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Does lateral lift-off occur in static and dynamic activity in a medially spherical total knee arthroplasty? A pulsed-fluoroscopic investigation

**S. Key,
G. Scott,
J.G. Stammers,
M. A. R. Freeman†,
V. Pinskerova,
R. E. Field,
J. Skinner,
S. A. Banks**

South West London
Elective Orthopaedic
Centre, Epsom, United
Kingdom

■ S. Key, MBBChir, FRCS (Orth),
Arthroplasty Fellow,
■ G. Scott, MBBS, FRCS, Professor
of Orthopaedics,
■ J.G. Stammers, MBBS, FRCS
(Orth), Arthroplasty Fellow, Royal
London Hospital, London, UK.
■ M. A. R. Freeman, MD(Cantab),
MD(Hons Gothenberg), FRCS,†
M.A.R Freeman has deceased since
the submission of this manuscript.

■ V. Pinskerova, PhD, MD,
Associate Professor, First
Orthopaedic Clinic, Faculty of
Medicine, Charles University,
Prague, Czech Republic.

■ R. E. Field, PhD, FRCS, FRCS
(Orth), Professor of Orthopaedic
Surgery, St George's, University
of London, London, UK; Director
of Research, South West London
Elective Orthopaedic Centre,
Epsom, UK.

■ J. Skinner, MBBS, FRCS, FRCS
(Orth), Consultant Orthopaedic
Surgeon, Royal National Orthopaedic
Hospital, Stanmore, UK.

■ S. A. Banks, PhD, Professor
of Mechanical and Aerospace
Engineering, University of Florida,
Gainesville, Florida, USA.

Correspondence should be sent to
S. Key; email:
steve.key325@gmail.com

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Objectives

The medially spherical GMK Sphere (Medacta International AG, Castel San Pietro, Switzerland) total knee arthroplasty (TKA) was previously shown to accommodate lateral rollback while pivoting around a stable medial compartment, aiming to replicate native knee kinematics in which some coronal laxity, especially laterally, is also present. We assess coronal plane kinematics of the GMK Sphere and explore the occurrence and pattern of articular separation during static and dynamic activities.

Methods

Using pulsed fluoroscopy and image matching, the coronal kinematics and articular surface separation of 16 well-functioning TKAs were studied during weight-bearing and non-weight-bearing, static, and dynamic activities. The closest distances between the modelled articular surfaces were examined with respect to knee position, and proportions of joint poses exhibiting separation were computed.

Results

Overall, 1717 joint poses were analyzed. At a 1.0 mm detection threshold, 37 instances of surface separation were observed in the lateral compartment and four medially ($p < 0.001$). Separation was activity-dependent, both laterally and medially ($p < 0.001$), occurring more commonly during static deep flexion in the lateral compartment, and during static rotation in the medial compartment. Lateral separation occurred more frequently than medial during kneeling (7/14 lateral vs 1/14 medial; $p = 0.031$) and stepping (20/1022 lateral vs 0/1022 medial; $p < 0.001$). Separation varied significantly between individuals during dynamic activities.

Conclusion

No consistent association between closest distances of the articular surfaces and knee position was found during any activity. Lift-off was infrequent and depended on the activity performed and the individual knee. Lateral separation was consistent with the design rationale. Medial lift-off was rare and mostly in non-weight-bearing activities.

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Article focus

- We explore whether the *in vivo* coronal kinematics of the medially stabilized GMK Sphere (Medacta International AG, Castel San Pietro, Switzerland) total knee prosthesis are consistent with its design philosophy and mirror the native knee.
- Closest distances between the articular surfaces were measured during a range of weight-bearing and non-weight-bearing, static, and dynamic activities.

- The incidence of separation events was compared with existing literature studying other implants.

Key messages

- Separation was infrequent but dependent on the activity and individual knee.
- Overall, more separation events were seen laterally than medially, consistent with the design rationale and implantation technique, and mirroring the greater lateral laxity of the native knee.

- Lateral separation was more common during static deep flexion, while medial occurred mostly during non-weight-bearing static rotation, but no consistent relationship was found between implant position and lift-off.

Strengths and limitations

- This is the first study to explore *in vivo* coronal kinematics of a medially stabilized knee prosthesis during a range of functional activities.
- The conclusions are limited to well-functioning knees and we make no comment about the relationship of kinematics to outcome.
- The accuracy of image-matching techniques limits the detection of subtle separation.

