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# REGENETEN◊ Bioinductive Implant in full-thickness rotator cuff tears: 12-month results from a prospective multi-centre registry

McIntyre LF, McMillan S, Trenhaile SW, Bishai SK, Bushnell BD. Full-thickness rotator cuff tears can be safely treated with a resorbable bioinductive bovine collagen implant: one-year results of a prospective, multicenter registry. *Arthrosc Sports Med Rehabil.* 2021;3(5):e1473-e1479.

Available at: Arthroscopy, Sports Medicine and Rehabilitation

## Key points

**Significant improvements** in pain, shoulder function and health-related quality of life at 12 months postoperatively (p<0.001)

**Consistent outcomes** regardless of preoperative tear size (small/medium vs large/massive)

## Overview

- An analysis of outcome data from patients with full-thickness rotator cuff tears enrolled into a prospective registry study (the REBUILD Registry), conducted at 17 sites in the USA
- A total of 210 patients (mean age, 57.5 years) received a REGENETEN Implant to augment repair of full-thickness tears
  - The specific repair technique was left to surgeon discretion
- Preoperative tear size: 12 small (<1cm; 5.7%), 92 medium (1-3cm; 43.8%), 75 large (3-5cm; 35.7%) and 31 massive (>5cm; 14.8%)
- Outcomes included postoperative recovery and PROMs, which were assessed preoperatively and postoperatively at 2 and 6 weeks, and 3, 6 and 12 months
- Twelve-month follow-up data were available for 192 patients

## Results

- At 6 and 12 months, ASES, SANE, VR-12 PCS and WORC were significantly improved from preoperative values (p<0.001; Figure)
  - MCIDs were met or exceeded by 90.5% of patients for ASES, 84.3% of patients for SANE and 87.2% of patients for WORC
  - VR-12 MCS was significantly improved at 6 months (p=0.002); no significant difference to preoperative values at 12 months
- An ad-hoc analysis demonstrated similar results at 12 months regardless of tear size
- Mean duration of postoperative recovery (days): sling time, 36.3; return to driving, 24.0; return to work, 48.4; return to non-overhead sports, 105.4, return to overhead sports, 131.7
- Revision rate of 9.4% (18/192 patients, 22 procedures in total); re-tear (n=11), infection (n=3), shoulder stiffness/adhesive capsulitis (n=3), bursitis (n=1) or implant displacement after a fall (n=1)

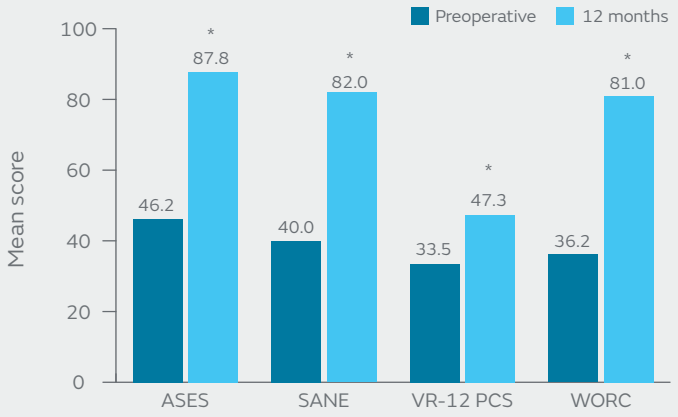


*Figure. Mean PROM scores before and 12 months after repair of full-thickness tears augmented with the REGENETEN Implant.*
** p<0.001 vs preoperative value*

## Conclusions

In 192 patients with full-thickness tears receiving a REGENETEN Implant with surgical repair, significant improvements in pain, shoulder function and health-related quality of life were reported at 12 months, with consistent outcomes regardless of preoperative tear size. The author noted that postoperative recovery compared favourably with existing literature for standard techniques.

**Abbreviations**
ASES = American Shoulder and Elbow Surgeons, MCID = minimal clinically important difference, PROMs = patient-reported outcome measures, SANE = Single Assessment Numeric Evaluation, VR-12 MCS = Veterans RAND 12-Item Health Survey Mental Component Score, VR-12 PCS = Veterans RAND 12-Item Health Survey Physical Component Score, WORC = Western Ontario Rotator Cuff Index

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32188 V1 1021 Published October 2021. 

Developed by Evidence Communications, Global Clinical & Medical Affairs
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