


# A randomised controlled trial (RCT) of stable rotator cuff tears treated with an isolated bioinductive repair (IBR) using the REGENETEN<sup>®</sup> Bioinductive Implant demonstrated better clinical outcomes and faster recovery, compared to sutured repair at 2 years

Camacho Chacón JA, Rojo VR, Martinez AM, et al. An isolated bioinductive repair vs. sutured repair for full-thickness rotator cuff tears: 2-year results of a double blinded, randomized controlled trial. *J Shoulder Elbow Surg.* Published online May 09, 2024. doi:10.1016/j.jse.2024.03.043.


Available at: [Journal of Shoulder and Elbow Surgery](#)  

## Key points


Compared with sutured repair, stable rotator cuff repairs treated with an IBR using the REGENETEN Implant resulted in:



**Superior collagen organisation**  
(seen on biopsy)



**Significantly better PROMs at all time points**  
(ASES and CMS scores)



**Significantly faster return to work**

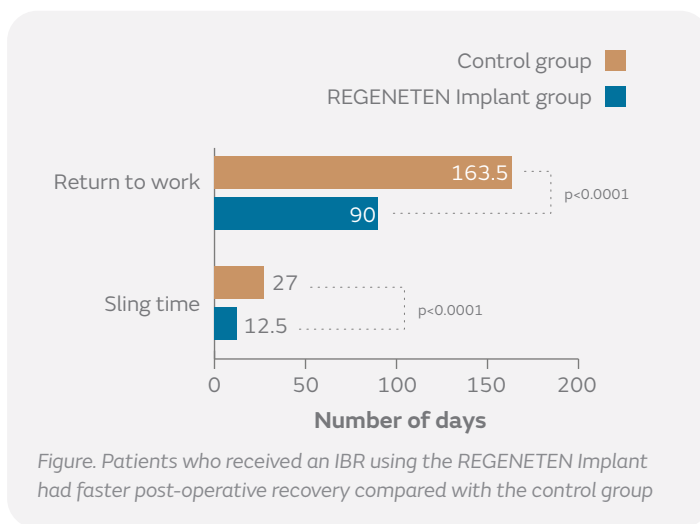
## Overview

- Blinded, single-surgeon, RCT assessing the healing rate and patient-reported outcome measures (PROMs) of an IBR using the REGENETEN Implant compared to sutured repair at 2-year follow-up
- 60 patients with full-thickness rotator cuff tears (<2.5cm), with an intact rotator cable, were randomised and blinded to receive either:
  - Arthroscopic transosseous-equivalent repair (control group; n=30)
  - IBR using the REGENETEN Implant (REGENETEN Implant group; n=30)
- Primary outcome was tendon quality on biopsy at 6 months
- Secondary outcomes were PROMs: American Shoulder and Elbow Society (ASES) score, Constant-Murley Shoulder (CMS) score and Visual Analogue Scale (VAS) pain score; tendon thickness and healing at 6, 12 and 24 months; sling time (days); physical therapy (sessions) and return to work (days)

## Results

Patients who received an IBR using the REGENETEN Implant demonstrated:

- Superior collagen organisation, without inflammation, seen on biopsy (p<0.0001)
  - Control group showed poorly organised collagen in 80% of patients
- Significantly thicker tendon at 6 months, compared to the control group, maintained throughout the follow-up period (p<0.0001)
- Healed tendon at 12 months (all patients had 100% tendon gap fill-in)
- Significantly better ASES and CMS scores at all timepoints, compared to the control group (p<0.0001)
  - Significantly lower VAS pain score at 6 months, compared to the control group (p<0.0001)
  - No difference in VAS pain score between groups at 24 months
- Significantly faster return to work and fewer days in a sling (p<0.0001; Figure)
- Significantly fewer physical therapy sessions (p<0.0001)



## Conclusions

In a randomised controlled trial, stable full-thickness rotator cuff tears treated with an isolated bioinductive repair using the REGENETEN Implant resulted in robust healing, significantly less sling time, significantly better PROMs and significantly faster return to work, compared with sutured repair.

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