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Radiological Evaluation of TATE Elbow Cartridge Positioning in Dogs

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<th>Veterinary and Comparative Orthopaedics and Traumatology</th>
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Objective: To evaluate the radiological effect of varying elbow flexion angle and elbow orientation on the measurement of component position for first (1G) and second generation (2G) TATE elbow cartridges, and to test intra/inter-observer variability of measurements.

Materials and methods: A cadaveric thoracic limb was implanted with a 1G then 2G cartridge, and mounted in lateral recumbency on an acrylic platform. The platform was tilted by set increments up to 10° in both planes, and radiographs were performed at each angle before repeating with the limb in caudocranial positioning. A deterministic trigonometric model was used to show how component angles should vary with changes in orientation, and these were compared to those measured by two observers. Humeral component angle (HCA), radioulnar component angle (RCA), varus/valgus cartridge alignment angle (VVA), and the cartridge height:isthmus width ratio (CIR) were evaluated. Angles within 5° of the zero degrees inclination angle and ratios within 0.2 of the zero degrees inclination ratio were defined as acceptable.

Results: Observer component angles for both cartridges were accurate and precise for inclinations up to 10° except for HCA during adduction/abduction. CIR values were within the acceptable limit for inclinations up to 7.5° in both planes.

Clinical significance: Acceptable limits of limb inclination during positioning for TATE elbow replacement cartridge assessment were defined. All component measurements were sufficiently accurate and precise to be considered for evaluation of component position in clinical cases.
Figure 1: a) True mediolateral radiograph of the elbow with the medial (blue circle) and lateral (yellow circle) portions of the humeral condyle perfectly superimposed. Three 2mm steel balls were positioned on Play-Doh that was placed on the medial aspect of the elbow (white dots). b) A compass was used to draw arcs (black dotted circles) on the Play-Doh from the centre point of each ball (yellow dots). The intersect of the three arcs (white cross) was the condyle centroid. c) After marking the centroid using a kirschner wire, a drill C-guide was used to advance a 2.5mm drill bit across the humeral condyle. d) Mediolateral radiograph showing the hole in the centre of the humeral condyle.
Figure 2: Radiographs were taken with the elbow at both 90° of flexion (a) and 135° of flexion (b). Viewing software was used to position the elbow precisely. Purple ellipse = humeral head, red circle = margin of the humeral component of the cartridge, blue circle = centre of the epiphyseal region of the distal radius, yellow lines = mechanical axes of the humerus and radius. The angle between the lines cranial to their intersect defined the elbow flexion angle.

40x20mm (600 x 600 DPI)
Figure 3: Examples of the apparatus for positioning the elbow in various combinations of abduction/adduction/internal rotation/external rotation.  a) For the mediolateral projections, the limb was positioned at either 90° of elbow flexion (shown) or 135°, and an Ellis pin was placed in the previously drilled condylar hole to align the elbow joint exactly parallel with the x-ray beam. b,c) Examples of 135° elbow flexion angle with 10° of external rotation. The inclination in the craniocaudal plane measured in b) was 10°, and in the proximodistal plane measured in c) was 0°. d) Elbow positioned for a caudocranial projection with 2.5° flexion.

481x384mm (300 x 300 DPI)
Figure 4: a) mediolateral and b) caudocranial bone model projection of the elbow illustrating the descriptors used to define specific movements of the limb in each plane.

409x204mm (300 x 300 DPI)
Figure 5: a) Measurement of the position of the humeral component relative to the humeral mechanical axis (the humeral component angle). b) Measurement of the position of the radio-ulnar component relative to the humeral mechanical axis (the radio-ulnar component angle). c) Measurement of the cartridge height to ulnar isthmus width ratio. d) Measurement of the varus/valgus cartridge alignment angle. Mediolateral images: Purple ellipse = humeral head, red circle = articular surface of the humeral/radio-ulnar component, yellow line = mechanical axis of the humerus, blue line = component line, $\theta$ = component angle, measured between the yellow and blue lines cranial to their intersect (orange), green line = isthmus width, purple line = cartridge height. Caudocranial image: Long yellow line = line passing through the centre of the ellipse and the mid-portions of the most distal aspect of the radio-ulnar component, short yellow line = line from distal aspect of the first line to the mid-portions of the proximal extent of the radio-ulnar component, $\theta$ = varus/valgus cartridge alignment angle.
Figure 6: Illustration of how the circles were templated for best fit depending on the appearance of components with changing inclination. a) Circular template of the radio-ulnar component. b) Best fit oval template of the radio-ulnar component. c) Three circle template of the radio-ulnar component when the limb was inclined in adduction or abduction. d) Three circle template of the radio-ulnar component when the limb was inclined in external rotation or internal rotation. See text for further details.

