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High Prevalence of Radiographic Outliers and Revisions with Unicompartmental Knee Arthroplasty

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Background: Alignment outcomes and their impact on implant survival following unicompartmental knee arthroplasty (UKA) are unclear. The purpose of this study was to assess the implant survival and radiographic outcomes after UKA as well as the impact of component alignment and overhang on implant survival.

Methods: We performed a retrospective analysis of 253 primary fixed-bearing and mobile-bearing medial UKAs from a single academic center. All UKAs were performed by 2 high-volume fellowship-trained arthroplasty surgeons. UKAs comprised <10% of their knee arthroplasty practices, with an average of 14.2 medial UKAs per surgeon per year. Implant survival was assessed. Femoral coronal (FCA), femoral sagittal (FSA), tibial coronal (TCA), and tibial sagittal (TSA) angles as well as implant overhang were radiographically measured. Outliers were defined for FCA (>±10° deviation from neutral), FSA (>15° of flexion), TCA (>±5° deviation from neutral), and TSA (>±5° deviation from 7°). "Far outliers" were an additional >±2° of deviation. Outliers for overhang were identified as >3 mm for anterior overhang, >2 mm for posterior overhang, and >2 mm for medial overhang.

Results: Among patients with a failed UKA, revision was performed at an average of 3.7 years (range, 0.03 to 8.7 years). The cumulative revision rate was 14.2%. Kaplan-Meier survival analysis demonstrated 5 and 10-year survival rates of 88.0% (95% confidence interval [CI] = 82.0% to 91.0%) and 70.0% (95% CI = 56.0% to 80.0%), respectively. Only 19.0% (48) of the UKAs met target alignment for all 4 alignment measures, and only 72.7% (184) met all 3 targets for overhang. Only 11.9% (30) fell within all alignment and overhang targets. The risk of implant failure was significantly impacted by outliers for FCA (failure rate = 15.4%, p = 0.036), FSA (16.2%, p = 0.028), TCA (17.9%, p = 0.020), and TSA (15.2%, p = 0.034) compared with implants with no alignment or overhang errors (0%); this was also true for far outliers (p < 0.05). Other risk factors for failure were posterior overhang (failure rate = 25.0%, p = 0.006) and medial overhang (38.2%, p < 0.001); anterior overhang was not a significant risk factor (10.0%, p = 0.090).

Conclusions: The proportions of UKA revisions and alignment outliers were greater than expected, even among high-volume arthroplasty surgeons performing an average of 14.2 UKAs per year (just below the high-volume UKA threshold of 15). Alignment and overhang outliers were significant risk factors for implant failure.

Level of Evidence: Therapeutic Level IV. See Instructions for Authors for a complete description of levels of evidence.

Unicompartmental knee arthroplasty (UKA) is an alternative to total knee arthroplasty (TKA) in patients with unicompartmental osteoarthritis. UKA offers many potential advantages in terms of pain relief, satisfaction, recovery time, functional outcomes, and many others[1-12]. As a result of these advantages, UKA utilization has outpaced TKA growth 3-fold from 1998 to 2005[13-15]. Not surprisingly, this growth rate is expected to continue in the coming decade, with a predicted 6-fold increase in utilization by 2030[16].

Despite its advantages, however, the long-term survivorship of UKA remains concerningly low. While studies of the Oxford UKA (Biomet) by the designing centers[17,18] and others[19]

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TABLE I Patient Demographics

	Fixed-Bearing	Mobile-Bearing	Overall
No.	162	91	253
Mean age *(yr)*	63.2	62.2	62.9
Mean BMI *(kg/m²)*	29.6	31.6	30.3
% male	41.4	48.4	41.4

have demonstrated 10-year UKA survival rates as high as 94% to 97%, the 10-year survival rates have ranged from 82%[20-22] to 92%[23] in the vast majority of other published series. Additionally, 10-year rates of 81% to 88% have been found in large registry databases[2,24,25]. Similarly, Medicare and MarketScan[26] data on overall UKA failure rates in the U.S. population have demonstrated 7-year survival rates of 81% and 74%, respectively, significantly lower than the survival rates for TKA (96% and 92%, respectively)[26].

