


Accelerometer-Based Navigation in Total Knee Arthroplasty for the Management of Extra-Articular Deformity and Retained Femoral Hardware: Analysis of Component Alignment

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Abstract

Purpose Recent advances in total knee arthroplasty (TKA) include an accelerometer portable system designed to improve component position and alignment. The purpose of this study is to evaluate whether accelerometer navigation system can be a valuable option in complex TKAs for extra-articular deformity of the lower limb or in case of retained femoral hardware.

Methods A group of 13 patients underwent TKA with an accelerometer navigation system. Three patients had a tibial extra-articular deformity, six had a femoral extra-articular deformity, and four had an intramedullary nail in the femur. Preoperative and postoperative mechanical axes were measured from full-length lower extremity radiographs to evaluate alignment. The alignment of prosthetic components in the frontal and sagittal planes was determined by postoperative radiographs.

Results At 30-days postoperative radiographic check, the hip knee ankle angle was within 2.0° (0 ± 1) of the neutral mechanical axis. The alignment of the tibial component on the frontal plane was 90.0° (range 89–91) and on the sagittal plane 5.0° (range 3–7). The alignment of the femoral component on the frontal plane was 90.0° (range 89–91) and on the sagittal plane 3.0° (range 0–5).

Conclusion The alignment of the prosthetic components has been accurate and comparable to other navigation systems in literature without any increase in surgical times. The accelerometer-based navigation system is therefore a useful technique that can be used to optimize TKA alignment in patients with extra-articular deformity or with lower limb hardware, where the intramedullary guides cannot be applied.

Level of Evidence This is an observational study without a control group, Level III.

Keywords

- ▶ total knee arthroplasty
- ▶ computer navigation
- ▶ extra-articular deformity
- ▶ mechanical axis alignment

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Introduction

Total knee arthroplasty (TKA) is a satisfactory consolidated procedure to improve function and to obtain a good relief from pain in osteoarthritis. The success and longevity of this procedure however is strictly correlated with lower limb alignment, components position, and ligament balancing.^{1–7}

For decades, a stable knee with a neutrally aligned lower limb has been one of the primary goals of TKA because it was supposed to be important for successful clinical outcomes and implant survivorship.⁸ Therefore, the aim of mechanical alignment technique for TKA is not to restore the constitutional patient-specific alignment,⁹ but rather to systematically create a “biomechanically friendly prosthetic knee.”⁸

When osteoarthritis is combined with a femoral or tibial extra-articular deformity, performing a TKA and restoring neutral mechanical axis can turn the surgery into a challenge.

Femoral or tibial deformity for previous trauma or surgery may compromise the use of conventional intramedullary instrumentation for TKA because of distortion of the bony canal or the presence of hardware.

In these cases, many systems can support the surgeon to make the surgery accurate bypassing the problems related to deformity such as navigation, robotics, patients-specific instrumentation, or the use of extramedullary guide. However, they have some disadvantages related to the cost, to the complexity of their use, the learning curve, and the necessity of preoperative magnetic resonance or computed tomography.

Recent advances in TKA include an accelerometer portable system (iAssist, ZIMMER BIOMET, Warsaw, Indiana, United States) designed to improve component position and alignment, which is smart, easy to use, and cheap.

iAssist is an intelligent cutting block system that provides intraoperative matching of bone cuts and overall alignment at each surgical step, using an internal position-sensing technology integrated into microelectronic pods that attach to cutting blocks. This technology allows positioning the cutting blocks without intrusion into the intramedullary canal.

The purpose of this study is to evaluate whether iAssist system can be a valuable option in complex TKAs for extra-articular deformity of the lower limb or in case of retained femoral hardware.

Our hypothesis is that this new technology enables the surgeon to make accurate bone resections and restore the neutral mechanical axis in these complex TKAs where conventional intramedullary instrumentation could not be used.

Methods

Patients

This was a prospective study. At the Orthopaedic Clinic, University of Florence, a group of consecutive 13 patients with primary knee osteoarthritis associated with extra-articular deformity were recruited between May 2016 and September 2017 to undergo TKA with the iAssist navigation system. The mean inclusion criterion was a moderate to severe osteoarthritis associated to extra-articular deformity. For the knee to be included in the study, the extra-articular

deformity had to be an angular deformity that should be corrected with a TKA without any violation of the collateral ligament insertion according to the Wang's criteria.¹⁰

Exclusion criteria included active infection, severe co-incident hip arthritis, neurological disorders, prior knee arthroplasty or patellectomy, fixed deformity greater than 15°, needing of a previous osteotomy cause not meeting of the Wang's criteria,¹⁰ worker's compensation claims, cancer, metabolic bone disease, osteoporosis/osteopenia (diagnosed or treated with medication), and active immunosuppressive disorder requiring cytotoxic drugs, corticosteroids, or irradiation.

