Handheld Navigation Device and Patient-Specific Cutting Guides Result in Similar Coronal Alignment for Primary Total Knee Arthroplasty: a Retrospective Matched Cohort Study

Michael E. Steinhaus, MD · Alexander S. McLawhorn, MD, MBA ·
Shawn S. Richardson, MD · Patrick Maher, MD · David J. Mayman, MD

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Abstract *Background:* Proper alignment of total knee arthroplasty (TKA) is essential for TKA function and may reduce the risk of aseptic failure. Technologies that prevent malalignment may reduce the risk of revision surgery. *Questions/Purposes:* The purpose of this study was to compare two competing TKA systems that purport improved alignment: patient-specific instrumentation (PSI), and a handheld portable navigation device (NAV). *Methods:* After IRB approval, 49 consecutive PSI TKAs (40 patients) were matched based on preoperative characteristics to 49 NAV TKAs (40 patients) performed by a single surgeon. A blinded observer measured alignment on digital radiographs. Operating room records were reviewed for procedure times. Two-tailed paired sample *t* tests and McNemar's test were used as appropriate. Alpha level was 0.05 for all tests. *Results:* Preoperative cohort characteristics were not different. Mean postoperative long-leg mechanical alignment was within $\pm 1^\circ$ of neutral for both groups, although statistically different ($p = 0.026$). There were no other significant

differences in coronal alignment. PSI exhibited significantly greater posterior tibial slope (4.4°) compared to NAV (2.7°) ($p = 0.004$); PSI resulted in significantly more outliers ($>6^\circ$; $p = 0.004$). Procedure time for unilateral TKAs was lower for PSI (74.4 min) compared to that for NAV (80.6 min; $p = 0.023$). *Conclusion:* NAV and PSI technologies provided excellent coronal plane alignment. NAV was better for sagittal tibial slope, while PSI procedure times were shorter for unilateral TKA. The impact of these technologies on patient-reported outcomes and TKA survivorship is controversial and should be the focus of future research.

Keyword computer-assisted surgery · total knee arthroplasty · digital radiography

Introduction

Many studies support that accurate coronal alignment of the mechanical axis is important for the success of total knee arthroplasty (TKA) [4, 12, 19, 35]. Consequently, many surgeons target neutral (0°) overall mechanical alignment in the coronal plane [1]. Conventional intramedullary and extramedullary cutting guides do not reliably achieve this goal [23, 28]. Recent meta-analyses have shown that computer-assisted surgical (CAS) techniques result in more reliable control of mechanical axis alignment in TKA [6, 22], although there are few studies comparing specific CAS techniques [18, 30].

The KneeAlign (OrthAlign Inc., Aliso Viejo, CA) system for TKA is a handheld accelerometer-based navigation device, which seeks to combine the accuracy of CAS techniques with the convenience of smaller, handheld surgical instruments [22]. Previous studies have reported that this device places 95–97% of tibial components within $\pm 2^\circ$ of a neutral mechanical axis [22, 23, 25], and 95% of tibial components are within $\pm 2^\circ$ of 3° of posterior slope [22].

Level of Evidence Therapeutic Study, Level III

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M. E. Steinhaus, MD · A. S. McLawhorn, MD, MBA (✉) ·
S. S. Richardson, MD · D. J. Mayman, MD
Department of Orthopedic Surgery, Hospital for Special Surgery,
535 East 70th Street,
New York, NY 10021, USA
e-mail: McLawhornA@hss.edu

P. Maher, MD
Department of Orthopedic Surgery,
University of Pittsburgh,
Kaufmann Building, 3471 Fifth Avenue, Suite 1010,
Pittsburgh, PA 15213, USA

Extramedullary guides placed 68% of tibial components within $\pm 2^\circ$ of a neutral mechanical axis, and 72% were placed within $\pm 2^\circ$ of 3° of posterior slope [22]. The KneeAlign 2 (KA2; OrthAlign Inc., Aliso Viejo, CA) was developed to aid in the distal femoral resection. One study has demonstrated that KA2 is at least as accurate as a large-console, imageless CAS system in achieving neutral mechanical axis, and tibial and femoral component alignment, and is associated with a significant reduction in tourniquet time [28].

