Received: 13 March 2023 | Revised: 24 May 2023 | Accepted: 26 June 2023

DOI: 10.1111/vsu.13993

CLINICAL RESEARCH

WILEY

Medial versus lateral transcondylar screw placement for canine humeral intracondylar fissures: A randomized clinical trial

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Abstract

Objective: To determine the influence of screw direction on complications following transcondylar screw placement for the treatment of canine humeral intracondylar fissures (HIFs).

Study design: Equivalence, parallel group, randomized clinical trial.

Sample population: Fifty-two client owned dogs (73 elbows).

Methods: Transcondylar screw placement was randomized to either a medial or lateral approach. The primary outcome was the incidence of postoperative complications.

Results: There were 37 cases in the lateral approach group and 36 cases in the medial approach group. There was a significantly greater proportion of postoperative complications following placement of transcondylar screws from a lateral to medial direction ($p = .001$). There were seven cases with complications (19%) in the medial approach group versus 23 cases with complications (62%) in the lateral approach group. The majority of complications were seromas ($n = 13$) and surgical site infections ($n = 16$) with 4 complications requiring further surgery. Implant area moment of inertia (AMI), normalized to bodyweight, was lower in dogs with a major complication ($p = .037$).

Conclusion: Transcondylar screws placed from lateral to medial for canine HIFs had a greater proportion of postoperative complications in this randomized clinical trial design. Implants with a lower AMI, relative to bodyweight, were more likely to lead to major complications.

Clinical significance: We recommend placing transcondylar screws from medial to lateral for canine HIFs to reduce the risk of postoperative

Presented at the British Veterinary Orthopaedic Association (BVOA) Autumn Meeting November 24, 2022, Leeds, UK.

complications. Relatively small diameter implants had an increased risk of major complications.

1 | INTRODUCTION

Humeral intracondylar fissure (HIF) is a condition predominantly affecting Spaniels which can cause either a persistent lameness or a humeral condylar fracture without major trauma.[1–3] This condition has also been described as an incomplete ossification of the humeral condyle (IOHC).[1] This name may be inaccurate for adult dogs with this condition as there are case reports reporting progression of a partial HIF to a complete HIF[4] and also de novo formation of a HIF in a previously normal humeral condyle.[5]

HIF is occasionally identified incidentally when imaging of the contralateral humerus is performed on dogs with unilateral humeral condylar fractures.[6,7] In the specific instance of an incidental HIF in Spaniels it has been shown that 18% of these cases go on to suffer a subsequent humeral condylar fracture with a further 6% becoming lame and requiring surgical treatment.[8]

Treatment of the lame dog with a HIF or an incidental HIF has been described using a transcondylar screw with or without an autogenous bone graft.[2,9–12] Complications following placement of a transcondylar screw have been reported to range from 15% to 69%.[9,12–16] The most common reported complications are seromas or surgical site infections, and the incidence of these complications is much greater when compared with other clean orthopedic procedures.[17–19] Implant failure has also been reported following placement of a transcondylar screw,[20] which can occur up to 4 years following surgery.[13] This has led to recommendations to place a large transcondylar implant with a large area moment of inertia (AMI),[21] to reduce the risk of implant failure. Recently this recommendation has been questioned as overly large implants may increase the risk of intraoperative medial epicondylar fissure fractures.[22]

Several studies have reported a reduced complication rate or no difference in complication rate in dogs with a HIF with placement of screws from a medial to lateral direction when compared with historic data on cases with screws placed from a lateral to medial direction.[14,23,24] However, placing screws from medial to lateral comes with a higher risk of inadvertently penetrating the elbow joint, due to the shape of the humeral condyle.[25] Given that the level of scientific evidence on this topic is low, and separate studies report contradictory findings, many surgeons tend to decide on screw direction based on personal preference.[13,22]

Clinical decision making based on surgeon preference, where no single treatment option is clearly more effective than the other, is termed clinical equipoise.[26] This state of clinical equipoise presents the opportunity to design an ethically sound randomized clinical trial. When trying to inform clinical decision-making, in both the medical and veterinary profession, the highest level of evidence relies on conducting a randomized clinical trial.[27]

The aim of this study was to provide the highest level of evidence to determine if the direction of transcondylar screw placement has any effect on the incidence of postoperative complications in dogs with HIFs. The null hypothesis was that there would be no difference (equivalence) in the incidence of complications between medial and lateral screw placement. As a secondary hypothesis we explored whether the AMI of the implants used was related to the incidence of implant failure.

2 | MATERIALS AND METHODS

2.1 | Animals

Ethical approval for the study was granted by the University of Bristol ethical review committee (VIN/18/061). Client consent for entry into the clinical trial was gained during initial consultation using a client consent form (Appendix A). CONSORT guidelines for reporting randomized clinical trials were followed from the point of study design through to manuscript preparation for publication.[28] For dogs to be eligible for trial enrolment they needed to have been diagnosed with either a unilateral or bilateral HIF on computed tomography (CT) and have been recommended transcondylar screw placement by a veterinary orthopedic specialist. All cases were enrolled from a single veterinary referral hospital in the United Kingdom by individual surgeons managing these cases. Cases with condylar fracture receiving a transcondylar screw in addition to a lateral plate or antirotational Kirschner wire were not enrolled in the trial. The trial design was a parallel group randomized clinical trial with an allocation ratio of 1:1. Once the clinical decision to place a transcondylar screw had been made, in consultation with the pet owner, cases were randomly allocated to receive the transcondylar screw from either medial or lateral. Prior to study commencement, a list stating the direction of screw placement was made by one author (DC). This list was generated using

