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Original Research

# The Role of Imageless Computer-Assisted Navigation During Total Knee Arthroplasty on Femoral Component Sagittal Alignment and Outcomes

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## ABSTRACT

*Background:* While total knee arthroplasty (TKA) is highly successful, 15%-20% of patients are not satisfied postoperatively, which may be due to alignment of the TKA components. Imageless computer navigation was developed to increase implant alignment accuracy and precision, but controversy surrounds the patient benefit of this technology. The target of femoral sagittal alignment and its role in patient-reported outcomes (PROMs) after TKA using assistive technology has not been well-defined.

*Methods:* Femoral sagittal alignment, 30-day complications, and PROMs through 1 year were collected retrospectively from unilateral elective TKA patients who underwent surgery between July 2020 and February 2023. Two surgeons equally versed in conventional and imageless navigation techniques participated in patient record identification. Students *t*-tests and chi-square tests of proportion were used to compare outcomes, 30-day complications, and alignment.

*Results:* Completed PROMs were available for 387 patients; 181 in the computer navigation group and 206 in the conventional arthroplasty group. PROMs were statistically significantly different between groups, favoring computer navigation (P = .014 at 12 months). Lateral femoral angle measurements were greater in females who underwent TKA with computer navigation (P < .001). Of note, 14 patients in the conventional technique group returned to the emergency department within 30 days, as compared to 4 in the navigation group (P = .033).

*Conclusions:* PROMs are improved in the navigation group compared to the conventional technique group. Fewer patients in the navigation group returned to the emergency department. Navigation appeared to provide a small benefit compared to conventional techniques, though final lateral femoral angle was not predictive of outcomes. Additional surgical characteristics may need to be examined to determine the reasons for the differences in outcomes between these techniques.

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#### Introduction

Total knee arthroplasty (TKA) is a highly successful and effective procedure for end stage osteoarthritis [1,2]. Unfortunately, 15%-20% of patients are not satisfied following their surgery, experiencing pain and instability, as well as an awareness of the artificial nature of their joint [2-5], which may be due, in part, to the increased mechanical demands patients are placing on their TKA [6].

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Restoration of Macquet's line to neutral is one of the goals of TKA, such that the centers of the femoral and tibial components are both positioned along the mechanical axis in coronal and sagittal planes [6,7]. Therefore, postoperative alignment of a TKA should ideally be within  $0^{\circ} \pm 3^{\circ}$  of the mechanical axis in both planes [6,8]. A randomized control trial in 2009 by Choong *et al* [9] found that knees aligned within 3 degrees in the coronal plane had superior patient-reported outcomes (PROMs) and better functional scores at 1 year.

When TKA components are misaligned, the patient may experience component loosening, reduced TKA lifespan due to abnormal wear patterns, reduced functional outcomes, and the need for revision surgery [7,10,11]. Tibial component alignment in

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the sagittal plane, and coronal alignment of both components has been extensively reported on in the arthroplasty literature. Femoral component sagittal alignment has been minimally reported, particularly in relation to PROMs. A targeted femoral sagittal alignment has been proposed to be  $0^{\circ}-3^{\circ}$  of flexion based on analysis of native distal femoral flexion [12]. In order to minimize the chance of malalignment, imageless computer-assisted navigation has been used to assist during TKA [6,8] in order to increase implant alignment, and decreasing outliers [8,13,14].

Controversy surrounds imageless computer assisted navigation, as recent literature reviews have indicated few benefits over conventional TKA, as the impact of imageless navigation on functional outcomes and radiographic endpoints is not clear [6]. Imageless navigation has also been associated with longer operating time and higher cost [6].

The purpose of this study was to evaluate the ability of an imageless computer-assisted navigation system to place femoral components precisely in patients undergoing TKA. Patient outcomes, intraoperative measures, and postoperative complications were also measured. This research will add to the growing evidence base surrounding the use of this technology in TKA. We hypothesize that the use of computer navigation will result in fewer alignment outliers and equivalent or better patient outcomes than conventional methods.