Although patient-centered risk factors such as younger age and higher body mass index (BMI) may increase the risk of UKA failure[27-29], technical surgical errors have consistently been identified as a significant risk factor for early failure[30-35]. Optimal component alignment and overhang can be challenging in UKA, which is often performed through a smaller incision with less exposure than are used in TKA[36]. While multiple reports have described a relationship between implant malalignment and both poor functional outcomes and poor implant survival[30,36-41], there is still debate about whether the pervasive issue of implant malalignment is the true cause of the poor survival of UKA[33,42] or whether it is implant-specific.

In addition to component alignment, component overhang is an important factor under the control of surgeons performing UKA[43]. Tibial components should be sized and implanted in a fashion that minimizes soft-tissue irritation but maximizes cortical bone support. Medial tibial overhang of ≥3 mm has been demonstrated to be a significant risk factor for decreased Oxford Knee Scores (OKS) and increased pain[43]. Posterolateral overhang has led to similar decreases in postoperative outcomes measures[44]. In cadaveric studies assessing the impact of tibial overhang on medial collateral ligament (MCL) load after TKA, overhang of >2 mm was found to nearly double MCL load[45], a potential mechanism for postoperative pain. For these reasons, UKA manufacturers have published recommendations for optimal implant alignment and positioning[46].

The primary aim of this study was to assess the overall clinical and radiographic outcomes of UKA at a high-volume academic center. The secondary aims were to assess the impact of component malalignment and overhang on implant survival.

Materials and Methods

Study Design

This study was a single-center analysis of primary medial fixed-bearing UKAs (n = 162) and mobile-bearing UKAs (n = 91) performed by 2 high-volume, fellowship-trained, arthroplasty surgeons at a single academic center. Each surgeon performed only fixed-bearing or mobile-bearing UKAs. UKA accounted for <10% of their overall knee arthroplasty practice, with the surgeons performing an average of 14.2 UKAs per year. Although these surgeons were high-volume arthroplasty surgeons, they were not considered high-volume UKA surgeons according to Baker et al.[47], who demonstrated that surgeons performing >15 UKAs per year have a decreased rate of failure. Institutional review board approval was obtained prior to the initiation of this study.

Male and female patients who underwent medial UKA at our institution between January 2008 and December 2017 when they were ≥18 years of age were included. Patient demographics are shown in Table I. UKA was performed in all patients using a standard approach without the use of custom cutting guides, patient-specific instrumentation, or fluoroscopy. Exclusion criteria for UKA included moderate to severe varus deformity, arthritis in the patellofemoral compartments, posterior tibial translation, and instability.

TABLE II Reasons for Revision

Reason for Revision	Definition	% (No.) of All Revisions (N = 36)
Revised outside hospital and thus could not be determined for this study		17 (6)
Infection		3 (1)
Fracture		6 (2)
Pain	Persistent unacceptable level of pain that did not respond to nonoperative measures in the absence of clear clinical or radiographically evident sources of pain	8 (3)
Progressive osteoarthritis	Radiographic evidence of substantial osteoarthritis progression in lateral or patellofemoral compartment and persistent pain correlating with degeneration of affected compartment	14 (5)
Mechanical failure	Pain with radiographic evidence of aseptic implant loosening or collapse	22 (8)
Malposition/instability	Instability or persistent pain with radiographic evidence of implant malposition	31 (11)

Clinical and Radiographic Outcomes

Implant survival and revision data were obtained from a retrospective review of clinical records and institutional databases. Radiographic and clinical records for each of the revisions were independently reviewed by the 3 senior surgeons involved in this study to determine a reason for the revision, as detailed in Table II. Femoral coronal and sagittal angles (FCA and FSA) and tibial coronal and sagittal angles (TCA and TSA) were measured on radiographs for all fixed-bearing and mobile-bearing UKAs. Digital measurements were performed by 2 authors on anteroposterior and lateral short-leg radiographs, which have been validated in comparisons with long-leg radiographs[48-54]. The methods used for the assessment of implant position and alignment are similar to methods used in previous studies[42], as detailed in Figure 1. The degrees of medial, anterior, and posterior overhang were also measured. Interobserver reliability was assessed on a subset of 25 radiographs.

