



## Detecting condylar contact loss using single-plane fluoroscopy: A comparison with *in vivo* force data and *in vitro* bi-plane data

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### ARTICLE INFO

#### Article history:

Accepted 24 February 2014

#### Keywords:

Fluoroscopic analysis  
Condylar lift-off  
Lift-off  
Shape matching  
Pose estimation

### ABSTRACT

Knee contact mechanics play an important role in knee implant failure and wear mechanics. Femoral condylar contact loss in total knee arthroplasty has been reported in some studies and it is considered to potentially induce excessive wear of the polyethylene insert. Measuring *in vivo* forces applied to the tibial plateau with an instrumented prosthesis is a possible approach to assess contact loss *in vivo*, but this approach is not very practical. Alternatively, single-plane fluoroscopy and pose estimation can be used to derive the relative pose of the femoral component with respect to the tibial plateau and estimate the distance from the medial and lateral parts of the femoral component towards the insert. Two measures are reported in the literature: *lift-off* is commonly defined as the difference in distance between the medial and lateral condyles of the femoral component with respect to the tibial plateau; *separation* is determined by the closest distance of each condyle towards the polyethylene insert instead of the tibial plateau. In this validation study, lift-off and separation as measured with single-plane fluoroscopy are compared to *in vivo* contact forces measured with an instrumented knee implant. In a phantom study, lift-off and separation were compared to measurements with a high quality bi-plane measurement. The results of the *in vivo* contact-force experiment demonstrate a large discrepancy between single-plane fluoroscopy and the *in vivo* force data: single-plane fluoroscopy measured up to 5.1 mm of lift-off or separation, whereas the force data never showed actual loss of contact. The phantom study demonstrated that the single-plane setup could introduce an overestimation of  $0.22 \text{ mm} \pm 0.36 \text{ mm}$ . Correcting the out-of-plane position resulted in an underestimation of medial separation by  $-0.20 \text{ mm} \pm 0.29 \text{ mm}$ . In conclusion, there is a discrepancy between the *in vivo* force data and single-plane fluoroscopic measurements. Therefore contact loss may not always be determined reliably by single plane fluoroscopy analysis.

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### 1. Introduction

The study of contact mechanics plays an important role in investigating polyethylene wear and implant failure in total knee arthroplasty. Contact loss between the femoral condyles and the polyethylene inlay may result in excessive loading on the side that retains contact and in high impact forces on the side that loses and regains contact. Consequently, contact loss may be related to excessive wear of the polyethylene insert in the knee implant (Andriacchi, 1994; Nilsson and Kärrholm, 1993; Dennis et al., 2001).

Some researchers have used pressure films during surgery to assess contact profiles (Sharma et al., 2007), but this cannot be

used to assess post-operative contact. Alternatively, a few instrumented knee implants have been used to assess the *in vivo* contact force during dynamic activities (Heinlein et al., 2007; Zhao et al., 2007). However, both methods cannot be applied on a large scale and are not applicable in a general clinical setting.

Single-plane fluoroscopy with 3D pose estimation techniques can be used to determine the relative position and orientation (pose) of the femoral component with respect to the tibial plateau (Dennis et al., 1996; Banks and Hodge, 1996; Komistek et al., 2003; Kaptein et al., 2003). Pose estimation from single-plane fluoroscopic data has an accuracy ranging from 0.09 mm to 0.40 mm for the two in-plane positions and from  $0.35^\circ$  to  $1.3^\circ$  for all three orientations (Banks and Hodge, 1996; Hoff et al., 1996; Mahfouz et al., 2003; Komistek et al., 2003; Kanisawa et al., 2003; Garling et al., 2005). With only a single X-ray focus, the accuracy in the out-of-plane position (medial–lateral), which can be up to 5 mm, is low compared to other directions (Prins et al. 2010).

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With relative poses for the femoral and tibial components, the distance between the femoral condyles and the tibial plateau can be measured and two measures for contact loss have been presented in the literature: lift-off and separation.