#### Material and methods

In this retrospective, single-center study, patients who underwent a TKA using conventional techniques were compared to those who underwent a TKA using computer-assisted navigation. During surgery, navigation was used to make the distal femur cut only. A target of  $0^{\circ}$  in the coronal plane and  $5^{\circ}$  of flexion in the sagittal plane was utilized. Five degrees were chosen to avoid notching and for anatomical flexion of the femoral component. The rationale for "femoral only" navigation use was to avoid Intramedullary



**Figure 1.** Lateral femoral sagittal angle measurement example. Example lateral view X-ray with red lines indicating the sagittal distal femoral axis and the perpendicular axis of the femoral component.

#### Table 1

Demographics for the navigation and conventional groups.

Demographics	Navigatio n = 181	n	Convention n = 206	onal	P value
Female gender	62.4%	113	66.9%	138	.879
Age (v)	68.9	±8.9	69.1	±8.5	.833
Body mass index $(kg/m^2)$	33.2	±6.2	32.9	±6.3	.689
Race		_		_	<.001
American Indian	0%	0	0%	1	
Asian	1%	1	2%	4	
Black or African American	2%	4	7%	15	
Pacific Islander	0%	0	0%	0	
Multiracial/Other	1%	2	6%	13	
White or Caucasian	96%	174	83%	170	
Unknown/Patient Refused	0%	0	1%	3	
Ethnicity					.129
Hispanic or Latino	2%	3	5%	11	
Not Hispanic or Latino	97%	175	92%	190	
Unknown/ Patient Refused	2%	3	2%	5	
ASA score					
1	0%	0	0%	0	
2	55%	100	31%	63	
3	44%	80	25%	51	
4	0%	0	0%	0	
Unknown	0%	1	45%	92	
Laterality	43% Left	78	54% Left	112	.027
Surgery time (min)	78	±12.6	77	±15.1	.499
Length of stay (d)	2.09	±0.46	2.17	±0.56	.147
Anesthesia type					.105
General	1%	2	5%	10	
Regional	1%	2	1%	2	
Spinal	98%	177	94%	194	
Pain levels					
Activity	4.32	±1.59	4.27	±1.58	.783
At rest	2.87	±1.45	2.86	±1.46	.960
Complications					
ED visit	2%	4	7%	14	.033
Readmission	1%	1	2%	4	.227

ASA, American Society of Anesthesiologists; ED, emergency department. Bold values indicate statistical significance (P < .05).

instrumentation, and that the femoral head is the only alignment landmark during TKA that is not visible. Tibial alignment was not registered, though tibial slope may influence outcomes. All operations were done via a medial parapatellar approach utilizing cruciate retaining or posterior stabilized implants. The majority of the implants were cruciate retaining implants, and the decision of cruciate retaining or posterior stabilized was based on clinician preference. Approximately two-thirds of the implants were Zimmer Persona and one-third were Smith and Nephew Genesis II, again per surgeon preference, and were equally distributed among both groups. Two surgeons who were equally well-versed in both conventional and navigated techniques participated in the study. The decision to use computer assistance or conventional alignment methods was due to surgeon preference or equipment availability. This study was approved by our institutional review board (HHC-2023-0112).

Patients aged 18-89 years, who were undergoing a unilateral TKA between July 2020 and February 2023 were included. If patients underwent a revision or conversion TKA, they were excluded, as were all patients who underwent a unicompartmental TKA.

Table 2KOOS scores for the Navigation and Conventional Groups.

KOOS	Preoperative	12 wk	6 mo	1 y
Navigation	52.37 ± 12.6	69.86 ± 12.1	74.54 ± 13.0	77.85 ± 12.9
Conventional	51.05 ± 13.0	67.05 ± 10.5	72.01 ± 12.5	73.87 ± 14.9

KOOS, Knee Injury and Osteoarthritis Outcome Score.

Table

 Table 3

 PROMIS-10 scores for the navigation and conventional groups, subdivided by the physical function and mental health domains.

PROMIS-10 scores	Preoperative	12 wk	6 mo	1 y
Physical function PROMIS-10				
Navigation	$42.87 \pm 6.2$	$48.14 \pm 6.6$	$49.80 \pm 7.2$	$49.58 \pm 7.3$
Conventional	$43.25 \pm 7.0$	$47.84 \pm 6.7$	49.31 ± 7.7	$48.63 \pm 8.0$
Mental health				
PROMIS-10				
Navigation	51.76 ± 7.8	$53.39 \pm 7.4$	$53.68 \pm 7.9$	$52.85 \pm 8.1$
Conventional	$50.97 \pm 8.0$	$52.16 \pm 7.8$	$52.55 \pm 8.3$	$51.31 \pm 7.9$

PROMIS-10, patient-reported outcome measure information system.

