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Isolated bioinductive repair with the REGENETEN◊ Implant results in earlier functional recovery compared to traditional repair of high-grade partial thickness rotator cuff tears: a prospective randomised controlled trial (RCT)

Wang A, Breidahl W, Ek ET, Falconer T, D'Alessandro P, Ebert JR. Early functional recovery is improved in patients treated with bioinductive collagen implant augmentation compared with standard arthroscopic repair of high-grade partial-thickness rotator cuff tears: A prospective randomized trial. *Orthop J Sports Med.* 2026 4;14(3):23259671261418675

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Key points

Compared to traditional rotator cuff repair, patients with high-grade partial tears treated with the REGENETEN Implant demonstrated:

- **Faster return** to activities of daily living (ADL)
- **Better shoulder-related quality of life** at 6 weeks (p=0.001) and 3 months (p=0.026)
- **High rate of tendon healing:** 90% at 12 months

Overview

- Prospective randomised controlled trial comparing traditional treatment of high-grade (≥50% tendon thickness involvement) partial thickness rotator cuff tears to isolated bioinductive repair with the REGENETEN Implant; including appropriate rehabilitation protocols.
- 41 patients (aged 35–75) with symptomatic high-grade partial thickness tears unresponsive to conservative treatment* were randomised
  - Takedown and double-row rotator cuff traditional rotator cuff repair (RCR; n=20)
  - Isolated bioinductive repair with the REGENETEN Implant (n=21)
- Inclusion criteria: MRI confirmed ≥50% tendon thickness involvement, correlated with symptoms and clinical exam, tear identified as the primary pathology responsible for pain and dysfunction
- At baseline, all participants had Sugaya grade 3 tears
- Patients assessed pre-operatively, at 6 weeks, 3, 6, 12 months
- Primary outcome: Western Ontario Rotator Cuff Index (WORC)† at 3 months
- Secondary outcomes: American Shoulder and Elbow Surgeons (ASES) Score, return-to-activity timelines, and MRI-based tendon integrity (Sugaya grading)

Results

Patients treated with isolated bioinductive repair with the REGENETEN Implant experienced superior early functional outcomes vs RCR:

- Rotator cuff quality of life (WORC) was better at 6 weeks (p=0.001) and 3 months (p=0.026)
- Pain reduction and improved function (ASES) was greater at 6 weeks (p<0.001)
- Patients returned significantly faster to key ADL milestones (Figure):
  - Permanent sling removal (p<0.001)
  - Driving (p<0.001)
  - Office/desk work (p=0.009)
  - Moderate chores (p<0.001)
- MRI outcomes showed no difference in tendon integrity at 6 or 12 months; at 12 months Sugaya grade 1–2 occurred in 90% of patients treated with isolated bioinductive repair with the REGENETEN Implant compared to 85% with traditional RCR, no full-thickness retears (Sugaya grade 4–5) were reported in either group

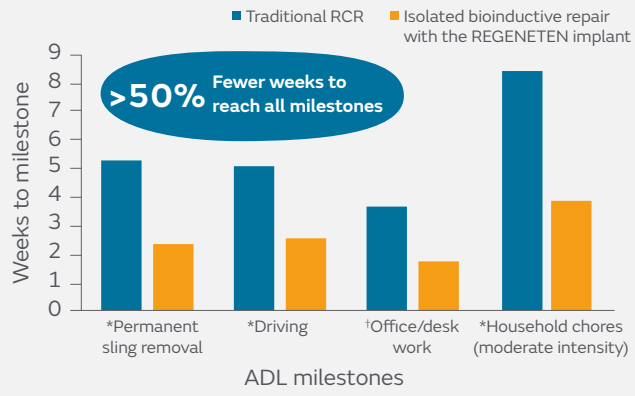

Figure. For all ADL milestones recovery was twice as fast in patients treated with isolated bioinductive repair with the REGENETEN Implant compared to traditional RCR

**p<0.001 †p<0.009*

Conclusions

Treatment of high-grade partial thickness tears, with isolated bioinductive repair with the REGENETEN Implant provided earlier functional recovery and faster return to daily activities compared to traditional RCR, with a high rate of tendon healing at 12 months.

*Persistent symptoms for >3 months despite conservative non-operative management including physiotherapy, oral anti-inflammatory medication and corticosteroid injections.
†The Western Ontario Rotator Cuff Index (WORC) is a validated, disease-specific patient-reported outcome measure assessing rotator cuff–related quality of life across five domains.
ADL = activities of daily living, ASES = American Shoulder and Elbow Surgeons Score, RCR = Rotator cuff repair.

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