Objective: To describe the surgical technique, clinical efficacy, and complications using the Simitri Stable in Stride® extracapsular articulating implant (EAI) to treat naturally occurring stifle instability due to cranial cruciate ligament (CrCL) insufficiency.

Study Design: Prospective case series.

Animals: Client-owned dogs with CrCL-deficient stifles (n=60 dogs; 66 stifles).

Methods: An EAI was applied to the medial aspect of the distal femur and proximal tibia after stifle exploration and treatment of joint pathology. Outcome measures included lameness score, time to weight bearing, and bilateral assessment of stifle stability, stifle range of motion (ROM), and thigh circumference (TC). Outcome measures were determined preoperatively and at intervals from 4.5 to 16.0 months (median 8.9 months) postoperatively. Data were excluded from bilaterally affected dogs <6 months after CrCL surgery on the contralateral limb, and from dogs with contralateral limb lameness.

Results: Within 24 hours of EAI surgery, dogs were weight bearing on 64 of 66 limbs at the walk. Incidence of major complications requiring surgical revision was 15.3% and minor complications was 10.2%. Postoperatively, there were significant improvements in lameness scores and ROM in 34 EAI-treated limbs meeting inclusion criteria, and the mean ROM returned to within normal limits. TC did not change in the operated limb, but decreased significantly in the control limb.

Conclusion: The EAI effectively stabilized the CrCL-deficient stifle, and significantly improved lameness scores and stifle ROM. Decreased TC in control limbs may have been due to early return to mobility and weight bearing on the EAI-treated limb.

Rupture of the cranial cruciate ligament (CrCL) is the most common cause of pelvic limb lameness requiring surgical intervention in dogs.1,2 Deficiency of the canine CrCL results in translational and rotational instability of the stifle joint. The optimal surgical treatment for the CrCL-deficient stifle provides immediate stabilization of the unstable stifle joint while allowing normal joint contact mechanics and movement in all planes.1,3 There are several common surgical treatments for canine CrCL deficiency, including extracapsular stabilization procedures using monofilament or multifilament braided materials and geometry-modifying osteotomy procedures, the most common of which are tibial plateau leveling osteotomy (TPLO) and tibial tuberosity advancement (TTA).3,4 However, there is currently no uniformly accepted best treatment of the canine CrCL-deficient stifle.2,4-12 Joint contact mechanics are altered by all current techniques and a decrease in range of motion (ROM) and progression of osteoarthritis are common findings postoperatively.8-12 Recently, it was proposed that an extracapsular articulating implant (EAI; Simitri Stable in Stride®, New Generation Devices, Glen Rock, NJ) could provide continuous translational and rotational stability to the canine CrCL-deficient stifle while closely mimicking the kinematics of the CrCL-intact stifle without the need for geometric modification.3,13-16

Initial designs for the EAI and rapid prototypes were developed with the assistance of the Red Deer College School of Innovation (Red Deer, AB, Canada) using 3D computer models from a computed tomography scan of the hind limb of a 33 kg Golden Retriever. Further development and manufacture of the surgical grade implants used in this study were completed with the assistance of New Generation Devices. Cadaveric testing of the implant during development of the EAI was used to test the viability of numerous design prototypes and to develop the surgical technique prior to commencing with this clinical study.

Biomechanical and 3D computer simulation modelling of the EAI predicted that it is capable of tolerating expected in vivo joint forces during gait for dogs in the weight range of this study and provides effective stabilization of the CrCL-deficient stifle.3,17,18 Biochemical testing found that the EAI allowed for a functional ROM and tolerated forces expected in vivo without deformation.17,18 Based on an in

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silico comparison using a 3D computer model, stifle joint biomechanics were improved in the EAI-managed stifle compared to the CrCL-deficient stifle joint and the EAI treated CrCL-deficient stifle was predicted to return ligament loads and tibial kinematics closer to the state of the CrCL-intact stifle than did the TPLO-managed stifle.³,¹⁴ The successful use of this EAI has previously been reported in 3 cases of canine stifle derangement.¹⁵,¹⁶

The purpose of this study was to describe the surgical technique, early clinical experiences, and outcomes in the initial series of 66 clinical cases using the EAI for stabilization of CrCL-deficient stifles.

MATERIALS AND METHODS

From September 2013 to August 2014, all dogs referred to our mobile surgical service for treatment of suspected CrCL deficiency were evaluated for inclusion in this first series of cases using the EAI. Criteria for inclusion included dogs weighing ≥25 kg, radiographic signs of CrCL disease, appropriate bone size relative to available implants, CrCL disease confirmed at surgery, and written owner consent for the procedure, including agreement to pursue prescribed postoperative care and follow-up evaluation. Surgical options for treatment were discussed with owners, initially by the referring veterinarian and subsequently by the surgeon, and included lateral fabellar suture, TPLO, and implantation of the EAI. All owners were aware of the experimental nature of the EAI. The EAI surgery was offered at the same cost as the TPLO surgery (which was higher than the cost of lateral fabellar suture surgery); therefore, there was no financial incentive to participate in the study. However, owners were informed that if there was a failure of the EAI that revision surgery would be performed at no charge. Initial exclusion criteria included dogs <25 kg, dogs deemed to not fit the implant based on radiographic measurements, and owners opting for another treatment. Stifles with concurrent injuries to the caudal cruciate ligament (CaCL), menisci, and/or collateral ligaments were not excluded from the study, nor were dogs with bilateral CrCL disease or those with concurrent luxating patella. For purposes of data analysis requiring comparison between the surgical limb and contralateral limb, outcome measures were excluded from stifles in dogs with bilateral disease if the contralateral (control) limb was <6 months postoperative of CrCL repair and in dogs with contralateral limb lameness.¹⁹