Microsoft Excel (Microsoft Corporation) using blocks of 10 for randomization. For bilateral HIF cases the side of the dog was randomized using an identical method. This allowed for these bilateral cases to receive transcondylar screws from different directions in the right and left elbow. For example, if the right elbow was randomly allocated to receive a screw from lateral to medial then the left elbow would receive a screw from medial to lateral. This allowed these bilateral cases to follow a paired design where the contralateral elbow acted as a dogs own control. The authors and surgeons were not blinded to group allocation. Cases were enrolled from the January 1, 2019 to January 21, 2022. There was no change to procedure or trial methodology during the trial period and no interim analysis was performed prior to the end of the study. The end date for the trial was decided based on a priori power analysis. It was estimated that we would need to recruit approximately 70 elbows based on previous data on the incidence of postoperative complications with the effect size set at 20%, alpha at 0.05 and power at 0.8. The primary outcome measure was predefined as the incidence of any type of postoperative complication. Follow-up data was collected to allow for a minimum follow-up of 6 months from surgery. Data recorded for each case included patient identification, date of surgery, age, breed, gender, weight, primary surgeon, reason for screw placement, computed tomography (CT) findings, surgical approach, implants, anesthetic details and any follow-up findings including information obtained from a scheduled telephone call with the owners.

2.2 | Imaging

All cases underwent CT examination of both elbows for the investigation of either unilateral humeral condylar fracture or forelimb lameness prior to inclusion into the study. Images were acquired using Siemens Emotion 16 slice 5th generation MSCT scanners (Siemens, Germany). For each elbow, data was collected using a helical acquisition with a slice thickness of 0.6 mm, a pitch of 0.8 and a 1 s tube rotation time. For each elbow, a set kVp of 130 and variable mA were used. Scans were performed using a 59-inch field of view and reconstructed with a 512 × 512 matrix size and a Siemens specific sharpening algorithm (U91 s ultrasharp) to optimize spatial resolution. All images were viewed using a window level of 600 and a window width of 3000 Hounsfield units. Dogs were sedated for CT with a combination of intravenous (IV) dexmedetomidine (Dexdomitor, Zoetis, Parsippany, New Jersey) (5–10 μg/kg) and methadone (Comfortan, Elanco, Indianapolis, Indiana) (0.2–0.3 mg/kg) or butorphanol (Torbugesic, Zoetis) (0.2–0.3 mg/kg). A CT diagnosis of a HIF was given if there was a hypoattenuating defect within the humeral condyle with adjacent sclerosis of the humeral condyle. Both complete and partial fissures were included. A complete fissure was defined as a hypoattenuating defect extending from the articular surface of the humerus to the supratrochlear foramen. A partial fissure was defined as a hypoattenuating defect that did not completely span the proximo-distal depth of the humeral condyle.[7] The presence or absence of medial coronoid process disease (MCPD) was determined based on a previous description of CT findings in Springer spaniels.[3]

2.3 | Anesthesia

Dogs were anesthetized with a combination of medications at the discretion of the attending specialist anesthetist. This included a combination of methadone (0.2–0.3 mg/kg IV) (Comfortan, Elanco), dexmedetomidine (3–10 μg/kg IV) (Dexdomitor, Zoetis) or acepromazine (ACP Injection, Elanco) (0.01–0.03 mg/kg IV). Anesthesia was induced with either propofol (Propoflo Plus, Zoetis) or alfaxalone (Alfaxan, Zoetis) given to effect and maintained with either isoflurane (Isoflurane-Vet 100%, Boehringer Ingelheim Animal Health, Germany) or sevoflurane (SevoFlo 100%, Zoetis). Prophylactic antibiotics in the form of cefuroxime (Zinacef, GlaxoSmithKline, UK) (20 mg/kg IV) were given at least 30 min prior to the start of surgery and repeated every 90 min until skin closure.

2.4 | Surgery

For transcondylar screw placement dogs were anesthetized, routinely prepared for aseptic surgery and transferred to the operating room. The surgical procedure for each case was standardized with all surgeons agreeing to a single method for transcondylar screw placement. This technique was similar to that described in a previous publication.[13] Implant type and size was decided by the primary surgeon for each case. Dogs were positioned in dorsal recumbency with either one or both forelimbs hung from a ceiling chain, secured using multiple sterile towel clamps and wrapped with sterile bandage. Sterile covers were applied to the intraoperative fluoroscopy unit (Philips BV Pulsera mobile C-arm, Phillips, Netherlands) and both mediolateral and craniocaudal views were acquired of the humeral condyle in preparation for surgery. A 1–2 cm medial or lateral skin incision was made over the humeral epicondyle until the epicondyle was visualized and mini gelpi retractors were used, at the surgeon's discretion, to retract the skin and soft tissues. A 1.6 mm Kirschner wire was inserted into the condyle to a depth of between 3 and 10 mm at the estimated ideal

