RESEARCH ARTICLE

Comparison of Clinical, Functional, and Radiological Outcomes of Total Knee Arthroplasty Using Conventional and Patient-Specific Instrumentation

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Received: 26 August 2019 *Accepted: 26 April 2020*

Abstract

Background: Recently, patient-specific instrumentation (PSI) systems have been developed in order to increase the accuracy of component positioning during total knee arthroplasty (TKA); however, the findings of previous studies are controversial in this regard. In the current randomized clinical study, the outcomes of computer tomography (CT)-based PS (patient specific)-guided TKA were compared to the results of conventional instrumentation (CVI) TKA. The guides were designed on the basis of distal femoral and proximal tibial pin orientation of the conventional related guides.

Methods: The present study was carried out on 24 TKA candidates randomly assigned to two PSI (n=12) and CVI (n=12) groups. The patients were postoperatively followed for 2 years. Then, the hip-knee-ankle angle (HKAA), femoral component flexion, and orientation of components in the coronal plane were measured. In addition, the Western Ontario and McMaster Universities Osteoarthritis (WOMAC) Index and Knee Society Score (KSS) questionnaire were completed for all the patients.

Results: The rate of the outliers of the HKAA was higher in the CVI group (41.7% and 8.3%; *P=0.077*); nevertheless, the difference was not significant in this regard. The rate of the outliers of other radiographic measurements and operational time were similar in both groups. Furthermore, there was no significant difference between the two groups in terms of the WOMAC and KSS.

Conclusion: The CT-based PS-guided TKA may result in the improved postoperative mechanical alignment of the limb and should be considered in complicated TKAs. However, future studies should investigate whether the results of PSI TKA support the considerably higher costs of this technique.

Level of evidence: II

Keywords: Mechanical alignment, Patient-specific instrumentation, Total knee arthroplasty

Introduction

Although total knee arthroplasty (TKA) is associated with satisfactory outcomes, there have been some concerns regarding the surgery. The positioning of the prosthetic components is one of the most concerning issues during TKA. The results of previous studies have shown that the implant malpositioning and postoperative malalignment of the limb could result in poor outcomes and decreased lifetime of the prosthesis (1-7).

New prostheses and more advanced systems are developed to enhance the accuracy of implant positioning and improve the outcomes of TKA (8). The aim of designing patient-specific instrumentation (PSI)

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THE ONLINE VERSION OF THIS ARTICLE ABJS.MUMS.AC.IR

is the simultaneous improvement of patient outcomes and surgical efficiency in TKA. The PSI enables a surgeon to preoperatively perform the intraoperative three-dimensional (3D) planning (9). In recent years, the employment of PSI has increased due to its crucial significance in implant positioning (10).

The principle of using PSI in TKA is the individualization of the surgical procedure for the patient. The advantages of this method include an accurate realignment of the normal mechanical axis following the accurate positioning of the components, improved functional outcomes, minimization of the need for repeated bone cuts, shortened surgical time, determination of the proper size of the prosthesis within a shorter time, facilitated placement of components, decreased bleeding during and after the surgery, and dispensing with reaming of the femoral medullary canal (11-18).

However, it should be noted that the above-mentioned findings are controversial. Some studies have shown that PSI is highly beneficial in achieving the proper alignment of the prosthesis; nevertheless, some other investigations have not reported improved alignment in case of using PSI (8, 9, 12-17, 19-23). Furthermore, even some studies have stated that PSI may increase the risk of improper implant positioning (i.e., outlier) (11, 24). In addition, the results related to shortened surgical time are highly inconsistent. Although some studies demonstrated that PSI leads to decreased surgical time, others have shown that operational time might increase (11, 17). This can be due to the intraoperative changes of the implant size related to mismatching the specific prosthesis and preoperative plan (8, 9, 23, 25).

Currently, due to a lack of evidence regarding the mid-term and long-term outcomes of using PSI in TKA, especially clinical outcomes, it is not possible to precisely evaluate the advantages of this method (8, 10); accordingly, it is necessary to carry out further studies in this regard. This prospective study compared the clinical, functional, and radiological outcomes of TKA using PSI and conventional instrumentation (CVI) and aimed to investigate the improvement of mechanical outcomes of TKA using PSI.

