Original Article

Patient-Specific Instruments Based on Knee Joint Computed Tomography and Full-Length Lower Extremity Radiography in Total Knee Replacement

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Abstract

Background: Restoring good alignment after total knee replacement (TKR) is still a challenge globally, and the clinical efficiency of patient-specific instruments (PSIs) remains controversial. In this study, we aimed to explore the value and significance of three-dimensional printing PSIs based on knee joint computed tomography (CT) and full-length lower extremity radiography in TKR.
Methods: Between June 2013 and October 2014, 31 TKRs were performed using PSIs based on knee joint CT and full-length lower extremity radiography in 31 patients (5 males and 26 females; mean age: 67.6 ± 7.9 years; body mass index [BMI]: 27.4 ± 3.5 kg/m^2). Thirty-one matched patients (4 males and 27 females; mean age: 67.4 ± 7.2 years; mean BMI: 28.1 ± 4.6 kg/m^2) who underwent TKR using conventional instruments in the same period served as the control group. The mean follow-up period was 38 months (31–47 months). Knee Society Score (KSS), surgical time, and postoperative drainage volume were recorded. Coronal alignment was measured on full-length radiography.
Results: Twenty-three (74.2%) and 20 (64.5%) patients showed good postoperative alignment in the PSI and control groups, respectively, without significant difference between the two groups ($\chi^2 = 0.68$, $P = 0.409$). The mean surgical time was 81.48 ± 16.40 min and 72.90 ± 18.10 min for the PSI and control groups, respectively, without significant difference between the two groups ($t = 0.41$, $P = 0.055$). The postoperative drainage volume was 250.9 ± 148.8 ml in the PSI group, which was significantly less than that in the control group (602.1 ± 230.6 ml, $t = 6.83$, $P < 0.001$). No significant difference in the KSS at the final follow-up was found between the PSI and control groups (91.06 ± 3.26 vs. 90.19 ± 3.84, $t = 0.95$, $P = 0.870$).
Conclusions: The use of PSIs based on knee joint CT and standing full-length lower extremity radiography in TKR resulted in acceptable alignment compared with the use of conventional instruments, although the marginal advantage was not statistically different. Surgical time and clinical results were also similar between the two groups. However, the PSI group had less postoperative drainage.

Key words: Alignment; Patient-Specific Instrument; Three-Dimensional Printing; Total Knee Replacement

Introduction

Total knee replacement (TKR), when successfully performed, can relieve pain and improve the quality of life of patients with severe osteoarthritis and other aseptic late-stage joint diseases. Proper alignment restoration is one of the most important factors affecting prosthetic longevity and clinical performance of TKR. Malalignment is usually defined as ±3° beyond the neutral position. Most TKRs are still performed using conventional instruments, with outliers in the malalignment rate reaching as high as 32%.[1,2] Malalignment can lead to multiple complications, such as instability and abnormal stress distribution, which consequently affects not only the satisfaction of the patient but also the survival of the implant.[3] Therefore, improving the accuracy of TKRs is still a challenge for all orthopaedic surgeons. The three-dimensional (3D) printing patient-specific instrument (PSI), based on 3-joint (hip,

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knee, and ankle) preoperative computed tomography (CT) or magnetic resonance imaging (MRI), has been used clinically for years.[4] As they enable visualized preoperative planning and reconstruction of the anatomic contour of the knee, PSIs may improve surgical accuracy, shorten surgical time, and reduce prevalence of complications.

However, the advantages of PSIs remain controversial. There have been sporadic reports illustrating the advantages of PSIs including a reduction in surgical time and improvement in coronal alignment. However, the value of PSI for TKR should be further evaluated. Moreover, the major disadvantages of the current commercially used PSIs include higher expenses due to 3-joint MRI or CT and additional radiographic exposures from the 3-joint CT. Considering that proper alignment could be achieved using conventional TKR based on full-length lower extremity radiography and contour and rotation could be decided using knee joint CT, we propose that PSIs could be designed based solely on knee joint CT and full-length lower extremity radiography. This could provide the potential benefits of lower medical costs and fewer radiographic exposures.

To our best knowledge, PSIs based solely on knee joint CT and standing full-length lower extremity radiography in TKR have been rarely reported. Therefore, we conducted a study to compare and analyze the value and significance of these particular PSIs in TKR.

Methods

Ethical approval

The procedures of study were in accordance with the ethical standards of the Peking University Third Hospital Medical Science Research Ethics Committee and with the *Helsinki Declaration* (revised in 2000). The ethical approval number was IRB00006761-IRB00006761-2016064. And the patients'consents were obtained before the study began.

Patients

Between June 2013 and October 2014, 62 patients on the unilateral TKR waiting list were prospectively enrolled by one surgeon (TIAN). TKR was performed using PSIs based on knee joint CT and full-length lower extremity radiography in 31 patients and using conventional instruments in another set of 31 patients. Although patients were not randomized to the use of PSI or conventional instruments, they were matched for age, sex, and deformity.

