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## Primary Arthroplasty

## Implant Survival and Function Ten Years After Kinematically Aligned Total Knee Arthroplasty

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## ABSTRACT

**Background:** Alignment in the varus or valgus outlier range of the tibial component, knee, and limb might adversely affect the long-term results of kinematically aligned total knee arthroplasty (TKA) particularly when patients are selected without restricting the degree of preoperative varus-valgus and flexion deformity.

**Methods:** A retrospective review of all patients treated in 2007 with a primary TKA determined the 10-year implant survivorship, yearly revision rate, Oxford Knee Score, and WOMAC. All 222 knees (217 patients) were aligned kinematically using patient-specific instrumentation without restricting the degree of preoperative deformity and with the restoration of the native joint lines and limb alignment. Mechanical alignment criteria categorized the alignments of the tibial component, knee, and limb as in-range or in a varus or valgus outlier range.

**Results:** The implant survivorship (yearly revision rate) was 97.5% (0.3%) for revision for any reason and 98.4% (0.2%) for aseptic failure. The percentage postoperatively aligned in the varus outlier (valgus outlier) range was 78% (0%) for the angle between the tibial component and mechanical axis of the tibia, 31% (5%) for the tibiofemoral angle of the knee according to the criteria by Ritter et al, and 7% (21%) for the hip-knee-ankle angle of the limb according to the criteria by Parratte et al. Patients grouped in the varus outlier range, valgus outlier range, and in-range had similar implant survival and function scores. The 10-year Oxford Knee Score (48 best) and WOMAC (0 best) averaged 43 and 7 points, respectively. **Conclusion:** With the limitation that a large case series unlikely represents the full range of preoperative deformities and native alignments, treatment of patients with kinematically aligned TKA with patient-specific instrumentation without restricting the preoperative deformity did not adversely affect the 10-year implant survival, yearly revision rate, and level of function.

**Level of evidence:** Level III, therapeutic study.

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Innovations in total knee arthroplasty (TKA), such as alignment strategies, are vetted over many years by the medical and scientific community before becoming the standard of care. After preliminary reports suggest that merit and randomized trials and meta-analyses recognize efficacy, studies of long-term implant

survivorship provide guidelines for patient selection and identify mechanisms of implant failure from which approaches to lower the risks of poor function and reoperation are devised [1–4].

Kinematic alignment (KA) is an innovation that corrects the arthritic deformity to the prearthritic or native constitutional alignment by coaligning the rotational axes of the femoral, tibial, and patella components with the 3 kinematic axes of the knee [5–9]. KA sets the femoral and tibial components coincident to the native tibial-femoral joint lines without releasing ligaments, which restores the native laxities, tibial compartment forces, Q-angle, and hip-knee-ankle (HKA) angle [10–15]. Restoring the native distal and posterior joint lines of the femur is straightforward as bone wear is rare and cartilage wear that averages 2 mm is limited to predictable locations in Kellgren-Lawrence Grade 3 or 4

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osteoarthritic knees with varus and valgus deformities [16]. Compensating for 2 mm of worn cartilage at 0° and 90°, and adjusting the tibial resection until the varus-valgus laxity with trial components is negligible in full extension restores native left to right symmetry of the HKA angle, distal lateral femoral angle, and proximal medial tibial angle in nearly all patients with negligible risk of varus alignment of the tibial component with respect to the native tibial joint line [17,18]. The postoperative joint line orientation after KA TKA is similar to the native knee and horizontal to the floor in single-leg stance, which results in a lower knee adduction moment than mechanically aligned (MA) TKA [19,20]. Accordingly, randomized trials, meta-analyses, multicenter national, and matched cohort studies show efficacy as patients treated with KA TKA reported significantly better pain relief, function, flexion, and a more normal feeling knee than those treated with MA TKA [6,20–27].

Although KA has many short-term benefits, concerns remain about the long-term consequences of the use of KA as components are set in anatomic orientations outside those recommended for MA, and about restricting the use of KA based on the degree of preoperative varus, valgus, and flexion deformity [28–30]. Randomized trials that did not restrict patient selection based on preoperative deformity and restored native alignment showed greater improvements in pain relief, patient-reported outcomes, and knee flexion in the KA group than the MA group [6,23]. Comparable results in the KA and MA groups were reported in one trial that restricted preoperative deformity [31] and another trial that restricted preoperative deformity and limited the postoperative correction to within MA criteria [32]. Hence, the expectation of success after KA TKA might be greater without restrictions on preoperative deformity and postoperatively the native joint lines and limb alignment are restored.