Materials and Methods

Within 2012-2014, 23 patients with 24 primary osteoarthritic knees (OA) undergoing TKA in Akhtar and Nikan hospitals of Tehran, Iran, were enrolled in the current randomized study. For one patient with bilateral knee osteoarthritis, TKA was performed in separate stages; the right and left knees were assigned to the CVI and PSI groups, respectively. The patients with secondary posttraumatic OA, septic arthritis, rheumatoid arthritis, tumors around the knee, deformity of lower limbs requiring osteotomy, and comorbidities affecting the gait, such as hemiplegia, were not included in the present study. Informed consent was obtained from all the patients. The subjects were randomly assigned to two PSI (n=12) and CVI (n=12) groups.

All of the patients were operated using cemented Deep Dish prostheses (Corin Medical Company, Cirencester, UK). These prostheses are identical to posterior stabilized (PS) mobile-bearing prostheses with a fixed posterior tibial slope (i.e., 10°). The femoral components were available in five sizes, including extra small, small, medium, large, and extra large. Likewise, tibial components were available in six sizes, including extra extra small, extra small, small, medium, large, and extra large. All surgeries were performed by the same surgeon through a medial parapatellar approach while the tourniquet was inflated.

Preoperatively, weight-bearing alignment view in anteroposterior (AP) and lateral views were taken for all patients, and the hip-knee-ankle angle (HKAA) was measured. The HKAA was defined as the angle between the line extending from the center of the femoral head to the center of the knee and line drawn between the center of the knee and center of the ankle [Figure 1]. In the PSI group, 3D computer tomography (CT) reconstruction of the lower limb (i.e., from the femoral head to talus) was performed before the operation.

The findings of the 3D CT images were used by Fanavaran Jarahyar Sharif Ltd. to design the digital 3D model of the femur and tibia bones [Figure 2]. Then, a preliminary

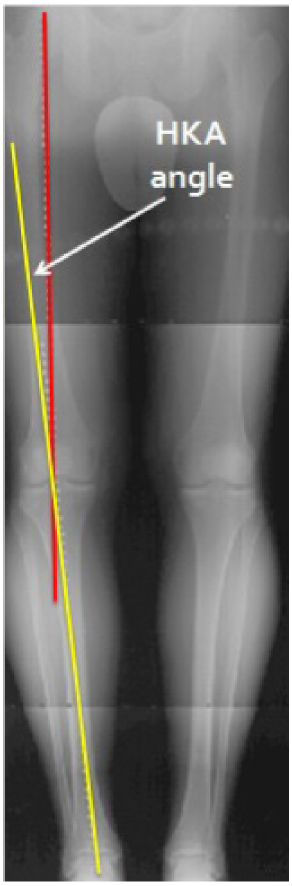

Figure 1. Measurement of hip-knee-ankle angle; the angle between the line from the femoral head center to the knee center and line between knee center and center of the ankle.

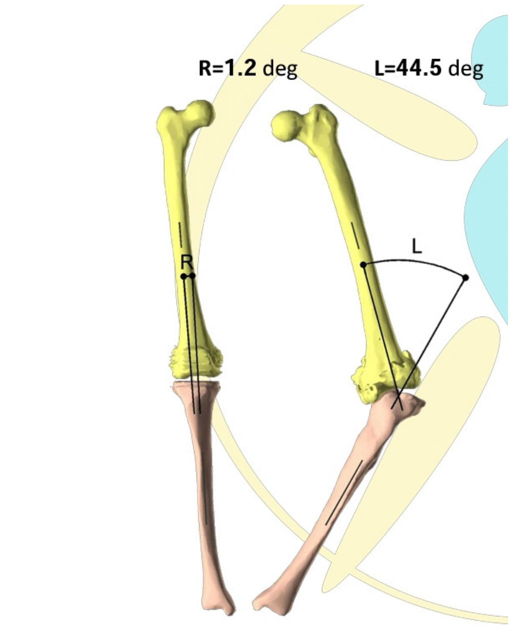

Figure 2. Reconstruction of long leg three-dimensional image of the lower limbs; investigation of the limb alignment in different knee flexion degrees and under weight-bearing.

preoperative plan was performed on the basis of the patients' imaging findings, including the level of bone resection and its size and alignment of the prosthetic components [figures 3A; 3B]. After the surgeon's approval, the patient-specific guide has been designed, and the guide was manufactured after rechecking by the surgeon [Figure 4].

