

Original Article
Surgery



Intra-articular replacement of a ruptured cranial cruciate ligament using the Mini-TightRope in the dog: a preliminary study

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 OPEN ACCESS

Received: Nov 25, 2019

Revised: Feb 12, 2020

Accepted: Apr 9, 2020

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Conflict of Interest

The authors declare no conflicts of interest.

Author Contributions

Conceptualization: Pinna S; Data curation:
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Methodology: Pinna S; Writing - original draft:
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ABSTRACT

Background: The TightRope System is a device developed to provide extracapsular stabilization of the cranial cruciate ligament (CCL) rupture in canine stifles. It was then also employed for the extra-articular treatment of shoulder instability and for the intra-articular treatment of hip luxation in dogs and cats.

Objectives: To evaluate the feasibility of the Mini-TightRope (mTR) System for the intra-articular treatment of CCL rupture in small breed dogs.

Methods: A cadaveric canine model was used to record the steps of the surgical procedure. Five client owned dogs weighing from 8 to 10 kg and from 2 to 12 years of age were enrolled in the prospective study in which the mTR device was implanted in the stifle joint to replace the ruptured CCL. The dogs were graded using the Bologna Healing Stifle Injury Index (BHSII) and radiographic osteoarthritis (OA) scores.

Results: The outcomes obtained at the time of the surgery (T0) and for the following 12 months (T12) showed an improvement in the functional parameters (BHSII from a median of 74.3 [range, 58.1–82.4] at T0 to 95.6 [range, 94.1–99.3] at T12]). The OA did not change in 3 dogs and increased by only 1 point in 2 dogs.

Conclusions: In this preliminary study, the mTR was a successful and repeatable intra-articular surgical procedure for all dogs. Additional studies related to the clinical application of the technique in medium-large dogs should be encouraged.

Keywords: Cranial cruciate ligament; stifle joint implants; synthetic grafts; dogs

INTRODUCTION

Cranial cruciate ligament (CCL) rupture is a common cause of lameness and the most common source of stifle osteoarthritis (OA) in dogs [1,2]. A surgical approach is suggested for re-establishing joint stability, preventing secondary OA and any concurrent meniscal injury [3-5]. Although it is known that the treatment of CCL rupture is recommended in medium-large dogs, there is disagreement regarding surgical or non-surgical treatment in small dogs [6]. Few studies have been carried out on small dogs to support the need for and the success of surgical treatment [4,7,8]. In the past, several surgical techniques were developed and employed in clinical practice, but no specific procedure was considered to be optimal [4,9].

Intra-articular techniques replace the function of the CCL with an autograft, allograft, xenograft or synthetic prosthesis [10]. Intra-articular techniques have been used since the 1950s [2,11]; however, due to their inferior outcomes [12,13], they were replaced by extra-articular sutures and tibial osteotomies which were associated with better outcomes [5,12]. Despite this, the majority of dogs developed OA after treatment, likely because not all these techniques replace the mechanical actions of the native CCL [14-16].

In humans, the most common method of anterior cruciate ligament reconstruction is the intra-articular placement of the graft (autograft or allograft) at the original attachment of the CCL. Presently, the replacement is associated with low rates of OA, i.e., < 20% of adult patients develop OA 2 years after cruciate ligament repair [17-19].

In veterinary medicine, the main limitations of a graft implant are graft resistance, graft fixation system, healing time and difficulty in controlling dog's activity after surgery [10,20,21]. Prosthetic ligaments can be employed in intra-articular reconstruction as permanent prostheses or as a scaffold which will be replaced by the tissue of the recipient [19,20], and synthetic augmentation of tendon graft [22]. Some prosthetic implants, such as braided polyester, have good biomechanical features and can be considered for CCL replacement [23]. Intra-articular placement of synthetic implants can generate adverse effects, such as synovitis, delayed healing, immune rejection and cartilage degeneration [10,22]. Nevertheless, a recent study has supported intra-articular biocompatibility of non-braided absorbable suture tape [22].

The TightRope (TR) and Mini-TightRope (mTR) were first used for the extra-articular treatment of CCL rupture [24], by means of the identification of the isometric points. Long-term and medium-term investigations revealed comparable OA progression and functional outcome between the TR and other popular techniques [24,25]. The TR was also employed for the extra-articular treatment of shoulder instability and for the intra-articular treatment of hip luxation in dogs and cats, without complications, or low rates of complications which required revision surgery [26-28]. The successes described in these reports were indicative of the proper functioning of the TR, and suggesting the intra-articular application of the TR for the replacement of CCL rupture in dogs to the authors.