Another concern is that KA TKA sets a high proportion of tibial components in varus relative to the mechanical axis of the tibia and aligns a proportion of knees and limbs in the varus or valgus outlier range according to MA criteria [14,29,33]. The range of the native HKA angle varies from 12° varus to –16° valgus among the world populace, which falls outside the bounds of postoperative alignment recommended for MA TKA [15]. A long-term study of implant survivorship and function after treatment with KA TKA is needed

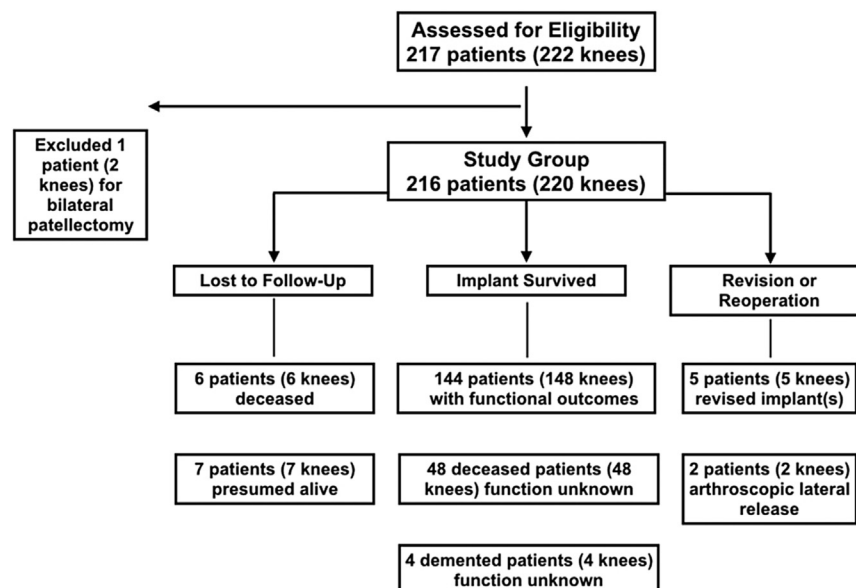
because practitioners of MA believe that alignment of components in the varus or valgus outlier ranges poses a higher risk of implant failure than in-range [34–36].

This study evaluated 222 knees (217 patients) treated with KA TKA with patient-specific instrumentation (PSI) without restrictions on the degree of preoperative varus, valgus, and flexion deformity and (1) determined implant survivorship, yearly rate of revision, and function as measured by the Oxford Knee Score (OKS) and Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) scores at 10 years, and (2) tested the hypothesis that categorizing alignment of the tibial component, knee, and limb in the varus or valgus outlier range does not adversely affect implant survival and function.

## Methods

After institutional review board approval, we performed a clinical and radiographic retrospective study of a prospectively collected database and evaluated the impact of alignment of the tibial component, knee, and limb on long-term implant survival and function. The primary indications for TKA were (1) disabling knee pain and functional loss unresolved with nonoperative treatment; (2) radiographic evidence of Kellgren-Lawrence Grade 3 or 4 arthritic change or osteonecrosis; and (3) any severity of varus or valgus and flexion deformities including multiple level deformities. During 2007, all TKA procedures were performed with KA by the lead author with use of first-generation PSI (OtisMed Corporation, Alameda, CA), the use of cruciate-retaining components (Vanguard; Biomet, Inc, Warsaw, IN), the use of cemented fixation of all components, and the use of a domed all-polyethylene patellar component [6]. The inclusion criteria were all patients treated with a primary TKA in 2007 without a workers' compensation claim. Excluded were patients with a patellectomy, patella fracture, prior arthroplasty, and malunion of an intra-articular knee fracture. Figure 1 is a flowchart of the structure of the study group, which consisted of 216 patients (220 knees). One patient with 2 TKAs was excluded because of a bilateral patellectomy.

The concept of KA and the surgical technique that uses PSI to align the femoral and tibial components coincident to the native joint lines of the knee after compensating for wear has been described [6,37]. Briefly, KA coaligns the rotational axes of the



**Fig. 1.** Flowchart showing the structure of the patients assessed for eligibility, included in the study group, and excluded because of prior bilateral patellectomy.

components with the 3 kinematic axes of the knee without ligament release, which are either parallel or perpendicular to the native joint lines [5,7,9]. The femoral and tibial components are introduced in such a way that the angle and level of the distal and posterior femoral joint lines and the tibial joint line are restored to the natural alignment for each patient using PSI. The process of creating the PSI begins with a standardized magnetic resonance imaging protocol of the knee. The projection of the knee in the magnetic resonance imaging scanner is such that the plane of the oblique sagittal image is perpendicular to the transverse axis in the femur, about which the tibia flexes and extends [38]. Proprietary software creates a three-dimensional (3D) model of the knee. The “arthritic” model is transformed into a “normal” model by filling articular defects and equalizing the gap between the medial and lateral compartments of the knee. Equalizing the gap restores the joint line and the alignment of the knee and lower limb to the normal prearthritic state. An algorithm shape fits the best-fitting 3D model of the femoral component to the articular surface of the 3D model of the “normal” femur, with a reproducibility of  $\pm 0.5$  mm for translations and  $\pm 0.5^\circ$  for rotations (OtisMed Inc). The software sets the anteroposterior axis of the tibial component perpendicular to the flexion-extension axis of the femoral component, which kinematically aligns the 2 components. The tibia is centered kinematically beneath the tibial component. The PSI that creates the bone cuts is designed to fit onto the arthritic knee and is manufactured from medical-grade plastic [6,37].

