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Primary Knee

Reoperation, Implant Survival, and Clinical Outcome After Kinematically Aligned Total Knee Arthroplasty: A Concise Clinical Follow-Up at 16 Years

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ABSTRACT

Background: The preceding study reported a 10-year follow-up of 222 kinematically aligned total knee arthroplasties (TKA) performed in 217 patients in 2007. As 35% of tibial components and 8% of limbs were in >3° varus, the present study assessed whether this adversely affected reoperation, implant survival, and function at 16 years.
Methods: We retrospectively reviewed a single surgeon's private practice database to determine the patients who underwent reoperation as well as Forgotten Joint Score and Oxford Knee Score.
Results: There were 7 patients who had a major reoperation (revision of a loose tibial component [n = 2], and revision of well-fixed component due to stiffness [n = 1], patella instability [n = 1], pain [n = 1], and infection [n = 2]). There were 5 who had a minor reoperation that retained the components, and 91 patients (94 TKAs) died. Implant survivorship was 93% using reoperation for any reason as the endpoint. The median (interquartile range) Forgotten Joint and Oxford Knee scores were 88 (57 to 100) and 45 (39 to 48) points, respectively.
Conclusion: The kinematically aligned TKA had a 7% reoperation rate at 16 years follow-up, comparable to or lower than reports of mechanically aligned TKA, which supports the concept of the unrestricted version of kinematic alignment in which the patient's prearthritic alignment is fully restored regardless of deformity.

Surgeons are investigating a personalized approach to total knee arthroplasty (TKA) to achieve high function, satisfaction, and a "forgotten" knee [1,2]. While neutral mechanical alignment (MA) is purported to be a favorite target for implant durability, it may alter natural knee kinematics, which can compromise subjectively reported clinical and functional outcome scores when compared to the kinematic alignment (KA) technique [3–5].

Surgeons who perform unrestricted (un)KA TKA do not limit its use based on the severity of the preoperative varus, valgus, and flexion deformity or limit the postoperative correction relative to the alignment target, which is 3-dimensionally setting the femoral and tibial components to restore the patient's prearthritic joint lines. Critics argue that because unKA disregards the MA target of neutral alignment of the limb and tibial component, those KA TKAs with postoperative varus alignment might have a high risk of alignment-related early failure [1]. However, multiple studies have assessed the implant survival of the KA TKA technique at 7-year, 10-

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year, and 13-year follow-up, early tibial baseplate migration as measured with radiostereometric analysis (RSA) at 1 and 2 years, and whether tibial compartment forces match those of the native knee. They have found no evidence to support that using unKA lowers implant survivorship up to 13 years, causes tibial component migration, or overloads the medial or lateral tibial compartments relative to native knee forces [6–11].

Because there are no reports of reoperation, implant durability, and function greater than 13 years after unKA TKA, we thought it appropriate to update our 10-year results since the technique set 35% of the tibial components in >3° varus up to 8° and 7% of the limbs in >3° varus up to 9° [6]. We hypothesized that the cohort would continue at 16 years to have a low incidence of major and minor reoperations (ie, those that retained the femoral and tibial components) and high function as measured by the patient-reported Forgotten Joint Score (FJS) and Oxford Knee Score (OKS).

Methods and Materials

After obtaining institutional review board approval (Pro00071754), we retrospectively reviewed a single surgeon's private practice database. We identified 217 consecutive patients who had 222 primary unKA TKAs performed in 2007, who did not have Worker's Compensation claims. Each unKA TKA had the following common characteristics: (1) component positioning with magnetic resonance imaging (MRI)–based patient-specific instrumentation; (2) a low-conforming implant design that retained the posterior cruciate ligament; (3) a domed, all-polyethylene patellar component; and (4) cementation of all components [6]. Varus and valgus measurements of coronal limb, knee, as well as femoral and tibial component alignments were available for 216 TKAs. Each patient, including those who did not have radiographic alignment measurements, received on the 16th anniversary of the unKA TKA, as part of a quality control protocol, a questionnaire asking whether they had a knee reoperation and to complete the FJS (100 best, 0 worst) and the OKS (48 best, 0 worst). In the original series, contact with the next of kin or primary care physician confirmed that the 54 patients (54 TKA's; 24%) who died did not have a reoperation. There were 7 patients who were not contactable, leaving 169 TKAs for analysis at 10 years. Between 10 and 16 years, 37 additional patients (39 TKAs) died without a reoperation and 3 were not contactable, leaving 107 patients (107 TKAs) available for analyses (Figure 1).