For each patient that was indicated for TKA, the above-listed criteria were applied and those who met the inclusion/exclusion criteria were offered enrolment in the study.

The lead surgeon informed patients about the study objectives and the unique features of the iAssist surgical guidance system. Written consent for study participation was obtained from all the patients.

Our study series consisted of eight male and five female, with an average age of 63.7 ± 2.3 . The mean body mass index was 28.6 ± 1.3 . All selected patients had a Grade IV osteoarthritis according to Kellgren–Lawrence classification. Among these, according to Ahlbäck classification, six had a corresponding Grade IV, four had Grade V, and the remaining three patients had a Grade III osteoarthritis. Three patients had a tibial extra-articular deformity, six had a femoral extra-articular deformity, and four had intramedullary nail in the femur (→ Fig. 1).

Surgical Technique

Our objective was to restore a neutral mechanical axis of the lower limb.

We also aim to obtain an alignment of the tibial component on the frontal plane within 90° with respect to the tibial mechanical axis and on the sagittal plane within 5° of tibial slope. For the femoral alignment, we aim to position the component on the frontal plane within 90° with respect to the femoral mechanical axis and on the sagittal plane within 3° of the femoral flexion.

Thirty minutes preoperative and 30 minutes postoperative a tranexamic acid intravenous (IV.) infusion (1 mg/kg) was administrated. Vancomycin 1 g IV was administrated within 2 hours before the surgery. Cefazolin 2 g IV was administrated 10 minutes before inflating the tourniquet. The lead surgeon (F.M.) was the same for all the patients. A tourniquet was applied at the thigh root and the tourniquet time was measured. A standard TKA was performed through a longitudinal anterior skin incision and a medial parapatellar arthrotomy.

iAssist does not require pins for optical tracking, as such, no additional incisions were made. Cutting blocks were affixed to the bone using the same pins as with conventional TKA. For the femur, a little spike was impacted for 2.5 to 3.5 cm at the mechanical axis entry point in the distal femur. The femoral reference pod was attached to the spike and the leg was then moved through a “stop-and-go” star configuration to acquire the hip center and orientation of the

