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ORIGINAL ARTICLE

Long-term outcomes of computer-assisted Ci™ navigation versus conventional total knee arthroplasty

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ABSTRACT

Objectives: The aim of this study was to investigate the long-term effects of computer-assisted Ci™ navigation on clinical, radiological, and functional results versus conventional total knee arthroplasty (TKA).

Patients and methods: Between January 2005 and July 2011, a total of 85 patients (36 males, 49 females; mean age: 66.2±5.2 years; range, 59 to 84 years) who underwent P.F.C. Sigma™ knee system implantation using computer-assisted Ci™ navigation system (BrainLAB®, DePuy International, Leeds, UK) and completed a minimum follow-up of eight years were included in the study. In the control group, a total of 100 patients (40 males, 60 females; mean age: 68.3±3.9 years; range, 60 to 79 years) who completed a minimum follow-up of eight years were randomly selected from a dataset of implanted P.F.C. Sigma™ knee systems in the same period using Specialist® 2 instrumentation without navigation. An implant survival analysis was used to compare implant survivorship between the groups throughout 12 years. The Knee Society Score (KSS) and range of motion (ROM) were assessed. Based on long-format X-ray images, the implant position in the frontal and sagittal planes was evaluated.

Results: The ratio for navigation to control group survival is approximately 1.01 at 12 years. The clinical outcomes showed no significant difference between the groups (knee scores, p=0.707 and functional scores, p=0.485). In the measured angles analysis, we observed a consistent pattern in both groups. In the control group, there was a trend toward implanting the tibial component with slight varus alignment (p=0.038) and a higher posterior slope (p<0.001). On average, the operation was prolonged by 13 min in the navigated group (p<0.001).

Conclusion: In conclusion, our study results demonstrate that while kinematic navigation in TKA improves the precision of implant alignment, it does not provide significant benefits in terms of long-term implant survival or functional outcomes compared to conventional TKA methods. The use of the computer-assisted Ci™ navigation system is associated with prolonged operation duration, although no technical complications related to the navigation device's software can be observed. Therefore, although navigation offers theoretical advantages in component positioning, its use may be more justifiable in cases with challenging alignment requirements rather than as a routine practice.

Keywords: Arthroplasty, arthroplasty outcomes, kinematic navigation, personalized endoprosthetics, total knee replacement.

Currently, total knee arthroplasty (TKA), also called as total knee replacement (TKR), is a common orthopedic surgery and one of the most successful procedures in all of medicine. The main indication is disabling pain caused by severe arthritis. During surgery, the affected articular surfaces of the knee joint are replaced with metal components and highly cross-linked polyethylene plastic.[1,2] The success of TKR is determined by many factors, such as patient selection, type of implant, fixation, bone and soft tissue quality, surgical technique, and other factors that can be controlled by the orthopedic surgeon. For the function and durability of TKR, the proper positioning of components is one of the most essential aspects controlled by the orthopedic surgeon. The main goal of proper alignment is to achieve an even load distribution on the joint line. Components implanted in an inaccurate position

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can lead to accelerated polyethylene wear, thereby loosening of the replacement.[3] Several studies have identified an anatomical tibiofemoral angle (aTFA) of 174° and an anatomical posterior distal femoral angle (aPDFA) of 90° as target alignment goals in TKA, although these may vary depending on the patient's height and limb morphology.[1,2,4,5]

Several computer-assisted techniques have been created and in use for more than two decades to implant TKA more accurately than can be done with traditional surgical techniques.[6] Computer-assisted systems include active robotic, semi-active robotic, and passive systems. A typical example of a passive system is navigation.[7,8] Although its use has been marginal, the contribution to the optimal position of implants compared to traditional surgical techniques has been proven.[9-12] Positioning of components has an impact on joint stability, range of motion (ROM), and correct limb alignment, as well as on the longevity of TKA.[13-17] In patients with complex anatomical conditions, such as significant deformities or post-traumatic alterations, navigation systems can provide enhanced guidance to achieve optimal alignment and balance. Another benefit of navigated TKA is the ability to utilize extramedullary femoral alignment, which is particularly advantageous in cases involving post-traumatic changes in the distal femur.

