Smith+Nephew

REGENETEN◊ Bioinductive Implant leads to tissue induction and high rates of tendon healing in patients with large and massive rotator cuff tears

Thon SG, O'Malley L, O'Brien MJ, Savoie FH. Evaluation of healing rates and safety with a bioinductive collagen patch for large and massive rotator cuff tears: 2-year safety and clinical outcomes. *Am J Sports Med.* 2019;47:1901–1908.

Available at: American Journal of Sports Medicine

Key points

Following double-row rotator-cuff repair with the REGENETEN Implant:

96% of patients had **complete tendon healing***

No implant-related adverse events reported (n=23)

Mean **tendon thickness increased**

*Healing was assessed by ultrasound (US) and magnetic resonance imaging (MRI) in the 2-year follow-up period.

Overview

- A prospective study of 23 patients (mean age, 57.9 years) with large (two tendon, [n=11]) and massive (three tendon, [n=12]) rotator cuff tears receiving primary (n=7) or revision (n=16) repairs
- Following a double-row repair, a REGENETEN Implant was applied over the repaired supraspinatus and infraspinatus tendons
- Primary outcome was safety. Secondary outcomes included tendon thickness as an assessment of tissue induction on each US examination (3, 6, 12 and 24 months) and on a single MRI (mean follow-up: 13 months), and American Shoulder and Elbow Surgeons (ASES) score at 24 months
- Standard post-operative rehabilitation protocol for large/massive rotator cuff tears was followed

Results

- No implant-related adverse events were reported
- Complete tendon healing in 96% (22/23) of patients on both imaging modalities (US and MRI)
- Treatment success, determined by healed rotator cuff tissue on both US and MRI, in 91% (21/23) of patients at 24 months; 1 healing failure and 1 clinical failure due to progression of glenohumeral osteoarthritis
- Mean tendon thickness increased from 6.29mm at 3 months to 7.72mm at 12 months, decreasing to 7.28mm at 24 months
- Mean ASES score was 82.87 at 24 months
- No significant difference in treatment success (Figure), tendon thickness or ASES score between primary and revision repair groups or between large and massive tear groups

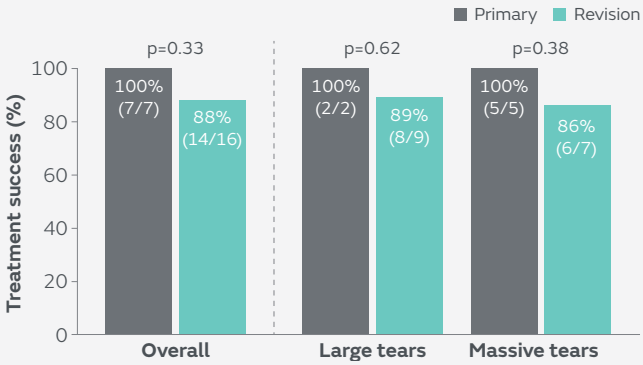

Figure. Percentage of patients achieving treatment success in primary and revision repairs

Conclusions

In conjunction with repair of large and massive rotator cuff tears, the REGENETEN Implant was a safe and effective treatment that induced tissue formation and resulted in high rates of healing in both primary and revision settings.

Considerations

Tendon thickness was measured at the lateral edge of the articular cartilage and slightly posterior to the bicipital groove; the authors suggested a usual thickness in normal rotator cuffs of 8mm with this measurement technique.

Sports Medicine, Smith & Nephew, Inc. 150 Minuteman Road, Andover MA, 01810 USA.
17164-en V3 0523. Published May 2023.

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