Data Analyses

As described in the initial report, statistical software (JMP Pro, 17.1.0, Cary, NC) computed implant survival using the Kaplan–Meier survivorship analysis with 95% confidence intervals with reoperation for any reason as the endpoint. The FJS and OKS were not normally distributed, so median [interquartile range] values were reported.

Results

Reoperation for 6 of 12 patients occurred in the first 2 years, and 6 between 6 and 16 years. For those who underwent reoperation, the range of tibial component alignment was 0 to 4° varus and limb alignment was −5 valgus to 3° varus. Overall, 7 unKA TKAs required a major reoperation, which consisted of revision of a loosened tibial component (n = 2), and removal of well-fixed femoral and tibial components for periprosthetic joint infection (n = 2), patella instability (n = 1), and stiffness (n = 1), There were 5 who required a minor reoperation defined by retention of the femoral and tibial components, which consisted of removing a loosened patella implant (n = 2), irrigation and debridement and liner exchange for infection (n = 1), and lateral release for patella instability (n = 2) (Table 1). The implant survival was 93% with reoperation for any reason (Figure 2). For the overall cohort, 35% of the tibial components were in >3° varus up to 8°, and 8% of the limbs were in >3° varus of up to 9° (Figures 3 and 4). The 75 patients who filled out the questionnaires (mean age 77 years, range 55 to 98 years, 45 women) had a median (interquartile range) FJS of 88 (57 to 100) points and an OKS of 45 (39 to 48) points.

Discussion

The introduction of alternative TKA alignment philosophies potentially prioritizing better function, such as KA, makes it particularly important for the collective orthopaedic community to understand the longer-term effects of postoperative alignment on implant survival and functional outcomes [12]. The most important findings of the present study, with a follow-up of 16 years, were

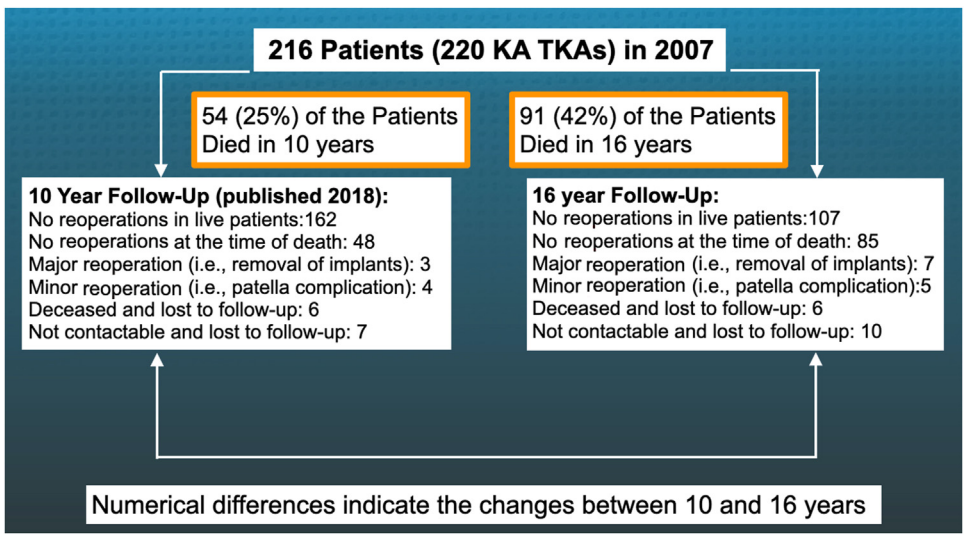

Fig. 1. Flowchart shows implant and patient condition and major and minor reoperations at 10-year and 16-year follow-ups.

