

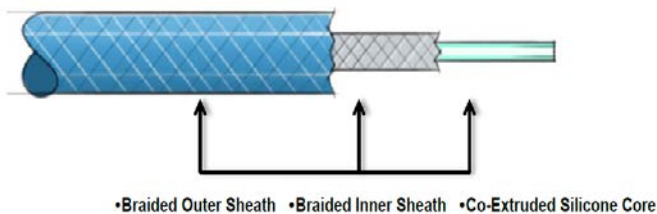
Comparative Evaluation of the DYNACORD™ Suture Silicone Core in a Porcine Safety Model

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BACKGROUND:

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.¹ 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.² Unlike other high-strength orthopedic sutures which experience laxity¹, the DYNACORD Suture is uniquely designed to shorten when compression is lost, thereby minimizing micro-motion and reducing gap formation.³

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). Use of silicone as a suture component is not unique as FiberWire® (Arthrex, Florida) suture also contains a similar material.⁴

METHODS:

The objective of this Good Laboratory Practice (GLP) animal study was to determine whether silicone debris from intentionally ruptured DYNACORD Suture knots migrate into the lymphatic system in a porcine model.⁵ The study was designed to be representative of a worst-case scenario to evaluate the safety profile of the silicone material in this model. Twelve Yorkshire pigs of matched weight, size, age, and sex underwent a bilateral knee capsulotomy. The Yorkshire pig was chosen for its similarities to humans in terms of healing rate and joint capsular anatomy as well as a heightened inflammatory response. The knee was chosen due to

the fact it primarily drains to just two lymph nodes. Similar in size, DYNACORD Suture particles (Test Group; n=6) or vitreous carbon particles (Control Group; n=6) were deposited into each knee. Approximately half of the particles (i.e. particles from 15 ruptured DYNACORD Suture knots or ~5 mL of vitreous carbon particles solution) were infiltrated into the joint space, the capsule was then closed, the remaining particles were placed on the capsule, and then the skin was closed (Table 1). The number of ruptured suture knots used in this study was based on an above average quantity of knots that would be tied in a rotator cuff repair (i.e. 6 knots). Then a safety factor of 5 was applied to this value to create a worst-case scenario.

Table 1. DYNACORD Suture Silicone Core Safety Study Design⁵

Description	DYNACORD Suture Particles (N=6)	Vitreous Carbon Particles (N=6)
Group	Test Group	Control Group
Implantation Scheme	DYNACORD Suture particle deposition in knee joints (bilateral) via capsulotomy and superficial exposure of knee	Vitreous Carbon particle deposition in knee joints (bilateral) via capsulotomy and superficial exposure of knee
Necropsy Time Point	6 weeks (± 2 days)	6 weeks (± 2 days)

Animal health, including incision site and clinical observations, body weights, and clinical pathology, was monitored at pre-determined, regular intervals. Additionally, lymph node examinations were performed by a veterinarian before surgery, daily for 14 days, then generally weekly thereafter and prior to necropsy. The animals were euthanized at 6 weeks and a limited necropsy was performed consisting of examination of the knee joint and the popliteal lymph node, inguinal lymph node, and iliac lymph node. Conducted by a certified lab, bilateral lymph nodes were then collected and processed for histomorphologic evaluation.

RESULTS:

After 6 weeks following infiltration into the knee joint and capsule in the porcine model, DYNACORD Suture particles were associated with overall favorable tissue responses in comparison to those seen with the vitreous carbon particles (control group). There was no evidence of foreign material particles in any DYNACORD Suture group lymph nodes when compared to the control group lymph nodes. The incidence of foreign material for the control group was 100% for the iliac lymph nodes, 50% for the inguinal lymph nodes and 0% for the popliteal lymph nodes.⁵ No visible migration of silicone debris from intentionally ruptured DYNACORD Suture knots was observed in any of the examined lymph nodes. Macroscopically, one animal from the DYNACORD Suture group had dark red discoloration of the left iliac lymph node and one animal from the control group had dark red discoloration of the left popliteal lymph node.⁵ Both cases corresponded histologically with extravasated erythrocytes, which likely occurred perimortem. Three animals from the control group had bilateral dark discoloration present in the subcutaneous layer (Figure 2) one of which histologically corresponded with multiple black foreign particles (Figure 3).

Figure 2: Macroscopic Observations of Right Knee Femur⁵

DYNACORD Suture (Test Group) Image



Note: Image from animal in DYNACORD Suture test group shows no abnormal macroscopic observations of the right knee femur.

Vitreous Carbon Particles (Control Group) Image



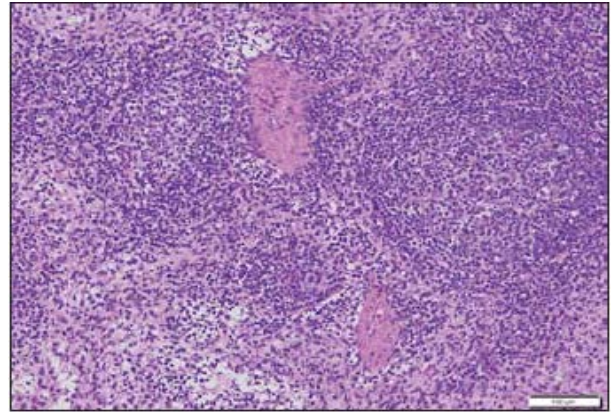
Note: Image from animal in control group shows bilateral dark discoloration present in both subcutaneous layer and joint capsule.

Figure 3: Left Iliac Lymph Node Images⁵

Slide Prep

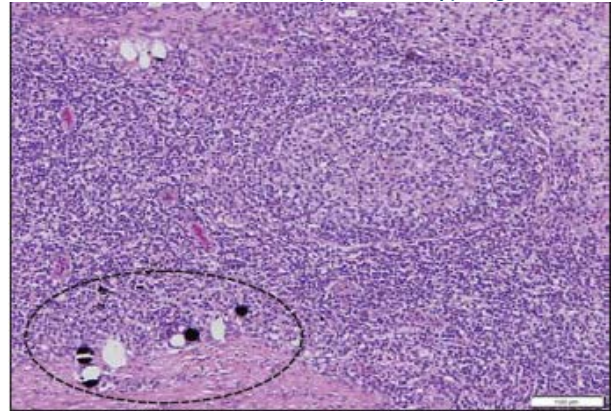
The harvested lymph nodes were bisected, the cut faces placed side-by-side, and embedded in paraffin. In this manner, each slide incorporated two sections of tissue. Slides were approximately 0.6 mm apart in the block and stained with Hematoxylin & Eosin (H&E). Tissues with macroscopic changes were paraffin processed and stained with H&E for histomorphologic assessment.

DYNACORD Suture (Test Group) Image



Note: Image from animal in DYNACORD Suture test group shows lymph node without foreign material particles.

Vitreous Carbon Particles (Control Group) Image



Note: Image from animal in control group shows lymph node with foreign material black particles. White spaces are the areas left empty by the carbon particles which moved during processing.

CONCLUSION:

The results of this pre-clinical study in a porcine model demonstrate that there was no visible migration of silicone debris from intentionally ruptured DYNACORD Suture knots into the lymphatic system. Histologically, lymph nodal inflammation was minimal regardless of treatment. Overall, DYNACORD Suture particles implanted into porcine knee joints did not exhibit any observed unfavorable tissue response.

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