The purpose of this study was to evaluate the feasibility of the intra-articular use of the Mini-TightRope System (intra-mTR) (Arthrex, USA) in small dogs with CCL rupture. The aim was to determine whether the mTR had reliable placement and fixation at the origin and insertion locations of the CCL, and whether it was capable of maintaining stifle stability in medium term follow-up.

MATERIALS AND METHODS

Synthetic CCL implant

A mTR implant is composed of 2 strands of fiberwire (FW) looped through 2 stainless steel buttons; the strands can be tied independently. A 5.5 mm round button (4-hole) and a 2.6 mm oblong toggle button (2-hole) anchored to a 1.6 mm needle are at the ends of the FW. The FW suture is constructed of a multi-strand long chain ultra-high molecular weight polyethylene core with a braided jacket of polyester and polyethylene.

The study consisted of 2 steps: cadaveric investigation and clinical application.

Step 1: experimental design

The intra-articular implantation of the synthetic graft (TR; Arthrex) was simulated in a mixed-breed dog cadaver using a non-sterile wire test sample. The right hind limb was removed from the dog which had died from natural causes; and the stifle joint was opened and prepared as an anatomic specimen, and the integrity of the CCL was confirmed. The medial condyle was removed using a surgical oscillating saw to expose the CCL; its femoral and tibial attachments were inspected and the ligament was then transected with a scalpel blade.

The landmarks described by Paatsama in 1952 [10] were used to drill the bone tunnels and a goniometer was used to establish the orientation of the tunnels. Employing a surgical drill guide, a femoral tunnel was drilled from a point between the lateral collateral ligament and the proximal trochlear ridge through the condyle to the cranial border of the femoral attachment of the native CCL. A goniometer was used to measure and record the orientation of the drill bit through the lateral femoral condyle to the long axis in the frontal plane of the femur (**Fig. 1**). A tibial tunnel was drilled from the tibial insertion of the native CCL to the medial aspect of the tibial crest, and the angle obtained between the tunnel and the long axis in the frontal plane of the tibia was also recorded. These measurements were crucial to making the tunnels in the correct orientation in the canine sample of the next step, and also to verify the accuracy of the procedure on the postoperative radiographic image.

The TR System needle was inserted through the tibial and femoral tunnels; the toggle button at the end of the FW was placed at the exit of the femoral tunnel applying gentle tension to the needle. At the tibial exit of the tunnel, the round button was held against the medial tibia bone, and the FW was placed in tension with a tensioner to simulate the steps of the procedure. The intra-articular portion of the FW was evaluated so as to position it correctly in relationship to the original attachment of the CCL (**Fig. 2**).

Step 2: clinical study

Client owned dogs referred for CCL rupture were evaluated for study enrollment. The inclusion criteria were: dogs with a history and orthopedic examination indicative of

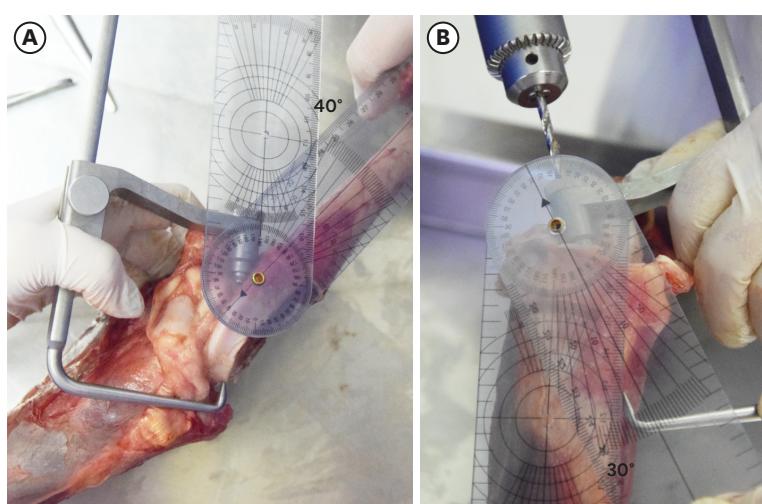


Fig. 1. The right stifle joint of the canine cadaveric model. The medial condyle of the femur has been removed to identify the intra-articular attachments of the CCL. The universal aiming device was positioned between the external landmarks and the origins of the CCL. A goniometer was placed to measure the orientation of the (A) femoral (40°) and (B) tibial (30°) tunnels, and the long axis in the frontal plane of both bone shafts. CCL, cranial cruciate ligament.

