



Comparative Study of Pinless Navigation System versus Conventional Instrumentation in Total Knee Arthroplasty

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Background: Optimal placement of the components and achieving a neutral mechanical axis are the main goals of total knee arthroplasty (TKA). Different computerised navigation systems are presently used for these purposes. This aim of this study was to compare the pinless navigation (PNA) TKA performed using iAssist with the conventional instrumented (CIN) TKA in terms of functional and radiological outcomes.

Methods: A total of 100 knees operated for TKA by a single surgeon were studied retrospectively for a period of 2 years. Weight-bearing postoperative radiographs of the knees along with scanograms of the lower limbs were used for measurements of component positioning, mechanical axis alignment, and number of outliers. Oxford knee scoring was used for functional analysis.

Results: No statistically significant difference was seen in the mean mechanical axis alignment (hip-knee-ankle angle), coronal alignment (α and β angles) and sagittal alignment (γ and δ angles) of the femoral and tibial components between the two groups. Though the percentage of outliers for mechanical axis alignment was lower in the PNA-TKA group than in the CIN-TKA group, the difference was not statistically significant ($p = 0.73$). The number of outliers for the femoral and tibial component positioning in coronal and sagittal planes was not statistically significantly different between the two groups. No statistically significant difference ($p = 0.68$) was noted between the two groups with respect to the Oxford Knee Score. The mean surgical time was greater in the PNA-TKA group by 11 minutes, which was statistically significantly longer ($p = 0.018$). Complications were seen in 6.89% of the cases in the CIN-TKA group, while none in the PNA-TKA group.

Conclusions: The accurate mechanical axis alignment and component positioning can be achieved with the conventional instrumentation, so the use of PNA system, which adds to the surgical cost, is questionable. Also, equally good short-term functional outcome can be achieved with the conventional instrumentation. The surgeon must be accustomed with the instrumentation of the PNA system, or it adds to the surgical time.

Keywords: *Navigation, Alignment, Total knee arthroplasty, Functional outcome, Radiological outcomes*

Total Knee Arthroplasty (TKA) is a successful treatment option that is beneficial to patients with arthritis of the

knee joint.^{1,2)} Pain relief, improved knee function, implant longevity, and patient satisfaction are the main goals of TKA.¹⁻⁴⁾ Compared to the conventional instrumentation technique, computer-navigated TKA has been widely used in the last decade, and reports claim improved accuracy of implant placement and alignment,¹⁻³⁾ leading to improved implant survival⁵⁾ and reduced failure rates.⁶⁾ Optimal placement of the implants within 3° of the mechanical axis of the lower limb is important to reduce implant wear and early implant failure.⁷⁾ Computer-assisted devices have

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been reported to reduce the number of outliers with more than 3° deviation with respect to the neutral mechanical axis.⁸⁾ However, there are also many studies that have failed to show the superiority of computer navigation over the conventional method in terms of alignment and component positioning.⁹⁾

The pinless navigation (PNA) technique for TKA was introduced in the 1990s to increase the accuracy of the cutting jigs, with the aim of improving mechanical alignment, implant survival, and functional outcomes.¹⁰⁾ It consists of accelerometers and gyroscopes, which are less bulky and simplify the navigation procedure without the need of inserting tracking pins.¹¹⁾ The current literature comparing the PNA-TKA with conventional instrumented (CIN) TKA is not very extensive. Some series have proved improved lower limb alignment and placement of components using PNA system.^{12,13)} This aim of this study was to compare PNA-TKA performed using iAssist with CIN-TKA in terms of mechanical axis alignment, component positioning, functional outcomes, surgical time, and complications.

METHODS

Patient Selection

A retrospective, observational study was conducted for patients operated between April 23, 2015, and May 17, 2018. The study was approved by the Ethical and Scientific Advisory Committee of Sir H. N. Reliance Foundation Hospital and Research Centre (IRB No. IEC/2017/DNB/ORTH/01). The waiver of consent was taken from the Ethical Committee to conduct the study. The surgery consent was taken from the patient. Patients who underwent primary TKA for osteoarthritis and inflammatory arthritis of the knee were included in the study. Those who had revision TKA, required constrained implants, and sustained peri-prosthetic fracture were excluded from the study. The decision for CIN or PNA was according to the choice of the patients, who were informed about both techniques.

Fifty-eight consecutive consented patients were included in the CIN-TKA group and 26 patients in the PNA-TKA group during the study period (Fig. 1). All the patients were followed for a period of 2 years except for two patients in the CIN-TKA group who died postoperatively on day 2 or 3 months. All the operations were performed by a single surgeon (VB) under spinal anaesthesia using a tourniquet. A standard medial parapatellar approach for the knee was used in all cases. Arthrotomy was done, which was followed by eversion of the patella and necessary soft-tissue releases to dislocate the knee.

