


REGENETEN[®] Bioinductive Implant used in the repair of medium-sized and large full-thickness rotator cuff tears leads to low re-tear rates at 24 months


Bushnell BD, Connor P, Harris HW, Ho CP, Trenhaile SW, Abrams JS. Two-year outcomes with a bioinductive collagen implant used in augmentation of arthroscopic repair of full-thickness rotator cuff tears: Final results of a prospective multi-center study. *Journal of Shoulder and Elbow Surgery*. 2022 July 01 [Epub ahead of print]


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Key points

Rotator cuff repair augmented with REGENETEN Implant demonstrated at 24 months:

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83.5% of patients with double-row repair were re-tear free
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>90.0% of patients had improvements that exceeded the MCIDs in ASES and CMS scores
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97.1% of patients surveyed were satisfied with the procedure

Overview

- A prospective, multicentre study evaluating patients who received either single- or double-row repair of medium-sized (1-3cm; n=66) and large (3-5cm; n=49) full-thickness rotator cuff tears augmented with REGENETEN Implant
- Outcomes assessed at 3, 12 and 24 months post-operatively included:
 - MRI evaluation of re-tear, tendon thickness and implant resorption
 - Clinical outcomes: American Shoulder and Elbow Surgeons (ASES) Shoulder and Constant-Murley Shoulder (CMS) scores

Results

- Overall re-tear rate of 4.6% at 3 months (3/66) and 10.6% at 12 months and 24 months (19/66) in medium tears. Overall re-tear rate of 20.4% at 3 months (10/49) and 24.5% at 12 months (12/49) and 28.6% at 24 months (14/49) in large tears
- Significantly lower re-tear rate in patients who had repair with double-row (12/91, 13.2%) technique than single-row (9/24, 37.5%) at 24 months (p=0.0061)
- Between baseline and 24-month follow-up, the average mean tendon thickness increased by 12.5% for medium tears and 17.1% for large tears
- More than 90% of patients had post-operative improvements in both medium and large tears in ASES Shoulder and CMS scores that exceeded minimal clinically important differences (p<0.001) (MCIDs; figure)
- 97.1% of patients surveyed were satisfied with the procedure; 100% would recommend the procedure to a friend
- Nine patients required re-operation: 7 for persistent symptoms, 1 for superficial infection and 1 for inflammation and osteopaenia

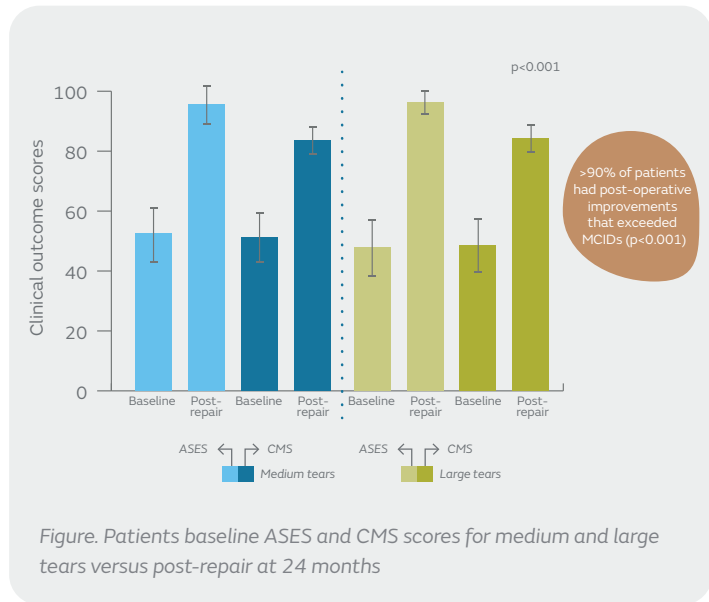


Figure. Patients baseline ASES and CMS scores for medium and large tears versus post-repair at 24 months

Conclusions

In combination with repair, the REGENETEN Implant led to low 2-year re-tear rates, improvements in pain and function and high patient satisfaction. The authors note that this study reports lower re-tear rates than studies evaluating standard repairs, especially in double-row repairs of large tears.

Considerations

Two surgeons performed single-row repairs, which presents a more limited comparison than with double-row repairs (n=9) especially given the re-tear following single-row repairs was significantly higher.