Implant alignment and overhang were described on a "per measurement" and a "per knee" basis. Per measurement assessments described the proportion of individual measurements (such as FCA) that represented outliers or far outliers. Per knee assessments described the proportion of knees that had any number of alignment or overhang outliers and far outliers.

Defining Postoperative Radiographic Outliers

Optimal alignment and overhang ranges were obtained from the Oxford manual[46]. FCA, FSA, TCA, and TSA outliers were defined as >±10° of deviation from the neutral axis, >15° of flexion, >±5° of deviation from the neutral axis, and >±5° of deviation from 7°, respectively. Far outliers were defined as measurements that fell an additional >±2° outside of these ranges[48]. Medial, posterior, and anterior overhang outliers were defined as >2 mm, >2 mm, and >3 mm of overhang, respectively.

Statistical Analysis

Statistical analysis was performed using SAS version 9.4 (SAS Institute). Kaplan-Meier survival analysis was used to

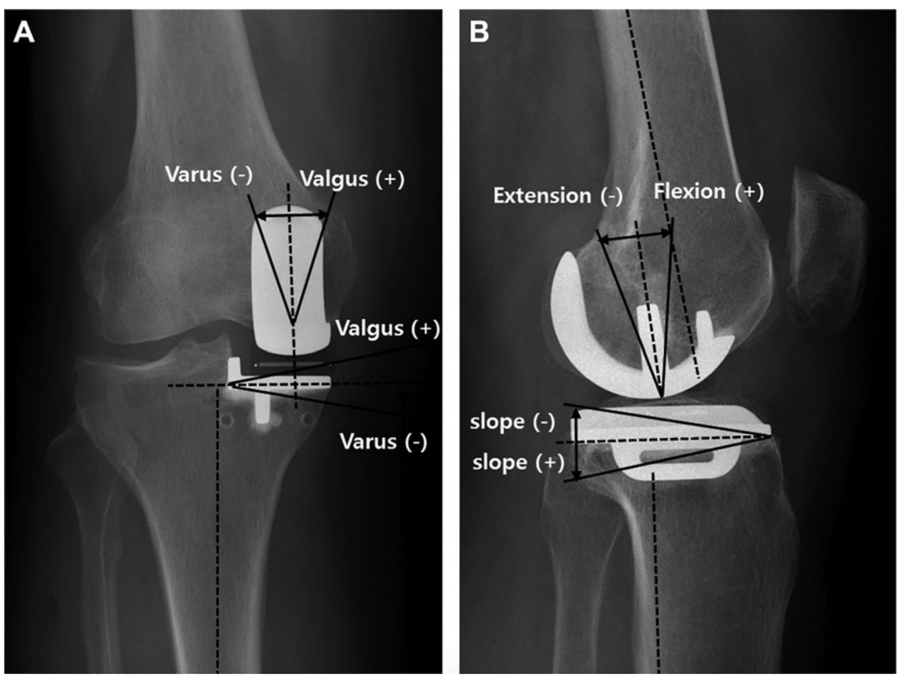

Fig. 1

Radiographic measurements performed in this study included FCA, FSA, TCA, and TSA as well as medial, posterior, and anterior overhang. FCA was measured on an anteroposterior radiograph (**Fig. 1-A**) as the medial angle between the anatomic axis of the femur and a line parallel to the femoral UKA component. FSA was measured on a lateral radiograph (**Fig. 1-B**) as the angle between the posterior cortex of the femur and the femoral component peg. TCA was measured on an anteroposterior radiograph as the medial angle between the anatomic axis of the tibia and a line parallel to the tibial plate. TSA was measured on a lateral radiograph as the posterior angle between the anatomic axis of the tibia and the tibial plate. Measurements were performed in the same manner for fixed and mobile-bearing UKAs, with the exception that 15° was added to the measurements of FSA to account for differences in implant design. Medial displacement was measured as the distance between the medial-most aspect of the tibial component and the medial-most aspect of the tibia on an anteroposterior radiograph. Anterior