For determining lift-off, the distances of the lowest point on each condyle with respect to the tibial plateau is calculated (Fig. 1). Lift-off is then determined as the difference between these two distances. (Stiehl et al., 1999a, 1999b; Dennis et al., 2001; Insall et al., 2002). It is a fairly straightforward measure, easy to calculate, and relies only on the relative orientation of the femoral component with respect to the tibial plateau. It neglects, however, the curved surface of the insert and, to distinguish contact loss from measurement error, a threshold of 0.5–1.0 mm (Stiehl et al., 1999a, 1999b; Dennis et al., 2001) must be applied.

Separation is defined as the closest distance (Fig. 1) between the femoral condyles and the polyethylene insert (Kanekasu et al., 2004). In theory, this is a more accurate measure, because it considers the shape of the insert and femoral condyles. However, the insert is not visible on X-ray fluoroscopy and a model must be used, and this is more sensitive to errors in the pose of the femoral component and the tibia plateau (*i.e.* the tibial component with its insert).

We suspect that the threshold of 0.5–1.0 mm may be too low to accurately distinguish loss of femorotibial contact from measurement error and that the large error in out-of-plane position may introduce additional error, especially when considering the curvature of the insert.

This study aims to assess the feasibility of using lift-off and separation as a surrogate measure for contact loss, when derived from single-plane fluoroscopy. *In vivo* force data from a patient with an instrumented knee prosthesis were collected and the medial and lateral forces on the tibial plateau were compared to lift-off and separation as measured with single-plane fluoroscopic analysis. In order to explore the results from this *in vivo* experiment further, the sensitivity of lift-off and separation to pose estimation errors was studied: in an additional bi-plane phantom experiment single-plane fluoroscopy is compared to bi-plane fluoroscopy evaluating the differences between lift-off and separation with high quality image data.

## 2. Methods

In each frame in a fluoroscopic examination, contact loss is detected by estimating the 3D pose of each component and subsequently calculating lift-off and separation.

### 2.1. Pose estimation

The pose of the prosthetic components can be estimated using various methods which have different accuracies, especially in the out-of-plane position (Prins et al.,

2010). As this affects the accuracy of separation measurements, we applied two pose estimation methods for fluoroscopy:

- **Standard:** a model-based pose estimation method minimizing the difference of the virtual projected contour of the implant model with the detected contour of the implant in the fluoroscopic image (Kaptein, 2003; Prins et al., 2010).
- **Corrected:** the same method as the *Standard* method was applied, but to reduce errors in the relative out-of-plane position, the femoral component was translated along the out-of-plane axis and centered above the tibial component (Banks and Hodge, 1996; Prins et al., 2010).

With both single-plane methods, the poses of the tibial component and the femoral component were estimated for each image frame. The poses of the insert were fixed with respect to the tibial component. For the validation of the above methods in the phantom experiment, gold standard bi-plane data were obtained by model-based pose estimation (Model-based RSA 3.21, Medis specials, Leiden, the Netherlands (Kaptein, 2003)), providing a very accurate pose measurement without a large error in the out-of-plane position. To ensure the highest possible accuracy, a reverse engineered (laser scan) model was used for the phantom experiment. The model was reduced to ~5000 triangles to reduce computation times. A CAD model was used in the *in vivo* experiment and reduced to ~5000 triangles as well (Kaptein et al., 2003).

### 2.2. Contact loss detection

To measure contact loss, two different measures are available with different nomenclature. In this paper we considered lift-off as defined by Stiehl et al. and separation as expressed in Kanekasu et al. (Stiehl et al. 1999a, 1999b; Kanekasu et al., 2004).

**Lift-off:** for lift-off, the points on the medial and lateral condyles closest to the plane through the tibial plateau were determined (Fig. 1). This results in a distance  $h_{med}$  and  $h_{lat}$  for each condyle. Their difference is defined as

$$\begin{aligned} \text{medial lift-off} &= h_{med} - h_{lat}, & \text{if } h_{med} > h_{lat} \\ &0, & \text{if } h_{med} \leq h_{lat} \\ \text{lateral lift-off} &= h_{lat} - h_{med}, & \text{if } h_{lat} > h_{med} \\ &0, & \text{if } h_{lat} \leq h_{med} \end{aligned}$$

Note that this implies that medial and lateral lift-off are mutually exclusive and that it is influenced only by the relative orientation of the femoral component with respect to the tibial component and not on the insert.