The operations on the patients of the CVI group were performed utilizing intramedullary rod guides on both sides. The femoral guide was set in a manner to reach 5 degrees of valgus for the stimulation of the natural difference between the femoral mechanical and anatomical axis. The distal femoral bone perpendicular to the femoral mechanical axis was cut. Furthermore, the cut of the proximal tibia was made perpendicular to the tibial anatomical axis. Excluding the use of PS guide in the PSI group, other parameters, such as anterior, posterior, and chamfer femoral cuts, wound closure, drain placement, and postoperative thromboprophylaxis and rehabilitation were the same within both groups. Partial weight-bearing and passive exercises were stated at the first postoperative day. Full weight-bearing was allowed as tolerated.

The patients were asked to attend the hospital 2 years after the operation for the last visit. At that time, weight-bearing alignment view of the lower limbs in the AP and lateral views were taken [Figure 5]. The medial angle between the tangent line to the joint surface of the femoral component and femoral mechanical axis was measured as the femoral component angle in the coronal plane (i.e., F angle [Figure 6]. Similarly, for the measurement of the tibial component angle (i.e., T angle), the medial angle between the tangent line to the joint surface of the tibial component and tibial mechanical axis was measured [Figure 6]. The values larger and smaller than 90° were considered valgus and

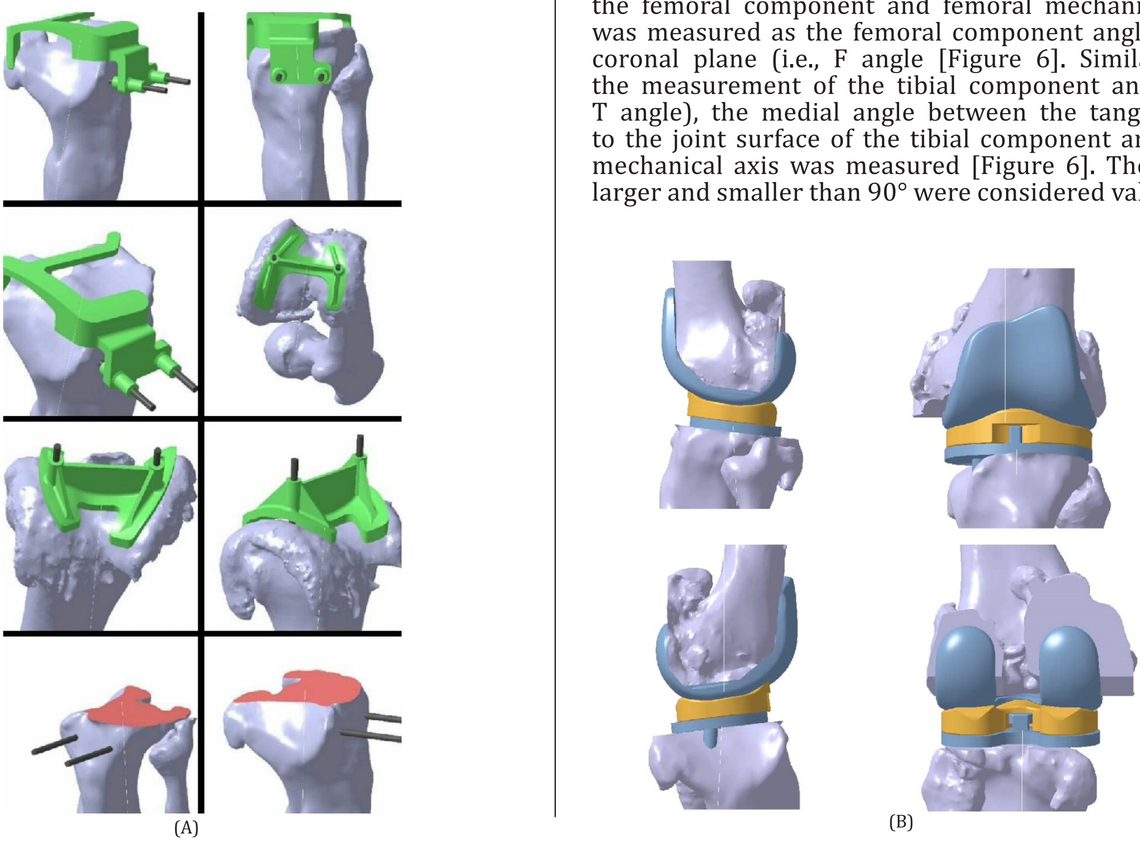

Figure 3. Preliminary preoperative plan, including (A) level of bone resection and its size in case of using patient-specific guide and (B) alignment of the prosthetic components.

Figure 4. Design and development of patient-specific guide based on the three-dimensional images.

Figure 5. Postoperative anteroposterior alignment view of a patient with bilateral total knee arthroplasty; operation of the right knee using conventional technique and left knee using patient-specific instrumentation.

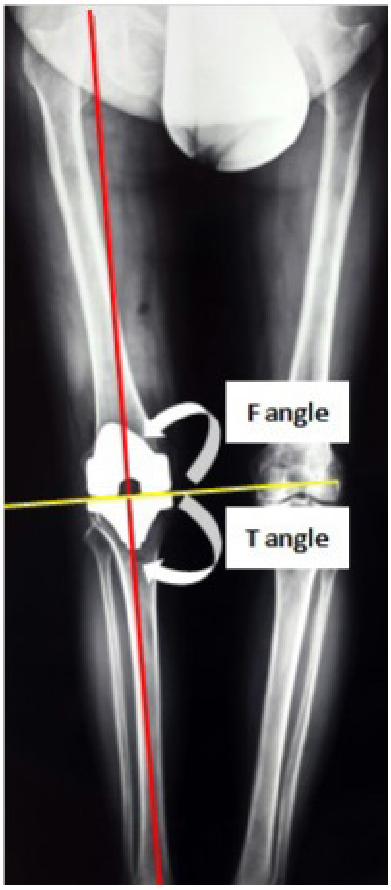

Figure 6. Measurement of *T angle*: the medial angle between the tangent line on the joint surface of the tibial component and tibial mechanical axis; *F angle*: the medial angle between the tangent line on the joint surface of the femoral component and femoral mechanical axis.

