Clinical outcomes associated with the initial use of the Canine Unicompartmental Elbow (CUE) Arthroplasty System®


Abstract — We evaluated mid- to long-term outcomes with respect to function and complications in dogs undergoing canine unicompartmental elbow (CUE) arthroplasty for treatment of medial compartment disease of the elbow. This prospective multicenter case series is the first group of clinical cases to receive CUE arthroplasty. Cases (each elbow that underwent CUE performed by a participating surgeon) were enrolled into an electronic database and prospectively followed to determine and record all associated complications, as well as functional outcomes. There were 103 cases from 18 surgeons. Final follow-up time ranged from 6 to 47 mo with a mean and median of 10 mo. Canine unicompartmental elbow was associated with 1 catastrophic (1%), 11 major (10.7%), and 28 minor (27.2%) complications. Outcomes following CUE were reported as full function in 49 cases (47.6%), acceptable function in 45 cases (43.7%), and unacceptable function in 9 cases (8.7%). We conclude that CUE arthroplasty is an appropriate consideration for treatment of medial compartment disease of the elbow in dogs.

Résumé — Résultats cliniques associés à l’utilisation initiale du système d’arthroplastie Canine Unicompartmental Elbow (CUE) Arthroplasty System®. Nous avons évalué les résultats à long et à moyen terme relativement à la fonction et aux complications chez les chiens subissant une arthroplastie du coude unicompartmental canin (CUC) pour le traitement de la maladie compartimentale médiale du coude. Cette série prospective de cas multicentres représente le premier groupe de cas cliniques à recevoir une arthroplastie CUC. Les cas (chaque coude qui a subi une CUC réalisée par un chirurgien participant) étaient inscrits dans une base de données électroniques et suivis de manière prospective afin de déterminer et de consigner toutes les complications connexes ainsi que les résultats fonctionnels. Il y avait 103 cas provenant de 18 chirurgiens. Le temps de suivi final s'échelonnait de 6 à 47 mois avec une moyenne et une médiane de 10 mois. Le coude compartimental canin a été associé à 1 complication catastrophique (1 %), à 11 complications majeures (10,7 %) et à 28 complications mineures (27,2 %). Les résultats après l’arthroplastie CUC ont été signalés comme une fonction complète dans 49 cas (47,6 %), une fonction acceptable dans 45 cas (43,7 %) et une fonction inacceptable dans 9 cas (8,7 %). Nous avons conclu que l’arthroplastie CUC est une considération appropriée pour le traitement de la maladie compartimentale médiale du coude chez les chiens.

(Traduit par Isabelle Vallières)
Introduction

Medial compartment disease (MCompD) is a frequent manifestation of canine elbow dysplasia (1–5). The authors use the term “medial compartment disease” of the canine elbow to describe clinical signs attributable to articular cartilage loss of the medial coronoid process of the ulna and medial aspect of the humeral condyle from any cause without significant lateral compartment articular cartilage pathology. MCompD is differentiated from medial coronoid disease, which can include fragmentation or fissuring of the medial coronoid process without cartilage loss, and from any condition of the elbow that includes significant articular cartilage pathology of the lateral compartment of the elbow. MCompD can progress to full-thickness cartilage loss on the medial coronoid process and humeral trochlea, even to the point of subchondral bone eburnation. Interestingly, despite severe changes in the medial compartment, the lateral compartment of the elbow including most of the radial head, the lateral coronoid process of the ulna, and the humeral capitulum generally remain grossly and arthroscopically normal in appearance with a distinct line of demarcation in the cartilage between the medial and lateral compartments (2,4–6).

Numerous treatments for MCompD have been described or are under investigation including non-surgical management, arthroscopic lavage and debridement, subtotal coronoid osteotomy, osteotomies to mitigate loading of the medial compartment including sliding humeral osteotomy, external humeral rotational osteotomy, proximal ulnar rotational osteotomy, proximal abducting ulnar osteotomy, and total or partial elbow arthroplasties (4,7–13). To date, none of these treatments have been documented to consistently provide a safe and effective means for returning dogs with MCompD to a desired level of function long term.