Non-weight-bearing 2-dimensional computer tomographic (CT) scanograms of the limb were obtained on the day of discharge using a previously described technique and were available for 202 of 216 knees [39–41]. The average radiation dosage of a scanogram is 0.5 mSv lower than a conventional long-leg radiograph [42]. The projection error of the measurement of the HKA angle from malrotation was limited to approximately  $\pm 1^\circ$  by repeating the scanogram until the posterior condyles were visible on either side of the flange of the femoral component [40]. Because KA sets the internal-external rotation of the femoral component coincident with the posterior joint line, and because the posterior joint line parallels the flexion-extension axes in the femur about which the tibia and patella flex and extend, positioning the flange between the posterior condyles projected the limb in a functional orientation in the coronal plane [11].

Between August 2017 and January 2018, a clinical assessment of implant survival and function was performed. Observers blinded to the patient's alignment, contacted patients independently of the treating surgeon by phone, e-mail, or postal service. Outdated contact information was updated with use of 5 “people search websites.” Whether the patient had further surgery on the knee for any reason was recorded and the operative note was obtained. Mentally competent patients completed the OKS (48 best, 0 worst) and WOMAC questionnaires (0 best, 96 worst).

One observer blinded to the reoperation status and function scores used a previously described technique to measure coronal alignment of the tibial component, knee, and limb on 202 long-leg CT scanograms [6,43]. The interclass coefficients for the measurement of knee (0.87) and limb (0.86) alignment indicate good reproducibility [41] and the reported intraobserver and interobserver measurement errors are  $< 1^\circ$  for all of the analyzed angles [35]. Alignment of the tibial component is the angle between the joint line of the tibial component and the mechanical axis of the tibia, knee alignment is the angle between the anatomic axes of the femur and tibia, and limb alignment is the angle between the mechanical axes of the femur and tibia [35,36]. The tibiofemoral angle of the knee was measured on long-leg CT scanogram with use of landmarks described on a knee radiograph by Ritter et al [36] and categorized into 3 ways: as in-range (between  $-2.5^\circ$  and  $-7.4^\circ$ ),

varus ( $> -2.5^\circ$ ), or valgus ( $< -7.4^\circ$ ). Limb alignment was categorized into 3 ways according to Parratte et al [35]: as in-range ( $0^\circ \pm 3^\circ$ ), varus ( $> 3^\circ$ ), or valgus ( $< -3^\circ$ ).

### Statistical Analysis

Data were recorded and analyzed using statistical software (JMP Pro 13.2.0, [www.jmp.com](http://www.jmp.com); SAS, Cary, NC). The mean, standard deviation, and 95% confidence interval (CI) described the distribution of continuous variables. Kaplan-Meier survivorship analysis, with 95% CI and with endpoints of either revision for any reason (defined as operations in which at least one of the components was changed) or aseptic failure (defined as operations in which at least one of the components was changed for reasons other than infection), determined implant survival. Censoring occurred on the date of revision surgery, last functional score, or death. The yearly rate of revision was computed by dividing the number of knees revised for any reason by the total number of observed years of implantation and multiplying by 100 [44]. A proportional hazards model and single-factor analyses of variance determined whether the category of postoperative alignment of the tibial component, knee, and limb affected 10-year implant survival and the OKS and WOMAC scores, respectively.

### Results

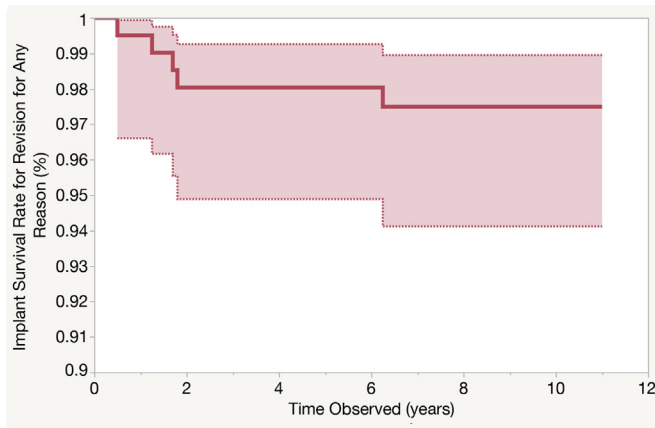
Twelve patients (13 knees) or 6% of the 216 patients (220 knees) had no updatable contact information and were lost to follow-up (Fig. 1). Six of these patients (6 knees) had died. Of the 94% of patients with follow-up, 153 patients (157 knees) were alive and 48 patients (48 knees) had died with no reoperations. The mean age of those with follow-up was  $77 \pm 10$  years (49–97), and 38% (78 of 203) were male. Table 1 summarizes preoperative patient demographics, motion, range of knee deformities, and function.

