Equivalent Six-Week Knee Motion and Patient-Reported Outcome Scores After Cementless and Cemented Total Knee Arthroplasty with a Kinematic Alignment Optimized Implant

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ABSTRACT

Introduction: Cemented kinematic alignment (KA) total knee arthroplasty (TKA) is popular due to its superior patient-reported outcome scores (PROs). A new cementless version of a KA-optimized implant is available. The femoral component features a 20° trochlear groove and medial spherical articulation. The tibial insert features a medial socket, creating native anterior-posterior stability and a lateral flat articular surface promoting native medial pivot rotation. The present study aimed to determine whether clinical outcomes for patients receiving the cementless KA-optimized implant are equivalent to those receiving the cemented version after six weeks. This comparison is essential because lower PROs could indicate delayed osteointegration of the components, like dysfunction associated with delayed fracture union.

Materials and Methods: The study included 95 cementless KA TKAs matched 1:1 with 95 cemented KA TKAs based on surgery date, age, preoperative knee deformity, sex, and surgeon. Patients completed the Oxford Knee Score (OKS) and the Knee Injury and Osteoarthritis Outcome Score for Joint Replacement (KOOS JR) both preoperatively and at six weeks, as well as the Forgotten Joint Score (FJS) at six weeks. A Wilcoxon two-sided equivalence test was used to test the null hypothesis that results were comparable for the cementless and cemented KA TKAs.

Results: The analysis included 114 females and 76 males, with a mean age of 68 years and a body mass index (BMI) of 31kg/m². Preoperatively and at six weeks, the age, sex distribution, BMI, knee extension and flexion, OKS, and KOOS JR scores for cementless and cemented KA TKAs were equivalent. At six weeks, the FJS scores were also equivalent.

Conclusion: The KA-optimized implant closely resembling native knee morphology did not show evidence of delayed osteointegration. After six weeks, knee motion and PROs were equivalent to those of the cemented implants. However, longer-term monitoring of this new cementless implant is necessary.

INTRODUCTION

Outcome data for newer cementless total knee arthroplasty (TKA) designs have shown mixed results. Registry studies indicate lower survivorship for these designs, while clinical trials have not demonstrated significant differences from cemented designs.[1,2] Therefore, early surveillance of new cementless implant designs is crucial before recommending widespread use.

This study evaluated a new cementless version of a cemented femoral and tibial component optimized for kinematic alignment (KA) that mimics the morphology of the native knee.[3] The KA-optimized implant femoral component features a 20° trochlear groove, that funnels the patella regardless of the orientation variations of the native quadriceps line of force and a medial spherical articulation. The 20° groove increases the likelihood that the quadriceps line of pull is within the groove rather than lateral, which helps to increase the Forgotten Joint Score (FJS).[4-6] The spherical condyle is essential for restoring medial pivot kinematics, like the native knee.[3,7]

The KA-optimized tibial component has an asymmetric configuration to promote maximum bone coverage. When best fit within the tibial resection's cortical boundary, the insert's anterior-posterior axis aligns parallel to the flexion-extension plane of the native knee.[8,9] The tibial insert features a medial socket, creating a ball-in-socket articulation that restores native anterior-posterior (A-P) stability, a lateral flat surface that promotes native medial pivot rotation that restores native patellofemoral kinematics, and the option of retaining or excising the posterior cruciate ligament (PCL).[7,10-12] In randomized trials of KA, the FJS is reported to be 10 points higher when kinematically aligning a medial ball-in-socket and lateral flat articular surface implant without PCL retention compared to a PCL-substituting implant. It is also 16 points higher than a PCL-retaining implant.[13,14]

Ideally, a TKA restores native knee kinematics. This restoration is achievable during daily activities and kneeling when components that mimic the morphology of the native knee are aligned kinematically.[7,15]

However, the medial ball-in-socket design's inherent A-P stability and flexion space tightening due to PCL retention could overload the cementless tibial component-bone interface, potentially affecting early osteointegration. Additionally, KA TKA restores the pre-arthritic tibial joint line, which sets the tibial component in varus according to mechanical alignment (MA) criteria. Although radiostereometric analyses of the cemented version of the KA-optimized implant have shown baseplate stability with up to 10° of tibial varus, the potential adverse effect of a "varus" tibial baseplate alignment from restoring the pre-arthritic joint line on early osteointegration and implant survival of the cementless version has not been investigated.[16-19]

Unlike cemented implants, cementless components do not provide an immediate or guaranteed solid fixation. Delayed osteointegration with the femoral and tibial components, like delayed fracture healing, might be inferred when a cementless cohort shows a poorer return of early knee motion and lower patient-reported outcome scores (PROs) relative to patients with a cemented implant.

