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Outcome of cranial cruciate ligament replacement with an enhanced polyethylene terephthalate implant in the dog: A pilot clinical trial

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Abstract

Objective: To assess the 6-month outcome and survival of enhanced polyethylene terephthalate (PET) implants as a replacement for the cranial cruciate ligament (CCL) in dogs with spontaneous CCL disease (CCLD).

Study design: Pilot, prospective case series.

Animals: Ten client-owned large breed dogs with unilateral spontaneous CCLD.

Methods: Dogs were evaluated before and 6 months after intra-articular placement of a PET implant with the Liverpool Osteoarthritis in Dogs questionnaire and force platform gait analysis. Arthroscopy was performed 6 months after surgery to visually assess implant integrity.

Results: Scores on owner questionnaires and limb asymmetry improved in all dogs that reached the 6-month time point, by 51.7% ($p = .008$) and 86% ($p = .002$), respectively. The PET implant appeared intact and functioning in two stifles, partially intact and functioning in four stifles and completely torn in three stifles. One dog had an implant infection and was removed from the study. Evidence of deterioration and tearing occurred in the midbody of the implant.

Conclusion: Although function improved over the course of this study, only 2/10 implants appeared intact 6 months after placement.

Clinical significance: Implant survivability prohibits further clinical investigation using this implant.

1 | INTRODUCTION

Surgical management of dogs with cranial cruciate ligament disease (CCLD) is a common surgical procedure that generally results in an improvement in limb function in dogs as early as 6-months after surgery.[1–5] Reports of long-term outcome after surgery have suggested that progressive osteoarthritis (OA), residual femoral-tibial instability, late-onset meniscal tears and implant related complications may result in a reduced overall success rate.[6–9] These long-term outcomes contribute to the number of different surgical techniques performed and continued clinical investigation toward improved long-term patient outcomes.

Intra-articular reconstruction of spontaneous CCLD using an allograft and femoral transfix stabilization technique has been reported to provide a good to excellent clinical result.[10,11] However, second look arthroscopy showed that only 45% of grafts were intact and functional 1-year after surgery.[11] While this demonstrates that intra-articular allografts can survive and provide a successful outcome, it also shows that the current technique described does not provide a consistent, acceptable outcome.

An alternative approach to consider is the use of an implant as a CCL replacement. Polyethylene terephthalate (PET) ligaments have been used in humans since 1992.[12] Use of PET grafts for anterior cruciate ligament (ACL) reconstruction have often been met with encouraging results in people.[13–16] Less encouraging results have also been reported in people,[17] and in both induced[18] and spontaneous[19] animal models. A better understanding of the mechanical properties of the intact CCL and various CCL stabilization techniques,[20] possible reduced mechanical burden in quadrupeds compared to bipeds and enhanced manufacturing techniques for PET[21–24] provides a rational for clinical investigation.

The objective of this pilot, case series was to assess 6-month efficacy of an enhanced PET implant as a material to treat CCL failure in large breed dogs. We tested the null hypothesis that 6-month postoperative limb function in dogs receiving a PET implant would not improve compared to preoperative function using owner Liverpool OA in Dogs (LOAD) questionnaires and rear limb asymmetry via computational gait analysis as primary outcome measures.

2 | MATERIALS AND METHODS

Institutional Animal Care and Use Committee approved this study (no. 1191-37609A), and informed, written client consent was obtained for each dog enrolled. Owner incentive to participate included no cost for study procedures or treatment of study-related complications for 1 year after the conclusion of their participation in the study (including treatment failure). Ten dogs that presented for spontaneous unilateral CCL rupture were enrolled in the study. Owners were counseled on established treatments of CCLD in contrast to the investigational surgical procedure. All dogs were evaluated by a single investigator. Inclusion criteria included age greater than 1 year, bodyweight (BW) 25–40 kg, free from systemic disease (based on general physical examination, radiographs consistent with CCLD, complete blood count and serum chemistry panel), palpable femoral-tibial translation and free of other orthopedic and neurological conditions (based on orthopedic/neurological examination). Exclusion criteria included pregnancy, bilateral CCLD and previous surgery on the affected stifle.

