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Comparison of Semi-Cylindrical Recession Trochleoplasty and Trochlear Block Recession for the Treatment of Canine Medial Patellar Luxation: A Pilot Study

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Abstract

Objective The aim of this study was to describe an alternative method for trochleoplasty, semi-cylindrical recession trochleoplasty (SCRT), and compare it to trochlear block recession (TBR) in regard to recessed trochlear depth, patellar depth, patellar articular contact with the trochlea, recessed trochlear surface area, procedure time, complications and functional outcome.

Study Design Ten dogs with bilateral grade II-III medial patellar luxations underwent bilateral simultaneous correction surgery including tibial tuberosity transposition, lateral imbrication and trochleoplasty with one stifle each undergoing TBR and SCRT. Patients received pre-and postoperative stifle computed tomography scans and pre- and 8-week postoperative pressure platform analysis and physical examinations. Recessed trochlear depth, patellar depth, trochlear surface area, patellar articular contact, procedure time, complications and functional outcomes as measured by gait analysis were compared between the two techniques.

Results There was no significant difference in measured outcome variables between techniques at any time point. At the time of the 8-week reassessment, no patella had reluxated.

Conclusion Short-term follow-up shows similar functional outcomes between both techniques regarding rate of reluxation and limb function. The SCRT was subjectively easier to perform than TBR, particularly in small patients. The SCRT is an acceptable method of trochleoplasty for the treatment of medial patellar luxation in dogs and further studies evaluating long-term outcomes are justified.

Keywords
- ► patellar luxation
- ► stifle
- ► dog
- ► recession trochleoplasty
- ► computed tomography

Introduction

Patellar luxation, resulting from malalignment of the quadriceps mechanism and insufficient depth of the femoral trochlea, is a common orthopaedic disease encountered in canine patients.[1–10] When persistent lameness occurs due to patellar luxation, surgical realignment of the quadriceps mechanism and deepening of femoral trochlea are often recommended to stabilize the patella within the trochlear sulcus.[1,2,4,6–12] Complication rates following surgical correction vary between 13 and 48% with reluxation of the patella being one of the most common complications, accounting for 65 to 86% of major complications.[2,3,5–8] Given this frequency and complication rate, improvement in surgical techniques used to correct patellar luxation would be beneficial.

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The goal of trochleoplasty is to produce a deep and wide enough trochlear groove so that ~50% or less of the patella protrudes above the trochlear ridges.[8,12,13] Trochleoplasty in addition to realignment of the quadriceps mechanism via tibial tuberosity transposition results in a 5.1-fold reduction in the rate of patellar reluxation.[2] Several techniques for deepening of the femoral trochlea have been described, but techniques which preserve articular cartilage result in slower development of osteoarthritis as well as a faster return to function.[1,2,8,9,11,14]

Trochlear wedge recession (TWR) and trochlear block recession (TBR) are two common trochleoplasty techniques used to preserve articular cartilage. It has been previously shown in a cadaveric study that TBR results in improved proximal patellar depth, increased patellar contact with the recessed proximal trochlea and decreased rate of patellar reluxation during stifle extension compared with TWR.[1] These benefits result from the rectangular shape of the TBR which maintains the width of the osteochondral block proximally compared with the proximally tapered point of the TWR.[1] However, TBR can be technically challenging as care must be taken to prevent fracture of the osteochondral block while undermining it with an osteotome and several adjustments to the block and/or recessed bed are often necessary to achieve a press-fit with the correct depth of the femoral trochlea.[8] Despite the reported advantages of TBR, in one retrospective study the type of femoral trochlear osteotomy did not affect postoperative complication rate; limb function and progression of osteoarthritis were not addressed in that study.[15]

The objective of this study was to describe an alternative method for trochleoplasty, semi-cylindrical recession trochleoplasty (SCRT), and compare the technique to TBR. In this pilot, clinical, noninferiority trial, our null hypothesis was that surgical technique would not influence postoperative trochlear depth, patellar depth, patellar articular contact with the trochlea, percentage of recessed trochlear surface area, procedure time, complications or limb function.