location for transcondylar screw insertion[25] using a Colibri II handpiece (DePuy Synthes, Raynham, Massachusetts). Orthogonal fluoroscopic views of the humeral condyle were repeated and the Kirschner wire position and angle was adjusted as required until optimal placement was achieved. The Kirschner wire was then advanced across the humeral condyle using the Colibri II (DePuy Synthes) handpiece until it was just palpable on the opposite side without penetrating the skin. Frequent saline lavage was used for cooling during Kirschner wire advancement. Orthogonal fluoroscopic views of the humeral condyle were repeated to confirm optimal Kirschner wire placement. For a 4.5 mm cortical transcondylar screw (DePuy Synthes) a 3.2 mm cannulated drill bit (DePuy Synthes) was threaded over the 1.6 mm Kirschner wire and used to enlarge the hole over the Kirschner wire. This drill bit was used in short bursts with constant saline lavage and was withdrawn for both cleaning and lavage to cool the drill bit after every 2–3 s of use. For 5.5 mm cortical transcondylar screws (DePuy Synthes) the 3.2 mm cannulated drill hole was enlarged with a 4.0 mm drill bit using the same short burst technique. Both the 4.5 mm cortical and 5.5 mm cortical screws were placed in positional fashion and not placed as lag screws. For placement of a 4.5 mm shaft screw (Veterinary Instrumentation, UK), previous recommendations were followed[9] using a combination of preoperative CT measurements, intraoperative fluoroscopy and drill stops (Veterinary Instrumentation). Large, pointed reduction forceps were positioned across the condyle, and an appropriately sized cortical thread tap was used for all implants before transcondylar screw placement. The optimal desired screw length was for one or two screw threads to be present external to the transcortex. Intraoperative orthogonal fluoroscopic views of the humeral condyle were obtained to confirm this. The surgical site was flushed with saline prior to routine closure of the antebrachial fascia with absorbable suture material (Monocryl, Ethicon, Raritan, New Jersey) and skin sutures (Ethilon, Ethicon) were placed in the skin. Postoperative orthogonal radiographs were taken in all cases and no postoperative bandage material was applied except for an absorbent adhesive dressing (Primapore, Smith & Nephew, UK) which was applied and maintained for 24 h postoperatively in all cases.

2.5 | Postoperative management

All cases received postoperative analgesia including methadone (0.2–0.3 mg/kg IV every 4 h) (Comfortan, Elanco) or buprenorphine (0.02 mg/kg IV every 6 h) (Vetergesic, CEVA Animal Health Ltd, UK) as required and a nonsteroidal anti-inflammatory (meloxicam [0.1–0.2 mg/kg IV] [Metacam, Boehringer Ingelheim Animal Health]). Antibiotics were not continued following surgery in any case and no cases were discharged with a postoperative course of antibiotics. Cases were discharged from the hospital once they were comfortable and weight bearing on the operated limb, which was usually the following day. Owners were instructed to limit their dogs to short lead exercise only for the next four to 6 weeks and were specifically asked to call the veterinary referral hospital if they saw any signs of a complication such as a seroma, infection or worsening lameness. Owners were instructed to visit their local veterinary practice 10–14 days following surgery for suture removal and the local veterinary practice were given written advice regarding reporting of complications, specifically seromas and surgical site infections in the early postoperative period. Owners were also told to expect a telephone follow-up more than 6 months following the surgery.

2.6 | Follow-up assessment

Definitions of complications were based on previously published criteria.[29] In summary, a catastrophic complication is a complication or associated morbidity that causes permanent unacceptable function, is directly related to death, or is the cause of euthanasia. A major complication is split into two categories. Major type 1; requires surgical treatment to resolve (e.g., implant failure or persistent infection) or major type 2; requires medical treatment to resolve (e.g., surgical site infection). A minor complication is a complication that does not require medical or surgical treatment to resolve (e.g., seroma). A surgical site infection was recorded if any of the following criteria were identified: purulent drainage from the surgical site, organisms isolated from bacterial culture of an aseptically collected sample of fluid, tissue or an implant, pain and lameness that improved with antibiotics following cytological suspicion of infection when no organisms were identified.[30] A seroma was recorded if a fluid filled swelling was identified at the surgical site without any evidence of heat, pain, discharge or worsening lameness. If any cases were prescribed antibiotics, despite clinical notes suggestive of a seroma, these were classified as surgical site infections for reporting of complications and statistical analysis.

Perioperative data (0–3 months) was collected from clinical records up to discharge from the hospital and from clinical records at a 6–8 week postoperative assessment. This postoperative assessment was held as a telephone conversation with the owner if no complications had been identified by them. If complications were encountered, such as a seroma, suspected surgical site

infection or persistent lameness; appropriate investigations were performed such as x-rays, joint aspirates and/or bacterial culture and sensitivity at the index veterinary referral hospital. Long-term follow-up (>6 months) was collected by telephone conversation with owners. Follow-up for all cases was conducted once, approximately 7 months following final case inclusion. Owners were asked a standard set of questions; if any further surgery had been performed, whether they were aware of any signs consistent with a seroma or surgical site infection in the postoperative period, whether any lameness had improved following surgery and whether the dog was lame at the time of follow-up. This lameness was subjectively graded as mild, moderate or severe by the owner, as previously described in studies on the same topic.[13,16]

2.7 | Statistical analysis

Descriptive demographic and clinical data are presented. Continuous data were assessed for normality graphically and using Shapiro-Wilk tests. Median, interquartile range (IQR) and range are reported for non-normally distributed data and mean, and standard deviation (SD) are reported for normally distributed data. Categorical data are presented showing the count and percentage.

