Research Paper

Total Knee Replacement with iASSIST Navigation System

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A B S T R A C T

Background/Purpose: The iASSIST system is a novel navigation system for total knee replacement. It is based on accelerometers built within electronic pods attached to the instruments within the operative field. The objective of this study was to compare the accuracy of iASSIST navigation with that of the conventional alignment technique.

Methods: A total of 91 patients (92 knees) retrospectively matched for age, gender, preoperative range of motion, and lower limb deformity underwent total knee replacement using iASSIST navigation (45 patients, 46 knees) or conventional instrumentation (46 patients, 46 knees). Operative time and radiological alignments were compared.

Results: The use of iASSIST navigation resulted in fewer outliers (as defined by >3° deviation from the neutral mechanical axis) in lower limb alignment. Operative time with iASSIST navigation was not longer than that using conventional instruments.

Conclusion: iASSIST navigation reduces the incidence of lower limb malalignment without adding extra time to the procedure.

Introduction

The optimal alignment for total knee replacement is still controversial. The traditional rule of a neutral mechanical axis with implants placed perpendicular to the femoral and tibial mechanical axis has been questioned. Some studies have shown similar clinical results despite malalignment. There is also the development of a kinematically designed knee, hoping to improve clinical results. Regardless of belief, the aim to improve accuracy of bone cut continues to be an area of development in total knee replacement.

A novel accelerometer-based navigation system, iASSIST Knee System (Zimmer, Warsaw, IN, USA), was developed in 2012. The iASSIST consists of egg-sized electronic pods attached onto the instruments within the operative field. The pods containing an accelerometer electronic component captures information on the motion, and lower limb deformity underwent total knee replacement using iASSIST navigation (45 patients, 46 knees) or conventional instrumentation (46 patients, 46 knees). Operative time and radiological alignments were compared.

Results: The use of iASSIST navigation resulted in fewer outliers (as defined by >3° deviation from the neutral mechanical axis) in lower limb alignment. Operative time with iASSIST navigation was not longer than that using conventional instruments.

Conclusion: iASSIST navigation reduces the incidence of lower limb malalignment without adding extra time to the procedure.

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Methods

Patient selection

From June 2015 to December 2015, 55 patients (56 knees) diagnosed with tricompartmental osteoarthritis of the knee who failed conservative measures underwent primary total knee replacement using the iASSIST computer navigation system in a single centre. All the operations were performed by or under the supervision of joint surgeons. Retrospective matched pairing of 46 patients (46 knees) who received total knee replacement in our centre in 2015 was performed based on age, gender, preoperative range of motion, and lower limb alignment.

Surgical technique for the control group

Both groups of patients underwent total knee replacement using fixed-bearing posterior-stabilized implants (NexGen Complete Knee Solution Legacy Knee; Zimmer, Warsaw, IN, USA); the medial parapatellar approach was adopted with tourniquet control at 280 mmHg. In the control group, distal femur was prepared using an intramedullary rod. Setting of the femoral valgus cut angle was based on the preoperative long film measurement of the angle sustained between the shaft axis and the mechanical axis of femur such that the distal femur bone cut was perpendicular to the femoral mechanical axis. In case of femoral bowing, a line simulating the pathway of the intramedullary rod was drawn; the angle formed between this line and the mechanical axis of the femur represented the femoral valgus cut angle. The proximal tibia was prepared with an extramedullary guide to achieve bone cut perpendicular to the tibial mechanical axis. The overall alignment was checked after placing trial implants, and further bone cut could be made if needed. The patella was resurfaced in both groups. All patients underwent postoperative physiotherapy according to the rehabilitation protocol in our centre.

Surgical technique for the iASSIST group

The iASSIST navigation system made use of the disposable electronic pod attached to the resection instrument to acquire and displace information on lower limb alignment; the system was placed entirely within the surgical field such that surgical workflow is similar to that of the conventional method. Femoral registration was performed by impacting a bone spike to the distal femoral sulcus 10 mm anterior to the posterior cruciate ligament. A reference pod was inserted over the spike and fixed. Femoral coordination was acquired by multiple jerky stop-and-go movements of the leg. The information was transferred to a laptop-sized computer placed within the operation theatre via a secured local wireless (Wi-Fi) network. The distal femoral resection guide attached with a cutting guide pod was coupled to the bone spike. The computed alignment information was then transferred to and displaced on the cutting guide pod by light-emitting diode indicators (Figures 1 and 2). Adjustment of the femoral resection guide in coronal and sagittal planes was made based on the information provided on the cutting guide pod. The aim of bone resection was to achieve 0° varus and 3° flexion. Postresection validation was performed by attaching a reference pod to the bone cut surface and placing the lower limb in abduction, adduction, and neutral positions. Again the alignment information is displaced on the cutting guide pod, and further bone cut could be made if needed. Tibial registration began with placing an extramedullary tibial guide containing a cutting guide pod to the tibia. The tibial resection guide together with a reference pod attached was assembled to the extramedullary tibial guide and fixed by three screws (Figure 3). Tibial coordination was acquired by placing the lower limb in abduction, adduction, and neutral positions. Data acquired by the reference pod were transferred to the laptop-sized computer via Wi-Fi and then displaced on the cutting guide pod. The cutting guide pod on the extramedullary tibial guide was detached and coupled to the tibial resection guide (Figure 4). The extramedullary guide was then removed. Adjustment of the tibial resection guide in coronal and sagittal planes was made based on the information displaced on the cutting guide pod. The planned tibial bone cut was 0° varus and 7° posterior slope. Resection of proximal tibia could be performed once the position of the resection guide was satisfactory. Coronal alignment and slope of the proximal tibia could be validated after resection. Adjustment to resection could be made if needed.