Materials and Methods

Subjects

This study received institutional IACUC (Institutional Animal Care and Use Committee) approval, and written, informed client consent was required for patient inclusion. Owners received a discount for participation in the study which they were made aware of prior to enrolment in the study (owner financial incentive was included in the informed client consent form). Ten healthy, adult dogs with naturally occurring medial patellar luxation were included in the study. Inclusion criteria included (a) bilateral grade II–III medial patellar luxation according to the Putnam classification[16] causing clinical lameness (reported by the owner or found during the physical examination), (b) no history of trauma, (c) no other orthopaedic conditions including cranial cruciate ligament rupture or marked skeletal deformities of the hindlimbs and (d) candidates for simultaneous bilateral surgery[17] based on history of both hindlimbs being affected, bilateral luxating patellas with stifle pain on examination, no other patient co-morbidities and owner confidence they could follow postoperative recommendations.

Computed Tomography

Preoperative and postoperative stifle computed tomography (CT) scans were performed using a 64-slice helical CT scanner (Toshiba Aquilion 64, Canon Medical Systems, Tustin, California, United States). All images were acquired at the following CT settings: 120 kV, 200 mA, 5.81-second scan time, 0.5-mm contiguous slices, bone resolution with a small scan field of view. The preoperative CT scan was performed under heavy sedation with the patients placed in dorsal recumbency with the limbs extended caudally and the stifle joints slightly bent at an angle of ~150 degrees and the patella maintained within the trochlear groove.[1] Postoperative CT scans were performed under general anaesthesia immediately following surgery with the patients positioned similarly. Measurements were made using an image-analysis software programme (Carestream Image Suite V4, Carestream Health, Rochester, New York, United States).

Measurements taken from the digital CT images included preoperative trochlear width and the following measurements were taken from the CT and/or calculated as previously described[1]: (1) pre- and postoperative trochlear depth, (2) pre- and postoperative patellar depth and change in patellar depth, (3) pre- and postoperative patellar articular contact with the trochlea and (4) the percentage of recessed trochlear surface area. Trochlear width was measured using the single transverse CT image at the centre of the reduced patella by drawing a straight line across the top of the trochlear ridges from the centre of the medial side to the centre of the lateral side (►Fig. 1). Measuring trochlear width preoperatively helped guide SCRT blade selection for each patient (SCRT blade diameter was equal to or less than 1 mm less than trochlear width). Final blade width selection was an intraoperative decision.

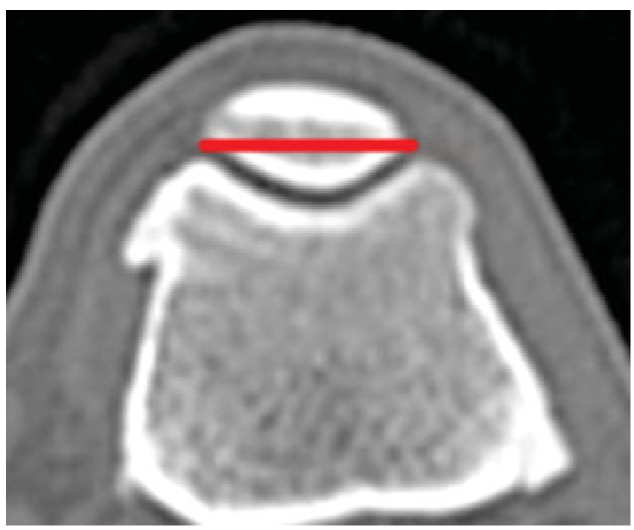

Fig. 1 Trochlear width was measured using a single transverse computed tomographic image at the centre of the patella by drawing a straight line across the top of the trochlear ridges from the centre of the medial side to the centre of the lateral side (red line).