Similar to Stiehl et al., we considered lift-off above 1.0 mm to represent actual contact loss, and values below 1.0 mm as measurement errors (Stiehl et al. 1999a, 1999b).

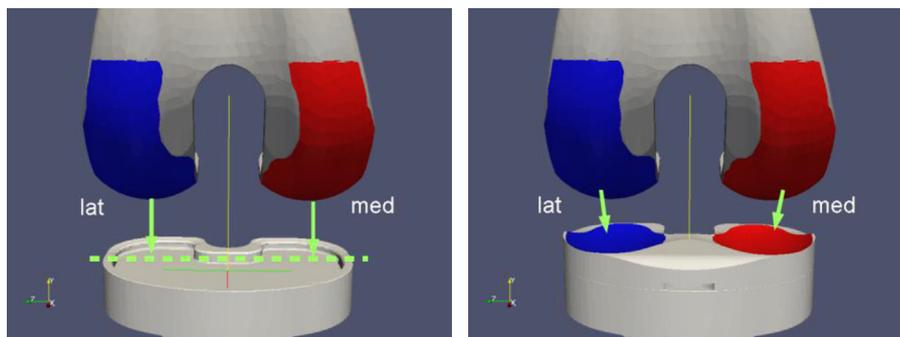
**Separation:** separation takes the insert geometry into account with the insert position fixed to the tibia plateau. The distance is calculated for the medial and lateral part as follows (Fig. 1):

1. For each point  $p$  on the insert, the closest distance  $d(p)$  towards a face of the corresponding part on the femoral component was calculated.
2. For each point  $q$  on the femoral component, the closest distance  $d(q)$  towards the corresponding part on the insert was calculated.

Separation is determined as the minimal distance:

$$\text{Separation} = \min(\min(d(p)), \min(d(q)))$$

Note that separation is not mutually exclusive, since both medial and lateral separation can occur simultaneously. We also used a threshold of 1.0 mm to distinguish actual contact loss from measurement errors.



**Fig. 1.** Lift-off (left figure) is calculated as the difference in distance between the lowest points on the medial and lateral condyles of the femoral component and the plane through the tibia-plateau. Separation (right figure) is calculated as the closest distance between a point on a condyle and a point on the corresponding part of the polyethylene insert.

### 3. *In vivo* experiment

The *in vivo* data used in this study were collected in a previous study by Zhao et al. (2007) and consist of *in vivo* force data from a patient with a custom instrumented knee implant and *in vivo* fluoroscopic data (Zhao et al., 2007). The instrumented knee implant has four uniaxial force sensors at known locations (D'Lima et al., 2005). We calculated the medial force as the sum of the forces applied to the two medial sensors, and lateral force as sum of the forces on the lateral sensors. In order to determine the predominant location of the contact forces, the relative medial force was calculated as the percentage of the total force that was medial. We compared the medial and lateral contact force data to lift-off and separation from fluoroscopic data.

Simultaneously with collecting the force data, lateral fluoroscopic images were acquired (Precise Optics P1808 C-arm, 23 cm image intensifier, continuous beam of ~75 kVp and 1 mA using an electronically shuttered video camera with 1–2 ms exposures). Images were recorded to digital video tape, transferred to a computer and corrected for geometric distortion using bilinear interpolation (Banks and Hodge, 1996).

During the force and fluoroscopic data acquisition, the patient performed a variety of tasks. Four fast and four slow gait cycles on a treadmill were collected. The full dataset with force data was recorded. The fluoroscopic data were recorded at 30 frames per second (fps) and between 15 and 25 fluoroscopic frames surrounding heelstrike were manually selected based on flexion angle for each gait cycle. Similarly, 10–15 frames were selected around toe-off in each gait-cycle.

Three dynamic step-up activities were collected with approximately 30 frames for each step-up (10 fps). Stair stepping was performed with the subject's foot on a 20 cm riser with the toes pointed directly forward. Images were recorded as the subject stepped up directly into full weightbearing extension on the replaced knee, without swinging through the opposite leg, and then immediately reversed direction and lowered themselves to rest upon the contralateral leg. The subject was offered hand support for balance but could not lift with their arms.