Patients who did not complete preoperative PROMs were also excluded. There were 387 patients who met eligibility criteria.

All patients were given the Knee Injury and Osteoarthritis Outcome Score for Joint Replacement (KOOS JR) and the Patient-Reported Outcome Measure Information System (PROMIS-10) preoperatively, at 12 weeks, 6 months, and 1 year, as is standard of care.

At the first postoperative appointment, which occurs approximately 2 weeks postsurgery, 3 radiographs were taken, as per standard of care. A weight bearing antero-posterior view, a lateral view, and a patellofemoral view were obtained. The lateral X-ray was used to evaluate femoral sagittal alignment. The imaging analysis was performed by a trained research assistant and validated by the senior surgical team. The alignment of the femoral component was evaluated using the knee society radiographic evaluation method, evaluating the angle between the most distal femoral fixation surface with respect to the axis of the femoral shaft [15], as seen in Figure 1.

Chi-square tests of proportion were used to compare categorical variables, such as readmission or the presence of a surgical complication. Continuous variables, like length of stay or operative time, were compared using independent group's *t*-tests. Count data or frequency-based items are presented as medians and ranges, while continuous data are presented as means and standard deviations. PROMs at each set of time points were compared using paired *t*-tests. Femoral sagittal alignment angle measurements



**Figure 2.** Lateral femoral measurements, subdivided by navigation type, and sorted by gender. Patients in both the conventional and navigation groups were further subdivided by gender. Purple box plots show the range of lateral femoral sagittal angle measurements. The lateral femoral angle is statistically significantly greater in females undergoing TKAs with navigation (5.8° vs 4.4°,  $P \le .001$ ). TKA, total knee arthroplasty.

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KOOS scores for females in the navigation and conventional groups
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KOOS Female only	Preoperative	12 wk	6 mo	1 y
Navigation Conventional	52.71 ± 13.0 51.01 ± 12.9	69.99 ± 11.5 67.54 ± 11.5	75.50 ± 13.3 72.91 ± 13.3	78.67 ± 11.7 75.31 ± 15.4

KOOS, Knee Injury and Osteoarthritis Outcome Score.

were binned into 3 groups,  $0^{\circ}$ -3.5°, 3.6°-7°, and >7° for subsequent analysis. This midpoint range was set based on the stratification of the data.

All analyses will be conducted using Excel 2016 (Microsoft) or Stata, version 17 (StataCorp). All results yielding P < .05 were considered to be statistically significant.

## Results

Out of the 387 patients who met eligibility criteria, 181 were in the computer navigation group and 206 were in the conventional arthroplasty group. Patient demographics are shown in Table 1. There is no difference seen in sex, age, body mass index, or ethnicity between groups. More patients who identify as Black or African American or as multiracial were in the conventional arthroplasty group (P < .001). Surgical parameters were also assessed. American Society of Anesthesiologists (ASA) scores were similar across groups. Surgical time was not different between the groups, with the average surgical time being 1 minute longer in the navigation group (Table 1). Additionally, the anesthesia type was similar in both groups. Pain levels were also equivalent in both groups, both at rest (P = .960) and with activity (P = .783). More patients in the conventional arthroplasty group had left knees operated on (54 vs 43%, P = .027).

Preoperatively, there was no difference seen in KOOS or PROMIS-10 scores between those patients for which navigation was used as compared to those for which conventional arthroplasty was used (Tables 2 and 3). KOOS scores showed that at 12 weeks (P = .015), 6 months (P = .052) and 1 year (P = .014), there is a statistically significant difference favoring computer navigation (Table 2). This difference remains small (approximately 2.5 points) until the



**Figure 3.** KOOS scores were not dependent on lateral femoral angle in either the conventional or navigation groups Patient lateral femoral angles were divided into 3 ranges (0°-3.5°, 3.6°-7°, and 7.1°+) and KOOS JR scores were evaluated in the conventional and navigation groups. Preoperative KOOS scores are shown in blue, 12-week KOOS scores in red, 6-month KOOS scores in green, and 12-month KOOS scores in yellow. KOOS, Knee Injury and Osteoarthritis Outcome Score.