All TKRs were performed by one senior surgeon. The surgical time and postoperative drainage volume were recorded. The postoperative alignment was measured on full-length lower extremity radiographs 2 weeks after surgery.

Patient-specific instrument preparation

All patients in the PSI group underwent knee joint CT and standing full-length lower extremity radiography 2 weeks before admission. During the CT scan, at least 10 cm long distal femur and proximal tibia were included. Frontal standing full-length lower extremity radiographs were obtained for each patient. The digital data from the CT scan and full-length radiography were imported into the computer, and a 3D reconstruction was performed using the Mimics software (Materialise, Belgium). The reconstructed knee joint model and lower extremity radiographs were combined using the Siemens NX9.0 software (Siemens, Germany) to measure the mechanical axes and the angle between mechanical and anatomical axes of the femur. Interepicondylar axes and posterior condylar axes were identified and used to guide the rotation. The contacting foot of the PSI was designed based on the subchondral bone contour of distal femur and proximal tibia [Figure 1].

Surgical protocols and postoperative measurements

A tourniquet was applied and inflated to 300 mmHg (1 mmHg = 0.133 kPa) before skin incision and deflated after skin closure and compressively dressed. Medial parapatellar approach was used for all patients. Distal femur resection was performed in fixed 5° valgus in the conventional instrument group, while patients in the PSI group were strictly guided by cutting block. Any remaining cartilage in the footprint areas was removed before placing the PSI. All implants used were cemented, posterior-stabilized, fixed-bearing components (Beijing AKEC Medical Co., Ltd., Beijing, China). The PSIs were designed by the surgeon and engineer together and were also made by Beijing AKEC Medical Co., Ltd. The same protocols were used regarding blood management, pain management, and rehabilitation for patients in both groups. Negative pressure drainage was used for all patients and was removed 24 h after surgery.

Surgical time and postoperative drainage were recorded. Clinical outcomes were evaluated using the Knee Society Score (KSS) preoperatively and at 3, 6, and 12 months postoperatively. The coronal mechanical axis alignment was measured on full-length radiographs 2 weeks after surgery. The alignment was defined as positive (+) for a varus angle and negative (−) for a valgus angle. Neutral alignments within the limit of ± 3° were considered satisfactory.

Statistical analysis

Statistical analysis was performed using SPSS 19.0 (IBM, USA). All normally distributed measurement data were presented as a mean ± standard deviation (SD) and analyzed by Student's t test. The dichotomous variables were described as the number of cases and percentages and analyzed using the Chi-square test. The multiple linear regression analysis was performed for the relevant factors influencing the alignment of the lower extremity. Statistical significance was set at $P < 0.05$ (two tailed).

Results

The PSI group comprised 5 male and 26 female patients, with a mean age and body mass index (BMI) of 67.6 ± 7.9 years and 27.4 ± 3.5 kg/m^2, respectively. Thirty patients had a varus deformity, with a mean degree of 15.1° ± 8.5°. One patient had valgus deformity, with a

