



Contents lists available at ScienceDirect

Journal of Biomechanics

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Does the condylar lift-off method or the separation method better detect loss of contact between tibial and femoral implants based on analysis of single-plane radiographs following total knee arthroplasty?

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ARTICLE INFO

Article history:

Accepted 19 January 2019

Keywords:

Fluoroscopy
Bi-planar
Knee replacement
Aseptic loosening
Tibial insert wear

ABSTRACT

Background: Loss of contact between the femoral and tibial implants following total knee arthroplasty (TKA) has been related to accelerated polyethylene wear and other complications. Two methods have been used to detect loss of contact in single-plane fluoroscopy, the condylar lift-off method and the separation method. The objectives were to assess the ability of each method to detect loss of contact.

Methods: TKA was performed on ten cadaveric knee specimens. Tibial force was measured in each compartment as specimens were flexed from 0° to 90° while internal-external and varus-valgus moments were applied. Single-plane radiographs taken simultaneously with tibial force were analyzed for loss of contact using the two methods. Receiver operating characteristic (ROC) and optimum threshold distances were determined.

Results: For the lift-off method and the separation method, the areas under the ROC curves were 0.89 vs 0.60 for the lateral compartment only and 0.81 vs 0.70 for the medial compartment only, respectively. For the lift-off method, the optimum threshold distances were 0.7 mm in the lateral compartment only and 0.1 mm in the medial compartment only but the false positive rate for the medial compartment only almost doubled. For both compartments jointly, the areas under the ROC curves decreased to 0.70 and 0.59 for the lift-off and separation methods, respectively.

Conclusion: When detecting loss of contact using single-plane fluoroscopy, the lift-off method is useful for the lateral compartment only but not for the medial compartment only and not for both compartments jointly. The separation method is not useful.

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1. Introduction

Loss of contact between the femoral and tibial components during normal daily activities following total knee arthroplasty (TKA) is an important event of interest. This is because loss of contact in a compartment has been related to accelerated polyethylene wear in the contralateral compartment (Jennings et al., 2007) and might cause complications due to overloading in a single compartment such as subsidence (Berend et al., 2004) and/or aseptic loosening all of which would require revision.

Based on analysis of single-plane radiographs taken during fluoroscopy, two methods have been used previously to detect loss of

contact, the lift-off method (Stiehl et al., 1999) and the separation method (Kanekasu et al., 2004) (Fig. 1). In each method, a threshold distance is selected and loss of contact is assumed to occur when that threshold distance is exceeded. Due to errors in determining the relative pose of the components, a common threshold distance used for each method has been selected arbitrarily as 1.0 mm (Prins et al., 2014) but neither has the optimal threshold distance, which best detects actual loss of contact, nor has the method that better detects actual loss of contact been determined.

One tool for determining the method that has the better detection ability and the optimum threshold distance is the receiver operating characteristic (ROC) curve which is a graphical plot that illustrates the detection ability of a binary classifier system as its discrimination threshold is varied (EP12-A2, 2007). The ROC curve is created by plotting the true positive rate against the false positive rate at various discrimination thresholds (https://en.wikipedia.org/wiki/Receiver_operating_characteristic). Because the area

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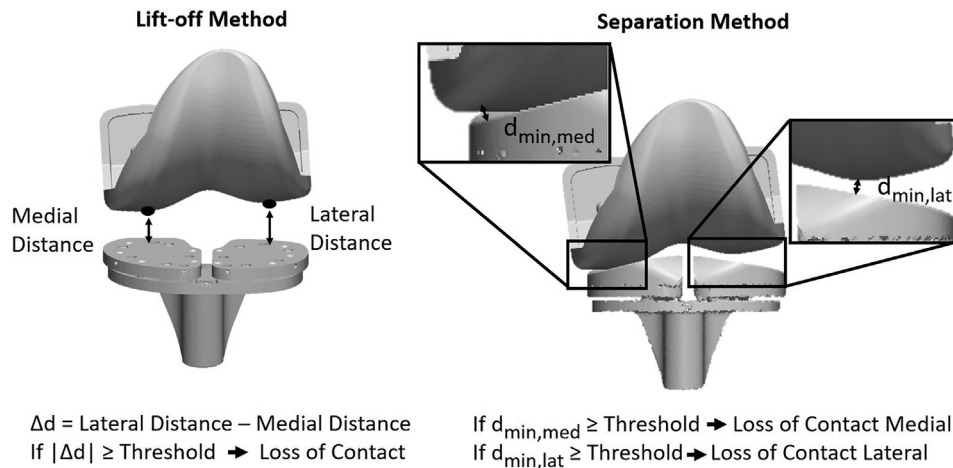


Fig. 1. Diagram illustrating the lift-off method and the separation method. The lift-off method computes the difference in distance of the lowest point of each of the medial and lateral femoral condyles from the proximal surface of the tibial baseplate whereas the separation method computes the minimum distance separating a femoral condyle from the articular surface of the tibial insert. A fundamental difference between the two methods is that the separation method considers the curvature of the tibial insert whereas the lift-off method does not. For both methods, loss of contact is assumed to occur when the respective quantity computed exceeds a threshold distance.

under the curve quantifies the diagnostic ability (Hanley and McNeil, 1982), the method which has better detection ability is the method with the greater area. The optimum discrimination threshold can be determined based on the Youden index which is the discrimination threshold that maximizes the difference between the true positive rate and the false positive rate (Ruopp et al., 2008).