Table 5KOOS scores for males in the navigation and conventional groups.

KOOS Male only	Preoperative	12 wk	6 mo	1 y
Navigation	51.82 ± 12.1	$\begin{array}{c} 69.64 \pm 13.2 \\ 66.06 \pm 8.0 \end{array}$	72.95 ± 12.5	76.61 ± 14.7
Conventional	51.12 ± 13.3		70.19 ± 10.7	70.86 ± 13.3

KOOS, Knee Injury and Osteoarthritis Outcome Score.

1-year mark, where there is a 5-point difference between groups (Table 2). PROMIS-10 scores, both mental health and physical health domains, remained not statistically significantly different at all time points (Table 3).

Lateral femoral angle measurements were stratified by navigation type and further subdivided by gender. In both cases, females who underwent a computer-navigated TKA had a higher lateral femoral angle measurement (5.8° vs 4.4°,  $P \le .001$ ) than females who had a TKA using conventional techniques (Fig. 2). Males did not show a significant difference in lateral femoral angle measurements (4.5° vs 4.3°, P = .607) when comparing computer navigation to conventional TKA techniques (Fig. 2). KOOS scores were not significantly different in females in the navigation and conventional groups, though the navigation group trended about 3 points higher at the 1-year time point (KOOS preoperative [P =.302], 12 weeks [P = .094], 6 months [P = .125], and 1 year [P = .100]) (Table 4). In male patients, there is a statistically significant difference in KOOS scores at 1 year (P = .033) of approximately 6 points; however, the other time points were not statistically significantly different (KOOS preoperative [P = .749], 12 weeks [P = .058], and 6 months [P = .168]), see Table 5.

Lateral femoral angles were further subdivided into  $3.5^{\circ}$  ranges (0°- $3.5^{\circ}$ ,  $3.6^{\circ}$ - $7.0^{\circ}$ ,  $7.1^{\circ}$ +) and KOOS were assessed for each lateral femoral angle range. There were no statistically significant differences in KOOS scores for each range and time point tested between the conventional and the navigation groups (Fig. 3, Table 6), indicating that the positive change in KOOS scores seen in the navigation group was across all lateral femoral angle ranges.

Emergency department (ED) visits and readmissions were assessed 30 days post index surgery for both groups. There are stark differences between the conventional and navigation groups. Statistically significantly more patients from the conventional group went back to the ED (P = .033) and a larger number were readmitted (Table 1). In the navigation group, 2 patients returned to the ED for constipation. One returned for leg pain, and 1 returned for palpitations. The 1 admission in the navigation group was due to an exacerbation of chronic congestive heart failure secondary to severe aortic stenosis. In the conventional group, 14 patients returned to the ED and 4 were readmitted. Reasons for ED visits were varied, but there were 3 with cardiovascular complaints, 3 with urinary complaints (urinary retention or infection), 3 with pain

exacerbation, 2 patients with constipation, 2 with wound dehiscence, and 1 prosthetic joint infection. Of those who were readmitted, 2 of the patients with cardiovascular concerns were subsequently diagnosed with a pulmonary embolism and 1 non-STelevation myocardial infarction, respectively. The prosthetic joint infection patient was readmitted for a debridement, as was one of the patients who presented with wound dehiscence.

## Discussion

Small but statistically significant differences in the KOOS scores were found between the conventional and the navigational groups with the navigation group scoring higher, especially at the 1-year time point. While the navigated group scored about 6 points higher than the conventional group, minimal clinically important difference for KOOS JR is 11.1 at 1 year [16]. Additionally, there were no differences found in the PROMIS-10 scores between the 2 groups, supporting the conclusion that the differences between these 2 techniques is minimal in terms of PROMs. This supports the conclusions of meta-analysis by Lee *et al* [17].