24x6mm (600 x 600 DPI)
Table 1: Table to show the intra-observer and inter-observer variability limits of agreement for the component measurements. LoA = limits of agreement.
Figure 7: Graphs to show one of the four deterministic HCA data sets (a) and one of the four observer HCA data sets (b). All four of the deterministic and observer graphs showed very similar trends and so are not shown. Note that on the deterministic graph, increasing the inclination up to 10° had almost no effect on the component angle, whereas there was a more obvious deviation from the zero inclination angle up to 10° of inclination on the observer measured graph.
Table 2: Table to show the inclination, as predicted by the deterministic model, required to cause the measured component angle to change by 5° from the zero degrees inclination angle. For varus/valgus cartridge alignment angle during internal and external rotation, since the zero degrees inclination angle was less than 5°, the change in inclination did not exceed 5° because the angle gradually reduced to zero. ML = mediolateral, CC = caudocranial, 1G = first generation cartridge, 2G = second generation cartridge.

<table>
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<tr>
<th>Elbow model</th>
<th>Humeral component angle</th>
<th>Radio-ulnar component angle</th>
<th>Varus/valgus cartridge alignment angle</th>
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<tr>
<td></td>
<td>Abduction/Adduction</td>
<td>Abduction/Adduction</td>
<td>Flexion/Extension</td>
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<td>ML, 1G at 90° elbow flexion angle</td>
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<td>CC, 2G</td>
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<td>Elbow model</td>
<td>Humeral component angle</td>
<td>Radio-ulnar component angle</td>
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<td>ML, 1G at 90° elbow flexion angle</td>
<td>5.8° (10° AB)</td>
<td>1.13° (7.5° ER)</td>
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<td>1.78 (10° AD)</td>
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<td>4.39° (10° AD)</td>
<td>1.22° (10° ER)</td>
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<td>2.04° (10° IR)</td>
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<td>CC, 1G</td>
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<td>4.6° (10° IR)</td>
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<td>CC, 2G</td>
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<td>3.79° (10° ER)</td>
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Table 3: Table to show the greatest deviations in measurements from the zero degrees inclination angle (for HCA, RCA and VVA) or zero degrees inclination ratio (for CIR) for the various elbow models and component measurements. The angles shown in red indicate those which were greater than 5° from the zero degrees inclination angle. The second greatest deviation is also shown for HCA with the ML, 2G at 135° elbow flexion elbow model for completeness, as this was the only other angle greater than 5° from the zero degrees inclination angle. The values shown in blue relate to cartridge height to ulnar isthmus width ratio, and indicate values that were greater than 0.2 from the zero degrees inclination ratio. ML = mediolateral, CC = caudocranial, 1G = first generation cartridge, 2G = second generation cartridge, AB = abduction, AD = adduction, ER = External rotation, IR = Internal rotation.
Figure 8: Graphs to show one of the four deterministic RCA data sets (a) and one of the four observer RCA data sets (b). All four of the deterministic and observer graphs showed very similar trends and so are not shown. Note that on the deterministic graph, increasing the inclination up to 10° had almost no effect on the component angle, whereas there is a more obvious deviation from the zero degrees inclination angle up to 10° of inclination on the observer measured graph.
Figure 9: Graphs to show the 1G deterministic and observer measured VVA data sets. The 2G graphs showed the same trend and so are not shown. Note that on the deterministic graph, increasing the inclination up to 10° had almost no effect on the component angle, whereas there is a more obvious deviation from the zero degrees inclination angle up to 10° of inclination on the observer measured graph.
Figure 10: One of the four CIR graphs demonstrating the observer measured change. All four graphs showed a very similar trend and so are not shown.
Figure 11: Examples of the effect of positioning on the appearance of the components in mediolateral projection. Key: 2.5, 5, 7.5, 10 = degrees, AD = adduction, AB = abduction, ER = external rotation, IR = internal rotation.

313x307mm (300 x 300 DPI)
Figure 12: Examples of the effect of positioning on the appearance of the components in caudocranial projection. Key: 2.5, 5, 7.5, 10 = degrees, E = extension, F = flexion, ER = external rotation, IR = internal rotation.

122x170mm (300 x 300 DPI)
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Figure 8: Graphs to show one of the four deterministic RCA data sets (a) and one of the four observer RCA data sets (b). All four of the deterministic and observer graphs showed very similar trends and so are not shown. Note that on the deterministic graph, increasing the inclination up to 10° had almost no effect on the component angle, whereas there is a more obvious deviation from the zero degrees inclination angle up to 10° of inclination on the observer measured graph.