Two static activities, kneel and lunge, were collected, with approximately 20 frames each (10 fps): Kneeling was performed with the implanted knee placed on a padded chair at approximately 90° flexion, while the extended contralateral limb supported most of the body weight. The subject was asked to bend from 90° flexion to maximum comfortable flexion while lateral fluoroscopic images were recorded. Lunging was performed with the subject's foot placed on a 20-cm riser. The subject was asked to slowly bend to maximum comfortable knee flexion, in an exaggerated shoe-tying posture, while images were recorded. Their motions were not constrained and the subject was allowed to lift their heel if that permitted a greater range of flexion. An investigator offered to hold the subject's hands or forearms as a safety measure to prevent a fall. Unfortunately, it was not possible to synchronize in time the data collection of the contact force from the instrumented knee and the collection with single-plane fluoroscopy. This makes a fine-grained comparison difficult between fluoroscopy and force. Instead, we report over complete trials the mean and minimum medial and lateral force. If there has been loss of contact, this should show as a low minimum force and as high lift-off and separation in the fluoroscopic data.

The accuracy of the force sensors has been reported to be in the range of 0.3–3.2% with load experiments at 178–712 N (Kaufman et al., 1996). A worst-case error of 3.2% at the highest tested load of 712 N, would imply a worst-case error bound of 23 N. At the start of this experiment we decided on a safe threshold of 50 N to detect actual contact and to prevent detecting false-positive contact loss.

In summary, a low medial force (below 50 N) suggests medial contact loss and similarly for the lateral side, less than 50 N indicates lateral contact loss. This is compared to the maximum medial or lateral, lift-off and separation from single-plane fluoroscopy: high lift-off or separation suggesting contact loss. An equal medial and lateral force from the instrumented knee implies that no contact loss has occurred and thus no large lift-off or separation values should be measured from the fluoroscopic data.

### 4. Phantom experiments

We performed two experiments with highly accurate data from a bi-plane setup, to assess the effect of errors in the out-of-plane position. The first experiment compares bi-plane lift-off to bi-plane separation and measures their difference, independent of the error in the out-of-plane position. The second experiment evaluates the effect of out-of-plane position error from single-plane fluoroscopy on lift-off and separation.

The experimental setup consisted of a bi-plane flat panel fluoroscopic system (Super Digital Fluoroscopy (SDF) system, Toshiba Infinix: Toshiba, Zoetermeer, The Netherlands). The image sensors were positioned perpendicular to each other and the X-ray focus positions relative to the image plane were calculated using a calibration box (Koning et al., 2007; Kaptein et al., 2011).

The phantom experiment was performed with a medium size cruciate-substituting prosthesis fixed in sawbones with a 5 mm thick tibial insert (PFC-Sigma CS, DePuy Orthopaedics, Warsaw, IN). The tibia-sawbone was fixed with clamps, to prevent the phantom from leaving the field of view.

Two motions of the femur were captured with 15 fps: in the first motion, the femur moved from full extension to 90° of flexion, then to approximately 20° abduction, back to 20° adduction and finally back to full extension. In the second motion, the femur started at 30° of flexion, moved to full extension and some internal/external rotation (roughly 20°) was performed. In this experiment there was actual contact loss at the medial condyle through parts of both runs, while we tried to keep the lateral condyle in contact with the insert. 282 frames were collected and used for both experiments, 146 frames in the first and 136 in the second run

#### 5. Phantom experiment 1: lift-off vs. separation

The first experiment was performed comparing *bi-plane lift-off* directly to *bi-plane separation*. Paired student's *t*-test was used to test for significant differences. We assumed that the accuracy of pose estimation is sufficiently high with bi-plane fluoroscopy that the differences between the measurements can be attributed to the differences between the methods.

#### 6. Phantom experiment 2: effects of measurement accuracy

The second experiment investigated the effect of single-plane measurement accuracy. The *bi-plane separation* is derived from femoral and tibial poses from high quality bi-plane data and it takes the insert-shape correctly into account when measuring contact loss. This makes *bi-plane separation* our "*Bi-plane separation reference*" measurement. Similar to the *in vivo* experiment, we calculated *lift-off* and *separation* each with single plane pose estimation methods: *Standard* and *Corrected*. The differences with respect to *Bi-plane separation reference* were calculated and a Student's *t*-test was used to test for significant differences.