The primary aim was to investigate the association between transcondylar screw placement direction and the incidence of postoperative complications. The randomization of characteristics for the two exposure groups were compared for continuous variables using *t*-tests if normally distributed and Wilcoxon rank-sum tests for non-normally distributed variables. Comparison of categorical variables was made using chi-squared tests and Fisher's exact tests for variables with less than five observations in a category. The association between the two exposure groups and the incidence of postoperative complications was assessed using binary conditional regression modeling on an intention-to-treat basis. Conditional regression accounted for the paired design of the study, with dogs having undergone bilateral surgery acting as their own control. In addition, possible confounding factors were explored within the conditional regression model to examine for substantial changes in the parameter estimates (>10%). Variables assessed during analysis included the demographic factors; age (<3, 3–6, or ≥6 years), breed, bodyweight (<20 or ≥ 20 kg), sex and neuter status and limb. Case factors included whether the HIF was partial or complete and whether contralateral fracture repair was performed at the same time as screw placement for the HIF. Surgical factors included order of surgery (dogs ranked in order of date surgery was performed), supervising clinician, surgery time, implant type, implant AMI[a] normalized to bodyweight and anesthetic induction agent. A further analysis explored the difference in implant AMI normalized to bodyweight between dogs with and without the presence of major postoperative complications using a Wilcoxon rank-sum test.

One dog was randomized to have the screw placed from medial to lateral but due to an intraoperative complication from a Kirschner wire breaking, this screw was placed from lateral to medial. As for an intention-to-treat analysis, this procedure was retained in the analysis as a medial to lateral screw placement. This dog went on to have a postoperative complication.

Absolute risk reduction (ARR), the relative risk (RR) and the number needed to treat (NNT) were calculated where appropriate. Statistical significance was set at $p < .05$ throughout. Statistical analyses were performed using Stata 17.0 (StataCorp, College Station, Texas, 2021).

a. Implant AMI $= \pi r^4/4$(where $r = 0.5 \times$ core diameter of the screw), Implant AMI normalized to bodyweight = Implant AMI/bodyweight (kg). The core diameter of the screws used is as follows: 4.5 mm cortex: 3.0 mm, 5.5 mm cortex: 4.0 mm, 4.5 mm shaft: 4.5 mm.[9,31]

3 | RESULTS

3.1 | Trial recruitment and randomization

In total, 73 elbow procedures from 52 dogs were included in the study between January 2019 and January 2022. Of the 52 dogs, 21 had bilateral screw placement (of these 18 were undertaken under a single anesthetic and 3 were staged with two separate anesthetics). Of the 73 procedures, 37 (50.6%) were randomized to be placed from lateral to medial and 36 (49.3%) were randomized to be placed from medial to lateral. As described in the methods for the statistical analysis, one case suffered an intraoperative complication whereby the Kirschner wire inserted from medial to lateral broke prior to screw placement and so the screw was placed from lateral to medial in this case. There were no significant differences between the characteristics of each of the two groups enrolled in the study (Table 1).

3.2 | Signalment

The dog breeds represented were the Springer spaniel (23; 44.2%), Cocker spaniel (18; 34.6%), cross breed (9; 17.3%) and Labrador (2; 3.8%). Of the crossbreed dogs,

TABLE 1 Results of randomization process for the study.

Risk factor	Category	Lateral placement group ($n = 37$)	Medial placement group ($n = 36$)	p-value
Breed	Cocker spaniel	12	13	.620
	Crossbreed	7	3	
	Labrador	1	2	
	Springer spaniel	17	18	
Number of screw placements under a single anesthetic	Unilateral	19	17	.908
	Bilateral	18	18	
Bodyweight (kg)	Median (IQR)	19 (15–21)	19 (16–21)	.587
Age (years)	Mean (SD)	4.3 (1.9)	4.3 (2.2)	.841
Gender and neuter status	FE	6	6	.970
	FN	8	8	
	ME	10	8	
	MN	13	14	
Order of surgery (ranked from 1 to 52)	Mean (SD)	26.3 (14.9)	26.9 (16.3)	.866
Supervising clinician	A	8	7	.915
	B	5	4	
	C	13	10	
	D	10	12	
	E	0	1	
	F	1	2	
Total surgical time (min)	Median (IQR)	55 (40–75)	65 (45–80)	.189
Contralateral fracture repair	Number	2	1	.143
Implant type	4.5 mm cortex	14	15	.189
	4.5 mm shaft	9	3	
	5.5 mm cortex	14	18	
Implant AMI relative to bodyweight	Median (IQR)	0.51 (0.29–0.78)	0.49 (0.23–0.64)	.430
Induction agent	Alfaxalone	8	11	.230
	Propofol	28	20	
Limb	Left	20	18	.729
	Right	17	18	
Complete or partial HIF	Partial HIF	14	16	.566
	Complete HIF	23	20	

Note: All $p > .05$ indicate there was no known characteristic that was unintentionally biased to either group ($n = 73$).
Abbreviations: AMI, area moment of inertia; FE, female entire; FN, femal neutered; HIF, humeral intracondylar fissure; IQR, interquartile range; ME, male entire; MN, male neutered; SD, standard deviation.

eight were listed as a spaniel cross. Median bodyweight was 19 kg (IQR 16–21; range 13–32). Of the 52 dogs, 33 (63.5%) were male (20 neutered) and 19 (36.5%) were female (10 neutered). Mean age was 4.4 years (SD 2.0; range 0.3–9.1). Dogs included in the study were managed by six different surgeons. Three surgeons undertook the majority of the surgeries ($n = 16$, 16, and 12) and three clinicians undertook five, two, and one procedures, respectively.

3.3 | Presenting problem

A total of 33 dogs (63.4%) were initially presented for investigation of a forelimb lameness. The lameness was unilateral in 29 dogs and bilateral in four dogs. Lameness was graded as mild in 13 dogs, moderate in 13 dogs and severe in six dogs. A total of 19 dogs (36.5%) were initially presented for treatment of a contralateral humeral condylar fracture. This was a bicondylar humeral fracture in

five dogs and a fracture to the lateral portion of the humeral condyle in 14 dogs.