Figure 9: Graphs to show the 1G deterministic and observer measured VVA data sets. The 2G graphs showed the same trend and so are not shown. Note that on the deterministic graph, increasing the inclination up to 10° had almost no effect on the component angle, whereas there is a more obvious deviation from the zero degrees inclination angle up to 10° of inclination on the observer measured graph.

Figure 10: One of the four CIR graphs demonstrating the observer measured change. All four graphs showed a very similar trend and so are not shown.
Figure 11: Examples of the effect of positioning on the appearance of the components in mediolateral projection. Key: 2.5, 5, 7.5, 10 = degrees, AD = adduction, AB = abduction, ER = external rotation, IR = internal rotation.

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Introduction

Elbow osteoarthritis (OA) is the most frequent cause of forelimb lameness in dogs (1) and may occur as a sequela to developmental conditions including elbow dysplasia (2), incongruity secondary to premature growth plate closure (3,4), and traumatic conditions such as luxation or intra-articular fracture (5). Numerous surgical techniques have been described in an effort to ameliorate the pain associated with developmental elbow disease as well as the OA that may ensue (6-9). However, progression of OA may sometimes render the patient in intractable pain and recalcitrant lameness. In cases where this pain is poorly controlled by conservative measures and poor clinical function is persistent, salvage surgery, such as elbow replacement may be considered in an effort to improve patient comfort and quality of life.

The first canine prototype hinged total elbow replacement was implanted by Chancrin (1989) and later Lewis (1996), the latter author reporting pilot data on a small cohort of research dogs (10). High complication rates and poor function with these constrained systems resulted in archiving of these designs with subsequent development of a semi-constrained cemented system. This was released commercially in the late 1990’s and evaluated in dogs both without elbow OA and a clinical cohort with naturally occurring OA (11,12). Satisfactory results were observed but with a 20% incidence of complications including infection, luxation and humeral/ulnar fracture. Discontentment with this system clinically has resulted in the development of several new total or partial arthroplasty systems (13-15) one of which is the TATE elbow system, a semi-constrained cementless bi-component resurfacing implant (16); a recent retrospective study evaluating this system showed good clinical results in a majority of cases, but with a high complication rate (17).

Protocols for evaluation of component placement following arthroplasty have been shown in both human beings and dogs to be important in predicting the success of surgery as well as the risk of complications occurring (18-24). Preliminary retrospective evaluation of TATE elbow component positioning has been performed by de Sousa et al (17). However, measurements were not standardised in this study, firstly due to radiographs that excluded the long axis of the humerus for
measurement, and secondly, any effect of variable elbow flexion angle or positioning of the elbow on the measurement of component position was not evaluated. Any influence of elbow positioning on the measurement of TATE component position is important in developing a protocol for component position measurement that is accurate and repeatable, thus facilitating the objective correlation of component positioning with clinical outcome.

The aim of this study was to evaluate the radiological effect of varying both elbow flexion angle and elbow orientation on the measurement of component position for first generation (1G) and second generation (2G) TATE elbow cartridges, and to test intra-observer variability and inter-observer variability of the measurements. Our hypothesis was that significant differences in the measured verses actual position of components would occur as a function of varying these parameters.
Materials and Methods

Preparation of the model:

A right thoracic limb was harvested from a dog that had been euthanized for reasons unrelated to this study and following owner consent having been given for the dog to be used for research purposes. Ethical approval for the veterinary investigation was given by the XX Animal Welfare and Ethical Review Body. The limb was disarticulated at the scapulohumeral joint and the muscles then removed from the humerus and antebrachium. The collateral ligaments of the elbow and carpus/manus, and the interosseous muscle between radius and ulna, were preserved. The limb was then wrapped in saline soaked gauze swabs, bagged, archived and stored at -20°C. The limb was left to thaw at room temperature for 24 hours prior to experimental use.