2.1 | Treatment

The PET implant (New Generation Devices, Naples, FL) was 174 × 7-mm in diameter, braided with 150 longitudinal fibers and coated with a citrate-based polymer, poly(octamethylene citrate) (POC) composited with hydroxyapatite (HA).[25] Prior to this study, mechanical testing using previously published methods[20] was performed for the proposed surgical technique demonstrating the yield load at 3-mm of displacement (523.3 ± 50.2 N) and stiffness (212.1 ± 13.7 N/mm) were similar to the normal CCL in dogs of similar size to the dogs enrolled in our clinical study.[26]

An anesthesiologist induced and maintained anesthesia with individualized protocols. Each dog was aseptically prepared for surgery with a standard hanging limb technique and treated with perioperative antibiotics (Cephazolin 25 mg/kg, IV every 90-min). Arthroscopy was performed to confirm complete tear of the CCL, to inspect the medial and lateral menisci and to ensure no other pathology (e.g., osteochondrosis) existed. A medial arthrotomy was then performed to debride the torn CCL and when a medial meniscal tear when identified, treat with a partial meniscectomy of the injured portion. The surgical technique was slightly modified from previous descriptions of intra-articular reconstructions performed in dogs.[19,20] An aiming device (Arthrex, Naples, FL) was used to drive a 2.4 mm pin from the center of the origin of the CCL toward the lateral cortex of the femur at an angle of approximately 35° to the long axis of the frontal plane of the femur, exiting at the caudolateral femur. Establishing the drilling angle was assisted using a protractor with a swing arm. A 7 mm cannulated drill bit (Arthrex, Naples, FL) was then used to create the femoral bone tunnel. A tibial bone tunnel was drilled in a similar fashion from the insertion of the CCL at an angle of 55° to the long axis of the tibia in the frontal plane, exiting the medial tibial cortex.

The PET implant was passed through both tunnels and secured to the femoral cortex using a single bi-cortical screw and spiked washer (4.5-mm Bi-Cortical Post and spiked washer; Arthrex Vet Systems). The stifle was placed in a neutral position (∼135°), tension was applied to the implant by clamping the distal end of the implant and pulling on the clamp by hand, and the implant was secured to the medial tibial cortex using a single bi-cortical screw and spiked washer. The implant was wrapped around the screw so additional tension would be placed on the implant as the screw was tightened. Finally, the implant was secured within both tunnels using 5.5 mm absorbable interference screw (Citrelock-BP Tendon Interference Screw, Citrate Innovations LLC, Naples, FL) with the implants placed from the intra-articular aspect of the bone tunnels. Free ends of the implant were trimmed. After implant placement and based on previous work,[10,20] femoral-tibial translation was estimated to be <3.0 mm by finding no palpable femoral-tibial translation. The joint and soft tissues were copiously lavaged with sterile saline and closed in a routine manner. After postoperative radiography, a modified Robert Jones soft-padded bandage was placed on the surgically treated leg to help reduce postoperative limb swelling and cover the surgical incision until the time of discharge from the hospital. While perioperative analgesic protocols were individualized, all included an oral nonsteroidal anti-inflammatory drug and an opiate as the premedication, preoperative epidural and postoperative analgesic regimen until the time of discharge. Dogs were discharged 1 day after surgery with a nonsteroidal anti-inflammatory drug regimen for 1 week. Owners were instructed to restrict their pet's activity to 10–15-min leash walks 3–4 times daily for 8 weeks.[11] For weeks 8–12, owners were instructed to increase the length of the walks up to 30 min and to include trotting in a straight line. After 12 weeks, normal activity was allowed.