Implant and Preoperative Planning

The EAI was available in one size, in right and left configurations (Figs 1 and 2) and comprised an ASTM F-138 compliant 316L stainless steel femoral and tibial plates and an ultra-high-molecular-weight polyethylene (UHMWPE) tibial plate insert (GUR 1050, type 2, Celanese, Irving, TX). Cortical locking screws (3.5 mm, New Generation Devices) were used for application of the EAI. Radiographic assessment of the affected limbs included lateral and craniocaudal radiographic projections of the limb with the stifle in full extension. Preoperative measurements made on the calibrated extended lateral radiograph aided in case selection and isometric positioning of the femoral plate and more specifically the femoral ball (Fig 3).³,¹³,¹⁵,¹⁶,¹¹,¹²

Surgical Procedure (Figs 4 and 5)

Surgery was performed by one surgeon (NE) with dogs positioned in dorsal recumbency. The affected limb was aseptically prepared and draped to provide full access from the proximal femur to the distal tibia. All dogs received perioperative cefazolin (22 mg/kg IV). A 15 cm curvilinear skin incision was centered over the medial stifle (Fig 4A), the skin was reflected cranially, and a 10–15 mm medial parapatellar arthrotomy was performed to evaluate and treat stifle joint pathology. Damaged portions of the cruciate ligaments were debrided and meniscal tears were treated by partial meniscectomy. Medial meniscal release procedures were not performed. The incised medial retinaculum were closed in a single layer using a simple continuous pattern of 0 poliglecaprone 25.

An incision was made parallel to the tibial crest through the conjoint tendons of the sartorius, gracilis, and semitendinosus muscles and reflected caudally exposing the medial collateral ligament (MCL) and proximal tibia (Fig 4B). The incision was extended proximally between the cranial and caudal bellies of the sartorius muscle exposing the vastus...
medialis. The femur was exposed by bluntly dissecting cranial to the tendon of the pectineus thus freeing up the vastus musculature while preserving the descending genicular artery and medial articular nerve (Fig 4C). To facilitate having the femoral plate in close contact with the femoral diaphysis, a soft tissue tunnel extending distally from the exposed femur and exiting at the level of the distal patella was bluntly created using curved Mayo scissors (Fig 4D). The tunnel remained deep to the descending genicular artery and medial articular nerve but superficial to the joint capsule. With the leg if full extension, a 22 gauge 0.75 inch hypodermic needle was used to locate and mark the most proximal

Figure 2 (A) Magnification of the lateral view of the articulation illustrating the ball of the femoral plate engaged within the travel channel of the tibial insert. (B) Cross section of the ball of the femoral plate at the level of the black line as viewed from the top. The femoral ball (gray) is pressure fit into and laser welded on both sides of femoral plate (blue). The UHMWPE insert (gold) pressure fits and locks into the opening of the tibial plate (green). The tibial insert slides over the femoral ball allowing for 6 mm of movement within the channel while the beveled flanges of the insert (arrows) allow for ~10° of internal and external rotation of the tibial plate relative to the femoral plate. The tibial insert prevents metal to metal contact between the plates.

Figure 3 (A) The double-ended black and red arrows represent preoperative measurements made on the calibrated extended lateral radiographic image of the stifle. The yellow asterisk (*) represents the isometric ball position and is located b mm from the caudal end of line c. (B) Measurements of the lengths of distances a, c, and d are used to determine if the dimensions of the femur will accommodate the extracapsular articulating implant (EAI). For the EAI to fit a dog, the following measurements must be achieved: a ≥ 10 mm; c ≥ 30 mm; and d ≤ 15 mm. (C) To find the isometric ball position during surgery a stay suture is placed at b – 6 mm from the proximal tibia (centered over the medial collateral ligament) to mark the location for the distal edge of the femoral plate.
Figure 4  Sequential photographs of surgical procedure demonstrating key points in the surgical technique–surgical approach. (A) Curvilinear skin incision centered over the medial stifle. (B) Tibial incision through the conjoined tendons of the sartorius, gracilis, and semitendinosus muscles and reflected caudally exposing the medial collateral ligament (MCL) and proximal tibia. (C) Vastus medialis retracted cranially exposing femur. The descending genicular artery and medial articular nerve are located at tip of periosteal elevator. (D) Soft tissue tunnel bluntly created with curved scissors. (E, F) Twenty-two gauge hypodermic needle marking the proximal aspect of the tibia on the cranial border of the MCL. Calipers measuring the predetermined distance for stay suture placement (forceps) centered on the MCL.

Figure 5  Sequential photographs of surgical procedure demonstrating key points in the surgical technique–implant positioning. (A) Stifle in full extension with femoral plate inserted through the soft tissue tunnel in contact with the stay suture (arrow). Femoral ball is centered over the MCL and proximal holding pin is then engaged as shown. (B) Isometricity confirmed by flexing the stifle and observing that the stay suture travels around the edge of the femoral plate (arrow). (C) Distal holding pin is engaged and a locking drill guide is inserted into femoral plate hole1. (D) Tibial plate is engaged such that the ball is in the center of the travel channel (as shown in Fig 2) and the screw segment is aligned with the thickest portion of the proximal tibia and the distal holding pin engaged into the medial cortex. (E) Appearance of complete extracapsular articulating implant prior to closure. (F) Fascia is closed over the plate. Subcutaneous tissues and skin are closed routinely.
aspect of the tibia at the level of the cranial border of the MCL (Fig 4E,F). Calipers were used to measure the predetermined distance proximal to the needle to place an absorbable stay suture that marked the location for the distal edge of the femoral plate (Fig 3).