Thus, this case-matched study tests the hypothesis that, after six weeks, knee extension, knee flexion, and PROs following KA TKA with a KA-optimized implant and PCL retention will be equivalent between patients with cementless and cemented implants.

MATERIALS AND METHODS

An Institutional Review Board approved a retrospective analysis of deidentified patient data (Pro00084429) obtained from a prospectively archived records database. Each patient met the following criteria before undergoing KA TKA: fulfilled the Centers for Medicare & Medicaid Services guidelines for medical necessity for TKA and presented with Kellgren–Lawrence Grade III to IV osteoarthritis. Patients were treated with any severity of varus or valgus deformity or any degree of flexion contracture. They were excluded if they had a history of knee fractures treated with open reduction and internal fixation, inflammatory or septic arthritis, or lower extremity neurologic disorders.

On the day of the initial consultation, but before seeing the surgeon, each patient filled out the Oxford Knee Score (OKS) (48 best, zero worst) and Knee Injury and Osteoarthritis Outcome Score Joint Replacement (KOOS JR) (100 best, zero worst) and provided patient demographics on an iPad. In addition, the physician assistant measured the knee's extension, flexion, and alignment deformity with a long-arm goniometer and recorded it on the iPad.

In May 2024, two surgeons began receiving a limited inventory of a new cementless version of KA-optimized femoral and tibial components (GMK SpheriKA, Medacta International, Castel San Pietro, Switzerland, www.medacta.com, accessed on November 5, 2023). Patients received the cementless implant with PCL retention when the intraoperative inventory had the patient's correct size. All others received the cemented version. The surgical technique used manual instruments and caliper verification of bone resections to align the components to the articular surfaces of

the patient's pre-arthritic knee through a mid-vastus approach with a reported accuracy greater than robotics and a negligible learning curve for the inexperienced surgeon.[20,21] The details of the three balancing steps, which are gap-balancing the tibial resection to restore a tight rectangular space with a spacer block in extension, restoring the pre-arthritic medial tibial slope, and selecting the optimal insert thickness with an insert goniometer, are previously described.[22,23] Caliper measurements of the bone resections, which confirm the setting of the femoral and tibial components resurfaced the pre-arthritic knee, were recorded intraoperatively on a verification sheet and in the operative note. These measurements verify that the setting of the components met the criteria of KA and provide a quantitative record that the components restored the pre-arthritic joint lines within 0.5mm, which is an accuracy necessary to optimize post-operative OKS and FJS.[24] The surgeon directly impacted the baseplate onto the resected surface without adding autologous bone chips that are reported to be effective in attaching cementless porous-coated total knees (Fig. I).[25]

The cementless KA-optimized femoral component is constructed from a Co-Cr-Mo alloy (ISO 5832-4). It includes a titanium plasma spray coating with a 1000 ± 200μm thickness and a 30% to 70% porosity. Additionally, it fea-