Table 1
Spread Sheet of Treatment History and Demographics of Each Patient With Major and Minor Reoperation After Kinematically Aligned Total Knee Arthroplasty.

Patient Number	Severity of Reoperation	Time From Primary TKA	Age (At Revision) and Sex	Reason for Reoperation	Type of Reoperation	TCMA Angle	HKA Angle
1	Minor	3 mo	58, woman	Patella instability	Lateral release, retention of well-fixed components	3° varus	−3° valgus
2	Major	6 mo	58, woman	Infected TKA	Two-stage revision of well-fixed components	0° varus	−5° valgus[a]
3	Minor	1 y	58, woman	Patella instability	Lateral release, retention of well-fixed components	4° varus[a]	−1° valgus
4	Major	1 y 3 mo	69, man	Patella instability	Revision of well-fixed components	0° varus	−1° valgus
5	Major	1 y 7 mo	65, man	Posterior subsidence tibial component	Revision tibial component and reduction of posterior slope	4° varus[a]	2° varus
6	Minor	1 y 10 mo	65, man	Infected	Debridement, antibiotics, implant retention (DAIR)	3° varus	−4° valgus[a]
7	Minor	6 y 3 mo	68, man	Loose patella implant	Removal of loose patella implant	4° varus[a]	3° varus
8	Major	9 y 5 mo	60, woman	Infected	Two-stage revision of well-fixed components	3° varus	0°
9	Major	10 y 5 mo	61, man	Loose tibial component	Revision	2° varus	5° varus
10	Major	12 y 10 mo	81, man	Painful knee	Revision of well-fixed components	2° varus	3° varus
11	Major	12 y 11 mo	62, woman	Stiffness periarticular heterotopic bone	Revision of well-fixed components	0°	−4° valgus[a]
12	Minor	14 y 6 mo	61, woman	Loose patella implant	Removal of loose patella implant	3° varus	3° varus

TCMA, tibial component-mechanical axis angle; HKA, hip-knee-ankle.
[a] Outlier according to mechanical alignment criterion.

that unKA TKA had a low 7% reoperation rate for any reason and high function as measured by the FJS and the OKS.

The present study's 93% implant survival for any reason after unKA TKA at 16 years compares favorably or better to other reports of KA and MA TKA. At 7-year follow-up, a study of the combined results from the Australian and New Zealand Joint Replacement Registries reported that 97% of patients with KA TKA and 97% with MA TKA had no reoperations [10]. At 13 years, a randomized trial reported implant survival of 82% after KA TKA and 84% after MA TKA [7]. Two case series of MA TKA reported an implant survival of 85% at 15 years and 82% at 20 years [12,13]. Hence, unKA TKA, which restores the patient's prearthritic joint lines, does not increase the reoperation risk relative to MA TKA at 16 years.

A posterior mechanism causes tibial component failure after unKA TKA, which differs from varus collapse after MA TKA [14–16]. Failure after KA occurs when the posterior slope is excessive relative to the prearthritic stage, which causes flexion space laxity, which can precipitate posterior subsidence of the tibial baseplate or posterior edge wear of the insert [15]. Of the 0.9% (2 of 222) of tibial components that failed in the present study, one had a reverse or less posterior slope than the contralateral knee, and the other was indeterminant as the revision radiographs and the operative note were unavailable. The 0.9% tibial component failure rate is comparable to the 0.2% (1 of 441) KA TKAs revised for insert failure at 7 years, no tibial component failures out of 44 KA TKAs followed for 13 years, and 0.7% (40 of 6,070) tibial component failure rate after MA TKA at 7 years [7,10,17].

