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Comparison of osteotomy technique and jig type in completion of distal femoral osteotomies for correction of medial patellar luxation. An in vitro study

Original Citation:	
Availability:	
This version is available http://hdl.handle.net/2318/1686612	since 2022-05-10T10:28:59Z
Published version:	
DOI:10.3415/VCOT-16-06-0086	
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1 Title: Comparison of osteotomy technique and jig type in completion of distal femoral osteotomies for 2 correction of medial patellar luxation: An in vitro study. 3 4 **Structured Summary** 5 **Objectives:** Femoral osteotomies are frequently completed to correct malalignment associated with 6 patellar luxation. The objectives of this study were to compare the use of: 1) two different types 7 8 of jig; 2) different types of osteotomy in the realignment of canine femoral bone models which 9 possessed various iterations of angulation. 10 11 Methods: 12 Models of canine femora possessing distal varus, external torsion and a combination of varus 13 and torsion underwent correction utilizing two alignment jigs (Slocum jig versus Deformity 14 Reduction Device (DRD)) and either a closing wedge ostectomy (CWO) or an opening wedge osteotomy (OWO). Post-correctional alignment was evaluated by radiographic assessment and 15 16 compared between groups. 17 18 **Results:** 19 The use of the Slocum jig resulted in frontal plane overcorrection when used with CWO in models of femoral varus, and when used with OWO in models of femoral varus and external 20 torsion when compared to other techniques. The DRD tended to realign the frontal plane closer 21 22 to the post-correction target value in all angulation types. The use of both jigs resulted in 23 undercorrection in the transverse plane in models with varus and torsion. 24 25 **Clinical significance:** 26 Jig selection and osteotomy type may lead to different post-correctional alignment results 27 when performing distal femoral osteotomies. Whereas OWO allows accurate correction when used with either jig to address frontal plane deformities, the DRD can be utilized with both 28

CWO and OWO to correct torsion-angulation femoral deformities to optimize frontal plane
 alignment.

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Introduction 33 Medial patellar luxation (MPL) is a common orthopedic disorder affecting the canine stifle (1-2). 34 35 Despite extensive research, the etiopathogenesis remains incompletely understood (3-5). Abnormalities in distal femoral morphology including excessive femoral varus and external 36 torsion have been postulated to contribute to MPL (3-7). In cases of MPL in which femoral 37 38 malalignment is documented in the frontal plane specifically, a corrective osteotomy can 39 normalize femoral alignment (8-11). Although threshold alignment values for the correction of the femur remain a controversial topic, current recommendations in larger breed dogs with 40 concurrent MPL include varus deformities in excess of 10°-12° or if the anatomic lateral distal 41 femoral angle (aLDFA) is greater than 102° (8,12-17). 42 Reports describe completing a distal femoral osteotomy (DFO) for femoral alignment correction 43 with the assistance of a Slocum tibial plateau leveling osteotomy jiga to both provide temporary 44 45 fixation of the osteotomy site and to maintain alignment while internal fixation is applied 46 (8,18). Slocum jig application to the femur in the frontal plane can assist angular correction following the completion of a distal femoral osteotomy by opening or closing the double-hinged 47 arm of the jig (Figure 1A). Axial alignment of the femur can be corrected by bending the distal 48 transfixation pin either medially or laterally inducing distal femoral internal or external torsion, 49 respectively (19). Despite the popularity of this method, disadvantages exist with the use of the 50 Slocum jig on the femur in the frontal plane. The presence of only one transfixation pin for each 51 segment does not provide rigid stability of the osteotomy and additional fixation devices may 52 53 be required prior to plate application. Further, torsional correction performed with the Slocum jig can lead to a translational deformity because the location where the distal pin is bent is 54 offset from the axis of the bone. This secondary deformity must then be corrected visually prior 55 to stabilization (20). Alternatively, to avoid this translational deformity, the two jig pins can be 56 57 placed in what will be the resulting sagittal plane of each segment thus allowing the jig to be

applied after realigning the two segments (21). However, using the jig in this fashion requires it to be detached from the bone during correction, which can be counterproductive in maintaining reduction.