Patient-specific instrumentation (PSI) uses preoperative cross-sectional imaging to create patient-specific cutting guides to improve accuracy and increase efficiency with fewer steps, fewer instrument trays, and shorter surgical times [2, 11, 31]. However, a recent systematic review concluded that PSI for TKA has not reliably improved postoperative limb or component alignment when compared with conventional instrumentation [38]. The VISIONAIRE system (Smith & Nephew, Memphis, TN, USA) combines preoperative magnetic resonance imaging (MRI)-based component templating with an anteroposterior (AP) long-leg preoperative radiograph to improve postoperative mechanical alignment. Compared to computed tomography (CT)-based PSI, MRI-based PSI accounts for residual articular cartilage, which may allow more accurate fit of the PSI cutting guides on the femur and tibia intra-operatively [20]. Yet, studies specific to VISIONAIRE PSI report conflicting results [9, 10, 21, 32, 33, 42].

The purpose of this study was to compare the radiographic results and operative times for the KA2 and VISIONAIRE systems for primary TKA. This study asked the following questions: (1) How does postoperative long-leg mechanical alignment compare for VISIONAIRE and KA2 TKAs? (2) How do the two systems compare on other relevant alignment measures (tibial and femoral component coronal alignment, femorotibial anatomical alignment, and tibial component sagittal alignment)? and (3) How do procedure times compare for the two systems?

Patients and Methods

Institutional review board approval was obtained prior to initiating this retrospective matched cohort study. Forty consecutive patients (29 female, 11 male) who received 49 primary TKAs with the VISIONAIRE system between July 2011 and December 2013 were included. All patients had complete preoperative and 6-week postoperative radiographic studies, demographic data, and intra-operative timing data. All procedures were performed for a primary diagnosis of osteoarthritis of the knee, and the same implant was used for all TKAs (Legion Primary, Smith & Nephew Inc., Memphis, TN, USA). These subjects were matched 1:1 with patients who underwent TKA with the KA2. Matching was performed based on age, gender, body mass index (BMI), procedure laterality, TKA implant, preoperative diagnosis, and preoperative long-leg coronal alignment. KA2 TKAs were performed between May 2012 and May 2013. KA2 patients without preoperative and 6-week

postoperative radiographic studies, missing demographic data, and missing intra-operative timing data were not considered for matching. There were no specific indications for using the VISIONAIRE system over using KA2.

The senior author (DJM) performed all TKAs at an urban specialty hospital. Combined spinal-epidural anesthesia with a saphenous nerve block was used for all cases. A tourniquet was used variably. A standard midline anterior incision was made down to the level of the extensor mechanism, and a medial parapatellar arthrotomy was used to access the joint. The patella was resurfaced in all cases, and the patellar cut was made freehand first. The distal femoral osteotomy was performed prior to the proximal tibial osteotomy. All components were cemented. The same multilayer arthrotomy and wound closures were performed in all cases. The total procedure time was defined as the time between initial incision and skin closure. This time was recorded prospectively in the medical record, and it was available for all included surgeries. Postoperatively, patients were allowed weight-bearing and progressive knee range of motion as tolerated.

The technique used for implementing the KA2 system has been previously described [24, 25, 27, 30]. For the distal femoral resection, the knee was placed in 90° of flexion. The femoral jig-cut block assembly was pinned perpendicular to Whiteside's line against the distal femur, centering the jig over the intercondylar notch, just anterior to the posterior cruciate ligament insertion. The display console and reference sensor were attached to the femoral jig. The center of rotation of the hip was acquired by taking the hip through a series of rotational arcs. The position of the cutting block was determined in both the coronal and sagittal planes and adjusted according to display console feedback. Targets for the distal femoral osteotomy were 0° in the coronal plane (perpendicular to the mechanical axis of the femur) and 3° of flexion in the sagittal plane. The resection depth was set, and the cutting block was pinned to the distal femur. The display console, sensor, and jig were removed, and the distal femoral osteotomy was performed through the cut block. Next, the display console and sensor were attached to the tibial jig. The jig was centered over the medial third of the tibial tubercle, with its proximal aiming probe placed at the center of anterior cruciate ligament footprint. The jig was secured to the tibia with two pins and a spring around the calf. Offset of the aiming probe and jig were registered, followed by registration of the lateral and medial malleoli. Thus, the mechanical axis of the tibia was determined, and orientation of the cutting block was adjusted to 0° of coronal alignment (perpendicular to the mechanical axis of the tibia) and 3° of posterior tibial slope. The cut guide was then pinned to the tibia, and a resection stylus applied to set the depth of the tibial resection. Sizing and final preparation of the femur and tibia were accomplished with conventional instrumentation. Femoral rotation was set perpendicular to Whiteside's line, and tibial rotation was aligned to the middle third of the tibial tubercle and the anterior tibial crest.

