Clinical Comparison of a Novel Extracapsular Stabilization Procedure and Tibial Plateau Leveling Osteotomy for Treatment of Cranial Cruciate Ligament Deficiency in Dogs

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Submitted March 2009
Accepted August 2009

DOI:10.1111/j.1532-950X.2010.00658.x

Objective: To develop and test a novel extracapsular technique, TightRope CCL technique (TR), and compare its 6-month clinical outcomes to tibial plateau leveling osteotomy (TPLO) in dogs with cranial cruciate ligament (CCL) deficiency.
Study Design: Prospective clinical cohort study.
Animals: Medium, large, and giant breed dogs ($n = 47$) with CCL deficiency.
Methods: Before clinical use, TR was evaluated by mechanical testing and the surgical technique was developed and evaluated in canine cadavers. For the clinical study, dogs were assigned to either TR ($n = 24$) or TPLO ($n = 23$) groups and the assigned technique performed after arthroscopic assessment and treatment of joint pathology. Postoperative management was standardized for both groups. Outcome measures were performed immediately postoperatively and up to 6 months after surgery and included complication types and rate, subjective measurement of cranial drawer and tibial thrust, subjective assessment of radiographic progression of osteoarthritis (OA), and function using a validated client questionnaire (6 months only).
Results: TR with a fiber tape suture had superior mechanical properties for creep, stiffness, yield load, and load at failure. Duration of anesthesia, total surgical time, and stabilization procedure (TR versus TPLO) were all significantly ($P < .001$) shorter for TR compared with TPLO. Complications requiring further treatment occurred in 12.5% of TR cases and 17.4% of TPLO cases. No significant differences were noted between groups for cranial tibial thrust, but cranial drawer was significantly ($P < .05$) lower in TR stifles at all postoperative time points. No significant differences were noted between groups for radiographic OA scores. No statistically or clinically significant differences were noted between TR and TPLO for scores for each of the client questionnaire categories.
Conclusions: TR resulted in 6-month outcomes that were not different than TPLO in terms of radiographic progression of OA and client-evaluated level of function. TR was associated with shorter anesthesia and surgery times as well as a lower complication rate.
Clinical Relevance: The TR technique is safe and effective and can be considered an appropriate surgical option as part of the overall treatment plan for CCL deficiency in dogs.

Cranial cruciate ligament (CCL) deficiency in dogs is a common and costly problem for which there are multiple treatment modalities. Whereas numerous techniques have been investigated, none have proven optimal in terms of technical ease, associated costs, prevention of secondary pathology, complication rate, complication types, or mid- to long-term outcomes. No technique for treatment of CCL deficiency has been shown superior to others in terms of functional outcome.[1–6] Recent evidence suggests that mid- and long-term outcome measures including kinetics, kinematics, and radiographic progression of osteoarthritis (OA) show no statistically or clinically significant differences

Presented in part at the 35th Annual Veterinary Orthopedic Society Conference, Big Sky, MT, March 8–15, 2008.

between tibial plateau leveling osteotomy (TPLO) and extracapsular suture stabilization (ESS) techniques, for functional success.[1–5]

Reported complication rates for TPLO, ESS, tibial tuberosity advancement, and cranial closing wedge osteotomies range from 17% to 59%,[1,7–19] which is less than optimal for surgical procedures performed hundreds of thousands of times annually. Based on the peer-reviewed literature, osteotomy procedures for CCL deficiency in dogs consistently have higher overall and major reported complication rates than other CCL techniques.[1,7–14] Therefore, we sought to investigate a stifle stabilization technique that had the potential to address perceived shortcomings of current techniques, specifically to incur minimal morbidity, address all aspects of CCL deficiency, allow for repeatable placement in the most isometric position possible, and consistently result in successful functional outcomes with low overall and major complication rates in a cost effective manner. We prospectively compared the outcomes of a novel ESS procedure called the TightRope CCL technique (TR), to TPLO in dogs with CCL deficiency. We evaluated outcomes by assessing subjective measurement of cranial drawer and cranial tibial thrust at 8 weeks and 6 months after surgery, and patient function using a validated client questionnaire[20] and subjective assessment of radiographic progression of OA[2] at 6 months after surgery with the a priori clinically significant effect size set at 10% differences for all outcome measures.