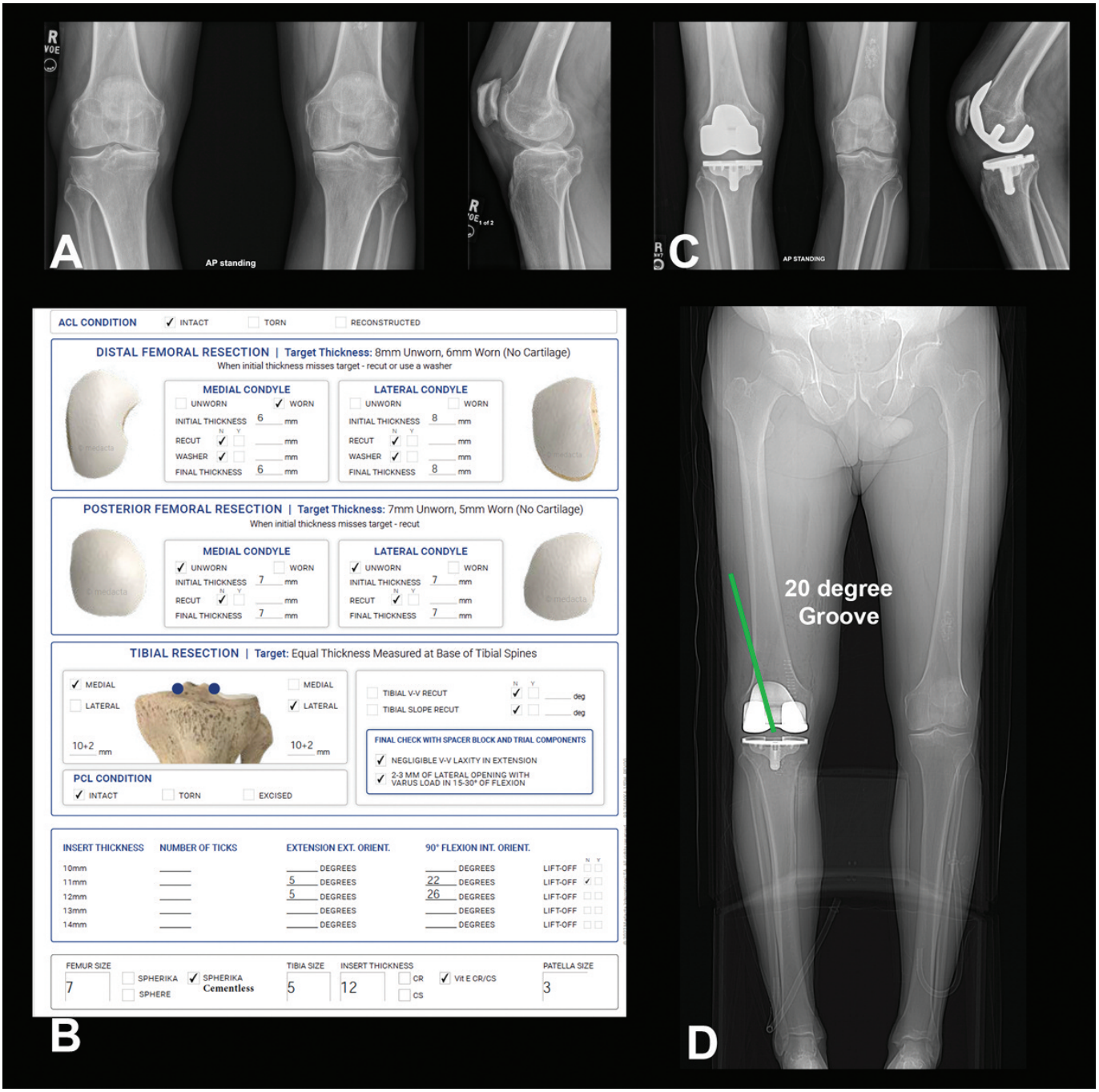

Figure 1. Preoperative weight-bearing radiographs (A), an intraoperative verification sheet documenting the caliper-measured thickness of the femoral and tibia resection thickness (B), postoperative weight-bearing radiographs six weeks postoperatively (C), and a non-weight-bearing long-leg computed tomography (CT) scanogram (D) of a typical patient who underwent a KA TKA with PCL retention.

Table I
Power analysis results for each of the five dependent variables

Dependent Variable	Standard Deviation	Difference to Detect, d	Total Sample Size
Range of Motion			
Extension [27]	6	5	64
Flexion [28]	12	10	64
Patient-Reported Outcome Scores			
Oxford Knee Score [29]	6	5	64
KOOS JR [30]	18	18	44
Forgotten Joint Score [31]	20	14	90

KOOS JR, Knee Injury and Osteoarthritis Outcome Score for Joint Replacement

tures a hydroxyapatite (HA) coating on the titanium plasma spray, measuring 80 ± 20µm in thickness.

