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Postoperative mechanical alignment analysis of total knee replacement patients operated with 3D printed patient specific instruments: A Prospective Cohort Study

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ABSTRACT

Objective: Total knee replacement (TKR) is a surgical treatment for final stage gonarthrosis. The lifespan of the prosthetic implants used in TKR surgery is a major interest for the orthopaedic research community.Previously, proper implant alignment of the implants has been advocated for longevity of the TKR surgery. Recently, patient-specific (PSI) instruments have been proposed to improve the mechanical alignment of the TKR by permitting better implant positioning over conventional TKR surgery. The aim of this study is to compare the mechanical alignment results of patients operated with PSIs and conventional instruments.

Methods: Two groups of 20 patients chosen in a quasi-random manner have been compared in this study. In the first group femoral distal and tibial osteotomies were made by a PSI which was produced by the patients' computed tomography scans. All osteotomies in the control group were made with the TKR set's routine instruments by conventional means. Patients' preoperative and postoperative mechanical femorotibal angles (mFTA), femoral coronal angles (FCA), tibial coronal angles (TCA) were measured and the number of outliers which showed more than 3° of malalignment were counted in both groups for comparison.

Results: The average postoperative mFTA was found to be 2.09° for the PSI group and in was found to be 2.84° for the control which was not statistically significant. The comparison of postoperative FCA and TCA also did not show significant difference between the groups. The number of outliers showing more than 3° of malalignment per group were found to be 1 out of 20 (5%) for the PSI group and 7 out of 20 (35%) for the control which was statistically significant.

Conclusion: In this study patient-specific instrumentation provided significantly better mechanical alignment compared to conventional TKR for the frequency of outlier cases with malalignment beyond 3°. PSI proved no significant difference when the groups were compared for mFTA, FCA and TCA. Our findings support that PSI may improve TKR alignment by improving the ratio of the outlier patients with marked malalignment.

Level of Evidence: Level III, Therapeutic Study.

Introduction

TKR is a surgical procedure which takes role in the final stage gonarthrosis. Since the disease gets more severe with aging the number of TKR surgeries to be performed is on the rise and expected to further rise parallel to the increase in global life expectancy.[1]

Since early stages of the TKR surgery, orthopaedic research community has been interested in increasing the longevity of the

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TKR. Many different determinants have been proposed which have been shown to affect the TKR longevity. So far implant design and materials, cement chemistry and cementing techniques and postoperative knee alignment are the ones that have been extensively investigated.[2]

The postoperative knee alignment is one of the contributing factors for TKR long term survivorship.[3,4] Although previous research on this determinant is still controversial It is today widely accepted that poor alignment for TKR is related to shorter lifespan of the implant.[4,5]

Traditionally, the TKR surgery have been done with the utilization of standard instruments that help with the adjustment for extremity alignment. The standard instruments of a modern TKR set have evolved widely in the recent years to help with better postsurgical alignments. However, still being general instruments which offer no real patient matching it is believed that it offers limited potential for patients with complex deformity and marked obesity.[6]

With the recent advancement and dissemination of rapid prototyping technology, computer assisted surgery and patient specific instrumentation have been proposed as new methods of implantation in TKR presumably offering better alignment for patients.[7,8] These systems offer precision through planning with 3 dimensional (3D) lower extremity computer models.[9,10] With the PSI method, the 3D model of the extremity is studied in a 3D design software for simulations of the ideal surgical osteotomies which are then used to design and produce the PSI.[11,12] Theoretically, use of PSI in TKR surgery should provide precise osteotomies just as they were planned in the 3D design software, thus it should also improve the mechanical alignment of the patients when compared to the conventional surgery.[9,10,13] Yet, in practice there seems to be factors affecting the mechanical alignment of TKR surgeries performed with PSIs. Generally, the current literature investigating the role of PSI on the postoperative mechanical alignment advocates that PSI does not improve mechanical alignment, with some of them finding it beneficial.[13–17] As a result, the orthopaedic research community is still not settled on the role of PSI for providing better postoperative mechanical alignment for TKR patients.

In this study we aim to provide new evidence on the role of PSI on the postoperative alignment of TKR patients. For this purpose, we compare the mechanical alignment of total knee replacement surgeries performed with a patient specific instrument to the conventional method.

Materials and methods

Ethical committee approval from institutional ethical board was obtained. A total of 40 patients who have admitted to our clinic with end stage gonarthrosis were accepted to the study in a prospective quasi-random manner to form two cohorts. Group I consisted of 20 patients which were operated with patient specific instruments and group II consisted of 20 conventionally operated patients. Patients with more than 30° varus, all valgus knees and patients with less than 90° of flexion were excluded from the study.