For accurate placement of the TATE cartridge around the centre of rotation (COR), the following protocol was employed. The limb was radiographed to obtain a true mediolateral radiographic projection of the humerus as published in a previous study (25). Play-Doh (Hasbro, China) was applied over the medial portion of the humeral condyle and three 2mm diameter steel balls (Simply Bearings, UK) were placed on top, each approximately 120° to each other (Figure 1 a)). The radiograph was repeated with a 100mm calibration marker positioned level with the steel balls. The image was imported into viewing software (OsiriX MD, Pixmeo, Switzerland) and two concentric circles were drawn centred over the humeral condyle, the circumferences of which defined the medial and lateral portions of the humeral condyle as described by Wood et al (2016) (25). The image was calibrated to 100% magnification, the centre point of the circles defined (X), and then the distance from X to each respective steel ball was measured and recorded. The steel balls were then removed from the Play-Doh, and a compass with a radius corresponding to the measured distance between each steel ball to X was placed in the centre of each ball indentation. Arcs for each ball were then marked corresponding to the measured distance to X. The condyle centroid was then defined as the point where the three arcs intersected (Figure 1 b)). A 1.6mm Kirschner wire (Veterinary Instumentation, UK) and orthopaedic drill (Colibri II, SynthesVet, UK) were then used to
pierce the Play-Doh at the marked centroid and to create a 5mm deep hole in the medial portion of
the condyle at that position. This protocol was repeated by taking a radiograph with the limb in
lateromedial projection. A drill C-guide (SynthesVet, UK) was then placed in the medial and lateral
condylar holes and a 2.5mm drill bit was advanced across the humeral condyle to mark its COR
(Figure 1 c)). A mediolateral radiograph was obtained to confirm that the hole was in the exact
centre of the humeral condyle (Figure 1 d)). A BioMedtrix first generation (1G) TATE elbow
arthroplasty cartridge was then implanted into the limb as previously described (26). The cartridge
was centred around the COR hole, thus making it orthogonal to the mechanical axis of the humerus
in the sagittal plane, as described by Wood et al (2016) (25). The medial epicondylar osteotomy was
reduced and stabilised with two 2.7mm cortical screws (SynthesVet, UK) in the medial epicondylar
ridge. In a variant to the previously described surgical technique for TATE elbow replacement, a
3.5mm screw was not placed in the transcondylar hole, rather this hole was left empty in order to be
used as a reference for the next part of the experiment.

**Limb positioning:**

*Mediolateral projection*

The limb was mounted on a 15mm x 500mm x 500mm acrylic sheet (Trent Plastics Fabrications, UK),
with the mechanical axis of the humerus parallel to the lateral edge. This was done by ensuring that
the centre of the humeral head and humeral condyle were the same distance to the lateral edge. A
goniometer was used to position the elbow by eye at 90° of flexion and a 2.4mm Ellis pin (Veterinary
Instrumentation, UK) was placed in the COR hole in the humeral condyle. Modelling clay (Newplast
TM, Newclay Products Limited, UK) was used to support the proximal humerus and distal
antebrachium, which was then adjusted until the pin was exactly parallel to the centre of the x-ray
beam, thus appearing as a circle in the centre of the humeral condyle. Using a technique similar to
that previously described to define the mechanical axes of bones (25) and using OsiriX MD software,
an ellipse of best fit was superimposed over the humeral head, and two circles, one defining the
circular margin of the humeral condyle centred over the Ellis pin, and the other defining the centre of the epiphyseal region of the distal radius, were applied. Lines were drawn through the centres of the circles and ellipse, thus defining the mechanical axes, and the angle between these lines cranial to their intersect was measured. The elbow was progressively adjusted with repeat exposures until the angle on the cranial aspect of the elbow between the two lines was exactly 90° (Figure 2 a), and later 135° (Figure 2 b). This radiograph was labelled ‘90° elbow flexion angle and 0° inclination’. The Ellis pin was removed, and the platform was then tilted by set increments (2.5°, 5°, 7.5° and 10°) relative to the x-ray table using modelling clay wedges. A digital inclinometer (Chronos Engineering Supplies, UK) placed on top of the platform was used to confirm the inclination induced in orthogonal planes (Figure 3 a-c). The directions of platform tilt were named according to limb movement relative to the shoulder joint (with a fixed scapula). Tilting the platform up and down was defined as adduction and abduction, and tilting it from side to side was defined as external rotation and internal rotation (Figure 4 a). A radiograph was taken at each angle. The method was performed with the elbow flexion angle at both 90° and 135°.

Caudocranial projection

The Ellis pin was replaced in the COR hole, and the limb was fully extended and placed on the platform with the long axis parallel to the side. The limb was positioned such that the Ellis pin was equidistant from the platform at both of its ends in order to position the humerus in true caudocranial. A radiograph was taken in this position and labelled ‘0° inclination’. The platform was then tilted by the same set increments (Figure 3 d). The directions of platform tilt were again named according to limb movement relative to the shoulder joint (with a fixed scapula). Tilting the platform up and down was defined as flexion and extension, and tilting it from side to side was called external rotation and internal rotation (Figure 4 b). A radiograph was taken at each angle. The 1G TATE cartridge was then explanted from the elbow, the 2G cartridge implanted, and the method was repeated.
Radiological assessment:

Radiological examination was performed by two independent observers (XX/XX) on two occasions one week apart. A protocol was followed to objectively measure component position, similar to that described by Wood et al (2016) (17) and as illustrated in Figure 5. On mediolateral projections, the humeral and radio-ulnar components were assessed relative to the humeral mechanical axis, and the cartridge height to ulnar isthmus width ratio was calculated. On caudocranial projections the cartridge was assessed for varus/valgus malalignment. Each measurement was repeated for every variation of elbow position.