Because the method that better detects loss of contact is unknown and because the optimal threshold distances have not been determined, this study had two objectives. Based on analysis of single-plane radiographs using the lift-off method and the separation method, one objective was to use the areas under ROC curves to assess the ability of each method to detect loss of contact, and the second was to determine the optimal threshold distances using the Youden index.

2. Methods

To assess the ability in detecting loss of contact using the lift-off method and the separation method, the tibial contact forces were measured experimentally in ten fresh-frozen cadaveric left-side knee specimens (mean age = 80.9 ± 12 years, range = 51–92 years; 8 male and 2 female) simultaneously while taking single-plane radiographs. Each specimen was thawed, dissected, and potted in metal tubes to allow for the bones to be fixed in place during exposure of the radiographs.

After dissection and potting, kinematically aligned total knee arthroplasty (TKA) was performed on each specimen with generic instruments (Howell et al., 2013), a transpatellar approach (Merican et al., 2009), and commercially available posterior cruciate-retaining femoral and tibial components (Persona, Zimmer Biomet, Warsaw, IN) implanted without soft tissue release. When performing the procedure, the orthopedic surgeon selected the appropriate sized femoral and tibial components for each specimen. Once the cement mantles holding the commercially available components had cured, the tibial component was removed and a custom tibial force sensor was inserted into the cement mantle (Fig. 2) (Roth et al., 2017). The articular surfaces of the custom tibial force sensor were 3D printed from an acrylic-like plastic (VeroWhite, Objet Eden260VS, Stratasys, Ltd.) and matched the size and shape of the insert of the tibial component selected by the surgeon. The tibial force sensor measured the force and center of pressure (i.e. contact location) independently in each compartment. Only the tibial force measurement was of interest in this

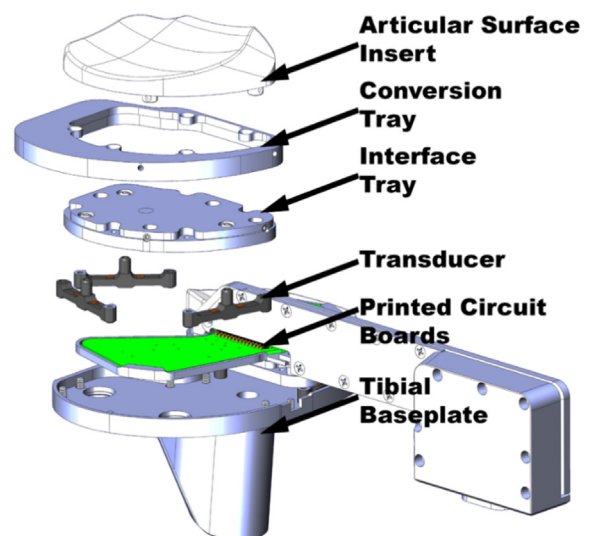


Fig. 2. Image showing an isometric view of the custom tibial force sensor with the medial compartment exploded to show the five layers. The first layer, which is the most distal, is a modified tibial baseplate (Persona CR size D, Zimmer, Inc.) that has been hollowed out from the proximal surface. The second layer consists of printed circuit boards that are used to complete the Wheatstone bridge circuit of each of the six transducers. The third layer consists of two triangular arrays of three custom transducers each; one array is in the medial compartment and the other is in the lateral compartment. The fourth layer consists of the medial and lateral trays. The interface trays provide a rigid connection between the transducers and the tibial articular surface inserts, which make up the fifth layer. Conversion trays can be attached to the interface trays to accommodate larger articular surface inserts. The fifth and most proximal layer consists of independent medial and lateral tibial articular surface inserts, which are 3D printed (Grey 60, Stratasys Ltd, Eden Prairie, MN). These inserts have same the articular shape as the standard tibial articular surfaces and come in different sizes and thicknesses so that the overall size and thickness of the tibial force sensor match those of the standard tibial component with the proper thickness articular surface. Once assembled, the internal cavity between the hollowed out baseplate and interface trays was filled with a low stiffness dielectric gel (SYLGARD™ 527 Silicone, Dow Corning, Midland, MS) to seal the electrical components but not interfere with the load transfer. The root mean squared errors (RMSEs) in force and contact location are ≤ 6.1 N and ≤ 1.6 mm respectively.

study. Once the kinematically aligned TKA procedure was completed, the exposure was closed using two transverse screws through the patella.