The baseplate of the cementless KA-optimized tibial component is made of Titanium Alloy (Ti6Al4V—ASTM F2924). It is manufactured using 3D printing technology, achieving on the underside, stem, and cruciate wings a porosity of 65% and an average pore size of 620µm. The insert features a medial ball-and-socket design and a lateral flat articular surface that closely mimics the anatomy of the native knee.[3] Each patella was resurfaced with a cemented anatomic component.

All patients were treated following a protocol designed to safely discharge individuals aged 50 to 89 from the hospital on the day of surgery, minimizing the readmission risk. The recovery plan emphasized exercises that patients could perform without the guidance of a physical therapist.[26]

Before discharge, patients received instructions on self-administering active range-of-motion exercises, using a walker, and navigating stairs. For the first two weeks post surgery, they were advised to keep their knee elevated above heart level, get up hourly when awake to perform a short walk, and practice knee range-of-motion exercises for a few minutes, focusing on achieving movement between 0 and 90°. Patients were encouraged to stop using the walker when they felt confident.

Patients were prompted to resume their daily activities at the two-week mark gradually. Six weeks after surgery, they completed the same preoperative questionnaires and the FJS, which ranges from 0 (worst) to 100 (best), using an iPad before meeting with the physician assistant. The physician assistant measured postoperative active knee extension and flexion during this appointment using a long-arm goniometer.

Statistical analysis

The first 140 cementless KA total knee arthroplasties were matched to a randomly chosen cemented KA TKA based on several criteria: the date of surgery (within ± 6 weeks), age (within ± 5 years), preoperative knee deformity (either varus or valgus), sex (male or female), and surgeon. Only the matched pairs of cementless and cemented KA TKAs were included in this study.

A sample size calculation was performed using a free online equivalence trial calculator for five dependent variables: knee extension, flexion, OKS, KOOS JR, and FJS (Sealed Envelope, https://www.sealedenvelope.com/power/continuous-equivalence/, last accessed November 1, 2024). The significance level was set at 0.05, and the power (1 - Beta) was established at 90%. The equivalence limits (d) were defined based on the reported minimally clinically important differences for the effect size (d). The values for (d) are as follows: 5° for extension,[27] 10° for flexion,[28] 5 points for the OKS,[29] 18 points for the KOOS JR,[30] and 14 points for the FJS,[31] as detailed in Table I. Therefore, the minimum sample size required for the cementless and cemented cohorts was 90 patients each.

Statistical software was used to calculate the mean and standard deviation (SD) for dependent variables that followed a normal distribution (JMP Pro, 18.0.1, http://www.jmp.com, accessed on December 29, 2024). A Student's T-test was employed to assess the significance of differences. For variables that did not meet this criterion, as determined by a Goodness-of-Fit test, the median and interquartile range (IQR) were calculated. An equivalence analysis using the Wilcoxon test evaluated the null hypothesis that results were comparable for cementless and cemented implants by setting the significance level at 0.05, the power (1 - Beta) at 90%, and the difference to detect (d) based on the reported minimal clinically important differences. The computation established the lower equivalence bound, upper equivalence bound, and maximum p-value and determined equivalence or non-equivalence between patients with cementless and cemented implants. This analysis was performed on knee extension and flexion, the OKS and the KOOS JR at preoperative and six-week follow up, as well as the FJS at six weeks. A Fisher's Exact test was also conducted to evaluate the significance of differences in the proportions of females and males across the cohorts.

RESULTS

Out of the first 140 consecutive cementless KA TKAs performed, 45 cases were excluded because a matching cemented KA TKA could not be found due to strict criteria. Ultimately, 95 patients who received cementless implants were matched with 95 who received cemented implants. The group comprised 114 females and 76 males, with an average age of 69 ± 8 years and a BMI of 32 ± 6kg/m². One of the two surgeons performed 105 of the 190 KA TKAs. The distribution of sex, along with age and BMI, was similar for both the cementless and cemented KA TKAs (Table II). Preoperatively, the knee extension and flexion and the OKS and KOOS JR were equivalent in the cementless and cemented KA TKAs (Table III). At six weeks, both groups showed equivalent knee extension and flexion, OKS, KOOS JR, and FJS (Table IV).