Introduction

The sagittal stability and kinematics of the GMK Sphere total knee arthroplasty (TKA) have been described in 15 patients (16 knees).¹ Using an established pulsed fluoroscopic analysis,² it was determined that this prosthesis enabled posterior rollback of the femoral component in the lateral compartment of the TKA, approximating half the rollback found in non-arthritic knees.¹ The prosthesis is designed to accommodate lateral rollback of the femoral component without imposing any guided pathway, while the medial condyle does not roll back (Fig. 1). This closely mirrors numerous studies into normal knee movement.³⁻⁸

Normal non-arthritic human knees have some coronal laxity in flexion, particularly laterally.⁹ The greater part of the medial and lateral femoral condyles approximate to a sphere.¹⁰ Mapping the proximal tibial articular surface has revealed the medial surface to be concave, matching the convexity of the medial femoral condyle, while the lateral surface is flat.^{10,11} Accordingly, one can understand how the coronal movements shown previously⁹ might occur by revolving around the centre of the essentially spherical medial femoral condyle when the collateral ligaments are relaxed within limits conferred by the cruciate ligaments.

The primary aim of this study was to explore *in vivo* whether the GMK Sphere's design and implantation technique produce coronal laxity laterally while remaining stable medially, mirroring the coronal kinematics of the normal native knee and supplementing the previously reported sagittal and axial kinematics.¹ We investigated how the coronal kinematics vary during functional static and dynamic activities, the relationship to implant position, and consider whether unacceptably frequent separation events occur that may lead to edge loading and accelerated polyethylene wear.

Patients and Methods

Patients. This cohort has been described in full previously.¹ Ethical approval was provided and informed

written consent obtained. Briefly, 16 knees in 15 patients (six males (one bilateral) and nine females) were studied. Their mean age was 66 years (53 to 76) and mean body mass index (BMI) was 30 kg/m² (20 to 35). Surgery was performed by three of the authors (GS, JGS, or REF), with the intention of leaving the lateral flexion gap larger than the medial so that the lateral joint line could be opened when a varus force was applied. The mean postoperative interval was 10.25 months (6 to 19) and all patients were sufficiently rehabilitated to perform the activities safely. On the day of the study, their mean postoperative Knee Society Scores¹² were 86 points (80 to 90) for the knee and 89 points (80 to 100) for function, and the mean postoperative Oxford Knee Scores^{13,14} were 40 points (34 to 48). The mean range of movement from active maximum extension to maximum supine flexion (non-weight-bearing) was 108° (SD 8).

Radiological methods. The kinematic investigation has been described in full previously.¹ Briefly, the fluoroscopic unit (Precision RXi Digital System; GE Healthcare, Chalfont-St-Giles, United Kingdom) was positioned to obtain a sagittal projection of the knee. Images for dynamic activities were processed at 15 frames per second. Single images were used for static activities. An established method of image matching was used to reconstruct the 3D position of the components.^{2,15} This shape-matching process has standard errors (SE) of approximately 0.5° to 1.0° for rotations, and 0.5 mm to 1.0 mm for translations in the sagittal plane.¹⁶

We reprocessed the data and optimized the image matching for coronal plane analysis. All image processing was performed by a single trained observer for consistency (SK) (intraclass correlation coefficient (ICC), two-way mixed single measures, absolute agreement model = 0.84; 95% confidence interval (CI), 0.79 to 0.88; n = 176; six-month interval). The method for determining surface separation has been described previously.¹⁷ Tibial and femoral articular surfaces were each discretized into a cloud of points with a maximum separation of 1 mm, and divided into medial and lateral articular surfaces. These point clouds were positioned in the joint pose for each frame of data and the shortest distance computed between each point on the femoral surface and all points on the tibial polyethylene insert. The closest distance between the articular surfaces was then measured for each compartment. Despite being a previously accepted technique for detecting lift-off,^{17,18} thresholds for detecting true articular surface separation are controversial. Translational and rotational measurement errors will affect apparent surface separation. The SE using this technique was shown previously to be 1.2 mm.¹⁷ A threshold of 2.4 mm has been used previously to detect surface separation,^{17,18} while others have used thresholds of 0.5 mm,¹⁹⁻²¹ 0.75 mm,²²⁻²⁵ and 1.0 mm.^{26,27} The selected detection threshold will affect the likelihood of either over- or underestimating the true incidence of surface

