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ORIGINAL STUDY

Non-invasive navigation in total knee arthroplasty : a validation study

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The purpose of this study was to evaluate intraoperative alignment during total knee arthroplasty using a handheld navigation system, iAssist, in comparison with conventional optical surgical navigation.
Sixty-two consecutive patients were enrolled in this prospective study. iAssist was used to determine implant component positioning. Orientation of the cuts were verified using a conventional optical surgical navigation system. We compared the iAssist system with the conventional system in terms of accuracy, percentage of outliers, bias, and precision.
The occurrence of component malalignment was low. Taking standard radiography as the reference, there were no relevant differences between the handheld device and optical navigation in terms of measurement of accuracy or in outlier occurrence. Bias was small for both technologies, and precision was comparable.
The study provides preliminary evidence that the use of iAssist leads to satisfactory implant alignment. The results from this study imply that iAssist could be a viable alternative to conventional optical navigation.

Keywords : Total knee arthroplasty ; navigation ; non-invasive.

INTRODUCTION

Previous studies have shown that coronal, sagittal, and rotational plane outliers are linked with inferior function after total knee arthroplasty (TKA) *(1,3,4)*. In order to minimise these outliers in component positioning and alignment, surgical navigation TKA was introduced *(17)*. Meta-analyses have shown that TKA performed with surgical navigation reduces the risk of mechanical malalignment of the knee, the risk of coronal plane malalignment for the tibial and femoral components, and the risk of femoral flexion and tibial slope malalignment *(11,17)*. Although not consistently reported in the literature, large registries show advantages in terms of implant survival for younger patients undergoing TKA with surgical navigation *(14)*. However, the widespread use of surgical navigation has been hindered by an increased risk of infection, complications related to the pin site, a longer operative time, and perceived complexity of the procedure *(2,8,15)*.

Patient-specific instrumentation (PSI) has been developed to minimize the shortcomings of surgical navigation while improving the accuracy of component placement compared with conventional instrumentation. However, several meta-analyses have confirmed that PSI does not improve the accuracy

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of alignment of the components in TKA compared with conventional instrumentation *(6,18,19)*.

New navigation systems that make use of accelerometers and gyroscopes have recently been introduced. These systems are less bulky than conventional systems, do not require the insertion of tracking pins, and make the surgical navigation more straightforward *(7,16)*. One of these is iAssist Knee System (Zimmer Biomet, Warsaw, IN, USA), which consists of two disposable pods that are secured to the resection guides and communicate with each another via internal radiofrequency networks. Information about the orientation of the coronal and sagittal axes are captured by these pods, and this enables navigation and verification of the distal femoral and tibial bone cuts. The remainder of the procedure, including ligament balancing, is carried out in a standard fashion. There have been few studies comparing these new navigational devices to conventional systems *(7,13)*.

The aim of this study was to assess alignment obtained with iAssist. We also evaluated intraoperative alignment during TKA using iAssist in comparison with conventional optical surgical navigation. We hypothesized that the difference between iAssist and optical surgical navigation is negligible in terms of the measurement of alignment of femoral and tibial component placement.

MATERIALS AND METHODS

From June 2012 to November 2013, 62 TKAs were consecutively enrolled in this prospective study. Patients requiring primary TKA for primary osteoarthritis were eligible. Patients with a history of ipsilateral knee surgery (with the exception of arthroscopy) or ipsilateral trauma to the knee were excluded. All patients consented to participate in the study. The study cohort consisted of 35 females and 27 males. The mean age of the population was 66.9 ± 8.7 (range, 40-87) years.

The implant's initial target position was set to obtain a neutral hip-knee in the coronal plane and a 3° posterior slope of the tibia in the sagittal plane. iAssist was used to perform navigation. The bone cuts, starting with the tibia, were performed independently. For preparation of the tibia, a pod was connected to an extramedullary (EM) rod, which provided a reference for the tibial mechanical axis. Clamps placed around the malleoli and centred on the tibia secured the arrangement distally. Additionally, this structure was impacted proximally between the tibial spines. Gyroscopes and accelerators were activated, which transmitted the axis determined by this EM rod to the iAssist pod.

For the femur, in order to obtain the reference femoral mechanical axis, a bone spike with a pod clipped to it was inserted into the distal femur, and then centred on the intercondylar notch deemed to be the distal reference point. Kinematic determination of the femoral head centre was used to obtain the proximal reference point. The centre was determined through quickly moving the hip through abduction, the neutral position, and adduction while flexing the knee. According to the information provided by the LED indicators, the distal femoral-cutting guide was then oriented in the coronal and sagittal planes. The orientation of the cut was assessed using a validation step, and corrected if necessary. With the alignment rotated upon Whiteside's line, a 4-in-1 femoral cutting guide was used to prepare the femur.

