Online Supplementary Material to:

Evaluation of an intra-articular synthetic ligament for treatment of cranial cruciate ligament disease in dogs: a six-month prospective clinical trial
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Appendix I

Initial histologic assessment of synthetic ligament tissue ingrowth properties and host tissue responses (peri-implant interface membranes) was performed following implantation in rat subcutaneous tissues (1). The synthetic ligament was further evaluated in research dogs that underwent clinical assessment following stifle synthetic ligament implantation, which included visual lameness evaluations, surgical site examinations, and cranial drawer testing. The dogs were humanely euthanatized six to 11 months following synthetic ligament implantation for post-mortem evaluations, which included comparative biomechanical testing of implanted versus contralateral normal stifles, gross and histological assessments of tissue ingrowth and peri-implant and synovial tissue responses. Analysis of this proprietary data supported that the synthetic ligament had favourable mechanical and biological properties for consideration as a cranial cruciate ligament replacement.

Appendix II

Surgical procedure

The affected limb was aseptically prepared for surgery and patients were placed in dorsal recumbency. A betadine-impregnated adhesive drape\(^a\) was applied. A 2-3 cm medial parapatellar arthrotomy was performed and joint evaluation was facilitated by use of a small Gelpi retractor and a stifle distractor\(^b\). The infrapatellar fat pad and any remaining cranial cruciate ligament were fully debrided using either an arthroscopic shaver\(^c\) or rongeurs. Joints were evaluated with particular attention paid to the medial meniscus. Torn medial menisci were debrided while intact menisci were left undisturbed. The stifle distractor was removed but the joint was left open.

The proximal medial aspect of the tibia was approached separately or as an extension of the parapatellar incision.

With the stifle in maximum flexion, an aiming device\(^d\) was used to introduce a 20 cm long, 2.0 mm diameter drill bit into the cranial portion of cranial cruciate ligament origin. Drilling in a distal to proximal direction, the drill bit was aimed and advanced to exit the lateral metaphyseal cortex at the level of the proximal pole of the lateral fabella. A 3-5 cm incision was made in the skin over the exiting drill bit and extended to the level of the lateral femur by blunt dissection of the soft tissues. The femoral bone

\(^a\) Ioban 2: 3M Health Care, St. Paul, MN, USA
\(^b\) Securos, Fiskdale, MA, USA
\(^c\) Karl Storz, Tuttingen, Germany
\(^d\) Acufex Director: Smith and Nephew, London, UK
tunnel was created by advancing a 4.5 mm cannulated drill bit over the 2.0 mm drill bit in a proximal to distal direction until it exited at the level of the cranial cruciate ligament origin. A Freer elevator was used to help protect the caudal cruciate ligament and adjacent articular cartilage.

The tibia was prepared by incising and reflecting the fascia and the caudal sartorius muscle insertion. Using the aiming device and the long 2.0 mm drill bit, a 4.5 mm bone tunnel was created by starting at the medial aspect of the proximal tibia and advancing in a distal to proximal direction to exit within the cranial cruciate ligament insertion. The desired angle was such that the lateral edge of the tunnel passed parallel to the tip of the lateral spine of the intercondylar eminence at an angle of approximately 60 degrees to the articular surface of the tibia. Copious sterile 0.9% saline solution lavage was applied during drilling of both tunnels and used to remove any generated bone debris. An arthroscopic shaver or a pneumatic burr was used to remove any edges that could cause synthetic ligament abrasion at the cranial portion of the femoral (Figure 1A) and the caudolateral portion of the tibial tunnel articular apertures (Figure 1B). The synthetic ligament was passed through both bone tunnels such that the cross stitched sections remained outside of the tunnels.

Figure 1: Edges (red borders) at the cranial portion of the femoral (A) and the caudolateral portion of the tibial (B) tunnel articular apertures that were debrided to help minimize synthetic ligament abrasion.

Three centimeters proximal to the lateral femoral bone tunnel opening, a 3.2 mm drill bit was advanced perpendicular to the long axis of the femur. A 4.0 mm self-tapping cortical screw of sufficient length to engage both cortices while accommodating a 14 mm spiked washer was placed through a 5 mm slit created in the cross-stitched portion of the synthetic ligament with a number 11 blade. The screw and washer combination was tightened firmly to affix the ligament to the femur. All screw and washer implants were 316L stainless steel.

The femoral bone tunnel length was measured with a depth gauge and a 5.0 mm titanium interference screw length was selected that would occupy the maximum amount of the tunnel without breaching the articular surface. The tibial end of the synthetic ligament was grasped with a large pair of needle drivers and firm distal tension maintained to ensure no slack existed between the post and the tunnel. To facilitate interference screw insertion cranial to the synthetic ligament, an aperture dilator was introduced into the tunnel to compress it against the caudal aspect of the femoral bone tunnel. Parallel insertion of the interference screw within the medullary bone tunnel and cranial to the synthetic ligament was ensured by use of an instrument that acted as both a driver and a tunnel guide.

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Hall Zimmer Surgairtome Two Pneumatic Powered Drill: Warsaw, IN, USA
The knee was fully flexed and extended approximately 10 times while the synthetic ligament remained under tension to remove slack from the system. Tibial bone tunnel depth was measured. With the stifle angle maintained at an approximately 135° and firm distal tension maintained on the synthetic ligament exiting the tibia, the same process described for interference screw insertion into the femur was repeated for the tibia with the exception that the aperture dilator compressed it cranially and the screw was inserted caudal to the synthetic ligament. A screw and spiked washer were placed in the synthetic ligament emerging from the tibia bone tunnel in the same fashion as described for the femur. Proper synthetic ligament placement and tension was confirmed when, during stifle range of motion, there were no restrictions, no impingement of the caudal cruciate ligament by the synthetic ligament, or synthetic ligament interference within the femoral notch and no cranial drawer instability present. Routine closure was performed and cranial drawer instability measured again (time 0).

**Post-surgical management**

All patients remained hospitalized overnight following surgery. A self-adhesive wound dressing covered the surgery site until dogs were discharged. Patients received cefazolin (22 mg/kg IV) eight hours after the initial preoperative dose and either hydromorphone (0.05 mg/kg) or morphine (0.5 mg/kg) intravenously if modified-Glasgow pain scores indicated a need for additional analgesia. Cold pack application was performed immediately after surgery then every four hours thereafter, and hock, stifle and hip passive-range-of-motion (PROM) was performed every eight hours on the operated limbs.

**Postoperative care therapy**

**Week 1:** Stifle passive range of motion within patient tolerance levels three times/day followed by cold pack application for 15 minutes, 15 minute duration leash walks three to four times a day, and confinement to a single small room when the dog was indoors.

**Week 2:** Leash walks were extended to 30 minutes and warm moist heat application replaced cold packs and then preceded the otherwise unchanged passive range of motion directions. At the end of week two, dogs were presented for skin staple removal and examination.

**Weeks 3 and 4:** Indoor restrictions and passive range of motion were discontinued and leash walks modified to include use of a long leash (3-4.5 meters) for the multiple daily 30 minute walks. All patients were presented at the end of four weeks following surgery for examination (awake and sedated) Owners were instructed to discontinue all postoperative restrictions and a return to unlimited activity was allowed.


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1 Primapore: Smith & Nephew, Andover, MA, USA