Following closure, the specimen was placed inverted in a fixture with the tibia resting on top of the femur and an 89 N compressive load applied to the distal end of the tibia using a dead weight. The purpose of applying the 89 N compressive load was to insure that the femoral condyles were seated in the concave surfaces of the tibial insert when the tibiofemoral joint was in the neutral position (i.e. no varus-valgus or internal-external moments applied). Thus when either a varus or valgus moment of sufficient magnitude was applied, loss of contact would occur in only one compartment and contact would be maintained in both compartments in internal-external rotation. The fixture allowed for six degree-of-freedom motion of the tibiofemoral joint and positioned the tibiofemoral joint in any flexion angle from 0° to 120° (Fig. 3).

Twenty 24 cm × 30 cm single-plane radiographs were collected for each specimen. The center of the X-ray source was aligned with the center of the film with a 1 m principal distance. The specimen was placed in an oblique sagittal orientation of approximately 10°–15° between the X-ray source and film, approximately 25 cm from the film. The oblique sagittal orientation was used to better shape match the 3D model to 2D images by making the silhouette produced exhibit distinguishing features of the 3D model in both the sagittal and coronal planes. Films were exposed with the x-ray source (model HF80H+, MinXray Inc., Northbrook, Illinois) to produce radiographs using the following parameters: 60 kV tube voltage, 0.28 s exposure time. During each exposure, the tibia sat on the femur in one of twenty randomized positions, each consisting of a combination of flexion angle (0°, 30°, 60°, and 90°) and internal-external (I-E) rotation, varus-valgus (V-V) rotation, and neutral rotation of the tibia on the femur. During the exposures of the radiographs, the sequence of the four flexion angles was randomized and the positions of the tibia on the femur were randomized within each flexion angle. The internal and external rotations of the tibia on the femur were produced by manually applying between a 0.5 N m and 3.0 N m internal or external moment to the distal tibia to cause rotation of the tibia on the femur without subluxation of the tibiofemoral joint (Blankevoort et al., 1988). The

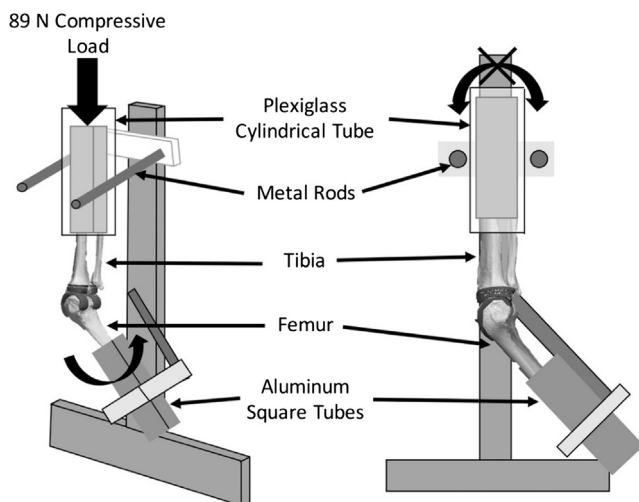


Fig. 3. Schematic showing the testing fixture and aluminum square tubes used to position the cadaveric specimens. The femur was rigidly fixed in all degrees of freedom, except flexion-extension, by clamping the femoral aluminum square tube to the fixture. The tibia rested on top of the femur and only flexion-extension was constrained. Flexion-extension of the tibia was constrained by placing a plexiglass cylindrical tube around the tibial aluminum square tube and placing the plexiglass cylindrical tube between two metal rods. These two metal rods together with the plexiglass cylindrical tube prevented the tibia from flexing or extending without restricting any of the other degrees of freedom. By means of a dead weight, an 89 N compressive load was applied to the distal end of the inverted tibia to ensure contact between the femoral component and tibial force sensor.

varus and valgus rotations were produced by manually applying a varus or valgus moment sufficient to cause the lateral and medial tibial forces respectively to measure zero as indicated by the tibial force sensor. When a radiograph was exposed, the tibial force sensor outputs were simultaneously collected in each compartment.

Using the collected radiographs, the absolute 3D positions and orientations of the two components were determined in each radiograph with 3D model-to-2D image registration (Banks and Hodge, 1996; Mahfouz et al., 2003) performed using open source software (JointTrackAuto, www.sourceforge.net/projects/joint-trackauto). Using the default settings for greyscale, edge detection, and optimization parameters, the software determined the 3D position and orientation of each component expressed in the laboratory coordinate system in the form of two translation vectors and six 3-1-2 Euler angles. Once the translation vectors and 3-1-2 Euler angles were determined, a correction was made to the position of the femoral component to center it over the tibial component in the out of plane (i.e. approximately medial-lateral) direction. The correction was necessary due to the difference in materials of the femoral and tibial components inducing a translation bias. This correction was performed by finding the centers of the femoral and tibial components in the medial-lateral (M-L) direction and translating the femoral component until the two M-L centers were in the same location in the out-of-plane direction (Prins et al., 2010). This produced a centered translation vector with the same 3-1-2 Euler angles output by JointTrackAuto.