The primary challenges of using navigation in TKA include a steep learning curve for surgeons, high implementation and maintenance costs, and occasional technical issues which can complicate procedures.[18] Potential errors may occur due to wrong positioning of pointers and transmitters, obstruction of the infrared signal, or dirty reflectors or cameras. Severe osteopenia can lead to the movement of pins that are placed in bones to hold trackers. As a result, further measurements may be inaccurate. Positioning of the cutting blocks is guided by a navigation system, but making a resection is a surgeon´s responsibility. Bending of the saw blade during resection while cutting through a sclerotic part of the bone can cause inaccuracies and lead to malalignment.[19] Comparison of conventional and computer-navigated total knee arthroplasties is a topic of many studies with short-term follow-up.[20-26]

In the present study, we hypothesized that kinematic navigation in TKA could enhance long-term clinical and radiological outcomes compared to conventional techniques. We, therefore, aimed to investigate the long-term effects of computer-assisted navigation on clinical, radiological, and functional results versus conventional TKA.

PATIENTS AND METHODS

This retrospective study was conducted at St. Anne's University Hospital and Faculty of Medicine, Masaryk University, Department of Orthopaedic Surgery between January 2005 and July 2011. A total of 215 P.F.C. Sigma™ knee systems were implanted using computer-assisted Ci™ navigation system (BrainLAB®, DePuy International, Leeds, UK). Of them, 85 (36 males, 49 females; mean age: 66.2±5.2 years; range, 59 to 84 years) who completed a minimum follow-up of eight years were included in the study. In the control group, a total of 100 patients (40 males, 60 females; mean age: 68.3±3.9 years; range, 60 to 79 years) who completed a minimum follow-up of eight years were randomly selected from a dataset of implanted P.F.C. Sigma™ knee systems in the same period using Specialist® 2 instrumentation without navigation. The selection was made using a random number generator. Instrumentation Specialist® 2 utilizes intramedullary targeting of the femoral component and extramedullary targeting of the tibial component (Table I). A written informed consent was obtained from each participant. The study protocol was approved by the St. Anne's University Hospital Brno Ethics Committee (date: 09.10.2024, no: EK-FNUSA-25/2024). The study was conducted in accordance with the principles of the Declaration of Helsinki.

Procedures with kinematic navigation were performed by two experienced orthopedic surgeons. The control group included patients operated on by five experienced orthopedic surgeons in knee endoprosthetics. The same surgical technique and principles were applied in all cases. Conventional TKA procedure was done using the mechanical alignment technique in all cases.

The Ci™ navigation system is an intraoperative image-guided localization system which enables the tracking of surgical tools through a passive sensor system. It creates an individual three-dimensional (3D) model of the patient's bone by acquiring multiple landmarks on the bone surface. The Ci™ software is a planning and navigation tool with touch screen control. It operates on a wireless Ci™ navigation system that utilizes passive reflective spheres and two infrared cameras emitting infrared flashes to track the movement of surgical instruments. These passive reflective spheres are attached to the

TABLE I
Patient characteristics: P.F.C. sigma TKA with Ci™ navigation *vs.* conventional instrumentation

	Navigation group (n=85)			Control group (n=100)			
Features	n	%	Mean±SD	n	%	Mean±SD	*p*
Age at inclusion (year)			66.2±5.2			68.3±3.9	<0.05
Sex							
Female	49	57.6		60	60		
Male	36	42.4		40	40		
Average follow-up (year)			109.1±28.3			105±24.5	0.292
Body mass index (kg/m^2)			30.7±4.8			31.1±5.1	0.585
Diagnosis							
Primary osteoarthritis	85	100		100	100		
Surgical approach							
Medial prepatellar	85	100		100	100		

TKA: Total knee arthroplasty; SD: Standard deviation.

surgical instruments and to one or more reference probes securely fixed to the patient's bone. Each ball reflects the infrared flashes from the cameras, creating a unique infrared reflective image. Both cameras digitize these images, capturing the reflective spheres from different angles. The software then calculates the 3D positions of the reflective spheres on the instruments relative to those on the reference probe. Once the patient's registration is complete, the exact position of the surgical instruments relative to the patient can be determined. During surgery, the instruments can be monitored in real-time using an attached touch screen monitor.