Implant survival was 97.4% reflecting revisions for any reason ( $N = 5$ ) (Fig. 2) and 98.4% reflecting revisions exclusively for aseptic failure ( $N = 3$ ) (Fig. 3). The yearly revision rate was 0.3% (95% CI 0.09–0.64) for any reason and 0.2% (95% CI 0.03–0.48) for aseptic failure. Altogether, there were 5 patients (5 knees) for whom revision surgery was undertaken (2.5%), defined as removal or exchange of at least one of the components. Postoperative infection occurred in 2 patients (2 knees). At 6 months, 1 patient had a 2-stage revision in another state. At 22 months, the other patient

**Table 1**  
Preoperative Clinical Characteristics, Motion, Deformity, and Function.

| Preoperative Demographics and Clinical Characteristics                          | Number of Patients or Knees | Mean (SD) or Number (%) | Range                  |
|---|-----------------------------|-------------------------|------------------------|
| Preoperative demographics   |                             |                         |                        |
| Age (y)   | N = 216                     | 67 (10.1)               | 39–93                  |
| Gender (male)   | N = 216                     | 82 (37%)                |                        |
| Body mass index (kg/m <sup>2</sup> )  | N = 198                     | 31 (6.1)                | 14–49                  |
| Preoperative motion and deformity   |                             |                         |                        |
| Extension ( $^\circ$ )  | N = 192                     | 10 (8.5)                | –5 to 40               |
| Flexion ( $^\circ$ )  | N = 192                     | 113 (12.6)              | 80–150                 |
| Varus (+)/valgus (–) deformity ( $^\circ$ ) [measured from standing radiograph] | N = 214                     | –1 (6.2)                | 14 varus to –20 valgus |
| Preoperative function   |                             |                         |                        |
| Oxford score (48 is best, 0 is worst)   | N = 150                     | 18 (7)                  | 4–39                   |
| Knee society score (100 is best, 0 is worst)                                    | N = 144                     | 43 (16.7)               | 0–75                   |
| Knee function score (100 is best, 0 is worst)                                   | N = 143                     | 42 (18.5)               | 0–90                   |

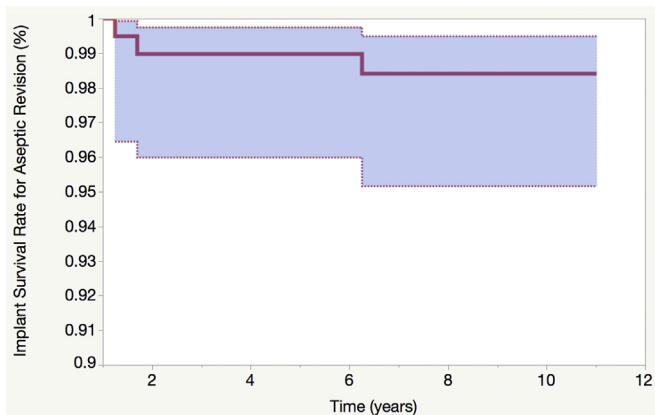
SD, standard deviation.



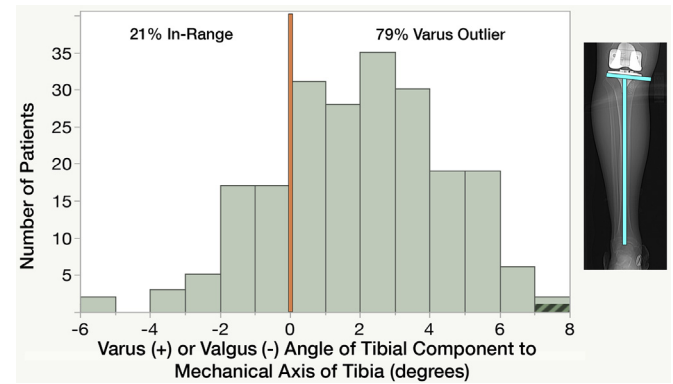
**Fig. 2.** Kaplan-Meier survivorship curve (solid red line) with 95% confidence intervals (dotted red lines) for revision for any reason as the endpoint. The 5-year survival rate was estimated at 98.0% (95% CI 94.8–99.5; number at risk: 184) and the 10-year survival rate was estimated at 97.5% (95% CI 94.5–99.0; number at risk: 141).

required a lavage and insert exchange and was free of infection with a 44-point OKS at 10-year follow-up. Tibial component loosening occurred in 1 patient. At 20 months, the tibial component had subsided posteriorly that was associated with a reverse tibial slope of 8° (error in placing tibial guide) and was revised with a long-stem tibial component set to the slope of the contralateral knee.

