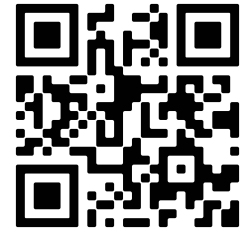


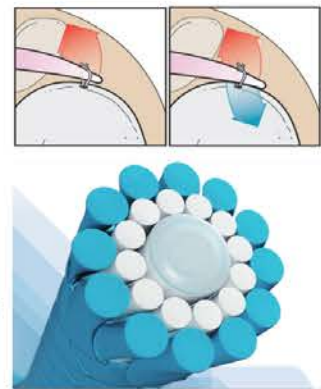
DYNACORD™ Suture: A Summary of the *in vivo* Preclinical Evidence




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1. Introduction

- Reliable re-approximation of soft tissue to bone or other soft tissue is key to a successful repair.
- DYNACORD™ Suture is a high-strength suture designed to:
 - adjust to the stress of the local environment
 - maintain an appropriate level of tension across the repair
- The goal of this study was to review the existing *in vivo* animal data (3 GLP studies)



3. Results

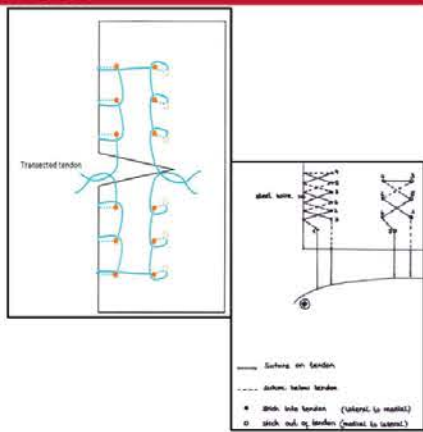
- Study #1 [1]
 - No evidence of cheesewiring or necrosis by DYNACORD™ Suture or competitive suture at either timepoint
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- H&E-stained section showing cut edge of tendon (black arrows) and voids where DYNACORD™ suture was used in repair

4. Discussion

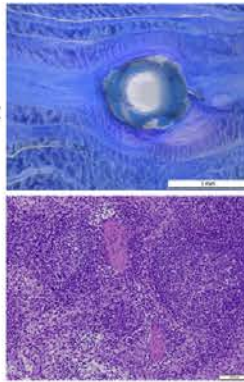
- Demonstration of the safety profile and efficacy in these animal models was most important result of these studies:
 - No evidence of tissue necrosis, systematic toxicity, or suture degradation at 6 weeks [1].
 - DYNACORD™ Suture damages tendon tissue less than competitive sutures [2].
 - No evidence of particulates from DYNACORD™ Suture was found in the joint tissues or in the draining lymph nodes [3].
- We look forward to publishing clinical results as they become available

2. Methods

- Study #1 [1]
 - Ovine; partially cut mid-infraspinatus; n=5 for three groups and 6 for one group (6 week test suture)
 - Endpoints: 5 days and 6 weeks
 - Assess tendon tissue response
- Study #2 [2]
 - Ovine; completely avulsed infraspinatus; n=6 per group
 - Endpoints: 6 weeks and 13 weeks
 - Assess tendon tissue response
- Study #3 [3]
 - Porcine; n=6 animals (12 knees) per group
 - Endpoint: 6 weeks
 - Assess tissue response to implanted particulates and determine if particulates enter draining lymphatic system



3. Results (Cont.)

- Study #2 [2]
 - Considering the biological aspects of tendon healing, DYNACORD™ Suture was less damaging than competitive suture
 - Statistically significant differences were found in:
 - Tendon disruption at 6w (p=0.002)
 - Fibrosis at 6w (p=0.028) and 13w (p=0.010)
 - Total histologic evaluation at 6w (p=0.006)
 - Study #3 [3]
 - No evidence of DYNACORD™ Suture particulates migrating into draining lymph nodes
 - No evidence of macroscopic joint damage observed
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5. Conclusion

- The safety profile and efficacy of DYNACORD™ Suture have been demonstrated in these animal models:
 - Maintained re-approximation of cut edges of soft tissue
 - Improved or equivalent tendon healing characteristics

- References:
 - 1. Favorito, P. J., Spenciner, D. B., Muench, T. R., Bartrom, J., & Ryu, R. K. (2019). Safety evaluation of A laxity-minimizing suture at 5 days and 6 weeks after repair of a Sheep INFRASPINATUS TENDON. *Journal of Shoulder and Elbow Surgery*, 28(1), 164-169. doi:10.1016/j.jse.2018.05.043
 - 2. Darwiche, S. (2020). Evaluating the efficacy of DYNACORD™ suture – Histological evaluation of treated tendons.
 - 3. Barber, F. A., Spenciner, D. B., Zani, B. G., & Melidone, R. (2019). Suture-based debris behavior in the draining lymph nodes of a porcine knee: A study of silicone, polyethylene and carbon. *Arthroscopy, Sports Medicine, and Rehabilitation*, 1(2). doi:10.1016/j.asmr.2019.09.006