Abstract

Introduction: 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 current randomized clinical study, the outcomes of CT-based pin guided PSI TKA were compared with results of conventional instrumentation TKA (CVI).

Materials and methods: There were 50 TKA candidates, which assigned randomly to two equal groups of PSI and CVI. The patients were followed for 2 years, postoperatively. After 2 years, the hip knee ankle angle (HKAA), femoral component flexion and orientation of components in coronal plane were measured. Also, Western Ontario & McMaster Universities Osteoarthritis (WOMAC) Index and knee society score (KSS) were completed for all patients. Other variables included volume of blood loss and operational time.

Results: The rate of outliers of HKAA was observed significantly higher for CVI group (44% Vs 12%, p=0.025). The rate of outliers of other radiographic measurements and the operational time were the same. The volume of blood loss was significantly higher in CTKA group (226.3±21.4 CC vs 187.3±25.5 CC, p<0.001). Furthermore, there was no significant difference in term of WOMAC and KSS.

Conclusion: CT-based pin guided PSI TKA can significantly improve the postoperative mechanical alignment of the limb and significantly decrease the postoperative blood loss.

Keywords: total knee arthroplasty, patient-specific instrumentation, mechanical alignment, blood loss

Introduction

Although total knee arthroplasty (TKA) is associated with satisfactory outcomes, however, there are some concerns regarding the surgery. One of the most important concerns in TKA is associated with the positioning of the prosthetic components. Previous studies have shown that the implant malpositioning and postoperative misalignment of the limb which 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 a patient specific instrumentation (PSI) is mainly associated with simultaneous improvement of patient outcomes and surgical efficiency in TKA. Indeed, PSI enables a surgeon to preoperatively perform the intraoperative 3-D planning (9). In recent years, employment of PSI has increased due to its crucial significance on implant positioning (10). The principle of using PSI in TKA is personalization the surgical procedure for the patient. The advantages of this method can include accurate realignment of the normal mechanical axis following accurate positioning of the components, improved functional outcomes, minimizing the need to cut and remove bones, shortened surgical time, reduced operation costs, determination of proper size of prosthesis within a shorter time, facilitated placement of components, decreased bleeding during and after surgery, dispensing with reaming of the femoral medullary canal, and reduced thromboembolic complications (11-18).

However, it should be noted that these findings are controversial. Some studies have shown that PSI is highly beneficial in achieving proper alignment of prosthesis (12-17), whereas some other investigations have not reported improved alignment once PSI was used (8, 9, 19-23). Furthermore, even some studies have stated that PSI may increase the risk of improper implant positioning (outlier) (11, 24). In addition, the findings related to shortened surgical time are highly inconsistent. While some believe that PSI leads to decreased surgical time (11, 17), others have shown that the surgical time might be increased. This can be due to the intraoperative changes of the implant size related to mismatching of the specific prosthesis and the preoperative plan (8, 9, 23, 25). Currently, due to lack of information regarding the midterm and long-term outcomes of using PSI in TKA, especially clinical outcomes, it is not possible to evaluate the advantages of this method precisley (8, 10). Accordingly, the necessity of conducting further studies is clear and evident. In this prospective study, we compared clinical, functional, and radiological outcomes of TKA using PSI and conventional instrumentation (CVI). **The purpose of the study was to investigate whether PSI can improve the outcomes of TKA.**

Materials and methods

Between 2012 and 2013, 50 patients with primary knee osteoarthritis (OA), underwent unilateral TKA in Akhtar Hospital, were enrolled in the current randomized study. The patients with posttraumatic OA, septic arthritis, rheumatoid arthritis, perigenicular tumors, deformity of lower limbs requiring osteotomy, and comorbidities affecting the gait such as hemiplegia were not included in the current study. Patients were asked to sign informed consent. They were assigned into two equal groups randomly: PSI group and CVI group.

All of the patients were operated using cemented Deep Dish prosthesis (Corin Medical Company, Cirencester, UK). These prostheses are identical to posterior stabilized (PS) mobile-bearing prostheses and have a fixed posterior tibial slope (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 medial parapatellar approach while tourniquet infiltrated.

Initially, long leg radiography in anteroposterior and lateral views were obtained and hip knee ankle (HKA) angle was measured. HKA angle was defined as the angle between line extending from the center of the femoral head to the center of the knee and the line drawn between center of the knee and center of the ankle (Fig. 1). In PSI group, 3-D CT reconstruction of the lower limb (from femoral head to talus) was performed 4 weeks before the operation. The long leg X-ray and 3-D CT images were processed using Jarrahyar-e-Sharif software. Then, a preliminary preoperative plan was formulated based on the patient's properties including level of bone resection and its size, and alignment of the prosthetic components. After the surgeon's approval, the manufacturer produced the patient specific guides.