There are several explanations for the high tibial component survivorship in unKA TKA with a mean patient surveillance of 12.5 years (range: .3 to 16 years), which might be unexpected since 35% of the tibial components were in >3° varus up to 8° in the present study. The unKA procedure sets the varus-valgus orientation of the tibial component to restore the prearthritic tibial joint line. The maximum 8° tibial varus in the present study did not exceed the maximum 9° varus tibial joint line of the nonosteoarthritic knee reported for a European cohort of 308 patients and an Asian cohort of 100 patients [18,19]. Also, RSA measurement of tibial component migration with varus alignment up to 9° was negligible 1 and 2 years after KA TKA [8,9]. In addition, gait analysis showed that the joint line of an unKA TKA was more parallel to the ground than an MA TKA, markedly reducing the knee adduction moment and risk of medial overload [20]. Finally, unKA TKA performed without releasing ligaments, including the posterior cruciate ligament, restores native knee medial and lateral tibial compartment forces from full extension to 90° flexion [11,21,22], which may not occur in some reports of restricted KA, functional alignment, and MA TKA even after the release of healthy ligaments [23–25].

The 2.2% (5 of 222) minor reoperation rate for patellar complications in the present study is higher than the rate of 0.6% (3 of 441) after unKA TKA and 0.04% (8 of 19,731) after MA TKA at 7-year follow-up, and lower than the 11.3% (5 of 44) after unKA TKA and 6.8% (3 of 44) after MA TKA at 13-year follow-up [7,10]. Limiting flexion of the femoral component to less than 11° relative to the sagittal anatomic axis of the femur might have reduced the risk of reoperation for patella instability and a loosened patellar implant as it promotes early engagement of the patella in the trochlea [26,27]. The mean flexion of the femoral component for the 5 patients was 15°, caused by a surgeon's error in setting poorly fitting femoral patient-specific cutting guides in excessive flexion relative to the preoperative plan. Currently, the preferred technique to reduce the risk of flexing the femoral component is to use a distal cutting block attached to an intrafemoral positioning rod, which reduced femoral component flexion by a mean of 5° degrees relative to the femoral patient-specific cutting guide used in the present study [28].

