Evidence in focus

Study summary

Schlegel TF, et al. *J Shoulder Elbow Surg* (2017)*

Smith+Nephew

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REGENETEN® Bioinductive Implant induces tendinous tissue formation in patients with partial-thickness (PT) tears of the supraspinatus (SS) tendon

Significant and clinically meaningful benefits were demonstrated in validated assessments of pain and function

Study overview

- A prospective, multi-center, open-label trial in 33 patients (mean age, 54.6 years) with PT tears of the SS tendon
- All patients received REGENETEN Bioinductive Implant over the bursal surface of the tendon following arthroscopic subacromial decompression without repair
- Tendon thickness and tear size were assessed by MRI preoperatively and at 3 months and 1 year following surgery
- Clinical outcomes were measured using American Shoulder and Elbow Surgeons (ASES) and Constant-Murley assessments, preoperatively and at 3 months and 1 year postoperatively

Key results

MRI outcomes

- At 1 year, 23 patients (70%) had a reduction in tear size of at least one grade from baseline
- Additionally, 8 patients (24%) had no visible defect at 1 year
- Tear progression only occurred in one patient, who did not follow the rehabilitation protocol
- No patients underwent revision surgery
- Significant increase in mean tendon thickness in both intermediate and high grade tears at 1 year ($p<0.01$; Figure 1)
- No significant differences in tendon thickness between:
  - Intermediate and high-grade tears
  - Articular surface and bursal-sided defects

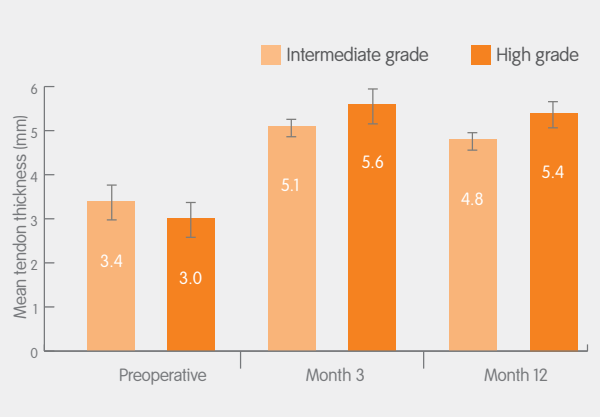

Figure 1. Mean change in tendon thickness (± standard error) across intermediate and high grade tears. At month 12, $p=0.003$ and $p<0.0001$ for intermediate and high-grade tears respectively, versus preoperative measures

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Evidence in focus (continued)

Key results (continued)

Patient outcomes

- Significant improvements in ASES shoulder index, pain and shoulder function scores at 1 year (all p<0.0001)
  - Improvements in ASES pain and ASES shoulder index scores were approximately twice the minimal clinically important differences (MCIDs; Figures 2 and 3)
- Significant improvement in Constant-Murley shoulder score from 57.1 at baseline to 81.4 at 1 year (p<0.0001), greater than twice the MCID of 10.4
- At 1 year, 30 patients (94%) agreed or strongly agreed that they were satisfied with the results of their procedure
- Recovery was considered rapid by the investigators when compared with patients undergoing tear conversion and repair:
  - Mean sling time: 23.3±2.4 days
  - Mean return to work: 30.5±12.0 days
  - Mean duration of physical therapy: 18±1.6 visits

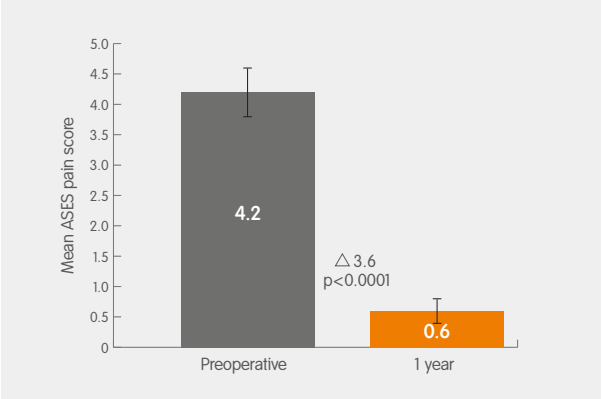

Figure 2. Mean ASES pain score before and after treatment with the REGENETEN Bioinductive Implant; MCID: 1.4

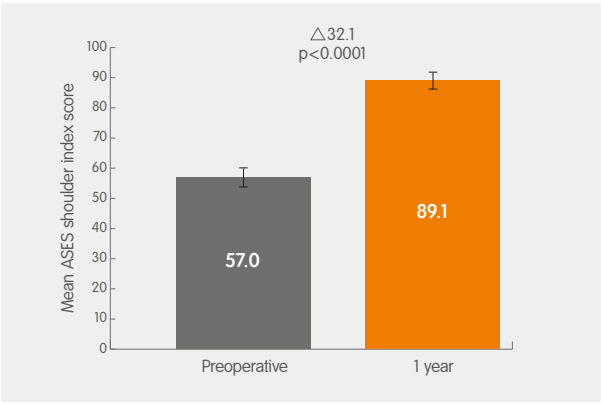

Figure 3. Mean ASES shoulder index score before and after treatment with the REGENETEN Bioinductive Implant; MCID: 12.01-16.92

Conclusion

The REGENETEN Bioinductive Implant biologically augments healing, increasing tendon thickness and potentially improving the biomechanical environment of the lesion. Therefore, REGENETEN Bioinductive Implant represents a promising treatment for patients with intermediate and high-grade PT tears of the SS tendon.

Study citation

*Schlegel TF, Abrams JS, Bushnell BD, Logan Brock J, Ho CP. Radiologic and clinical evaluation of a bioabsorbable collagen implant to treat partial thickness tears: a prospective multicenter study. *J Shoulder Elbow Surg* 2017;27(2):242-251.
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