There were no differences found between the KOOS scores across all the sagittal femoral angle ranges; however, overall scores in the navigation group were higher in all tested ranges. This is in contrast to 2 current studies, both of which reported that slight to moderate femoral flexion resulted in improved PROMs [18,19]. Demographically, women were found to have a higher sagittal femoral angle within the navigation group, possibly due to an increased femoral bow in most female patients. The bow of the femur may influence the calculation of sagittal alignment because full sagittal femoral X-rays are not possible. Interestingly, we noted improved PROMs in the navigation group, but they were not related to femoral sagittal position.

There was a much higher readmission and return to ED rate within the conventional group. The reasons behind this are not clear. Computer navigation could play a role in lower complication rate, but additional confounders, such as race, could also be a factor. Three patients, or 21% of patients, who experienced a complication in the conventional group, did not identify as "White or Caucasian." This disparity is also seen in analyses of racial disparities by Hu *et al* [20]. Additional studies are warranted to look at the impact of race on TKA outcomes. The authors believe that the race differences between the conventional and navigation groups seen in this study was not due to restrictions, cost, or bias.

## Limitations

As this is a retrospective analysis, there are many potential limitations to this study. Data were collected at a single orthopaedic

Table	6

KOOS scores striated by lateral femoral angle range

KOOS	Preoperative		12 wk		6 mo		1 y	
Navigation 0-3.5°		P = .985		<i>P</i> = .064		<i>P</i> = .220		<i>P</i> = .085
Conventional 0-3.5°	$51.90 \pm 12.6$		68.87 ± 12.7		$73.04 \pm 11.0$		76.97 ± 12.7	
	$51.85 \pm 13.6$		$65.12 \pm 10.0$		$70.39 \pm 12.1$	<b>D</b>	$72.05 \pm 14.1$	B 000
Navigation 3.6-7°	53.14 ± 13.2	P = .271	70.85 ± 11.6	P = .059	74.36 ± 14.0	P = .296	78.57 ± 13.0	P = .066
Conventional 3.6-7º	51.05 ± 11.3		67.71 ± 10.0		72.26 ± 12.1		74.31 ± 14.1	
Navigation 7.1°+	51.72 ± 11.6	<i>P</i> = .871	69.41 ± 12.8	<i>P</i> = .943	75.82 ± 13.0	<i>P</i> = .705	77.68 ± 13.6	P = .628
Conventional 7.1°+	51.31 ± 9.7		69.62 ± 12.1		74.62 ± 14.2		75.65 ± 17.7	

KOOS, Knee Injury and Osteoarthritis Outcome Score.

hospital, using patients from only 2 surgeons. Navigation was not utilized on the tibial cut, as all landmarks are visible on the tibia. The goal of navigation at our institution is to flex the femur and to avoid Intramedullary instrumentation and Extramedullary guides were to perform the tibial cut. The authors feel this is still a navigated knee, as navigation is used on the femoral cut. The authors do not get routine postoperative scanograms/mechanical axis alignment X-rays post-operatively, and therefore cannot provide information on coronal alignment of the participants. While all efforts were made to ensure the X-rays had the same exposure alignment, small variations in patient alignment could not be accounted for. The retrospective design of the study may help eliminate observer bias but does not allow patients to be anonymized to a treatment group.

#### Conclusions

The use of computer navigation to achieve femoral flexion during TKA did not result in improved PROMs. Controversy exists over whether navigation overall provides significant clinical benefit, or enough clinical benefit to justify the cost to the patient. This study showed small but significant differences between navigated and conventional TKA, with higher KOOS and lower readmission/ED visit rates. These findings suggest further research into the role of femoral sagittal position in TKA is necessary.

#### **Conflicts of interest**

The authors declare there are no conflicts of interest. For full disclosure statements refer to https://doi.org/10.1016/j. artd.2024.101455.

## **CRediT** authorship contribution statement

Ahana Nagarkatti: Writing – review & editing, Writing – original draft, Visualization, Investigation, Formal analysis. Sara Strecker: Writing – review & editing, Writing – original draft, Visualization, Validation, Project administration, Methodology, Formal analysis, Data curation. Durgesh Nagarkatti: Writing – review & editing, Supervision, Investigation, Conceptualization. Dan Witmer: Writing – review & editing, Supervision, Methodology, Investigation, Data curation.

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