displacement was measured as the distance between the anterior-most aspect of the tibial component and the anterior-most aspect of the tibia on a lateral radiograph. Posterior displacement was measured as the distance between the posterior-most aspect of the tibial component and the posterior-most aspect of the tibia on a lateral radiograph. (Reproduced, with permission, from: Koh IJ, Kim JH, Jang SW, Kim MS, Kim C, In Y. Are the Oxford(®) medial unicompartmental knee arthroplasty new instruments reducing the bearing dislocation risk while improving components relationships? A case control study. Orthop Traumatol Surg Res. 2016 Apr;102[2]:183-7. Copyright © 2016 Elsevier Masson SAS. All rights reserved.)

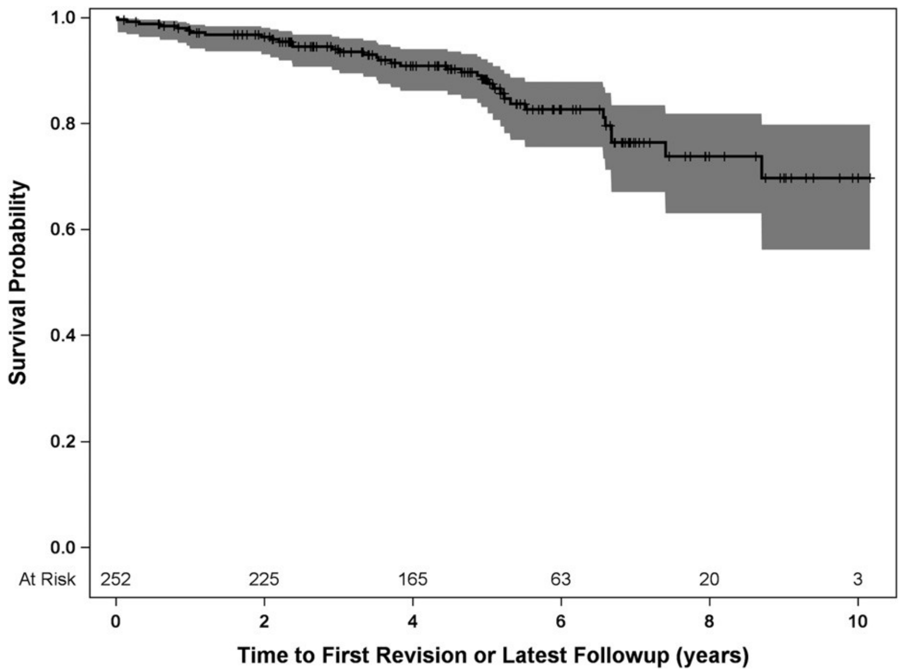

Fig. 2
Kaplan-Meier survival curve for UKA. The shading indicates the 95% CI.

determine 5 and 10-year survival rates. Fisher exact tests were used to compare categorical variables, whereas t tests were used to assess continuous variables. Sample sizes used for our subgroup analyses of failure risk were small, precluding the use of a covariate analysis of risk factors for revision. Therefore, the influence of age, sex, and BMI as potential confounders for implant malalignment was independently assessed using Fisher exact and t tests to detect interactions between these demographics and implant malalignment. The threshold for significance was $p < 0.05$.

Results

Revisions and Complications

Follow-up occurred at an average of 4.9 years (range, 0.03 to 10.2 years). We identified 36 revisions, which were performed at an average of 3.7 years (range, 0.03 to 8.7 years) postoperatively, yielding a cumulative failure rate of 14.2%. The survival rate was 88.0% (95% confidence interval [CI] = 82.0% to 91.0%) at 5 years and 70.0% (95% CI = 56.0% to 80.0%) at 10 years (Fig. 2). In total, 17% (6) of the revisions were performed at an outside institution and we lacked sufficient data to determine the reason for revision. The most common modes of failure leading to the remaining 30 revisions were implant malalignment/instability (31%), mechanical failure (22%), osteoarthritis progression (14%), and unexplained pain (8%) (Table II).