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The Deformity Reduction Device (DRD)^b, allows the correction of frontal and transverse plane deformities while providing rigid temporary fixation (20,22) (Fig. 1B). The DRD acts as a hybrid external skeletal fixator composed of an arch connected to a bar via a cannulated hinge. Both the arch and bar accommodate the attachment of clamps which can hold two transfixation pins each to secure the jig at four points. The central hinge of the jig is cannulated to accept a 1.6mm wire that can be temporarily inserted in the center of rotation of angulation (CORA) to allow the alignment of the jig to the deformity. When the DRD's rod and arch are oriented perpendicularly to one another, the frontal plane position of the jig is in its neutral position (0°). On the frontal plane the hinge allows the correction of 60° in varus or in valgus. This correction is achieved through a micrometric screw drive, which makes incremental changes in the alignment, visually confirmed by gradations printed on the surface. The arch allows 45° of torsional correction internally or externally from neutral with a second micrometric screw drive which can also be confirmed with a built in goniometer. The DRD must be applied to a malaligned femur by pre-angulating the jig to match the bone deformity based on the presurgical planning. Following osteotomy, the jig is incrementally adjusted to correct the angulation to a predetermined end point. Further, the connecting rod can be translated medially or laterally to the arch's position by 15mm by loosening a dedicated holding screw which secures it to the hinge to correct secondary translations. No study has yet been performed to test whether its use would improve post-correctional alignment over conventional methodologies.

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The first objective of this study was to compare the resulting femoral alignment in both the frontal and transverse planes after executing a DFO with the Slocum jig versus the DRD.

Because distal femoral angulation may be corrected via different osteotomy techniques, we further sought to examine the interaction of jig and type of osteotomy. Specifically, our second

objective was to compare femoral alignment following opening wedge osteotomy (OWO) versus closing wedge ostectomy (CWO) using both jig types. We hypothesized that no differences would exist in post-correctional femoral alignment between the two types of jig, nor between the two types of correctional osteotomy.

Materials and Methods

Femoral Bone Models

Solid foam femoral models^c (n=100) based on a normal canine femur from an approximately 25kg dog were utilized for this study. The original normal femur possessed an aLDFA of 94° and a femoral torsion angle (FTA) of 25° and thus, these values represented post-correction target values we sought to achieve following corrective osteotomy and stabilization. The models were created with specific deformities that can contribute to MPL: distal varus (aLDFA=123°), external torsion (FTA=10°) and a combination of distal varus and external torsion of the same magnitudes (Fig. 2). The different types of bone malalignment were custom created by the manufacturer using a cutting jig to obtain perfect replications (n=20) of each deformity.

Radiography

Digital radiographic views (craniocaudal and axial) were obtained for each model to execute pre-surgical planning via the CORA methodology thereby confirming the deformity location and magnitude. To standardize radiographic views of each bone based on previous reports of acceptable standards of femoral positioning (9,12,23-25), custom-made positioners were fashioned for each model type from commercially available floral foam^d bricks. To achieve the craniocaudal view, models were positioned with the caudal surface embedded in the positioner, with the anatomic axis of the bone parallel to the table and perpendicular to the X-ray beam. Proper parallel positioning of the femoral diaphysis was confirmed with the use of a level placed on the cranial cortex of the femur (Fig. 3). Radiographs were deemed acceptable if 1) the femoral condyles and trochlear ridges were symmetrical (12,13,22,25) and 2) the inclination angle of the femoral head and neck was 130° ± 5° (26). To achieve the axial view, the models were positioned with the head, neck and greater trochanter embedded in the

positioner such that the femoral shaft was perpendicular to the table and parallel to the X-ray beam. Radiographs were deemed acceptable if the shaft appeared as concentric rings, the femoral head and neck were clearly visible and the condyles appeared symmetrical (13).

Pre-surgical planning

A single investigator (X) did the pre-surgical planning utilizing the CORA methodology on one representative model from each group (10,27). An aLDFA of 94° was utilized to determine the distal femoral anatomic axis for those models which possessed distal varus. The CORA location and magnitude were measured and recorded. The transverse bisecting line (tBL) was then determined for each frontal plane deformity (Fig. 4A). The dimensions of both OWO and CWO were calculated based on the CORA magnitude (19°) and the bone's diameter along the tBL. The transverse plane was assessed by measuring the FTA on the axial radiographs of one representative model from each group as has been previously described (13). Measurements less than 25° were considered to reflect external torsion whereas deviations in the FTA greater than 25° revealed internal torsion. As all torsionally affected models possessed 15° external torsion, the amount of correction required was converted from degrees to millimeters by calculating the circumference (*C*) of the femur at the level of the proposed corrective osteotomy ($C = 2\pi r$) divided by 360°.