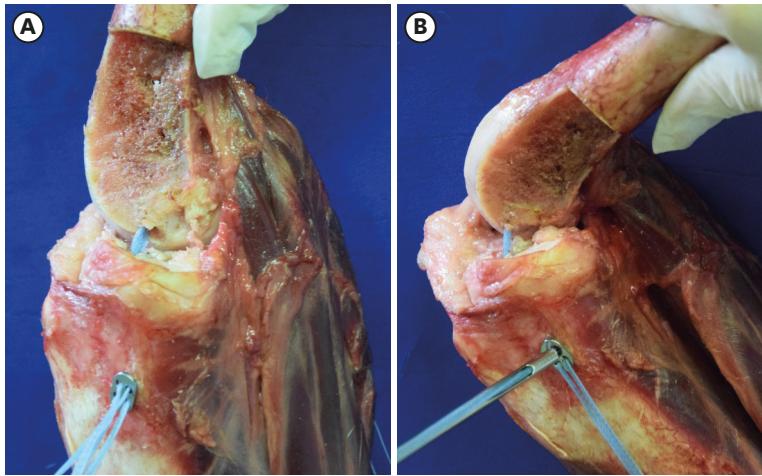


Fig. 2. Two views of the same canine stifle as **Fig. 1**. The medial condyle has been removed, and the intra-articular portion of the synthetic graft is seen in both the extension (A) and the flexion (B) of the joint.

spontaneous CCL rupture, < 10 kg body weight, > 1 year of age, lameness evident for at least one month (lameness score 0 to 4) [29], and none to mild signs of OA (score 0 to 4) [30,31]. The exclusion criteria were: failure of previous interventions, concurrent patellar luxation and hip dysplasia, and a history of other systemic diseases. The owners were informed regarding the novel employment of the implant and that it had already been used for extra-articular stifle stabilization and also in other joints. The owners agreed to bring their dogs for re-examination at 1, 3, 6 and 12 months after surgical treatment. At the time of enrollment, written informed consent was obtained from each owner.

Clinical and radiographic evaluations

To evaluate medium-term outcome, orthopedic and radiographic examinations were carried out before surgery, and at 1, 3, 6 and 12 months after surgery (T0, T1, T3, T6 and T12, respectively). The Bologna Healing Stifle Injury Index (BHSII) (normalized score from 0 to 100) was completed by both the owner and the clinician at each time point (<https://www.frontiersin.org/articles/10.3389/fvets.2019.00065/full#supplementary-material>) [29]. Both the owner and the clinical investigator were blinded to the scores from their prior completion of the form. On a scale of 0–100, a score of 0 indicated the presence of serious stifle joint problems and a score of 100 indicated the absence of any problems. Clinical parameters of the BHSII-Clinical Record (BHSII-CR), such as lameness, stifle pain, and synovial effusion (score 0–4), were also extracted from the Bologna Index and were assessed individually [29]. The cranial drawer test was rated positive/negative, and in addition, the tolerance of moving weight bearing onto the affected limb was recorded as no/yes. A single investigator evaluated all the dogs.

Lameness was scored as 0 = none; 1 = slight: slightly altered movement, function preserved; 2 = altered movement, function preserved; 3 = moderate: altered movement, function impaired and 4 = severe: altered movement, function lost. The stifle pain was assessed by means of the patient's reaction to palpation and passive movement of the stifle joint. Synovial effusion was also assessed by means of palpation; the increased joint fluid which pushes the synovial membrane forward around the caudal and lateral aspects of the patellar ligament was recorded. Both pain and effusion joint parameters were scored as 0 = none; 1 = slight; 2 = mild; 3 = moderate and 4 = severe [29].