The femoral plate was inserted through the soft tissue tunnel and positioned such that the screw segment was parallel to the long axis of the distal femoral diaphysis, the distal edge was level with the stay suture, and the ball was centered over the MCL (Fig 5A). A 5/64 inch holding pin was engaged through the proximal pin hole into the medial cortex. Isometricity was confirmed by flexing the stifle and observing that the stay suture travels around the edge of the femoral plate and adjustments were made if required (Fig 5A,B). The distal femoral holding pin was then engaged into the medial cortex. A locking drill guide (New Generation Devices) was inserted into femoral plate hole 1, the hole drilled, tapped, and a cortical screw placed to compress the plate to femur (Fig 5C). Holes 2 and 3 were drilled as per hole 1 and locking screws applied bicortically. Holding pins were removed and the screw in hole 1 was replaced with a locking screw. The tibial plate was engaged such that the articulation was as parallel as possible, the ball was in the centre of the travel channel, and the screw segment was aligned with the thickest portion of the proximal tibia and the distal holding pin engaged into the medial cortex (Figs 2 and 5D). The cranially subluxated tibia was reduced and the proximal holding pin engaged. Prior to permanent implantation, plate placement was reassessed to ensure the articulation remained relatively parallel and there was no implant interference during flexion and extension of the stifle. The tibial screws were applied as for the femoral plate (Fig 5F). Closure of the surgical site over the EAI was achieved by apposition of the incised fascial layer between the bellies of the sartorius muscle over the femoral plates and of the insertional fascia of the incised conjoined tendons over the tibial plates using 2-0 poliglecaprone 25 (Fig 5F). The subcutaneous tissue and skin were closed routinely. Postoperative radiographs were taken to assess placement of EAI and screw engagement (Fig 6).

**Postoperative Care**

Postoperative analgesia was typically achieved with an injectable nonsteroid anti-inflammatory drug (NSAID) and injectable opioid for the first 24 hours followed by oral administration of an NSAID for 4–8 weeks postoperatively. Cefazolin (22 mg/kg orally every 12 hours) was administered for 3 days postoperatively. The study protocol did not restrict the use of medications for treatment of pain either in hospital or at home. Ice was applied for 25 minutes 3 times daily while in hospital and continued at home twice daily for the first 7 days. Dogs were discharged the day after surgery with instructions to immediately begin a home rehabilitation program that included passive ROM exercises, massage, and controlled leash walking. The rehabilitation exercises began with 10 repetitions each of passive flexion and extension of the stifle and then of the hip, performed 3 times daily and 5–10 minutes of leash walking 3–4 times daily for the first week. Confinement to a kennel or small room was recommended when unsupervised and a belly band was only used when on stairs or slippery surfaces as a precaution and not to support the dog’s weight. Sit to stand exercises were introduced after 2 weeks and confinement discontinued as long as there was access to good footing and no vigorous play was allowed. Swimming and walking in water were also encouraged when practical. Instructions provided for increases in the intensity, frequency, and duration of exercise over a 12–16 week period. The use of professional rehabilitation services was not restricted. After 12–16 weeks, most dogs were allowed to return to unrestricted off leash preinjury activity levels. Written and verbal postoperative rehabilitation recommendations were provided to all clients at the time of discharge and were discussed with the client within the first 24 hours of discharge; however, degree of compliance by the client could not be controlled and was not documented. Clients were instructed to return to the referring clinic for 6 month postoperative radiographs.

**Animal Evaluation**

Age, sex, weight, breed, lameness score, bilateral stifle stability, stifle ROM, and thigh circumference (TC) were recorded preoperatively on the day of surgery. Lameness was graded on a scale of 0–5 with scores of 0 signifying no appreciable lameness and 5 continuous nonweight bearing lameness at the walk. Cranial tibial translation was assessed by the cranial drawer test and internal tibial rotation was subjectively assessed as within or exceeding normal limits. Stiff ROM was recorded as the maximum comfortable degree of flexion and extension measured using a plastic hand-held goniometer with an arm length of 18 cm, positioned over the stifle with the proximal arm centered over...
the femoral diaphysis and the distal arm centered over the
tibial diaphysis of the anesthetized dog.22,23 Proximal TC
was measured circumferentially at the level of the flank on
the anesthetized dog in lateral recumbency using a flexible
measuring tape placed perpendicular to the femur of the
extended limb.22 Intraoperatively, dogs were subjectively
evaluated for damage to CrCL, CaCL, menisci, and collateral
ligaments. CrCL and CaCL tears were subjectively graded as
partial if <90% of the ligament was torn and complete if
≥90% was torn.23 Collateral ligament and meniscal injuries
were also noted if detected during surgery.