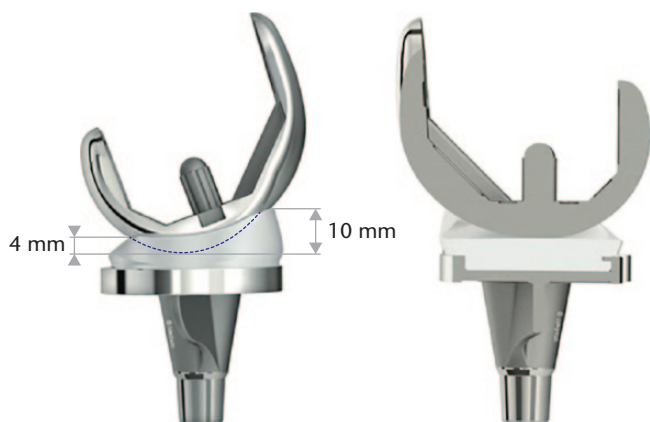


Fig. 1

The GMK Sphere prosthesis incorporates a spherical medial tibiofemoral articulation (left) to provide anteroposterior stability over the 0° to 100° flexion arc, and a sagittally flat and coronally partially conforming lateral tibial surface to permit longitudinal rotation (right).

separation. To obtain results comparable with the existing literature, we analyzed the data at each of these thresholds. For simplicity, however, only results using a 1.0 mm threshold have been presented here, representing a balance between the more specific 2.4 mm threshold and more sensitive lower thresholds. The CI for single sample measurements being within ± 1.0 mm of the actual distance is 60% given the SE of 1.2 mm. However, since results in the upper tail of the distribution will still represent true separation even if outside the CI, the probability of a result above the 1.0 mm threshold representing true separation is 0.8. The reader is directed to the supplementary material for full results at other thresholds. The proportion of images capturing articular surface separation using the defined thresholds was computed for each activity.

The static postures investigated were maximum flexion kneeling and lunging,^{16,28-31} and seated internal and external rotation. The dynamic activities were stepping up and down on a 22 cm step without swing-through of the contralateral limb,^{8,28,29} a smooth weight-bearing pivoting motion from a position of femoral internal rotation about a fixed foot placement with the toes pointed outward to a position of femoral external rotation, performed in both flexion and extension, and finally the subject was asked to lock their weight-bearing knee into hyperextension.

Statistical analysis. The primarily sagittal plane activities (kneeling, lunging, hyperextension, and stepping) were analyzed with respect to implant flexion. The rotational activities (static internal and external rotation and pivoting in flexion and extension) were analyzed with respect to both implant flexion and rotation, presented as internal rotation of the tibial component with respect to the femoral component. Linear correlation (Pearson's correlation coefficient, r) was used to explore relationships between measured closest distances and implant

position. A *post hoc* sensitivity analysis was performed to determine the minimum detectable correlation coefficient given a power of 0.8 and significance level of 0.05 in view of the different sample sizes for each activity. McNemar's tests (exact test where required due to small frequencies) were used to compare the paired proportions of captured instances of separation between the medial and lateral compartments at the defined thresholds. The Freeman-Halton extension of Fisher's exact test was used to explore differences in proportions of captured separation between activities and between subjects for each dynamic activity where sufficient numbers of observations permitted analysis. Two-tailed tests were used in all cases and a p-value of < 0.05 was considered significant. Statistical tests were performed using SPSS v23.0 (IBM SPSS Statistics for Windows; IBM, Armonk, New York).

Results

A total of 1717 joint poses were analyzed across all activities. Overall, 41 instances of surface separation were captured using the 1.0 mm threshold, 37 of which occurred in the lateral compartment and four medially ($p < 0.001$; McNemar's exact test). The proportion of observed separations was activity-dependent, both laterally and medially ($p < 0.001$ both laterally and medially; Fisher-Freeman-Halton exact tests; see Fig. 2 and supplementary material for results at all thresholds analyzed).