3.4 | Computed tomography findings

A total of 28 dogs (53.8%) were diagnosed with bilateral HIFs on CT (56 elbows). A total of 21 of these 28 dogs (75%) received bilateral transcondylar screws during the study period either under a single anesthetic episode (25 dogs) or under two separate anesthetic episodes (3 dogs). Of the seven dogs with bilateral HIFs that only received a unilateral transcondylar screw, one dog had previously received a contralateral transcondylar screw but this was not performed during the study period and one dog went on to suffer a contralateral humeral condylar fracture 2 years following the initial diagnosis and unilateral transcondylar screw. Five of the six elbows with an "untreated" HIF had not suffered a fracture or episode of lameness during the study period with a median follow-up time of 700 days (range 342–1203). A total of 21 dogs (40.3%) had CT findings consistent with periosteal proliferation of the lateral epicondylar crest with concurrent HIF.[1] This finding was bilateral in eight of the 21 dogs. A total of 34 elbows (46.6%) were diagnosed with concurrent MCPD based on preoperative CT findings.

3.5 | Surgery

Over the study period three different implants were placed. These included 5.5 mm cortical screw ($n = 32$), 4.5 mm cortical screw ($n = 29$) and 4.5 mm shaft screw ($n = 12$). Five cases had planned additional surgery under the same anesthetic. These surgeries included contralateral fracture repair ($n = 3$), an ipsilateral elbow arthroscopy ($n = 1$) and contralateral transcondylar screw removal ($n = 1$).

3.6 | Anesthesia

In addition to the anesthetic protocol described, 16 elbows had a preoperative brachial plexus block, and 4 elbows had a preoperative radial, ulna, median and musculocutaneous (RUMM) nerve block with bupivacaine (1–2 mg/kg) (MSD, Rahway, New Jersey). Two elbows received intra-articular bupivacaine (1–2 mg/kg) (MSD) following surgery. The median anesthetic and surgical time for bilateral transcondylar screw placement was 185 min (range 150–250) and 75 min (range 55–150), respectively. The median anesthetic and surgical time for unilateral transcondylar screw placement was 125 min (range 90–295) and 45 min (range 25–90).

3.7 | Intraoperative complications

Two cases had intraoperative complications. One has already been described in the descriptive statistics above due to the change in approach for screw placement. The other case suffered a lateral epicondylar fissure fracture during surgery and a spiked washer was added to the transcondylar screw. Both cases with intraoperative complications went on to develop a seroma and so the complication incidence is captured in the data on postoperative complications.

3.8 | Follow-up

Long-term follow-up (greater than 6 months) was available for all cases. Overall, median follow-up time was 586 days (range 193–1280).

3.9 | All postoperative complications

A total of 30 of the 73 procedures had at least one postoperative complication resulting in an overall incidence risk of 41.1% (95% CI: 29.7–53.2). Complications occurred in seven procedures (19.4%) allocated to the medial approach group and in 23 procedures (62.2%) allocated to the lateral approach group (Table 2). Following conditional regression analysis, no additional variables were retained in the model as confounding factors. The final model using our primary outcome measure of all complications demonstrated that a significantly greater proportion of transcondylar screw procedures had a postoperative complication following a lateral approach, compared to a medial approach (OR = 6.11, 95% CI: 2.13–17.52, $p = .001$) (Table 3). The same result described using absolute risk reduction indicated that 42.8% (95% CI: 22.4–63.0) of elbow procedures were spared a postoperative complication as a result of having the transcondylar screw placed from medial to lateral, rather than from lateral to medial. The RR indicated that there was a 3.2 times greater risk of postoperative complications for the lateral approach group compared to the medial approach group (RR 3.2; 95% CI: 1.57–6.51). The NNT indicated that 2.3 screws placed by the medial approach could prevent one additional postoperative complication as a result of the lateral approach.

3.10 | Types of postoperative complications

Of the 30 elbows that suffered a complication there were 33 complication types as three elbows suffered two

TABLE 2 Summary of all cases with postoperative complications, organized by group allocation, following transcondylar screw placement for HIF ($n = 73$).

Group	Number with complication	% complication	95% confidence interval
Lateral placement ($n = 37$)	23	62.2%	44.8%–77.5%
Medial placement ($n = 36$)	7	19.4%	8.2%–36.0%
All procedures ($n = 73$)	30	41.1%	29.7%–53.2%

Abbreviation: HIF, humeral intracondylar fissure.

TABLE 3 Univariable associations with any postoperative complication following transcondylar screw placement for HIF using conditional regression ($n = 73$).

Risk factor	Category	Odds ratio	95% confidence interval	*p*-value
Placement approach	Lateral	**6.11**	**2.13–17.53**	**.001**
	Medial	-	-	
Breed	Cocker spaniel	-	-	.366
	Crossbreed	1.91	0.41–8.97	
	Labrador	1.24	0.10–15.75	
	Springer spaniel	2.59	0.87–7.71	
Bodyweight (kg)	<20	-	-	.121
	≥20	2.22	0.80–6.15	
Age group (years)	<3 years	-	-	.873
	3–6	0.75	0.25–2.26	
	>6 years	0.79	0.20–3.10	
Gender and neuter status	FE	2.05	0.52–8.18	.284
	FN	0.44	0.11–1.76	
	ME	1.15	0.34–3.83	
	MN	-	-	
Supervising clinician	A	-	-	.251
	B, E, and F	1.88	0.33–10.87	
	C	3.20	0.82–12.51	
	D	1.22	0.29–5.20	
Implant type	4.5 mm cortex	-	-	.534
	4.5 mm shaft	0.84	0.22–3.30	
	5.5 mm cortex	0.56	0.20–1.57	
AMI relative to bodyweight	<0.25	-	-	.954
	≥0.25	0.97	0.34–2.79	
Induction agent	Alfaxalone	-	-	.308
	Propofol	1.79	0.57–5.62	
Limb	Left	-	-	.729
	Right	0.85	0.33–2.18	
Complete or partial HIF	Partial HIF	-	-	.768
	Complete HIF	0.87	0.34–2.23	

Note: $p > 0.05$ were significant (in bold).