Postoperative CT images were assessed for fit of the osteochondral autograft into the recipient bed by looking for a gap between the recessed autograft and underlying subchondral bone.

Gait Analysis

Pressure-platform gait analysis (Walkway 4, Tekscan, Boston, Massachusetts, United States) was performed before and 8 weeks after surgery. A 2×0.75-m pressure measurement walkway mounted in the centre of, and level with, a 10-m runway was used for gait analysis. Output from the walkway was linked to a dedicated computer with software designed for collection of gait analysis data. Prior to data acquisition for every patient, the walkway sensors were equilibrated and calibrated in accordance with manufacturer's specifications. The same point calibration method with a three-legged, 25-kg phantom was used for each patient.[18] Before each session, dogs were weighed on an electronic scale and allowed to acclimate to the runway area and pressure platform. All dogs were walked across the pressure platform at a comfortable velocity by the same person at all time points. At the reassessment appointment, the walking velocity parameters were restricted to within 0.15 m/s of the preoperative velocity. Acceleration was not measured. A valid trial consisted of the dog walking at a consistent velocity in the aforementioned ranges across the entire pressure platform, each of the four limbs fully contacting the walkway at least once during a dog's passage and the dog walking in a straight line. A single observer evaluated each trial using the computer software and determined whether the trial was valid. The first five valid trials were used for data analysis. Pressure distribution data including peak vertical force (PVF) and vertical impulse (VI) were determined for each footfall for each of the valid trials as a percentage of body weight, and mean values were calculated. Since PVF and VI are not independent variables, a multivariate approach that evaluated PVF and VI together was used to evaluate limb function.[19–21] A symmetry index was calculated for pre- and postoperative PVF and VI using the formula $SI = [50 \times (PVF_{SCRT} - PVF_{TBR})/(0.5 \times (PVF_{SCRT} + PVF_{TBR}))] + [50 \times (VI_{SCRT} - VI_{TBR})/(0.5 \times (VI_{SCRT} + VI_{TBR}))$.

Procedures

Following preoperative CT measurements, patients were randomized using a coin toss so that the right limb would always be operated on first, but the surgical technique (SCRT or TBR) was randomized. Patients were anaesthetized, and then given an epidural and prepared for aseptic surgery. All surgeries were performed by a board-certified surgeon (MCG) who performed the technique on artificial bones and in cadavers in preparation for the study. Prior to the study, his preferred method of trochleoplasty was the TBR. Following exploratory lateral arthrotomy, corrective procedures were performed in the following order: trochleoplasty, tibial tuberosity transposition held in place with two Kirshner wires and lateral joint capsule/retinacular imbrication. The subcutaneous tissues and skin were closed routinely. After surgery of the right stifle was completed, surgery of the left stifle was performed using the alternate trochleoplasty technique.