The technique for the VISIONAIRE system has been previously detailed [9, 11, 14, 31]. MRI of the operative knee and ipsilateral AP long-leg standing radiograph were

sent to the manufacturer to create tibial and femoral resection guides. Target coronal positioning for both the femoral and tibial implants was perpendicular to the mechanical axis of the limb in the coronal plane. Axial images were used to determine femoral component rotation, which was set parallel to the surgical transepicondylar axis (defined by the medial sulcus and deep medial collateral ligament insertion and the lateral epicondyle), and posterior tibial slope was set to 3° . Preoperative plans were reviewed, modified, and approved by the surgeon. Intra-operatively, the VISIONAIRE jigs were pinned onto the femur and tibia and position assessed against the preoperative plan and conventional anatomical landmarks. Of note, the entire femoral preparation was completed prior to tibial preparation to ensure accurate tibial cutting guide placement. In this series, there were no deviations from the preoperative plan.

Radiographic measurements were completed in a manner previously described [27, 30]. Preoperative standing AP hip-to-ankle radiographs were reviewed, and femorotibial mechanical and anatomical angles were measured (Fig. 1a, b). Postoperative standing AP hip-to-ankle and lateral knee-to-ankle radiographs were obtained for each patient at 6 weeks postoperatively. The postoperative femorotibial mechanical and anatomical angles were measured, along with the coronal mechanical and anatomical alignment of the femoral

component (Fig. 2a, b), and the coronal and sagittal alignment of the tibial component (Fig. 3a, b). A single, blinded observer (SSR, a third-year orthopaedic surgery resident) performed all radiographic analyses using the hospital radiograph picture archiving and communication system (PACS; Sectra Imtec AB, Linköping, Sweden). A single observer was used, since prior studies have demonstrated good to excellent intra-observer and inter-observer inter-class correlation for measurement of the overall long-leg mechanical axis, coronal plane tibial and femoral alignment, and tibial posterior sagittal slope [25, 27, 30]. For convention, varus alignment was recorded as a positive value, while valgus alignment was recorded as negative. Posterior slope of the tibia in the sagittal plane was recorded as a positive value, and anterior slope was recorded as negative. Accuracy of each system was determined by comparing the measured postoperative results to the intra-operative goal, and variances were interpreted as a measure of precision for each cutting guide system. Additionally, error was calculated for each outlier for mechanical femorotibial, femoral, and tibial alignment angles and for posterior slope; error was defined the difference between the target value and the radiographic measurement. A second observer (ASM, an arthroplasty fellow) confirmed all measurements that were labeled as outliers.

Fig. 1. **a** The coronal mechanical femorotibial alignment was measured on standing anteroposterior (AP) hip-to-ankle radiographs. It was defined as the angle subtended by a line from the center of the femoral head, determined by the center of a best fit circle, and the center of the knee and a second line between the center of the knee and the midpoint of the subchondral talar surface. **b** The coronal anatomical femorotibial alignment was also measured on standing AP hip-to-ankle radiographs. It was defined as the angle subtend by a line bisecting the femoral diaphysis and a second line bisecting the tibial diaphysis.

Fig. 2. **a** The coronal mechanical alignment of the distal femur was defined as the mechanical lateral distal femoral angle (mLDFA) less 90°. The mLDFA was measured on standing anteroposterior (AP) hip-to-ankle radiographs. It was defined as the angle subtended by a line from the center of the femoral head, determined by the center of a best fit circle, and the center of the knee and a second line tangent to the distal femoral condyles. **b** The coronal anatomical alignment of the distal femur was defined as the anatomical lateral distal femoral angle (aLDFA) less 90°. The aLDFA was measured on standing anteroposterior (AP) hip-to-ankle radiographs. It was defined as the angle subtended by a line bisecting the femoral diaphysis and a second line tangent to the distal femoral condyles.