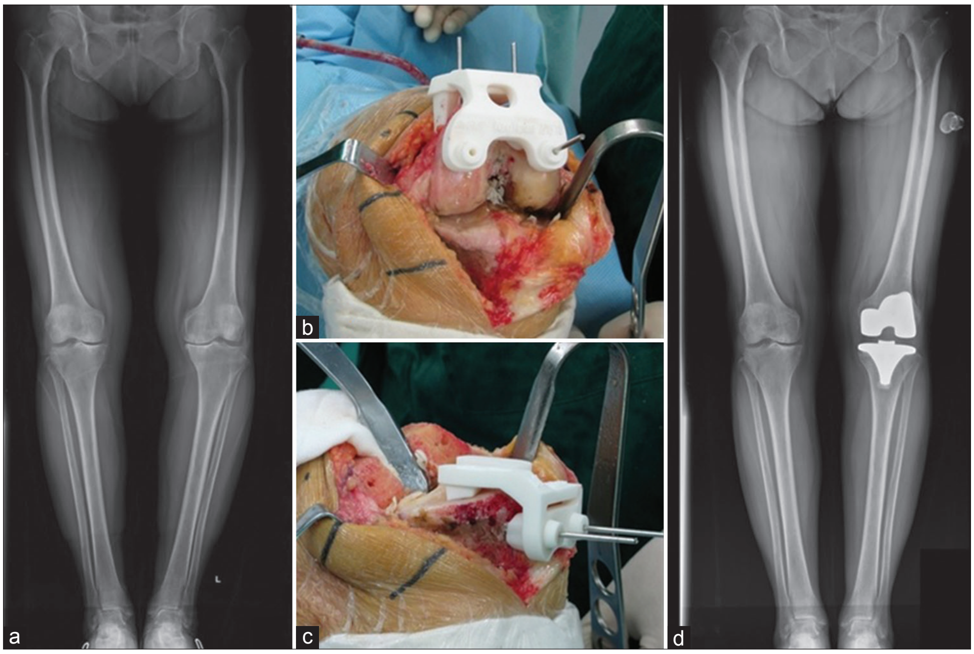

Figure 1: Representative images of primary total knee replacement guided by patient-specific instrument. (a) Lower extremity radiograph before the operation showed varus deformity of both knees, which was caused by primary osteoarthritis. (b) PSI on the femoral side as a cutting guide during surgery. (c) PSI on the tibial side as a cutting guide during surgery. (d) Lower extremity radiograph after the operation indicated satisfactory coronal alignment. PSI: Patient-specific instrument.

degree of 19.8°. Thirty-one patients were matched in the conventional instrument group. Four patients were male and 27 were female. Their mean age and BMI were 67.4 ± 7.2 years and 28.1 ± 4.6 kg/m^2, respectively. All the knees had varus deformity, with a mean degree of 14.9° ± 4.2°. There were no significant differences in gender, BMI, and the degree of deformity between the two groups (all P > 0.05). The mean surgical times were 81.48 ± 16.40 min and 71.96 ± 18.70 min in the PSI and control groups, respectively, with no significant difference found (t = 0.41, P = 0.055). The postoperative drainage volumes were 250.9 ± 148.8 ml and 602.1 ± 230.6 ml in the PSI and control groups, respectively, with a significant difference between the two groups (t = 6.83, P < 0.001). Twenty-three patients (74.2%) in the PSI group and twenty patients (64.5%) in the control group showed neutral alignment, although the difference between the two groups was not statistically significant (χ^2 = 0.68, P = 0.409). The preoperative KSS in the PSI group was 42.10 ± 5.62, and 44.29 ± 6.02 in the control group, without significant difference between the two groups (t = −1.48, P = 0.140). At the final follow-up, KSS improved to 91.06 ± 3.26 in the PSI group, and to 90.19 ± 3.84 in the control group, without significant difference between the two groups (t = 0.95, P = 0.870).

Discussion

A successful TKR relies on good deformity correction and alignment restoration. Malalignment in TKR can lead to multiple complications such as instability, repeated swelling, continuous pain, and polyethylene wear,[3,5,6] which decreases the patient satisfaction rate. Moreover, malalignment results in abnormal stress distribution, which is consequently linked to serious complications such as implant fracture.[7] Although computer-assisted surgery has been used for many years to achieve perfect alignment, conventional instruments are still predominantly used in TKR. With respect to conventional instruments, the most common causes of malalignment include canal opening point error, difficulty in finding the ankle center, and other factors. Currently, effective restoration of alignment of the lower extremity in TKR is still a challenge.

Computer-assisted navigation has potential advantages of improving the accuracy and thus reducing the prevalence of postoperative malalignment.[8] However, high cost, longer learning curve, and low efficiency (longer surgical time) dramatically limit its clinical application. In recent years, robots have been used in TKR, but they are more expensive than the conventional computer-assisted navigation system, and furthermore, they still lack medium- to long-term results.

With the progress in materials and 3D printing technology, PSIs have been applied in TKR for several years to improve alignment. Clinically, a PSI is often based on a CT or MRI of the hip, knee, and ankle. However, the results of clinical research and meta-analyses about PSI in TKR remain controversial.[9-12] Mattei *et al*.[13] reported that PSI improved not only the postoperative alignment on the frontal plane but also the rotation alignment. However, the results of a meta-analysis by Abdel *et al*.[14] found that PSI was not superior to the conventional instrument in TKR. Theoretically, the 3D printing PSI is supposed to improve the accuracy of TKR because the joint anatomical morphology and lower extremity deformities can be fully reconstructed through CT or MRI data. Anatomical structures could be erroneously identified from the imaging data and during preoperative planning.