Abbreviations: AMI, area moment of inertia; FE, female entire; FN, femal neutered; HIF, humeral intracondylar fissure; ME, male entire; MN, male neutered.

complications each. These were all surgical site infections that subsequently suffered implant failure ($n = 1$) or had the implant removed for another reason ($n = 2$). When all complications were divided into the various categories (Table 4) we found that only four cases suffered a complication requiring further surgery (major type 1). There

TABLE 4 Summary of the categories of postoperative complications following transcondylar screw placement for HIF ($n = 73$). Note, three cases suffered two complications giving a total of 33 complication types.

	Minor (seroma)	Major type 2 (surgical site infection)	Major type 1 (implant failure or removal)
Lateral	11	12	2
	$p = .012$	$p = .046$	$p = .978$
Medial	2*	4	2
All procedures	13	16	4

*One seroma in the medial group was in the dog that eventually had lateral screw placement due to an intraoperative complication.

was two in the lateral approach group and two in the medial approach group. The conditional regression analysis was rerun with the outcome of interest now set as all major type 1 complications ($n = 4$), rather than all complications ($n = 30$). There was no statistical difference in the incidence of major type 1 complications between the medial and lateral screw placement groups ($p = .978$).

A breakdown of the types of complications showed there were 13 minor complications (seroma), 16 major type 2 complications (surgical site infection which resolved with medical treatment) and four major type 1 complications screw failure (2), persistent lameness leading to screw removal (1) and a changed screw due to contralateral screw failure (1). Screw failure was identified 172 and 285 days following surgery in these two cases. When the outcome of interest for the conditional regression analysis was set as minor complications ($n = 13$) or major type 2 complications ($n = 16$) there was a statistical difference in the incidence of complications between the medial and lateral screw placement groups ($p = .012$ and $p = .046$, respectively) (Table 4).

To search for other findings of interest in this study population additional analysis was performed separate to the primary outcome measure of the study. This additional analysis found that the implant AMI normalized to bodyweight (AMI/bodyweight) was statistically lower in the dogs with a major type 1 complication ($n = 4$, median AMI/bodyweight 0.22, IQR 0.19–0.28) compared to those without a major type 1 complication ($n = 69$, median AMI/bodyweight 0.51, IQR 0.29–0.68, $p = .037$), indicating that an implant with a relatively small AMI was more likely to suffer a major type 1 complication.

We found there was no difference in the specific type of complications seen between the medial and lateral screw placement groups ($n = 30$; $p = .419$) and that there was no difference in the median surgical time ($p = .762$) or chronological order of surgeries ($p = .728$) between the procedures with and without a postoperative complication.

3.11 | Outcome

Of the 73 transcondylar screws placed, 21 (28.7%) were placed due to a perceived risk of future fracture and were not placed due to a presenting lameness. The remainder of screws ($n = 33$) were placed due to dogs presenting with a lameness affecting the limb. All but one owner reported an improvement in the degree of lameness following transcondylar screw placement. The one case that did not report an improvement was a 4-year-old Labrador that had bilateral transcondylar screw placement and a left elbow arthroscopy due to MCPD. This case suffered two complications; a left sided surgical site infection 1 week following surgery, and the left screw was changed 273 days following surgery due to persistent lameness. This dog was reported to still be moderately lame on the left forelimb at 926 days following surgery. Overall, 28 of 33 (84.8%) dogs with screws placed to resolve a forelimb lameness were not reported to be lame at long-term telephone follow-up. The remaining five of 33 dogs were reported to have a mild ($n = 4$) or moderate ($n = 1$) forelimb lameness by the owner.

4 | DISCUSSION

This randomized clinical trial found that transcondylar screws placed from medial to lateral develop fewer postoperative complications than screws placed from lateral to medial. We have reported the ARR (42.8%), RR (3.2), and NNT (2.3) to try to convey the clinical utility of this finding as there was a large difference in complication rates between the two groups (19.4% vs. 62.2%). It is important to note that the difference in complications was due to an increased incidence of seromas and surgical site infections in the lateral to medial screw placement group ($p = .012$ and $p = .046$, respectively). The majority of the reported complications resolved with either no treatment (seroma) or a course of antibiotics ranging from 5 days to 6 weeks (surgical site infection).

There was one case where it was intended that a medial to lateral screw be placed but this was changed to a lateral to medial screw intraoperatively due to a Kirschner wire breaking during medial placement. By undertaking an intention-to-treat analysis, it is possible that this led to slightly more cautious results but was included to limit the inclusion of bias. It was considered that a complication related to the intervention could have in itself have resulted in a postoperative complication, so it would be inappropriate to exclude this case. However, this case did develop a seroma which appeared to have a higher incidence in dogs with lateral placement, as opposed to medial placement.