In an attempt to address perceived deficiencies in optimal treatment options for dogs with MCompD, the Canine Unicompartmental Elbow (CUE) Arthroplasty System® (Arthrex Vet Systems, Naples, Florida, USA) (Figure 1) was developed and tested ex vivo (14). The CUE uses humeral and ulnar implants which are press-fit into bone to resurface pathologic weight-bearing areas of the medial compartment of the elbow. Our present study was designed to evaluate mid- to long-term outcomes with respect to function and associated complications in dogs undergoing CUE arthroplasty for treatment of medial compartment disease of the elbow. We hypothesized that CUE would be safe (catastrophic and major complications ≤ 20%) and effective (> 80% full or acceptable long-term outcomes) for use in client-owned dogs with symptomatic MCompD of the elbow. The desired safety and efficacy levels were set based on World Health Organization Guidelines (15) in conjunction with reported rates for currently used surgical alternatives to CUE (4,7–13).

Materials and methods

Centers were included after 1 or more of their surgeons completed a CUE training course, agreed to prospectively collect data detailed further in this report, and provided complete data sets for a minimum of 3 CUE cases. Cases were enrolled when participating surgeons documented fully informed client consent based on institutional animal care and use or medical ethics committee policies and procedures, and submitted information into a dedicated electronic database. Each elbow that underwent CUE was considered as a separate case. Cases were prospectively followed to determine and record all complications and functional outcomes based on established criteria (16). The indication for performing CUE was based on a documented diagnosis of MCompD, as defined, determined using the individual surgeon’s diagnostic algorithm. For each case included, arthroscopy and/or advanced imaging [computed tomography (CT) or magnetic resonance imaging (MRI)] were included in the diagnostic algorithm. Cases were excluded when required data were incomplete, the surgical procedure and/or postoperative care substantially deviated from study guidelines, or final follow-up data from at least 6 mo after CUE surgery were not obtained.

Anesthetic and analgesic protocols for CUE cases were left to the discretion of the individual surgeon as long as the protocols met the standard-of-care for veterinary surgery. Peri-operative antibiotics consisting of cefazolin, 22 mg/kg body weight (BW), IV, at least 30 min prior to incision and every 90 min during surgery, were administered in all cases with additional antibiotic therapy left to the discretion of the individual surgeon. The CUE was performed in 1 or both elbows of each dog using standard technique via either tenotomy or osteotomy [Figure 2; (14)]. For cases in this study, all CUE implants were medium or large cobalt chrome-Biosync ingrowth humeral components and medium or large polyethylene-only ongrowth ulnar components (14). Recommended postoperative care included placement and maintenance of a full-limb, soft-padded bandage for a minimum of 2 wk with at least 1 bandage change 1 wk after surgery.

Figure 1. Illustration of the Canine Unicompartmental Elbow (CUE) Arthroplasty System implants placed in the humerus and ulna for treatment of medial compartment disease of the canine elbow.
Activity was restricted to kennel-rest and walking on a short leash for the first 8 wk after CUE. After bandage removal, passive, active-assisted, and active range-of-motion exercises of the operated forelimb were to be initiated, if well-tolerated by the patient. Once healing was deemed sufficient 8 wk or more after surgery, the dog was allowed a progressive increase in activity over the subsequent 2 mo to return to full, unrestricted activity at 4 mo after surgery. Professional rehabilitation was encouraged after healing was sufficient, but was left to the discretion of the individual surgeon.

All cases \((n = 103)\) were re-evaluated at approximately 2 wk, 8 to 12 wk, and at least 6 mo after surgery. All cases were assessed by complete physical and orthopedic examination at each time point by the attending veterinarian, radiographs of the operated elbow at 8 to 12 wk at a minimum, and for level of function \((16)\) based on evaluation of gait at a walk and trot \((17)\) and client’s and/or trainer’s assessments at a minimum of 6 mo after surgery. Functional outcome \((16)\) and all complications \((16)\) were determined using the published definitions, below, at or after 6 mo post-surgery and recorded in the electronic database:

- **Full function** — restoration to, or maintenance of, intended level and duration of activities and performance from preinjury or predisease status (without medication).
- **Acceptable function** — restoration to, or maintenance of, intended activities and performance from preinjury or predisease status that is limited in level or duration and/or requires medication to achieve.
- **Unacceptable function** — all other outcomes.
- **Catastrophic complication** — complication or associated morbidity that causes permanent unacceptable function, is directly related to death, or is cause for euthanasia.
- **Major complication** — complication or associated morbidity that requires further treatment based on current standards of care.
- **Minor complication** — complication not requiring additional surgical or medical treatment to resolve.