Conventional TKA Technique

CIN-TKA was performed using standard extramedullary jigs for the proximal tibia with the aim of cutting the bone perpendicular to the tibial axis and intramedullary alignment jigs for the distal femur cut with an aim of achieving 6° of valgus. The anteroposterior (AP) sizing guide was positioned with respect to the Whiteside's line and an anterior referencing technique was used. The anterior, posterior, anterior chamfer, and posterior chamfer cuts for distal femur were performed with a 4-in-1 cutting guide. The intercondylar box cut was made depending on the use of posterior cruciate ligament-substituting (PS) implant. The femoral and tibial trial implants were impacted along with a spacer. Final femoral and tibial components were cemented and denervation of the patella was performed.

PNA-TKA Technique (iAssist)

The iAssist (Zimmer, Warsaw, IN, USA) is an accelerometer-based computer-assisted stereotaxic instrument system to assist the surgeon in positioning of orthopaedic implants intraoperatively. The feedback from the accelerometer and gyroscopes from the Pods is transmitted over a screen via Wi-Fi network. The femur was first prepared in all cases. A 7.9-mm intramedullary spike was impacted with respect to the Whiteside's line. The femoral reference Pod was then mounted on the spike, and femur registration was done by acquiring 13 stable positions by

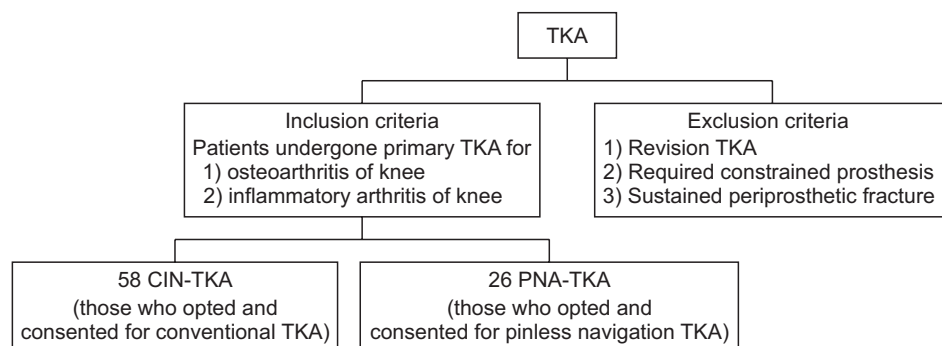


Fig. 1. Patient selection flowchart. TKA: total knee arthroplasty, CIN: conventional instrumented, PNA: pinless navigation.

accelerating and stopping the leg, creating a star-shaped pattern. Audio feedback was generated to confirm the acquisition of each stable position. The femoral resection guide was then attached to the femoral reference Pod and the distal femur cut was adjusted in terms of varus/valgus and flexion/extension using the green and gold screws, respectively; the degree of resection was reflected on the screen (Fig. 2). An appropriate distal femur cut was done with validation of the cut using a validation tool mounted with Pod. The anterior, posterior, anterior, and posterior chamfer cuts were done by conventional methods.

The proximal tibia cuts were performed using an extramedullary guide mounted with Pod. The distal part of the tibial alignment guide was installed over the ankle by firmly gripping the clamps around the malleolus. The proximal spikes were inserted into the tibia, consider-

ing the mechanical axis and rotation of the tibia while continuing to hold the distal clamps firmly around the malleolus. The tibia resection guide was then attached to the proximal part of the extramedullary guide. The tibia registration was done by positioning the leg in abduction, adduction, and neutral position. The proximal tibia cut was adjusted for varus/valgus and flexion/extension with green and gold screws, respectively, on the resection guide, which was reflected on the screen in degrees. An appropriate tibia cut was done by validation of the cut as was done for the femur. Then, the proximal tibia was ready to proceed with the next step.

Postoperative Radiological Assessment

As part of the standard institutional protocol, postoperative weight-bearing radiographs of the knees were taken in AP and lateral projections along with weight-bearing scanograms of the lower limbs once the patient bore weight comfortably. Component position and lower limb alignment were measured by two independent observers, one was a junior orthopaedic consultant (GS) and the other was an orthopaedic resident (RK). These measurements were repeated after 10 days as described below.