Mediolateral projection measurements

- Humeral component angle (HCA)

The humeral mechanical axis was determined using the previously described technique (25). An ellipse of best fit was templated onto the humeral head and a circle defining the articular surface was templated onto the humeral component of the TATE cartridge. A line passing through the centre of the ellipse and the centre of the circle was drawn (humeral mechanical axis), followed by another line drawn along the most proximal extent of the humeral component (humeral component line). The angle between the humeral mechanical axis line and humeral component line cranial to their intersect was defined as the HCA (Figure 5 a)).

- Radio-ulnar component angle (RCA)

An ellipse of best fit was templated onto the humeral head, and a circle defining the titanium-ultrahigh molecular weight polyethylene interface of the radio-ulnar component was templated onto the radio-ulnar component. The humeral mechanical axis was again marked by drawing a line which passed through the centre of the ellipse and circle, followed by another line drawn along the most proximal extent of the radio-ulnar component (radio-ulnar component line). The angle
between the humeral mechanical axis line and the radio-ulnar component line cranial to their intersect was defined as the RCA (Figure 5 b)).

- Cartridge height to ulnar isthmus width ratio (CIR)

The isthmus of the ulna was measured at the narrowest point of the trochlear notch, perpendicular to the caudal border of the ulna. This measured line was extrapolated to the most proximal aspect of the cartridge at that location, and the cartridge height was calculated by subtracting the isthmus width from the total width. The cartridge height to ulnar isthmus width ratio was calculated using the formula: 

$$\text{Cartridge height to ulnar isthmus width ratio} = \frac{\text{cartridge height}}{\text{ulnar isthmus width}}$$

(Figure 5 c)).

Caudocranial projection measurements

- Varus/valgus cartridge alignment angle (VVA)

An ellipse was templated onto the humeral head and a line passing through the centre of this ellipse and the mid-portion of the most distal aspect of the radio-ulnar component was added. A second line was placed from the mid-portion of the most distal aspect of the radio-ulnar component to the mid-portion of the proximal extent of the radio-ulnar component. The angle between the two lines was defined as the VVA (Figure 5 d)).

Protocols were devised for templating the circles of best fit to control the measuring technique as the radiographic shape changed with inclination, as shown in Figure 6. Image a) and c) show the limb tilted to cause abduction/adduction, and image b) and d) show the limb tilted to cause internal rotation/external rotation. In a) the limb was tilted by 2.5°, therefore the two sides of the cartridge were radiographically very close to one another and not easily distinguishable. A circle of best fit around the two sides of the (in this case humeral) component was therefore templated. Image b) shows templating of the radio-ulnar component with the limb also tilted by 2.5°. An ellipse of best fit
was templated as it was not possible to accurately position a circle. This method was performed for all radio-ulnar measurements. In c) the limb was tilted by 7.5°, therefore the two sides of the cartridge were radiographically much further away from each other. A circle of best fit was first templated onto one side of the humeral component, and this circle was then copied and pasted and positioned over the other side of the component. A third copy of the circle was then transposed to lie equidistant between these circles, and this third circle was used to measure humeral component angle. Image d) shows the appearance of the three circle technique when the limb was tilted in internal rotation/external rotation.

Determination of true component angles:

A deterministic trigonometric model was used to show how the component angles (HCA, RCA and VVA) should have varied with changes in orientation. The model determined how a visualised angle changes with inclination, not taking into account the shape of the cartridge. A 3D coordinates axes rotation matrix was used to calculate the theoretical angles, using the following formula below, where \( R_x(\theta) \) equals the component angle when the model is tilted in external rotation or internal rotation, and \( R_y(\theta) \) equals the component angle when the model is tilted in abduction or adduction.

\[
R_x(\theta) = \begin{bmatrix}
1 & 0 & 0 \\
0 & \cos \theta & -\sin \theta \\
0 & \sin \theta & \cos \theta
\end{bmatrix}
\]

\[
R_y(\theta) = \begin{bmatrix}
\cos \theta & 0 & \sin \theta \\
0 & 1 & 0 \\
-\sin \theta & 0 & \cos \theta
\end{bmatrix}
\]

The component angle when the limb was positioned at zero degrees of inclination, the zero degrees inclination angle, was defined as the average of the four observer measured zero degrees inclination angles (two per observer). The model was then used to calculate theoretical component angles at
2.5°, 5°, 7.5° and 10°. Angles at 20°, 30°, 40°, 50°, 60°, 70°, 80° and 90° were also calculated in order to identify trend lines on scatter graphs. As abduction and adduction, and flexion and extension inclination angles were equal (the difference being only positive or negative) these were recorded as one. This was the same for external rotation and internal rotation angles on both mediolateral and caudocranial projections.