Radiographs were subjectively evaluated by the attending surgeon to assess for complications based on implant position, radiolucencies associated with the implants, osteotomy site healing, and any other radiographic pathology noted. Subjective findings were reported for each case.

In addition, cases from the coordinating site \((n = 26)\) also underwent lameness grading \((17)\) prior to surgery and at 6 mo following CUE as follows:

0 — no observable lameness; 1 — mild, weight-bearing lameness with little, if any, change in gait; 2 — moderate, weight-bearing lameness, consistent, noticeable change in gait;

\begin{figure}
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\includegraphics[width=\textwidth]{postoperative_craniocaudal_radiographic_views_of_2_cases_included_in_this_study_showing_the_CUE_implant_positioning_and_associated_fixation_for_tenotomy_suture_anchor_left_and_osteotomy_cortical_screw_right_approaches.png}
\caption{Postoperative craniocaudal radiographic views of 2 cases included in this study showing the CUE implant positioning and associated fixation for tenotomy (suture anchor) (left) and osteotomy (cortical screw) (right) approaches.}
\end{figure}
3 — severe lameness with little weight-bearing on affected limb, marked change in gait; 4 — non-weight-bearing.

This subset of cases also underwent pressure-sensing walkway (GAITFour; Haverton, Pennsylvania, USA) analysis prior to surgery and at 6 mo following CUE, as previously described (18,19). Dogs were trotted on the walkway until 3 complete data sets were obtained. Mean percent body weight distribution (% BW) was determined for each limb using the 3 complete data sets based on total pressure index (TPI), and % BW for the operated limb was chosen a priori as the variable for reporting.

Using the recommended definitions and criteria for clinical orthopedic studies in veterinary medicine (16) full and acceptable outcomes are defined as “successful” and “effective” in that dogs with a debilitating disorder such as MCompD realize clinically significant improvements in order to be placed into either of these categories. It is important to note that all other outcomes are defined as “unacceptable function.” However, this does not mean that the dog is suffering or that the owner is dissatisfied, but rather serves as a stringent evaluation of level of function with respect to improvement (16).

Data were compiled and analyzed in blinded fashion with respect to surgeon and center. An analysis of variance (ANOVA) on ranks was used to determine statistical significance among centers. Fisher’s exact test was used to assess differences in proportions of complications and outcome categories between tenotomy and osteotomy approaches. Rank sum test and t-test were used to assess differences between pre-operative and post-operative lameness scores and pressure-sensing walkway data. Significance was set at $P \leq 0.05$.

### Results

A total of 103 cases from 18 surgeons at 15 centers met the inclusion criteria. Thirteen additional cases were excluded after enrollment screening based on a priori inclusion and/or exclusion criteria; these cases were not followed. The median number of cases included from each center was 5. Nine dogs underwent bilateral CUE surgeries staged at least 2 mo apart (range 2 to 12 mo; median = 7 mo), and 2 dogs underwent bilateral CUE surgeries during the same surgical episode. No statistically significant differences were noted between cases in which unilateral versus bilateral, staged or concurrent, CUE was performed or between sides in bilateral CUE cases for any outcome measure. However, the powers associated with these statistical comparisons were all below 0.2 based on the low number of bilateral cases included in this initial study.

The mean age of dogs in this study was 5.1 y (range: 10 mo to 13 y) and mean weight was 33.6 kg (range: 17.7 to 70.1 kg). Labrador retrievers ($n = 42$) were the most common breed treated with CUE in this study, followed by golden retrievers ($n = 29$), and German shepherd dogs ($n = 11$). Seventy-five (81.5%) dogs included in this study were classified by their owners as performance or working dogs. As defined by the study’s inclusion criteria, all dogs had clinical signs attributable to MCompD in the affected elbow(s) based on physical and orthopedic examination, radiographic signs of elbow osteoarthritis (e.g., subtrochlear sclerosis, medial humeral condylar sclerosis, and or osteophytosis), and articular cartilage loss of the medial coronoid process of the ulna and medial aspect of the humeral condyle based on direct surgical assessments, such that all cases were considered “end stage.” Ninety-nine (96.1%) cases had received various forms of non-surgical treatment for months to years prior to CUE surgery. Eighty-five (82.5%) cases had undergone some form of surgical treatment (e.g., arthroscopic-assisted fragment removal, arthroscopic-assisted subtotal coronoidectomy, open subtotal coronoidectomy) months to years prior to CUE surgery.