Time to return to weight bearing on the operated limb at
the walk was observed and recorded. Postoperative evalu-
ations of dogs were performed between November 2013 and
April 2015. For dogs having multiple postoperative evalu-
ations, outcome measures from the most current evaluations
were used for analysis. Postoperative lameness was graded
on the same scale of 0–5 based on physical observation veri-
fiﬁed by video evaluation. Postoperative outcome measures
also included bilateral assessment of stifle stability, comfort-
able stifle ROM, and TC. Mean postoperative ROM data
were compared to normal canine ROM (40–160°).23 Postop-
erative stifle stability and ROM measurements were per-
fomed in lateral recumbency. Postoperative TC was
measured with the stifle extended in lateral recumbency or in
standing for dogs that resisted being placed in lateral recum-
bency. A study of TC variables found no signiﬁcant differ-
ence between TC in anesthetized dogs versus relaxed awake
dogs.24 Due to the variations in TC that could be associated
with breed and size of dogs in our study, comparison of
changes in TC rather than comparison of actual measure-
ments were made.

Preoperative and postoperative stifle stability was
assessed by one clinician (NE), ROM, and TC measure-
ments were performed by another clinician (VB). Preoperative
lameness scores were assessed by both clinicians (NE and
VB) based on physical examination, video evaluation, and/or
description of lameness as observed by referring veterinari-
ans on the day of surgery. Postoperative lameness scores
were evaluated independently by both clinicians (NE and
VB). Slow motion video capture software (Coach’s Eye IOS
SDK v3.03, TechSmith Corporation, Okemos, MI) was used
to improve detection of mild lameness. The higher lameness
score was recorded if there was lack of agreement between
the two clinicians.

Postoperative complications, treatments, and outcomes
were recorded. Postoperative complications (≥6 months
postoperative) were deﬁned as major if surgical interвен-
tion was required or minor if no treatment or only medical treat-
ment was required.12,25 Postoperative limb edema was
expected to occur in the majority of dogs, as it does with
other CrCL procedures, and therefore was not included in
complication rates in this case series.

Statistical Analysis

Statistical analyses were performed using MedCalc Statistical
Software version 14.12.0 (MedCalc Software bvba, Ostend,
Belgium; http://www.medcalc.org; 2014). Data were examined
for normality using Shapiro Wilk tests and visual examination
of histograms or box-and-whisker plots. Normally distributed
data were evaluated using parametric tests for paired data (t-
tests), while non-Gaussian data and ordinal data were evaluated
using nonparametric tests for paired data (Wilcoxon signed
rank tests). Several paired comparisons were performed. First,
lameness scores were examined before and after surgery using
a Wilcoxon signed rank test. Because of co-relatedness of sev-
eral variables (eg, ﬂexion, extension, ROM), extension and
ROM were selected for comparisons. For comparison of the
change in extension and ROM between the surgical limb and
contralateral limb, dogs with unilateral CrCL disease and dogs
with bilateral disease where the contralateral (control) limb was
a minimum of 6 months postoperative of CrCL repair (with no
obvious sign of lameness in the contralateral limb) were
included. The same criteria were used for comparison of the
change in TC in the operated and control limbs. To examine for
relationships between recheck time and extension or TC, linear
regression analysis was performed after checking for violations
of assumptions. Proportions were compared using either χ^2 tests
or Fishers exact tests. For all comparisons, statistical signiﬁ-
ance was set at P < .05.

RESULTS

Dogs

CrCL repair with the EAI was performed on 60 dogs (36
spayed females and 24 castrated males) with a mean body
weight of 38.0 kg (range, 25.9–51.7 kg). The mean age was
5.8 years (range, 1.1–14 years). Breeds included Labrador
Retriever (14 dogs), Labrador Retriever crosses (9), mixed
breeds (8), Rottweilers (4), Bernese Mountain Dogs (4),
Golden Retrievers (3), Pit Bulls, Chesapeake Bay Retrievers,
Newfoundland Dogs, Siberian Huskies, Alaskan Malamutes
(2 each), and Catahoula Leopard Dog, Standard Poodle,
Rhodesian Ridgeback, Perro de Presa Canario, Dogo Argen-
tino, Bouvier des Flandres, German Shepherd Dog, and
Boxer (1 each).

Four of the EAI-treated dogs did not return for follow-
up and 3 dogs died of causes unrelated to the surgery at <6
months postoperatively. The remaining 59 stifles (53 dogs)
were followed for a minimum 6 months (range 6–18 months;
median 8 months) and are included in calculation of compli-
cation rates. Outcome measures from 34 stifles met the
inclusion criteria for data analysis (23 unilateral stifles and
11 bilateral stifles).

Surgical Findings

Sixty-six stifles with CrCL deﬁciency (33 left, 33 right) in 60
dogs were treated with the EAI. Six of 60 dogs (10.0%) were
treated bilaterally with the EAI (5 had staged procedures with
a minimum of 4 months between surgeries and 1 had both sti-
ﬂes treated concurrently). Dogs were assessed to have varying
degrees of joint pathology ranging from partial CrCL rupture
to multiligamentous injuries (Table 1). The two dogs with stifle derangements had primary repair of damaged collateral ligament injuries with 0 polydioxanone prior to implantation of the EAI, as has been previously described.\(^\text{15,16}\) The dog with concurrent injuries with LCL damage had a tibial tuberosity transposition prior to implantation of the EAI.