2.2 | Adverse events

Adverse events during any stage of the study were defined in accordance with previously reported literature,[27] recorded, and managed as clinically indicated. If a major complication occurred, the intervention was considered a failure, the dog was removed from the study and treatment options specific to the complication were discussed (e.g., implant removal, antibiotics, nonsurgical management, stabilization via extracapsular method or osteotomy) and provided at no cost to the owner. Treatment failures were defined as (1) owner reporting visible lameness at home, (2) a dog having greater than 20% limb asymmetry on gait analysis at 6-months after surgery,[10] or (3) a torn implant at second look arthroscopy. When treatment failure occurred treatment options, including surgery, were discussed with the owners.

2.3 | Outcome measures

All outcome measures were recorded before implant surgery and 6 months (or earlier when a dog was considered a treatment failure prior to 6 months) after surgery. At 6-months a general orthopedic examination was performed to identify adverse events that were not reported (including CCLD developing in the opposite, previously normal, stifle). Radiography was also performed immediately after every surgery. Documentation of femoral-tibial translation (none, minimal or obvious) was performed before (under general anesthesia) and after all surgeries (under general anesthesia) and during each orthopedic examination.[11] Owners completed a LOAD questionnaire[28] to ascertain owner perception of pet disease presence and severity in the home environment. Instructions for completion of the questionnaire were provided prior to each visit by the same technician. Force platform gait analysis (Model OR 6–5, AMTI, Watertown, MA) was used to objectively assess limb function. Gait analysis was performed at a walk (velocity 1.0 to 1.3 m/s; acceleration ± 0.05 m/s/s) and the first five valid trials were used for data evaluation. Orthogonal radiographs (mediolateral and craniocaudal) were used to evaluate the status of the radiopaque implants (interference screws, bicortical screws and washers). Arthroscopy was performed 6-months postoperatively using subpatellar portals just medial and lateral to the patellar tendon to document the status of intra-articular structures (e.g., medial meniscus) and the integrity of the PET implant. A system to arthroscopically evaluate the implants was modified from a previous description of second-look arthroscopy of anterior cruciate ligaments.[29] Implants were predefined as intact if there was no visible fraying, the implant was taut with probing and femoral-tibial translation was absent or minimal. Implants were defined as partially intact if visible implant fraying was present, the remaining implant was taut with probing, and femoral-tibial translation was absent or minimally present. Implants were defined as torn if the implant was not continuous, was loose with probing or obvious femoral-tibial translation was present.

2.4 | Statistical analysis

For the LOAD questionnaire, preoperative and 6-month total scores were evaluated. Only collected data was used for dogs with incomplete data sets ($n = 1$). For gait analysis, preoperative peak vertical force as a percentage of bodyweight (PVF) and vertical impulse as a percentage of bodyweight (VI) and asymmetry indices of rear limb PVF {[PVF Asym = (Normal PVF-Affected PVF)/(Normal PVF + Affected PVF)*0.5]*100} and VI {[VI Asym = (Normal VI-Affected VI)/(Normal VI + Affected VI)*0.5]*100} were calculated, averaged and recorded. In addition, gait analysis data was reported as net ground reaction force [NetGRF = (PVF/42.55) + (VI/14.09)], to provide context to the GRF data relative to a population of normal dogs.[10,11] Preoperative and 6-month limb function were evaluated. Data were checked for spurious observations by using summary statistics and plots. Assumptions of normality were tested and confirmed using a Shapiro–Wilk test. A Wilcoxon test was used to test change within the group over time. Data are presented as mean ± standard deviation. Statistical significance was defined as $p < .05$.

