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Comparative Evaluation of DYNACORD™ Suture in an Ovine Tendon Repair Safety Model

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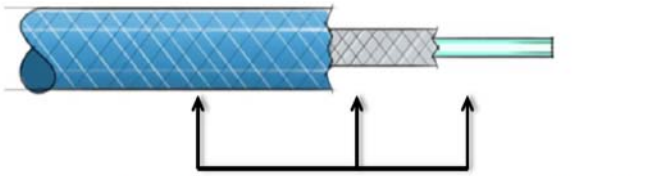
BACKGROUND:

Over the past few decades, surgical rotator cuff repair has evolved from an open approach to an all-arthroscopic approach. One of the major benefits of the arthroscopic approach is the ability to repair the rotator cuff without detachment or manipulation of the deltoid. However, failure of tendon healing after rotator cuff repair is common and occurs in approximately 20% of cases, depending on tear size.[1] Common failure modes during the healing period are suture laxity, creep and knot slippage which lead to a lack of consistent tissue approximation to bone or other soft tissue.[2] DYNACORD™ Suture (DePuy Synthes Mitek Sports Medicine, Massachusetts) is a high-strength, orthopedic suture designed to minimize suture laxity in soft tissue repair procedures in order to preserve consistent tissue approximation while improving footprint compression during the healing period.[3] Unlike other high-strength orthopedic sutures which experience laxity[2], the DYNACORD Suture is uniquely designed to shorten when compression is lost, thereby minimizing micro-motion and reducing gap formation.[4]

Figure 1. Representation of DYNACORD Suture Layers



DYNACORD #2 Suture is a high strength orthopedic suture that is composed primarily of an outer ultra-high molecular weight polyethylene (UHMWPE) sheath, inner polyester (PET) sheath and a silicone/salt filled core (Figure 1). There is a direct correlation between the salt concentration within the silicone core and the ability of the suture to resist laxity.

METHODS:

A pre-clinical, Good Laboratory Practice (GLP) study was conducted to evaluate and compare the safety of DYNACORD Suture and FiberWire® (Arthrex, Florida) suture via an examination of the tissue response to the approximation forces applied to an ovine (sheep) tendon repair model.[5] To simulate a worst-case scenario in this pre-clinical study, the co-extruded silicone core of the DYNACORD Suture was designed with a 1.4 times higher NaCl concentration than the DYNACORD Suture that will be used in the clinical setting. Sheep were selected for this study because of the similarities to humans in terms of healing rate and shoulder anatomy. Using either DYNACORD or FiberWire Suture, a defect in the right infraspinatus tendon of 20 sheep was repaired using two parallel series of locking suture patterns. The tendon was transected half-way at the midpoint between the sutures (Figure 2). The two sutures were then brought together and tied with a 40N approximation force on the repair. This represents an upper limit level of the force remaining on a completed repair based on a study conducted by DePuy Synthes with practicing surgeons.[6] The DYNACORD Suture has been designed not to add excessive approximation force on a repair (Figure 3).[3] Immediately post-surgery, each animal was placed in a suspension system (non-weight bearing) for up to two weeks. At 5 days and 6 weeks post-operative, animals were weighed, euthanized, and a necropsy was performed. Conducted by a certified lab, the right infraspinatus tendon and the repair site (including the surrounding soft tissue), select tissues, and the regional draining lymph nodes were macroscopically examined, histologically processed, and microscopically evaluated.

RESULTS:

The results of the study show that there were no major complications associated with the tendon repair in either the DYNACORD Suture group or FiberWire group following 5 days and 6 weeks post-surgery (Table 1).[5] The amount of surgical trauma noted at necropsy and microscopically were similar between the treatment groups at both time points. The surgical trauma was appropriately resolved between these observational periods in both groups. There were no differences between the microscopic findings in the tendon transection sites repaired by either the DYNACORD Suture group or FiberWire group at 5 days post-surgery. The gap between the cut edges of the tendon was filled

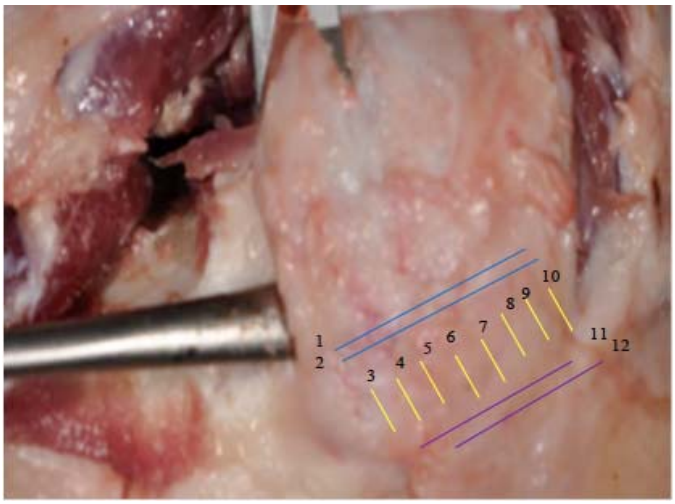


Figure 2: Orientation for Trimming[5]

Note: The blue lines (Reference Lines 1 and 2) in the image represent sections taken through the tendon located above the repair/article site. The purple lines (Reference Lines 11 and 12) in the image represent sections taken through the repair site distal to the repair site. The yellow lines (Reference Lines 3 through 10) in the image represent sections taken through the area of the tendon that were transected or were in line with the area transected.