Static activities: deep flexion. We obtained kneeling poses of 14 knees in 13 patients, and lunging poses of 15 knees in 15 patients. The data are summarized in Table I, and Figures 3a and 3b. No correlation was confirmed between measured closest distance and flexion for either activity, in either the medial or lateral compartments (Table II). The number of captured instances of surface separation was significantly greater for the lateral compartment than for the medial during kneeling but not lunging (Table III).

Static activities: rotation. We obtained external rotation poses of 11 knees in ten patients, and internal rotation poses of 13 knees in 12 patients (Table IV; Figs 3c and 3d). There was no correlation between either rotation or flexion and measured closest distance in either compartment for either activity (Table II). There was no difference in surface separation between the medial and lateral compartments in either activity (Table III).

Dynamic activities. Hyperextension was observed in ten knees (nine patients) with a total of 182 poses (median 18 poses/knee; 7 to 28). The results are summarized in Table I and Figure 3e. The relationship between flexion angle and measured closest distance varied between individual knees (supplementary material). Overall, there was no definite relationship between flexion angle and medial closest distance and, although statistically significant, only minimal correlation laterally (Table II). There

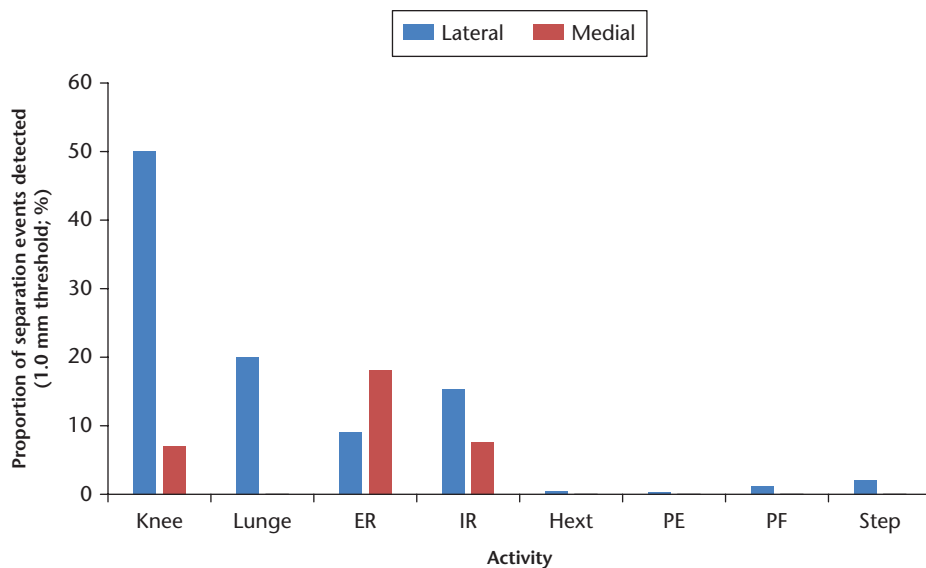


Fig. 2

Proportion (%) of separation events detected during each activity for lateral and medial compartments. ER, external rotation seated; IR, internal rotation seated; Hext, hyperextension; PE, pivoting extended; PF, pivoting flexed.