3 | RESULTS

Ten dogs were enrolled in the study; dog breeds included Labrador retriever (5), mixed breed (2), German shepherd (1), Golden retriever (1) and a Greater Swiss mountain dog (1). Mean dog age (age in years and months was converted to years plus months/12 to two decimals) and weight were 6.36 ± 2.2 years (median: 5.75; range: 4.92–10.67 years) and 32.0 ± 2.3 kg (median: 31.85; range: 28.1–35.4 kg), respectively. At the time of the initial surgery, a torn medial meniscus was identified in three stifles, and partial, caudal pole meniscectomy was performed.

3.1 | Adverse events

One major complication occurred in one dog during the study. Two weeks after surgery, at the time of suture removal, marked stifle swelling was identified by the dog's local veterinarian and an oral, broad-spectrum, bactericidal antibiotic (cephalexin 22 mg/kg orally every 12 h) was prescribed. The dog remained on this antibiotic until recheck examination 7-weeks postoperatively. At that time, the dog was primarily nonweightbearing on the operated leg and would only toe-touch during a slow walk. The stifle was moderately swollen and painful, but no abnormal femoral-tibial motion was present (performed when sedated for radiography). Radiographs showed stifle swelling with bone loss in both the femoral and tibial bone tunnels (Figure 1). Surgical exploration with removal of the implants and culture and sensitivity were recommended. At the time of surgery, the PET implant, interference screws and medial meniscus were intact and appeared to be functioning. However, because of the risk of infection all implants were removed and the dog was removed from the study. After flushing the affected areas with saline an aerobic culture was collected; no growth was reported. In spite of these results, antibiotic treatment was continued for 3-weeks after surgery. At the time of manuscript submission no additional surgery had been performed on this dog because the owner was satisfied with their pet's function at home.

3.2 | Outcome measures

Owner LOAD scores before surgery were 24.0 ± 5.9 (range: 16–36) and decreased ($p = .008$) to 11.6 ± 6.8 (range: 2–24) after surgery (Figure 2). Limb asymmetry (PVF asymmetry + VI asymmetry/2) before surgery was 50.82 ± 25.29% and it decreased ($p = .002$) to 7.12 ± 29.91% after surgery (Figure 2). Peak vertical force (% BW) before surgery was 30.35 ± 4.73 and it increased ($p = .009$) to 39.27 ± 2.59 after surgery. Vertical impulse (% BW) before surgery was 9.01 ± 2.29 and it increased ($p = .017$) to 12.1 ± 1.57 after surgery. NetGRF before surgery was 1.37 ± 0.25 and it increased ($p = .004$) to 1.76 ± 0.16 after surgery. At the 6-month recheck, femoral-tibial translation (performed before and after arthroscopy under general anesthesia) was recorded as none in six dogs and minimal in three dogs.

Radiography performed 6 months after surgery showed no adverse events associated with the radiopaque implants. The interference screws were noted as partially absorbed in all stifles without evidence of migration. (Figure 3) At the time of 6 month second-look arthroscopy, medial meniscus