MATERIALS AND METHODS

Feasibility in Cadavers and Mechanical Testing of Implants

Before starting a prospective clinical trial, the surgical technique for the TR procedure was developed using the novel device and implantation system (TightRope CCL®, Arthrex Vet Systems, Naples, FL) in large-breed canine cadavers (n = 14) euthanatized for reasons unrelated to this study. Surgical approach, order of procedural steps, drill hole entrance and exit points, and techniques for implant placement, tensioning, and securing as subsequently described were determined.

Additionally, the mechanical properties of 2 different TR configurations (TR with a fiber tape suture [FiberTape, Arthrex Vet Systems] and TR with #5 fiber wire suture [Fiberwire, Arthrex Vet Systems]) were determined and compared with 4 different commercially available ESS systems: a suture system using #5 fiber wire suture (CCL Suture Kit, Arthrex Vet Systems) with knot fixation (5FW), 80# test monofilament leader line with crimp clamp fixation (Securos, Fiskdale, MA; MLL), XGEN CCR System with #5 OrthoFiber (Securos; XGEN), and the LigaFiba Iso Toggle System with braided polyethylene fiber (Jorgensen Laboratories, Loveland, CO; LF). Mechanical loading of the constructs was performed using an axial servohydraulic dynamic testing system (Instron 8871, Instron, Canton, MA) with a 5 kN load cell attached to the crosshead. Two clevis and dowel fixtures were secured to the crosshead and the testing surface. Two custom aluminum blocks were used to simulate the dimensions and orientation of the femur and tibia of a large-breed dog (based on measurements from the cadaver work) at a standing angle so as to mimic the clinical situation for ESS. The construct samples were prepared by securing the 2 custom fixtures 10 mm apart in a vice. Loading of the constructs was controlled using commercially available software (Wavemaker, Instron). The constructs were given a 5 N pre-load then cyclically loaded under load control from 10–100 N sinusoidally, at 1 Hz for 100 cycles. After cycling, 5 N preload was re-established and the constructs were loaded to failure at 20 mm/min by distracting the aluminum blocks to mimic uniplanar cranial translation of the tibia. Data were collected at 500 Hz. Yield load, ultimate load, stiffness, and cyclic displacement (total displacement in mm after cyclic testing) for each sample were calculated from load displacement curves using software (Origin Scientific Graphing and Analysis Software, OriginLab Corp., Northampton, MA). Mode of failure for each construct was recorded.

Prospective Clinical Cohort Study

Inclusion Criteria. The clinical component of this study met the guidelines of our institution's animal care and use committee for privately owned canine patients. Dogs admitted (October 2006–April 2007) for unilateral hindlimb lameness confirmed to be caused by CCL deficiency were considered for study inclusion. Dogs were enrolled when the owners consented to TR or TPLO, and to allowing relevant short- and mid-term data to be collected, analyzed, and reported. Dogs were excluded when concurrent orthopedic and/or neurologic disorders requiring treatment were diagnosed (including contralateral CCL deficiency), dogs weighed < 15 kg, or owners did not consent to treatment or follow-up data collection.

Diagnosis and Procedure Selection. CCL deficiency in enrolled dogs was based on palpation of affected stifle joint effusion, pain, periarticular fibrosis, abnormal cranial drawer, and/or abnormal cranial tibial thrust, as well as radiographic findings consistent with secondary OA. After diagnosis, written consent for surgical treatment was obtained and the dog was scheduled for surgery. Tibial plateau angle (TPA)[21] was determined from preoperative radiographs and recorded in the medical record. Treatment type (TR, TPLO) was not completely randomized, but rather was determined by discussion between the surgeon (J.C.) and the client before surgery based on the client's willingness to have 1 of the procedures, or either procedure, performed on their dog. Procedure type was determined by the client when that client was only willing to have 1 of the procedures performed (n = 21), and was determined by randomized paired assignment alternating between TPLO and TR when the client was willing to have either procedure performed (26). All clients received a financial incentive (total bill for all procedures in both groups was identical and fixed) to participate in this study.

Operative Preparation. All surgical procedures were performed by 1 surgeon (J.C.). Dogs were premedicated, anesthetized, positioned in dorsal recumbency, and prepared for aseptic surgery of the affected stifle using a hanging limb technique. Cefazolin (22 mg/kg intravenously [IV]) was administered at induction of anesthesia, every 90 minutes during surgery, and then every 6 hours after surgery for 24 hours. Strict adherence to aseptic technique was followed throughout all aspects of the procedure. The affected stifle of each dog was arthroscopically evaluated[22] and treated as necessary based on CCL, articular cartilage, and meniscal pathology noted. For all dogs, the CCL was completely debrided regardless of remaining amount. No meniscal releases of any type were performed, but damaged meniscus, when present, was treated by partial meniscectomy. TR or TPLO was then performed to correct stifle instability.