Surgical technique and postoperative care

In all cases, the patients were operated in the supine position with a loaded pneumatic tourniquet on the thigh of the operated limb. The aim was to achieve a neutral mechanical alignment. Operations were performed under prophylactic antibiotic coverage with consistent prevention of thromboembolic disease with low-molecular-weight heparin. We used a medial parapatellar minimally invasive approach with a skin incision length of 10 to 15 cm. Probes were placed on the bone surface in the region of the distal femur and proximal tibia from mini-incisional inputs. These rigid probes were firmly attached to the bone by bicortical screws and, thus, their loosening during the operation was prevented. The probes are equipped with special reflective spheres that reflect infrared radiation. Communication between the computer and the operated limb is ensured through infrared rays that are emitted and captured by a special camera. The computer includes a touch screen that the surgeon controls directly. This is covered with sterile foil. Based on the movement analysis of the lower limb and the surface registration of points from the lower limb with a special pointer, the center of the hip, knee, and ankle joint is determined.

The computer processes the data obtained during point registration and displays the current mechanical axis in flexion and extension of the knee joint and the resulting value of the mechanical axis of the lower limb required by the surgeon. In the next step, the placement of the tibial and femoral components was planned. The surgeon placed the tibial resection block under the control of computer navigation, which would enable optimal processing of the proximal part of the tibia in all planes. This was followed by a careful measurement in 90-degree flexion of the knee and, then, in full extension of the knee joint with an inserted "gap-balancer (spreader)" with tensiometer, and a resection of the distal femur was performed. This was followed by processing of the distal femur condyle using a resection template, the precise anteroposterior and rotational positioning of which is again controlled by the computer. After the final implantation of the components, a final verification of the placement of the components and the resulting mechanical axis of the lower limb was performed (Figure 1).

Postoperative rehabilitation took place in the same way as for conventional TKR.

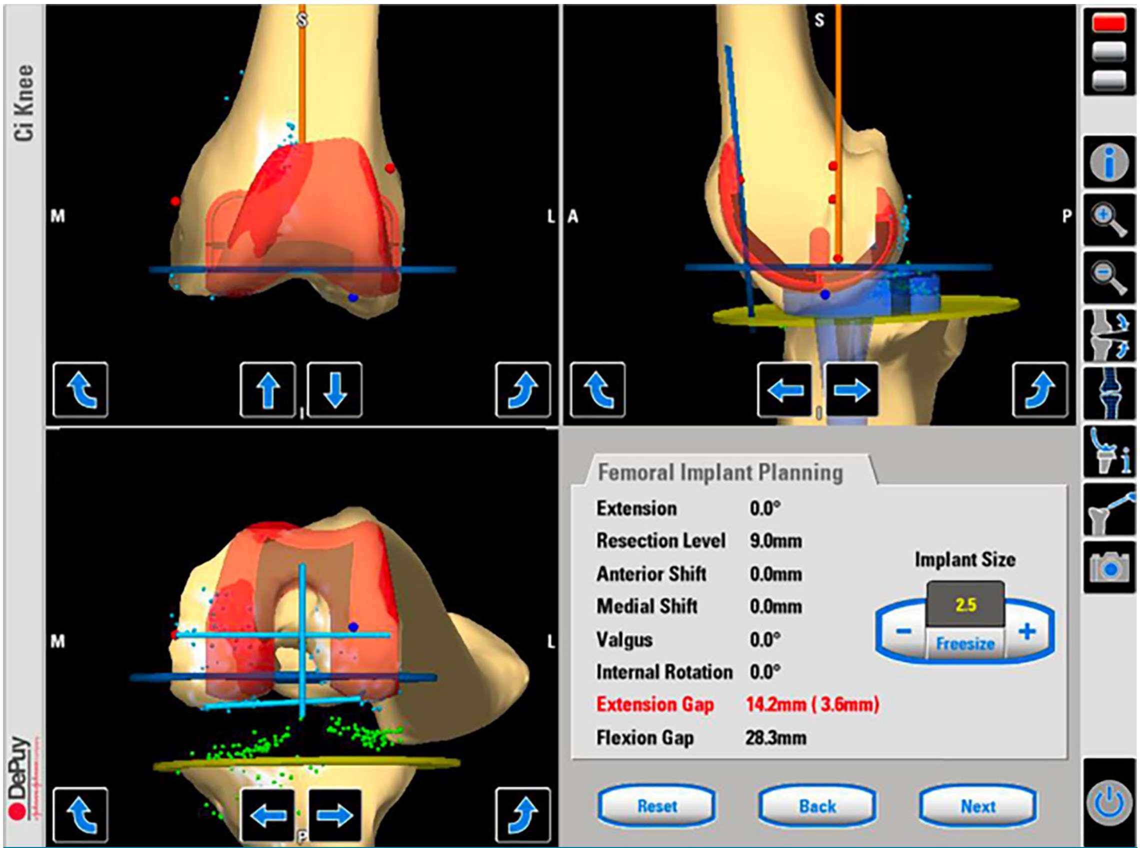

FIGURE 1. Intraoperative screenshot of the Ci™ system displaying the view of femoral implant planning in the coronal, sagittal, and transverse planes. The femoral implant planning section shows the extension and flexion gaps.