## 7. Results

### 7.1. In vivo experiment

The mean, standard deviation and minimum force, medially and laterally are presented in Table 1. In addition the medial portion is presented as a percentage of the total force in the same table. Table 2 presents the lift-off and separations measured using pose estimation on the same *in vivo* datasets.

**Heelstrike and Toe-off:** the heelstrike and toe-off force data showed minimum medial contact forces of 39 N and 11 N respectively and minimum lateral forces of 87 N and 76 N. The medial values were below 50 N, suggesting that there could have been a few instances with actual loss of contact.

Fluoroscopic heelstrike data shows maximal lift-off on the medial side of 5.11 mm with corresponding separation of 2.24 mm and 2.6 mm for the *Standard* and *Corrected* methods. Laterally, similar lift-off and separation values were found, ranging from 4.04 mm to 5.06 mm for the three methods. The fluoroscopic toe-off data shows potential lift-off on the lateral side with 2.20 mm lift-off and 2.28 mm for the *Standard* method and 0.91 mm for the *Corrected* method.

Thus, both force data and lift-off/separation data indicate that loss of contact is possible in both the heelstrike and toe-off data.

**Step-up:** the force data is distributed 54–46% medial–lateral over the step-up, with a small standard deviation of 7%. Even at the minimum (236 N or 206 N) there is still sufficient contact force to rule out loss of contact. The fluoroscopic data for the step-up motion presents lift-off values larger than the threshold of 1.0 mm (medial: 1.2 mm, lateral 1.25 mm), but separation stays well below 1.0 mm for the *Standard* and *Corrected* methods. We attribute these separation values to measurement noise.

**Table 1**

Mean, standard deviation and minima for medial and lateral force and for the relative medial force for five datasets. Values in bold are below the predefined threshold of 50 N.

	Medial (N)			Lateral (N)			Relative medial (%)		
	Mean	Std	Min	Mean	Std	Min	Mean	Std	Min
Heelstrike	452	323	<b>39<sup>a</sup></b>	388	174	87	48	13	12
Toe-off	429	329	<b>11<sup>b</sup></b>	376	173	76	46	14	3
Step-up	813	258	234	705	239	206	54	7	28
Kneel	116	17	86	88	11	68	57	3	47
Lunge	607	109	474	433	65	356	58	1	56

<sup>a</sup> Medial contact loss in heelstrike, consistent with the lift-off/separation data in Table 2.

<sup>b</sup> Medial contact loss in toe-off, disagreeing with the force data in Table 2.

**Table 2**

Maximal lift-off, separation (*Standard*) and separation (*Corrected*) for the medial and lateral condyle for all five tasks: heelstrike, toe-off step-up, lunge and kneel. Note from the results of phantom experiment 1 that lift-off is not influenced by the error in the out-of-plane position. Values in bold are above the lift-off threshold of 1.0 mm.

	Medial (mm)			Lateral (mm)		
	Lift-off	Separation ( <i>Standard</i> )	Separation ( <i>Corrected</i> )	Lift-off	Separation ( <i>Standard</i> )	Separation ( <i>Corrected</i> )
Heelstrike <sup>a</sup>	<b>5.11<sup>a</sup></b>	<b>2.24<sup>a</sup></b>	<b>2.60<sup>a</sup></b>	<b>5.06</b>	<b>4.53</b>	<b>4.04</b>
Toe-off	0.59	0.88	0.03	<b>2.20</b>	<b>2.28</b>	0.91
Step-up <sup>b</sup>	<b>1.20<sup>b</sup></b>	0.53	0.03	<b>1.25<sup>b</sup></b>	0.66	0.03
Kneel	0.46	0.05	0.05	0.49	0.19	0.04
Lunge <sup>c</sup>	0.00	0.68	0.03	<b>2.56<sup>c</sup></b>	<b>2.97<sup>c</sup></b>	<b>2.38<sup>c</sup></b>

<sup>a</sup> Medial lift-off and separation consistent with the force data in Table 2.

<sup>b</sup> Medial and lateral lift-off, disagreeing with separation and with the forces in Table 2.

<sup>c</sup> Lateral lift-off and separation, disagreeing with the force data in Table 2.

Therefore, the force data and the separation measurement show that no loss of contact has occurred during the step-up, whereas the lift-off data showed loss of contact.