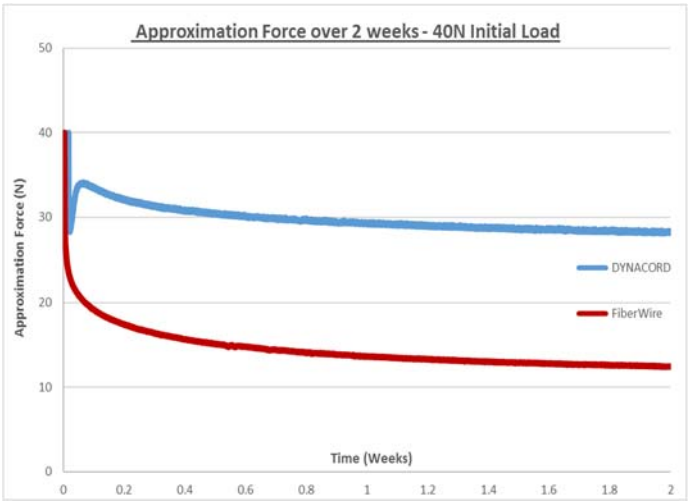


Figure 3: Remaining Approximation Force Over 2 Weeks[3]

Note: 40N initial load applied to both sutures at t=0. The DYNACORD Suture has been designed not to add excessive approximation force to the repair.

Table 1: Summary Results of Pre-Clinical Sheep Study [5]

Endpoint	DYNACORD Suture (n=10)	FiberWire Suture (n=10)
Microscopic and Necropsy Evaluations:		
o Evidence of **article particulate formation** and **migration** at 5 days or 6 weeks?	No	No
o Evidence of **tissue necrosis** of the repaired tendon at 5 days or 6 weeks?	No	No
o Evidence of **systemic toxicity** associated with exposure of suture at 5 days or 6 weeks?	No	No
o **Surgical trauma** appropriately **resolved** between 5 days and 6 weeks?	Yes	Yes
o Evidence that sutures had an **adverse impact** on the examined organs at 5 days or 6 weeks?	No	No
Surgical and Macroscopic Observations:		
o Gap observed between the two ends of the tendon at 5 days or 6 weeks?	No	Yes*

*Gap formation observed in four sheep in the FiberWire group (two at 5 days and two at 6 weeks). The gap between the two ends of the tendon (if present) was measured in three places (where the transection began, the middle of the transection, and the caudal edge of the transection).[5]

with fibrin for all of the animals in this study and was considered to be the normal first step in the healing of a transected tendon. At 6 weeks post-surgery, the healing was considered the same between groups. There were no particulates generated or formed in association with either the DYNACORD Suture group or FiberWire group and no evidence of degradation. There was also no evidence of a systemic effect associated with exposure to either DYNACORD or FiberWire Sutures. Additionally, there was no evidence of tissue necrosis in either group. In the FiberWire group, a gap formation between the two ends of the tendon was observed in four sheep (two at 5 days and two at 6 weeks). No gapping was observed in the DYNACORD Suture group.[5]

CONCLUSION:

The results of this pre-clinical study in an ovine tendon repair model demonstrate that both the DYNACORD Suture and FiberWire suture have an acceptable safety profile and that tissue healing was appropriately resolved in both groups at 5 days and 6 weeks post-rotator cuff repair. Even though the DYNACORD Suture used in this study had a higher NaCl concentration (to simulate a worst-case scenario) results show that there was still no strangulation or necrosis of the tissue. Further research should aim to validate these findings in a clinical setting.

REFERENCES:
(1) Lädermann A, et al J ISAKOS. 2016 Jan;1(1):32-37.
(2) Hurwit D, Journal of Arthroscopic and Related Surgery, Vol 30 No11; Page 1406-1412.
(3) DePuy Synthes. Study# 103394861.
(4) DePuy Synthes. A GLP Study - Evaluating the efficacy of DYNACORD Suture. Study# 103435970.
(5) DePuy Synthes. A GLP Study – Evaluating the safety of DYNACORD Suture. Study# 103434703.
(6) DePuy Synthes. Study# 103300792.

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