

REGENETEN[®] Bioinductive Implant in full thickness rotator cuff tears: Interim results from a triple-blinded, multi-centre, randomised controlled trial

Ruiz Iban MA, Navlet MG, Marco SM, et al. The Effect on healing rate of the addition of a bioinductive implant to a rotator cuff repair. Preliminary report presented at: The European Society for Surgery of the Shoulder and Elbow (SECEC) Annual Congress; September 7–9, 2022; Dublin, Ireland.

Key points

Compared with rotator cuff repair alone, the rotator cuff repair augmented with the REGENETEN Implant demonstrated:

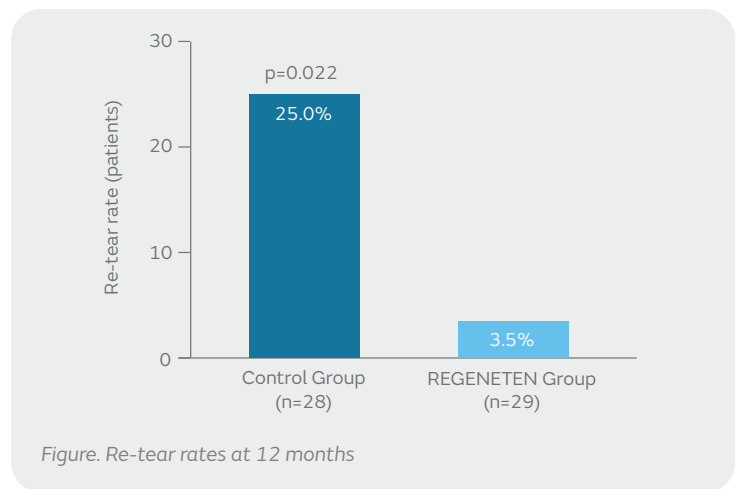


Overview

- Interim analysis of a triple-blinded, multi-centre, randomised controlled trial comparing the healing rate of rotator cuff repair in full thickness tears (1–4 cm, n=57)
- Patients were randomised to receive either:
 - arthroscopic transosseous equivalent rotator cuff repair (standard repair) (n=28)
 - the same repair augmented with the REGENETEN Implant (n=29)
- MRI assessed re-tear rate at 12 months using the Sugaya classification (re-tear defined as Sugaya Types IV and V)

Results

- Significantly lower re-tear rates in the REGENETEN Implant versus Control Group at 12-month follow-up (3.5% versus 25.0% p=0.022; figure)
- No differences in post-operative complications between groups
- The failure rate at the musculotendinous junction was significantly lower in the REGENETEN Group (3.5% versus 22%, p=0.044)
- Post-operative fatty infiltration was lower in the REGENETEN Group compared to the Control Group (10% versus 25%)



Conclusions

In a triple-blinded, multi-centre, randomised controlled trial, interim results indicate that repair of full-thickness rotator cuff tears augmented with the REGENETEN Implant led to significantly lower re-tear rates compared to standard repair alone.

Considerations

These are interim results, the final results are planned to be presented at the International Society of Arthroscopy, Knee Surgery and Orthopaedic Sports Medicine (ISAKOS) in 2023.