**Kneel:** the kneeling force data demonstrates a consistent relative contact force on the medial side with a mean of 57%, with a standard deviation of 3%. The fluoroscopic data for the kneel task shows no hint of contact loss with lift-off and separations remaining below 0.5 mm.

In the kneel data, both force data and lift-off/separation data indicate that no loss-of contact has occurred.

**Lunge:** the lunge task showed the most interesting discrepancy between force and fluoroscopic data (Fig. 2). Forces on the medial side accounted for 58% of the total force with negligible standard deviation, indicating that no contact loss had occurred during the lunge motion. Fluoroscopic data showed large lateral lift-off values of 2.56 mm, with similar separation values (*Standard*: 2.56 mm, *Corrected*: 2.38 mm).

The force data showed that no loss of contact had occurred during the lunge motion, while both the lift-off and the separation measures were well above the threshold for measuring contact loss, indicating lateral condylar contact loss.

### 7.2. Phantom experiment 1

Fig. 3 presents medial and lateral lift-off and separation. Clearly visible is the similarity in the shape of the profiles, but also the large amount of variation in some regions. Medially, the mean difference between lift-off and separation was 0.20 mm ( $p < 0.001$ ) with a standard deviation of 0.35 mm and maximum value of 0.82 mm. Laterally, the difference was  $-0.24$  mm ( $p < 0.001$ ) with a standard deviation of 0.30 mm and maximum of 1.04 mm. With lift-off thresholds in the literature ranging from 0.5–1.5 mm, the maximum difference of 1.04 mm and 0.82 mm indicates that there is a discrepancy between lift-off and separation.

### 7.3. Phantom experiment 2

The two pose estimation methods showed the same differences between lift-off and separation (Table 3):  $0.22 \text{ mm} \pm 0.36 \text{ mm}$  medially and  $-0.25 \text{ mm} \pm 0.29 \text{ mm}$  laterally.

On the other hand, the separation measure demonstrated a little more variation in its differences with respect to the *Bi-plane separation reference* method: medially, the *Standard* method overestimated the amount of separation by 0.22 mm ( $p < 0.001$ ), while the *Corrected* method underestimated it by  $-0.20$  mm ( $p < 0.001$ ). The standard deviations were relatively small for single-plane fluoroscopy: 0.35 mm and 0.29 mm for the *Standard* and *Corrected* methods, respectively.

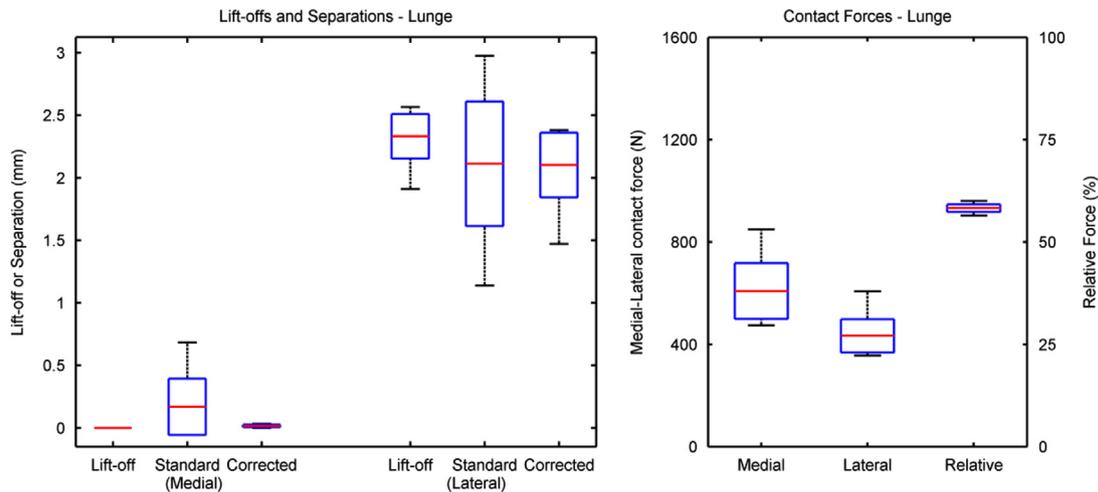


Fig. 2. Boxplots for the fluoroscopic lift-off and separation (both with the Standard method and the Corrected method) on the left side and the contact force on the right side for the Lunge dataset.