Surgery

All surgeries were performed by the same two surgeons under general anesthesia. NexGen CR-Flex knee prosthesis (Zimmer Biomet, Warsaw, IN, USA) total knee implant was used in all cases. Anterior midline incision, medial parapatellar arthrotomy without flipping of the patella was used as standard approach for all patients. After this standard exposure the patients in the PSI group received distal femoral and tibial osteotomies by means of the PSI (Fig. 1a). On the other hand, TKR surgical set's standard intramedullary femoral distal osteotomy guide and extramedullary tibial osteotomy guides were used to make these osteotomies in the non-PSI group. After

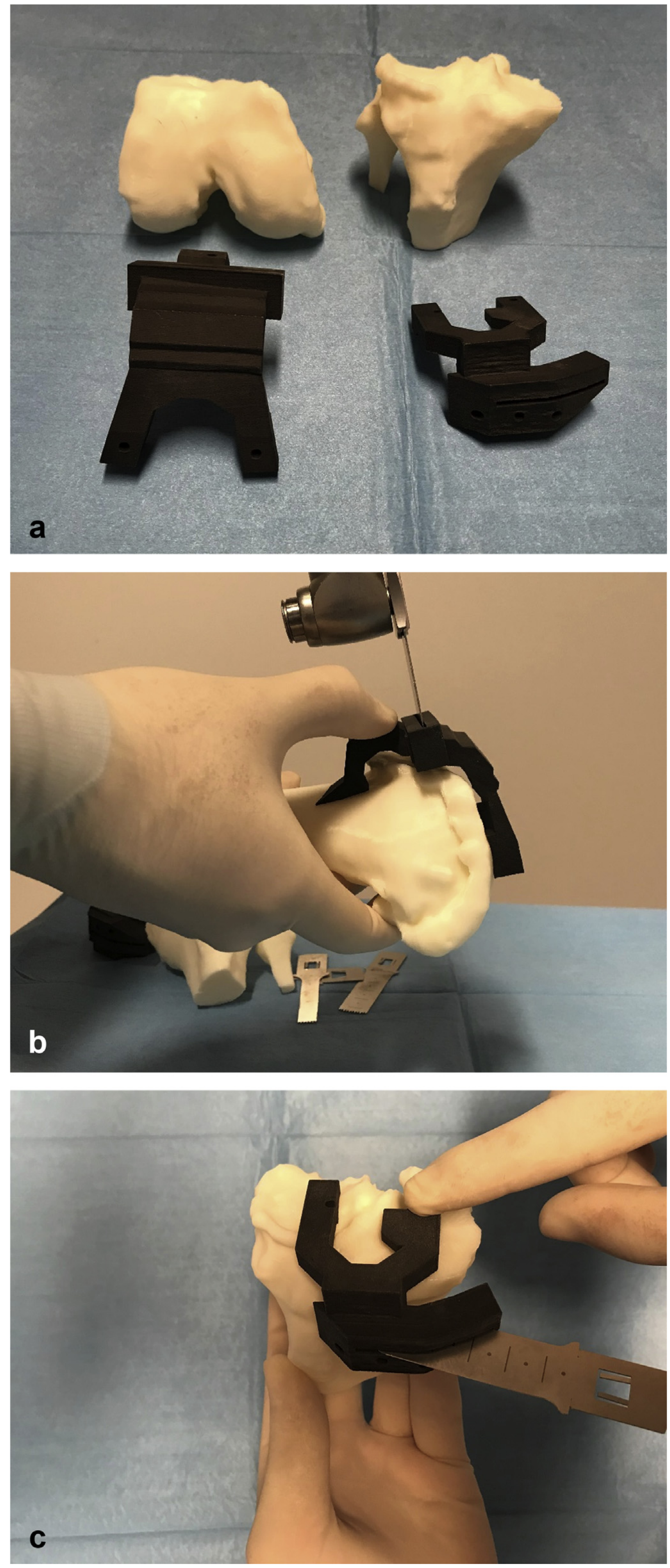

Fig. 1. **a**: Patient specific instruments (PSI) and 3D printed solid models of the patient's femur and tibia. **b** and **c**: Patient specific instruments (PSI) and 3D printed solid models of the patient's femur and tibia coupled together with a saw blade within the slit of the guides representing osteotomy planes.

completion of these osteotomies the remaining femoral osteotomies and component's rotation wise adjustments were made using the standard instruments of the TKR set in both groups.