Radiographic Outcomes

No differences between the fixed-bearing and mobile-bearing groups were found in terms of cumulative failure rates (12.3% compared with 17.6%, p = 0.254) or rates of overall outliers (12.7% compared with 10.2%, p = 0.556), far outliers (14.0% compared with 13.2%, p = 0.850), or combined close and far outliers (21.0% compared with 19.0%, p = 0.700). There were no also significant differences between the groups in terms of age, BMI, or sex. Therefore, the 2 implant types were combined in our analysis.

When assessed on a per measurement basis, the combined proportion of FCA, FSA, TSA, and TCA measurements that represented implant outliers and far outliers was 13.7% and 17.0%, respectively (Table III). The combined proportion of anterior, posterior, and medial overhang measurements that represented outliers was 10.8% (Table IV). When assessed on a per knee basis, 55.7% (141), 54.2% (137), and 81.0% (205) of the knees had at least 1 outlier or far outlier measurement in the femoral component, in the tibial component, and overall, respectively (Table V). In addition, 22.9% (58) of the knees

TABLE III Implant Alignment on Per Measurement Basis

	% of Measurements			
	Aligned	Outlier	Far Outlier	Any Outlier
Femoral measurements				
FCA	87.4	5.1	7.5	12.6
FSA	49.8	14.6	35.6	50.2
Both	68.6	9.9	21.5	31.4
Tibial measurements				
TCA	58.5	22.1	19.4	41.5
TSA	81.4	13.0	5.5	18.6
Both	70.0	17.6	12.5	30.0
All measurements	69.3	13.7	17.0	30.7

TABLE IV Overhang on Per Measurement and Per Knee Bases

	%
Measurements*	
Anterior overhang	4.7
Posterior overhang	13.4
Medial overhang	14.2
Overall	10.8
Knees†	
0 overhang outliers	72.7
1 overhang outlier	22.9
2 overhang outliers	3.6
Any	27.3

*The values represent the percentages of the anterior, posterior, and medial overhang measurements that were outliers. †The values represent the percentage of the knees that had overhang outlier(s).

had 1 overhang outlier and 3.6% (9) had 2 overhang outliers (Table IV). Scatterplots of implant alignment are shown in Figures 3-A and 3-B. The interobserver reliability in detecting alignment and overhang outliers was 96.0%.

Radiographic Outcomes and Revision Risk

The rate of failure among knees that had no alignment or overhang outliers was 0%. However, the risk of implant failure was significantly impacted by outliers for FCA (failure rate = 15.4%, p = 0.036), FSA (16.2%, p = 0.028), TCA (17.9%, p = 0.020), and TSA (15.2%, p = 0.034). Far outliers also had a significant effect, and a dose-response effect was observed between the number of outlier and far outlier measurements for a given knee and the risk of implant failure (Table VI).

While anterior overhang was not a significant risk factor for implant failure (failure rate = 10.0%, p = 0.090), posterior (25.0%, p = 0.006) and medial (38.2%, p < 0.001) overhang were significant risk factors (Table VII).

Only 11.9% of the knees met all alignment and overhang targets.

Differences in age, sex, and BMI were not associated with an increased risk of FCA, FSA, TCA, or TSA outliers. Age was associated with an increased risk of medial overhang outliers and BMI was associated with an increased risk of TSA far outliers (Table VIII).