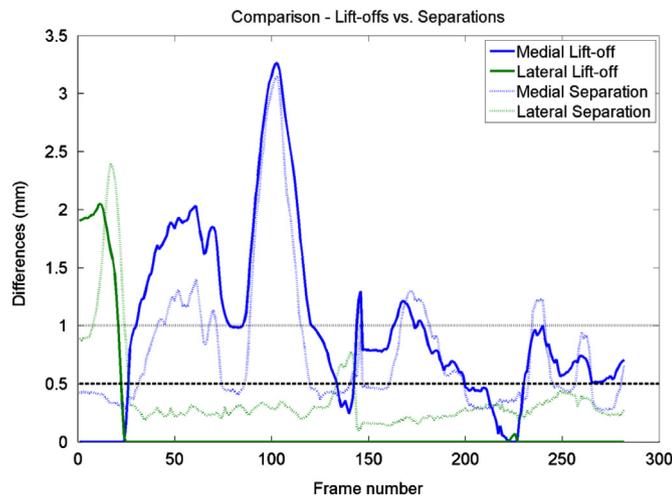


Fig. 3. Lift-off and Separation assessed using the estimated prosthesis poses from a stereo phantom measurement. The solid lines indicate the lift-offs over all frames, whereas the dotted lines indicate the corresponding separation. Note how the medial lift-off shows a similar shape as the separation, but with large differences in many frames. The black dashed lines indicate the thresholds of 0.5 and 1.0 mm often used when distinguishing lift-off from contact loss.

Table 3  
Differences with respect to the *Bi-plane separation reference method* for lift-off and separation as measured on single-plane data with the *Standard* and *Corrected* methods.

	Medial (mm)		Lateral (mm)	
	Mean	Std	Mean	Std
<b>Lift-off</b>				
Standard method	0.22	0.36	-0.25	0.29
Corrected method	0.22	0.36	-0.25	0.29
<b>Separation</b>				
Standard method	-0.22	0.35	0.21	0.49
Corrected method	-0.20	0.29	-0.31	0.29

Laterally, similar results were obtained: with the *Standard* method showing a difference in separation of 0.21 mm with respect to the *Bi-plane separation reference method* with a standard deviation of 0.49 mm. The *Corrected* method showed a difference of -0.31 mm and a standard deviation of 0.29 mm.

### 8. Discussion

Condylar lift-off as measured with single-plane fluoroscopic analysis has been reported in the literature as a surrogate measure for contact loss (Stiehl et al., 1999a, 1999b; Dennis et al., 2001; Insall et al., 2002). Separation was introduced later as a more accurate measure for actual contact loss (Kanekasu et al., 2004). In this study, we compared lift-off and separation as measured from single plane fluoroscopy with a gold standard measurement using *in-vivo* data, as well as phantom data.

The *in vivo* fluoroscopic and force data present a mixed outcome. For kneeling and gait activities, the force data and lift-off or separation data are consistent. In kneeling, both the force data and the single-plane fluoroscopy suggest that no loss of contact occurred. In gait, the measured forces were below the 50 N threshold, suggesting contact loss may have been possible. However, with 12 N and 3 N measured, it is still feasible that there was contact with low loads and our data do not allow us to discriminating this from loss of contact.

Lift-off during gait has been reported before in the literature (Stiehl et al., 1999a, 1999b; Dennis et al., 2003) with lift-off values of several millimeters, comparable to these results. However, our results demonstrate a possible mismatch of fluoroscopic lift-off values with actual force measurements. Actual loss of contact during gait has not been verified with measurements other than fluoroscopy, but it has been predicted in a single emg-driven model study (Kumar et al., 2013)

However, the stair and lunge data were inconsistent. The stair forces show no loss of contact, consistent with the separation measures, but lift-off was demonstrated. The forces measured during the lunge activity indicate no loss of contact, while the single-plane fluoroscopic measures indicate lateral condylar lift-off (2.5 mm) and separation (2.5 mm). There are two possible explanations for the discrepancies in the lunge data: first, single-plane fluoroscopy is not a sufficiently accurate basis for measuring condylar contact loss. Second, the lunge images show the posterior femoral cortex could be in contact with the tibial insert, creating a posterior impingement that transmits load while the lateral femoral condyle is not touching the tibial articular surface. The data available do not allow further discrimination of these two possibilities.