For both the tibial and the femoral components, the information provided by the iAssist pod was used to determine the necessary adjustments in the position of the tibial cutting guide. Orientation of the cuts were verified using a conventional optical surgical navigation system (Brainlab, Brainlab AG, Munich, Germany). In case of a deviation of 2° or more from the targeted position, a modification of the position of the cutting guide was performed and controlled by the iAssist system. A Vanguard Posterior-Stabilized System (Zimmer Biomet) was used in all cases.

Standardized and lateral radiographs were taken 6 weeks postoperatively. A single evaluator (NG) then performed the radiographic measurements. Femoral coronal alignment was defined as the angle between the articular surface of the femoral component and the mechanical axis of the femur, with an ideal perpendicular angle of 90° *(19)*. Femoral sagittal alignment was defined as the angle between the distal femoral cut line and the femoral anterior cortex, with an ideal angle of 3° *(19)*. Tibial component

Table I. — Postoperative implant position as measured by radiography

		Mean ± SD [°]	Malalignment (n [%])
Tibia, coronal plane	Coronal plane (n = 62)	90.9 ± 1.8	5 (8.1)
	Sagittal plane (n = 62)	3.2 ± 2.5	8 (12.9)
Femur, sagittal plane	Coronal plane (n = 59)	90.5 ± 1.5	0 (0.0)
	Sagittal plane (n = 60)	2.3 ± 2.1	4 (6.7)

Abbreviation: SD, standard deviation

coronal alignment was defined as the angle between the inferior surface of the tibial component and the tibial mechanical axis *(19)*. Tibial component coronal alignment was set at 90°. Tibial sagittal was defined as the angle between the line representing the posterior inclination of the tibial plateau and the line perpendicular to the line through the centre of the diaphysis of the tibia *(10)*. The tibial slope angle was set at 3°.

Ethics committee approval (reference : B096201734117) was obtained prior to study commencement, and all patients provided informed consent.

Component positioning was expressed as mean ± standard deviation, and as number (percentage) of components malaligned. Malalignment was defined as measurements greater than 3° from the intended value *(18)*. Accuracy was evaluated by assessing the absolute value of the difference between intraoperative values obtained with the iAssist and a conventional optical navigation system relative to postoperative radiography. Bias was calculated by evaluation of the difference between intraoperative values obtained with the iAssist and the conventional navigation system relative to postoperative radiography, and as percentage of patients with greater than 3° deviation of iAssist and the conventional navigation system relative to postoperative radiography. Precision was evaluated by means of the 95 percent limit on the differences between iAssist and radiography and optical navigation and radiography, respectively. Limits of agreement were defined as 1.96 times the standard deviation around the mean difference *(5)*.

Continuous variables were compared using paired t-tests, categorical variables were compared employing Fisher's exact tests. SPSS 17.0 (SPSS Inc., Chicago, Illinois) was used for statistical analysis. P-values of <0.05 indicated statistical significance.

RESULTS

None of the cases required cessation of the procedure. No intraoperative or early postoperative complications were noted. Component alignment as measured by standard radiography is presented in Table I.

The accuracy (mean of the absolute difference between iAssist /optical navigation and radiography) ranged from 1.3° for femoral component coronal plane alignment to 1.5° for tibial component coronal plane alignment for iAssist. For optical navigation, these values were 1.4° for the femoral and 1.4° for the femur, with no statistically significant differences between them (Table II).

Bias was small (less than 1°) for both iAssist as for optical navigation. The differences reached the level of significance for tibial component alignment in the coronal ($p = 0.004$) and in the sagittal plane ($p = 0.046$). In terms of deviation greater than 3°, there were no significant differences found between the two methods, with the exception of coronal plane alignment of the femoral component, for which 0 knees (0%) were identified as outliers using iAssist, whereas optical navigation identified 8 knees (13.6%) as outliers ($p = 0.003$). Precision between the two technologies, as determined by the 95% limits of agreement, was comparable.

DISCUSSION

An important finding of this study was that, with standard radiography as the reference, iAssist led to an accurate alignment of the components in TKA. A recently published meta-analysis revealed a proportion of malalignment using standard instrumen-

Table II. — Accuracy and precision of intraoperative alignment measurement during total knee arthroplasty