Following measurements were done for coronal alignment. (1) Hip-knee-ankle (HKA) angle on scanogram (Fig. 3): it is measured between the mechanical axis of the femur and the mechanical axis of the tibia.¹⁴ It represents the overall alignment of the lower extremity and is usually 180° .^{2,15} The outliers were recorded as those lying outside ± 3 of 180° . (2) α and β angles (femoral and tibial component coronal alignment, respectively) on an AP radiograph of the knee¹⁶ (Fig. 4): the α angle is measured between the

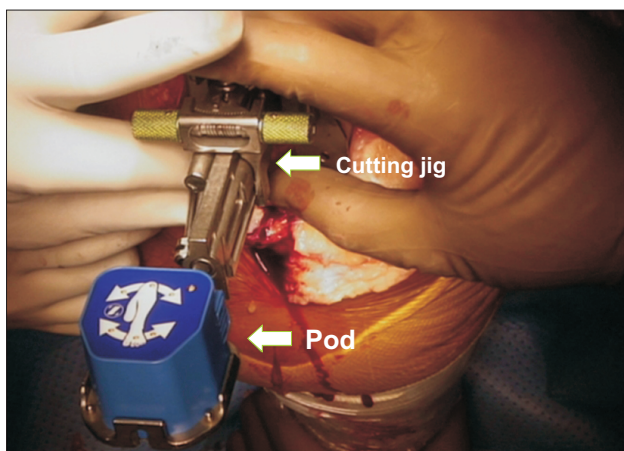


Fig. 2. Femoral reference Pod with a cutting jig.



Fig. 3. Hip-knee-ankle (HKA) angle measurement.

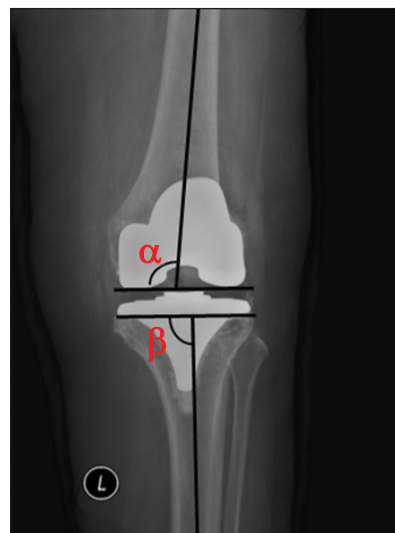


Fig. 4. Measurement of α and β angles.

line across the inferior margin of the femoral component and the femoral shaft axis. The femoral component usually is implanted in 5° to 7° of valgus to the anatomical axis of the femur, the amount necessary to re-establish a neutral mechanical axis of the limb.^{2,17} For this study purpose, the target of the femoral component placement was 6° of valgus and outliers were recorded as those lying outside ± 3 of 6° . The β angle is measured between the line across the base of the tibial plate and the tibial shaft axis. The tibial component should be placed in the neutral alignment of 90° .¹⁷ The outliers were recorded as those lying outside ± 3 of 90° .

Following measurements were done for sagittal alignment: (1) γ angle (femoral flexion angle) on a lateral radiograph of the knee (Fig. 5): the γ angle is measured between the frontal femoral cortex and the inner frontal



Fig. 5. Measurement of γ and δ angles.

part of the femoral component. The ideal γ angle recommended by various studies^{18,19} varies between 0 and 10° . The outliers recorded as those lying outside ± 3 of 0° – 10° . (2) σ angle (tibial slope angle) on a lateral radiograph of the knee^{16,18} (Fig. 5): The σ angle is measured between the line across the base of the tibial plate and the tibial shaft axis. The ideal σ angle is 86° .¹⁸ Also, the recommendations vary depending on the implants: PS and cruciate-retaining (CR) types. PS or CR implants (Zimmer-Nexgen or Biomet-Vanguard) were used in the study. Although calculated for this study, no outlier limit was defined due to the wide recommended range to prevent inaccuracy and confusion.

Functional Assessment

Functional assessment by Oxford Knee Score (OKS) at 2 years was done for all patients (except for the 2 in the CIN-TKA group who died). The data were collected during in person follow-up visit or with video/tele-consultation.

Surgical Time and Complications

Surgical time was measured from the start of incision till closure. Morbidity and mortality along with complications, if any, were noted.

Statistical Analysis

The data of the two groups were compared using the unpaired *t*-test for continuous variables (age, body mass index, HKA, α , β , γ , σ angles, OKS, and surgical time) and chi-square test for categorical variables (sex). Statistical significance was defined as a *p*-value of ≤ 0.05 . Inter- and intrarater reliability was measured using one way random single-measure intraclass correlation coefficients (ICCs) with associated 95% confidence intervals (CI) to gauge the precisions of the ICCs.