TPLO Procedure. TPLO was performed as previously described[23] by an experienced TPLO-certified, board-certified surgeon (J.C.).

TR Procedure. For TR, the TR device with fibertape was used, which is designed for dogs weighing > 18 kg. A skin incision was made on the lateral aspect of the stifle from the lateral fabella to lateral tubercle of insertion of the biceps tendon/iliotibial band (tubercle of Gerdy in human nomenclature). The lateral fascia was incised along the same line just caudal to the tendon of insertion of the biceps femoris muscle to expose the lateral fabella, lateral joint capsule, and tubercle of Gerdy. After careful palpation, the TR guide wire was positioned 2 mm cranial and distal to the lateral fabella–femoral condyle junction and within the caudal portion of the lateral femoral condyle. The guide wire was advanced into the distal femur using a wire driver or drill at a proximally directed angle so that the wire traversed the distal femur and exited the distal diaphysis of the femur on the medial side immediately caudal to the vastus medialis muscle at the level of the proximal pole of the patella with the stifle at a weight bearing angle ($\sim$140°). Once optimal placement of the guide wire was ensured so that its entry point was in the caudal aspect of the lateral femoral condyle, it did not enter the joint, and its exit point allowed for button placement directly onto dense cortical bone of the distal femur, then a 1.5–2 cm incision was made over the exit point of the guide wire with the stifle in extension and sharp dissection was continued to facilitate subsequent seating of the femoral button directly on to femoral bone.

The TR cannulated drill bit in a drill was placed over the guide wire and used to drill a hole in the femur from lateral to medial over the wire after its path. Once the drill bit exited the medial aspect of the femur through the medial incision, the guide wire was pulled out of the drill bit medially. The point of the TR needle was then placed in the cannulation channel of the drill bit and pushed through the femoral tunnel from medial to lateral following the drill bit as it was retracted laterally. Tension was then applied laterally on the TR needle and medially on the fiber tape suture to align the TR toggle button along the axis of the femoral tunnel. The TR toggle button was then advanced through the femoral tunnel from medial to lateral until it exited on the lateral aspect of the stifle. The femoral button was left outside the skin on the medial aspect of the stifle.

The long digital extensor (LDE) tendon was palpated within the muscular groove of the proximal lateral aspect of the tibia and a 5 mm incision was made in the fascia and joint capsule immediately caudal and parallel to the LDE. The LDE was gently retracted cranially to allow for placement of the TR guide wire within the muscular groove caudal and slightly distal to the tubercle of Gerdy. The guide wire was advanced into the proximal tibia using a wire driver or drill at a craniodistally directed angle so that the wire traversed the proximal aspect of the tibia and exited the proximal metaphysis of the tibia on the medial side midway between the caudal border and tibial crest. Once optimal placement of the guide wire was verified, the TR cannulated drill bit was placed over the guide wire and used to drill a hole in the tibia from lateral to medial over the wire. Neither the wire or drill bit exited the skin over the medial aspect of the tibia and no medial skin incision was made. The drill bit and guide wire were retracted, and the TR needle was advanced through the tibial tunnel from lateral to medial while the LDE was retracted cranially. The TR needle was pulled through the skin on the medial aspect of the stifle and the TR toggle button was advanced through the tibial tunnel from lateral to medial until it exited into the subcutaneous space on the medial aspect of the stifle. The toggle button was then manually flipped in the subcutaneous space to align perpendicular to the tibial tunnel and the fiber tape suture pulled on the lateral side of the tibia to seat the toggle firmly against the medial tibial cortex. The TR pull-through suture was cut and the TR needle and pull-through suture removed.

The fiber tape suture was pulled tight on the lateral aspect of the stifle and all twists removed so that the strands were flat and firmly against the lateral joint capsule deep to the fascia. The fiber tape suture strands were pulled taut on the medial aspect of the femur and the TR button advanced through the medial incision to seat firmly and completely on distal femoral cortical bone. The stifle was held at a weight-bearing angle and the free ends of the fiber tape suture were tied over the button (Fig 1). The fascia of the vastus medialis and sartorius was apposed over the femoral button and knot, and the subcutaneous tissues and skin closed routinely. The lateral fascia was imbricated using 2–3 modified Mayo mattress sutures and the lateral subcutaneous tissues and skin closed in layers.