The operations on the patients of CVI group were performed utilizing intramedullary rod guides in both sides. The femoral guide was set in a manner to reach 5 degree of valgus to simulate the natural difference between femoral mechanical and anatomical axis. We tried to cut the distal femoral bone perpendicular to the femoral mechanical axis. Furthermore, the cut of the proximal tibia was made perpendicular to the tibial anatomical axis. Excluding the use of cutting blocks in 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.

Patients were asked to attend the hospital two years after the operation for the last visit. At this time, long leg radiography in AP and lateral views was performed. The postoperative radiographic measurements included HKA angle and orientation of femoral and tibial components in sagittal and coronal planes. Our goal was to achieve an HKA angle of 180° with the operation. The values above and below 180° were considered valgus and varus, respectively. To measure the femoral component angle in coronal plane (F angle), the medial angle between the tangent line on the joint surface of femoral component and the femoral mechanical axis was measured (Fig 2). Similarly, to measure the tibial component angle (T angle), the medial angle between the tangent line on the joint surface of tibial component and the tibial mechanical axis was measured (Fig. 2). The values larger and smaller than 90° were considered valgus and varus, respectively. To measure the flexion of femoral component, the angle between the tangent line on the anterior surface of the component and the anterior femoral cortex in the sagittal view was measured (Fig. 3). Our aim was to place the femoral component within 0-3° of flexion. In all measurements, a deviation larger than 3° off the intended values was recorded as outlier. To investigate the functional outcomes, Western Ontario & McMaster Universities Osteoarthritis (WOMAC) Index and Knee society knee score (KSS) were completed. Other measured variables included operational time (the time between skin incision to wound closure), length of hospital stay and volume of postoperative bleeding accumulated in drains in the first two postoperative days. Furthermore, the intraoperative and early and late postoperative complications were recorded. Finally, the data were compared between two groups.

In order to compare quantitative data, t-test or Mann-Whitney U test was used. Additionally, Chi-square was utilized to compare the qualitative variables. SPSS software (Ver. 15.0) was used for statistical analysis. P<0.05 was considered significant.

Results

Two groups were identical in term of age, gender, body mass index and preoperative HKA angle (Table 1). The mean of radiographic measurements including postoperative HKA angle, T angle, F angle and femoral component flexion were compared in Table 2, showing no significant difference between two groups. However, Table 3 compared the incidence of outliers in each of the radiographic variables and total incidence of outliers. The incidence of outliers of HKA angle in CVI group was significantly greater compared with PSI group (p=0.025). The incidence of outliers in other parameters did not differ significantly. The operational time was shorter in PSI group; however, the difference did not reach a significant level (Table 4). The volume of postoperative bleeding was significantly lower in the PSI group (p<0.001) (Table 4). Also, the outcomes of treatments based on WOMAC index and KSS questionnaire were the same in two groups.

Discussion

The most important conclusion of the current study was that TKA using CT-based PSI can substantially improve the postoperative alignment of the lower limb.

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

Numerous attempts have been made to increase the accuracy of implant positioning with improved overall alignment of the lower limb. In recent years, navigation systems and PSI have been increasingly employed worldwide, which can be very helpful, specially when using of an extra- or intra-medullary guide is not possible.

Although in some studies desirable effects of PSI (12-17) have been reported, however, there are some studies, which do not support using PSI (8, 9, 19-23). The controversial findings of previous studies necessitate performing more studies regarding PSI in total joint arthroplasty. Accordingly, in this RCT, we compared clinical, functional, and radiological outcomes of CT-based PSI TKA and conventional instrumentation TKA. In the current study, it was found that PSI was significantly effective in decreasing the number of outliers in mechanical axis of the limb in coronal plane (44% vs. 12%). However, in other radiographic parameters, no significant difference was found in terms of the number of outliers, possibly due to the small sample size of the current study. It seems that if the number of patients participated in our study was larger, more reliable outcomes would have been achieved. In the current study, prediction the size of the components was absolutely true for all patients enrolled in PSI group. Though this should be noted that probably the TKA system employed in this study has its own influence on this finding. The determination of the component size is performed qualitatively. Numerical determination method can facilitate prediction of the proper size of the component. Furthermore, in the current study, the short-term clinical and functional outcomes were the same. Andrel et al. revealed that PSI can improve the mechanical alignment of the limbs and decrease the number of outliers, however, no improvement in short-term clinical outcomes was found (14). Further, Ferrera et al. and Vide et al. indicated that the number of outliers of the mechanical axis in coronal plane (a deviation greater than 3°) was significantly lower in PSI group compared to CVI group (12, 13). **Heyes et al., Nabavi and Olwill and Renson et al. have reported favorable outcomes using PSI in TKA (15-17).**