The TBR was completed as previously described using a hobby saw and osteotome.[1,11] The amount of time from the initiation of the osteotomy to the final placement of the osteochondral graft in the recipient bed was recorded. The SCRT osteotomies were performed using a SCRT hole saw attached to a high-speed drill (Striker, Kalamazoo, Michigan, United States). The SCRT hole saws were machined from medical grade 316L stainless steel with a 0.28 mm kerf. Available hole saw diameter sizes included 4 to 12, 14, 16 and 18 mm. The diameter of the hole saw used was determined using the preoperative CT measurement of trochlear width and intraoperative discretion comparing the size of the saw to the width of the trochlear groove (►**Fig. 2A**); the goal was to have the blade extended to the centre of the medial and lateral trochlear ridges with any error on a slightly narrow hole saw diameter. The SCRT was performed as follows: a customized aiming guide (AR-1510H and AR-1510F, Arthrex, Naples, Florida, United States) was used to place a 1.1-mm Kirschner wire (K-wire) from distally to proximally, beneath the centre of the trochlea. This pin began just proximal to the intercondylar fossa and exited centred and ~5 mm proximal to the most proximal aspect of the femoral trochlear articular cartilage (►**Fig. 2B**). A custom-made cutting guide (machined polyether ether ketone) was used to guide the SCRT hole saw. The cutting guide was placed on the K-wire so the osteotomy would remove a superficial osteochondral semi-cylinder (►**Fig. 2C**). The exact location of the pin exit site, the size of the osteochondral segment and the amount of bone removed depended upon patient size, change in patellar depth desired and location of the patellar luxation (based on visual evidence of wear of the medial femoral trochlear ridge). For example, if the base of the patella visually rested at the proximal aspect of the femoral trochlear cartilage at a functional stifle angle at the time of surgery and we wanted to deepen the groove 3 mm, a pin exit site 5 mm proximal to the femoral trochlear cartilage would be selected. This would allow for an initial cut to include all cartilage on the femoral trochlear cartilage and allow for a second cut to deepen the groove. The change in depth of the patella was measured from the CT and confirmed in surgery by measuring how many millimetres the femoral trochlear groove would be deepened for 50% of the patella to sit below the femoral trochlear ridges. This measurement correlated with the adjustment necessary on the cutting guide. If we elected to make the second osteotomy 3-mm deeper than the first, we would move the cutting guide two holes deeper on the K-wire (holes on the cutting guide were 1.5-mm apart). Individual variability, as described above, required intraoperative discretion. The initial cut was made using the cutting guide and hole saw and the osteochondral semi-cylinder was set aside in a blood-soaked gauze (►**Fig. 2D–F**). The cutting guide was then repositioned on the K-wire in hole of the guide that would allow for ostectomy of the correct depth and a second osteotomy was made (►**Fig. 2G**). When the second osteotomy was completed, the bone was set aside in a blood-soaked gauze (used for bone graft at the tibial tuberosity site) and the osteochondral autograft was replaced in a recessed position (►**Fig. 2H, I**). If