Loss of contact of the femur on the tibia was determined using the lift-off method and the separation method (Fig. 1). The lift-off method calculated the difference in distance between the lowest point of the lateral femoral condyle and the lowest point of the medial femoral condyle relative to the proximal surface of the baseplate of the tibial component and did not include the tibial insert in the calculation (Banks et al., 1997; Dennis et al., 1996). If the distance from the lowest point of the lateral femoral condyle to the proximal surface of the tibial baseplate was greater than the distance from the lowest point of the medial femoral condyle to the baseplate, then the difference was termed the lateral lift-off distance (a positive number). Conversely, if the distance from the lowest point of the lateral femoral condyle to the proximal surface of the tibial baseplate was less than the distance from the lowest point of the medial femoral condyle to the baseplate, then the difference was termed the medial lift-off distance (a negative number). Lateral loss of contact was determined to have occurred when the lateral lift-off distance exceeded a threshold distance (e.g. > 1.0 mm) whereas medial loss of contact was determined to have occurred when the absolute value of the medial lift-off distance exceeded the threshold distance. The separation method calculated the shortest Euclidian distance between each tibial component point and all the femoral component points for each compartment. Loss of contact in either or both compartments was determined to have occurred when the shortest distance termed the separation distance exceeded a threshold distance (e.g. > 1.0 mm).

To assess the ability of each method to detect loss of contact, receiver operating characteristic (ROC) and total operative characteristic (TOC) curves were determined for a range of threshold distances. For each threshold distance in the range, the 2 by 2 contingency table was computed. Based on the values in this table, the true positive rate was plotted against the false positive rate for the ROC curve whereas the number of true positives was plotted against the number of true positives plus the number of false positives for the TOC curve. The area under the ROC curve indicated the discriminative ability of the method and represented the probability that a randomly chosen subject with loss of contact is correctly ranked with greater suspicion than a randomly chosen subject without loss of contact (Hanley and Mc Neil, 1982). An area

Table 1

Definitions of outcomes from the 2×2 contingency tables used to form the receiver operating characteristic (ROC) and total operating characteristic (TOC) curves for determining loss of contact. Definitions are given for a single compartment only and for both compartments jointly using the lift-off method and the separation method.

	Single compartment		Both compartments	
	Tibial force sensor	Loss of contact method	Tibial force sensor	Loss of contact method
True positive	Force equals zero in a compartment	Absolute lift-off distance or separation distance is greater than or equal to threshold distance in the same compartment	Force equals zero in a compartment	Absolute lift-off distance or separation distance is greater than or equal to threshold distance in either or both (separation only) compartments
False positive	Force is greater than zero in a compartment	Absolute lift-off distance or separation distance is greater than or equal to threshold distance in the same compartment	Force is greater than zero in both compartments	Absolute lift-off distance or separation distance is greater than or equal to threshold distance in either or both (separation only) compartments
True negative	Force is greater than zero in a compartment	Absolute lift-off distance or separation distance is less than threshold distance in the same compartment	Force is greater than zero in both compartments	Absolute lift-off distance or separation distance is less than threshold distance in both compartments
False negative	Force equals zero in a compartment	Absolute lift-off distance or separation distance is less than threshold distance in the same compartment	Force equals zero in a compartment	Absolute lift-off distance or separation distance is less than threshold distance in both compartments

of 0.9–1.0 is considered very good, of 0.8–0.9 good, of 0.7–0.8 fair, of 0.6–0.7 poor, and of 0.5–0.6 fail (EP12-A2, 2007). For each method, ROC curves and corresponding areas and TOC curves were determined for three cases – loss of contact in the lateral compartment only, the medial compartment only, and the medial and/or lateral compartments jointly.

In the latter case for the lift-off method, loss of contact was detected when either the absolute medial lift-off distance or the lateral lift-off distance exceeded the threshold distance (Table 1). In the latter case for the separation method, loss of contact was detected when either the medial separation distance or the lateral separation distance or both exceeded the threshold distance. For each case, the optimal threshold distance was determined using the Youden index which is the threshold distance that maximizes the difference between the true positive rate and the true negative rate (Ruopp et al., 2008).