Table 1 . Patient Demographics

Variable	CIN-TKA group	PNA-TKA group	<i>p</i> -value
Number of patients	58	26	-
Unilateral TKA	49	21	-
Bilateral TKA	9	5	-
Total knees	67	31	-
Sex			
Female	46 (7 bilateral, 53 knees)	23 (3 bilateral, 26 knees)	
Male	12 (2 bilateral, 14 knees)	3 (2 bilateral, 5 knees)	0.42
Age (yr), mean \pm SD	66.20 \pm 9.43	65.09 \pm 10.18	0.63

CIN: conventional instrumented, TKA: total knee arthroplasty, PNA: pinless navigation, SD: standard deviation.

RESULTS

A total of 58 patients were operated with CIN-TKA (9 bilateral cases included) and 26 patients were operated with PNA-TKA (5 bilateral knees included), thus forming a 2 to 1 ratio (Table 1). The mean age of the CIN-TKA group was 66.20 ± 9.43 years and that of the PNA-TKA group was 65.09 ± 10.18 years. There was no statistically significant difference between the two groups with respect to age. (Table 1). Radiologically, there was no statistically significant difference in the mean HKA, mean α , β , γ , and δ angles between the two groups. (Table 2). The percentage of outliers for HKA and α , β and, γ angles in the PNA-TKA

group was less than that in the CIN-TKA group, but the difference did not reach statistical significance (Table 3).

The preoperative OKS for the CIN-TKA group and PNA-TKA group improved from 20.67 ± 3.27 and 20.69 ± 2.51 , respectively, to 45.67 ± 2.42 and 45.88 ± 1.45 , respectively, at 2 years of follow-up (Table 4). There was no statistically significant difference ($p = 0.68$) in the mean OKS between the CIN-TKA (45.67 ± 2.42) and PNA-TKA (45.88 ± 1.45) groups at 2 years of follow-up (Table 4). The mean surgical time was shorter in the CIN-TKA group (80.17 ± 14.27) than in the PNA-TKA group (91.80 ± 17.76), showing statistically significant difference ($p = 0.018$) (Table 4).

Complications seen in the CIN-TKA group (6.89%) and PNA-TKA group (0%) were not statistically different ($p = 0.17$) (Table 5). Regarding the 4 complications in the CIN-TKA group, 1 patient died due to myocardial infarction during the same admission; 1 patient died due to pulmonary embolism 3 months later; 1 patient had anterior femoral cortex perforation while intramedullary drilling; 1 patient had foot drop (ankle dorsiflexion 1/5) on the same day of surgery, which was recovered within 3 months. No complication was noted in the PNA-TKA group. Interobserver correlation was good to excellent for radiological assessment in the CIN-TKA group except for the β angle, which was moderate (0.40). Interobserver correlation was

Table 2. Radiological Outcome

Variable	CIN-TKA group	PNA-TKA group	p-value
HKA (°)	177.63 ± 1.90	177.82 ± 2.17	0.69
α (°)	94.84 ± 1.91	94.95 ± 1.59	0.79
β (°)	90.16 ± 1.17	89.98 ± 1.48	0.55
γ (°)	9.82 ± 2.85	9.87 ± 3.04	0.94
δ (°)	86.98 ± 1.74	86.35 ± 1.57	0.12

Values are presented as mean \pm standard deviation.

CIN: conventional instrumented, TKA: total knee arthroplasty, PNA: pinless navigation, HKA: hip-knee-ankle.

Table 3. Number of Outliers

Variable	CIN-TKA group	PNA-TKA group	p-value
HKA	12 (17.91)	4 (12.90)	0.73
α	10 (14.92)	3 (9.67)	0.69
β	2 (2.98)	1 (3.22)	0.57
γ	12 (17.91)	5 (16.12)	0.85

Values are presented as number of outliers (%).

CIN: conventional instrumented, TKA: total knee arthroplasty, PNA: pinless navigation, HKA: hip-knee-ankle.

Table 4. OKS and Surgical Time

Variable	CIN-TKA group	PNA-TKA group	p-value
OKS			
Preoperative	20.60 ± 3.27	20.69 ± 2.51	0.90
2-Year follow-up	45.67 ± 2.42	45.88 ± 1.45	0.68
Surgical time (min)	80.17 ± 14.27	91.80 ± 17.76	0.02

Values are presented as mean \pm standard deviation.

OKS: Oxford Knee Score, CIN: conventional instrumented, TKA: total knee arthroplasty, PNA: pinless navigation.