Statistical Analyses

Continuous data was summarized as means with standard deviations and ranges, and comparisons between the two cohorts were performed using the two-tailed paired sample *t* test. The Shapiro-Wilk test was used to check continuous data for normality, and Levene's test was used to compare sample variances. Categorical data were summarized as counts and percentages, and comparison of categorical data was completed using McNemar's test. For the long-leg mechanical axis as well as coronal alignment of the tibial and femoral components, $>3^\circ$ was considered a varus outlier, while $<-3^\circ$ was considered a valgus outlier. For femorotibial anatomical alignment, $>2^\circ$ was considered a varus outlier, while $<-8^\circ$ was considered a valgus outlier. For tibial component alignment in the sagittal plane, $>6^\circ$ was considered a posterior slope outlier, while $<0^\circ$ was considered an anterior slope outlier. Inter-observer interclass correlation coefficients (ICCs) were determined for all outlier measurements. All statistical analyses were performed using SPSS Statistics Version 22 for Macintosh (IBM Corp., Armonk, NY, USA). An alpha level of 0.05 was considered statistically significant for all tests.

Results

There were no statistically significant differences between the two groups with regards to age, BMI, gender, laterality, bilateral cases, or preoperative overall mechanical or anatomical alignment (Table 1). Mean long-leg mechanical alignment was $0.7^\circ \pm 2.7^\circ$ and $-0.3^\circ \pm 2.1^\circ$ for KA2 and VISIONAIRE TKAs (Table 2), respectively ($p=0.026$). On average, KA2 TKAs were placed in greater varus and VISIONAIRE TKAs placed in greater valgus (Fig. 4). Differences in varus/valgus outliers were not statistically different. Mean error for the 11 KA2 femorotibial outliers was 2.8° of varus $\pm 4.2^\circ$, and mean error for the five VISIONAIRE outliers was 3.2° of varus $\pm 4.1^\circ$ ($p=0.938$).

The mean mechanical alignment of the tibial component in the coronal plane was similar for both groups (Fig. 5). The proportions of varus and valgus outliers were not different between groups (Table 2), although there were no KA2 tibial outliers and six VISIONAIRE outliers. Further, the variances for tibial alignment were significantly different ($p=0.033$), suggesting that KA2 resulted in more precise tibial alignment. The mean error for the VISIONAIRE outliers was 2.8° of valgus $\pm 3.6^\circ$. The mean mechanical

Fig. 3. **a** The mechanical tibial alignment was defined as 90° less the mechanical medial proximal tibia angle (mMPTA). The mMPTA was measured on anteroposterior (AP) hip-to-ankle radiographs, and it was defined as the angle subtended by a line representing the mechanical axis of the tibia, which was drawn from the midpoint of the subchondral talar surface to the midpoint of the inferior margin of the tibial tray, and a second line drawn tangent to the inferior margin of the tibial tray. **b** Posterior tibial slope was measured on standing lateral tibia-fibula radiographs. It was defined as 90° less the posterior-inferior angle subtended by a line from the midpoint of the subchondral surface of the tibial plafond to the midpoint of the inferior margin of the tibial tray and a second line tangent to the inferior margin of the tibial tray.

alignment of the femoral component in the coronal plane was similar for both groups (Fig. 6). The proportions of varus and valgus outliers were not significantly different. Mean error for KA2 femoral outliers was 2.3° of varus $\pm 3.7^\circ$, and mean error for VISIONAIRE femoral outliers was 2.6° of valgus $\pm 3.9^\circ$ ($p=0.116$). Anatomical femorotibial and femoral alignments were not different between groups (Table 3).

The VISIONAIRE group demonstrated a significantly greater mean postoperative posterior tibial slope of

$4.4^\circ \pm 3.0^\circ$ (range, -3.0° to 11.3°) compared to the KA2 group (Fig. 7), which had a mean postoperative posterior tibial slope of $2.7^\circ \pm 2.1^\circ$ (range, -1.6° to 6.6° ; $p=0.004$). In addition, there were significantly more posterior outliers ($>6^\circ$ posterior tibial slope) in the VISIONAIRE group, with 14 subjects having $>6^\circ$ posterior tibial slope, compared to two patients in the KA2 group ($p=0.004$). There were seven KA2 TKAs (14%) with anterior tibial slope (i.e., $<0^\circ$) and four VISIONAIRE TKAs (8%) with anterior slope ($p=0.549$). Mean