For both methods when considering both compartments jointly, it should be noted that outcomes can be correct but for the wrong reason. For the lift-off method for example, an instance where loss of contact actually occurred in one compartment (i.e. tibial force sensor read zero) but the lift-off distance exceeded the threshold distance in the contralateral compartment where loss of contact actually did not occur would be categorized as a true positive which is correct but for the wrong reason. Likewise, for the separation method, the separation distance in one compartment could exceed the threshold distance when loss of contact actually did not occur whereas the separation distance in the contralateral compartment did not exceed the threshold distance when loss of contact actually did occur leading to the same outcome as above for the lift-off method. This scenario where a true positive was indicated but for the wrong compartment occurred six and three times for the lift-off and separation methods, respectively. The outcome definitions in Table 1 when considering both compartments jointly were necessary because discriminating between compartments could result in conflicting outcomes.

Table 2

Values for the Youdan Index, the optimum threshold distance determined using the Youdan Index, and the areas under the curve (AUC) for the receiver operating characteristic (ROC) curve and the total operating characteristic (TOC) curve. Values are given for both the lift-off method and the separation method for detecting loss of contact in the lateral compartment only, the medial compartment only and the lateral and medial compartments jointly. Based on the area under the ROC curve, G indicates good detection, F indicates fair detection, P indicates poor detection, and FA indicates failed detection.

	Lift-off method			Separation method		
	Lateral	Medial	Lateral & medial	Lateral	Medial	Lateral & medial
Youdan Index	0.64	0.54	0.32	0.22	0.36	0.19
Optimum threshold distance (mm)	0.7	0.1	0.7	0.1	0.02	0.40
AUC (ROC)	0.89 (G)	0.81 (G)	0.70 (F)	0.60 (P)	0.70 (F)	0.59 (FA)
AUC (TOC)	0.81	0.74	0.61	0.58	0.66	0.56

3. Results

The areas under the curves for the lift-off method were greater than those of the separation method (Table 2) (Figs. 4 and 5). For the lateral compartment only, the area under the curve was 0.89 vs 0.60 for the lift-off method and the separation method respectively. For the medial compartment only, the area under the curve was 0.81 vs 0.70 for the lift-off and separation methods respectively. Hence, the lift-off method was classified as a good detector (i.e. area > 0.8) for loss of contact in the lateral component only and a good detector for loss of contact in the medial compartment only. The separation method was classified as a poor detector (i.e. area between 0.6 and 0.7) for loss of contact both in the lateral compartment only and in the medial compartment only. When loss of contact in the lateral and/or medial compartments jointly was assessed, the area under the ROC curve for the lift-off method of 0.7 was still greater than that for the separation method of 0.59 but the classifications degraded to fair and failed, respectively (Table 2) (Fig. 6).

The optimum threshold distances were 0.7 mm and 0.1 mm for the lift-off method in the lateral compartment only and in the medial compartment only, respectively (Table 2). Based on the contingency tables, the true positive rates (TPR) were the same for both optimum threshold distances but the false positive rate (FPR) for the medial compartment only was almost double that for the lateral compartment only (Table 3). Both the precision and accuracy were greater for detecting loss of contact in the lateral compartment only than in the medial compartment only.

4. Discussion

Because two methods have been used to determine loss of contact in fluoroscopic studies of knee function following total knee arthroplasty and because neither method has been evaluated for

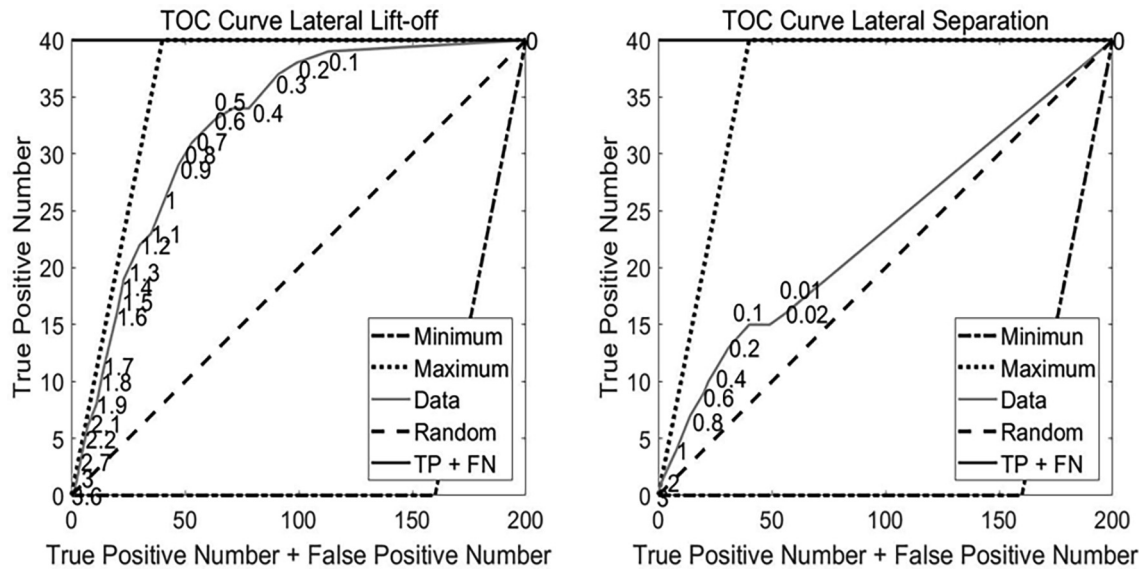


Fig. 4. Total Operating Characteristic Curves (TOCs) for detecting loss of contact in the lateral compartment only for the lift-off method and the separation method. The optimum threshold distance determined using the Youdan index was 0.7 mm for the lift-off method.