For the surgical approach, 32 cases received tenotomy and 71 cases received osteotomy. With respect to implants, 55 cases received medium humeral and medium ulnar implants, 39 cases received large humeral and large ulnar implants, 3 cases received medium humeral and large ulnar implants, and 6 cases received large humeral and medium ulnar implants. Implant size was chosen at the individual surgeon’s discretion based on intra-operative assessments using the CUE instrumentation as described (14).

The CUE was associated with 1 catastrophic (1%), 11 major (10.7%), and 28 minor (27.2%) complications. The combined major and catastrophic complication rate (11.7%) was significantly less ($P = 0.018$) than the 20% maximum set a priori. The catastrophic complication occurred in a dog that was euthanatized at the owner’s request based on perceived
failure to improve after CUE surgery. No further follow-up was
provided or allowed for this case. Major complications were
comprised of medial epicondylar avulsion/nonunion (n = 3)
(Figure 3), implant malpositioning (n = 3), incisional/extra-
articular infection (n = 3), carpal flexor contraction (n = 1), and
intra-operative anconeal fracture (n = 1). The most common
minor complication was persistent pain and lameness during the
first 8 wk after surgery (n = 9) followed by subclinical medial
epicondylar displacement/delayed union (n = 5) and transient
carpal hyperextension (n = 4). No statistically significant differ-
ences were noted between tenotomy (1 catastrophic, 5 major,
12 minor) and osteotomy (0 catastrophic, 6 major, 16 minor)
for probability of complications for any of the categories of
complications. All of these complications were noted within the
first 6 mo after surgery and no additional CUE-related com-
lications were reported on any of these cases for up to 47 mo
after surgery. No clinical, radiographic, or histologic evidence
for implant loosening, subsidence, symptomatic wear, or wear
debris-related pathology was noted. Three dogs were euthana-
tized for unrelated reasons (thyroid carcinoma, soft tissue sar-
coma, contralateral brachial plexus nerve sheath tumor) during
the study period. In these cases, limb retrieval with subjective
histologic assessment of CUE implants in situ was performed
(Figure 4) after client consent was sought and obtained.

Final follow-up time ranged from 6 to 47 mo with a mean
and median of 10 mo. Outcomes following CUE were reported
as full in 49 cases (47.6%), acceptable in 45 cases (43.7%),
and unacceptable in 9 cases (8.7%) (Figure 5). The combined
full and acceptable outcome rate (91.3%) was significantly
greater (P = 0.02) than the minimum of 80% set a priori.
Sixty-seven (89.3%) of the 75 performance-working dogs
returned to intended level of function after CUE based on
owner and/or trainer assessments, which was also significantly
greater (P = 0.024) than 80%. No statistically significant dif-
ferences were noted between tenotomy (18 full, 10 acceptable,
4 unacceptable) and osteotomy (31 full, 35 acceptable, 5 unac-
ceptable) for probability of outcome for any of the classifica-
tions of outcome used in this study. No statistically significant
differences in combined full and acceptable outcome rate were
noted when comparing cases with final follow-up times < 2 y
to those with final follow-up times > 2 y.

Complications and outcomes from sites (n = 7) contributing
5 or more cases to the study were analyzed to determine if there
were any statistically significant effects of site-of-performance
on these variables. No statistically significant differences were
noted among centers for likelihood or severity of complications.
However, 1 center was associated with a significantly lower level
of outcome (P = 0.003) compared to all other centers analyzed.

For cases treated at the coordinating site (n = 26), lameness
grade for affected limbs 6 mo after CUE (mean: 0.4 ± 0.6) was
significantly lower (less lame) (P < 0.001) than pre-operative
lameness grade (mean: 2.7 ± 0.7). For these cases, mean
percent body weight distribution (% BW) for affected limbs
6 mo after CUE (mean: 28.1 ± 1.7) was significantly greater
(P < 0.001) than pre-operative % BW (mean: 21.5 ± 2.5)
(Figure 6). Statistically significant differences between tenotomy
and osteotomy approaches were not seen for either outcome measure or time point.

