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REGENETEN◊ 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. *Orthop J Sports Med.* 2021;9(8):23259671211027850.

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Key points

Significant improvements in pain, shoulder function and health-related quality of life at 3 and 12 months postoperatively (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 received a REGENETEN Implant:
  - 241 in an isolated bioinductive repair (without surgical repair)
  - 31 to augment a takedown and repair, all in grades 2 or 3 tears
- Preoperative tear size (Ellman classification): 49 grade 1 (<3mm), 101 grade 2 (3-6mm) and 122 grade 3 (>6mm tears)
- 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 227 patients

Results

- All PROMs were significantly improved at 3, 6 and 12 months from preoperative values, except VR-12 MCS, which was only significant at 12 months (p<0.05; Table)
  - MCIDs for ASES, SANE and WORC scores were met or exceeded by >90% of patients at 12 months
- In higher grade tears (≥grade 2) and compared with the augmented takedown and repair group, isolated bioinductive repair resulted in:
  - Significantly better ASES, SANE and WORC scores at 2 and 6 weeks (p<0.05)
  - No significant differences in 12-month outcomes, except VR-12 PCS, which was significantly improved with isolated bioinductive repair (p=0.0213)
  - Significantly less sling time (19.1 vs 34.3 days; p<0.0001) and faster return to non-overhead sports (72.2 vs 128.9 days; p=0.0192); no other significant differences in recovery

*Table. Mean PROM scores (± standard deviation) before and after treatment of partial-thickness rotator cuff tears with the REGENETEN Implant.**

	Preoperative	3 months	12 months
ASES pain	**5.5** ± 2.4	**2.1** ± 2.4†	**1.1** ± 2.0†
ASES function	**14.1** ± 6.2	**18.9** ± 6.9†	**26.1** ± 5.9†
ASES overall	**46.8** ± 18.2	**71.9** ± 20.5†	**88.1** ± 17.9†
SANE	**41.7** ± 19.9	**69.9** ± 19.4†	**86.2** ± 18.2†
VR-12 MCS	**51.9** ± 13.2	**54.6** ± 12.0	**55.4** ± 8.9†
VR-12 PCS	**35.3** ± 8.4	**43.1** ± 8.3†	**49.2** ± 9.3†
WORC	**36.4** ± 16.6	**64.0** ± 22.6†	**83.7** ± 21.7†

** Overall population (n=227): includes both isolated bioinductive repair and augmented takedown and repair groups*
† p<0.02 vs preoperative values

Conclusions

In 227 patients with partial-thickness tears receiving a REGENETEN Implant either alone or with 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 comparable 12-month outcomes to augmented takedown and repair.

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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