Surgical correction

The bone models were divided into five groups based on the pre-determined deformity and type of osteotomy they would undergo (OWO versus CWO) (Table 1). All corrections were completed by two surgeons (A and B), whose practices are limited to veterinary orthopaedic surgery (X), during separate sessions. Half of each group underwent correction with the assistance of the Slocum jig whereas the other half utilized the DRD. Thus, the sample size for each group, jig type and surgeon was five models. In an attempt to replicate identical corrections within each grouping, the location and dimensions of the proposed osteotomies were drawn with pencil directly on each bone model based on the predetermined location of the CORA from the pre-surgical plan. Further, for groups 4 and 5, which possessed both varus

and torsion, a torsion reference line (TRL) was drawn on the cranial cortex of the model and across the proposed wedge osteotomy, to represent a starting point from which torsion would be corrected (Fig. 4B). The jigs were applied to each bone model. The Slocum jig required the placement of two negative profile threaded transfixation pins oriented craniocaudally. For application of the DRD, a 1.6mm wire was first inserted into the CORA craniocaudally on the bone. Then, the cannulated hinge of the DRD was positioned on the CORA wire to align the jig proximodistally on the bone. The DRD utilized the placement of four negative profile threaded pins; the two proximal pins oriented craniocaudally in the proximal segment, while the two distal pins were oriented both craniomedially and craniolaterally in the distal segment. Once all transfixation pins were placed, the CORA wire was removed.

Osteotomies were executed with an oscillating saw. Models in group 1 underwent a transverse osteotomy along the CORA. In groups 2 and 4, lateral CWO were executed in the form of a right triangle whose base was oriented along the tBL. The height of the removed wedge was calculated from multiplying the tangent of the CORA magnitude by the diameter of the bone along the tBL. For groups 3 and 5, medial OWO were performed along the tBL, and the wedge was opened to match the same height calculated for groups 2 and 4 confirmed via measurement with caliper. In groups 4 and 5, torsion was corrected following the varus correction utilizing the jig as previously described. The amount of torsional correction was confirmed by measuring the offset in the TRL to ensure it matched the amount determined in the pre-surgical planning phase (Fig. 4C). Group 1 underwent simple torsional correction along the transverse osteotomy in similar fashion. Following the osteotomy, the bones were aligned with only the jig providing temporary stabilization.

All osteotomies were secured using one of two types of non-compressing 3.5mm, six-hole, locking plate^e: condylar (#V3006) for groups 1,2 and 3 and a straight (#V3203) for groups 4 and 5, each secured with screws of appropriate length (28). Plates in groups 1,2 and 4 were applied to the lateral surface of the femur while plates in groups 3 and 5 were secured to the medial cortex to buttress the medially oriented gap that resulted from the opening wedge.

Osteotomies on each model were then secured with a liquid adhesive^f, including those of the OWO groups which had the resulting gaps completely filled with glue which solidified over a period of hours. When all osteotomies were secured, the plates were removed and each model was assigned a random number. Because the pin number and pattern between the two jigs differed, additional holes were drilled in each model to mimic the alternative jig type in order to blind the post-correction observer. Each model was radiographed in both the frontal and transverse planes using foam positioners. The post-correctional aLDFA and FTA were measured and recorded as indication of frontal and torsional plane alignment. The radiographic images of all bone models were measured three times on a dedicated workstation using digital radiographic software^g by a single investigator (X) who was blinded to both the type of jig used and the surgeon who executed the correction.

Statistical Analysis

Statistical analysis was performed using a statistical software package^h with significance set at p < 0.05. Median values for post-correctional aLDFA and FTA measurements were determined and compared within each group between jig type and surgeon using a non-parametric Kruskal-Wallis test. Further analysis was performed evaluating the association between jigs and osteotomy type utilized for each type of deformity via Kruskal-Wallis test analysis. Significant differences were assessed using a Wilcoxon post-hoc test with Bonferroni correction.