its ability to detect loss of contact, the objectives of this study were to assess the ability of each method to detect loss of contact and the second was to determine the optimal threshold distances. The most important findings of this study were that (1) although the lift-off method was classified as a good detector for loss of contact in the lateral compartment only and in the medial compartment only, the lift-off method was a better detector for loss of contact in the lateral compartment only than in the medial compartment only, (2) the lift-off method was not useful for detecting loss of contact with both compartments considered jointly because of the relatively small area under the ROC curve, and (3) the separation method was classified as a poor detector making this method unsuitable for detecting loss of contact in single-plane fluoroscopic studies.

Considering that the lift-off method was classified as a good detector for loss of contact in the lateral compartment only and in the medial compartment only, it is of interest to assess the use-

fulness of this method for each compartment. To make this assessment, the false positive rates should be examined. The false positive rate for detecting loss of contact in the medial compartment only was about double that for detecting loss of contact in the lateral compartment only (Table 3). This increase in the false positive rate for detecting loss of contact in the medial compartment only was reflected by the result that the number of false positives exceeded the number of true positives. In contrast, the number of false positives was less than the number of true positives for the lateral compartment only. Hence to avoid excessive errors in detecting loss of contact in the medial compartment only, the lift-off method should be used for detecting loss of contact in the lateral compartment only but not in the medial compartment only.

Given that the lift-off method is useful primarily for detecting loss of contact in the lateral compartment only but not the medial compartment only, the question arises as to whether the lift-off

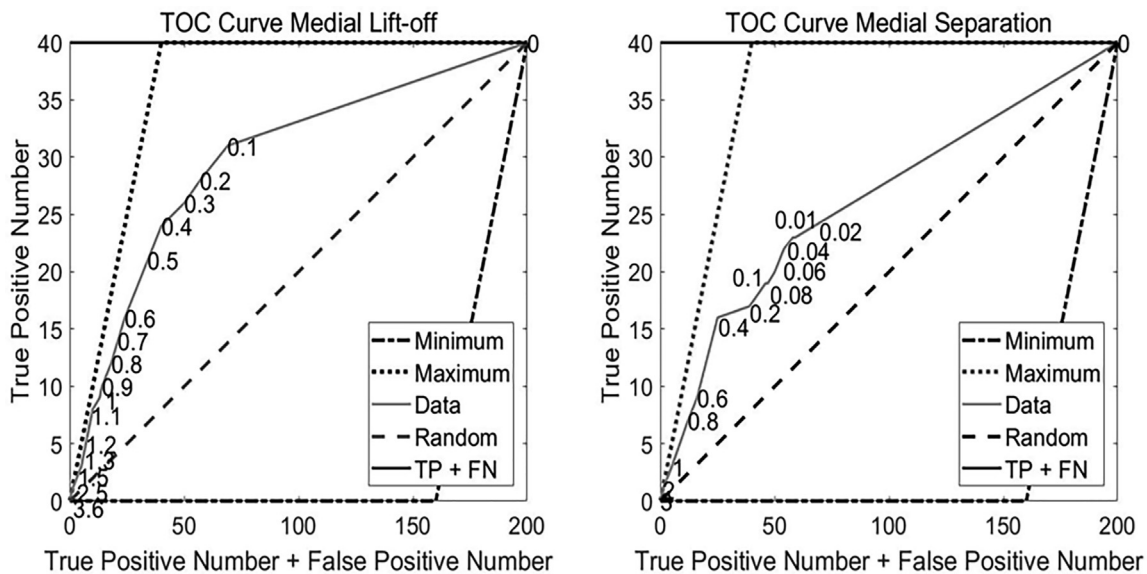


Fig. 5. Total Operating Characteristic Curves (TOCs) for detecting loss of contact in the medial compartment only for the lift-off method and the separation method. The optimum threshold distance determined using the Youdan index is 0.1 mm for the lift-off method.