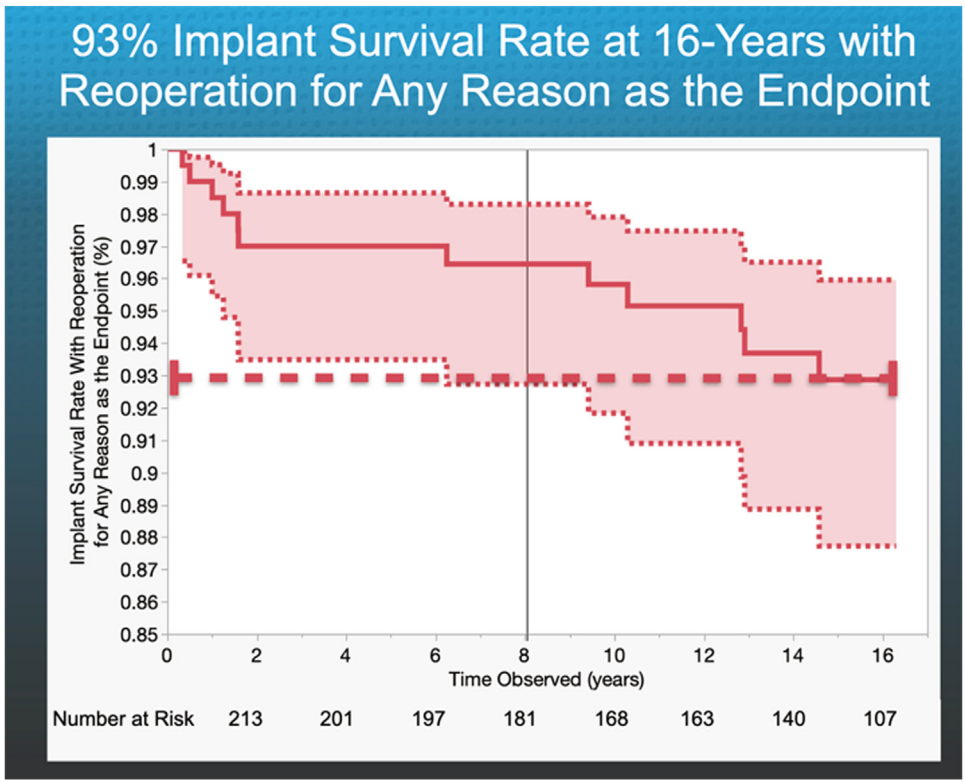

Fig. 2. Kaplan–Meier survival curve shows a 93% survival rate at 16 years with any reoperation as the endpoint.

The high median FJS of 88 points and OKS of 45 points after unKA TKA may be associated with achieving the alignment targets of restoring the patient's pre-arthritic limb, femoral, and tibial phenotypes, which is necessary according to a multi-surgeon study of MA TKA. At one-year follow-up, the MA TKA study reported that patients with a post-operative femoral/limb phenotype within 0 ± 1 of the pre-arthritic category had a 41/32 point better FJS, 8/10 point better OKS, and 16/20 point better WOMAC score relative to those with a post-operative phenotype change of more than one category, respectively [29].

Practitioners of restricted and inverse kinematic alignment and functional alignment are concerned that the risk of reoperation

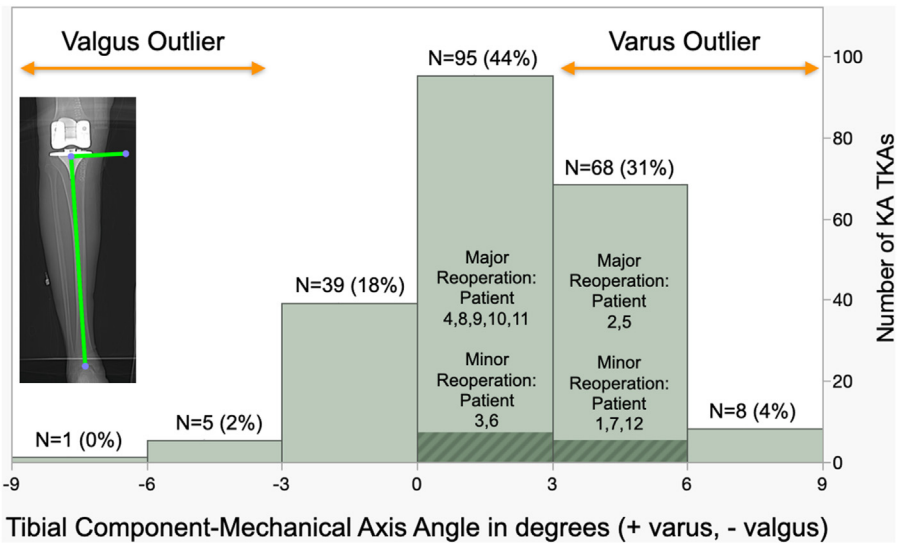

Fig. 3. The distribution of the tibial component-mechanical axis angle shows the number (N) and percentage (%) of kinematically aligned total knee arthroplasties within the in-range (0 ± 3°), varus outlier, and valgus outlier range, and the text overlays identify those patients with a major and minor reoperation (the hatched region in each column) by the number corresponding to their treatment history listed in Table 1.