Patella complications occurred in 4 patients (4 knees). At 15 months, 1 patient had a full revision in another state for an onset of recurrent lateral patellofemoral instability at 2 months associated with 18° of flexion of the femoral component (error in placing femoral guide). At 75 months, the other patient had a removal of a patella implant at another institution that became loose at 48 months. At 10 months, 1 patient had an arthroscopic lateral release for an onset of recurrent lateral patellofemoral instability at 7 months associated with 25° of flexion of the femoral component and had a 40-point OKS at 10-year follow-up. At 3 months, 1 patient had an arthroscopic lateral release for an onset of recurrent lateral patellofemoral instability at 1 month associated with 13° of flexion of the femoral component and had a 43-point OKS at 10-year follow-up. The average body mass index at the time of the primary TKA of  $36 \pm 6$  for the 7 subjects with reoperation for infection, implant removal, or patella complications was greater than the



**Fig. 3.** Kaplan-Meier survivorship curve (solid red line) with 95% confidence intervals (dotted red lines) for aseptic revision as the endpoint. The 5-year survival rate was estimated at 99.0% (95% CI 96.0–99.8; number at risk: 183) and the 10-year survival rate was estimated at 98.5% (95% CI 95.5–99.5; number at risk: 140).



**Fig. 4.** Distribution of the angle of the tibial component with respect to the mechanical axis of the tibia for 202 KA TKAs. According to Parratte et al's [35] mechanical alignment criteria, 79% of the tibial components were in the varus outlier range (ie,  $> 0^\circ$ ) and 21% were in-range ( $\leq 0^\circ$ ). The oblique hatch mark indicates the subject with the greatest angle of the tibial component.

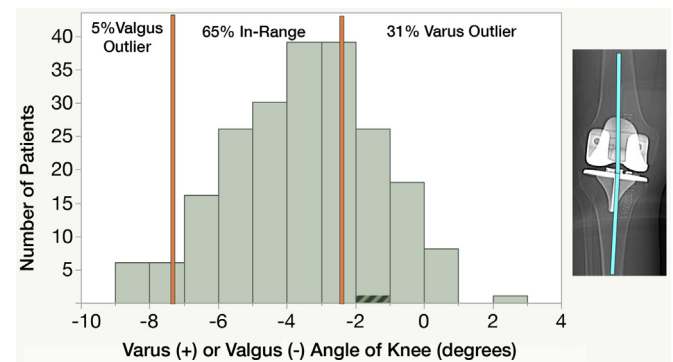
body mass index of  $30 \pm 6$  for those subjects without reoperation ( $P < .02$ ).

Regarding the effect of the category of the range of postoperative alignment on implant survival at 10 years, measurements were available for 202 of the 207 knees in the study group not lost to follow-up. Using MA criteria, the percentage postoperatively aligned in the varus (valgus) outlier range was 78% (0%) for the tibial component, 31% (5%) for the knee, and 7% (21%) for the limb (Figs. 4–6) [35,36]. The category of postoperative alignment of the tibial component, knee, and limb did not affect implant survival ( $P = .2288-.4164$ ) (Table 2).

Regarding the effect of category of the range of postoperative alignment on function, both a scanogram of the lower limb and 10-year function scores were available for 144 knees. The OKS averaged 43 (95% CI 42.4–44.4) and the WOMAC score averaged 7 (95% CI 5.5–9.3) (Table 1). The category of postoperative alignment of the tibial component, knee, and limb did not affect the mean OKS and WOMAC scores ( $P = .0530-.3596$ ) (Table 3).