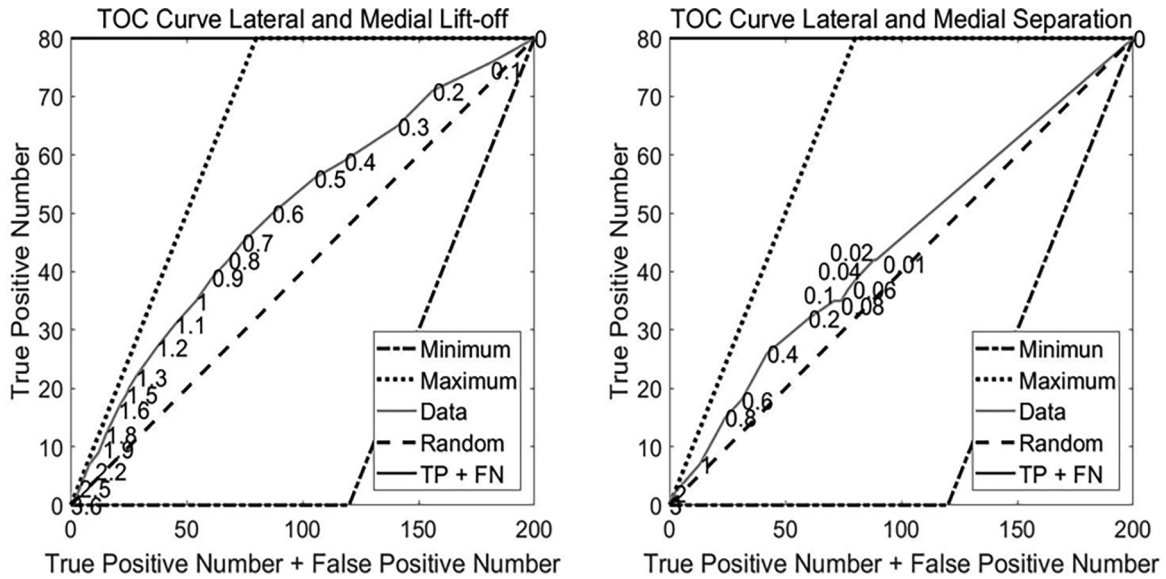


Fig. 6. Total Operating Characteristic Curves (TOCs) for detecting loss of contact in the medial and/or lateral compartments jointly for the lift-off method and the separation method. The areas under the corresponding ROC curves (not shown) are 0.70 and 0.59 for the lift-off and separation methods respectively. Based on these values, neither method was a good detector of loss of contact when both compartments were considered jointly.

method applied in the lateral compartment only is useful in detecting loss of contact in normal daily activities. Following mechanically aligned TKA, the adduction moment in gait is not significantly different from that of the native knee for cruciate-retaining and posterior stabilized component designs (McClelland et al., 2007) and an adduction moment develops in normal subjects regardless of the hip-knee-angle alignment (Andrews et al., 1996). Accordingly, it might be reasonably expected that loss of contact in the lateral compartment would occur more frequently than loss of contact in the medial compartment. This expectation has been confirmed in single-plane fluoroscopic studies of deep knee bend where the lift-off method was used to detect loss of contact (Dennis et al., 2001). The expectation is also confirmed by studies of causes of revision. For example, 3152 TKAs were examined of which 41 were tibial revisions (Berend et al., 2004). Of these, about 50% were due to medial bone subsidence and none were due to lateral bone subsidence indicating considerably higher loading in the medial compartment than the lateral compartment. With the need to detect loss of contact in the lateral compartment only being arguably more important than the need to detect loss of contact in the medial compartment only, the ability of the lift-off method to detect loss of contact in the lateral compartment only renders this method useful for that purpose.

Table 3

Contingency tables for the optimum threshold distances of 0.7 mm and 0.1 mm for the lift-off method detecting loss of contact in the lateral compartment only and in the medial compartment only respectively. Also given are the true positive rate which is the probability of truly detecting loss of contact when it does occur, the false positive rate which is the probability of falsely detecting loss of contact when it does not occur, the precision which is the probability of truly detecting loss of contact when it does occur considering the total occurrences where loss of contact was detected either truly or falsely, and the accuracy which is the probability of a correct detection (i.e. either positive or negative) for this optimum threshold distance.

Lateral compartment only		Medial compartment only	
Number of true positives = 31	Number of false positives = 22	Number of true positives = 31	Number of false positives = 38
Number of false negatives = 9	Number of true negatives = 138	Number of false negatives = 9	Number of true negatives = 122
True positive rate (TPR) = 0.72		True positive rate (TPR) = 0.72	
False positive rate (FPR) = 0.14		False positive rate (FPR) = 0.24	
Precision (PPV) = 0.58		Precision (PPV) = 0.45	
Accuracy (ACC) = 0.84		Accuracy (ACC) = 0.76	

However, it should be recognized that a ‘good’ detection still translates into substantial errors in detecting loss of contact. For the optimal threshold value of 0.7 mm determined in this study, loss of contact in the lateral compartment when it actually did occur would be detected only 72% of the time (Table 3). Furthermore 14% of the time, loss of contact would be falsely detected when it did not occur. Because the number of false positives considerably exceeded the number of false negatives (Table 3), the lift-off method will inflate the detected number of instances where loss of contact occurred.