Table 1 Preoperative patient characteristics

	KneeAlign2	VISIONAIRE	<i>p</i> -value
Demographics			
Age, years (mean $\pm$ SD; range)	63.6 $\pm$ 8.3; 50 to 84	63.6 $\pm$ 11.0; 42 to 85	0.948
BMI (kg/m^2) (mean $\pm$ SD; range)	30.2 $\pm$ 5.4; 18.8 to 47.0	30.2 $\pm$ 6.0; 19.1 to 42.3	0.882
Female (<i>n</i> , %)	33, 67.3%	36, 73.5%	0.581
Right (<i>n</i> , %)	25, 51.0%	25, 51.0%	1.000
Bilateral (<i>n</i> , %)	9, 18.4%	9, 18.4%	1.000
Preoperative alignment			
Mechanical long-leg (degrees) (mean $\pm$ SD; range)	2.8 $\pm$ 6.5; -14.9 to 15.9	2.4 $\pm$ 6.2; -11.1 to 13.5	0.454
Anatomical femorotibial (degrees) (mean $\pm$ SD; range)	-4.2 $\pm$ 7.3; -24.3 to 10.1	-4.2 $\pm$ 6.8; -20.1 to 8.3	0.934

SD standard deviation, BMI body mass index

Table 2 Postoperative mechanical alignment

	KneeAlign2	VISIONAIRE	<i>p</i> value
Postoperative long-leg (degrees) (mean $\pm$ SD; range)	0.7 $\pm$ 2.7; -6.9 to 7.7	-0.3 $\pm$ 2.1; -3.7 to 7.4	0.026 ^a
>3° (<i>n</i> , %)	9, 18.4%	4, 8.2%	0.063
<-3° (<i>n</i> , %)	2, 4.1%	1, 2.0%	1.000
Postoperative tibial (degrees) (mean $\pm$ SD; range)	-0.6 $\pm$ 1.3; -3.0 to 2.9	-0.5 $\pm$ 1.9; -6.3 to 4.2	0.595
>3° (<i>n</i> , %)	0, 0%	1, 2.0%	1.000
<-3° (<i>n</i> , %)	0, 0%	5, 10.2%	0.063
Postoperative femoral (degrees) (mean $\pm$ SD; range)	0.1 $\pm$ 1.8; -3.2 to 4.4	-0.4 $\pm$ 1.8; -5.2 to 3.1	0.196
>3° (<i>n</i> , %)	3, 6.1%	1, 2.0%	0.625
<-3° (<i>n</i> , %)	1, 2.0%	3, 6.1%	0.625

SD standard deviation

^a Statistically significant

error for KA2 tibial slope outliers was 2.2° anterior $\pm$ 3.3°, and mean error for VISIONAIRE outliers was 2.9° posterior $\pm$ 4.3° ($p=0.003$). The inter-observer ICCs were excellent for all outlying measurements (Table 4). Variances for all postoperative measurements, other than tibial coronal alignment, were not statistically different (Table 5).

On average, unilateral TKAs were performed significantly faster with VISIONAIRE (74.4 $\pm$ 11.1 min; range, 58 to 116 min) than with KA2 (80.6 $\pm$ 12.7 min; range, 59 to 111 min; $p=0.023$). For bilateral VISIONAIRE TKAs, mean procedure time was 131.8 $\pm$ 17.2 min (range, 107 to 151 min), and it was 140.6 $\pm$ 14.0 min (range, 114 to 156 min) for the KA2 group. The mean procedure times for bilateral procedures were not significantly different ($p=0.206$).

Discussion

Proper alignment is generally regarded as essential for the long-term success of TKA [1, 11, 35]. Thus, techniques that improve alignment postoperatively may reduce the risk of revision surgery [39]. Multiple competing technologies exist which purport to improve alignment for TKA but have

variable success [7, 18, 38]. This study sought to compare two commonly used advanced technologies for TKA: VISIONAIRE PSI, and KneeAlign 2, a handheld accelerometer-based navigation device. Both systems achieved mean postoperative mechanical alignment within $\pm 1^\circ$ of neutral, tibial, and femoral component coronal alignment within $\pm 1^\circ$ of neutral, and similar femorotibial anatomical alignment. PSI TKAs in this series tended to be aligned in relatively more valgus than KA2 TKAs, which were on average in more overall varus. VISIONAIRE TKAs had significantly greater posterior tibial component slope with more outliers having posterior slope $>6^\circ$ than the KA2 group. Unilateral VISIONAIRE TKAs were performed on average 6 min faster than KA2 TKAs, but there was no significant difference observed for bilateral procedure times.

This study has several limitations. First, it was retrospective and includes a small number of subjects treated by a single surgeon with a single implant. Patients were not randomized to either TKA system, which introduces the possibility of selection bias. However, patients were matched with similar baseline characteristics, and the senior surgeon is a high volume provider with extensive experience with both TKA systems and there was no specific indication

Fig. 4. These histograms illustrate the distribution frequency of the mechanical femorotibial alignment for KneeAlign 2 (KA2) and VISIONAIRE (patient-specific instrumentation [PSI]) total knee arthroplasties (TKAs). Positive values are varus, and negative values are valgus.