Data interpretation:

Intra-observer and inter-observer variability

Intra-observer and inter-observer variability between measurements was evaluated using Student’s t-tests and the Bland-Altman method (27). Student’s t-tests were used to identify bias between each observer’s first and second measurements (intra-observer) and between both observers (inter-observer) e.g. whether one set of measurements was higher or lower. Significance was defined as a p value ≤0.05. For inter-observer variability, permuted block randomisation was used to select observer values in order to ensure that each set of component angle/ratio values was made up of an even but varying combination of first and second measurements made by observer 1 and 2. All Bland-Altman plots were evaluated for bias between the two sets of data, and the 95% limits of agreement (LoA – the mean difference in measurements ±1.96 standard deviations) were recorded. The plots were also evaluated for trends, for example if the difference between data sets became larger or smaller as the average measurement changed.

Component angle/ratio measurement

For each set of component measurements (HCA, RCA, VVA, and CIR), permuted block randomisation was used to determine which of the two observers, and which of the observer’s two values, would be selected for analysis. Scatter graphs for each set of values were then plotted. This was repeated for each combination of cartridge generation, elbow flexion angle and component measurement,
resulting in the following series of data and graphs: 1G HCA at 90° elbow flexion angle, 1G HCA at 135° elbow flexion angle, 2G HCA at 90° elbow flexion angle, 2G HCA at 135° elbow flexion angle, 1G RCA at 90° elbow flexion angle, 1G RCA at 135° elbow flexion angle, 2G RCA at 90° elbow flexion angle, 2G RCA at 135° elbow flexion angle, 1G CIR at 90° elbow flexion angle, 1G CIR at 135° elbow flexion angle, 2G CIR at 90° elbow flexion angle, 2G CIR at 135° elbow flexion angle, 1G VVA and 2G VVA.

The two sets of data (deterministic and observer measured values) were then compared. An angle ≤ 5° from the zero degrees inclination angle, and a cartridge height to ulnar isthmus width ratio ≤ 0.2 from the zero inclination ratio were defined as acceptable.
Results

Intra-observer variability:

Observer 1

First and second measurements for HCA were all within 7° of each other. The LoA were -4.2° to 4.4°. The measurements outside of these were for an adduction inclination of 5°. For RCA they varied by no more than 2.3° (LoA -1.9° to 1.6°), and for VVA the largest difference was 1.7° (LoA -0.8° to 1.3°). The largest difference for CIR was 0.1 (LoA -0.06 to 0.05) (Table 1). Student’s t-tests for each set of data showed no significant differences between the first and second measurements (p values >0.05). No trends were identified on the Bland-Altman plots.

Observer 2

First and second measurements for HCA were all within 4.9° of each other and the LoA were -2.8° to 2.2°. The measurements outside of the LoA were during an adduction inclination of 10°. For RCA they varied by no more than 1.8° (LoA -1.3° to 0.8°), and for VVA the largest difference was 1.5° (LoA -1.1° to 1°). The largest difference for CIR was 0.04 (LoA -0.03 to 0.04) (Table 1). Student’s t-tests for each set of data showed no significant differences between the first and second measurements (p values >0.05). No trends were identified on the Bland-Altman plots.

Inter-observer Variability:

First and second measurements for HCA were all within 11.1° of each other (LoA -7.3° to 3.8°). Measurements outside of the LoA were during adduction at 10° inclination. For RCA the measurements varied by no more than 1.9° (LoA -1.6° to 1.4°), and for VVA the largest difference was 1.5° (LoA -1.4° to 1.5°). The largest difference for CIR was 0.03 (LoA -0.02 to 0.02) (Table 1). Student’s t-tests for each set of data showed no significant differences between observers (p values >0.05). No trends were identified on the Bland-Altman plots.
**Humeral component angle:**

Graphs depicting one of the four deterministic HCA data sets and one of the four observer HCA data sets are shown in Figure 7. All four of the deterministic and observer graphs showed very similar trends. The deterministic graphs showed that for both abduction and adduction, the HCA only started to change significantly from the zero degrees inclination angle at around 50° inclination. After this inclination, the angles changed by more than 5° (Table 2). For internal and external rotation, the HCA only started to change significantly from the zero degrees inclination angle at around 40° inclination. After this inclination, the angle changed by more than 5° (Table 2). The observer measured HCA graphs showed that during adduction, internal rotation or external rotation of the limb, despite a gradual deviation away from the zero degrees inclination angle with increased limb inclination, the values all remained within 5° (specifically within 4.4°). However, during abduction, an increase in inclination of 10° for the 1G cartridge and 10° and 7.5° for the 2G cartridge resulted in a change in the measured HCA greater than 5° from the zero degrees inclination angle (Table 3).