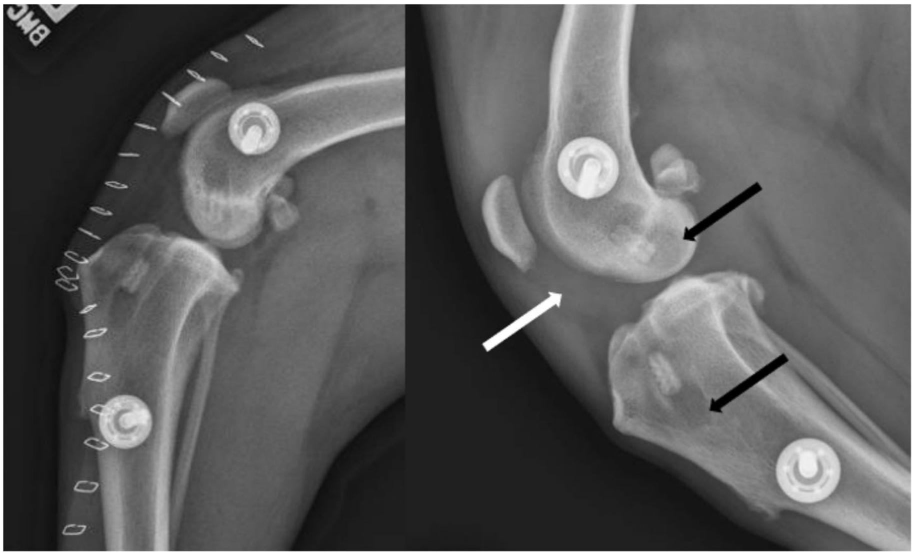

FIGURE 1 Mediolateral radiographs (immediate postoperative radiograph on the left; 7-weeks after surgery on the right) of the stifle obtained on the dog with worsening of lameness and stifle swelling (white arrow) 7-weeks postoperatively. Note the loss of bone in both femoral and tibial tunnels (black arrows)

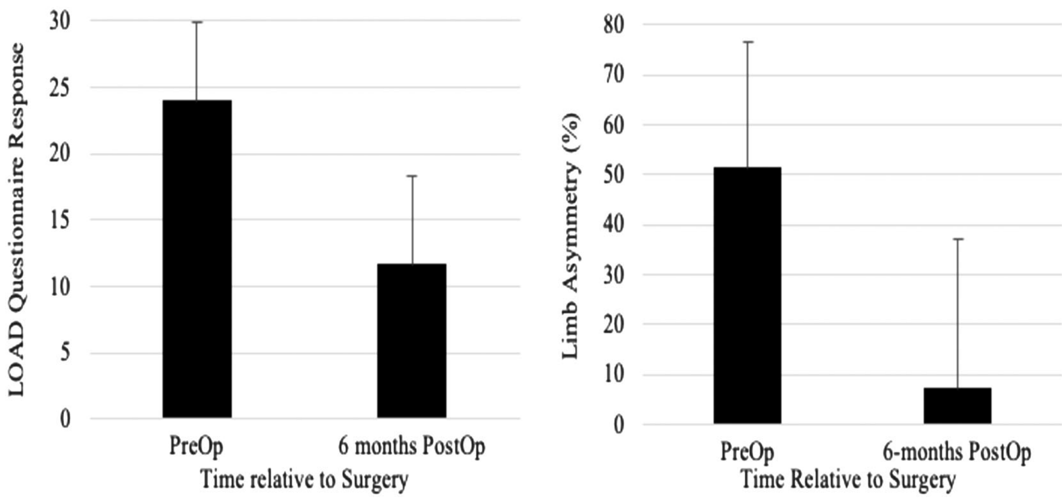

FIGURE 2 Responses to the Liverpool Osteoarthritis in Dogs questionnaire (left) and limb asymmetry (right); both measures decreased from before surgery to 6-months postoperatively

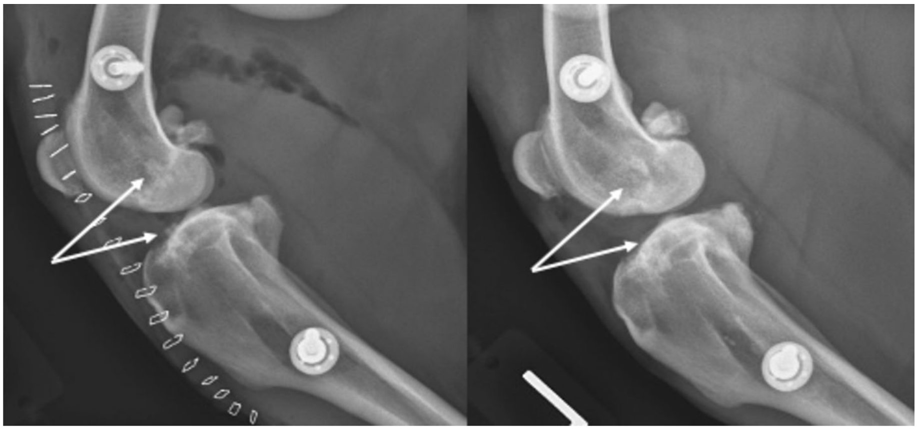

FIGURE 3 Immediate postoperative (left) and 6-month preoperative mediolateral stifle radiographs. Note the partial resorption of the interference screws (white arrows) that was noted in all stifles at the 6-month time point