Fig. 5. These histograms illustrate the distribution frequency of the mechanical medial proximal tibial alignment (MPTA) for KneeAlign 2 (KA2) and VISIONAIRE (patient-specific instrumentation [PSI]) total knee arthroplasties (TKAs). Positive values are varus, and negative values are valgus.

for using one system over the other. The single implant served as a control, limiting any variation that might accompany different devices, but may limit the study's generalizability. Second, the amount of experience required to gain proficiency with these systems is not known. However, computer-based navigation systems have been shown to have a fast learning curve, with initial longer operative and tourniquet times [8, 17, 37]. The KA2 system is similar to conventional extramedullary guides and is therefore simple to learn, with orthopedic surgeons showing substantial reduction in procedure time after experience with just four cadavers [26]. Third, slight variations in limb position during acquisition of radiographs can affect alignment measurements [40]. Computed tomography can measure alignment controlling for variations in limb position. However, CT is

associated with numerous downsides (e.g., increased patient radiation, greater cost, and implant artifact that can prevent precise measurements), and prior studies have shown measurements on radiographs to be reliable and reproducible [25, 27, 30, 40]. It should be noted that reliance on two-dimensional radiographs in this study prevented assessment of sagittal femoral alignment and rotational alignment of both the tibial and femoral components. PSI may offer specific benefit for axial component alignment [20], but we were unable to investigate this postoperative parameter using plain radiographs. Fourth, a single observer measured all radiographs once, but the inter-observer ICCs were high for outliers. Although intra-observer ICCs were not determined in this study, good to excellent intra-observer and inter-observer ICCs for measurement of the overall long-

Fig. 6. These histograms illustrate the distribution frequency of the mechanical lateral distal femoral alignment (LDFA) for KneeAlign 2 (KA2) and VISIONAIRE (patient-specific instrumentation [PSI]) total knee arthroplasties (TKAs). Positive values are varus, and negative values are valgus.

Table 3 Postoperative anatomical alignment

	KneeAlign2	VISIONAIRE	<i>p</i> value
Postoperative femorotibial (degrees) (mean $\pm$ SD; range)	-6.5 ± 3.4 ; -15.0 to 2.8	-6.9 ± 3.2 ; -11.9 to 6.5	0.549
Postoperative aLDFA (degrees) (mean $\pm$ SD; range)	-6.0 ± 2.4 ; -10.3 to 0.3	-6.5 ± 2.0 ; -13.5 to -3.9	0.244
>2° (<i>n</i> , %)	0, 0%	0, 0%	1.000
<-8° (<i>n</i> , %)	9, 18.4%	8, 16.3%	1.000

SD standard deviation, aLDFA anatomical lateral distal femoral angle

leg mechanical axis, coronal plane tibial and femoral alignment, and tibial posterior sagittal slope have been previously published [25, 27, 30]. Fifth, while neutral mechanical alignment is generally regarded as the target for TKAs [1], the importance of neutral mechanical alignment for modern TKAs has been questioned [33], and alternative targets have been proposed [15, 16]. Finally, this study did not examine patient-reported outcomes, implant survivorship, or cost data, which are additional factors influencing decision-making regarding the adoption of new health care technologies.

This study demonstrates that excellent overall mechanical alignment can be obtained with both the VISIONAIRE and KA2 systems. In a recent study comparing the KA2 and a large console, imageless CAS system, the mean mechanical alignment was -0.1° with 92.5% of TKAs in the KA2 cohort implanted within $\pm 3^\circ$ of neutral mechanical alignment [30]. Interestingly, a greater proportion of KA2 subjects in our study (22.5%) were varus/valgus outliers than in this study (7.5%), the reasons for which are unclear. The current VISIONAIRE femorotibial mechanical alignment results are similar, if not better, than those reported by prior studies. Pfitzner et al. compared MRI- and CT-based PSI with conventional instrumentation and found a 1.0° variation from neutral alignment in the VISIONAIRE group with a 7% outlier frequency ($\pm 3^\circ$ from neutral) [34]. Similarly, Noble et al. compared VISIONAIRE to conventional instruments in a prospective randomized study, reporting 1.7° variation from neutral alignment [31]. Finally, Daniilidis

et al. found an average hip-knee-ankle angle of 2.5° from neutral for subjects with VISIONAIRE, with an outlier ($\pm 3^\circ$ from neutral) frequency of 11% [11], similar to the 10.2% outlier frequency in our study.

