

High patient satisfaction reported with the REGENETEN® Bioinductive Implant

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



Study overview

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



Key results

- 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 1 and 2)
- 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

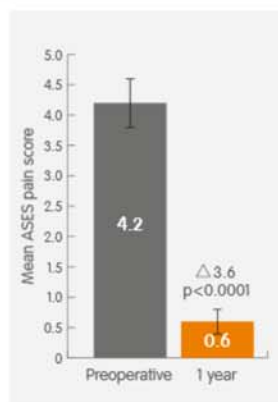


Figure 1. Mean ASES pain score before and after treatment with the REGENETEN Bioinductive Implant; MCID: 1.4

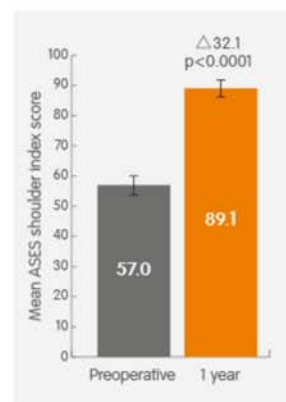


Figure 2. Mean ASES shoulder index score before and after treatment with the REGENETEN Bioinductive Implant; MCID: 12.01-16.92



Conclusion

REGENETEN Bioinductive Implant achieved clinically meaningful improvements in patient outcomes, with high levels of patient satisfaction. Preservation of the native cuff anatomy with biological augmentation of degenerative tissue may support a more rapid recovery than tear conversion and repair.



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.

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