FIGURE 4 Arthroscopic images of an intact (left), partially torn (middle) and completely torn (right) PET implant 6-months postoperatively. The implant which appears intact is partially covered with tissue. Individual fibers appear separated from the main implant in the partially torn implant. Note the presence of midbody tear in the torn implant (right) with portions on the left and right of the image; the caudal cruciate ligament is in the background

status had not changed in any case. The PET implants were found to be completely intact and functioning in two stifles, partially intact and functioning in four stifles and completely torn in three stifles.[29] (Figure 4) Based on visual inspection of the partially and completely torn PET implants, implant failure was by a tear in the midbody of the implant.

4 | DISCUSSION

In this prospective, pilot, case series a validated clinical measurement instrument for osteoarthritis and gait analysis results were statistically improved at the 6-month postoperative evaluation compared to the preoperative evaluation. Thus, we rejected our null hypothesis that 6-month postoperative limb function in dogs receiving a PET implant would not improve compared to preoperative function using owner Liverpool OA in Dogs (LOAD) questionnaires and limb asymmetry as primary outcome measures.

This investigation led to several findings that could help advance intra-articular reconstruction. Although the enhanced PET implant stabilized with bi-cortical screws, spiked washers and absorbable interference screws had acceptable ex vivo mechanical properties, only two of 10 dogs had completely intact PET implants 6 months postoperatively, an outcome that is too inconsistent to merit additional clinical investigation. Although it is unclear which initial mechanical characteristics might be required for a reconstruction technique to be successful,[20] in the author's opinion, ex vivo load to failure mechanical properties may only help predict which implant/stabilization combinations have less chance of survival in an in vivo environment. However, these, and other,[11] clinical results suggest that they do not predict intermediate or long-term clinical survival. Since these implants failed mid-body, it is possible that cyclic fatigue contributed to their mechanism of failure. Future studies could consider investigating the number of cycles that are clinically relevant in a dog recovering from CCLD surgery via a validated activity monitor, identifying a stifle brace that reduces the mechanical requirements of a CCL surgery or combining intra-articular reconstruction with an osteotomy technique to potentially reduce strain[30] on the reconstruction.

The stabilization technique, empirically, was technically simple with no intermediate term implant complications. Technical challenges during preclinical and clinical work with a previously described technique[10,11] led to identification of a technique that capitalized on common techniques to stabilize a graft or implant (i.e., combining bicortical screws, spiked washers and absorbable interference screws) while using equipment and procedures common to veterinary orthopedics. In this study, PET failures appeared to be associated with midbody implant failure. Since we did not identify failures or complications associated with the method of implant fixation, it was technically simple and only a slight modification from previously published methods,[19,20] it has acceptable ex vivo mechanical performance[26] and the technique could likely be performed using a minimally invasive approach we think this method of stabilization could be considered for future stabilization of a graft or implant.

These results, if considered with a previous report,[11] support the use of second look arthroscopy as a clinical research tool as long as there is full ethical approval of the methods and informed client consent that addresses the risks of the procedure. Owner questionnaire and gait analysis findings incompletely describe outcome with respect to stifle joint function. Owner LOAD questionnaires and limb asymmetry improved in nine of nine stifles that reached the 6-month time point, yet only six of nine implants were completely or partially intact and functional. The dogs in this study, beyond the one that had a major complication, clinically improved. When 6-month patient outcomes from this study are compared with a previous report where intra-articular reconstruction was performed for CCLD and grafts were intact and functioning at 1-year,[11] both show similar improvement. In the study population presented in this study, mean LOAD scores were 11.6 compared to just under 10[11] and mean limb asymmetry was 7.12% compared to just over 10.[11] Thus, it seems reasonable to conclude that clinical improvement at 6-months from CCLD surgery is more complex than just reconstructing stifle mechanics and may include other factors such as addressing meniscus status, weight loss, regular activity, and so forth. However, if we consider factors that might influence patient outcome one or more years after surgery (e.g., late meniscal tear and OA progression) reconstructing stifle mechanics should remain a treatment goal.