In early cases, it was found that the paucity of visible and palpable landmarks over the medial stifle made positioning of the EAI more challenging in vivo than on cadavers. The method of applying preoperative radiographic measurements during surgery was refined during the clinical series based on evaluation of immediate postoperative radiographs and further evaluation of cadaveric application of the EAI (Fig 3). Changes made in later cases included use of the MCL as a reliable landmark for applying the radiographic measurements, ensuring the condyles were superimposed in the extended lateral view to improve accuracy of measurements, and identification of maximum condylar dimensions for the implant (Fig 3). In addition, a standard adjustment of 1.5 mm was made to account for the articular cartilage and the joint space when measuring up from the proximal tibia instead of using measurements of the joint space obtained on the radiographs. It is our opinion that the joint space is artificially increased on a radiograph due to manual extension of the limb and that the space may also slightly decrease at surgery subsequent to loss of synovial fluid during the arthrotomy. Use of the measurement of the joint space obtained on the radiographs consistently placed the femoral plate proximal to its ideal position. The use of the stay suture to verify the isometric position was also introduced in later cases and markedly improved accuracy of placement of the femoral plate.

Other technical challenges included difficulty engaging the locking drill guide, particularly in the femoral plate screw holes, where it was found that the holding pins interfered with placement of the guide. Bending of the holding pins aided in placement in most cases; however, when the threads of the drill guide would not engage after several attempts a non threaded drill guide was used. A longer and thinner locking drill guide has subsequently been developed by New Generation Devices and the angle and position of the holding pin holes have been changed to eliminate interference with the drill guide.

### Complications

The major complication rate was 15.3% (9/59 stifles; Table 2) and the minor complication rate was 10.2% (6/59 stifles; Table 3). Complication rates were based on the total number of stifles observed to have either a major or minor complication after the EAI surgery, there were no stifles represented in both categories and 1 stifle in each category had multiple complications. There were no clinical signs of postoperative infection or postliminary meniscal tears observed during the time frame of the study. No second look arthrotomies were performed. There was a significantly higher complications rate in the first half of the study compared to the second half \(P = .03\) and there was an association noted between larger dog body weight (>40 kg) and the incidence of major complications \(P = .03;\) Table 4. There were more stifles from dogs weighing >40 kg (51.5 vs. 19.2%; \(P = .01\) enrolled in the first half of the study than in the second half.

When required, revision of the EAI was relatively straightforward, requiring only exposure of the screw segment of the affected plate(s) and removal of the screws after which options for revision included repositioning the EAI plates or complete removal and proceeding with another CrCL surgical procedure (Fig 7). When repositioning of the EAI was not considered an option, one of the other CrCL surgical techniques (eg, TPLO) could be performed as the stifle geometry was unaltered during application of the EAI and screw holes/fractured screws are distal to the osteotomy site.

Obtaining postoperative radiographs was difficult due to the involvement of 17 clinics over a large geographic area and reluctance of clients to return for sedation of clinically normal dogs. Postoperative radiographs were obtained on 29 of 59 stifles (49.2%) and were limited to dogs with suspected complications and for dogs sedated for other conditions including evaluation of suspected contralateral limb CrCL deficiency. For stifles without complications \(n = 18\), there was no evidence of screw loosening or EAI failure, there was minimal, or no, joint effusion and minimal, or no, radiographic signs of progression of osteoarthritis (Fig 7).

### Outcome Measures

Preoperatively all affected stifles (66/66) had positive cranial drawer test and palpable rotational instability. Immediately after implantation, all 66 stifles had negative cranial drawer test and palpable rotational stability. Within 24 hours of surgery, 64 of 66 affected limbs treated with the EAI were weight bearing, dogs were weight bearing on 66/66 limbs within 48 hours.

Thirty-four dogs that met the inclusion criteria were evaluated between 4.5 and 16 months following surgery (median 8.9 months). There was significant improvement in postoperative lameness scores and ROM in the affected limbs (Table 5). Postoperatively, the mean ROM of the EAI treated limbs was within the normal limits for the canine stifle.\(^23\) Mean ROM for EAI-treated limbs was greater than mean ROM in contralateral limbs previously treated with

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**Table 1:** Stifle injuries noted intraoperatively in 66 stifles from 60 dogs

<table>
<thead>
<tr>
<th>Joint pathology</th>
<th># Stifles</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>CrCL partial</td>
<td>13</td>
<td>19.7</td>
</tr>
<tr>
<td>CrCL complete</td>
<td>53</td>
<td>80.3</td>
</tr>
<tr>
<td>Concurrent CaCL partial</td>
<td>14</td>
<td>21.2</td>
</tr>
<tr>
<td>Concurrent CaCL complete (with MCL and LCL damage)</td>
<td>2</td>
<td>3.0</td>
</tr>
<tr>
<td>Concurrent medial meniscus</td>
<td>35</td>
<td>53.0</td>
</tr>
<tr>
<td>Concurrent lateral meniscus</td>
<td>2</td>
<td>3.0</td>
</tr>
<tr>
<td>Concurrent medial and lateral meniscus</td>
<td>16</td>
<td>24.2</td>
</tr>
<tr>
<td>Concurrent luxating patella</td>
<td>1</td>
<td>1.5</td>
</tr>
</tbody>
</table>

CrCL, cranial cruciate ligament, CaCL, caudal cruciate ligament; MCL, medial collateral ligament; LCL, lateral collateral ligament
TPLO (7 dogs) or extracapsular stabilization (1 dog); however, the numbers were too few to compare these data statistically. Preoperative TC of affected limbs was significantly less than preoperative TC of the contralateral limb \( (P < .001; \) Table 5) due to atrophy of the affected limb and compensatory hypertrophy of the contralateral limb. Postoperatively, TC did not significantly change on average in the affected limb; however, TC significantly decreased on average in the contralateral limb (Table 5). The difference in change in TC between the affected and contralateral limb was significant \( (2.0.6 \text{ vs. } 2.1.8 \text{ cm}; \ P = .013) \). There was no effect of recheck time on changes in either extension or TC when evaluating stifles that had final recheck evaluations from 4.5 to 16.0 months postoperatively (flat line regression; \( P = .90 \)).