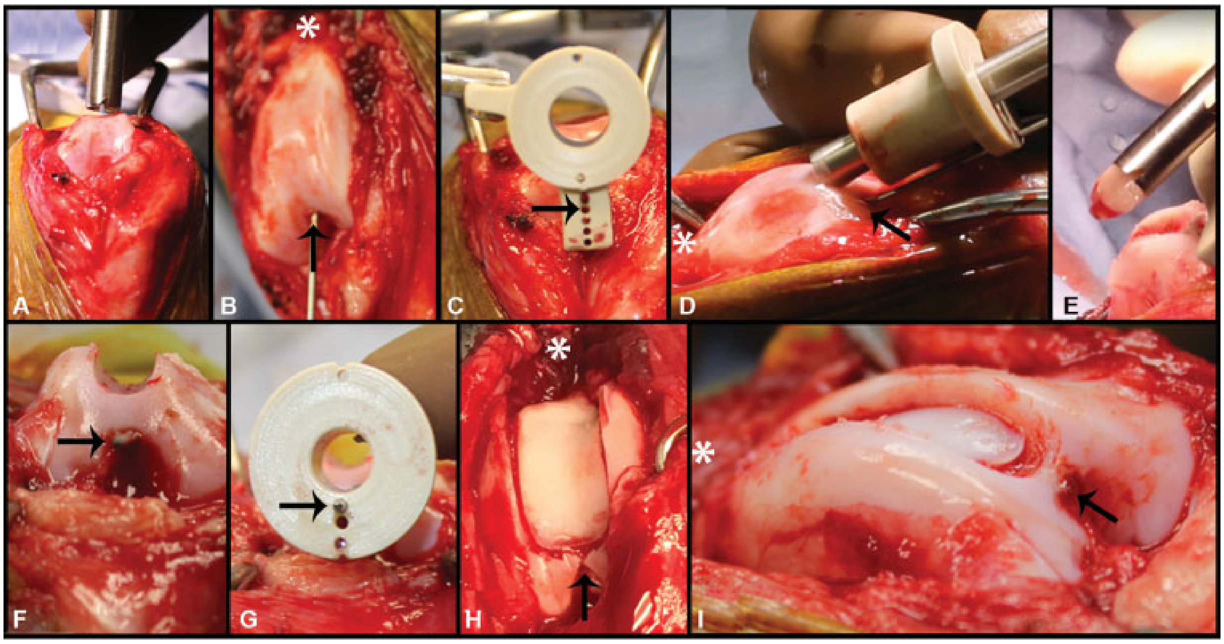

Fig. 2 The SCRT procedure. (A) Distoproximal view of the trochlea to select SCRT blade size. (**B**) Dorsal view showing placement of the SCRT guidewire. The white asterisk (*) indicates guidewire exit point, and the black arrow indicates guidewire entrance point. (**C**) Distoproximal view of placement of the guide on the guidewire for initial osteotomy to remove a superficial osteochondral semi-cylinder centred between the trochlear ridges. (**D**) Mediolateral view of the initial osteotomy made with the SCRT blade. (**E**) Image of the osteochondral semi-cylinder maintained within the SCRT blade after the initial osteotomy. (**F**) Distoproximal view of the trochlear groove after the initial osteotomy. (**G**) Placement of the guide on the guidewire for the second osteotomy. (**H**) Dorsal and (**I**) mediolateral view of the completed SCRT procedure. SCRT, semi-cylindrical recession trochleoplasty.

the depth of recession was subjectively determined not to be deep enough, the osteochondral graft was set aside, and the process repeated (with or without the guide) to further deepen the trochlear recession. The K-wire was removed. The complete time of the procedure just before placement of the K-wire to the removal of the K-wire was recorded. Intraoperative technical errors that occurred with either procedures were recorded.

Following postoperative CT scans, soft padded bandages were applied to both limbs overnight. Analgesic medications were administered overnight including hydromorphone (0.05 mg/kg SQ every 4 hours as needed for pain) and a nonsteroidal anti-inflammatory drug. Patients were sent home with instructions for the owners to administer an oral nonsteroidal anti-inflammatory drug for 14 days, codeine (1–2 mg/kg by mouth every 8–12 hours for 7 days) and trazodone (5 mg/kg by mouth every 8–12 hours as needed for the duration of the activity restriction). Owners were instructed to ice the incisions for 10 minutes, four times per day for the first 2 days after returning home. In addition, uniform controlled exercise instructions were provided including leash/sling walking for 5 minutes three to four times per day for the first 4 weeks, 10-minute walks three to four times per day for weeks 5 to 6 and 15-minute walks three to four times per day for weeks 7 to 8. Exercise restriction was advised beyond the instructed walks.

Reassessment

Sutures were removed at 10 to 14 days postoperatively. Eight weeks following surgery, patients were seen for a reassessment. At the 8-week reassessment, a history, physical examination (re-examination of medial patellar luxation grade) and pressure platform gait analysis (Tekscan) were performed. After gait analysis, patients were sedated with butorphanol (0.3 mg/kg intravenously) and dexmedetomidine (2 µg/kg intravenously) and radiographs were obtained of both stifles to assess bone healing of the tibial tuberosity transposition. Radiographic healing was subjectively evaluated to guide exercise instructions after the 8-week reassessment. Medial patellar luxation grade was also assessed under sedation.

Data Analysis

The continuous data (TBR versus SCRT) were analysed using a paired *t*-test. The following response variables were evaluated: pre- and postoperative trochlear depth, postoperative change in trochlear depth, pre- and postoperative patellar depth, postoperative change in patellar depth, pre- and postoperative patellar articular contact with the trochlea, per cent recessed trochlear surface area, procedure time, pre- and postoperative PVF and pre-and postoperative VI. Complication rates and fit of the autograft into the recipient bed are described for each surgery type; there were not enough events to warrant statistical comparison. A difference in major complication rate of $>10\%$ between groups was determined to be clinically significant. Pre- and postoperative symmetry indices were assessed using 95% confidence intervals for the mean, with a mean symmetry difference of $>6\%$ being considered clinically significant.[22]

Results

Study Subjects

Five neutered male dogs and five spayed female dogs were included in the study. Mean body weight was 11.5 ± 5.9 kg (standard deviation [SD]) (range: 3.9–21.5 kg) and mean age was 3.65 ± 2.40 years (SD) (range: 1–9 years).