varus, respectively.

To measure the flexion of the femoral component, the angle between the tangent line on the anterior surface of the component and anterior femoral cortex in the sagittal view was measured [Figure 7]. It was aimed was to set the HKAA at 180° and place the femoral component within 0-3° of flexion. In all measurements, a deviation larger than 3° off the intended values was recorded as an outlier. For the investigation of the functional outcomes, the Western Ontario and McMaster Universities Osteoarthritis (WOMAC) Index and Knee Society Score (KSS) questionnaire were completed for all the patients. Finally, the data were compared between the two groups.

The Mann- Whitney U test was used in order to compare the quantitative data. Additionally, the Fisher's exact test was utilized to compare the qualitative variables. The SPSS software (version 15.0) was used for the statistical analysis of the data. A *P-value* of less than 0.05 was considered statistically significant.

Figure 7. Measurement of femoral component flexion: the angle between the tangent line on the anterior surface of the component and anterior femoral cortex in the sagittal plane.

Results

There was no difference between the two groups in terms of age, gender, body mass index, and preoperative HKAA [Table 1]. The mean values of radiographic measurements, including the postoperative HKAA, T angle, F angle, and femoral component flexion, were compared indicating no significant difference between the two groups [Table 2]. However, Table 3 tabulates the incidence of the outliers in each of the radiographic variables and total incidence of the outliers. The incidence rate of the outliers of HKAA in the CVI group was greater, compared to that reported for the PSI group; however, the difference was not significant (*P=0.077*). The incidence of the outliers in other parameters was not significantly different. The operational time was shorter in the PSI group; nevertheless, the difference did not reach a significant level [Table 4]. In addition, the outcomes of the treatments based on the WOMAC index and KSS questionnaire were similar in the two groups [Table 4].