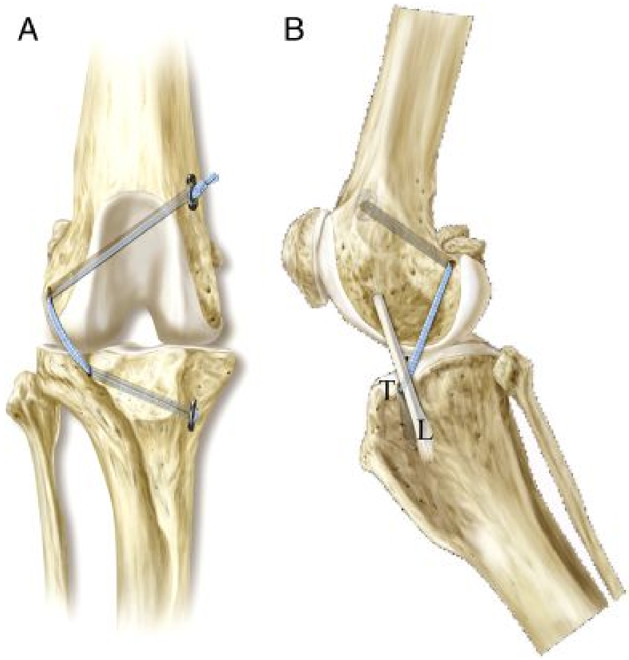

Figure 1 Illustrations of a canine stifle with the TightRope CCL implant positioned and viewed from the cranial (A) and lateral (B) aspects. T, tubercle of insertion of the biceps tendon/iliotibial band (tubercle of Gerdy); L, tendon of origin of the long digital extensor muscle.

All intraoperative findings and complications were determined and recorded.

Postoperative Care. Immediate postoperative radiographs were obtained, a full-limb soft-padded bandage applied, and dogs were admitted to the intensive care unit for postoperative management. TPA was measured from postoperative radiographs and recorded for all TPLO cases. Postoperative management was standard for elective orthopedic cases at our institution and included 16–20 hours in the intensive care unit, administration of IV cefazolin, IV fluids, IV analgesics, bladder management, and bandage care. All dogs were moved to the surgery wards the day after surgery. The soft-padded bandages were maintained for 12–36 hours depending on the amount of swelling and the appearance of the incision, and then removed. Dogs were discharged 2–5 days after surgery.

Owners were instructed to administer a nonsteroidal anti-inflammatory drug (NSAID) for 10 days after surgery and tramadol (1–4 mg/kg orally twice daily) for 3 days (dosing based on concomitant NSAID administration and clinical experience). Instructions for postoperative care were standardized for all dogs and included monitoring and care of the incisions with staple removal 10–14 days after surgery, strict confinement of the dog when unobserved, strict activity restriction limited to short-leash walking for urination, defecation, and 5-minute maximum short-leash walks for 8 weeks after surgery, with recheck examinations at 8 weeks and 6 months after surgery. All postoperative complications observed and reported were assessed, addressed accordingly, and recorded.

Outcome Measures

All dogs were assessed ~8 weeks and 6 months after surgery. Physical and orthopedic examinations were performed and all findings recorded. Dogs were sedated (medetomidine IV) and cranial drawer and cranial tibial thrust were subjectively measured in millimeters by 1 examiner (J.C.) and recorded. Both cranial drawer and tibial thrust were used as outcome measures to include data that most clinicians would incorporate in a comprehensive preoperative and postoperative assessment of their patients, to provide multiple measures of postoperative stifle stability, and to standardize the outcome measures for both cohorts. With the dog still sedated, orthogonal projection digital radiographs of the treated stifles were obtained and immediately assessed for healing, implant status, and radiographic evidence of pathology. Radiographs were subsequently scored by one examiner (C.C.) for degree of radiographic OA using a reported system.[24] Function was evaluated 6 months postoperatively using the 11-point Texas A&M Client Questionnaire.[20]

Data Analysis

Statistical analyses were performed using software (Sigma Stat®, San Rafael, CA). Means ± SD were determined for each outcome variable. Data were assessed for significant differences among construct types for mechanical testing using 1-way ANOVA. Because of unequal variance, a Kruskal–Wallis 1-way ANOVA on Ranks was used to compare differences in stiffness. Analyses for differences between TPLO and TR was performed using t-test for continuous data (age, weight, TPA, cranial drawer, tibial thrust, visual analog scores [VAS] from client questionnaire) and rank sum test for categorical data (radiographic score). A z-test was used to examine differences in complication rates. Significance was set at $P < .05$.