The postoperative recovery process began in the intensive care unit (ICU), where patients initiated early mobilization under close supervision. On the second day following surgery, they were transferred to a standard care room and commence ambulation with the guidance of a physiotherapist, utilizing a walker or crutches for support. During the first week, patients were advised to limit weight-bearing on the operated limb to approximately one-third of their body weight, allowing sufficient time for the soft tissues to heal. Patient discharge was on average on Day 6 after surgery. As recovery progressed, they gradually reduced their reliance on assistive devices and steadily increased weight-bearing on the limb. At six weeks postoperatively, most patients were able to fully bear weight on the operated limb. Further follow-up visits were planned in the outpatient setting at 6 and 12 weeks after the operation. The load on the operated limb was gradually increased and, after two to three months, full load on the operated limb was allowed.

Outcome assessment

The Kaplan-Meier survival analysis was used to compare implant survivorship between the Ci™ navigation device and the control group models during a 12 years of study period. In the implant survival analysis, the number at risk represented the number of patients who were still being followed and were at risk of experiencing the event of interest at a given time point. The Knee Society Score (KSS) and ROM was assessed at eight years of follow-up. The KSS consists of the knee score, which assesses the knee's clinical status by focusing on pain, stability, ROM, and alignment (maximum score: 100 points), and the functional score (FS), which evaluates the patient's ability to perform daily activities, such as walking and climbing stairs (maximum score: 100 points). Based on long-format X-ray images, we evaluated the implant position in the frontal and sagittal planes (Figure 2). Four independent observers (orthopedic surgeons) conducted the measurements.

While constructing anatomical angles in postoperative images with an endoprosthesis, the line of the joint surface was interspersed with the plane of bone resection - the cement-bone interface. In the frontal plane, we measured the aTFA, which includes the anatomical axis of the femur with the anatomical axis of the tibia. In the area of the distal femur, we measured in the frontal area the anatomical lateral distal femoral angle (aLDFA) plane. We also calculated the aPDFA, a radiographic measurement used to assess the posterior slope of the distal femur. The aPDFA is defined as the angle between the femoral anatomical axis and the posterior articular surface of the distal femur in the sagittal plane. We measured the anatomical on the proximal tibia medial proximal tibial angle (aMPTA). In the sagittal plane, we constructed an anatomical posterior proximal tibial angle (aPPTA), which expresses the dorsal inclination of the tibial joint components. The aPPTA is defined as the angle formed between the anatomical axis of the tibia and the posterior articular surface of the proximal tibia, measured in the sagittal plane. The target angle values differ in dependence on the type of implant (Table II).[27-30] In case of conventional TKA, the optimal tibial slope is typically set at 3°. This same tibial slope value was incorporated into the navigation software by the manufacturer.[31] The operation duration was defined as the time from the beginning of the skin incision to the final skin suture.