Contrary to the current study, there are some studies not approving the mentioned advantages of PSI. Many of such studies have even shown that PSI may result in increased number of errors. Recently, in a clinical trial, Abane et al. found that PSI has no role in reducing the outliers. Outliers were found in 32.8% of patients in the CVI group compared to 32.2% in the PSI group. Further, 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 than the one finally obtained (20). Identical functional outcomes and similar revision rates in the study by Chen et al. do not justify application of PSI in large scale, specially due to the high costs and considerable amount of time (21). In addition to these studies which found no difference between PSI and conventional instrumentation, Chen et al. indicated that PSI is associated with increased outlier of HKA angle (24).

In the current study, the surgical duration was shorter in PSI group, but nevertheless the difference between the two groups was not significant. This finding is similar to Renson et al. and Noble et al. findings, where surgical duration was shorter in the PSI group (11, 17). In contrary, in addition to these findings, Stronach et al. revealed that it is even possible that PSI results in prolonged operation time (25). Furthermore, Zhu et al., Kotela et al. and Abane et al. stated that there is no significant difference in terms of surgical duration between PSI and conventional TKA (8, 9, 23). Importantly, for investigations on the effects of utilizing PSI on operational time, the required time for preoperative planning should not be neglected.

In the current study, the postoperative bleeding volume was significantly lower in the PSI group compared to the CVI group. As there is no need for reaming of the femoral medullary canal in PSI, it seems plausible that application of this method results in decreased intra- and post-operative bleeding volume and decreased risk of thromboembolic complications. In previous studies, it has been well shown that reaming the intramedullary guide significantly increase the risk of pulmonary embolism (26). In another study, it has been demonstrated that computer assisted TKA, when compared with conventional method, significantly reduced the risk of systematic emboli (27). Like current study, Nabavi, Olwill, and Rathod et al. found that PSI TKA could result in a significant reduction in bleeding volume and requirement of blood transfusion (16, 18). However, despite these studies, Zhu et al., Abane et al. and Kotela et al. found no difference in hemoglobin drop, bleeding volume and rate of blood transfusion (8, 9, 23).

As mentioned above, a large number of studies with different methods, investigating population and controversial findings, has lead to confusion and inability in decision-making for using or not using PSI in TKA. There are some systematic reviews showing no benefit has achieved using PSI in TKA. For example, recently Mannan et al. demonstrated that PSI cannot improve implant positioning and mechanical alignment of the lower extremity (28). Furthermore, in a systematic review, Zhang et al. have shown that PSI leads to decreased accuracy of implant positioning and increased number of outliers (29).

Based on above-mentioned statements, it is too early to recommend using PSI as a routine method in a wide extent. Further studies are still required. Additionally, it seems that different study designs and application of different PSI systems may affect the outcomes of the previous studies. In the majority of performed studies, MRI-based PSI has been used (9, 12, 15), whereas in a few number of them, like our study, CT-based PSI has been employed (14). It is necessary to introduce a comprehensive protocol to design relevant studies and evaluate the efficacy of PSI. Thus, it will be possible to make decisions about utilizing PSI in TKA based on the findings of the relatively similar studies.

The current study had some limitations. We did not evaluate the alignment of components in axial plane due to postoperative CT scan was required which caused the patients to be exposed to X-ray. It also seems that the number of patients enrolled in our study was not large enough. If the sample size was larger, more reliable results might have been obtained. Moreover, the follow-up period was short and it is necessary to compare the mid-term or long-term outcomes of PSI TKA and conventional TKA in future studies.

Conclusion

CT-based PSI can effectively improve the overall postoperative mechanical alignment of lower limb and decrease the rate of deviation from the neutral axis. Further, application of PSI resulted in decreased postoperative bleeding volume that may subsequently decrease the rate of blood transfusion. However, future studies are necessary.

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Figure legends

Fig 1. Measurement of hip knee ankle angle. The angle between the line from the femoral head center to the knee center and the line between knee center and center of the ankle

Fig 2. Measurement of *T angle*: the medial angle between the tangent line on the joint surface of tibial component and the tibial mechanical axis; and *F angle*: the medial angle between the tangent line on the joint surface of femoral component and the femoral mechanical axis.

Fig 3. Measurement of femoral component flexion: the angle between the tangent line on the anterior surface of the component and the anterior femoral cortex in the sagittal plane