Since limbs from each dog were split into groups (TBR or SCRT), there were 10 limbs in each group. After randomization of surgical technique, both the TBR group and SCRT group consisted of five right and five left limbs. Median preoperative medial patellar luxation grade was 2.5 (range: 2–3) for both techniques.

CT Measurements

There was no difference between preoperative trochlear depth, postoperative trochlear depth, postoperative change in trochlear depth, pre- and postoperative patellar articular contact and recessed trochlear surface area between the procedures (►**Table 1**).

There was a difference in pre- and post-operative patellar depth between procedures, but there was no difference in the change in patellar depth between the procedures.

Postoperative CT images showed a gap between the recessed trochlear block and underlying subchondral bone postoperative in 3 of 10 TBR stifles; there were no gaps present in SCRT stifles ($p = 0.25$) (►**Fig. 3**).

Table 1 Pre- and postoperative CT measurement data.

Variable	Time	TBR mean (SE)	SCRT mean (SE)	Difference	*p*-Value	Confidence interval low	Confidence interval high
Trochlear depth (mm)	Pre	1.37 (0.23)	1.38 (0.25)	−0.01	0.932	−0.268	0.248
Trochlear depth (mm)	Post	2.64 (0.44)	2.97 (0.46)	−0.33	0.191	−0.858	0.198
Change in trochlear depth (mm)	Post	1.27 (0.28)	1.59 (0.32)	−0.32	0.241	−0.896	0.256
Patellar depth (%)	Pre	2.89 (0.86)	5.67 (1.52)	−2.787	0.017	−4.936	−0.638
Patellar depth (%)	Post	18.79 (2.05)	26.20 (3.96)	−7.406	0.057	−15.074	0.262
Change in patellar depth (%)	Post	15.91 (1.43)	20.53 (3.80)	−4.62	0.257	−13.26	4.02
Patellar articular contact (mm)	Pre	159.28 (17.49)	172.98 (17.11)	−13.707	0.206	−36.469	9.055
Patellar articular contact (mm)	Post	146.44 (20.36)	173.03 (24.82)	−26.587	0.166	−66.493	13.319
Recessed trochlear surface area (%)	Post	93.88 (7.97)	92.52 (9.13)	1.361	0.82	−11.747	14.47

Abbreviations: CT, computed tomography; SCRT, semi-cylindrical recession trochleoplasty; SE, standard error; TBR, trochlear block recession.

