between groups
- No difference in the number of serious or minor complications

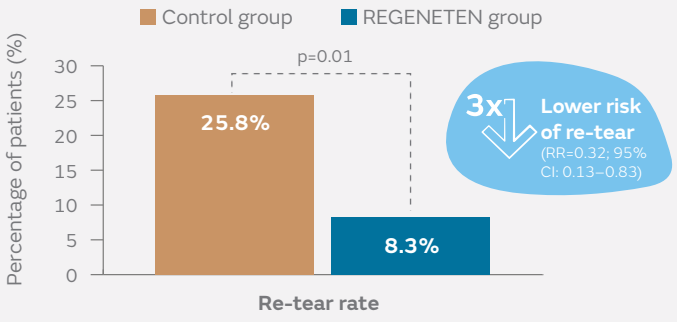


Figure. Percentage of patients with a re-tear assessed on MRI in the control group and REGENETEN Implant group at 12-months post-operatively

Conclusions

In a randomised controlled trial, results assessed on MRI at 12-months post-operatively demonstrated that repair of medium and large full-thickness tears augmented with the REGENETEN Bioinductive Implant led to better tendon integrity, reduced risk of re-tear and significantly lower re-tear rates compared with repair alone.

Abbreviations: CI = confidence interval; RR = relative risk.

*2 patients were lost at follow-up. †>80% footprint coverage without tension.

This material is intended for healthcare professionals. For detailed product information, including indications for use, contraindications, precautions and warnings, please consult the product's applicable Instructions for Use (IFU) prior to use.

Developed by Evidence Communications, Global Clinical & Medical Affairs
www.smith-nephew.com