

## REGENETEN<sup>®</sup> Bioinductive Implant maintains repair integrity in full-thickness (FT) rotator cuff tears

Repair integrity supported by rapid induction of new tendon-like tissue which matures and integrates with native tendon



### Study overview

- A preliminary analysis of a prospective study of 9 patients (mean age, 56.4 years) with tears of the supraspinatus tendon (8 medium-sized FT tears; 1 high-grade partial-thickness tear converted to a FT tear during surgery)
- All patients received a REGENETEN Bioinductive Implant over the bursal surface of the tendon following standard repair
- MRI and clinical outcome assessments were conducted preoperatively and at 3, 6, 12 and 24 months postoperatively
- Tendon thickness measurements were compared to published values from young healthy adults to determine the relative amount of tissue generation



### Key results

- No MRI evidence of re-tear or gap formation, with the integrity of all repaired tendons intact at 24 months
- Significant increase in mean tendon thickness versus published values at 3, 6, 12 and 24 months ( $p < 0.01$ ), with an average of 2mm new tissue over the bursal surface (Figure)
- New tissue rapidly matured, improved in quality and was indistinguishable from the native tendon by 12 months
- From 12 to 24 months, tendon thickness slightly decreased, likely reflecting continued functional remodeling
- Significant improvement in clinical scores at 24 months versus preoperative measures
  - Constant-Murley score and Constant-Murley pain score (both  $p < 0.001$ )
  - American Shoulder and Elbow Surgeons (ASES) score and ASES pain score (both  $p < 0.001$ )
- Outcomes were satisfactory for 8/9 patients (89%) at 24 months

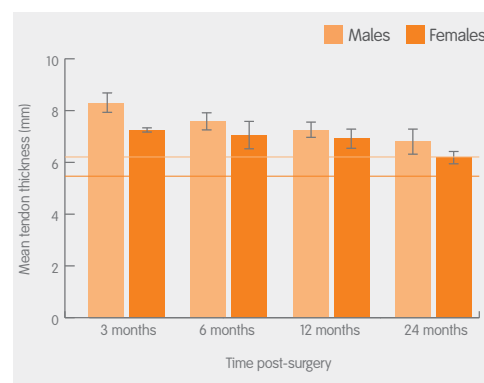


Figure. Mean ( $\pm$  standard error of mean) tendon thickness in male ( $n=6$ ) and female ( $n=3$ ) patients compared to published normal average thicknesses (horizontal lines) for healthy males and females;  $p < 0.01$  at all time points



### Conclusion

Through the generation of rapidly maturing new tendon-like tissue, REGENETEN Bioinductive Implant facilitates restoration of the normal tendon footprint and ultimately maintains repair integrity of full-thickness tears over 24 months. These findings are consistent with previous pre-clinical research and a finite element analysis.



### Study citation

\*Bokor DJ, Sonnabend D, Deady L, et al. Preliminary investigation of a biological augmentation of rotator cuff repairs using a collagen implant: a 2-year MRI follow-up. *Muscles Ligaments Tendons J*. 2015;5(3):144-150. Available at: [Muscle, Ligaments and Tendons Journal](http://Muscle.Ligaments and Tendons Journal)