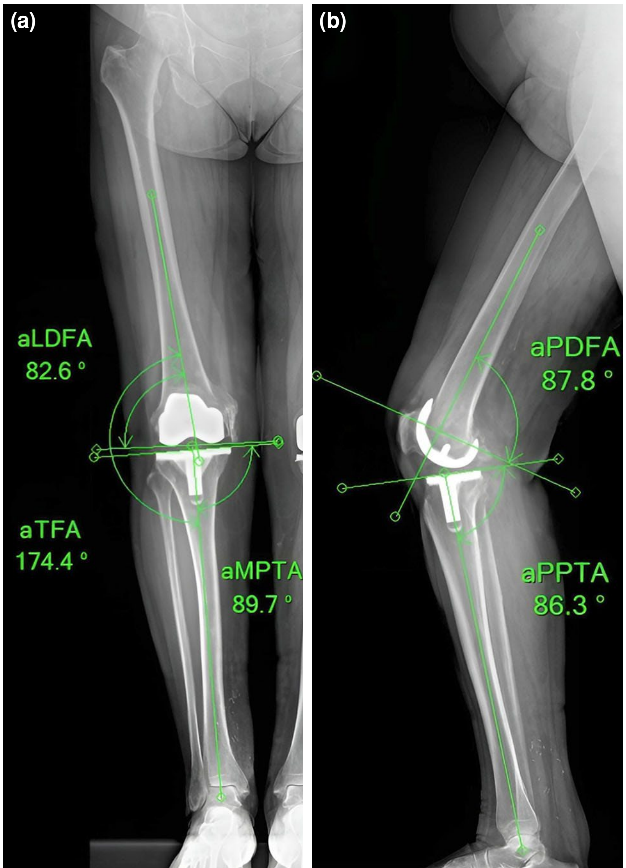

FIGURE 2. Postoperative X-rays of the lower limb with anatomical angular measurements following endoprosthesis implantation. **(a)** Frontal view. **(b)** Lateral view.

Statistical analysis

Statistical analysis was performed using the R software version 4.0.5 in the RStudio (R Foundation, Vienna, Austria). The normality of the data was assessed using the Shapiro-Wilk test. Descriptive data were expressed in mean ± standard deviation (SD), median (min-max) or number and frequency, where applicable. The non-parametric Mann-Whitney U test was employed to evaluate the statistical significance of these differences. For analyzing the relationship between categorical variables, the Fisher exact test was utilized. A *p* value of <0.05 was considered statistically significant.

RESULTS

Implant survival

The five-year implant survival was 1.00 (number at risk: 85) for the navigation group and 0.99 for the control group (number at risk: 99). The ratios (rates) for navigation to control group survival are approximately 1.01 at 5 years and 1.02 at 8 and 12 years, showing a small and consistent survival advantage for the navigation group. However, since the p-value is 0.392, these differences are not statistically significant (Figure 3).

TABLE II
Postoperative radiographic assessment of TKA component position

Measured angle	Target angle values
aTFA	174°
aLDFA	84°
aPDFA	90°
aMPTA	90°
aPPTA	87° (3° of tibial slope)

TKA: Total knee arthroplasty; aTFA: Anatomical tibiofemoral angle; aLDFA: Anatomical lateral distal femoral angle; aPDFA: Anatomical posterior distal femoral angle; aMPTA: Anatomical medial proximal tibial angle; aPPTA: Anatomical posterior proximal tibial angle.

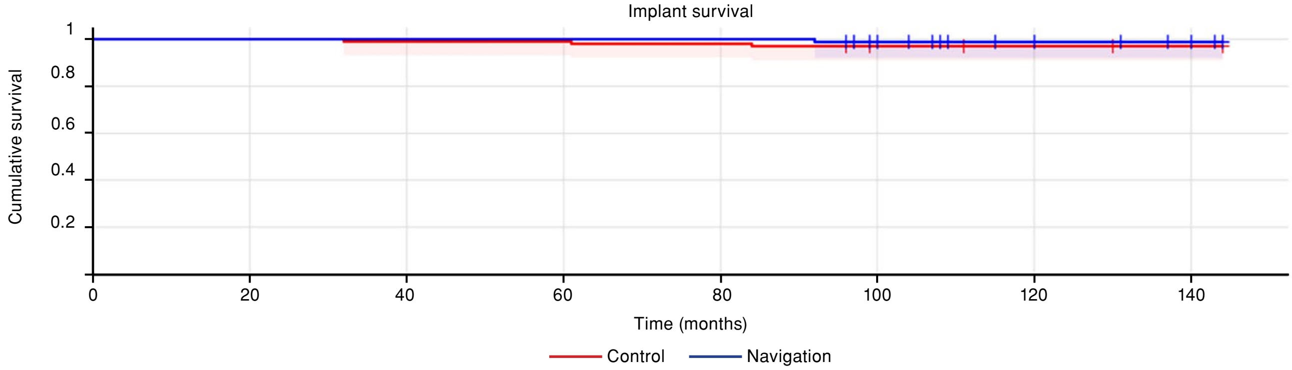

FIGURE 3. Cumulative 12-year implant survival curve of P.F.C. Sigma TKA implanted using a Ci™ navigation device (blue color), compared to the control group of P.F.C. Sigma TKA implanted using conventional instrumentation (red color).
TKA: Total knee arthroplasty.