The PET implant used as an implant in this study is referred to as enhanced because of the manufacturing techniques used to improve its biomechanical and biochemical properties beyond the general-purpose polymer.[21,23,31] For example, it is reported that resistance to traction varies with the number of longitudinal PET fibers and when there are greater than 100 strands it is far stronger than the human anterior cruciate ligament.[23] The osseointegration process of PET is impeded by its native hydrophobic properties and biocoatings, such as hydroxyapatite and citrate-based coatings, have a positive effect in the induction of osseointegration within a bone tunnel.[22,31] Finally, braiding techniques have improved hydrophilicity and mechanical strength of PET implants[18,23] and the implant diameter was larger than that previously described in a clinical veterinary study.[19] Regardless, research not performed in a clinical veterinary setting must be interpreted carefully. It is important to note that this polymer is nonabsorbable; an absorbable implant might provide a reduced risk of late infection.[32]

There are several limitations to this study. Assessment of the implant was subjective and it is possible that implants assessed as intact or partially intact were not functional. We palpated for femoral-tibial translation and arthroscopically probed the implant to assess implant function in this pilot study; objective assessment of femoral-tibial instability[8] should be considered as an outcome measure before any new procedure is adopted. The final angle of the femoral and tibial tunnels insertion was not documented. Although we found it relatively easy to estimate the angles drilled, we did not perform postoperative computed tomography to confirm them. In contrast to a previous report,[11] we did not have problems establishing the angle desired because of interference from the femoral condyle. Patient anatomy may have contributed to this difference. We did not document implant tension during surgical placement. We pulled on the implant to make it as tight as possible when placing the screw and spiked washer, ensured the implant was wrapped around the screw in a manner such that tension within the implant would be increase as the screw was tightened and documented the lack of femoral-tibial translation after implantation. To increase tension in the implant beyond what was achieved here, specialized equipment would need to be developed. The statistical power of this exploratory study was intentionally low and there was no control group. We elected to study 10 dogs for 6-months in this investigational, pilot study because we felt it would provide enough clinical information to justify a go-no go decision for future research while limiting risk to patients. A large, randomized, multi-institutional clinical trial comparing a new technique to standard of care should be considered only if justified by strong supportive data of the investigational technique. We did not include a lameness examination by the veterinarian as an outcome measure. This decision was made because a subjective outcome measure (owner survey) was used, an objective outcome measure of limb function was used, the study was not blinded so the results would be biased and lameness examinations has been shown to provide unreliable results.[33] Finally, only intermediate term findings are reported. While long term follow-up was not a component of this study design, owners were informed that treatment of implant related complications (e.g., lameness, pain, infection) would be financially covered (if treatment was performed at the study site) for 1-year after the conclusion of their participation in the study.

Isometric placement of an enhanced PET implant in dogs with spontaneous CCLD improved function, as measured by owner survey and gait analysis, despite implant failure in eight of 10 dogs. Although this technique led to good ex vivo and initial in vivo mechanical characteristics, only 2/10 implants remained intact and fully functional at 6 months after surgery. Although dogs may clinically improve without survival of the reconstructive surgery for CCLD,[11] the high failure rate of the technique reported here prevents further consideration of this implant as a replacement for the CCL in dogs.

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CONFLICT OF INTEREST

The authors declare no conflicts of interest related to this report.

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