DISCUSSION

The most important finding of the present study, which evaluated the early clinical outcomes of a new cementless version of a KA-optimized implant featuring a 20° trochlear groove, a medial ball-in-socket conformity, and a lateral flat articular surface implanted with

PCL-retention, is that patients with cementless and cemented implants exhibited similar knee extension and flexion and equivalent scores on the OKS, KOOS JR, and FJS six weeks after surgery. The absence of evidence of poorer knee motion and function at six weeks relative to the cemented implant supports the inference that there was no clinical evidence of a delayed osteointegration of the cementless components. This preliminary analysis is reassuring, especially considering that some earlier designs of cementless TKA and registry studies have raised concerns about early failures and unsatisfactory clinical outcomes.[1,32]

The return of knee motion and PROs with unrestricted weight-bearing and self-directed rehabilitation using a cementless KA-optimized implant are comparable to a report of the cemented implant, where 190 patients aged between 48 and 85 were discharged on the same day as their surgery. These patients with cemented implants successfully managed their motion exercises independently, stopped using walkers, and resumed normal activities without assistance from a physical therapist or visiting nurse.[26] In the present study, one patient who underwent cementless KA TKA and another with the cemented implant was readmitted to the hospital. This experience has reinforced our confidence in the safety of performing cementless KA TKA on an outpatient basis, with the expectation of a median

Table II
Differences in preoperative demographics between matched patients who received a cementless or cemented KA-optimized femoral and tibial component implanted using KA and PCL retention

Demographic	Cementless (N=95)	Cemented (N=95)	Significance
Sex (Male/Female)	38/57	38/57	NS, p=1.000 *
Age (Years)	68 ± 8 (range, 49–85)	68 ± 8 (range, 50–87)	NS, p=0.7595 **
Body Mass Index (kg/m^2)	31 ± 6 (range, 18-46)	31 ± 6 (range, 16-45)	NS, p=0.9815 **

Variables reported as a number or mean (standard deviation)
NS: not significant
* Fischer's exact test
** Student's T-Test

Table III
Equivalence results of preoperative knee extension and flexion and patient-reported outcome scores between matched patients who received either a cementless or cemented KA-optimized femoral and tibial component implanted using kinematic alignment with PCL retention

Preoperative Motion and Patient-Reported Outcomes Scores	Cementless (N=95)	Cemented (N=95)	Difference to Detect, d	Result of Equivalent Test, Upper and Lower Equivalence Bounds, and Maximum p-Value
Knee Extension	10° [0°l–12°]	10° [0°–15°]	5°	Equivalent, 5° and -4°, p<0.0001
Knee Flexion	115° [115°–120°]	115° [112°–122°]	10°	Equivalent, 6° and -7°, p<0.0001
Oxford Knee Score	22 [13–27]	19 [12–25]	5 points	Equivalent, 2 and -5, p=0.0364
KOOS JR	47 [34–57]	42 [32–52]	18 points	Equivalent, 5 and -8, p<0.0001

Variables reported as median [interquartile range]
KOOS JR: Knee Injury and Osteoarthritis Outcome Score for Joint Replacement

Table IV
Equivalence results of six-week knee extension and flexion and patient-reported outcome scores between matched patients who received either a cementless or cemented KA-optimized femoral and tibial component implanted using KA with PCL retention

Six Week Motion and Patient-Reported Outcomes Scores	Cementless (N=95	Cemented (N=95)	Difference to Detect, d	Result of Equivalent Test, Upper and Lower Equivalence Bounds, and Maximum p-Value
Knee Extension	0° [0°–3°]	0° [0°–3°]	5°	Equivalent, 10° and -9°, p<0.0001
Knee Flexion	116° [113°–126°]	120° [115°–126°]	10°	Equivalent, 7° and -5°, p<0.0001
Oxford Knee Score	29 [22–37]	29 [23–35]	5 points	Equivalent, 3 and -4, p=0.0002
KOOS JR	59 [52–66]	59 [50–68]	18 points	Equivalent, 8 and -8, p<0.0001
FJS	31 [10–60]	29 [10–54]	14 points	Equivalent, 3 and -4, p=0.0012

Variables reported as median [interquartile range]
KOOS JR: Knee Injury and Osteoarthritis Outcome Score for Joint Replacement; FJS: Forgotten Joint Score

value of knee flexion from 0° to 116° at six weeks.