TABLE III
Knee score evaluation: Ci™ navigation *vs.* conventional instrumentation in P.F.C. sigma TKA

Overall	KS: Navigation	KS: Control	Difference	95% CI	*p*
Mean±SD	82.01±2.94	81.83±3.49	–0.18	–1.12 to 0.76	0.707
N.Valid	84	97			

KS: Knee score; TKA: Total knee arthroplasty; CI: Confidence interval; SD: Standard deviation.

Functional outcomes

The mean knee scores of patients of the navigation group at eight years were 82.01±2.94 versus 81.83±3.49) in the control group (mean difference: –0.18, 95% CI: –1.12 to 0.76; p=0.707) (Table III, Figure 4). The mean functional scores of patients of the navigation group at eight years were 77.94±3.70 versus 78.33±3.85 in the control group (mean difference: –0.39°, 95% CI: –0.71 to 1.49; p=0.485) (Table IV).

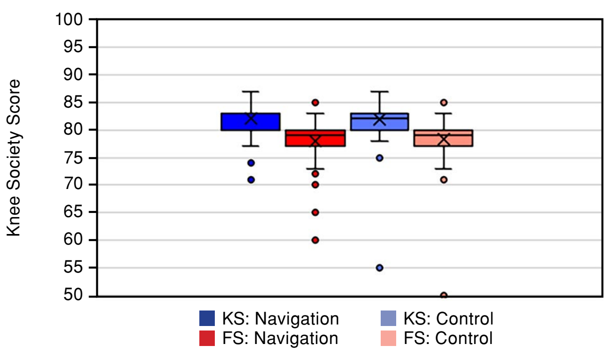

FIGURE 4. Knee Score (KS) and Function Score (FS) evaluation of patients with P.F.C. Sigma TKA implanted using a Ci™ navigation, compared to the control group of patients with P.F.C. Sigma TKA implanted using conventional instrumentation.
TKA: Total knee arthroplasty.

Range of motion

The mean maximum flexion of the navigation group was 104.35±11.35°. The control group achieved a mean maximum flexion of 102.1±11.0° (mean difference: –2.25°, 95% CI: –5.53 to 1.03; p=0.178) (Figure 5). In the navigation group, three cases exhibited a flexion contracture with a mean of 6.66±2.9°. Conversely, in the control group, flexion contracture was observed in three cases, with a fixed value of 5±0°. No cases in either group required manipulation under anesthesia, arthroscopic intervention, or open lysis of adhesions.

Radiographic assessment

In the radiographic assessment, the measured values of the angles in the frontal and sagittal plane did not significantly differ in the placement of components in the frontal plane and on the side femoral components, as well as tibial components (Table V). The only notable difference

TABLE IV

Function score evaluation: Ci™ navigation *vs.* conventional instrumentation in P.F.C. sigma TKA

Overall	FS: Navigation	FS: Control	Difference	95% CI	*p*
Mean±SD	77.94±3.70	78.33±3.85	0.39	–0.71 to 1.49	0.485
N.Valid	84	97			

FS: Function score; TKA: Total knee arthroplasty; CI: Confidence interval; SD: Standard deviation.

TABLE V

Radiological assessment: Ci™ navigation *vs.* conventional instrumentation in P.F.C. sigma TKA

	Navigation	Control	Difference		
	Mean±SD	Mean±SD	Mean	95% CI	*p*
aTFA	173.98°±2.76°	174.21°±3.30°	0.23°	–0.66 to 1.12	0.611
aLDFA	83.81°±2.27°	83.51±2.48°	–0.30°	–0.99 to 0.39	0.395
aMPTA	88.77°±2.86°	88.23±2.85°	–0.54°	–1.37 to 0.29	0.201
aPDFA	88.53°±2.33°	87.72±2.86°	–0.81°	–1.57 to -0.04	<0.05
aPPTA	87.31°±1.14°	85.88±1.91°	–1.43°	–1.89 to -0.96	<0.05

TKA: Total knee arthroplasty; CI: Confidence interval; SD: Standard deviation; aTFA: Anatomical tibiofemoral angle; aLDFA: Anatomical lateral distal femoral angle; aMPTA: Anatomical medial proximal tibial angle; aPDFA: Anatomical posterior distal femoral angle; aPPTA: Anatomical posterior proximal tibial angle.