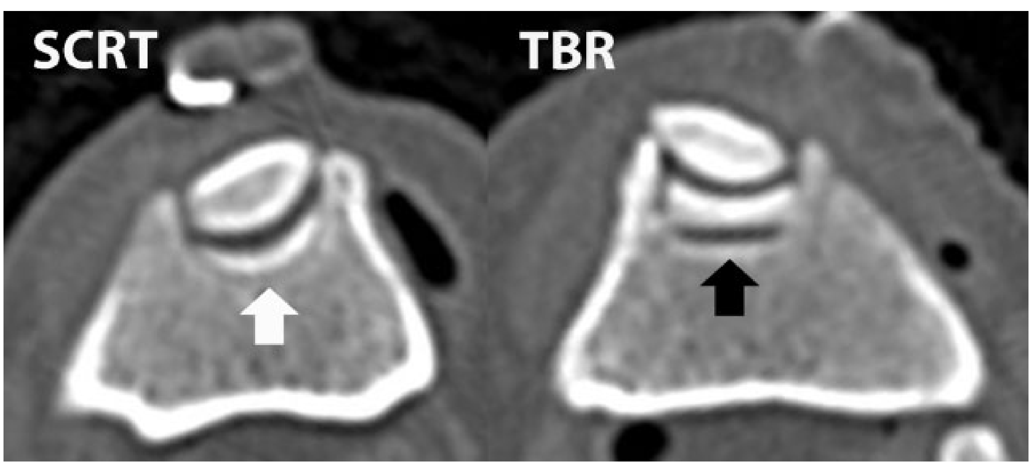

Fig. 3 Postoperative computed tomographic images of the stifles of the same dog demonstrating the precise fit of the SCRT (white arrow) and the gap between the TBR and the recipient bed (black arrow), indicating imprecise fit. SCRT, semi-cylindrical recession trochleoplasty; TBR, trochlear block recession.

Procedure Time

There was no difference in procedure time (TBR: 10.7 ± 0.6 minutes, SCRT: 9.4 ± 0.6 minutes, $p = 0.169$).

Technical Errors and Complications

There were no technical errors or intraoperative complications in the SCRT group. In the TBR group, 3 of 10 blocks fractured intraoperatively while cutting the femoral trochlea with the osteotome. One of the block fractures was complete and extended through the cartilage and subchondral bone, and the remaining two block fractures were incomplete and extended through the subchondral bone but not the cartilage. The blocks were used in all cases.

One postoperative adverse event, a superficial incisional infection, induced acute nonweightbearing lameness of the limb. The infection was treated with cephalexin (22 mg/kg by mouth every 12 hours for 14 days) and the infection was resolved at a 7-day reassessment. This limb was in the SCRT group and the adverse event was reported as unlikely to be from the choice of surgical technique. There were no patellar reluxations or other complications during the study period.

Eight-Week Reassessment

At the 8-week reassessment, healing of the tibial tuberosity transposition was subjectively reported by a board-certified radiologist as complete (callus present, no osteotomy visible) in 3 of 20 stifles, moderate (callus present, osteotomy barely visible) in 11 of 20 stifles, mild (callus present, osteotomy mostly visible) in 4 of 20 stifles and delayed union (no callus present, osteotomy clearly visible) in 0 of 20 stifles. Bone healing was unable to be determined due to positioning in 2 of 20 stifles with no difference in healing between treatment groups. All dogs had a patellar luxation grade of zero at the 8-week reassessment.

Pressure Platform Gait Analysis

There was no difference in preoperative or 8-week postoperative PVF or VI between techniques (►**Table 2**).

Although all dogs included in this study had reported history and physical examination abnormalities attributed to their medial patellar luxations, 7 of 10 dogs had a preoperative mean asymmetry of <6%. Preoperative mean asymmetry was 2.05% ($p = 0.582$, SD: ± 11.35; range: –8.93 to 31.36; 95% confidence interval: –6.07 to 10.18). In the 8-week postoperative period, one dog was >6% asymmetrical on the TBR limb and two dogs were >6% asymmetrical on the SCRT limb. This difference was not significant between groups. Eight weeks after surgery mean asymmetry was −4.27% ($p = 0.318$, SD: ± 12.76; range: −35.21 to 7.12; 95% confidence interval: −13.4, 4.87). Since these confidence intervals include both clinically relevant (>6%) and clinically irrelevant (<6%) values, we cannot claim with 95% confidence that the procedure is either worse or noninferior.

Discussion

Since we did not identify a statistical or clinical difference in any of the studied variables, we failed to reject our null hypothesis. Consequently, in this study population we found SCRT an acceptable method of trochleoplasty for the treatment of medial patellar luxation in dogs.