In terms of specific component alignment, this study found excellent mean alignment for both groups, with both systems achieving means within 1° of neutral mechanical alignment for both the tibia and femur. For the tibial component, there were no outliers in the KA2 group, while 12.2% of VISIONAIRE subjects had tibial alignment outside of $\pm 3^\circ$ from neutral; for the femoral component, 92% of subjects in each group had femoral alignment within $\pm 3^\circ$ of neutral. Nam et al. also reported excellent results with KA2, noting 0.04° variation from the tibial mechanical axis with no outliers (beyond $\pm 3^\circ$ from neutral), and -0.1° variation from femoral mechanical axis with 1.3% outliers (beyond $\pm 3^\circ$ from neutral) [30]. Prior literature pertaining to VISIONAIRE TKAs is conflicting, with some studies reporting good results [9, 10, 34] and others reporting unsatisfactory results [21, 32, 40].

In two studies of the VISIONAIRE system, Conteduca et al. noted tibial component alignment in the coronal plane of 1.2° with satisfactory alignment ($\pm 2^\circ$ from neutral) in 83.3%, and femoral component alignment of 1.2° with satisfactory alignment ($\pm 2^\circ$ from neutral) in 92.6% [9, 10]. Pfitzner et al. reported similar findings, with tibial component alignment of 1.0° , with a 3% outlier ($\pm 3^\circ$ from neutral) rate, and femoral component alignment of 1.0° , with a 3% outlier ($\pm 3^\circ$ from

Fig. 7. These histograms illustrate the distribution frequency of the sagittal tibial slope for KneeAlign 2 (KA2) and VISIONAIRE (patient-specific instrumentation [PSI]) total knee arthroplasties (TKAs). Positive values indicate posterior sagittal slope, and negative values indicate anterior sagittal slope.

Table 4 Inter-observer intra-class correlation coefficients for outliers

	N	ICC	95% CI	
			Lower bound	Upper bound
Total	74	0.993	0.989	0.995
aLDFA	17	0.852	0.636	0.944
mLDFA	8	0.991	0.957	0.998
Long-leg	16	0.977	0.923	0.993
Tibia	27	0.984	0.966	0.993
Slope	6	0.988	0.916	0.998

ICC intra-class correlation coefficient, CI confidence interval, aLDFA anatomical lateral distal femoral angle, mLDFA mechanical lateral distal femoral angle

neutral) rate [34]. However, Lustig et al. reported alignment within 3° of the planned position only 55–79% of the time for coronal, sagittal, and surgical transepicondylar axes [21], while Ollivier et al. and Victor et al. reported having to abandon VISIONAIRE intra-operatively in 17.5 and 22% of TKAs, respectively, due to unsatisfactory alignment [32, 42]. Some of the variability in results may relate to particular surgical methods or to the reference standard used to assess error. For example, in the present study, the entire femoral preparation was completed first in order to optimize placement of the tibial cutting guide. Further, some studies used postoperative imaging as the reference standard [34], while others used intra-operative assessments based on computer-assisted navigation instruments [21, 32, 42].

In the sagittal plane, the KA2 group achieved an average slope closer to 3° of posterior slope (2.7°) compared to the VISIONAIRE group (4.4°). In addition, there were more posterior outliers (>6° posterior slope) in the subjects with VISIONAIRE TKAs (18.4%) than with KA2 TKAs (0%), with similar rates of anterior outliers (<0° posterior slope) in both groups (8.2% for VISIONAIRE, 14.3% for KA2). In a recent study of the KneeAlign device, Nam et al. reported a mean posterior slope of 3.3°, with 95% of tibial components within 2° of 3° posterior slope [24]. Achieving satisfactory sagittal alignment appears to be particularly difficult with PSI systems. In two studies of VISIONAIRE, Conteduca et al. reported mean deviation of 1.16° to 3.8° from a posterior tibial slope of 3°, with satisfactory alignment ($\pm 2^\circ$ from 3° posterior) in only 41.6% of subjects [9, 10], while Lustig et al. and Victor et al. reported satisfactory alignment of tibial slope ($\pm 3^\circ$ from 3° posterior) of 80.7 and 78.7%, respectively [21, 42]. Yet, Pfizner et al. reported 1.0° deviation from 3° of posterior slope, with an