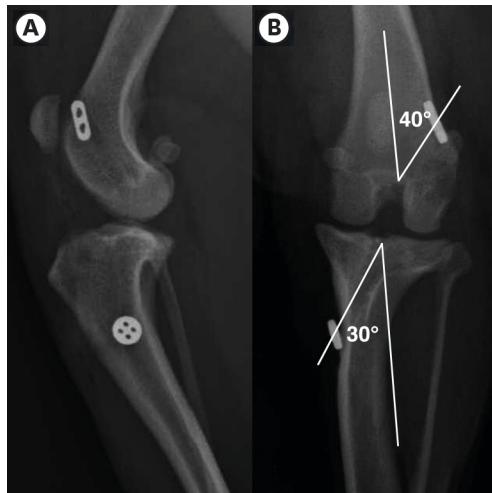


Fig. 3. Mediolateral (A) and caudocranial (B) stifle radiographs of the dog ID 1 taken 3 months after surgery. The images show the position of the buttons and the orientation of the tunnels.

Finally, mediolateral and caudocranial radiographs of each stifle were taken to evaluate the changes in OA, the position of the buttons and the presence of osteolysis phenomena around the implant (**Fig. 3**). For each stifle joint, a score from 0 to 4 based on the amount of new bone and bone density (0 = no signs of OA; 1 = slight: soft-tissue swelling; 2 = mild-OA: early osteophytes early osteophytes, roughening along the joint capsule margins and/or sclerosis; 3 = moderate-OA: obvious osteophytes and subchondral sclerosis and 4 = severe-OA: marked osteophytes and severe subchondral sclerosis) was assigned [30,31].

Complications during the follow-up of the study were investigated. Loosening or breaking of the FW, modification of the position of the buttons, infections or enlargement of the bone tunnel were considered to be possible postoperative complications.

Statistical analysis

Breed, age, body weight, sex, limb and BHSII data were collected. The data were analyzed using a statistical software program (MedCalc Software 16.8.4; MedCalc, Belgium). Non-normal distribution was assessed using the Shapiro-Wilk test, and the results from the statistical analysis were reported as medians and ranges. The Friedmann test was used to investigate the changes during the follow-up for the non-parametric data (rejected normality), and the Fisher's exact test was used to compare the distribution of the categorical data. Significance for all the analyses was set at $p < 0.05$.

Pre and postoperative care

Premedication was provided by acepromazine (Prequillan; ATI, Italy) (10 µg/kg, intramuscularly [IM]) and methadone hydrochloride (Semfortan; Eurovet Animal Health B.V., The Netherlands) (0.3 mg/kg, IM), followed by fentanyl (Fentadon; Dechra Pharmaceuticals, UK) (2 mcg/kg, intravenously [IV]) and propofol (Proposure; Boehringer Ingelheim, Germany) (1 mg/kg, IV) for the induction. During surgery, anesthesia was maintained with isoflurane (IsoFlo; Zoetis, USA) in oxygen and air. All dogs received cefazolin sodium (Cefazolina Teva; Teva, Italy) (30 mg/kg, IV) at the time of anesthetic induction and every 90 min during surgery.

Postoperative analgesia was obtained using methadone (0.1–0.2 mg/kg, IM every 4 h) or buprenorphine (Buprenodale; Dechra Pharmaceuticals) (10–15 µg/kg IM every 8 h) for the first 24 h, followed by tramadol hydrochloride (Altadol; Formevet, Italy) (2–4 mg/kg, orally, every 8 h) for 2 day. All dogs received cephalaxin (Rilexine; Virbac, France) (30 mg/kg, orally, every 12 h for 10 day) and robenacoxib (Onsior; Novartis, Switzerland) (1 mg/kg, orally, once a day) for 7 day.

The owners were instructed to limit physical activity for 20 day before allowing the dogs to resume normal levels of activity.

Surgical technique

Each dog was placed in dorsal recumbency, and the limb was aseptically prepared. A lateral arthrotomy was performed, and the joint was explored to evaluate menisci, osteophytes and cartilaginous lesions. A meniscectomy was performed when the meniscus was damaged; no meniscal release was executed on intact menisci, and the remaining cruciate ligament was debrided in all patients.