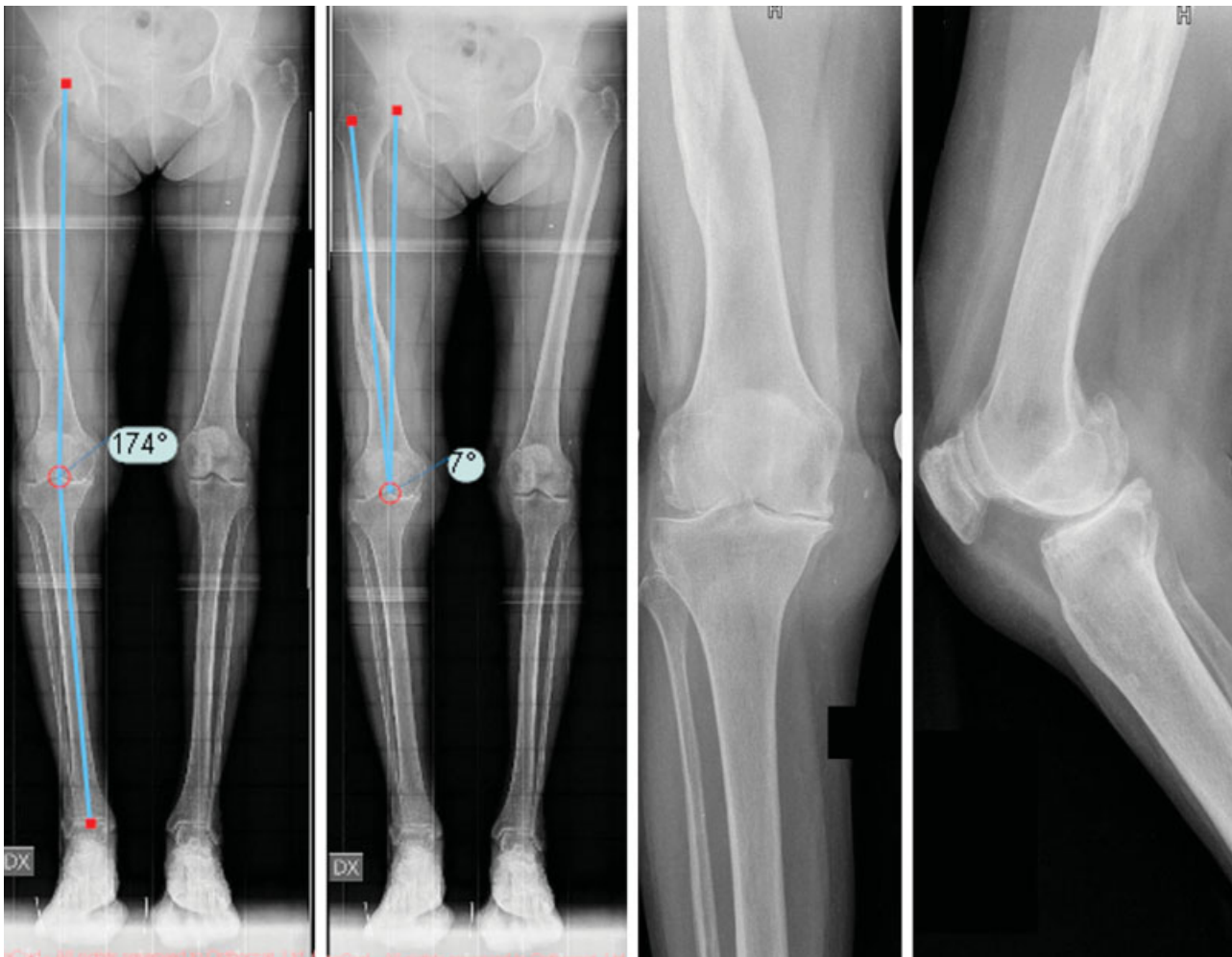


Fig. 1 Example of extra-articular deformity: mid-third triplanar femur shaft deformity.

mechanical axis. A femoral adjustment pod and cutting guide were then attached to the spike and the cut orientation (flexion/extension and varus/valgus) was modified with a distal femur cut perpendicular to the mechanical axis planned for all patients (→ **Fig. 2A**). The distal femoral resection guide was then affixed to the distal femur and the spike and sleeve assembly were removed. The cut was made and a validation pod was used to confirm cut accuracy.

A similar process was used for the tibia. The proximal spike of the extramedullary guide was impacted at the mechanical axis entry point between the tibial spines. The distal portion of the guide consisted of self-centering clamps over the malleoli such that the instrumentation was fixed over the center of the ankle. The guide was then rotationally-oriented to be in line with the medial third of the tibial tubercle and was fixed in place. The leg was then brought into abduction, adduction, and back to neutral to allow the digitizer to register the tibial mechanical axis and transfer it to the pods attached to the tibial resection guide. The tibial resection guide was then adjusted to correct the coronal alignment, and the slope and depth of the cut were determined using a classic stylus (→ **Fig. 2B**). Following resection, a validation tool was then used to confirm the cut orientation.

If necessary, an additional cut is performed to adjust the alignment according to the optimal position as recorded from the iAssist screen.

At the end of the procedure, with trial component in place, a ligament release was performed to balance the knee in extension and in flexion. In 11 cases, a posterior stabilized tibial insert was used and in two cases a constrained condylar knee was necessary to increase the stability of the knee because of larger flexion gap.

At the day of surgery, when anesthesia wore off, patients remained standing and started walking with two crutches with physiotherapist's assistance. First day postoperatively, patients started with continuous passive mobilization with ROM from 0° to 90° as tolerated. Between the third and fourth day postoperatively, patients were trained to walk upstairs and in the fourth to fifth day after surgery, they were dismissed.

Outcome Measurements

A clinical evaluation was conducted using the Knee Society score, recorded before surgery and in the postoperative period, after 1 month and 6 months.