Results

When post-correctional alignment in frontal and transverse planes between the jig types and surgeons were compared within each group, no differences were detected for groups 1, 2, 3 and 4. However, in group 5 (external torsion with varus treated by OWO), a difference was detected between surgeons when using the Slocum jig with one surgeon significantly undercorrecting the frontal plane deformity (p = 0.007). However, no difference between surgeons or jigs was noted in the transverse plane for group 5.

After pooling data for both surgeons, no differences in frontal or transverse plane alignment were detected in group 1 (torsion only) when the transverse osteotomies were completed with the Slocum jig versus the DRD jig. The post-correctional FTA range for both jigs was between 25°-28°. However, analyzing jig and osteotomy interaction revealed that post-correctional alignment was significantly affected by both jig and osteotomy type in all models which possessed a varus component (groups 2-5). The use of the Slocum jig in conjunction with a CWO to treat distal varus (group 2) resulted in significantly different post-correctional alignment in both frontal and transverse planes compared to when the DRD or OWO was used. Specifically, when the Slocum jig was used to correct varus deformities via CWO, significantly lower aLDFA values resulted, thus representing an overcorrection of 3°-4° when compared with OWO (group 3) utilized with either jig (p = 0.004 and 0.012 respectively)(Fig. 5). Additionally, the Slocum jig also resulted in higher FTA values in the same deformity group compared to those obtained with the use of the DRD in conjunction with either CWO or OWO (p = 0.003 and 0.03 respectively) signifying an overcorrection, or surgeon-created internal torsion, of approximately 7° (Fig. 6). When the Slocum jig was used to assist with the varus-torsion deformity correction via OWO (group 5), a significant overcorrection of about 4° in the frontal plane was noted when compared with DRD used with either CWO or OWO (p = 0.005 and 0.0014 respectively) (Fig. 7). In group 5, the use of the DRD resulted in frontal plane alignment close to the target value of 94° and was significantly different than values obtained from the combination of Slocum jig with either OWO or CWO (p = 0.0014 and 0.009 respectively). Post correctional FTA values, in group 5, were not different between jig or osteotomy types (Fig. 8). Values were below the FTA target value of 25°, thus representing undercorrections of between 3° and 8°.

Discussion

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This study represents the first attempt to compare the efficacy of various techniques utilized to correct malalignment in the canine femur. In an attempt to limit confounding variables and test a large number of deformity iterations, we utilized femoral bone models. TO ascertain if an optimal technique exists that provides more accurate alignment of the femur, we examined

two methods of corrective osteotomy paired with two different jigs. Based on our results, our null hypotheses were rejected. Regardless of identical pre-surgical deformity planning, jig selection and osteotomy type may result in significant variation in post-correctional alignment.

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Some potentially important differences were detected between techniques. For example, when correcting distal femoral varus with a CWO utilizing the Slocum jig, an overcorrection (aLDFA = 90.8°) was detected when compared with all other groups, achieving statistical significance with OWO + Slocum (aLDFA = 94.2°) and OWO + DRD (aLDFA = 93.7°) techniques and nearing it with use of a CWO + DRD (aLDFA = 93.2° , p = 0.08). A possible explanation could be the combined nature of how the dimensions of a CWO will dictate the amount of angular correction that is achieved when the Slocum jig is used which possesses large versatility (owing to the fact that only a single pin secures it to each segment) and no reference guide with which to validate correctional accuracy. As such, if care is not taken to execute a wedge ostectomy with precise dimensions, closing the resulting angular gap to achieve complete apposition prior to fixation utilizing the Slocum jig can result in subtle malalignment. And our results would indicate that frequently, the wedge excised was greater than planned, thus resulting in overcorrection and a lower aLDFA than desired which may have been prohibited if a jig with a built in goniometer had been utilized. If an oversized wedge is accidentally removed while utilizing the DRD a precise correction would still be achievable as the goniometer would dictate the degree of correction, but at the cost of a gap in the osteotomy. The performance of an overly aggressive wedge while using the Slocum jig would achieve better cortical apposition, but at the cost of over-correcting the deformity. Thus, when examining a complex deformity (groups 4 and 5), use of the Slocum jig once again resulted in the greatest degree of correctional error. Specifically, the median aLDFA of the OWO + Slocum jig was 90.7° which was significantly less than the resulting aLDFA acquired with both osteotomy techniques utilizing the DRD (94.3° with CWO and 94.6° with OWO). We theorize that with a more secure linkage between jig and bone, the presence of micrometric screw adjustment capability and a built in goniometer to confirm correctional magnitude, the DRD represents a higher precision instrument for the correction of femoral angulation. Further evidence of this is that the only technique which demonstrated

significant variation between the two test surgeons utilized the Slocum jig in group 5, thus suggesting its efficacy may be more user dependent.