Based on the steps performed on the canine cadaveric model, the stifle joint was flexed at 60° and the femoral and tibial tunnels were drilled with a 2.7 mm drill bit at a 40° inclination to the long axis in the frontal plane of the femur and 30° inclination to the long axis in the frontal plane of the tibia (**Fig. 4**). A universal aiming device (IMEX Veterinary Inc., USA) and 2 pins suitably bent, 40° and 30°, respectively, were used to obtain the correct orientation of the tunnels. The intra-articular aperture of the tunnels coincided with the CCL attachments. The needle was inserted into the tibial and femoral tunnels, in a medial to lateral direction, it was pulled until its exit from the femoral tunnel, and the oblong button was rotated 90° on the bone surface of the lateral aspect of the femoral condyle. The needle was then removed. The joint was held in a weight bearing position (135°–140°) while tension was applied on the FW to the external aperture of the tibial tunnel using the Tensioner (Arthrex).

Using the tip of the tensioner, the larger button was held against the cortex of the tibia, one of the FWs was stretched until the appropriate tension was achieved and the cranial drawer motion was neutralized. The stifle joint was flexed and extended 10 times to remove slack

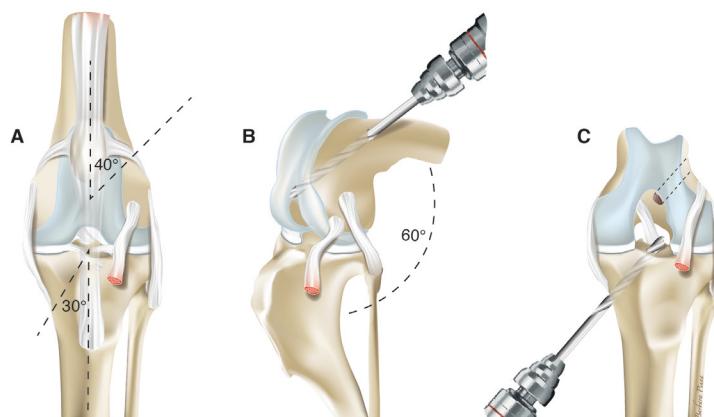


Fig. 4. Illustration of the steps of the surgical procedure. (A) Femoral and tibia tunnel orientations. (B) The femoral tunnel is drilled through the lateral condyle to the femoral attachment of the native CCL. (C) The tibial tunnel is drilled from the medial aspect of the tibial crest and tibial insertion of the native CCL. CCL, cranial cruciate ligament.

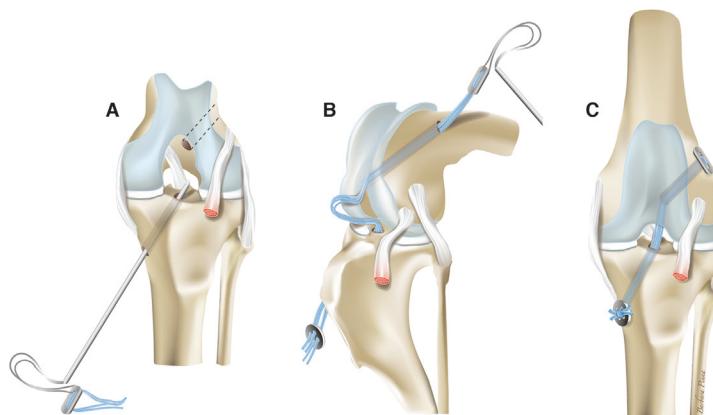


Fig. 5. Illustration of the intra-articular insertion procedure of the Mini-TightRope System. (A) With the joint flexed, the needle is inserted through the tibial tunnel in a medial to lateral direction and (B) through the femoral tunnel. The oblong button is laid flat to allow it to advance through the tunnels. Once the oblong button has exited from the femoral tunnel, it is rotated on the bone surface of the lateral aspect of the femoral condyle and, (C) with the joint extended, tension is applied over the larger button against the medial aspect of the tibia.

from the FW suture, the drawer and tibial thrust tests were negative, and the FW was knotted over the button with a single knot and reinforced with 4 to 6 throws. The strands can be tied independently; therefore, when the tensioner was removed from the first strand of FW, the second one was tied at the same manner (**Fig. 5**). Routine closure was performed. The amount of tension applied, operative time and intraoperative difficulties were recorded. Radiographs were taken immediately after surgery.

RESULTS

In the step 1, the surgical procedure carried out on the canine cadaveric model produced the following results. The inclinations of the femur and tibia bone tunnels were measured at 40° and 30°, respectively.