Statistical analysis was performed using SPSS statistics software (IBM, Armonk, New York, United States). The

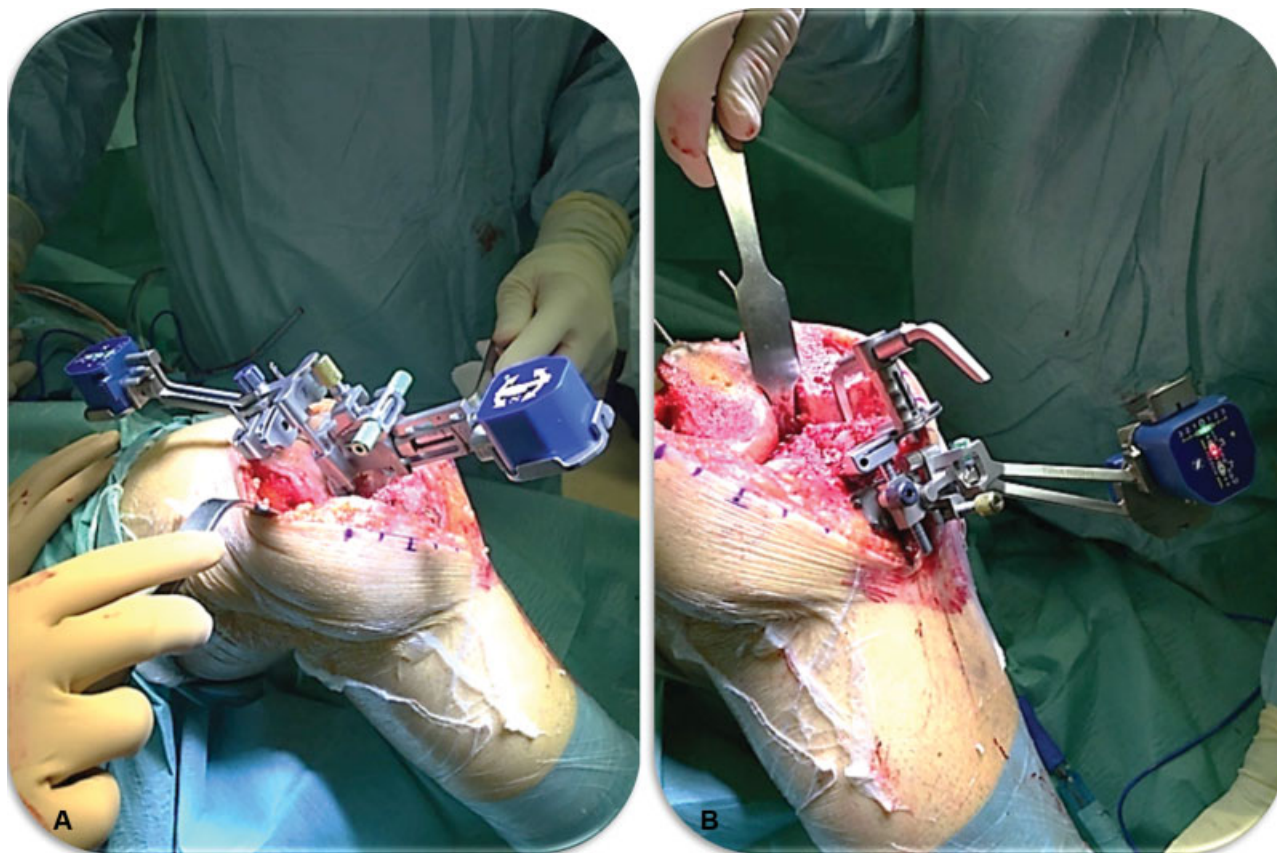


Fig. 2 iAssist system: femur validation and cut pods (A); tibia validation and cut pods (B).

clinical parameters were evaluated with the calculation of the mean and standard deviations (SD). Changes in the knee and function scores between preoperative and 1-month follow up and between preoperative and 6-months follow up were compared using the Student *t*-test, taking *p*-values of less than 0.05 as statistically significant with a 95% confidence interval.

Preoperatively and 30-days postoperatively, a radiological analysis was performed with full-length lower extremity radiographs in the frontal plane; in the sagittal plane a full-length femur and tibia radiographs were performed too.

Additional projections in anterior–posterior and lateral-side of the knee under load and an axial of the patella were also performed.

For each case, a preoperative planning has been set up by evaluating the mechanical and anatomical axes, measured with appropriate software very accurately (to within 1°),¹¹ from full-length lower extremity radiographs (Maquet view) to evaluate alignment.