**DISCUSSION**

Our study is the first prospective clinical trial of a novel EAI designed to provide immediate and continuous translational and rotational stability to the CrCL-deficient stifle. Outcome measures indicated that treatment of the CrCL-deficient stifle with EAI was associated with significant improvement in stifle translational and rotational stability, lameness scores, and ROM. As there was no osteotomy, healing after EAI application was limited to healing of intra-articular and periarticular soft tissues and rehabilitation of the muscles supporting the stifle joint. All dogs were weight bearing and able to begin rehabilitation exercises within 48 hours of surgery, which may be a benefit of a procedure that provides immediate stabilization without the restrictions required with osteotomy procedures.\(^{19,23,25–27}\) Complication rates were relatively low for a new procedure and were significantly lower in the second half of the study as experience was gained in the technique and case size selection.

Direct comparisons between outcomes and complications of studies of different CrCL surgeries are problematic due to differences in study design and animal populations. The overall complication rate for the EAI procedure could be considered comparable to rates reported for TPLO, TTA, and ES.\(^{10,12,25–33}\) Major complications requiring second surgeries after the EAI procedure occurred in 15.3% of dogs compared with major complication rates for TPLO (12.6–17.4%).

**Table 2** Major complications after use of extracapsular articulating implant (EAI) in 59 stifles

<table>
<thead>
<tr>
<th>Complication</th>
<th># Stifles</th>
<th>Additional details</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disarticulation</td>
<td>4*</td>
<td>Occurring at 2 weeks, 4 weeks, 5 months, and 10 months postop</td>
<td>Removal of EAI with repositioning of femoral plate (2 stifles); replacement of tibial plate with larger size (1); revision to TPLO (1)</td>
</tr>
<tr>
<td>Screw fracture</td>
<td>2*</td>
<td>3.5 mm, nonbicortical screws in dogs &gt;45 kg occurring at 1 and 11 months postop</td>
<td>Removal of EAI and revision to TPLO</td>
</tr>
<tr>
<td>Screw loosening</td>
<td>1</td>
<td>47.5 kg dog with multiple screw loosening at 1 month postop</td>
<td>Removal of EAI and revision to TPLO</td>
</tr>
<tr>
<td>Screw loosening/bending</td>
<td>1</td>
<td>Associated with traumatic event (client noncompliance) at 2 weeks postop</td>
<td>Removal of EAI and revision to TPLO</td>
</tr>
<tr>
<td>Surgical site reaction</td>
<td>1</td>
<td>Idiopathic osseous metaplasia and extensive periarticular fibrosis resulting in frozen joint 1 month postop in 10-year-old dog</td>
<td>Owner elected intraoperative humane euthanasia due to multiple health and behavioral issues</td>
</tr>
<tr>
<td>Draining tract</td>
<td>1</td>
<td>Periosteal reaction/draining tract at 8 months postop</td>
<td>Removal of tibial component of EAI only</td>
</tr>
</tbody>
</table>

*1 dog that had repositioning of the femoral plate subsequently fractured screws and is included in both complication categories.

TPLO, tibial plateau leveling osteotomy.

**Table 3** Minor complications after use of EAI in 59 dogs

<table>
<thead>
<tr>
<th>Complication</th>
<th># Stifles</th>
<th>Additional details</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Seroma</td>
<td>4*</td>
<td>Within 2 weeks postop</td>
<td>None – spontaneously resolved</td>
</tr>
<tr>
<td>Wound dehiscence</td>
<td>1</td>
<td>Due to licking</td>
<td>Correct use of Elizabethan collar as per postop instructions</td>
</tr>
<tr>
<td>Disarticulation</td>
<td>1*</td>
<td>Noted incidentally at 10 months postop</td>
<td>None – dog was clinically normal and stifle continues to be palpably stable at 18 months</td>
</tr>
<tr>
<td>Screw fracture</td>
<td>1</td>
<td>Noted incidentally on radiographs at 4 months when presented for contralateral CrCL rupture</td>
<td>None – EAI remains palpably stable and dog is clinically normal</td>
</tr>
</tbody>
</table>

*1 dog is represented in 2 complication categories.

CrCL, cranial cruciate ligament.
TTA (12.3–38.0%), and extracapsular stabilization procedures (7.2–12.5%). However, the types of complications reported were markedly different and did not include meniscal tears or osteotomy-related complications.12,19,25,28,31,33

Postliminary meniscal tears are commonly reported after TPLO, TTA, and ES, but were not observed with EAI even though meniscal releases were not performed.7,10,12,19,25,34,35 An in silico study predicted that the EAI would significantly reduce peak relative tibial translation and rotation and offer biomechanical advantages to the CrCL-deficient stifle during the stance phase of stride.3 It is our opinion that by immediately improving rotational and translational stability the menisci are spared further damage. While no second look arthrotonomies were performed to verify our findings, there was no clinical evidence of lameness, pain on palpation, or audible meniscal clicks noted in any dog that would be suggestive of a subsequent meniscal tear. However, we acknowledge that we only report here on a limited number of cases over a relatively short time span and that sensitivity of detection of a meniscal click may be affected by experience of the examining clinician. It remains to be seen whether EAI has a truly lower incidence of postliminary meniscal tears than other CrCL procedures.