was recorded in the inclination of the femoral (mean difference: –0.81°, 95% CI: –1.57 to –0.04; p=0.038) and tibial components (mean difference: –1.43°, 95% CI: –1.89 to –0.96; p=0.001). The mean values of aPDFA 88.53±2.33° and aPPTA 87.31±1.14° were in favor of the navigated group, compared to optimal angle values, indicating a more precise

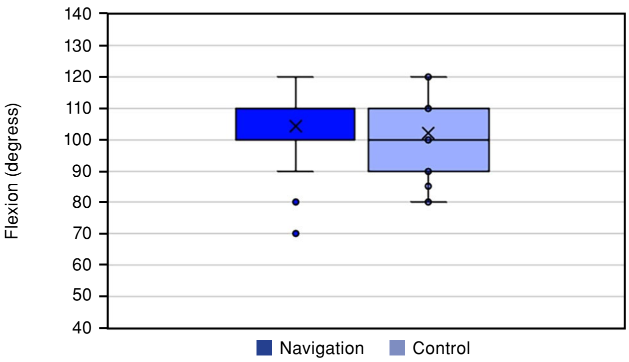

FIGURE 5. Maximum achieved flexion (in degrees) of patients with P.F.C. Sigma TKA implanted using a Ci™ navigation device, compared to the control group of patients with P.F.C. Sigma TKA implanted using conventional instrumentation.
TKA: Total knee arthroplasty.

placement of components in this plane. In general, greater values of standard deviations were recorded in the control group.

Operation duration

The mean operation duration using a Ci™ navigation device was 91.6±12.2 min. The conventional TKA surgery had a lower mean operation duration of 78±13.9 min (mean difference: –13.60, 95% CI: –17.42 to –9.77; p≤0.001) (Table VI).

Complications

There were four major complications in our study: three in the control group and one in the navigation group. Specifically, the control group experienced one case of aseptic loosening and two cases of infection, while the navigation group had one case of infection. Throughout our use of the Ci™ kinematic navigation system, we encountered no technical complications related to the software of the navigation device. The probe anchoring mechanism proved to be reliable, securely fixing the probe in place without any instances of loosening during the surgical procedures. There was a unique case where rigid probes could not

TABLE VI
Surgery duration: Ci™ navigation *vs.* conventional instrumentation in P.F.C. sigma TKA

Overall	Surgery duration: Navigation (min)	Surgery duration: Control (min)	Difference	95% CI	*p*
Mean±SD	91.6±12.2	78±13.9	–13.60	–17.42 to -9.77	<0.05
N.Valid	85	100			

TKA: Total knee arthroplasty; CI: Confidence interval; SD: Standard deviation.

be anchored due to severe osteoporosis in the patient's bone. In this case, we opted to perform the operation using traditional techniques, and the patient was subsequently not included in our analysis. Fortunately, in none of the cases, we observed any periprosthetic fractures, a risk which is often associated with the holes created in the bone for the screws used to secure the probes in the distal femur and proximal tibia.

DISCUSSION

In the present study, we investigated the long-term effects of computer-assisted navigation on clinical, radiological, and functional results versus conventional TKA. Our study results showed that using kinematic navigation in TKA provided more precise alignment of the femoral and tibial components compared to conventional methods. However, this increased accuracy did not translate into clinical differences in implant survival, functional outcomes, or ROM between the groups in the long term. Both groups had comparable KSS and achieved similar levels of ROM after surgery. Additionally, the utilization of the Ci™ navigation device led to prolonged surgery. No technical issues with the navigation system were encountered, although challenges were noted in cases with poor bone quality.

The benefits of navigation in TKA for achieving improved clinical outcomes, enhanced radiological alignment, and increased longevity of knee replacements have been widely debated and are in the focus of numerous studies, most of which involve short-term patient follow-ups.[21,23-25,32] In many studies, navigation's contribution to the optimal position of implants compared to traditional techniques has been proven.[9-11,33] However, there is still not enough information regarding whether proper alignment and positioning of the components due to the usage of computer navigation contribute to the function and longevity of a TKR.[16,34,35] Therefore, it is of utmost importance to evaluate the contribution of navigation techniques after a long-term follow-up of patients.