Surgeons who assess tibial component alignment using MA criteria often mistakenly conclude that cemented TKA KA will result in a higher rate of varus tibial component failure than MA. Multiple international and long-term implant survival surveillance and radiostereometric analyses of baseplate migration of cemented KA TKA do not support this position.[16-19, 33-35] Naturally, there is a responsibility to perform further studies to determine the risk of varus failure of the tibial component and long-term implant survival of this KA-optimized cementless implant.

KA aims to position the cementless and cemented tibial baseplate to resurface the pre-arthritic knee and restore the varus-valgus and posterior tibial slope orientations, achieving biomechanical and biological benefits. For instance, the mechanical properties of the tibial resection surface tend to be more uniform when the orientation planes of the tibial resection parallel the pre-arthritic joint surface compared to those perpendicular to the tibia's long axis, which is a shortcoming of the MA technique.[36] Research involving cadaver tibiae has demonstrated that when the proximal tibia is resected to match the pre-arthritic surface, the load-carrying capacity increases by 40%, and stiffness improves by 70% when compared to cuts made perpendicular to the tibia's long axis.[37] Kinematic alignment procedures that use manual instruments can accurately achieve the varus-valgus orientation of the tibial baseplate within ± 2°.[38,39]

Moreover, tibial components are more prone to subsidence when implanted with an angular deviation in posterior slope of 5° and 8° ± 2° relative to the pre-arthritic orientation.[37,40] Kinematic alignment procedures that use manual instruments can accurately achieve the pre-arthritic slope within ± 2° of the contralateral healthy knee in 85% of cases, which is advantageous, as it allows for internal tibial rotation during flexion in the range of 15° to 19° similar to the native knee.[22,41]

One limitation of the present study is that it does not comprehensively evaluate all patients considered for cementless implants. Several factors influence the osteointegration of these implants, including body mass index (BMI), sex, autoimmune diseases, metabolic bone diseases, and corticosteroid use, among others. The 95 patients treated with cementless implants in this study reflect a typical clinical practice of two surgeons. Those considering cementless fixation should consider the demographics associated with these results, which include a majority of females (60%), a mean age of 68 years (ranging from 49 to 85), and a mean BMI of 31 (ranging from 18 to 46 kg/m²).

Another limitation is that the implantation technique used for the baseplate and the preparation of the stem's porosity, which enabled bone ingrowth, may restrict the generalizability of the findings. The tibial baseplate was intentionally undersized to fit within the cortical rim, so it did not provide additional structural support.[42] Additionally, no cancellous bone chips or slurry were applied between the tibial resection and the baseplate, despite evidence suggesting that these materials could enhance osteointegration.[25] Notably, the stem of the tibial baseplate had a porosity of 65% to encourage bone ingrowth, which is somewhat unique compared to most other cementless baseplates that typically rely on porosity on the underside of the baseplate and peripheral fixation pins for ingrowth.[43] Despite these conditions, patients with cementless implants treated with unrestricted weight-bearing had equivalent six-week outcomes to those with the cemented version.

CONCLUSION

In summary, the preliminary results of the cementless version of the KA-optimized femoral and tibial components that enables PCL retention and excision have eased our concerns regarding potential limitations in the early return of knee motion and undesirable PRO scores compared to the cemented version. Consequently, we will increase the frequency of using the cementless version while accepting there is an inherent responsibility to the patient and fellow surgeons to monitor implant survival through short-term radiostereometric analysis and longitudinal clinical studies.

AUTHORS' DISCLOSURES

Dr. Howell receives grant/research and financial support from Medacta. He is also a consultant and is on the speakers' bureau for Medacta. Dr. Nedopil is a consultant for Medacta. Dr. Hull receives grant/research support from Medacta and is also a paid speaker for Medacta. Mr. Akhtar has no conflicts of interest to disclose.

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