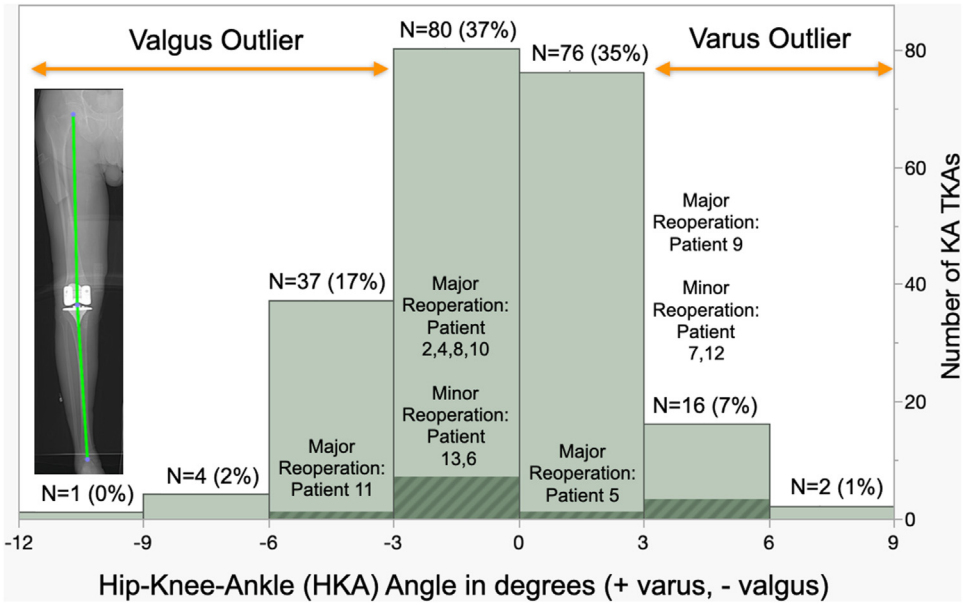

Fig. 4. The distribution of the hip-knee-ankle angle shows the number (N) and percentage (%) of kinematically aligned total knee arthroplasties within the in-range (0 ± 3°), varus outlier, and valgus outlier range, and the text overlays identify those patients with a major and minor reoperation (the hatched region in each column) by the number corresponding to their treatment history listed in Table 1.

could be high in TKAs implanted with "unrestricted" kinematic alignment as the tibial component and limb can be set in >3° varus and in the so-termed 'outlier range' according to mechanical alignment criteria. The 7 major and 5 minor reoperations in the present study, though insufficient in number for statistical analysis, were not confined to the varus outlier categories (>3°). For example, the distribution of KA TKAs according to the tibial component-mechanical axis angle showed more patients who have major reoperations within the in-range category (N = 5) than in the varus outlier range (N = 2) (Figure 3). Similarly, the distribution of KA TKAs according to the hip-knee-ankle angle showed more patients with major reoperations within the in-range category (N = 5) than in the varus outlier range (N = 1) and valgus outlier range (N = 1) (Figure 4). These findings are consistent with Parratte's study of mechanically aligned TKAs that showed a postoperative mechanical axis of 0 degrees ± 3 degrees did not improve the 15-year implant survival rate [13]. Hence our findings support the concept of unKA TKA, which is approved by the U.S. Food and Drug Administration to fully restore the patient's prearthritic joint lines of the knee for 2 implant designs.

The present study has limitations. As with many greater than 10-year follow-up studies, 42% of patients had died, and hypothetically, had the deceased patients lived the entire 16 years, the 7% reoperation rate might have been higher. As knee radiographs were not obtained at 16 years, we could not report the incidence of radiographic signs of loosening in patients without clinical signs of implant failure. Another is that the FJS and OKS were obtained from only 70% of the alive patients at 16 years who had a mean age 77 years and only 49% of the original cohort. The median values might not represent younger patients performing vigorous activities with a higher expectation of a normal feeling and functioning "forgotten" knee.

Conclusions

In conclusion, the survivorship of the tibial component after KA TKA, which set 79% of the tibial components in varus and within the range of nonosteoarthritic knees in Europe and Asia, supports the complete restoration of the prearthritic joint lines without the limits required by restricted KA, inverted KA, and functional alignment TKA.

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