RESULTS

Mechanical Testing (Table 1)

TR with fiber tape suture had significantly ($P < .001$) lower cyclic displacement than all other constructs tested. TR with fiber wire suture had significantly lower cyclic displacement ($P < .003$) than 5FW, MLL, XGEN, and LF. No other differences in cyclic displacement were significant.

TR with fiber tape suture had significantly ($P < .05$) greater stiffness than 5FW, MLL, XGEN, and LF. TR with fiber wire suture had significantly greater stiffness ($P < .05$) than MLL and XGEN. No other differences in stiffness were statistically significant.

TR with fiber tape suture and LF had significantly ($P < .001$) greater yield loads than TR with fiber wire suture, 5FW, MLL, and XGEN. TR with fiber wire suture

Table 1 Mean (± SD) Values for Materials Testing of CCL Implants

	Tightrope with Fiber Tape	Tightrope with Fiber Wire	#5 Fiber Wire with Knot	80# Monofilament with Crimp Clamp	XGEN CCR System with OrthoFiber	LigaFiba Iso Toggle System
Cyclic displacement (mm)	1.6 ± 0.2^{a}	2.5 ± 0.2^{b}	3.0 ± 0.4^{c}	3.3 ± 0.2^{c}	3.9 ± 0.3^{c}	3.3 ± 0.9^{c}
Stiffness (N/mm)	164 ± 24^{a}	$78 \pm 9^{a,b}$	$57 \pm 8^{b,c}$	43 ± 1^{c}	40 ± 5^{c}	$66 \pm 15^{b,c}$
Yield load (N)	922 ± 188^{a}	604 ± 98^{b}	386 ± 121^{c}	343 ± 21^{c}	$445 \pm 158^{b,c}$	919 ± 253^{a}
Ultimate load at failure (N)	$1{,}002 \pm 109^{a}$	637 ± 89^{b}	$493 \pm 152^{b,c}$	388 ± 32^{c}	$502 \pm 37^{b,c}$	$1{,}112 \pm 10^{a}$

Within a row, different superscript letters indicate groups significantly different from the other ($P < .05$).

had significantly greater yield load than fiber wire suture with a knot ($P = .006$) and the crimped monofilament ($P = .001$). No other differences in yield load were statistically significant.

TR with fiber tape suture and LF had significantly ($P < .001$) greater ultimate loads at failure than TR with fiber wire suture, 5FW, MLL, and XGEN. TR with fiber wire suture had significantly ($P < .001$) greater ultimate load at failure than the crimped monofilament. No other differences in ultimate load at failure were statistically significant.

Dogs

Twenty-four stifles in the TR group and 23 stifles in the TPLO group met inclusion criteria. There were no significant differences in age (TR mean = 64.7 ± 26.7 months [range, 12–134 months]; TPLO mean = 68.4 ± 30.2 months [range, 21–134 months]), weight (TR mean = 38.5 ± 14.3 kg [range, 21.0–80.5 kg]; TPLO mean = 38.8 ± 16.3 kg [range, 17.6–83.8 kg]), or preoperative radiographic score (TR mean = 8.0 ± 4.2 [range, 1–16]; TPLO mean-6.8 ± 3.3 [range, 1–15]) between groups. Preoperative TPA for TR dogs (mean = 28.2 ± 3.5°; range, 20–34°) was significantly ($P = .034$) higher than for TPLO dogs (mean-25.8 ± 3.4°; range, 19–31). Mean postoperative TPA for TPLO dogs was 5.7 ± 2.1° and range was 1–11°. Pre- and postoperative TPA had no detectable effects on outcome measures studied, but the data are included to show that no bias for lower TPA in TR dogs occurred.

Mean duration of anesthesia (including preparation, performing epidural anesthesia, arthroscopy, TR or TPLO, postoperative radiographs, bandaging, and transport to recovery) for dogs in the TR and TPLO groups was 109.9 ± 16.5 minutes (range, 79–142 minutes) and 133.9 ± 23.7 minutes (range, 98–192 minutes), respectively. Total surgical duration including arthroscopic procedures, ranged from 27 to 60 minutes (mean, 40.8 ± 8.1 minutes) for TR and 46 to 95 minutes (mean, 58.1 ± 11.9 minutes) for TPLO. Time to perform the TR or TPLO procedure alone ranged from 8 to 23 minutes (mean, 16.0 ± 4.8 minutes) and 23 to 61 minutes (mean, 33.8 ± 10.3 minutes), respectively. All of the measured times listed above were significantly ($P < .001$) shorter for TR compared with TPLO.