The intra-articular femoral insertion of the CCL was in the shape of a segment of a circle, bigger than the diameter of the drill bit; therefore, the cranial site of this insertion area was chosen as the intra-articular exit of the femoral bone tunnel. This point was considered suitable for maintaining the tension of the implant during the stifle joint passive movements.

In the step 2, 5 dogs were enrolled. The median age was 10 years (range, 2–12), median weight was 9 kg (range, 8–10). The tension applied to the implant was 10–12 pound-force (lbf) without any correlation to age or weight. All the intra-mTRs were performed by the same experienced surgeon and, on average, required 40 min. The total BHSII score and the OA score are reported for each dog (**Table 1**).

The improvements in lameness, effusion joint, cranial drawer test, and BHSII index were statistically significant ($p < 0.05$) one month after the surgery (T1) (**Table 2**).

The individual evaluation of each patient revealed that one dog (ID 2) did not show lameness at T1; at T3, lameness was scored as 0 in all dogs. Pain upon manipulation of the stifle was evident only in dog ID 4 at T1; the statistical analyses were not significant in the sample groups

Table 1. Signalment and outcomes data at baseline (T0) and 12 months after surgery (T12)

Dog ID	Breed	Age (yr)	Weight (kg)	Sex	Limb	Meniscectomy	lbf/N	BHSII		OA	
								T0	T12	T0	T12
1	Mixed-breed	3	10	M	L	Yes	12/53.4	74.3	95.6	0	0
2	Jack Russell Terrier	2	9	M	R	Yes	12/53.4	63.2	94.1	2	3
3	Maltese	11	6	F	R	No	10/44.5	58.1	99.3	2	2
4	Mixed-breed	10	9	F	R	Yes	12/53.4	82.4	95.6	0	1
5	Maltese	12	6	F	L	No	10/44.5	80.1	99.3	2	2

T, time of follow-up in months; N, newton; lbf, pound-force; BHSII, Bologna Healing Stifle Injury Index (score 0–100); OA, osteoarthritis (score 0–4).

Table 2. Outcome measurements at baseline (T0) and during follow-up

Parameter	Time of follow-up (mo)					<i>p</i> value [‡]
	T0	T1	T3	T6	T12	
Lameness	3 (1–3)	1 [‡] (0–1)	0 (0–0)	0 (0–0)	0 (0–0)	< 0.001
Stifle pain	1 (0–3)	1 (0–1)	0 (0–0)	0 (0–0)	0 (0–0)	> 0.05
Effusion joint	1 (0–1)	0 [‡] (0–2)	0 (0–1)	0 (0–0)	0 (0–0)	0.022
Positive drawer test*	5 (5)	0 (5) [‡]	0 (5)	0 (5)	0 (5)	0.008
Tolerance to increased weight [†]	5 (5)	4 (5)	1 (5) [‡]	0 (5)	0 (5)	0.047
BHSII	74.3 (58.1–82.4)	80.1 [‡] (61.0–83.1)	94.9 (85.3–100)	94.9 (92.6–99.3)	95.6 (94.1–99.3)	< 0.001
Radiographic OA	2 (0–2)	2 (0–2)	2 (0–2)	2 (0–3)	2 (0–3)	> 0.05

Medians and ranges are listed.

T, time of follow-up in months; BHSII, Bologna Healing Stifle Injury Index; OA, osteoarthritis.

*Number of dogs out of 5 with positive/negative drawer sign; [†]Number of dogs with positive reaction out of 5 dogs evaluated for tolerance to displacement weight through contralateral limb lift (no/yes); [‡]*p* value.

at each check-up. Slight effusion was still recorded only in dog ID 2 at T3. The tolerance to increased weight on the affected limb changed from positive to negative (*p* = 0.047) at T3. The median BHSII score improved progressively at each check-up from T0 to T12.

Finally, the OA did not change in 3 dogs (ID 1, 3 and 5) while OA increased by 1 point score between T3 and T6 in dog ID 2, and between T1 and T3 in dog ID 4. Statistical evaluation of signs of OA was not significant at each comparison over time.

No complications were observed, and difficulty in carrying out the procedure was not found.