Table I. Summary of sagittal plane activities

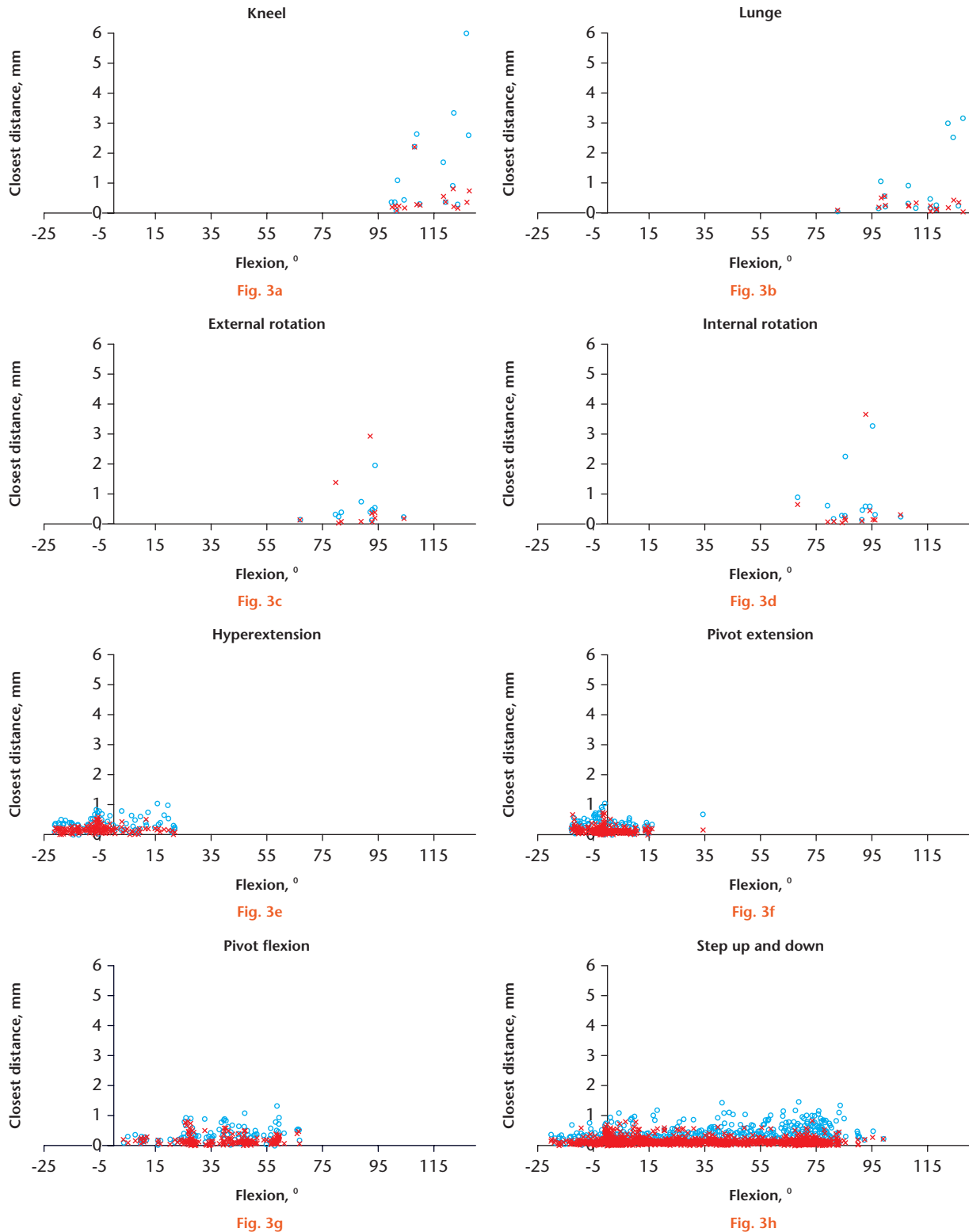
Activity	Measurement	Flexion, °	Lateral closest distance, mm	Medial closest distance, mm
Kneeling	Median	110.0	0.9	0.3
	Minimum	99.8	0.1	0.1
	Maximum	127.5	6.0	2.2
Lunging	Median	113.4	0.3	0.3
	Minimum	82.8	0.1	0.1
	Maximum	127.9	3.2	0.6
Hyperextension	Median	-6.9	0.3	0.2
	Minimum	-21.3	0.0	0.0
	Maximum	21.8	1.1	0.6
Step up and down	Median	28.1	0.3	0.1
	Minimum	-20.2	0.0	0.0
	Maximum	99.2	1.5	0.8

was no difference in surface separation events between the lateral and medial compartments at the 1.0 mm threshold (Table III). Numbers were sufficient to analyze variation between individual knees only at the 0.5 mm threshold and were found to be significant at that threshold (supplementary material).

Pivoting in extension was observed in 14 knees (14 patients) with a total of 281 poses (median 20.5 poses/knee; 4 to 37). The data are summarized in Table IV and Figure 3f. The relationship between implant position and measured closest distance was again highly variable between individual knees (supplementary material). Overall, we were unable to demonstrate any clear relationship between either flexion or internal rotation and measured closest distances in either compartment (Table II). There was no difference between medial and lateral separation at the 1.0 mm threshold (Table III). Again, individual variation between knees could only be analyzed at the 0.5 mm threshold but was found to be significant at that level (supplementary material).