The current most commonly used PSI has several limitations. CT scan of the hip, knee, and ankle joints not only means higher cost for the patients but also results in exposure to a higher dose of radiation. An MRI is more expensive than a CT, and it is also difficult to determine the cartilage contour for the engineers and orthopedic surgeons, which could result in the inaccurate design of the PSI. Owing to the shortcomings and limitations of 3-joint CT and MRI in the design of PSI, we started to only use the knee joint CT, combined with standing full-length lower extremity radiography, to design PSI. Based on CT images of the knee joint, the anatomical morphology of the distal femur and proximal tibia and also the posterior condylar and transepicondylar axes were identified. Therefore, the morphology and attaching point of the PSI could be designed, and rotational alignment of the femur and tibia was determined. In contrast, the full-length lower extremity radiography provided information on the existence of extra-articular deformity and the angle between the anatomical and mechanical axes of the femur, which guided the design of the PSI. Our study found that the use of PSIs based solely on knee joint CT and full-length lower extremity radiography in TKR dramatically reduced the drainage volume, which might have resulted from not opening the femoral canal and relatively fewer procedures during surgery. The accuracy of TKR using a PSI compared with the conventional instrument has only improved marginally, although there is no statistically significant difference. Further studies with large sample size and randomized controlled trials are required to validate the statistical significance of this type of PSI. Surgical time in the PSI group was longer than that in the conventional group, although there was no statistical difference. According to the authors' opinion, the surgical time might be longer initially until the surgeon surpasses the learning curve for using the PSI.

As Zhao *et al*.[2] reported postoperative malalignment of the femur when conventional instruments were used, the PSI has an intrinsic advantage with respect to guiding the femoral bone cut. Caillouette and Anzel[15] reported fat embolism during the intramedullary procedure in conventional TKR; however, there was no complication in the knee replacement using PSI. Moreover, the approach in the PSI group avoided opening the femur canal, which led to decreased blood loss.

Compared with those of previous reports,[16] our method provided fairly good results, which compromised the accuracy of PSIs solely based on knee joint CT and full-length lower extremity radiography. Moreover, there are particular advantages to our method including fewer radiographic exposures and lower medical cost. In addition, as fewer instruments are involved, the sterilization cost might be reduced and the turnover time of instruments might be shorter. Another potential benefit is the decreased risk of infection, as few surgical equipment are involved in our method. Therefore, we believe that PSIs based on knee joint CT and full-length lower extremity radiography will have a role to play in TKR in the future.

This study has some limitations including the retrospective analysis design. In addition, the measurement of alignment might have been affected by knee joint function. However, standard full-length radiography was performed, and the alignments were measured by one surgeon to maximally reduce the associated error. Another limitation is the short-term follow-up, but knee joint function score and alignment are believed to remain stable 2 years after surgery.

In summary, the results of the present study showed that PSIs based solely on knee joint CT and full-length lower extremity radiography significantly reduced the drainage volume and could result in an acceptable restoration of the alignment of the lower extremity compared with the conventional instrumentation. Compared with the PSI based on 3-joint CT or MRI, our PSI dramatically reduced patient cost and radiographic exposure and did not sacrifice the alignment restoration. The potential advantages of this type of PSI include a reduced number of surgical tools to be used and reduced logistic and sterilization costs. Therefore, we believe that PSIs based on knee joint CT and full-length lower extremity radiography might have certain advantages over conventional instruments and PSIs based on 3-joint CT or MRI. Our group has conducted a prospective randomized study to further clarify the value and advantage of this technology in TKR.

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Conflicts of interest

There are no conflicts of interest.

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基于膝关节CT和下肢全长X线片的个性化截骨导板在全膝关节置换术中的应用

摘要

背景： 目前，重建术后良好力线仍然是全膝关节置换术（TKR）的一大挑战，同时应用患者个性化截骨导板（PSIs）的临床意义仍存争议。我们的研究，皆在探讨基于膝关节CT和下肢全长X线片的3-D打印PSI，在TKR中的应用价值。

方法： 在2013年6月至2014年10月，有5名男性和26名女性（PSI组，平均年龄67.6 ± 7.9岁；体重指数27.4 ± 3.5 kg / m^2）在基于膝关节CT和下肢全长X线片的PSI辅助下，共完成了31台TKR手术。同期，由同一术者应用常规手术工具完成了31名匹配患者的TKR手术（男性4名，女性27名；平均年龄67.4±7.2岁；平均BMI 28.1±4.6 kg / m^2）作为对照组。术后平均随访时间为38个月（31-47个月），记录膝关节评分（KSS），手术时间和术后引流量，并在术后下肢全长片上测量冠状位力线。计量资料采用t检验，计数资料采用卡方检验进行比较。

结果： 术后PSI组和对照组中分别有23例（74.2％）和20例（64.5％）力线优良，两组比较差异无统计学意义（χ^2 = 0.68，P = 0.409）。PSI组和对照组平均手术时间分别为81.48±16.40和72.90±18.10 分钟，结果差异无统计学意义（t = 0.41，P = 0.055）。PSI组术后引流量为250.9 ± 148.8 ml，明显少于对照组（602.1 ± 230.6 ml，t = 6.83，P < 0.001）。两组术后最后一次随访KSS评分组间无显著差异（t = 0.95，P = 0.870）。

结论： 与常规手术工具相比，使用基于膝关节CT和下肢全长X线片的PSI辅助，同样可在TKR术后获得良好力线。尽管两种方法的手术耗时和临床结果相似，但PSI组术后引流量更少。