PSI and mounting of the PSI

The PSIs for group I were designed by one of the authors who did not join the surgical procedures (Fig. 1a). The design of the PSIs were based on the CT scans obtained in our institution. An axial ortho-CT scan with 1-millimeter slice thickness was obtained which included the hip and ankle joints with a Siemens SOMATOM Definition Flash CT scanner (Siemens Healthcare GmbH, Erlangen, Germany). The PSIs were printed with a medical 3D printer (EOS P 760, Maisach, Germany) from medical grade polyamide material (EOS Pa2200, Maisach, Germany) and were sterilized with a standard autoclave with the other instruments needed for the surgery. Since it is crucial mounting of the PSI was done by as follows: The pictures depicting the correct positioning of the PSI as well as 3D printed knee mockups which were provided with the PSI was used to determine proper positioning of the PSI thus, the contact regions of the PSI with the patient's joint (Fig. 1b,c). Meticulous cartilage and soft tissue removal from these regions were performed to make sure for proper fitting of the PSI. Afterwards the PSI was laid on to the joint maneuvering gently while seeking visually for conformity and full contact in all contact points of the PSI (Fig. 2a,b). After mounting with pins, PSI was double checked visually for proper positioning by the pictures and 3D printed knee mockup rehearsals. Once no doubt was left for PSI's positioning a sagittal saw was used to make the related osteotomies through the slits on the PSI.

Measurements and statistical method

Preoperative and postsurgical standing antero-posterior digital ortho roentgenograms were used to evaluate the alignment by two blinded observers and average of these measurements were used. GE Centricity PACS software was used to measure all the angles. Mechanical femorotibial angle (mFTA), femoral coronal angle (FCA) and tibial coronal angle (TCA) were measured by two different orthopaedic surgeons who were blind to patient information (Fig. 3a–d). The mean values of the two measurements were calculated and used for statistics. All statistical analysis was performed with IBM SPSS Statistics for Windows, Version 21.0 (IBM Corp., USA). The difference for mFTA, FCA and TCA were tested for statistical significance with Mann–Whitney U test. Further analysis was performed by determining the number and ratio of outliers in each group which showed more than 3 degrees of coronal misalignment. Depending on the expected count values of outlier values in the groups the ratio of outliers were analyzed either with Chi–Square test or Fisher's Exact test.

Results

PSI group consisted of 5 male and 15 female patients whereas non-PSI group consisted of 4 male and 16 female patients. The mean age for patients in PSI group was 68.6 ± 8.6 years when compared to 70.5 ± 7.1 years of age for non-PSI group.

The average preoperative mFTA was 11.7°±4.40 in the PSI group whereas it was 11.1°±6.32 for the non-PSI group. Postoperative mFTA was 2.09°±1.27 in the PSI group and 2.84°±2.19 for non-PSI group. The mean FCA value for PSI group was found to be 89.6°±1.96 whereas it was found to be 88.30°±2.1 for the non-PSI group. The mean TCA for PSI group was found to be 89.8°±1.44 whereas it was found to be 89.4°±2.39 for the non-PSI group. Table 1 is provided to demonstrate the relevant data used to compare the groups.

The number of outlier patients which demonstrated more than 3° of malalignment in postoperative mechanical femorotibial angle (mFTA) values were 1 out of 20 (5%) for the PSI group, whereas it was found to be 7 out of 20 (35%) for the non-PSI group. Table 2 summarizes these findings in a crosstabulation table. Two-sided Fisher's exact test ($p = 0.04$) showed that the patients operated with the PSI have significantly less probability to have an mFTA value indicating malalignment beyond 3°.

The outlier values showing more than 3° malalignment for either of the TKR components [femoral component (FCA) or tibial components (TCA)] were counted separately without paying attention if they resulted in mechanical (mFTA) malalignment. The count of outliers for any of the TKR components was found to be 2 out of 40 (5%) implants for the PSI group whereas it was found to be 11 out of 40 (27.5%) outliers for non-PSI group. Table 3 summarizes these findings in a crosstabulation table. The Chi–Square test revealed that the PSI operated patients have significantly lower chance to have any of their TKR components malaligned beyond 3° [X^2 (1, N = 40) = 7.44, $p = 0.006$].

On the other hand, no significant difference was found between the groups for postoperative mFTA ($p > 0.05$), postoperative FCA ($p > 0.05$) and postoperative TCA ($p > 0.05$) measurements with Mann–Whitney U test.