The errors in detecting loss of contact given in Table 3 should be considered a worst case. When varus and valgus moments were applied, they were increased gradually just to the point that the tibial force sensor read zero. Although the actual gap between the articular surfaces is unknown, the gap would have been minimal because any gap would have caused the tibial force sensor to read zero and because the varus and valgus moments were not increased further once the tibial force sensor registered zero. Since the detection of loss of contact depends on the height difference of the femoral condyles from the tibial baseplate, the less the gap between the articular surfaces in the direction the moment was applied the greater the errors from the 3D model-to-2D image registration process would affect the reliability of the detection.

To explain the finding that loss of contact was detected more reliably in the lateral compartment than the medial compartment, the difference in distance computed between the lateral and medial femoral condyles from the plane of the tibial baseplate for the lift-off method was examined for all applications of varus and valgus moments. From this examination, the average difference in the computed distance from the application of a varus moment causing loss of contact in the lateral compartment was considerably greater than the average difference in the computed distance from the application of a valgus moment. Although varus and valgus moments were increased gradually until the tibial force sensor just registered zero, the actual gap created between the articular surfaces might have been greater in the lateral compartment than the medial compartment because the knee is considerably more lax by about a factor of two under the application of a varus moment than a valgus moment (Roth et al., 2015). The greater the gap, the more reliably loss of contact will be detected. However, because the knee is tighter (i.e. less lax) under the application

of valgus moments than varus moments, it is naturally more difficult to develop a relatively large gap in the medial compartment than in the lateral compartment in which case our results reflect the native physiology of the tibiofemoral joint. However, the native varus-valgus laxity difference could be affected depending on soft tissue release which is often performed in mechanically aligned TKA (Bellemans et al., 2010; Kanamiya et al., 2002) but rarely performed in kinematically aligned TKA.

The finding that the lift-off method was not a useful detector for loss of contact when both compartments were considered jointly can be appreciated based on the results for each compartment only. The large disparity in the optimum threshold distances of 0.7 mm for the lateral compartment only and of 0.1 mm for the medial compartment only necessitated a compromise in the optimum threshold distance for both compartments jointly. Because the Youden index returned an optimal threshold distance of 0.7 mm, which was equal to that of the lateral compartment only (Table 2), clearly applying this distance to detecting loss of contact in the medial compartment only where the optimal threshold distance was 0.1 mm would degrade correctly detecting loss of contact in that compartment. Accordingly, the overall quality of the detection was downgraded from good to fair (Table 2) rendering the lift-off method of little use in detecting loss of contact in both compartments jointly.

The finding that the separation method was a poor detector of loss of contact and hence not useful in single-plane fluoroscopy is not surprising based on findings from previous research. One previous study determined the location of tibial contact using three methods and found that the errors were greatest for the method which computed the contact location based on the minimum separation distance of the femoral condyle from the tibial insert when the curvature was considered (Ross et al., 2017). This previous study is particularly germane to the present study because it used the same specimens with the same implants, the same alignment, and the same tibial force sensor. Although the separation method is unsuitable for use in single-plane fluoroscopic studies, the detection ability might be better in dual-plane fluoroscopic studies where the errors in the relative 3D positions and orientations of the components (Li et al., 2008) are lower than those in single-plane fluoroscopy (Banks and Hodge, 1996; Mahfouz et al., 2003).

The primary limitation of this study is that a single anatomic component design was used which required that the tibial component be internally rotated 7° on average when aligned kinematically relative to the rotation when aligned mechanically. Hence the results reported herein may not apply to different component designs and/or different alignment methods. However, the company which manufactures the Persona component line (i.e. Zimmer Biomet) recently received FDA approval for an instrument set designed specifically to facilitate kinematically aligned TKA. Because this company has the largest market share worldwide of TKA components and because the Persona design is the flagship line, it might reasonably be expected that the number of TKAs using the Persona design aligned kinematically will increase in the coming years. Given this, fluoroscopic studies using this particular combination of component design and alignment method are inevitable in which case the results herein will have direct relevance to assessing loss of contact. In fact, the authors are engaged in such a fluoroscopic study and will report findings in future publications.

5. Conclusion

Although the lift-off method was classified as a good detector in detecting loss of contact in the lateral compartment only and in

detecting loss of contact in the medial compartment only, the false positive error rate was inflated for detecting loss of contact in the medial compartment only. Hence the lift-off method is useful for detecting loss of contact in the lateral compartment only. The separation method at best was classified as fair in detecting loss of contact in either compartment only and should not be used in single-plane fluoroscopic studies.

Acknowledgment

We acknowledge the financial support provided by the National Science Foundation (Award No. CBET-1067527) and Zimmer, Inc., (Award No. CW87468) and the assistance provided by Sipeng Wang in creating the ROC and TOC curves. The authors would like to thank individuals who donate their remains and tissues for the advancement of education and research. The authors have no personal or financial conflict of interest that influenced this work.

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