outlier rate ($\pm 3^\circ$ from 3° posterior) of only 10% [34]. Other authors have speculated that posterior slope may be more variable with PSI, since a lateral radiograph is not used for the preoperative plan [9]. In particular, the VISIONAIRE system limits the sagittal assessment of the tibia to 11 cm distal to the joint line. Therefore, variation in native posterior tibial slope can lead to variability in the posterior slope of the tibial resection [21]. In contrast, posterior slope for the KA2 is determined relative to the overall mechanical axis of the tibia, which is defined by the center of the anterior cruciate ligament footprint proximally and the center of the tibial plafond distally, as approximated through weighted interpolation between points registered on the medial and lateral malleoli [24].

The clinical relevance of improved radiographic alignment over conventional TKA is controversial, with both the short-term and long-term benefits of these technologies remaining unclear. In their study of VISIONAIRE TKAs, Pfizner et al. reported no difference in Knee Society pain and function scores and Western Ontario and McMaster Universities Arthritis Index (WOMAC) for the PSI and conventional TKA groups at 3 months postoperatively [34]. Similarly, Nam et al. report no benefit in range of motion or patient-reported outcomes for PSI compared to conventional TKAs, as well as no difference in the number of outliers ($\pm 3^\circ$ from neutral) for long-leg alignment, at a mean follow-up of greater than 2 years [29]. Other studies have noted similar findings [43, 44]. Results from the Australian Orthopaedic Association National Joint Replacement Registry found that use of computer navigation for primary TKA was associated with a reduction in the overall rate of revision and the of rate revision for aseptic loosening in patients less than 65 years of age [39], but results from the New Zealand National Joint Registry suggested a statistically insignificant trend toward greater revision rates for TKAs performed in the same age group with navigation compared to conventional instrumentation [36].

Finally, mean procedure time for unilateral VISIONAIRE TKAs were slightly shorter than for unilateral KA2 TKAs (74.4 vs. 80.6 min). There were only nine bilateral cases for each TKA system. Therefore, the study may have been underpowered to demonstrate a difference in procedure times for bilateral TKAs, especially since the differences were small. Nam et al. reported mean tourniquet times that were 6 min shorter for KA2 TKAs than for CAS TKAs [30]. A recent systematic review on PSI reported mixed findings in terms of procedure time [38]. Of the level I studies, one reported no difference in operative time [13], and others noted differences of only 5–7 min for PSI compared to conventional methods [5, 31].

In conclusion, in the hands of an experienced surgeon, both KA2 and VISIONAIRE technologies can provide clinically equivalent mechanical alignment in the coronal plane. The KA2 appears to be superior for sagittal tibial slope, while VISIONAIRE affords shorter procedure times for unilateral TKAs. While PSI may be associated with reduced procedure time and the use of fewer trays, these differences may not be clinically significant, and increased preoperative planning requirements may negate these benefits. While these technologies provide accurate mechanical alignment,

Table 5 Comparison of variances (precision)

	Levene statistic	p value
Anatomical femorotibial angle	0.646	0.424
Mechanical femorotibial angle	3.885	0.052
Anatomical LDFA	1.082	0.301
Mechanical LDFA	0.098	0.755
Medial proximal tibial angle	4.678	0.033
Tibial slope	3.458	0.066

LDFA lateral distal femoral angle

the impact on patient outcomes [34, 43, 44], costs [3, 41], and implant survivorship [36, 39] remains unclear. Since these technologies appear to achieve improved alignment compared to published series using conventional instrumentation [24], they are likely the appropriate tools to investigate the merits of alternative alignment targets, such as kinematic alignment [15, 16]. Future research should include larger sample sizes, focus on rotational and alternative alignment targets using these technologies, and determine long-term patient outcomes and implant survivorship.

Compliance with Ethical Standards

Conflict of Interest: Michael E. Steinhaus, MD; Alexander S. McLawhorn MD, MBA; Shawn S. Richardson, MD; and Patrick Maher, MD have declared that they have no conflict of interest. David J. Mayman, MD reports grants and personal fees from Stryker/Mako and Smith & Nephew, other from OrthAlign, outside the work.

Human/Animal Rights: All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2008 (5).

Informed Consent: Informed consent was waived from all patients for being included in the study.

Required Author Forms Disclosure forms provided by the authors are available with the online version of this article.

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