Clinical and radiological evaluation

Perioperative clinical variables including age, gender, preoperative range of motion, and duration of surgery were recorded. In the iASSIST group, the planned resection angle for femur and tibia in the coronal plane and the post-bone cut verification angles were documented. If any resections were made after validation, the validation process was repeated and the final verification angles were documented. A standardized radiographic evaluation was performed in all patients. Coronal hip to ankle radiographs were taken at standing position with the knee in full extension preoperatively and at 6 months after surgery. The anterior surface of the patella was placed perpendicular to the X-ray source, with the toes pointing forward. Radiographs with malrotation, as defined by the asymmetry of medial and lateral femoral condyles, will be...
excluded. All the radiographs were reviewed, and measurements were made by the same author. Three measurements were made on the coronal hip to ankle radiographs: (1) lower limb mechanical axis, which was the angle formed between the mechanical axis of the femur (line connecting the centre of femoral head with the knee centre) and the mechanical axis of the tibia (line connecting the knee centre and the centre of ankle mortise) with 0° as target; (2) coronal femoral component angle, which was defined as 0° if the transcondylar line of the femoral component was perpendicular to the mechanical axis of the femur; and (3) coronal tibial component angle, which was defined as 0° if the base of the tibial tray was perpendicular to the mechanical axis of the tibia. We defined a positive value for valgus alignment and a negative value for varus alignment. Up to 3° deviation from the targeted mechanical axis was considered acceptable in our study. Alignments outside this range were classified as outliers.

Statistical analysis

All quantitative variables were described as mean and standard deviation of the mean. The Student unpaired t test was used to analyse the age, duration of surgery, preoperative range of motion, preoperative lower limb mechanical axis, postoperative lower limb mechanical axis, coronal femoral component angle, and coronal tibial component angle of the two cohorts. Categorical variables including gender and number of outliers were analyzed using Fisher exact test. A p value ≤ 0.05 indicates a statistically significant difference.

Results

Two cases were excluded from the study due to failure in registration, three cases were excluded due to tibial resection guide loosening, and five cases were excluded due to malrotation in postoperative radiographs. Of the remaining 45 cases (46 knees), there was no significant difference in age, gender preoperative range of motion, and lower limb alignment compared with the control group (Table 1).

The means of the planned resection angle, post-bone cut verification angle, final verification angle, and coronal femoral and tibial component angles are shown in Table 2. The mean difference between pre- and post-femoral bone cuts was −0.35 ± 0.92°, and for the tibia it was 0.02 ± 1.31°. The mean difference between the final intraoperative verification and the radiographical measurement was −0.02 ± 1.40° for the femur and 0.02 ± 1.45° for the tibia.

| Table 1 | Baseline data in two groups of patients |
|---------|----------------------------------------|
| Age (y) | Conventional: 71.1 ± 8.4, iASSIST: 69.0 ± 6.2, p = 0.135 |
| Males/Females | Conventional: 8/38, iASSIST: 8/38, p = 0.99 |
| Preop ROM (°) | Conventional: 109.46 ± 13.59, iASSIST: 109.02 ± 16.55, p = 0.891 |
| Preop MA (°) | Conventional: −10.74 ± 8.16, iASSIST: −9.59 ± 9.07, p = 0.524 |

MA — lower limb mechanical axis; ROM — range of motion.
Compared with the conventional group, the iASSIST group had overall less deviation in mechanical axis and component position. The mean lower limb mechanical axis in the iASSIST group was $-0.19 \pm 2.06^\circ$ versus $-0.69 \pm 3.18^\circ$ in the control group. The mean coronal femoral component angle in the iASSIST group was $-0.37 \pm 1.36^\circ$ versus $-0.90 \pm 2.21^\circ$ in the control group. The mean coronal tibial component angle in the iASSIST group was $0.24 \pm 1.43^\circ$ versus $0.25 \pm 2.62^\circ$ in the conventional group. The difference is however not statistically significant (Table 3).

This study found significantly fewer outliers in the lower limb mechanical axis in the iASSIST group (13.0% vs. 32.6%, $p = 0.045$). There was no significant difference in the duration of surgery, which was 91.5 ± 15.6 minutes for the iASSIST group and 93.3 ± 18.1 minutes for the control group ($p = 0.613$; Table 4).