In our study, the clinical outcomes as measured with KSS did not show any significant difference between the groups. Similarly, previous studies have reported that postoperative outcomes, as measured by KSS, have shown no statistically significant differences.[22,32,36-38] Synder et al.[39] reported significantly improved postoperative KSS and there was also dissimilarity between postoperative KSS in the navigation group. As expected, we found a significantly longer operating time in the navigated group patients. On average, the operation was prolonged by 13 min for the navigated operation. A minimum of 10 min is required for placing rigid probes bicortically in the bone and conducting the collection of reference points using a navigation device.[22,40] Numerous studies have investigated parameters such as blood loss, the volume of drainage, the transfusion volume, Visual Analog Scale, and length of hospital stay presenting comparable results.[37,40-42]

Based on the statistical processing of the measured values of the angles in the frontal and sagittal plane, we found no statistically significant differences in the placement of components in the frontal plane and on the side femoral components, as well as tibial components. However, a discrepancy was observed in the sagittal plane, particularly in the inclination of the femoral and tibial components. The mean values of aPDFA and aPPTA were in favor of the navigated group, indicating a more precise placement of components in this plane. Our results differ from other studies, where there was no significant difference in the alignment of components between computer-navigated and conventional TKA.[22,32,37,38,41,43] Through our analysis of measured angles and comparing deviations from the optimal axial placement, we observed a consistent pattern in both groups. Specifically, there was a tendency to implant the femoral component at a greater flexion angle and with increased valgosity. Additionally, in the group which underwent conventional TKA without the use of kinematic navigation, there was a trend toward implanting the tibial component with slight varus alignment and a higher posterior slope. Conversely, in the group which we utilized kinematic navigation, we found a higher percentage of cases where the tibial component was implanted with moderate varus alignment compared to the optimal position.

In their study, Luan et al.[6] compared conventional techniques to computer navigation, the accuracy of component alignment was higher with computer navigation. These results are consistent with ours, where more accurate component placement favors the navigated group. The accuracy of component positioning was also evaluated in the article by Bové et al.,[20] who compared two navigation systems (Navitrack®-OS Knee and BrainLAB® system). There was no significant difference in the postoperative component positioning between the systems, and the accuracy of component positioning using the navigation systems was over 90%. Similar results can be observed in a meta-analysis where the iAssist® navigation system was compared to a conventional technique.[44] Another study compared the long-term results of the VectorVision® navigation system (BrainLAB® AG, Feldkirchen, Germany) and Stryker Navigation 2.0 (Stryker Mahwah, NJ, USA) with a conventional procedure.[45] The median follow-up in the aforementioned study was 13.19 years for the navigation group and 12.9 years for the conventional procedure group. The KSS scores were comparable in both groups, which is consistent with ours.

There are inconsistent results of ROM in the literature between computer-navigated and conventional TKA. Chávez-Valladares et al.[46] reported that conventional TKA group demonstrated an improved flexion ROM, while the computer-navigated group showed improved extension ROM. Other studies found that ROM was not significantly different between TKA performed with or without a navigation system.[37,47] The findings of our study also showed that there were no significant differences in ROM between computer-navigated and conventional TKA.

The main strengths of this study include its large sample size, and the use of the same implant comparing the kinematic navigation to conventional surgical technique using mechanical alignment. The follow-up is also relatively longer. Although the study was conducted in a specific department with particular surgical practices and patient populations, it may limit the generalizability of the results to other settings or patient demographics. Despite using a random number generator to select patients for the control group, the possibility of selection bias remains. Additionally, only two experienced surgeons performed all surgeries in the navigation group, while five surgeons performed the procedures in the control group, introducing variability in surgical skill, which may have influenced the outcomes.

In conclusion, our study results demonstrate that while kinematic navigation in TKA improves the precision of implant alignment, it does not provide significant benefits in terms of long-term implant survival or functional outcomes compared to conventional TKA methods. The use of the computer-assisted Ci™ navigation system is associated with prolonged operation duration, although no technical complications related to the navigation device's software can be observed. Therefore, although navigation offers theoretical advantages in component positioning, its use may be more justifiable in cases with challenging alignment requirements rather than as a routine practice.

Data Sharing Statement: The data that support the findings of this study are available from the corresponding author upon reasonable request.

Author Contributions: Concept, design, writing, editing: L.N., V.A.; Supervision, references and fundings, materials: L.N., T.T.; Data collection, analysis: P.B., L.N., M.K, M.M.; Literature review: P.B., M.K, M.M. All authors approved the final version of this manuscript.

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