Discussion

In this study, we assessed the clinical and radiographic outcomes of medial UKA and the impact of implant alignment and overhang on revision risk. The 5 and 10-year implant survival rates of 88% and 70%, respectively, were far below those for TKA[55]. The most common indications for revision were implant malalignment, mechanical failure, and osteoarthritis progression. Overall, >30% of all alignment measurements in this study represented outliers, with 17.0% representing far outliers. Only 19.0% of knees had optimal alignment of both the femoral and the tibial component. Furthermore, only 72.7% met anterior, posterior, and medial overhang targets. Most surprisingly, only 11.9% met both the alignment and the overhang targets. Implant malalignment as well as posterior and medial overhang were significant risk factors for revision.

Our findings of poor implant survival fall along the gradient of mixed results associated with the survival of UKAs in the published literature. UKA has an excellent track record in "designer series" and early studies assessing UKA survival[17,18,56,57], findings that have been corroborated in non-designer series such as reported by Lisowski et al. (90.6% survival at 15 years)[20]. While these results are impressive, the vast majority of analyses of the long-term survival of UKAs have reproducibly demonstrated a high rate of failure in the hands of a diverse group of surgeons at multiple different institutions[2,20-26,42]. Objective data from arthroplasty registries have corroborated these findings[2,24,25], with as low as a 60% 15-year survival rate in the Finnish Arthroplasty Register[58].

Large-scale analyses of UKA failure data have frequently identified low surgeon volume as a risk factor[47,59,60], and low surgeon volume is a potential systematic source of error driving the high rate of failure in many registry studies. However, we believe that the mechanism by which low surgeon volume impacts implant survival has not been fully elucidated. Still, the fact that the 2 leading causes of UKA failure are aseptic loosening and osteoarthritis progression, both of which are mechanistically related to uneven load distribution[36,61,62], suggests that the drivers of this phenomenon may be mechanical in nature. This logic is supported, for example, by studies implicating implant malalignment as a potential mechanism for the high revision rates among low-volume surgeons[60].

While this evidence points toward implant alignment as a potential cause of premature UKA failure, the impact of alignment on clinical outcomes is a point of contention. Despite the current study and others indicating that postoperative alignment influences implant survival[30,36-41,63], many authors have reported that the clinical impact of small deviations from target alignment is unclear[64-67]. Although we agree that deviation on the order of 2° to 3° from neutral/optimal alignment is unlikely to impact clinical outcomes, it seems apparent that gross malalignment would have an impact on knee function and wear characteristics[48]. Our study, therefore, demonstrates 2 important points. First, while minor deviation from neutral/optimal alignment may not influence outcomes,

TABLE V Implant Alignment on Per Knee Basis

	% of Knees	
	Aligned	Outlier(s)*
FCA and FSA	44.3	55.7
TCA and TSA	45.8	54.2
All measurements	19.0	81.0

*Femoral outliers represent the proportion of knees with FCA or FSA malalignment or far malalignment. Tibial outliers represent the proportion of knees with TCA or TSA malalignment or far malalignment.