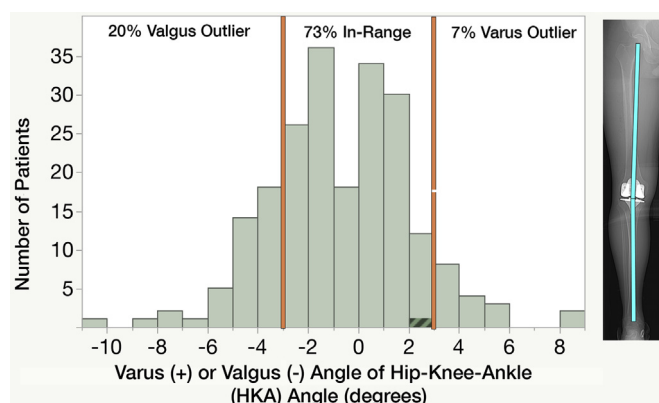
## Discussion

The most important finding of this study that treated patients with KA TKA with PSI without restrictions on the preoperative deformity was that alignment of the tibial component, knee, and



**Fig. 5.** Distribution of the anatomic angle of the knee for 202 KA TKAs. According to Ritter et al's [36] mechanical alignment criteria, 31% were in the varus outlier range ( $> -2.5^\circ$ ), 5% were in the valgus outlier range ( $< -7.4^\circ$ ), and 65% were in-range (between  $-2.5^\circ$  and  $-7.4^\circ$ ). The oblique hatch mark indicates that the angle of the knee was in varus for the subject with the greatest angle of the tibial component.





**Fig. 6.** Distribution of the HKA angle for 202 KA TKAs. According to Parratte et al's [35] mechanical alignment criteria, 20% were in the varus outlier range ( $>3^\circ$ ), 7% were in the valgus outlier range ( $<-3^\circ$ ), and 73% were in-range (between  $0^\circ \pm 3^\circ$ ). The oblique hatch mark indicates that the HKA angle was in-range for the subject with the greatest angle of the tibial component.

limb in the varus and valgus outlier ranges did not adversely affect the 10-year implant survival, yearly revision rate, and level of function.

Three limitations should be discussed. First, the findings in this study pertain to ranges of preoperative knee deformities from  $14^\circ$  varus to  $-20^\circ$  valgus and flexion contractures of up to  $40^\circ$ , and postoperative limb alignment ranging from  $9^\circ$  varus to  $-9^\circ$  valgus. For comparison, the postoperative limb alignment ranging from  $9^\circ$  varus to  $-9^\circ$  valgus in this study is broader than the range of  $4^\circ$  varus to  $-5^\circ$  valgus reported for limbs with no skeletal abnormalities in patients treated with a TKA in the contralateral limb, and narrower than the  $12^\circ$  varus to  $-16^\circ$  valgus reported for the world populace [15,18]. Second, the lack of follow-up of 6% of patients, of which 7 were alive and 6 were deceased, could have over-estimated implant survivorship. Over-estimation might occur when a patient is contacted and refuses to participate; however, none of the patients alive were locatable. Third, these results represent a designer surgeon's experience, which requires independent confirmation as designer surgeons tend to report lower failure rates and higher function than nondesigner surgeons [45].

The 10-year implant survivorship and yearly revision rate after KA TKA are comparable to 2 single-surgeon series of MA TKA that showed no adverse effects of outlier alignment on implant survival [34,35]. Using aseptic revision at 10 years as the endpoint, the 98.5% implant survival after 220 KA TKAs was 8.5% higher than the ~90%

implant survival after 398 MA TKAs in the United States [35], and 4.5% higher than the ~94% implant survival after 270 MA TKAs in the United Kingdom [34]. The estimated number of revisions for 1000 patients is 15 for KA TKA, and 90 and 60 respectively for the 2 MA TKA studies [34,35]. The 0.3% (95% CI 0.09–0.64) yearly revision rate after KA TKA is 0.3% lower than the 0.64% (95% CI 0.44–1.19) yearly revision rate after MA TKA reported by a national registry for the same implant design [44]. Hence, alignment in the varus (valgus) outlier range of 78% (0%) of the tibial components, 31% (5%) of the knees, and 7% (21%) of the limbs according to MA criteria did not adversely affect the 10-year implant survivorship after KA TKA when compared to MA TKA.

A varus mechanism causes failure of the tibial component after MA TKA, which presents as either polyethylene wear or catastrophic varus collapse of the tibia especially in obese subjects and is associated with postoperative alignment in the varus outlier range [46–49]. In contrast, a posterior mechanism causes failure of the tibial component after KA TKA, which presents as either posterior edge wear of the polyethylene insert or tibial subsidence and is associated with a postoperative slope  $7^\circ$  greater than the  $4^\circ$  average slope of the osteoarthritic knee [50]. In this study, 1 patient (0.5%) had posterior tibial subsidence which cannot be explained by alignment in the coronal plane as the tibial component and knee were in the varus outlier range and the limb in-range for the limb. Setting the slope of the tibial component parallel to the native medial tibial joint line lowers the risk of posterior insert wear and posterior tibial subsidence [17,50].