The purpose of this pilot clinical study was to determine if SCRT resulted in an obvious increase in adverse events or poorer clinical outcomes compared with the TBR. In this short-term outcome study, we compared left to right rear. We made no attempt to determine if dogs became more normal after surgery. Failure to detect differences between groups could be attributed to study design (e.g. study power or duration). The surgeon in this study was experienced performing the TBR, while the ten SCRT cases in this study were the first ten clinical cases performed. We designed the study in this manner because we felt that a clinically important difference between groups, especially when it comes to risk of the surgical procedure and short-term outcomes, would best be identified early in the use of a new surgical technique. Gait analysis was used in this study as an objective outcome measure to determine the influence of surgical technique on short-term limb function. Although all dogs included in this study had reported history and physical examination abnormalities attributed to their medial patellar luxations, 7 of 10 dogs had a preoperative mean asymmetry of <6%. This is thought to be due to the bilaterally symmetrical nature of these patients' lameness.

Subjectively, the SCRT technique was technically straightforward, provided precise osteotomies, was guided toward patient individual variation and still allowed for versatility. While TBR can be reliably performed, there may be some advantages to the SCRT procedure that should be considered. First, the rounded osteotomy from the hole saw reduces the chances of fracturing the femoral trochlear ridges when compared with square cuts. This may allow for a wide, yet

Table 2 Pre- and postoperative pressure platform analysis data

Variable	Time	Mean difference (block-SCRT)	*p*-Value	Confidence interval low	Confidence interval high
Peak vertical force (% BW)	Preoperative	−0.55	0.66	−3.35	2.24
Peak vertical force (% BW)	8 weeks postoperatively	1.15	0.40	−1.82	4.13
Vertical impulse (%BW*s)	Preoperative	−0.21	0.57	−1.00	0.58
Vertical impulse (%BW*s)	8 weeks postoperatively	0.47	0.23	−0.35	1.29

Abbreviations: BW, body weight; SCRT, semi-cylindrical recession trochleoplasty.

safe cut in the femoral trochlea. Second, the cutting guide and a thin walled saw blade allow for creation of an osteochondral autograft in very small dogs. The smallest patient in this study had a body weight of 3.9 kg and a 6-mm SCRT cutting guide and blade was used on this dog. There were two smaller blade sizes available (4 and 5 mm) in the instrumentation provided. The SCRT procedure was successfully performed on a patient weighing 1.9 kg at the authors' institution using a 5 mm blade; in our opinion TBR would have been technically challenging to perform in a patient this size. The SCRT uses a drill guide to place a pin that establishes osteotomy angle and exit point of the osteotomy on the femur. With TBR, the angle of the osteotome (in both planes) and exit of the osteotomy are completely dependent upon estimation by the surgeon. The cutting guide allows for depth control of the second osteotomy. If the goal is to deepen the groove 3 mm, the cutting guide is simply moved on the guide pin by 3 mm. One technical challenge that was identified with the SCRT technique is that the guidewire is small and flexible, so care must be taken not to deform the wire by raising or lowering the drilling hand.

The results of this pilot study could have been biased because all procedures were performed by a single surgeon, thus extrapolation of these results broadly to other practitioners may not be accurate. Additionally, short-term follow-up of 8 weeks might not be long enough to detect a difference in outcome or complications such as reluxation between the techniques.[4] Furthermore, while the use of subjects with bilateral disease offers an internal control for the procedures, bilateral procedures have the potential to affect the gait analysis outcome of the contralateral limb positively or negatively.

We found similar short-term outcomes were achieved with SCRT and TBR regarding depth of recession, complications and limb function. The SCRT was subjectively easier to perform than TBR, particularly in small patients. The SCRT is an acceptable alternative method of trochleoplasty for the treatment of medial patellar luxation in dogs and further studies evaluating long-term outcomes are justified.

Authors' Contributions

C.L.B.W. and M.G.C. contributed to study conception, design, and data acquisition and manuscript drafting. A. K.R. contributed to study design. M.D. contributed to data acquisition. All authors contributed to data analysis and interpretation, manuscript revision, and approval of submitted manuscript and are held publicly accountable for relevant content.

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Conflict of Interest

C.L.B.W. reports grants from University of Minnesota, during the conduct of the study. The other authors have no conflicts of interest, financial or otherwise, to report.

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