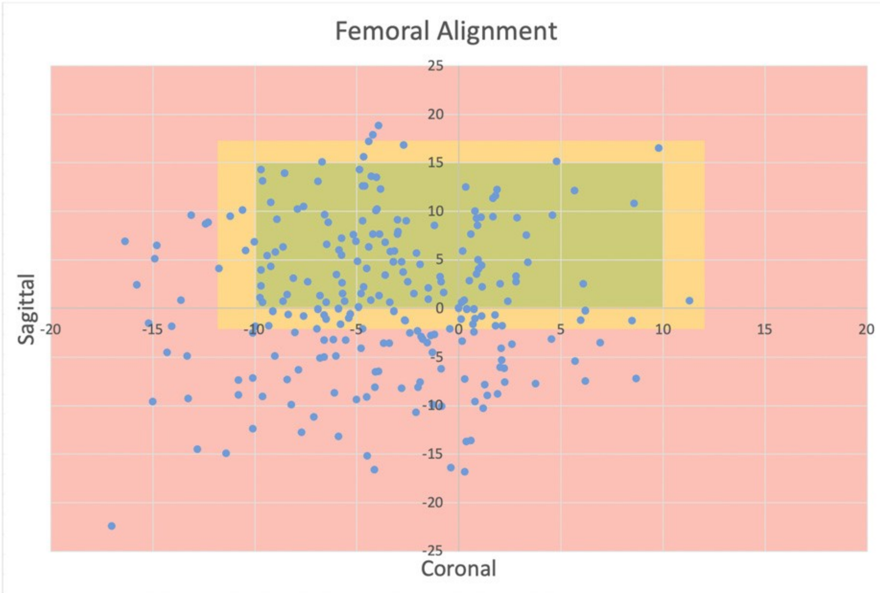

Fig. 3-A

Figs. 3-A and 3-B Scatterplots of femoral and tibial coronal and sagittal alignment. The region of optimal alignment is indicated by green shading; outliers that remain within ±2° of the optimal alignment targets are indicated with yellow shading; and far outliers, which are >±2° outside of optimal alignment, are indicated with red shading. **Fig. 3-A** Scatterplot for femoral alignment, which was considered optimal when the FCA deviated ≤±10° from the neutral axis and the FSA was ≤15° of flexion.

deviation outside of the predefined ranges used in this study is, in fact, sufficient to increase the risk of implant failure. Second, even if the impact of "close" outliers is still debated, the 17% rate of "far" outliers in our study makes it apparent that the proportion of these high-risk outliers in UKA is unacceptably high.

Based on our findings, there are 2 potential strategies to improve implant-survival outcomes of the treatment of unicompartmental knee arthritis: (1) favor the use of TKA or (2) develop strategies to improve UKA alignment and minimize overhang. While performing TKA in all patients with unicompartmental arthritis could improve implant survival, it would sacrifice the reported advantages associated with UKA[1-12] and decrease cost-effectiveness[8]. Developing strategies to decrease the prevalence of surgical errors and thus

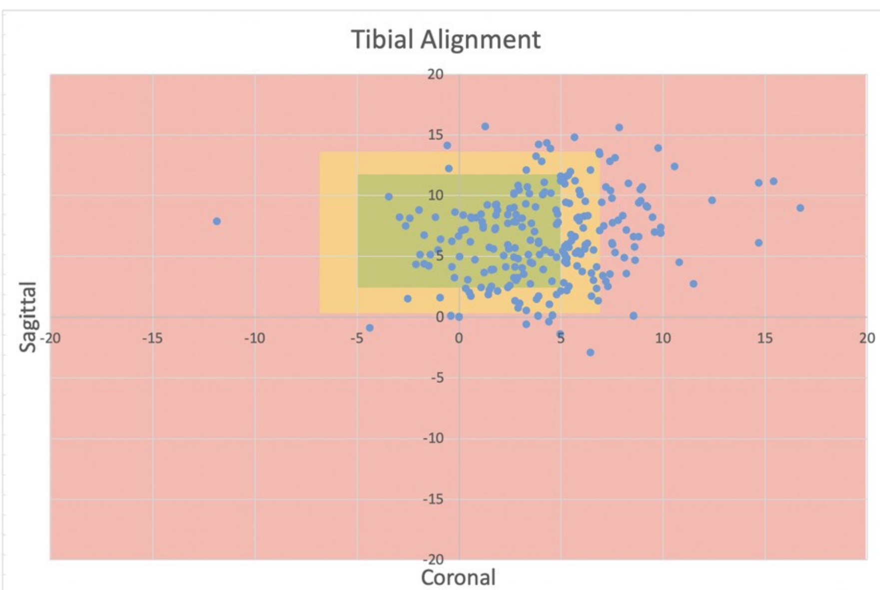

Fig. 3-B

Scatterplot for tibial alignment, which was considered optimal when the TCA deviated ≤±5° from the neutral axis and the TSA deviated ≤±5° from 7°.