### Discussion

Optical navigation in total knee replacement was shown to achieve better lower limb alignment and reduced the number of outliers compared with the conventional alignment technique. Their use is, however, limited by the complicated procedure, errors of registration, intraoperative line of sight issue, and increased operative time. The iASSIST navigation relies on accelerometers built within small electronic pods that resolve problems arising from optical navigation. Having the navigation system placed completely within the surgical field, surgeons can perform navigation as part of conventional workflow and potentially reduce operative time. Currently, only a few small-scale studies looked into the accuracy of the iASSIST navigation system. This study found that the iASSIST navigation system was accurate in producing our intended bone cut angle. The average errors of registration, intraoperative line of sight issue, and increased operative time. Currently, only a few small-scale studies looked into the accuracy of the iASSIST navigation system (Table 4).

This study compared the alignment accuracy between iASSIST navigation with conventional alignment techniques. Both lower limb alignment and implant placement were better in the iASSIST group; the difference was, however, not statistically significant. The lower limb mechanical axis was $-0.19 \pm 2.06^\circ$ in the iASSIST group compared with $-0.69 \pm 3.18^\circ$ in the control group ($p = 0.372$). Thiengwittayaporn et al. had similar finding in their study showing no significant difference in lower limb alignment between iASSIST navigation and conventional instruments; the mean lower limb mechanical axis in their study group was $-0.8 \pm 2.1^\circ$ versus $0.1 \pm 3.2^\circ$ in the control group ($p = 0.141$). Liow et al. demonstrated a statistically better lower limb alignment in the iASSIST group with a mean mechanical axis of $-1.0 \pm 1.4^\circ$ versus $-2.8 \pm 2.0^\circ$ in the control group ($p = 0.001$). Since the alignment in our control group sustained only minimal deviation from the target angle, together with a small sample size, our results were unable to reach a statistically significant level. On the contrary, we were able to demonstrate a significant 19.6% reduction in the number of outliers in the iASSIST group. The percentage of outliers was 13% in the iASSIST group versus 32.6% in the control group ($p = 0.045$). The result was similar to a meta-analysis of 29 studies comparing optical computer navigation with the conventional technique. Manson et al. had shown that mechanical axis malalignment occurred in 9.0% of optical computer navigation versus 31.8% in the conventional alignment method. Fewer outliers in the lower limb mechanical axis were also demonstrated in other studies on the iASSIST navigation system.

One concern with the implementation of navigation was the extra time added to the overall procedure, which might increase the incidence of deep infection due to longer exposure time. This study found that operative time in the iASSIST group was not significantly different from that in the control group. This was similar to the finding by Thiengwittayaporn et al. Although Liow et al. found longer operative time with the use of iASSIST navigation compared with the conventional instrument, their study group had a worse preoperative lower limb deformity compared with the control group. The extra operative time might not be solely due to the navigation system, but also due to more complicated soft tissue balancing.

From our experience with the iASSIST system, there was a learning curve, especially on the tibial side. Three cases were excluded due to loosening of the tibial resection guide. The resection guide was fixed to the proximal tibia by three screws placed in a convergent position, resulting in less than optimal fixation. The guide could loosen if the cutting saw blade was not placed coaxially with the tibial resection guide. Care must be taken to ensure optimal placement of the saw blade to avoid loosening of the tibial resection guide. The cutting guide pod on the tibial resection guide could sometimes be in the way of the cutting saw. The surgeon holding the saw might hit on the pod and loosen the resection guide. This could be prevented by disconnecting the cutting guide pod once the alignment was set before bone cutting.

Despite the encouraging result of the iASSIST navigation system, the drawback of this study was its retrospective nature. The study and control groups were not randomized, which might result in a selection bias. The authors were not blinded to the study and

### Table 2

| Planned resection angle (°) | Post bone cut verification angle (°) | Final verification angle (°) | CFA/CTA (%) |
|----------------------------|----------------------------------|-----------------------------|-------------|
| Femur 0 ± 0                | -0.35 ± 0.92                    | -0.35 ± 0.93                | -0.37 ± 1.36|
| Tibia 0 ± 0                | 0.02 ± 1.31                     | 0.22 ± 0.99                 | 0.24 ± 1.43 |

CFA – coronal femoral-component angle; CTA – coronal tibial-component angle.

### Table 3

| Conventional | iASSIST | $p$  |
|--------------|---------|------|
| MA (°)       | -0.69 ± 3.18 | -0.19 ± 2.06 | 0.372 |
| CFA (°)      | -0.90 ± 2.21 | -0.37 ± 1.36 | 0.172 |
| CTA (°)      | 0.25 ± 2.62 | 0.24 ± 1.43 | 0.972 |
| Outliners in MA (%) | 32.6 | 13.0 | 0.045 |

MA – lower limb mechanical axis.
control groups; this might result in biased estimation of the treatment effects.

Conclusion

In summary, our study demonstrates that the iASSIST navigation system is accurate in restoring the mechanical axis in total knee replacement. There is minimal difference between the intra-operative verification and the final X-ray measurement. The system reduces the incidence of lower limb malalignment without adding extra time to the procedure. The iASSIST navigation system combines the alignment accuracy of computer-assisted navigation with the simplicity of conventional alignment methods.

Conflicts of interest

All authors have no conflicts of interest to declare.

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