There were four complications overall (5%) that required surgical intervention (major type I), and these were distributed evenly with two complications in each group, with no statistical difference ($p = .978$). This rate of major type I complications is lower than the previously reported complication rate (15%) in a retrospective series of cases treated with a similar surgical technique.[13] We believe there are three potential considerations which may have led to this apparent reduction in major type I complication rates between the two studies, both of which were undertaken at the same institution. First, we have previously found that cases operated on earlier in the retrospective case series were more likely to suffer a complication and so the complication rate may have decreased with additional experience of the surgical technique. Second, the implant choice for cases in this randomized clinical trial consisted of implants with a larger AMI compared with the implants used in the retrospective case series. For example, four shaft screws (4.5 mm) and four cortex screws (5.5 mm) were used in the previous study across 82 elbows, with the majority of cases receiving a 4.5 mm cortex screw. For this study population surgeons chose to use a total of 12 shaft screws (4.5 mm) and 32 cortex screws (5.5 mm) across 73 elbows. This increase in the proportion of larger implants was decided on an individual case by case basis by each attending surgeon. Previous experience of broken 4.5 mm cortex screws may have influenced this change in implant choice and reduced the rate of major type I complications. Finally, the follow-up period for this study was shorter than for the previous retrospective series (median 586 vs. 774 days) which may have had an effect on the incidence of major type I complications. We chose a minimum follow-up of 6 months to strike a balance between attempting to capture the majority of complications, whilst also gathering results within a reasonable time frame. However, given that implant failure of transcondylar screws for HIFs have been reported 4 years (1460 days) following surgery,[13] it is still possible that some of the cases in this trial will develop an implant failure in the future which would increase the major type I complication rate. Given that these failures were most likely to be related to implant choice, and not to the direction of screw placement, we felt that extending the minimum follow-up period was very unlikely to have a significant effect on the primary outcome measure of this study.

Long-term follow-up for cases in this study was variable for each individual case as the follow-up data was collected from all cases 7 months following enrolment of the last case. This could have led to a degree of recall bias with owners of dogs with a longer follow-up time forgetting important information related to the case when questioned. Short-term follow-up for these cases consisted of the local veterinary surgeon removing skin sutures 10–14 days following surgery. There was no scheduled veterinary follow-up after this time point and so some of the minor self-limiting complications, such as seroma, may have been missed by the pet owner and the method of data collection. We believe it is unlikely that owners would forget a postoperative complication for their dog in the timeframe and therefore the effect of recall bias in this study is likely to be minimal.

Implant AMI, normalized to bodyweight, was statistically lower in the small group of cases with major type I complications ($n = 4$) compared to those cases without major type I complications ($p = .037$). The median AMI/bodyweight for the group with major type I complications was 0.22 versus 0.51 for cases without these complications. Based on these findings a useful calculation that could guide implant choice would be to place an implant with an AMI/bodyweight greater than 0.3 as there were no cases with implant failure in this case series, or the previous case series,[13] that met these criteria. This guidance should also be considered alongside recent recommendations to place an implant less than 41% of the narrowest portion of the humeral condyle, to reduce the risk of medial epicondylar fissure fractures.[22] Based on these recommendations, in most cases an implant of appropriate size with an appropriate AMI can be selected. Previous publications have reported the use of locking screws (5.0 mm)[10] or shaft screws[22] for the treatment of this condition due to their larger AMI relative to the overall implant diameter. Based on the criteria mentioned above, we have also recently used 4.0 mm locking screws for an overweight Spaniel with relatively small humeral condyles, because all previously reported implants would not meet the above-mentioned criteria.

We chose to investigate implant AMI, normalized to bodyweight, rather than any measure of humeral condyle size as there are many dogs with similar sized humeral condyles but varying weights due to their body condition score. It is our experience that most Spaniels we have

seen with this condition have a similar sized humeral condyle and therefore we would choose a similar size screw based on the CT images. We also thought that the measure of implant AMI, normalized to bodyweight, would be a more useful reflection of the forces experienced by the implant and therefore the likelihood of implant failure.

Almost half of the cases in this trial ($n = 34$, 46.6%) were diagnosed with concurrent MCPD prior to surgery but just one case had an arthroscopic subtotal coronoidectomy performed at the time of transcondylar screw removal. Despite the diagnosis of concurrent MCPD, 32 of 33 owners (97%) reported an improvement in the degree of lameness following transcondylar screw placement alone and only five of 33 dogs (15%) were reported to be lame at long-term follow-up. Based on this data and previous publications[3,13] we recommend transcondylar screw placement alone for cases with HIF and recommend reserving the treatment of MCPD for the small minority of cases that are persistently lame following surgery.

In the interests of antibiotic stewardship, it is interesting to note that the overall surgical site infection rate for the 73 procedures reported here was 23.3%. This was reduced to 11.1% for screws placed from medial to lateral. This compares with previous reports for this procedure[9,13,16] but of note is that none of the cases in this trial received prophylactic postoperative antibiotics. Previous publications have used postoperative antibiotics in the majority of cases following transcondylar screw placement,[9,12] likely due to the high previously published rate of postoperative infection.[16] We suspect that a significant contributing factor to the development of postoperative infection in these cases is related to the extreme heat that can inadvertently be generated during drilling of the sclerotic humeral condyle. In addition, reducing the incidence of seromas by placing screws from medial is also likely to also reduce the incidence of surgical site infections that develop following seroma formation.