DISCUSSION

The objective of this study was to evaluate the feasibility of the intra-articular technique for the treatment of CCL rupture using the mTR System. In addition, the reliability of the placement and fixation at the origin and the insertion locations of the CCL, and the capability of maintaining stifle stability over time were also investigated. To achieve this, the study was organized in 2 steps. In the first step, the correct position of the graft related to the intra-articular attachment of the native ligament was evaluated in the cadaveric model which made it possible to study the bone tunnel orientation. An interesting consideration was revealed; since the origin of the native CCL is in the form of a segment of a circle [32], it was not possible to match the internal exit of the femoral tunnel with the entire surface of the anatomic CCL attachment. Therefore, the Authors chose the cranial site of the origin of the native CCL, i.e., the attachment of the craniomedial band which remained taut in both the extension and flexion of the stifle. As recently reported, investigation regarding the 2 bands of the CCL would be required to improve the outcomes of the intra-articular anatomic replacement in dogs [33].

In the second step, the data obtained from the previous step and reported in clinical practice, simplified the procedure and made it repeatable. The outcomes recorded were elaborated by means of the BHSII which is a validated device useful for evaluating the process of healing of a stifle joint treated for CCL rupture with a set of objective and subjective parameters [29]. The significant improvement observed in the outcomes was indicative of joint stability and the effectiveness of the surgical technique 3 months after surgery. Joint stability was maintained for the 12 months of follow-up.

Conservative management of CCL rupture in small dogs allows good functional recovery, but evidence of OA increase over time has been reported [4,6]. In the present study small dogs (< 10 kg) were enrolled to assess a surgical technique aimed at re-establishing joint stability. It is known that the instability leads to lameness, pain and the secondary progression of OA [3,4]. The results of this study proved that significant improvement in these parameters was obtained in the dogs undergoing intra-articular replacement of the CCL using a mTR implant. Functional recovery, and no or slight development of OA were obtained, supposedly because the mTR offers an adequate and adjustable system of fixation. It is reasonable to believe that the tension applied to the implant and the mechanical property of the buttons at the ends of the FW were enough to prevent elongation and failure as reported in the literature when tested on other types of grafts or fixation techniques [16].

The aim of the radiographic examination was to reveal signs of OA and, especially, to analyze the radiographic bone pattern around the tunnels or implants. The lack of radiographic changes, except for light OA progression in 2 dogs (ID 2 and 4), could be significant regarding biocompatibility and adequate mechanical properties, such as fixation of the implant and stability of the joint.

Numerous papers have examined the progression of OA after carrying out various procedures for CCL reconstruction [3,9,29,34]. None of them claimed superiority of one surgical technique over other surgical techniques [4].

To the best of the Authors' knowledge, there are no other studies describing the intra-articular stifle use of the TR in clinical practice in dogs. In a recent canine model study, biocompatibility of intra-articular multistranded long-chain polyethylene suture tape, similar to an FW, was evaluated with a good outcome when implanted adjacent to the native anterior cruciate ligament [22]. Similarly, a preclinical animal model was described to evaluate novel graft types and fixation methods, indicating that hybrid double-bundle anterior cruciate ligament reconstruction allowed preserving knee function without the development of OA and significantly improved functionality [21]. These papers gave the Authors the impetus to design the present study.

Some studies have been conducted to evaluate the mechanical properties of a braided polyester fibre graft or allograft using various methods of fixation in intra-articular applications [16,35]. The results of the cadaveric studies were encouraging, but they were not sufficient to diagnose complications in clinical practice.

A limitation of the present study was the small sample surveyed which did not allow comparing the results to other studies in which braided non absorbable multifilament sutures were sometimes associated with surgical site infection [36,37], a complication which was not detected at any time in this study.

An additional limitation of this study was the absence of a control group; it is not ethical to withhold treatment from an animal with pain and obvious lameness according to the local ethical committee.

In summary, the intra-mTR technique was performed on small dogs (< 10 kg) as a preliminary study aimed at evaluating the feasibility and effectiveness of the treatment. Given the absence of postoperative complications, the low rates of OA development and the subjective outcome assessments over the medium term suggested the possible use of mTR for the intra-articular replacement of CCL rupture in small dogs, revealing the device to be secure in graft fixation and for maintaining stifle stability. The results obtained in the present study encourage additional research to prove feasibility in medium-large dogs in a larger scale study.

ACKNOWLEDGEMENT

The authors wish to thank Mrs. Barbara Pinna for her generous contribution regarding the drawings included in this manuscript.

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