Based on subjective assessment of degree of CCL disruption, meniscal tears, synovitis, and articular cartilage lesions, joint pathology was considered equivalent between groups. Stifles treated with TR had 17 functionally complete CCL disruptions and 7 partial disruptions, whereas those treated by TPLO had 15 complete and 8 partial disruptions. All CCLs were completely debrided using a motorized shaver. TR stifles had 14 medial meniscal tears diagnosed at surgery and TPLO stifles had 16 medial meniscal tears at surgery. All meniscal tears were treated by partial meniscectomy using arthroscopic knives, graspers, basket forceps, and/or a motorized shaver. One TR stifle had a lateral discoid meniscus. Degree of synovitis and articular cartilage pathology was variable among dogs, but was considered similar between groups.

Complications

Major complication (those requiring further treatment) rates were not significantly different between TR (12.5%) and TPLO (17.4%). When minor complications (those not requiring further treatment) were also included for the 6-month assessment period, there was still not a significant difference between TR (29.2%) and TPLO (39.2%). After surgery, TR was associated with implant failure/instability (n = 1), infection (1), meniscal tear (1), and seroma (1) and TPLO with fracture/failure (2), infection (1), meniscal tear (1), patellar tendinosis (1), incisional problems (1), and marked swelling/seroma (3). Whereas TPLO had higher rates for major complications and total complications compared with TR, these differences were not statistically different (power > 0.68).

Cranial Drawer and Tibial Thrust

Subjective assessment of cranial drawer and cranial tibial thrust showed no statistically significant differences in preoperative measurements between treatment groups. No statistically significant differences were noted between TR and TPLO for cranial tibial thrust at any of the postoperative evaluation times; however, cranial drawer was significantly ($P < .05$) lower in TR stifles when subjectively assessed immediately postoperatively and at 8-week and 6-month evaluation time points (Fig 2).

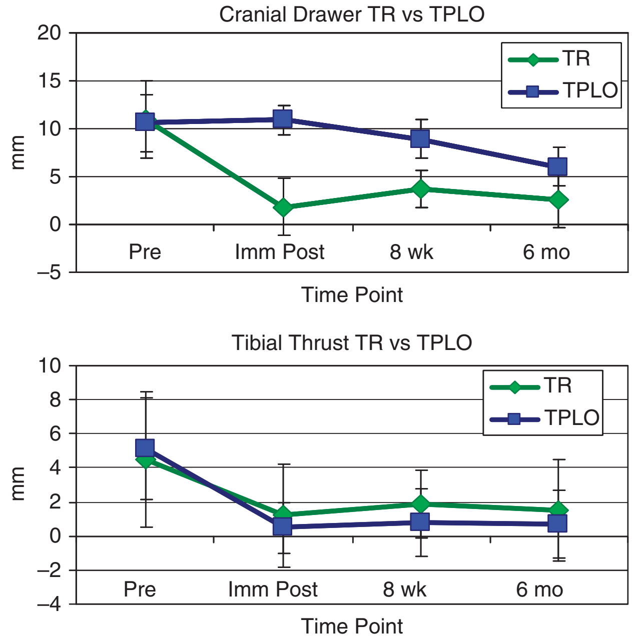

Figure 2 Mean ± SD cranial drawer (A) and cranial tibial thrust (B) subjective measurements in millimeters for the tightrope technique (TR) and tibial plateau leveling osteotomy (TPLO) groups at the 4 evaluation time points; no significant differences were noted for cranial tibial thrust. Cranial drawer was significantly ($P < .05$) lower in TR stifles immediately postoperatively and at 8 weeks and 6 months.