The primary aim of this study was to develop a clinical trial that was capable of confidently answering a clinical question that has created a state of clinical equipoise within the profession.[26] Limitations of this trial relate to the ability to apply these findings to all dogs having surgery to place a transcondylar screw in clinical practice. For example, the specific question answered here would be directly applicable to the surgical method described using fluoroscopy and a minimally invasive approach, but these findings may not be repeatable when using alternative surgical techniques.[9–12] The ability to apply these findings to different surgical methods will depend on what the underlying reason is for the increased seromas and surgical site infections in laterally placed screws. One possible theory relates to the screw head coming under external pressure when situated on the lateral aspect of the humeral condyle with the dog in lateral recumbency. If this is correct it would be interesting to see if the incidence of postoperative seromas and surgical site infections would be reduced if headless screws that are buried into the humeral condyle were used.

In conclusion, we found that placement of transcondylar screws from medial to lateral reduces the rate of postoperative complications using a randomized clinical trial study design. In addition, we also found that relatively small implants with a small ratio of AMI to bodyweight were more likely to fail in this study population of predominantly adult dogs with HIFs.

ACKNOWLEDGMENTS

Carwardine D, BVSc(Hons) MSc PhD DipECVS FHEA: Contributed to the design of the study, acquired data, interpreted data following analysis, drafted and revised the manuscript, approved the final version, and agrees to be accountable for all aspects of the work. Mather A, BVSc MSc: Contributed to the design of the study, acquired data, drafted and revised the manuscript, approved the final version, and agrees to be accountable for all aspects of the work. Schofield I, BVSc MSc(VetEpi) PhD: Contributed to the design of the study, analyzed data, interpreted data following analysis, drafted and revised the manuscript, approved the final version, and agrees to be accountable for all aspects of the work. Langley-Hobbs S, MA BVetMed DSAS(Ortho) DipECVS FHEA: Contributed to the design of the study, acquired data, drafted and revised the manuscript, approved the final version, and agrees to be accountable for all aspects of the work. Carbonell-Buj E, DVM: Contributed to the design of the study, acquired data, drafted and revised the manuscript, approved the final version, and agrees to be accountable for all aspects of the work. Belch A, BVMS MSc CertAVP(GSAS) DipECVS: Contributed to the design of the study, acquired data, drafted and revised the manuscript, approved the final version, and agrees to be accountable for all aspects of the work. Barthelemy N, DVM DipECVS: Contributed to the design of the study, acquired data, drafted and revised the manuscript, approved the final version, and agrees to be accountable for all aspects of the work. Parsons K, BVSc(Hons) PhD DipECVS FHEA: Contributed to the design of the study, acquired data, drafted and revised the manuscript, approved the final version, and agrees to be accountable for all aspects of the work.

CONFLICT OF INTEREST STATEMENT

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

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How to cite this article: Carwardine D, Mather A, Schofield I, et al. Medial versus lateral transcondylar screw placement for canine humeral intracondylar fissures: A randomized clinical trial. *Veterinary Surgery*. 2024;53(2):264-276. doi:10.1111/vsu.13993

APPENDIX A: Consent form for transcondylar screw study

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you and your dog. Please feel free to ask us if there is anything that is not clear.

Humeral intracondylar fissure, previously known as incomplete ossification of the humeral condyle, can lead to sudden fracture of the elbow without trauma. At Langford Vets we place transcondylar screws across the elbow to try to avoid these fractures occurring.

It is unclear whether the screw should be placed from the inside of the elbow to the outside or the outside of the elbow to the inside (Figure 1). The aim of this study is to compare the outcome, including the incidence of postoperative infection, after having either an inside to outside screw or an outside to inside screw. Currently at Langford Vets there is no preference for the placement of these screws amongst the orthopedic specialists. Your dog will be randomly assigned to have the screw placed either from inside to outside or from outside to inside.

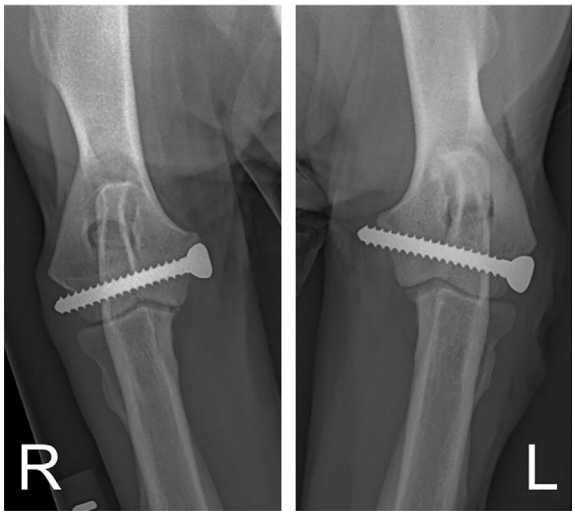

FIGURE 1 Postoperative x-rays of transcondylar screw placement.

There will be no additional costs for enrolling your dog in this study and they will be cared for in the same way as every other case we see. Routine follow-up involves a recheck appointment 6–8 weeks following surgery for x-rays and if your pet experiences any complications, including postoperative infections, we would like to see them for assessment and treatment. As usual, there would be an additional charge for these services.

We would like to contact you by telephone 12 months following the surgery to find out how your pet has been doing. This is the only additional requirement of the study.

If you would like any further information about this study please speak to someone within our orthopedic service who will be happy to help or specifically e-mail Darren Carwardine (darren.carwardine@bristol.ac.uk) for any additional questions.

Participation in this study is completely voluntary. If you would like your dog to participate in the study please print and sign the following statement:

I give informed consent for my dog..... to be enrolled in the transcondylar screw study at Langford Vets.

Signed:.....

Print name:.....

Date: .....