The center of the femoral head was defined using Moses circles. The preoperative center of the knee was determined using the midpoint of the two methods. The center of the line from the medial epicondyle border to the lateral epicondyle border at the level of the top of the intercondylar notch was demarcated. A second point at the center of the tibial plateau (measured at its widest level) was also demarcated. The midpoint of these two points in the center of the knee joint was determined to be the anatomical center of the knee. The

anatomical center of the ankle was defined as the midpoint of the superior facet of the talus.

Five angles were measured. In the frontal plane the hip knee ankle (HKA) angle was measured to determine the mechanical axis of the lower limb as a difference from the neutral mechanical axis defined as 0°. The mechanic lateral distal femur angle and the medial proximal tibial angle were measured to determine the alignment of the femur and the tibia respectively in the frontal plane.

To measure the alignment in the sagittal plane we used the posterior distal femur angle and the posterior proximal tibial angle.

To determine the amount of bone to be resected from the femur, a line perpendicular to the mechanical axes of the femur was drawn through the femoral condyle on the preoperative full-length weight-bearing radiograph of the affected limb. If the anticipated femoral condylar resection violated the integrity of the insertion of either the medial or the lateral collateral ligament the patient was excluded from the study and a two-step surgery was performed with a corrective extra-articular osteotomy, followed by a TKA later. For the tibia, the same Wang's criteria was applied.¹⁰

The five angles used in the preoperative radiographs were measured postoperatively to analyze the alignment of prosthetic components in the frontal and sagittal planes and were compared with intraoperative data provided by the navigation system (► Fig. 3).

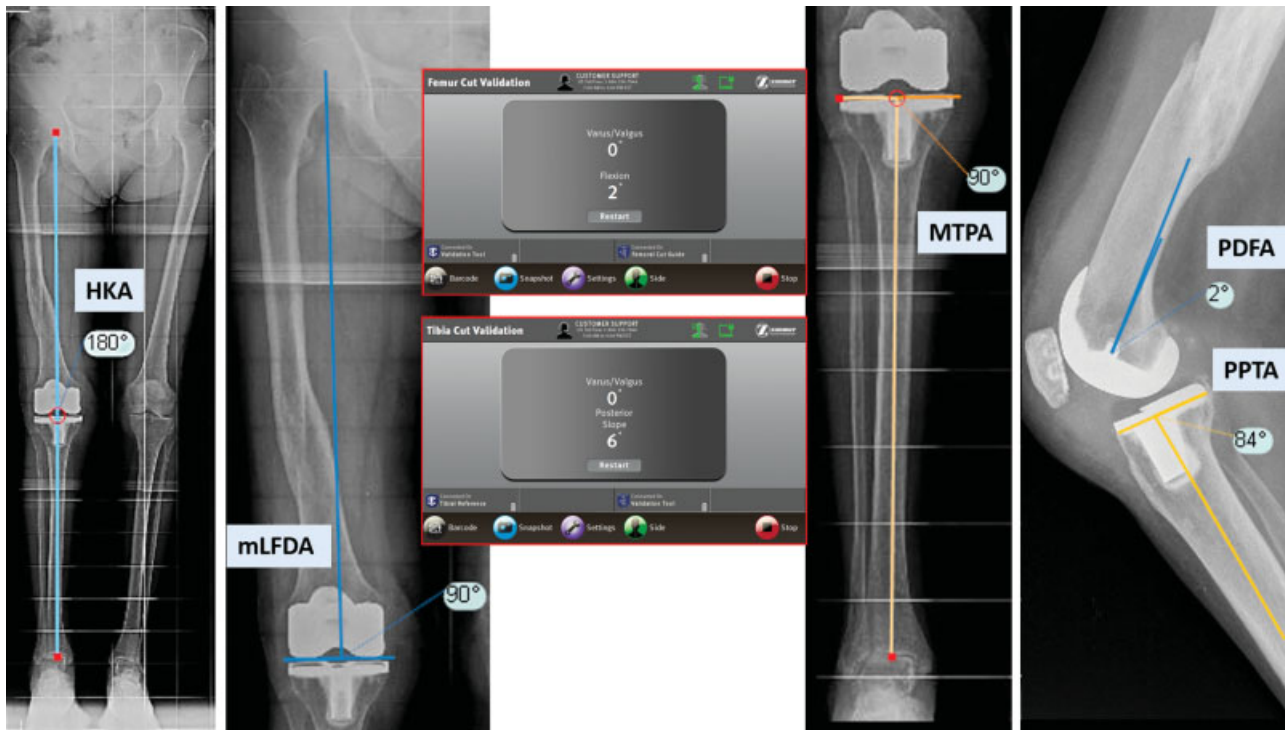


Fig. 3 Example of measurement of the five angles postoperatively and data provided by the navigation system intraoperatively for the same patient.