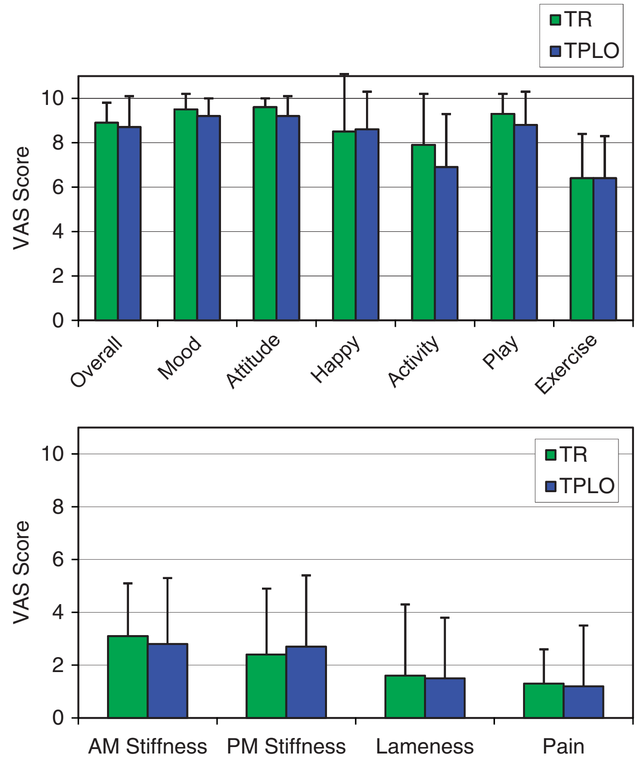

Figure 3 Mean ± SD visual analog scores (VAS) based on client evaluations at ~6 months after surgery using the Texas A&M Client Questionnaire.[20] The categories in which a higher score is considered superior are shown in A and the categories in which a lower score is considered superior are shown in B. No statistically or clinically significant differences were noted between the tightrope technique (TR) and tibial plateau leveling osteotomy (TPLO) groups for any category evaluated.

Radiographic Scoring

No significant differences were noted between TR and TPLO for change in mean radiographic OA score (TR = 1.9 ± 1.6; TPLO = 2.2 ± 2.4, respectively) or total radiographic score (TR = 10.4 ± 3.0; TPLO = 9.9 ± 3.5, respectively) at the 6-month postoperative end point. Both groups had numerically higher radiographic scores 6 months after surgery; however, the differences were not significant compared with preoperative scores for either group.

Functional Outcomes

No significant differences were noted between TR and TPLO for scores for each of the 11-point Texas A&M Client Questionnaire categories (Fig 3). Scores varied between groups as to which was numerically "better" for each outcome measure, but none were statistically different nor had a numerical difference of $> 10\%$, which was the level set for clinically significant differences in this outcome measure before data collection.

DISCUSSION

Based on procedure time, complication rate and severity, subjectively assessed stifle stability, radiographic progression of OA, and clients' assessment of function, the TightRope CCL technique, resulted in outcomes which were not different than TPLO for 6 months after surgery. The 2 cohorts were considered equivalent based on signalment, preoperative status of the joint, surgical treatment of the joint, and postoperative management. Therefore, for application to patients that are considered to be categorized within these cohorts, the data would suggest that TR and TPLO would have similar mid-term functional outcomes. As such, decision-making regarding choice of technique for similar patients can be appropriately made based on other factors including technical aspects of the procedure, client perception, cost, and safety.

The technical aspects of TR were a major consideration for clinical application from its inception. Our goals were to make it amenable to a minimally invasive approach, relatively easy to perform, repeatable, and consistently placed in a position that is considered as isometric as possible. Development of the technique in canine cadavers allowed us to assess this before clinical application so as to minimize patient morbidity and complications. The toggle fixation mechanism and the use of guide wires placed using consistent anatomic landmarks followed by cannulated drilling allow the TR device to be safely placed such that the functional fixation points are in locations similar to those determined most isometric for the lateral aspect of the canine stifle based on radiographic assessment.[25] Whereas the surgical approach described requires only small incisions, the TR technique is amenable to use with lateral or medial arthrotomies as well, and relative advantages and disadvantages exist for each. We recommend that the approach that allows the surgeon to accomplish the goals of surgery most accurately and consistently be used in conjunction with the TR technique for joint stabilization.

The other preclinical aspect of the development of the TR technique was comparative mechanical testing. In an attempt to most closely resemble the clinical situation for lateral extracapsular stabilization procedures, we set up a testing system that mimicked the anatomic configuration and dimensions of the canine stifle and included both cyclic and load-to-failure tests. The TR device proved superior for all variables examined. These superior mechanical properties combined with the theoretical advantages of bone tunnel fixation in both femur and tibia suggest that the TR technique may have potential advantages with respect to stifle stability and joint kinematics during formation of periarticular fibrosis compared with techniques which rely on soft tissue fixation or point-fixation. However, clinical comparisons among extracapsular techniques or *in vivo* assessment of joint kinematics after any of the surgical techniques used to address CCL deficiency has not been performed to our knowledge.