Pivoting in flexion was observed in ten knees (nine patients) producing a total of 179 poses (median 15.5 poses/knee; 9 to 27). The data are summarized in Table IV and Figure 3g. Overall, there were only weak associations between flexion and lateral closest distance, and between medial closest distance and both flexion and rotation; there was no overall relationship between lateral closest distance and rotation (Table II). Again, however, this was highly variable between individual knees (supplementary material). A difference between medial and lateral separation was not demonstrated at the 1.0 mm threshold (Table III). As before, numbers were insufficient to allow analysis of variation between individual knees at the 1.0 mm threshold, although this was significant at lower thresholds (supplementary material).

Stepping up and down was observed in all 16 knees producing 1022 poses (median 61 poses/knee, 23 to 141). The data are summarized in Table I and Figure 3h. There was only a weak overall correlation between lateral closest distance and flexion and, although statistically



Scatter plots of closest distance with respect to implant flexion for each activity. o, lateral; x, medial.

significant, only minimal negative correlation medially (Table II). In common with other dynamic activities, this was variable between individual knees (supplementary material). The proportion of captured instances of lateral

separation was higher than those of medial surface separation (Table III). It was possible to show significant variation in the incidence of lateral separation events between individual knees ($p < 0.001$; Fisher–Freeman–Halton

Table II. Correlation (Pearson's) between measured closest distances and implant position

Activity	Lateral closest distance/flexion angle, r; p-value	Medial closest distance/flexion angle, r; p-value	Lateral closest distance/rotation, r; p-value	Medial closest distance/rotation, r; p-value	Minimum detectable correlation, r
Kneeling	0.523; 0.055	0.079; 0.789	N/A	N/A	0.67
Lunging	0.456; 0.087	-0.210; 0.455	N/A	N/A	0.65
External rotation	0.271; 0.420	0.065; 0.850	-0.292; 0.383	-0.097; 0.778	0.74
Internal rotation	0.027; 0.931	0.095; 0.758	0.104; 0.736	0.026; 0.934	0.69
Hyperextension	0.188; 0.011*	-0.003; 0.964	N/A	N/A	0.21
Pivot extension	0.007; 0.910	-0.059; 0.324	-0.048; 0.424	0.028; 0.639	0.17
Pivot flexion	0.231; 0.002*	-0.276; < 0.001*	-0.067; 0.370	-0.191; 0.011*	0.021
Step up and down	0.262; < 0.001*	-0.105; 0.001*	N/A	N/A	0.09

*Statistically significant
N/A, not applicable

Table III. Comparison of medial and lateral separation events detected for each activity

Activity	Total number of poses	Number of instances of lateral surface separation (%)	Number of instances of medial surface separation (%)	p-value*
Kneeling	14	7 (50.0)	1 (7.1)	0.031†
Lunging	15	3 (20.0)	0 (0)	0.250
External rotation	11	1 (9.1)	2 (18.2)	1.000
Internal rotation	13	2 (15.4)	1 (7.7)	1.000
Hyperextension	182	1 (0.5)	0 (0)	1.000
Pivot extension	281	1 (0.4)	0 (0)	1.000
Pivot flexion	179	2 (1.1)	0 (0)	0.500
Step up and down	1022	20 (2.0)	0 (0)	< 0.001†

*McNemar's test

†Statistically significant

Table IV. Summary of rotational activities

Activity	Measurement	Flexion, °	Tibial internal rotation, °	Lateral closest distance, mm	Medial closest distance, mm
External rotation	Median	92.0	-2.1	0.4	0.2
	Minimum	66.9	-19.0	0.2	0.1
	Maximum	104.2	18.0	2.0	3.0
Internal rotation	Median	91.4	11.5	0.5	0.2
	Minimum	68.5	2.4	0.2	0.1
	Maximum	105.5	18.4	3.3	3.7
Pivot extension	Median	-1.9	-2.3	0.3	0.1
	Minimum	-13.1	-18.0	0.0	0.0
	Maximum	34.1	15.5	1.1	0.8
Pivot flexion	Median	39.3	2.7	0.3	0.2
	Minimum	3.4	-6.7	0.0	0.0
	Maximum	66.7	16.1	1.4	0.8

exact test). No medial separation events were observed at the 1.0 mm threshold. However, analysis of variation between medial separation events of individual knees was significant at the lower thresholds (supplementary material).