Table 1 Knee Society score and Functional score

	Mean preoperative (SD)	Mean 1 month (SD)	p-Value	Mean 6 months (SD)	p-Value
Knee score	43.3 (±12.3)	61.3 (±16.5)	<0.08	81.2 (±15.3)	<0.05
Function score	36.7 (±12.5)	58.8 (±16.2)	<0.08	79.3 (±16.5)	<0.05

Results

Mean follow up was 5.7 months (1–6). No intraoperative and postoperative surgical complications were reported in the series. The mean tourniquet time was 62 minutes (range 55–64 minutes). No blood transfusion has been necessary in the intra- and postoperative phase.

At the final follow up Knee and Functional scores increased from 43.3 to 81.2 ($p < 0.05$) and from 36.7 to 79.3 ($p < 0.05$), respectively (► **Table 1**).

Lower extremity mechanical axis measurements from preoperative full-length weight-bearing radiographs revealed a range from 17° varus to 15° valgus.

At 30-days postoperative radiographic check, the HKA angle was within 2.0° (0 ± 1) of the neutral mechanical axis.

The alignment of the tibial component on the frontal plane was 90.0° (range 89–91) and on the sagittal plane, 5.0° (range 3–7). The alignment of the femoral component on the frontal plane was 90.0° (range 89–91) and on the sagittal plane 3.0° (range 0–5) (► **Table 2**).

Discussion

With the iAssist system, we aimed to restore the neutral mechanical axis and to obtain an alignment of the tibial and femoral component on the frontal plane within 90° with

respect to the tibial and femoral mechanical axis and on the sagittal plane within 5° of the tibial slope and within 3° of the femoral flexion.

Our results showed that iAssist system enables the surgeon to restore the neutral mechanical axis components within 2° of tolerance.

The tibial component was aligned on the frontal plane at an average of 90.0° (range 89–91) and on the sagittal plane at 5.0° (range 3–7). The alignment of the femoral component on

Table 2 Data provided from measurement in full-length lower extremity radiographs, postoperatively

	Data provided from measurement in full-length lower extremity radiographs
Postoperative mechanical axis (HKA)	0 ± 1 degree
Postoperative mLFDA	90.0 degree (range 89–91)
Postoperative MPTA	90.0 degree (range 89–91)
Postoperative PDFA	3.0 degree (range 0–5)
Postoperative PPTA	5.0 degree (range 3–7)

Abbreviations: HKA, hip knee ankle; mLFDA, medial lateral femoral distal angle; MPTA, medial proximal tibial angle; PDFA, posterior distal femur angle; PPTA, posterior proximal tibial angle.

the frontal plane was 90.0° (range 89–91) and on the sagittal plane, 3.0° (range 0–5).

Extra-articular deformity around the knee is a surgical challenge to fight with conventional instrumentation when performing a TKA.

In most of the cases, an extramedullary guide is used for tibial cuts. However, in case of deformity, having precise and secure anatomical landmarks to place the cutting block with the correct slope and alignment is difficult also with an extramedullary guide. On the other hand, an intramedullary guide is often used for the femur. Obviously, in case of retained hardware in the canal or in case of a metaphyseal–diaphyseal deformity, the rod is impossible to use. Furthermore, standard valgus alignment guide has limited angles of choice. Staged surgical procedures, including osteotomy of the femur or tibia, followed by traditional TKA, can be used to recreate the correct mechanical axis, nevertheless increasing the risk of complications.¹² Therefore, in all these cases, having a system that bypasses the deformity could be helpful.

Computer-assisted stereotaxic navigation (CASN) was introduced as an adjunct to TKA surgery with the potential to improve positioning and alignment of the TKA prosthesis. Although recent meta-analyses demonstrated that the average coronal plane alignment after computer-assisted navigation TKA was not different from conventional TKA, the variability in the outcome was reduced.^{13–15} These meta-analyses concluded that it might be employed as a method of reducing error in prosthesis positioning, improving accuracy of postoperative lower-limb alignment.