**Radio-ulnar component angle:**

Graphs depicting one of the four deterministic RCA data sets and one of the four observer RCA data sets are shown in Figure 8. All four of the deterministic and observer graphs showed very similar trends. The deterministic graphs showed that for both abduction and adduction, the RCA only started to change significantly from the zero degrees inclination angle at around 30° to 40° inclination. After this inclination, the angle changed by more than 5° (Table 2). For internal and external rotation, the RCA also started to change significantly from the zero degrees inclination angle at around 30° to 40° inclination. After this inclination, the angle changed by more than 5° (Table 2). The observer measured RCA graphs showed that during abduction, adduction, internal rotation or external rotation of the limb, despite a gradual deviation away from the zero degrees inclination angle with increased inclination, the values all remained within 5° (specifically within 1.8°) (Table 3).
Varus/valgus cartridge alignment angle:

Graphs depicting the 1G deterministic and observer measured VVA data sets are shown in Figure 9. Both first and second generation graphs showed the same trend. The predicted angles graph showed that during both flexion and extension, the VVA only started to change significantly from the zero degrees inclination angle at around 60° inclination. After this inclination the angle changed by more than 5° (for 1G a change in VVA of 5° occurred at an inclination of 60.8°, for 2G the change was at 66.1°). For internal and external rotation, since the zero degrees inclination angle was less than 5°, the change in inclination did not exceed 5° because the angle gradually reduced to 0° (Table 2). The observer measured VVA graphs showed that during flexion, extension, internal rotation or external rotation of the limb, despite a deviation away from the zero degrees inclination angle with increased inclination, the values all remained within 5° (specifically within 4.4°) (Table 3).

Cartridge height to ulnar isthmus width ratio:

One of the graphs demonstrating the observer measured change in CIR is shown in Figure 10. All four graphs showed a very similar trend. An increase in inclination in all four orientations resulted in a positive linear deviation away from the zero degrees inclination ratio. Up to an inclination of 7.5° the values were all within 0.2 of the zero degrees inclination ratio, but at an inclination of 10° the values during abduction and adduction exceeded this with the exception of the G2 at 135° elbow flexion angle model (Table 3). A ratio of 1.0 occurred when the limb was inclined in adduction at 10° in all models except G2 at 135° elbow flexion angle.
Discussion

This study defines acceptable limits of limb inclination during positioning for radiological assessment of TATE elbow replacement cartridge, and validates the low variability in measurements of cartridge position. A test should be both accurate and precise to be clinically useful. Accuracy is the closeness of measurements of a quantity to its true value and precision is the consistency or repeatability of those measurements. Measurements within 5° of the zero degrees inclination angle, or within 5° of each other for intra-observer or inter-observer variability, were defined as acceptable. This value was chosen based on the study by De Sousa et al (2016) whereby alignment greater than 5° varus or valgus was considered imperfect (17). The results of that study indicated no association between outcome and component position, though the relatively low case numbers may have led to a type II statistical error. It has been reported that implant malalignment after elbow arthroplasty in people may predispose to uneven wear of components and component loosening (28), therefore we felt that the accuracy and precision of component position measurements should be an important consideration. To the author’s knowledge there have been no further studies investigating the relationship between cartridge alignment and clinical outcome, therefore further research is required.

Evaluation of intra-observer and inter-observer variability showed RCA and VVA to be the most precise, with differences between measurements not exceeding 2.3°. HCA was the least precise, especially when the limb was inclined ≥5° in adduction, but 99% of measurements were still within the defined acceptable limits of 5°. Evaluation of the predicted component angles showed that there should have been little change in angle when inclining the limb between 2.5-10°. Indeed the angles should have been within a maximum of 0.38° of the zero degrees inclination angle, and should only have changed by more than 5° after a minimum of 30° limb inclination (each prediction value was dependent on the component angle, inclination, elbow flexion angle and cartridge generation). The majority of observer measurements were within 5° of the zero degrees inclination angle during inclinations of 2.5-10° but were not within the predicted 0.38°. RCA and VVA were the
most accurate of the angle measurements, with inclinations of 10° in any of the four orientations not altering the zero degrees inclination angle by more than 1.8°. Measurement of HCA was the most inaccurate as some values were greater than 5° from the zero degrees inclination angle during abduction of the limb. Measurements for calculation of the CIR showed that with increased limb inclination the ratio increased, especially during abduction and adduction, and that an inclination of 10° would often result in a ratio greater than 1.0 (meaning that the isthmus width measured greater than the cartridge height). This could be a clinically significant error; the recommendation when placing a TATE cartridge is to ensure this ratio is less than 1.0 to reduce the risk of ulna fracture (29), therefore this level of inclination would lead one to incorrectly believe that the isthmus was too narrow. Unfortunately it was not possible to deterministically define the effect of inclination on the CIR due to the complexity of the cartridge dimensions. Accurate 3D computerised models of the cartridges would have been required to predict how the measurements of cartridge height and isthmus width should vary with inclination, and this was beyond the scope of the study.