		iAssist	**Optical navigation**	**p-value**
Tibia, coronal plane	n	62	62	-
	Accuracy [°] (mean ± SD*)	1.5 ± 1.4 (0 – 8.0)	1.8 ± 1.6 (0 – 6.5)	0.265
	Bias [°] (mean ± SD)	-0.6 ± 2.0	0.6 ± 2.3	0.004
	Deviation > 3° (n [%])	5 (8.1)	9 (14.5%)	0.395
	Precision [°] (LLoA† – ULoA‡)	-4.5 – 3.3	-3.8 – 5.1	-
Tibia, sagittal plane	n	62	61	-
	Accuracy [°] (mean ± SD)	1.9 ± 1.3	1.7 ± 1.3	0.270
	Bias [°] (mean ± SD)	-0.2 ± 2.3	0.6 ± 2.1	0.046
	Deviation > 3° (n [%])	10 (16.1)	10 (16.4)	1.00
	Precision [°] (LLoA – ULoA)	-4.7 – 4.4	-3.4 – 4.6	-
Femur, coronal plane	n	59	59	
	Accuracy [°] (mean ± SD)	1.3 ± 1.0	1.4 ± 1.4	0.596
	Bias [°] (mean ± SD)	-0.2 ± 1.6	0.1 ± 2.0	0.370
	Deviation > 3° (n [%])	0 (0.0%)	8 (13.6%)	0.003
	Precision [°] (LLoA – ULoA)	-3.4 – 3.0	-3.8 – 3.9	-
Femur, sagittal plane	n	60	60	-
	Accuracy [°] (mean ± SD)	1.8 ± 1.2	1.9 ± 1.3	0.484
	Bias [°] (mean ± SD)	0.2 ± 2.2	0.3 ± 2.3	0.890
	Deviation > 3° (n [%])	5 (8.3%)	10 (16.7%)	0.269
	Precision [°] (LLoA – ULoA)	-4.1 – 4.5	-4.4 – 4.9	-

Abbreviations: SD, standard deviation; LLoA, Lower Limit of Agreement; ULoA, Upper Limit of Agreement

tation was 7.9% and 21.2% for tibial coronal and sagittal plane alignment ; for the femur these values were 11.0% and 30.2% *(19)*. Hence, the present study implies that iAssist improves the accuracy of alignment of the components in TKA compared with conventional instrumentation. Another finding was that there were no major differences in accuracy between iAssist and optical navigation in the determination of implant component position. Bias expressed as the mean of differences between the two groups and radiography was small in all cases. Differences in bias between the iAssist and optical navigation are thought to be without clinical relevance. In terms of differences in deviation greater than 3° between the two methods and standard radiography, iAssist found a significantly lower proportion of patients that differed more than 3° from the radiographic measurements. Overall, the study findings indicate that the accuracy for measuring component positioning of iAssist is similar to the accuracy of optical navigation.

The iAssist is a simple system with pods clipped onto conventional cutting jigs within the surgical field. The system has been shown to support the surgeon intraoperatively, achieving accurate component alignment in the coronal and sagittal planes. In our experience, the iAssist system has a short learning curve, and the time required for calibration is significantly shorter than for conventional optical navigation. However, the system is unable to guide rotational alignment and soft tissue balancing.

The present paper provides incremental evidence on the effect of surgical accuracy of this new navigational device. As of today, the literature with regard to the effect of iAssist on alignment is conflicting. In a matched cohort study, Goh et al found no significant differences in outliers for hip-knee-ankle angle (HKA), coronal femoral and tibial component angle, or joint line elevation between iAssist and optical navigation *(9)*. In a randomized clinical trial comparing iAssist with optical navigation, Desseaux et al found no significant differences for the rates of HKA restoration (p = 0.30), correct coronal positioning of the femoral and tibial component (p= 0.12, respectively), or overall optimal alignment (p = 0.09) *(7)*. Significant differences in favour of iAssist were demonstrated for the values and angular deviations of HKA (p=0.02) and mechanical medial proximal tibial angle (p=0.01). No significant differences were found for mean duration of surgery (p = 0.06) and for the occurrence of navigation-related adverse events (p = 0.18). In another randomized clinical trial, Kinney et al compared iAssist with conventional instrumentation and noted significant alignment advantages. Four percent of patients had greater than 3° of tibial or femoral component malalignment in the iAssist group, compared with 36 percent in the conventional instrumentation group (p = 0.011) *(12)*. Advantages were also found in the variance seen in both the femoral mechanical axis (1.7° ± 0.2° versus 2.2° ± 0.3°, p < 0.005) and tibial mechanical axis (1.3° ± 0.1° versus 1.7° ± 0.2°, p < 0.005) compared to conventional instrumentation. No significant differences in tourniquet time (p = 0.86) or blood loss (p = 0.39) were found.

Our study has a number of limitations. Firstly, it assumes that radiography provides accurate information on component alignment. Secondly, radiographic analysis was performed by a single assessor at a single occasion ; hence no data on inter- and intraobserver variability were obtained. Thirdly, the study did not allow a direct comparison between iAssist and optical navigation in terms of surgical precision, as the actual cuts were not performed with optical navigation. Finally, the results only apply to the imageless navigation system employed in the present study and inferences may not be applicable to other systems.

To the best of our knowledge, this is the first study to report the efficacy of a disposable pod-based navigation system to determine component positioning when compared to traditional navigation system for TKA. Hence, additional studies are warranted to further validate this emerging technology.

CONCLUSION

The present study demonstrated that the use of the iAssist system led to a low occurrence of component malalignment. Furthermore, this handheld device has similar accuracy as traditional optical navigation system for intraoperative verification of bone cuts and limb alignment during TKA. In our opinion, compared with conventional optical navigation systems for TKA, the iAssist system is more compact and user-friendly, and provides a time-saving procedure. However, further studies, including studies assessing long-term clinical outcomes, are warranted.

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