Discussion

We have measured the closest distance between articular surfaces for each arthroplasty using an image-matching technique for a variety of dynamic and static conditions. We have not demonstrated any clear relationship between that and the position of the knee during any activity in either the medial or lateral compartment. While our data for dynamic activities support a trend for

increasing lateral and decreasing medial closest distances with higher flexion angles, we acknowledge that our static postures were capable of detecting only strong correlations with confidence due to the limited numbers of poses for these activities. Furthermore, we found the measured closest distances to be specific to each knee and activity-dependent, making it difficult to deduce any consistent pattern. However, we are constrained by the accuracy of the technique; it is known that measurement errors of 0.5 mm or 0.5° occur in single-plane fluoroscopic image matching, and such errors can dramatically affect apparent contact conditions inferred from kinematic data.³² Consequently, it is misleading to equate raw measured closest distances with actual separation, or

to make direct statistical comparisons about or between medially and laterally detected closest distances, as measurement accuracy in the order of microns or milliradians is required to draw such conclusions confidently.³²

Does the design of the GMK Sphere and the method of implantation lead to lateral lift-off? This depends on how lift-off is defined. It is an all-or-none event, so the quantification of separation distance is academic. The outcome of interest is whether actual separation occurs or not, and its detection is limited by the accuracy of the technique used. One would expect that if separation occurs, it would be more frequent on the lateral side in this implant, given the unconstrained lateral compartment and implantation with an intentionally lax lateral compartment to allow rollback laterally and tibial rotation during flexion.⁵ We observed this when applying lower thresholds, supporting the assertion that the implant functions as intended by the design. However, at higher thresholds this finding is muted, probably due to high specificity but low sensitivity at detecting lift-off. Therefore, larger numbers of images are required to demonstrate separation, which may partly explain why this was witnessed more in the step activity with greater numbers of images to analyze. Signal-to-noise concerns are an inevitable part of any measurement system. Although this technique may not allow the detection of subtle separation, we can say with 80% confidence that measured distances greater than 1.0 mm do represent true separation and, therefore, that we provide an accurate picture of the pattern of separation consistent with greater lateral laxity mirroring the native knee, and that is largely unaffected by the detection threshold, even if we cannot provide an exact rate. We also found that separation is dependent on individual knees and the investigated activity. Lateral separation appears to be more common during deep flexion activities, which again is consistent with the design replicating native knee function.⁹ Medial separation seems more common during the static rotational postures, where it occurred with similar frequency to lateral separation. It is not possible to explain the difference between individual knees based on the current study but surgical factors may be partly responsible.^{19,22,26,33,34}

Kanekasu et al¹⁷ reported surface separation occurring in the Japanese 'seiza' position in the lateral compartment of seven, and medial compartment of two, out of 18 posteriorly stabilized prosthetic knees using the same image-matching and surface-mapping techniques that we have used, with a 2.4 mm detection threshold. This mirrors our results for kneeling and lunging. They identified that separation was more common at greater than 130° of flexion but this was not achieved in any of our patients. Moro-oka et al¹⁸ also used the same technique to study posteriorly stabilized knees and reported at the same four detection thresholds as we have. The incidence of separation during kneeling and lunging in that study

was lower than ours at all thresholds and acknowledged to be low by the authors, compared with other reports. This was attributed to the gap-balancing technique used to achieve symmetrical flexion and extension gaps. This contrasts with the surgical technique for the GMK Sphere in which the lateral compartment is left intentionally lax.