We suspect that the discrepancies between the predicted component angles and the observer measured angles were related to the shape of the cartridge. At the zero degrees inclination angle, the cartridge appearance was two dimensional i.e. the width of the cartridge wasn’t visible. As the limb was inclined, the radiographic outline of the cartridge began to vary due to the three dimensions of the cartridge coming into view (Figure 11 and Figure 12); superimposition of the template circle over the cartridge component became less accurate, and when measuring the cartridge height and isthmus width it was not possible to differentiate between the other dimensions. We used specific protocols for templating the circles of best fit according to the radiographic outline of the cartridge in an attempt to control the method of measuring (Figure 6).

These techniques enabled good precision of the measurements, but likely still did not allow complete accuracy.

There are several limitations to this study. We devised a protocol to determine the centre of rotation of the humeral condyle prior to placement of the TATE cartridge. This was to ensure that the
cartridge was placed as accurately as possible so that meaningful conclusions could be drawn regarding the measurements. Despite what we considered to be a robust method, there were some aspects that could have led to error: 1) during placement of the compass into the centre of the modelling clay indentations of the steel balls, and 2) during marking of the condyle centroid through the Play-Doh using a Kirschner wire. However, the steel balls were only 2mm in diameter, therefore any error in marking was likely to be less than 1mm which would have had a negligible effect on the condyle measurements. The Play-Doh layer was as thin as possible to minimise inadvertent angulation of the Kirschner wire during condyle marking. Another limitation was the inability to know the true zero degrees inclination angles due to subtle variation in observer angle measuring technique. To obtain the most accurate values, we defined the zero degrees inclination angle for each component angle, cartridge generation and elbow flexion angle as the mean average of the four observer measurements. However, in order to establish the true zero degrees inclination angles the mechanical axis of the humerus would have needed to be more precisely defined. Paley (2002) described the mechanical axis as being the straight line connecting points at the centre of the joint surfaces proximal and distal to a long bone (30), and subsequently Wood et al (2014) developed a protocol that defined the humeral mechanical axis using radiography (25). Whilst the protocol provided a standardised method of measurement from a radiograph, any technique that relies upon human decision making (for example defining the ‘circle or oval of best fit’ over the humeral head or condyle) will inherently be susceptible to error. A computer-assisted system may have provided a more reliable method of measurement, but investigation into this was beyond the scope of the study. Finally, use of the radio-ulnar component to define varus/valgus component alignment angle may be susceptible to error in cases where there is medial or lateral joint space opening during positioning of the limb for radiography. This movement is limited by the tightness of the joint and should be minimal since the collateral ligaments are not transected during TATE elbow replacement surgery. However, it should be considered when evaluating cartridge position in cases where there is already a degree of joint laxity, or where it is present post-operatively. Whilst our study validates the
accuracy and repeatability of cartridge assessment in relation to elbow positioning for radiography, further research is required in to the benefit of performing such measurements. ‘Normal’ TATE component angles are yet to be defined; a preliminary retrospective evaluation of TATE elbow component positioning was carried out by de Sousa et al (2016), but the accuracy of the measurements may have been affected by the inability to measure the humeral mechanical axis, and the fact that it was not possible to determine whether the cartridges had been placed around the exact centre of rotation of the humeral condyle. The component angles in our study at zero degrees of inclination are likely to be more accurate since these limitations were overcome, however they were measured on a single limb; it is possible that breed-specific or individual differences in humeral shape may have an effect on component angles. Future studies are warranted to investigate the effect of conformation on the component angles. In addition, the measurements were performed with precise elbow flexion angles (90° or 135°); without this exact positioning, the radio-ulnar component angle would vary since it is measured relative to the humeral mechanical axis, and in a clinical setting spending time ensuring this may not be practical. It was not possible to define an accurate radio-ulnar mechanical axis to use as a reference for measurement of the radio-ulnar component due to removal of the radial head during the surgical procedure.

In summary, the results of the study suggest that measurement of HCA, RCA, VVA and CIR are accurate and precise and these parameters can be considered for evaluation of component position in clinical cases. Our experience of limb positioning during the experiment lead us to conclude that inadvertent inclination of the limb at 5° or greater in any of the four orientations relation to the table would be unlikely in a clinical setting. However, the effect of an individual animal’s conformation and the presence of joint disease that may limit joint range of motion and positioning remain to be quantified; we recommend that every effort is made when positioning for post-operative TATE views to avoid inadvertent abduction or adduction of the limb.
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