TABLE VI Risk of Revision as a Function of Alignment Outliers

	Failure Rate *(%)*	P Value*
Within optimal alignment and overhang ranges	0.0	—
Within optimal overhang range	6.3	—
FCA close outlier	15.4	0.036
FSA close outlier	16.2	0.028
TCA close outlier	17.9	0.020
TSA close outlier	15.2	0.034
FCA far outlier	26.3	0.006
FSA far outlier	14.4	0.036
TCA far outlier	14.3	0.038
TSA far outlier	35.7	0.002
1 close alignment outlier	13.7	0.040
2 close alignment outliers	21.4	0.014
3 close alignment outliers	33.3	0.003
1 far alignment outlier	13.8	0.040
2 far alignment outliers	22.2	0.011
3 far alignment outliers	33.3	0.003

*All p values were significant for difference with knees with optimal alignment and overhang.

TABLE VII Combined Risk of Failure Associated with Overhang Outliers

	Failure Rate *(%)*	P Value
Within optimal alignment and overhang ranges	0.0	—
Within optimal alignment range	9.8	—
Anterior overhang outlier	10.0	0.090
Posterior overhang outlier	25.0	0.006*
Medial overhang outlier	38.2	<0.001*
1 overhang outlier	24.1	0.006*
2 overhang outliers	44.4	<0.001*

*Significant for difference with knees with optimal alignment and overhang.

their subsequent impact on UKA failure, however, is challenging. Given that only roughly 50,000 UKAs are performed in the U.S. per year[13,68], it may be difficult for surgeons to maintain the recommended volume of >20 UKAs per year that is necessary to minimize risk. Therefore, we believe that efforts should be made to improve surgical technique in order to improve UKA component alignment and minimize overhang.

This study had many limitations. When interpreting the results of the current study, it is important to keep in mind that while the senior surgeons performed a sufficient number of UKAs to fall into the low revision risk categories according to Badawy et al.[59], they fell below the high-volume standards for UKA recommended by Baker et al.[47]. Therefore, our results may not be generally applicable to high-volume UKA surgeons. In a recent study by Bush et al.[69], for example, a high-volume UKA surgeon was shown to reliably implant UKA components in an accurate manner. Importantly, however, Bush et al. commented only on differences in root-mean-square (RMS) error compared with preoperative targets and not on the number of alignment outliers. Therefore, it is difficult to determine whether the number of alignment outliers is similarly elevated after procedures performed by high-volume surgeons despite minimal RMS deviation. Additionally, because the majority of UKAs are performed by low-volume UKA surgeons, we believe that these results apply to the majority of UKAs performed in the U.S. Another limitation of this study is the use of short-leg radiographs for the assessment of implant alignment. However, this methodology has previously been validated[48-54]. Finally, our limited sample size precluded the use of a robust analysis of covariates. However, due to the absence of a strong relationship between potential confounders and implant malalignment, it is unlikely that these factors were significant contributors to the observed interaction between malalignment and implant failure.

Conclusions

The results of the current study indicate that implant survival following UKA is lower than expected among high-volume

TABLE VIII Confounder Analysis

	P Value		
	Age	Sex	BMI
FCA outlier	0.889	0.999	0.603
FSA outlier	0.516	0.613	0.332
TCA outlier	0.754	0.495	0.906
TSA outlier	0.110	0.999	0.634
FCA far outlier	0.458	0.557	0.912
FSA far outlier	0.684	0.831	0.168
TCA far outlier	0.584	0.816	0.583
TSA far outlier	0.778	0.745	0.040*
Anterior outlier	0.878	0.248	0.249
Medial outlier	0.048*	0.795	0.268
Posterior outlier	0.618	0.999	0.467

*The impact of age, sex, and BMI on implant malalignment were investigated to determine whether they were potential confounding variables driving the observed relationship between implant malposition and failure. Age was found to have a significant effect on medial outliers and BMI was found to have a significant effect on TSA outliers. No others demonstrated a significant interaction.

arthroplasty surgeons performing a modest number of UKAs per year (an average of 14.2, which is less than the high-volume threshold of 15). The strong association between implant malalignment/overhang and revision risk suggests a potential mechanism for the high failure rates observed in this study. The ability of low-volume UKA surgeons to consistently attain accuracy in implant position is an important factor to investigate to help improve UKA survivorship. ■

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