A number of studies have used image-matching techniques with coronal plane reformatting and measurement of separation as the difference in measured distance between the tibial baseplate and femoral implant on the medial and lateral sides. The 0.5 mm, 0.75 mm, and 1.0 mm detection thresholds for lift-off have been used based on assessments of the accuracy of image matching and the inclusion of variable 'safety factors'.^{22,23,25} The incidence of lift-off in these studies has varied from 40% to 100% using a 0.5 mm threshold,¹⁹⁻²¹ 28% to 90% using a 0.75 mm threshold,²²⁻²⁵ and 19% to 100% with a 1.0 mm threshold.^{26,27} The reported differences have been attributed to surgical techniques, the implants investigated, and activities observed. It has been postulated that lift-off may contribute to edge loading and increased polyethylene wear.^{19,23} The incidence of separation we observed using the same thresholds, even during the highest-risk activities, has been at most comparable with, and in many cases considerably lower than, previous reports. However, we advise caution when interpreting studies measuring separation against the tibial baseplate rather than the articulating surface of the polyethylene insert, as femoral translation on a contoured articular surface will lead to apparent separation when the femoral component in fact remains in contact with the radiolucent polyethylene. Furthermore, lateral images provide the poorest measurement sensitivity for quantifying coronal rotation and mediolateral translation, while anteroposterior views provide the best measurement sensitivity for these parameters.³⁵ Therefore, image direction should also be considered when determining a detection threshold for separation from single-plane radiological images. The low frequency of observed separation in this study is consistent with investigations using instrumented implants to measure contact forces directly during various functional activities.³⁴

Does it matter if separation occurs in the GMK Sphere implant? If lateral lift-off occurs, it is probably well-tolerated by the congruent spherical medial compartment, affording area contact and avoiding edge loading^{36,37} without imposing any restriction to rotation.^{1,38} Medial lift-off is theoretically more problematic because of overloading the flat lateral polyethylene,³⁷⁻⁴⁰ but we have witnessed medial separation only rarely, and mostly in the non-weight-bearing static rotational poses. Medial pivot total knee prostheses have been found to generate fewer polyethylene wear particles than posteriorly stabilized or mobile-bearing implants,⁴¹ and registry data show promising revision rates compared with other designs.^{42,43}

We acknowledge that there are limitations in our study. First, there is uncertainty concerning the accuracy of image matching. Applying a conservative threshold for the detection of separation requires larger numbers of observations in order to be confident that real differences are not overlooked. Second, there is confounding variability in the number of poses for each patient during each activity, such that the overall result may be influenced by the proportion of poses per activity by each patient, and the proportion of total poses by each activity. However, the knees with the higher proportions of observed separation events were not seen to be outliers in terms of the number of poses for the individual knees. Third, the radiological capture rate limits the speed at which dynamic activities can be performed to maintain image quality. Fourth, patient selection had required a good clinical outcome, and the observations may differ in patients with a suboptimal clinical result. Since there are many reasons unrelated to implant design that may produce a poorly functioning prosthetic knee, restricting the study to well-functioning knees allows the intended design and implantation outcome to be assessed in relation to well-functioning native knees. This study is not intended to infer any conclusion about how the kinematics may be related to outcome. Despite these limitations, we are unaware of any previous report in the literature looking at separation of the surfaces of medially stabilized implants in a variety of dynamic and static activities.

In conclusion, by re-analyzing our image data we have confirmed that some patients do experience separation of the lateral bearing surfaces when they have been treated with a GMK Sphere TKA. With the detection threshold set at a previously published limit of 1.0 mm, only a few knees exhibited this phenomenon. This was observed mostly during the static deep flexion postures. At lower thresholds, this was detected more often, but shows considerable variation between patients and their activities, while at a 2.4 mm threshold separation was rare. Separation of the medial bearing was hardly found, irrespective of the detection limit. Some separation of the lateral compartment might be considered helpful in facilitating lateral rollback.

Supplementary Material

 Tables and figures showing full analysis of separation events at 0.5 mm, 0.75 mm, 1.0 mm, and 2.4 mm detection thresholds. The relationship between measured closest distances and implant position for individual knees during dynamic activities, as well as separation events, are also illustrated.

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Author contributions

- S. Key: Analyzed the data, Drafted the manuscript.
- G. Scott: Recruited the patients, Drafted the manuscript.
- J. G. Stammers: Supervised the fluoroscopy, Drafted the manuscript.
- M. A. R. Freeman: Conceptualized the study, Analyzed the data.
- V. Pinskerova: Conceptualized the study, Analyzed the data.
- R. E. Field: Designed the study, Led the application for ethical permission, Recruited the patients, Drafted the manuscript, Supervised the project.
- J. Skinner: Recruited the patients, Drafted the manuscript.
- S. A. Banks: Designed the study, Conducted the investigation, Acquired and analyzed the data, Drafted the manuscript, Supervised the project.

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Conflict of interest statement

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