Three biomechanical advantages explain the negligible risk of varus tibial loosening after KA TKA. First, KA restores the native joint lines and constitutional alignment without releasing ligaments, which provides more physiological strains in the collateral ligaments than MA TKA [51]. Second, this study balanced the TKA without releasing ligaments, which results in medial and lateral tibial compartment forces comparable to those of the native knee with no evidence of tibial compartment overload even when the alignments of the limb, knee and tibial component are within the varus or valgus outlier range [12,14]. Third, KA is an especially promising option for patients with large varus coronal bowing of the tibia because the adduction moment is lower than after MA TKA, which is associated with a lower risk of varus tibial loosening [20]. These biomechanical advantages explain why categorizing the alignment of the limb, knee, and tibial component in a varus or valgus outlier range according to mechanical alignment criteria after KA TKA did not predict the 10-year implant survivorship or patient-reported outcome and why the risk of tibial component failure from a varus mechanism is negligible [43,50].

**Table 2**

Implant Survival for the Categories of Postoperative Alignment of Varus Outlier Range, Valgus Outlier Range, and In-Range.

| Alignment Parameter/Implant Survival      | In-Range                     | Varus Outlier Range | Valgus Outlier Range | Significance <sup>a</sup> |
|---|------------------------------|---------------------|----------------------|---------------------------|
| Tibial component alignment category       | $\leq 0^\circ$               | $> 0^\circ$         |                      |                           |
| Percentage, number of TKAs                | 21%, N = 42                  | 79%, N = 156        |                      |                           |
| TKAs with aseptic revision                | 0                            | 3                   |                      |                           |
| Implant survival (number at risk) at 10 y | 100% (32)                    | 98% (106)           |                      | NS, P = .2288             |
| Knee alignment category                   | $-7.4^\circ$ to $-2.5^\circ$ | $> -2.5^\circ$      | $< -7.4^\circ$       |                           |
| Percentage, number of TKAs                | 65%, N = 128                 | 31%, N = 61         | 5%, N = 9            |                           |
| TKAs with aseptic revision                | 1                            | 2                   | 0                    |                           |
| Implant survival (number at risk) at 10 y | 99.2% (89)                   | 96.5% (42)          | 100% (7)             | NS, P = .4164             |
| Limb alignment category                   | $0^\circ \pm 3^\circ$        | $> 3^\circ$         | $< -3^\circ$         |                           |
| Percentage, number of TKAs                | 73%, N = 145                 | 8%, N = 15          | 19%, N = 38          |                           |
| TKAs with aseptic revision                | 3                            | 0                   | 0                    |                           |
| Implant survival (number at risk) at 10 y | 97.8% (100)                  | 100% (10)           | 100% (28)            | NS, P = .3879             |

TKA, total knee arthroplasty; NS, not significant.

<sup>a</sup> Values given are the chi-square value computed by a proportional hazards model used to determine whether the category of postoperative alignment of the tibial component, knee, and limb affected implant survival for aseptic revision at 10 y.

**Table 3**

Mean Oxford Knee Score and WOMAC Score for the Categories of Postoperative Alignment of Varus Outlier Range, Valgus Outlier Range, and In-Range.

| Alignment Parameter/Function Score   | In-Range <sup>a</sup>      | Varus Outlier Range <sup>a</sup> | Valgus Outlier Range <sup>a</sup> | Significance  |
|--|----------------------------|----------------------------------|-----------------------------------|---------------|
| Tibial component alignment (tibial component-mechanical axis of the tibia) | ≤0°                        | >0°                              |                                   |               |
| Oxford Knee Score (48 best, 0 worst)                                       | 21%, N = 31<br>42 (40–45)  | 79%, N = 113<br>43 (41–44)       |                                   | NS, P = .3494 |
| WOMAC score (0 best, 96 worst)   | 7 (5–14)                   | 9 (5–9)                          |                                   | NS, P = .3596 |
| Knee alignment (femoral-tibial angle)                                      | –7.4° to –2.5°             | > –2.5°                          | < –7.4°                           |               |
| Oxford Knee Score (48 best, 0 worst)                                       | 65%, N = 93<br>43 (42–44)  | 31%, N = 45<br>45 (43–47)        | 4%, N = 6<br>41 (36–46)           | NS, P = .0917 |
| WOMAC score (0 best, 96 worst)   | 9 (6–11)                   | 4 (1–8)                          | 12 (2–21)                         | NS, P = .0824 |
| Limb alignment (hip-knee-ankle angle)                                      | 0° ± 3°                    | >3°                              | < –3°                             |               |
| Oxford Knee Score (48 best, 0 worst)                                       | 72%, N = 104<br>44 (43–45) | 9%, N = 13<br>45 (41–48)         | 19%, N = 27<br>41 (39–44)         | NS, P = .1073 |
| WOMAC score (0 best, 96 worst)   | 7 (5–9)                    | 3 (1–6)                          | 12 (6–17)                         | NS, P = .0530 |

TKA, total knee arthroplasty; NS, not significant; CI, confidence interval.