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However, both jigs resulted in near uniform undercorrection of femoral torsion in the presence of varus apparent by FTA values that were consistently less than the target 25° in group 5. Such undercorrection equates to residual external torsion of the distal femur. Jig-guided correction of femoral torsion can be problematic, as the distal segment needs to be rotated about the anatomic axis of the bone. Completing this with the Slocum jig requires bending the distal jig pin at a point removed from the femur's axis, resulting in translation and potential undercorrection. The DRD's distal arch correction efficacy is predicated on having coaxial alignment of the virtual center of the arch over the femur's anatomic axis during jig placement. Should these axes be offset, secondary translation and undercorrection can result. While accurate torsional alignment was readily achievable in a torsion-only affected model (group 1), the additional complexity of the torsion-varus model of group 5 proved problematic, thus revealing introduced error when attempting to resolve both frontal and transverse deformities with a single osteotomy and sequential jig adjustments. The data from groups 2 and 3 suggest that the FTA is fairly conserved after resolving varus only. The DRD possessed post-correction FTA values of 21° and 24° following CWO and OWO, whereas the Slocum jig demonstrated postcorrection FTA values of 32.5° and 26° following CWO and OWO. Thus, other than a mild undercorrection noted with CWO completed with a DRD, varus correction with the other jig and osteotomy combinations did not apparently result in external torsion of the distal segment. The source of the error in torsional correction in varus-torsion models, therefore, remains undetermined and warrants further examination. Of obvious note is the remaining question of the clinical significance in the differences detected between techniques in the current study. In other words, will 4° of overcorrection of femoral varus with the use of a Slocum jig, or 7° of undercorrection of external torsion with either jig increase the risk of reluxation of the patella? Unfortunately, this work cannot answer those questions, and threshold alignment values of when correction is required, and when correction will fail remain unknown.

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Of equal importance to note are the limitations with this study. The results must be interpreted with caution because the use of models, while allowing both the control of a number of confounding variables and the optimization of sample size, is still only a facsimile of the clinical condition and lacks many critical anatomic features that exist with malalignment associated with patellar luxations. Further, not only did we compare various DFOs, but also the ability of two surgeons to execute those techniques. Thus, sources of variation are potentially introduced that are unrelated to the osteotomy type or jig used, such as the proficiency with which a CWO is performed by an individual. For example, for a CWO to correct varus only, it must be executed in the sagittal plane in uniaxial fashion, such that both arms of the ostectomy intersect along a single axis that is oriented craniocaudally. Any deviation from this results in a biaxial correction which will result in an oblique plane correction instead of a pure frontal plane correction. This potential source of error could be mitigated in future attempts with the use of a cut guide or template. As neither surgeon in this study uses such guides in clinical practice, the decision was made to allow each to execute all osteotomies as they would in a clinical case. Further, some evidence suggests that despite the use of osteotomy templates or guides, inaccuracy can still occur in the execution of CWO due to errors in handling the saw, using the template or the amount of osteotomy compression that may occur with some types of plating systems (29). We specifically chose a locking plate system to mitigate this potential source of error (28).

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In summary, when surgically addressing femoral malalignment both osteotomy type and jig selection can affect the post-correctional outcome in both the frontal and transverse planes. Care should be taken when executing either OWO or CWO in conjunction with less precise holding jigs, and means of double checking the magnitude of correction intra-operatively should be sought.

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Footnotes

318	a.	Slocum Enterprises, Eugene, OR, USA. US Patent No. 5,578.038
319	b.	Deformity Reduction Device jig, Hofmann SRL, Monza, Italy
320	c.	Pacific Research Laboratories, Inc (Sawbones®), Vashon Island, WA, USA
321	d.	Desert Foam® Dry Floral Foam bricks, FloraCraft®, Ludington, MI, USA
322	e.	Fixin, Traumavet S.r.l., Rivoli, Italy
323	f.	Loctite® Hot Melt Glue, Henkel Corporation, Rocky Hill, CT, USA
324	g.	OsiriX, Pixmeo Sarl, Bernex Switzerland
325	h.	R Project version 3.2.2, R Foundation for Statistical Computing, https://www.r-
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Figure and Table Legends

