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.

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Key points

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

- **3x** Lower risk of re-tear
- Significantly better tendon integrity (p=0.03)
- No additional complications

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

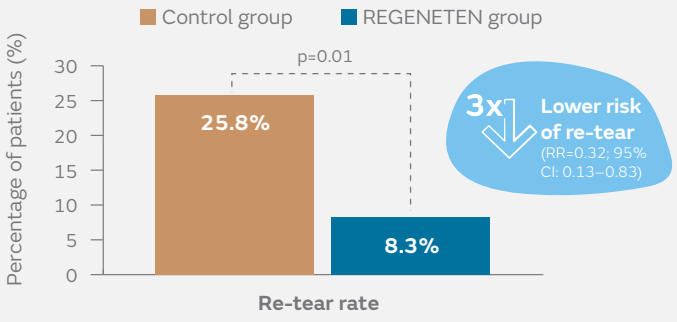

Figure. Percentage of patients with a re-tear assessed on MRI in the control group and REGENETEN Implant group at 12-months post-operatively

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.

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.

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