Table 5. Complications

Complication	CIN-TKA group	PNA-TKA group
Death	2 (myocardial infarction, 1; PE, 1)	-
Femoral cortex perforation while drilling	1	-
Foot drop	1	-
Total, no (%)	4 (6.89)	0

CIN: conventional instrumented, TKA: total knee arthroplasty, PNA: pinless navigation, PE: pulmonary embolism.

good to excellent for radiological assessment in the PNA-TKA group except for the β angle, which was bad (0.28).

DISCUSSION

Our study found that there was no statistically significant difference in the mean mechanical axis alignment (HKA) and mean coronal (α and β angles) or sagittal (γ and σ angles) component position between the CIN-TKA and PNA-TKA groups. We also found no statistically significant difference in the number of outliers for HKA and α , β , and γ angles between the CIN-TKA and PNA-TKA groups. Our results are consistent with the study of Chen et al.¹³⁾ and Maderbacher et al.²⁰⁾ who found no significant difference in the mean mechanical axis alignment (HKA) between conventional and pinless TKAs. In contrast, Liow et al.²¹⁾ noted significant improvement in the mean mechanical axis alignment with PNA as compared to conventional TKA. In terms of component positioning, our results are in accordance with studies of Liow et al.²¹⁾ and Keyes et al.,²²⁾ who observed no significant difference between the pinless and conventional TKAs. Reducing the number of outliers helps in achieving positive outcomes in maximum patients.²³⁾ Some studies have shown a significant reduction in the number of outliers for mechanical axis alignment of the lower limb and component positioning with the PNA system as compared to the CIN system,^{13,20,21)} which is contradictory to our results (Table 3).

The OKS at 2 years was comparable in both the CIN-TKA and PNA-TKA groups with no statistically significant difference ($p = 0.68$) in our study. Similar results for OKS have been found in a comparative study conducted by Zhu et al.²⁴⁾ Also no significant difference was seen in functional outcome between the conventional and computer navigation groups in a meta-analysis by Zamora et al.²⁵⁾ An increase in surgical time by approximately 11 minutes was noted in the PNA-TKA group as compared to the CIN-TKA group, which was a statistically significant difference ($p = 0.018$). However, it did not result in anaesthetic/systemic complications, an increased infection rate, or blood loss. The intraoperative steps such as femur and tibia registration and validation of the femur and tibia cuts add to the surgical time. The steps for registration of femur and tibia need to be done precisely, or they need to be repeated. The surgeon must be well versed with the instrumentation and surgical steps of the PNA system. The statistically significant increase in surgical time with computer navigation was also noted in other comparative studies by Gothesen et al.²⁾ and Maderbacher et al.²⁰⁾

The number of complications seen in the CIN-

TKA group was greater than in the PNA-TKA group, but it was not statistically significantly different ($p = 0.2$). We noted two deaths in the CIN-TKA group due to myocardial infarction and pulmonary embolism. Although it was beyond the scope of this study, it has been reported by Kalairajah et al.²⁶⁾ that there are possibly fewer chances of blood loss and systemic embolism with the PNA system as compared to the CIN system, as intramedullary drilling is not required in the PNA system. The steep learning curve and dependence on conventional instrumentation for determining the rotational alignment and implant size of femoral and tibial components are some of the drawbacks of PNA-TKA, which need to be taken into consideration. Also, as the pods are disposable, each patient operated with PNA-TKA was charged USD 675 extra for the use of PNA-TKA system ($p < 0.001$), which adds to the financial cost.

To our knowledge, our study was perhaps the first study done in the Indian subcontinent where patients have much varus deformity and also extra-articular deformity of the knee.^{27,28)} Although we did not do a priori sample size calculation, our sample size was comparable to that of previous studies by Maderbacher et al.²⁰⁾ and Liow et al.²¹⁾ Long-term studies with a large sample size and a multivariate analysis would be ideal to determine the true benefit of use of this technology. Short-term follow-up and small sample size are limitations of our study. We aim to further follow up patients for 10 years to assess the functional outcome.

This study demonstrates that the PNA does not result in statistically significant improvement in the (1) mechanical axis alignment of the lower limb (HKA angle); (2) accuracy of component positioning; or (3) reduction of the number of outliers as compared to the conventional instrumentation. The accurate mechanical axis alignment and component positioning can be achieved with the conventional instrumentation, so the use of PNA system, which adds to the surgical cost, is questionable. Also, equally good short-term functional outcome can be achieved with conventional instrumentation. The surgeon must be accustomed with the instrumentation of the PNA system, or it adds to the surgical time.

CONFLICT OF INTEREST

No potential conflict of interest relevant to this article was reported.

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