Figure 1. Photograph of the two types of jig utilized. A. A Slocum tibial plateau leveling osteotomy jig placed on the cranial cortex of an angulated femoral model. B. A DRD jig placed on the cranial cortex of an angulated femoral model. 1. The mediolateral translation mechanism. 2. The micrometric screw drive used to adjust frontal plane angulation at the level of the hinge. 3. The cannulated frontal plane hinge with built in goniometric reference placed over a 1.6mm wire inserted in the CORA of the bone model. 4. The micrometric screw drive used to adjust the transverse plane correction. 5. The transverse plane arch which secures the distal jig to the bone and allows torsion correction.

Figure 2. Photograph of each canine femoral deformity model. A. The 15° external torsion model (group 1). B. The 19° distal varus model (groups 2 and 3). C. The combined 15° external torsion, 19° distal varus model (groups 4 and 5).

Figure 3. Photograph of a representative model from group 3 (varus treated with an opening wedge osteotomy) after the ostectomy gap was filled and secured with liquid adhesive, the plate was removed and additional jig pin holes were drilled for blinding purposes. The model was placed in the foam positioner with level confirmation for craniocaudal view radiograph acquisition.

Figure 4. Schematic illustrating a femoral bone model from group 4. A. pre-surgical planning utilizing the CORA methodology, B. layout of proposed correction utilizing a CWO and marking the TRL for torsion correction C. post-correctional appearance following varus and torsion correction. CORA = center of rotation of angulation, PAA = proximal anatomic axis, DAA = distal

429 anatomic axis, tBL = transverse bisecting lines, JRL = joint reference line, CWO = closing wedge 430 ostectomy, TRL = torsion reference line. 431 432 Table 1. Groupings based on deformity and osteotomy type. CWO = closing wedge ostectomy, 433 OWO = opening wedge osteotomy 434 Figure 5. Box plot for varus affected femoral models (groups 2 and 3) examining comparisons 435 between osteotomy types and jig types (Wilcoxon rank-sum test, significance between groups 436 set at p < 0.05 and denoted by symbols) and their effects on frontal plane alignment as measured 437 438 by the aLDFA. Median value for post-correctional alignment for each is group provided. Dotted 439 line at 94° represents the target of correction of the frontal plane. aLDFA = anatomic lateral distal femoral angle, CWO = closing wedge ostectomy, OWO = opening wedge osteotomy, DRD = 440 Deformity Reduction Device. 441 442 Figure 6. Box plot for varus affected femoral models (groups 2 and 3) examining comparisons 443 between osteotomy types and jig types (Wilcoxon rank-sum test, significance between groups 444 445 set at p < 0.05 and denoted by symbols) and their effects on axial plane alignment as measured by the FTA. Median value for post-correctional alignment for each group is provided. Dotted line 446 at 25° represent the target of correction of the axial plane. 447 FTA= femoral torsion angle, CWO = closing wedge ostectomy, OWO = opening wedge 448 osteotomy, DRD = Deformity Reduction Device. 449 450 Figure 7. Box plot for varus and external torsion affected femoral models (groups 4 and 5) 451 452 examining comparisons between osteotomy types and jig types (Wilcoxon rank-sum test, 453 significance between groups set at p < 0.05 and denoted by symbols) and their effect on frontal plane alignment as measured by the aLDFA. Median value for post-correctional alignment for 454 each is group provided. Dotted line at 94° represents the target of correction of the frontal 455 456 plane. aLDFA = anatomic lateral distal femoral angle, CWO = closing wedge ostectomy, OWO = opening wedge osteotomy, DRD = Deformity Reduction Device. 457

458	
459	Figure 8. Box plot for varus and external torsion affected femoral models (groups 4 and 5)
460	examining comparisons between osteotomy types and jig types (Wilcoxon rank-sum test,
461	significance between groups set at p < 0.05 and denoted by symbols) and their effects on axial
462	plane alignment as measured by the FTA. Median value for post-correctional alignment for each
463	group is provided. Dotted line at 25° represents the target of correction of the frontal plane.
464	FTA= femoral torsion angle, CWO = closing wedge ostectomy, OWO = opening wedge
465	osteotomy, DRD = Deformity Reduction Device.