Disarticulation of the EAI occurred when the femoral plate was not isometrically implanted or applied such that the femoral and tibial plates were not relatively parallel at the articulation. Biomechanical testing indicated that the EAI would disarticulate when the rotational angle between the femoral ball and the tibial insert exceeded 43.5° causing the femoral ball to disengage from the travel channel.14,18 This degree of tibial rotation (internal or external) would only be expected to naturally occur as the result of extreme trauma, but may possibly occur with marked pre-existing tibial torsion in heavier dogs.14,18 In some situations disarticulation of an EAI may prevent joint damage that might occur if there was a more rigid connection, especially with a suboptimally positioned implant.36 All 5 disarticulations occurred in the first 20 cases (4 in the first 11), and 3 of 5 occurred in dogs >45 kg. Tibial torsion was also considered to be a contributing factor in 2 of these 5 cases. In later cases, contouring of the tibial plate was successfully used to compensate for tibial torsion. Experience with and refinements to the surgical technique during the course of this case series appear to have aided in the prevention of disarticulation in later cases (0 of 39).

Complications reported in our study can be categorized as implant failures or implant reactions. Implant failures were primarily attributed to technical errors in implant positioning and/or selection of dogs weighing >40 kg. Screw failures were only seen in dogs >40 kg (5 dogs). Screw failures were associated with the use of screws of insufficient strength and length in heavy dogs and suboptimal contouring of the plates. As a result of this finding it is now recommended that 4.0 mm locking cortical screws be used in hole 1 of the femoral and tibial plates in all dogs and in all screw holes of any dog >30 kg, having sufficient diaphyseal diameter to accept screws of this size, and that all screws must be fully bicortical. Countouring of the plates to increase the contact of the EAI to the femoral and tibial diaphysis (while maintaining a parallel articulation) may also reduce the incidence of screw fracture. Although perfect bone-plate apposition is not required to maintain rigidity with locking plates,
increasing the contact of the EAI through the screw segment should better distribute bone-plate-screw stresses.

Implant reactions included seromas and other tissue reactions of the surgical site. Seroma formation (4 dogs) was only reported in early cases and in dogs <40 kg. Dog size, minor technical errors during early development of surgical technique, and excessive postoperative activity could have been contributing factors. Periosteal reaction and a draining tract in 1 dog could have been attributed to poor contouring of the tibial plate resulting in a single point of diaphyseal contact at the distal end of the screw segment. Improving bone-plate apposition should also prevent this type of reaction. Minor wound dehiscence occurred in 1 dog and was the result of poor client compliance in use of an Elizabethan collar. The cause of a periarticular fibrosis with osseous and chondroid metaplasia occurring 4 weeks postoperatively in one 10-year-old dog is unknown. It should be noted that ASTM-compliant surgical grade stainless steel and UHMWPE both have well-established biocompatibilities.37,38

Early return to mobility is important for preventing loss of ROM (extension) after stifle surgery.36 Studies of other CrCL procedures have reported that preoperative stifle ROM and/or extension does not improve and often worsens after TPLO, TTA, and ES.19,39,40 Similar to other studies, dogs in our study had significantly smaller preoperative TC in the affected limb compared with the contralateral limb due to disuse atrophy in the affected limb and hypertrophy of the contralateral limb.2,10 There are conflicting studies on return of TC after TPLO, TTA, and ES.19,25,39,40 One study of TTA reported an increase in TC by 1 year, but not at 6 months.40 A study of TPLO reported that TC did not return to contralateral limb measurements after 1–5 years, while another study of TPLO and lateral fabellar suture reported an increase in TC when measured at 12 months postoperatively.19,39 This latter study did not compare the surgical limb to the contralateral limb nor did they exclude dogs that became bilaterally affected during the study.19 Based on the available serial data obtained in a limited number of EAI-treated stifles in the early postoperative period (2–12 weeks), it was anecdotally observed that stifles had an initial decrease in TC in the first 4 weeks postoperatively prior to increasing to preoperative levels by 4 months. This finding is consistent with other studies of dogs after CrCL surgery.26,39 Although there was no effect of time on changes in TC after 4 months in our study, the majority of stifles were <12 months postoperatively (median 8.9 months) and therefore it is unknown if the TC would continue to increase with time.

There were several confounding factors that could affect TC such as differences in time from injury to surgical stabilization, physical rehabilitation compliance by clients, dog weight and weight change, and degree of meniscal, CrCL, and CaCL damage. Following transection of the CrCL, it was reported that thigh muscle mass decreased by one third within 5 weeks, and therefore it could be expected that dogs with more chronic injuries would have a greater degree of preoperative muscle atrophy and corresponding hypertrophy in the contralateral limb due to increased weight bearing in that limb.19,26,40 Physical rehabilitation plays a large role in speed of return of thigh muscle after injury and surgery; however, physical rehabilitation in this series was performed by clients and therefore is an uncontrolled variable in recovery of the dogs in our study.19,26,40 Although dog weight was not significantly different preoperatively and postoperatively, weight loss (and gain) in some individuals may have contributed to the variation seen in the range of postoperative TC measurements. Stifles in our study varied from partial CrCL rupture to complete CrCL rupture combined with meniscal and multiligamentous injuries. This variation in the degree and types of stifle joint injuries in our case series might also be a variable affecting recovery. It is also possible that the muscles that aid in stabilizing the stifle joint do not increase in mass significantly after EAI surgery because of the continuous translational and rotational stability it provides to the joint.5 TC results for our study must be interpreted with these confounding factors in mind.