Discussion

The most important conclusion of the current study was that TKA using CT-based PSI can be associated with the improved postoperative alignment of the lower limb; however, the difference was not significant due to the limited sample size. The results of previous studies

Table 1. Comparison of age, gender, body mass index, and preoperative hip-knee-ankle angle between two groups

Group		Conventional instrumentation (n=12)	Patient-specific instrumentation (n=12)	*P-value*
Age		62.6±8.7	60.3±10.4	0.415
Gender	Male	4	6	0.68
	Female	8	6	
Body mass index (kg/m^2)		29.2±1.1	29.7±1.8	0.846
Preoperative hip-knee-ankle angle (degree)		170.5±6.6	171.3±4.7	0.212

Table 2. Comparison of radiographic parameters between two groups

Group	Conventional instrumentation (n=12)	Patient-specific instrumentation (n=12)	*P-value*
Hip-knee-ankle angle (degree)	179.3±1.6 (174.7-183.3)	178.8±1.4 (174.1-184.5)	0.417
T angle (degree)	88.9±1.8 (84-93.5)	88.4±1.8 (84.2-92.8)	0.672
F angle (degree)	90.4±1.2 (84-94.3)	88.9±1.7 (84.8±94.5)	0.163
Flexion of femoral component (degree)	3.7±1 (1-6)	3.1±1 (1-6)	0.223

Table 3. Comparison of the incidence of outliers in radiographic variables between two groups

Group	Conventional instrumentation (n=12)	Patient-specific instrumentation (n=12)	*P-value*
Hip-knee-ankle angle	5 (41.7%)	1 (8.3%)	0.077
T angle	4 (33.3%)	3 (25%)	0.5
F angle	4 (33.3%)	2 (16.7%)	0.32
Flexion of femoral component	7 (58.3%)	7 (58.3%)	1

Table 4. Comparison of the incidence of outliers in radiographic variables between two groups

Group	Conventional instrumentation (n=12)	Patient-specific instrumentation (n=12)	*P-value*
Operational time (min)	103.7±8.6	98.5±9.3	0.093
WOMAC Index	82.5±8.3	84±5.8	0.527
KSS	170.1±8.4	169.2±9.5	0.263

WOMAC: Western Ontario and McMaster Universities Osteoarthritis Index; KSS: Knee Society Score

have shown that the malpositioning of the prosthetic components in the coronal, axial, or sagittal plane can result in several problems, such as early loosening, increased erosion of the polyethylene, pain, and instability or increased probability of the supracondylar fracture (1-5). Greater than 3° of deviation in the coronal alignment of the lower limb can be associated with an increased risk of revision surgery and poorer functional outcomes (6, 7).

Numerous attempts have been made to increase the accuracy of implant positioning with the improved overall alignment of the lower limb. In recent years, navigation systems and PSI have been increasingly employed worldwide, which can be very helpful, especially in case the use of an extra- or intra-medullary guide is not possible. Although the desirable effects of PSI have been reported in some studies, there have been some studies not supporting the use of PSI (8, 9, 12-17, 19-23). The controversial findings of previous studies necessitate performing further studies regarding the use of PSI in total joint arthroplasty; accordingly, the present study compared the clinical, functional, and radiological outcomes of CT-based PSI TKA and CVI TKA.

In the current study, it was observed that PSI can be useful in decreasing the number of outliers in the mechanical axis of the limb in the coronal plane (41.7% and 8.3%). However, there was no significant difference in the radiographic parameters and number of outliers, possibly due to the small sample size of the current study. It seems that if the number of patients participating in the present study was larger, more reliable outcomes would have been achieved. In the current study, predicting the size of the components was absolutely true for all the patients enrolled in the PSI group; however, it should be noted that probably the TKA system employed in this study has its own influence on the aforementioned finding.