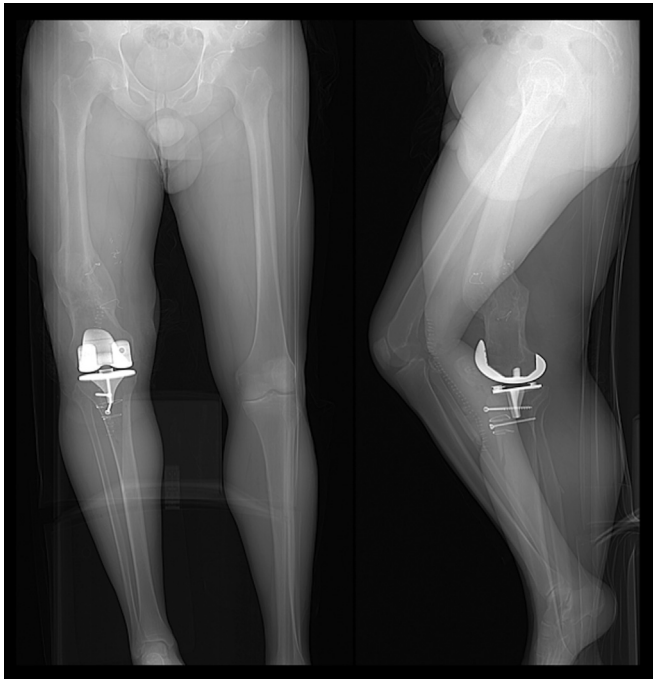
<sup>a</sup> Values given are the percent of TKAs, the number of TKAs (N), the mean function score rounded to the nearest integer, and the 95% CI of the function score in parentheses for patients who had both alignment and function scores at 10 y.

Flexion of the femoral component 13°–25° from the femoral anatomic axis due to incorrect seating of the patient-specific femoral guide in excessive flexion caused patellofemoral instability in this study, which was treated with either a revision (N = 1) or an arthroscopic lateral release (N = 2). As little as 10° of flexion increases the risk of patellofemoral instability by downsizing the femoral component ~1–2 sizes, reducing the cross-sectional area of the trochlea, reducing the proximal reach of the flange by ~8 mm, and delaying engagement of the patella during early flexion [52,53]. The design of the femoral component did not cause patellofemoral instability as KA restores the native trochlea morphology more closely than MA without overstuffing [30], and 3° of internal rotation about the center of the femoral component relative to MA negligibly increases the distance between the trochlear and lateral femur to ~1.5 mm [52]. A change in the native Q-angle did not cause

patellofemoral instability as KA restores the native Q-angle, whereas MA increases or decreases the native Q-angle in limbs with varus or valgus constitutional alignment, respectively [53]. The use of a distal referencing guide attached to an intraosseous positioning rod limits flexion of the femoral component to 1 ± 2° with respect to the femoral anatomic axis, which is 5° less than a patient-specific cutting guide and 10° less than patients with patellofemoral instability in another study [53,54]. Hence, limiting flexion of the femoral component to <5° might have reduced the risk of patellofemoral instability in this study [52–54].

Patients can have multiple level deformities in the coronal plane secondary to malunion or osteotomy of the femur and tibia in addition to medial or lateral osteoarthritis of the knee. Straightening these limbs to a 0° HKA angle is difficult and often requires extensive ligament releases. The low risk of varus tibial loosening suggests that KA might have a role in treating multiple level deformities. Accordingly, a 55-year-old male game warden with a history of an open and infected femoral shaft fracture secondary to a crocodile bite that healed with a 17° varus malunion after treatment with a vascularized soft-tissue graft was treated with a KA TKA. Ten years later the patient had a 44-point OKS and walked up to 10 miles/day with a 9° varus HKA angle (Fig. 7).

In summary, the use of KA performed with PSI without restricting the degree of preoperative varus-valgus and flexion deformity is an efficacious innovation in TKA. Reoperation in 4 of 7 cases was associated with errors of component placement in the sagittal plane and not the coronal plane. Strategies for mitigating the risk of reoperation are setting the tibial component parallel to the slope of the native medial tibial joint line and limiting flexion of the femoral component to <5° with respect to the femoral anatomic axis [50,53].



**Fig. 7.** Postoperative scanograms show a 17° varus and 23° flexion malunion of the femur with a patella baja secondary to a crocodile bite that was treated with KA TKA. The postoperative hip-knee-ankle angle was 9°. At 10 years the patient reported an Oxford Knee Score of 44, WOMAC score of 0, and the ability to walk up to 10 miles a day on uneven ground.

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