It is possible that due to the limited radiographic evaluation of cases with no apparent complications that there may have been decreased detection of implant-related complications and therefore the minor complication rate may have been underestimated. Radiographs were not evaluated by a board certified veterinary radiologist and due to the small number of stifles evaluated no conclusions about progression of osteoarthritis can be made at this time.

Our report does not directly compare the use of the EAI to other surgical techniques. There are a number of limitations that should be considered when interpreting the results of our study. This was a prospective study to report the efficacy of the EAI in all dogs meeting the minimum weight requirement referred to our surgical service during the defined time period. It is however possible that bias may have been introduced into the population of dogs prior to referral based on the referring veterinarians own experience with CrCL treatment options or when the referring veterinarians had previous experience with outcomes of EAI surgery. Furthermore, bias was likely introduced later in the study as we gained a better understanding of the maximum bone size limits of the implant. The fact that there were fewer dogs >40 kg in the second half of this study suggests there may have

### Table 5 Comparison of preoperative and postoperative outcome measures for 34 EAI-treated stifles. Mean ± SD or median (interquartile range)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Preoperative</th>
<th>Postoperative</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight (kg)</td>
<td>37.3 (32.3–42.4)</td>
<td>37.5 (32.8–41.5)</td>
<td>.40</td>
</tr>
<tr>
<td>Lameness score (out of 5)</td>
<td>4 (3–4)</td>
<td>0 (0–0)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>ROM treated (°)</td>
<td>105 ± 13.2</td>
<td>120 ± 5.8</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>ROM contralateral (°)</td>
<td>107 (100–114)</td>
<td>115 (108–120)</td>
<td>.08</td>
</tr>
<tr>
<td>Extension treated (°)</td>
<td>148 ± 8.8</td>
<td>158 ± 5.9</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Extension contralateral (°)</td>
<td>150 ± 8.0</td>
<td>153 ± 7.3</td>
<td>.17</td>
</tr>
<tr>
<td>TC treated (mm)</td>
<td>43.3 ± 3.6</td>
<td>43.3 ± 3.3</td>
<td>.29</td>
</tr>
<tr>
<td>TC contralateral (mm)</td>
<td>45.8 ± 4.0</td>
<td>44.1 ± 3.3</td>
<td>.007</td>
</tr>
<tr>
<td>Positive cranial drawer / excess internal tibial rotation (# stifles)</td>
<td>34</td>
<td>0</td>
<td>–</td>
</tr>
</tbody>
</table>

*Within normal canine range (95% CI, 118–122).23
been a bias toward smaller dogs as experience was gained in performing the procedure, determining maximum bone size limits of the EAI, and in response to some of the complications seen in larger dogs. Nonetheless, all dogs in the study were large or giant breed dogs and this change in weight distribution likely only affected the complication rate and should not be expected to alter the analysis of other outcome measures. The inclusion of dogs with bilateral CrCL disease could introduce a source of bias when analysing data; however, only dogs that were not lame on the contralateral limb and were >6 months postoperative of contralateral stifle surgery were included, consistent with inclusion criteria for at least one other CrCL study.

Another limitation is that assessment of outcome measures were not blinded and postoperative examination times varied. Postoperative evaluations were performed multiple times in some dogs (especially earlier in the study) while other dogs only had one evaluation. While it was initially intended that all dogs would have examinations at the same time intervals it proved to be logistically unattainable due to the geographic distance between participating clinics and difficulty coordinating schedules of the clients, referring clinics, and the investigators. It should be noted that statistical analysis showed no effect of recheck time on changes in TC or ROM. Another limitation is the subjective nature of lameness scoring, which is arguably more accurate for dogs with higher lameness scores (3–5) than those with lower scores (0–2), and very mild lameness may therefore be missed. However, as discussed, the use of video and slow motion analysis for postoperative lameness scoring may have improved the accuracy of the lower scores in this study. Lameness was only scored at the walk and it is possible that some dogs that were sound at the walk may have been lame at the trot. Preoperative lameness scores based on observation made by the referring veterinarians in cases that could not be examined by the authors may have resulted in some variability in preoperative lameness scores assigned; however, most affected limbs had high lameness scores preoperatively and all scores were assigned by the authors using the same criteria used postoperatively. The use of NSAID and analgesics was not restricted postoperatively and although no dog was reported to be on full dose NSAID, some dogs were on very low doses of NSAID, which may have masked mild lameness. Use of force plate analysis for lameness assessment may have provided a more objective outcome measure; however, this technique was not available for our study.

The clinical outcomes of this initial case series are very encouraging, particularly the high incidence of improvement in lameness scores, extension, and ROM, which support the predictions of in silico studies. The complication rates could be considered relatively low for a new procedure and future complication rates may be reduced by adherence to recommendations to limit use of this size EAI to dogs <40 kg, by using 4.0 mm locking screws in femoral and tibial plate hole 1, and in all holes in dogs >35 kg. To accommodate dogs outside of this size range, new sizes of this EAI have been designed and are currently in production and undergoing clinical trials.

ACKNOWLEDGMENTS

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DISCLOSURE

Drs. Barkowski and Embleton hold the patents and receive financial compensation based on sales of the implant, which has been licensed to New Generation Devices for manufacture and distribution and is commercially available as Simitri Stable in Stride®.

REFERENCES