Discussion

The data from this study suggest that CUE arthroplasty can be a safe and effective option for treatment of medial compartment disease of the elbow in dogs. The "serious" (combined catastrophic and major) complication rate of 11.7% in the first clinical cases to undergo CUE arthroplasty is lower than for other surgical treatments for MCompD in which the initial complication rates ranged from 17% to 25% (4,20). Importantly, all complications occurred within the first 6 mo after surgery, and no CUE implant-related complications, including loosening, subsidence or infection, were noted in this series of dogs. Successful outcomes, defined as cases attaining full or acceptable function by 6 mo after surgery, were reported in 91.3% of cases, which is considered appropriate for clinical use. Objective assessment of response to treatment using pressure-sensitive walkway assessment of function in a subset of cases showed significant improvements in operated-limb use 6 mo after CUE, further substantiating the subjective findings. Success rates based on subjective and objective assessments were maintained for up to 4 y after CUE; however, data from this initial cases series were not sufficient for a survival analysis (e.g., Kaplan-Meier).

While no statistically significant differences were noted in complication type or rate between tenotomy and osteotomy approaches in this study, osteotomy cases were associated with a lower serious complication rate (8.5%) compared to tenotomy cases (18.8%). In addition, osteotomy was associated with a higher rate of successful outcomes (93%) compared to tenotomy (87.5%). These findings, in conjunction with perceived benefits for surgical exposure, particularly for cases with extensive fibrosis and osteophytosis, and short-term postoperative recovery associated with the osteotomy approach, have made the osteotomy technique preferred for CUE cases. However, the tenotomy approach is considered acceptable and CUE surgeons should be adept at this technique with required implants available as it provides a "bail out" method for post-implantation stabilization when necessary (14).

No significant differences were noted among centers for likelihood or severity of complications, suggesting that, with appropriate training and adherence to protocol, this technique can be broadly applied with a consistently appropriate level of safety among surgeons and centers. This is further supported by the fact that the median number of cases included from each center was 5 with all but 2 centers contributing less than 10 cases. As all were each center's initial clinical cases, this suggests that the CUE procedure is amenable to success during a surgeon's "early learning curve." One center was associated with a significantly lower level of successful outcomes (74.1%) compared with other centers that contributed 5 or more cases. While it is not clear as to what caused this difference, factors which could be implicated include case volume (second highest number of cases), patient demographics, geographical differences, and/or post-enrollment protocol deviations.

The limitations of this study that should be considered when interpreting the data include the outcome measures employed, the duration of follow-up, and the lack of a cohort group for comparison. While the outcomes measures used in this study were primarily subjective in nature such that the potential for bias is introduced, objective data in the form of pressure-walkway assessment of limb use obtained for a representative subset of cases in this study corroborated the subjective findings. In addition, while surgeons were responsible for collecting and reporting their own outcomes data and 2 of the surgeons involved in the study have financial interest in CUE, functional outcomes were based on client's and/or trainer's assessments and outcomes for cases (34% of total); the outcomes for the 2 surgeons with financial conflicts were not significantly better than cases from surgeons without financial conflicts (66% of cases). The minimum follow-up time in this study was 6 mo after CUE; however, the mean final follow-up time was 10 mo after surgery with many cases having more extensive follow-up (20 cases > 1 y, 4 cases > 2 y, 3 cases > 3 y). These data suggest that CUE can be considered safe and effective for treatment of MCompD in dogs similar to those included in the present study. Prospective cohort studies further evaluating pre-operative patient characteristics and disease severity, and comparing treatments for this common problem can be appropriately initiated based on this initial clinical validation study.

The unique aspects of this study include the large number of centers involved and the inclusion of cases based on standard-of-care practices by participating surgeons such that the results broadly represent "real life" surgical practice. All dogs in this
study had clinical, radiographic, and surgical evidence for medial compartment disease with secondary osteoarthritis of the elbow, such that all cases were considered “end stage” by definition. Based on dog age, cause of MCompD, and previous medical (96% of cases) and surgical (83% of cases) treatments, a broad spectrum of relative severity was represented. Based on enrollment success and outcomes data, these factors did not markedly influence the ability to perform CUE or the safety or efficacy of the procedure. The results of this study suggest that the CUE System® can be considered relatively safe (catastrophic and major complications = 11.7%) and effective (91.3% full or acceptable outcomes) for trained surgeons to use in clinical canine patients with symptomatic medial compartment disease of the elbow.

References