The results from phantom experiment 1 demonstrate that lift-off is not equivalent to separation, because with separation (as the closest distance between insert and condyle) the insert geometry is taken into account. With an accurate bi-plane measurement,

separation can be considered an accurate measure of “contact loss”. With lift-off, the relation with the insert is not used at all and this can perhaps explain the measured values: the difference between lift-off and separation can be as high as 1 mm (see the first 20 frames for the lateral side in Fig. 3). Medially, there was a difference of approximately 0.5 mm throughout large parts of the dataset.

The results from phantom experiment 2 demonstrate a possible effect of error in the out-of-plane position on separation, but not on lift-off. The definition of lift-off indicates that it is only influenced by the relative orientation of the femoral component and hence there is no effect of the out-of-plane position. Separation, however, requires an accurate femoral and insert position, demonstrated by the differences in separation between the two pose estimation methods: the *Standard* method can overestimate the amount of separation (by 0.22 mm), while the *Corrected* method can underestimate it (by –0.20 mm). These over- and underestimations show that the separation measure is not necessarily a good alternative for lift-off, when determined with single-plane fluoroscopy.

In our phantom experiment we had a bi-plane fluoroscopic setup, with digital image detectors, yielding high quality images (high resolution, frame rate and contrast). This explains the relatively low standard deviations for lift-off and separation when compared to the *in vivo* data.

In the *in vivo* data, the image quality was considerably lower, resulting in a lower accuracy for pose estimation. We assume that this accounts for some of the discrepancies: lower image quality causes larger measurement errors in the femoral and tibial orientations, in turn yielding higher lift-off and separation values. Nonetheless, lower image quality is generally expected in clinical data and we are certain that similar discrepancies between *in vivo* force and lift-off or separation are possible in other clinical data. Especially when measuring lift-off occurrences using a threshold, it is likely that due to larger measurement errors some frames will demonstrate lift-off above the threshold. Another limitation was that good frame-by-frame synchronization was not available in the *in vivo* data. With synchronization, it would have been possible to investigate the exact relation between implant pose and measurement error in lift-off. Instead, we compared overall minimum and mean *in vivo* force to overall minimum and mean lift-off.

At a minimum, the discrepancy between high condylar forces and observed lift-off in the step activity suggest lift-off should not be used as an indication of condylar loss of contact. The lunge data present a similar discrepancy suggesting neither lift-off nor separation from single-plane fluoroscopy are reliable, but the possibility of posterior impingement weakens that conclusion. Another limitation of the study was that there was no quantitative measure, which could have convincingly said that there was loss of contact. Consequently a threshold of 50 N chosen to detect contact safely.

Furthermore, only a single prosthesis type was used which makes it difficult to extrapolate the results to other prosthesis types. Unfortunately, only a few instrumented knee designs exist, making it difficult to retrieve contact force data for other implants.

We conclude that lift-off and separation as measured with single-plane fluoroscopic analysis can lead to an overestimation of the magnitude and incidence of actual contact loss between the femoral component and tibial insert. If used, the separation measurement is shown to be a better indicator of contact loss, but should be reported with appropriate statistical confidence levels corresponding to the imaging and activity details of each study.

We do not dispute the possibility of contact loss after TKA and its possible effect on the wear of the polyethylene insert. We do, however, recommend taking great care when drawing conclusions

on contact loss based on single plane fluoroscopic analysis and a lift-off threshold of 1.0 mm. Higher lift-off thresholds may be more reliable, with the risk of not detecting condylar lift-off while it actually occurs. To further explore this, an *in vivo* bi-plane fluoroscopic experiment is needed, with synchronized measurements of internal contact forces from instrumented knee prostheses.

### Conflict of interest statement

All the authors certify that they have no financial; professional or other personal interest of any nature or kind that could be considered as influencing the position presented in; or the review of; this manuscript.

### Acknowledgments

We sincerely thank Darryl D'Lima, Cliff Colwell and BJ Fregly for sharing their eKnee data with us.

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