The primary stimulus for development of the TR technique was patient safety, specifically low morbidity as well as rate and severity of complications. In the peer-reviewed literature, osteotomy procedures are associated with higher and more severe complications in dogs undergoing surgery for CCL deficiency.[1,7–14] This trend held true in our study. TPLO was associated with numerically higher major and total complication rates compared with TR, but these differences were not statistically significant in our study; however, the difference in total complication rate reached the a priori level of 10% difference we considered clinically significant. In addition, surgery and anesthesia times were significantly shorter for TR compared with TPLO, which is consistently associated with lower morbidity.[26,27] The 12.5% major complication rate seen for TR in our study is the lowest reported in the peer-reviewed literature for initial clinical use of a CCL stabilization procedure.[1,7–19] Data collected from 21 centers initially using the TR technique have shown a major complication rate of 9.2% in the first 773 cases performed.[28]

Cost is definitely a common and valid consideration in choice of surgical technique in veterinary medicine. Like other techniques, costs associated with TR surgery will likely vary widely among centers. When determining associated costs, it would be important to consider those associated with anesthesia, time in surgery, instrument use and sterilization, and any complications that may occur in addition to instrument and implant costs.

Study Limitations

There are a number of limitations that must be considered when interpreting and applying the data from our study. While prospective with the 2 different surgical treatments as the primary variable examined, all dogs were not randomized to treatment; however, most dogs (55%) were randomized to treatment, and for the others, financial incentive was not a determining factor. Another limitation is that no blinded assessments were performed and functional outcome was determined based on a subjective, client-based scoring system and only at 6 months after surgery. Preoperative and short-term (8 week) assessments were not performed. We chose this instrument as our primary determinant of functional outcome because we wanted to make our data as clinically relevant as possible so that subsequent studies could be performed in any veterinary practice and clinicians could use the data to communicate to clients the results that they could expect to see after surgery. This questionnaire has been reported to be repeatable and valid for lameness assessment in dogs using force plate measurements as the reference standard,[20] and both treatments were evaluated using the same scoring system to addresses a spectrum of clinical function variables. All participating owners returned the completed questionnaire at study end, so that selection or exclusion bias was not an issue. However, the scoring system is not validated for performance and long-term outcomes were not assessed. Interestingly, no owner assessed their dog as "perfect" (e.g., score of 0 or 10 depending on category) in any category of assessment for either technique in our study. We suggest that this reflects an accurate assessment by clients based on the nature of CCL deficiency in dogs being a whole joint disease with secondary OA that no surgical technique can completely counteract. This also suggests that performance and detection biases were not issues in this study so that the outcomes data are valid and clinically applicable.

Poorer scores may have been associated with complications, but this was not separated out in our study because complications varied in severity and timing and our intent was to comprehensively evaluate "real life" outcomes without attempting to provide potential explanations for undesired outcomes as we believe that clinical decision making should be based on all available data. Based on experimental design and the stated limitations, our study would be considered to provide a level of evidence of 2, suggesting that the data can be directly applied to the clinical setting for patients similar to those included in this study with expectations for similar outcomes with respect to safety and efficacy. We set our clinically significant effect size at 10% for all outcome measures. This was based on our review of the literature and our clinical experience, which suggested that differences of $< 10\%$ in any of the outcome measures used in this study would not be consistently clinically detectable. For prospective cohort studies or randomized clinical trials, it is important to determine a clinically significant effect size a priori so that appropriate conclusions can be drawn.

These data suggest that the TightRope CCL technique can be successfully performed in medium, large, and giant breed dogs with CCL deficiency and result in 6-month outcomes which are not different than TPLO in terms of client-evaluated degree and level of pain and function, as well as subjective assessment of radiographic progression of OA. Duration of anesthesia and surgery was less for TR than TPLO and major and overall complication rates were lower for TR compared with TPLO. The TR technique is safe and effective and can be considered as a viable choice as part of the overall treatment plan for CCL deficiency in dogs.

ACKNOWLEDGMENT

The authors thank David Shepard, Anthony Orozco, Dr. Bob Cook, Dr. Will Wright, Dr. Antonio Pozzi, Dr. Mark Albrecht, and Dawn Knight for their contributions to this work.

Disclosure: Dr. James Cook is a paid consultant for and holds multiple patents with Arthrex including the TightRope CCL device. Mr. Karnes is an employee of Arthrex. Tightrope CCL devices are patent protected and were provided by Arthrex for this study.

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