Kuo et al¹⁶ and Klein et al¹⁷ reported an alignment within 1 to 2° of femoral and tibial mechanical-articular angles in patients with extra-articular deformity or retained hardware underwent TKA using CASN.

Liu et al¹⁸ reported that CASN TKA for osteoarthritis with extra-articular deformity resulted in satisfactory outcomes. Still, despite of these encouraging data, CASN has some disadvantages. Use of trackers with transosseous pins enhances the risk of weakening the anterior cortex of femur and tibia^{19–21} and of additional bleeding; furthermore, the system requires a recording chamber of the signal and the surgeon needs to observe a monitor during the whole operation. Several studies underline major surgical times and a learning curve of approximately 30 cases to overcome the delay in operating time.^{22,23}

Also CASN, the use of Robot technology shares with it the same disadvantages.^{24–26}

Doubtless, the accuracy in alignment, the safety and the possibility of a tissue-sparing surgery make the Robot a valid tool in operating room.^{24,25} Kim et al investigated the role of Robot-assisted surgery in intra-articular deformity, such as hemophilic arthropathy,²⁶ showing excellent accuracy of lower limb and component alignment. However, they concluded that “expensive cost, additional preparation time, and longer operation time with similar clinical results in hemophilic arthropathy should be concerned.” Furthermore, planning a surgery with Robot requires computed tomography (CT) scan that is not safe and comfortable for the patients. To

use CT scans the system needs dedicated softwares and a variable period to create the template, whereas not everywhere softwares using the Robots are available and optimized for TKA. Both the technologies are expensive and not all the health care centers can afford it.

Patient-specific instrumentation (PSI) is another option in complex TKA.^{27,28} Roh et al reported some increase in error rate on CT-based PSI compared with MRI.²⁹ However, creating the custom made cutting blocks needs almost 3 to 6 weeks, and during surgery no feedbacks for alignment or rotation are available. Many studies in the literature are discordant on outcomes obtained by the use of this system.^{28,30} Chen et al³¹ reported that the clinical outcomes were comparable between the PSI-TKA and conventional-TKA groups. Several authors report a minor accuracy compared with CASN. Lionberger et al²⁸ showed that accuracy within $\pm 3^\circ$ from neutral alignment was achieved in 90% of the CASN TKA, compared with 80% among the patient-specific instrumentation group. Similar findings were found compared with manual versus PSI with an accuracy of $\pm 3^\circ$.³² Using the same accuracy, Nunley et al found 32% of PSI compared with conventional 40%.³³

Our experience with this brand new tool seems to be efficient and adequate to achieve correct alignment during TKA. With respect to other expensive and complex technologies, this system is surely cheaper and easy to be applied for the management of complex TKA. No significant increments of surgical time and blood loss have been recorded in this series. The learning curve may be considered approximately five cases.

Our data are in line with the recent literature that have compared the accuracy in restoring the neutral mechanical axes of this internal position-sensing technology and conventional instrumentations.³⁴

On sagittal plane, we positioned the tibial component with 3 to 7° of slope and the femur component with a flexion from 0 to 5°. Kim et al³⁵ found that flexions of the femoral component of $>3^\circ$ or sagittal alignment of the tibial component of $<0^\circ$ or a tibial slope of $>7^\circ$ were risk factors for failure. However, their measurements on the sagittal plane referred to anatomical axes on the postoperative short lateral side radiographs of the knee, according to the Knee Society Radiographic Evaluation System. Our measurements, instead, are evaluated on the lateral side femur and tibia into full-length radiographs, referring to mechanical and nonanatomical axes.

Our study presents some limitations. Number of cases consisted only of 13 patients, but this limitation is accounted for the small incidence of osteoarthritis associated with extra-articular eligibility for TKA without a previous osteotomy step. The follow up was short and we reported the Knee score and Functional score without any comparison with the outcome of conventional TKA cases. However, our study wanted to be a radiographic analysis of the iAssist ability to restore neutral mechanical axes in case of extra-articular deformities.

In conclusion, we can affirm that the accelerometer-based navigation system is a useful technique that can be used to optimize TKA alignment in patients with extra-articular

deformity or with lower limb hardware, where the intra-medullary guides cannot be applied, with a good component positioning and restoration of the neutral mechanical axis.

Conflict of Interest

None declared.

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