Furthermore, in the present study, the short-term clinical and functional outcomes were similar. According to a study carried out by Anderl et al., it was revealed that PSI can improve the mechanical alignment of the limbs and decrease the number of outliers; nevertheless, no improvement in the short-term clinical outcomes was observed (14). Furthermore, Ferrera et al. and Vide et al. indicated that the number of the outliers of the mechanical axis in the coronal plane (a deviation greater than 3°) was significantly lower in the PSI group, compared to that reported for the CVI group (12, 13). Heyes et al., Nabavi and Olwill, and Renson et al. have reported the favorable outcomes of using PSI in TKA (15-17).

Contrary to the results of the current study, there have been some studies not supporting the aforementioned advantages of PSI. Some studies have even shown that PSI may result in an increased number of errors. Recently, in a clinical trial carried out by Abane et al., it was observed that PSI has no role in the reduction of outliers. In the aforementioned study, the outliers were noticed in 32.8% of patients in the CVI group, compared to 32.2% in the PSI group. In addition, the two groups had no significant difference in terms of clinical outcomes (9).

Moreover, Abdel et al. stated that the alignment measured during PSI TKA using intraoperative navigation is significantly different from the one that finally obtained (20). Similar functional outcomes and similar revision rates in a study conducted by Chen et al. do not justify the application of PSI in a large scale, especially due to the high costs and considerable surgical time (21). In addition to these studies which observed no difference between PSI and CVI, Chen et al. indicated that PSI is associated with an increased outlier of the HKAA (24).

In the current study, the operational time was slightly shorter in the PSI group; however, the difference between the two groups was not statistically significant. This finding is similar to the results of studies carried out by Renson et al. and Noble et al. in which operational time was shorter in the PSI group (11, 17). Conversely, in addition to the aforementioned findings, Stronach et al. revealed that it is even possible that PSI results in prolonged surgical time (25). Furthermore, Zhu et al., Kotela et al., and Abane et al. stated that there is no significant difference in terms of operational time between PSI and CVI TKA (8, 9, 23).

As mentioned above, a large number of studies with different methods and controversial findings have led to confusion and inability in decision-making for using or not using PSI in TKA. There have been some systematic reviews indicating that no benefit has been achieved in case of using PSI in TKA. For example, in a study recently carried out by Mannan et al., it was demonstrated that PSI cannot improve implant positioning and mechanical alignment of the lower extremity (26). Furthermore, in a systematic review, Zhang et al. have shown that the use of PSI leads to the decreased accuracy of implant positioning and increased number of outliers (27).

Based on the above-mentioned statements, it is required to perform further studies in order to recommend using PSI as a routine method. However, PSI is associated with substantially greater financial burden on the patients and healthcare system, as expected, not evaluated in the current study. It is necessary to carry out future studies to investigate whether the outcomes of PSI TKA support its markedly higher price because treatment cost is one of the most important factors affecting the selection of the method of treatment.

Additionally, it seems that different study designs and application of different PSI systems may affect the outcomes of previous studies. Magnetic resonance imaging-based PSI has been used in the majority of performed studies; however, CT-based PSI has been employed in a few studies, similar to the current study (9, 12, 14, 15). It is necessary to introduce a comprehensive protocol to design relevant studies and evaluate the efficacy of PSI. Therefore, it will be possible to make decisions about the utilization of PSI in TKA based on the findings of relatively similar studies.

The present study had several limitations. In the current study, the alignment of the components in the axial plane was not evaluated due to requiring a postoperative CT scan that caused the patients to be exposed to X-ray. The obtained results of the present study are not very reliable due to the small sample size. Moreover, the follow-up period was short, and it is necessary to compare the mid-term or long-term outcomes of PSI and CVI TKA in future studies. Finally, the cost of treatment was not investigated in the current study which was considerably higher in the PSI group, compared to that reported for the CVI group, and may affect the decision on using this method for TKA.

According to the obtained results, it can be concluded that CT-based PSI can be associated with the improved postoperative mechanical alignment of the lower limb and decreased rate of deviation from the neutral axis. However, based on the higher costs and complicated process, it may not be appropriate to routinely use PSI for all of the TKA patients. Selected patients may greatly benefit from this method.

Conflicts of interest: The authors declare that there is no conflict of interest.

Acknowledgments

The authors would like to appreciate the cooperation of Fanavaran Jarahyar Sharif Ltd. that helped in designing and producing the guides utilized in the current study.

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