

## REGENETEN<sup>®</sup> Bioinductive Implant in partial-thickness rotator cuff tears: 12-month results from a prospective multi-centre registry

Bushnell BD, Bishai SK, Krupp RJ, et al. Treatment of partial-thickness rotator cuff tear repairs with a resorbable bioinductive bovine collagen implant: 1-year results from a prospective multi-center registry. Presented at: AOSSM-AANA Combined 2021 Annual Meeting, July 7-11, Nashville, Tennessee, USA.

### Key points



**Significant improvements** in pain, shoulder function and health-related quality of life at 3 and 12 months postoperative ( $p < 0.05$ )



**Early clinical outcomes** were significantly improved with **isolated bioinductive repair** versus augmented takedown and repair in higher grade tears ( $p < 0.05$ )

### Overview

- An analysis of outcome data from patients with partial-thickness rotator cuff tears enrolled into a prospective registry study (the REBUILD Registry), conducted at 19 sites in the USA
- A total of 272 patients (mean age, 52.1 years) with partial-thickness tears were included in this analysis:
  - 241 (88.6%) received a REGENETEN Implant in an isolated bioinductive repair procedure (without surgical repair)
  - 31 (11.4%) received a REGENETEN Implant to augment a takedown and repair procedure
- Preoperative tear size (Ellman classification): 49 grade 1 tears (<3mm; 18.0%), 101 grade 2 tears (3-6mm; 37.1%) and 122 grade 3 tears (>6mm; 44.9%)
- Outcomes included postoperative recovery and PROMs, which were assessed preoperatively and at 2 weeks, 6 weeks, 3 months, 6 months and 12 months postoperatively
- Twelve-month data were available for 227 patients

### Results

- All PROMs were significantly improved at 12 months from preoperative values ( $p < 0.05$ ; Table), with all improvements meeting or exceeding minimal clinically important differences for each score
- At 2 and 6 weeks, patients with higher grade tears ( $\geq$  grade 2) receiving isolated bioinductive repair had significantly better scores for ASES score, SANE and WORC Index compared with patients receiving augmented takedown and repair ( $p < 0.05$ )
  - No significant differences at 12 months, except VR-12 PCS, which was significantly improved with isolated bioinductive repair ( $p < 0.05$ )
- Mean sling time was 19.6 days and mean times to return to work and driving were 33.3 days and 17.1 days, respectively (including both treatment groups)

Table. Mean PROM scores before and after treatment of partial-thickness rotator cuff tears with the REGENETEN Implant.\*

	Preoperative	3 months	12 months
ASES pain	5.5	2.1 <sup>†</sup>	1.1 <sup>†</sup>
ASES shoulder function	14.1	18.9 <sup>†</sup>	26.1 <sup>†</sup>
ASES shoulder score	46.8	71.9 <sup>†</sup>	88.1 <sup>†</sup>
SANE	41.7	69.9 <sup>†</sup>	86.2 <sup>†</sup>
VR-12 MCS	51.9	54.6	55.4 <sup>†</sup>
VR-12 PCS	35.3	43.1 <sup>†</sup>	49.2 <sup>†</sup>
WORC Index	36.4	64.0 <sup>†</sup>	83.7 <sup>†</sup>

\* Overall population (n=227) including both treatment groups  
<sup>†</sup>  $p < 0.05$  vs preoperative values

### Conclusions

In 227 patients with partial-thickness tears receiving a REGENETEN Implant with or without takedown and repair, significant improvements in pain, shoulder function and health-related quality of life were reported at 3 and 12 months. Isolated bioinductive repair offered improved early clinical outcomes and equivalent 12-month results to augmented takedown and repair.

#### Abbreviations

ASES = American Shoulder and Elbow Surgeons, 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