Discussion

Computerized systems including PSI have been advocated in the last decade to improve postsurgical extremity alignment for TKR patients. Numerous research on this field have been published with variable results.[6,7,17–21] The current research on the field is plagued

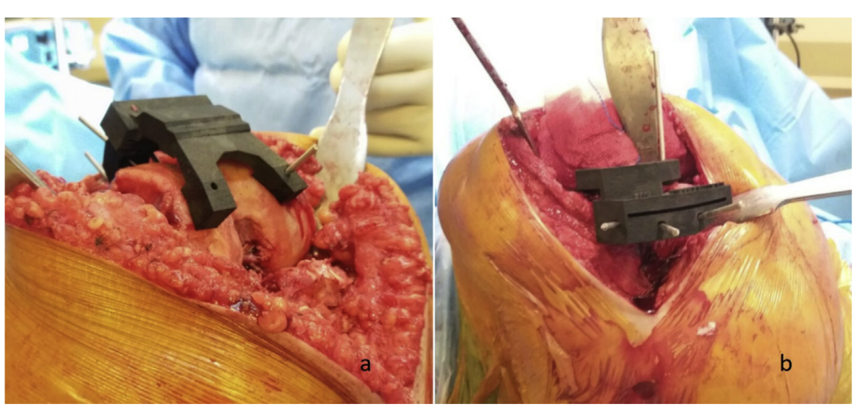

Fig. 2. a and **b**: Femoral and tibial patient specific instruments coupled with patient's bones during the surgery, before resection.

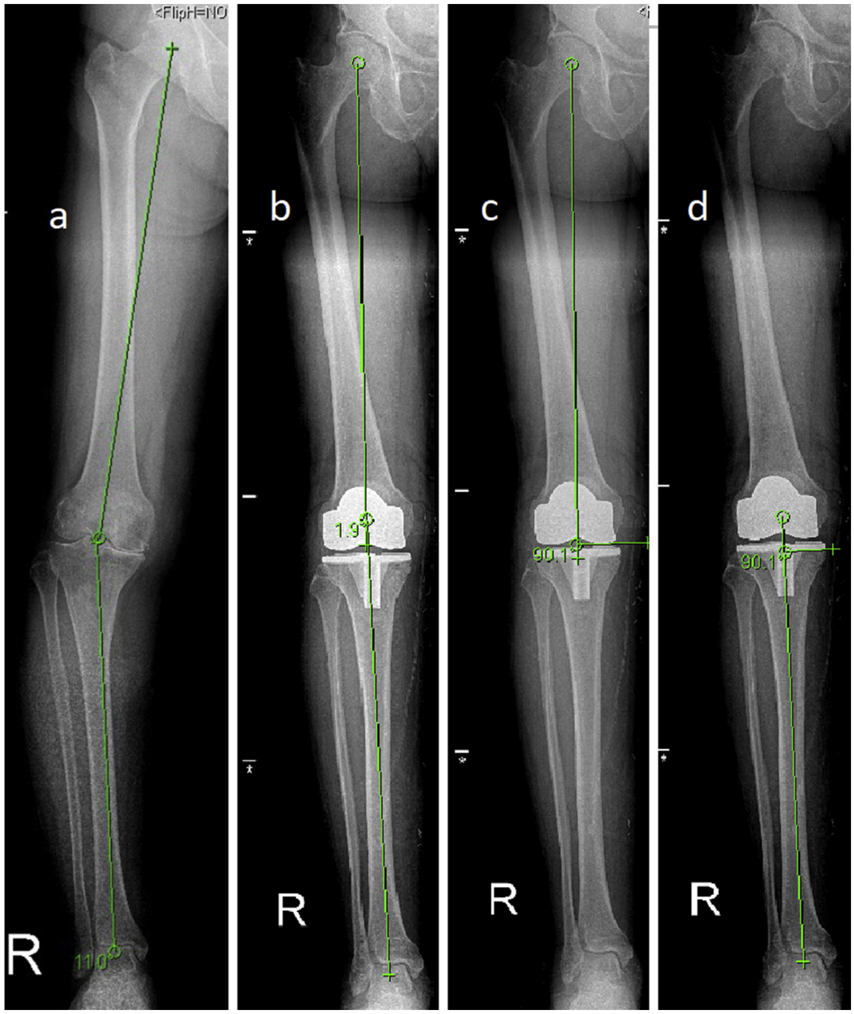

Fig. 3. **a**: Measurement of the mechanical femorotibial angle (mFTA) of a patient in an anteroposterior orthogram. **b**: Measurement of the mechanical femorotibial angle (mFTA) of a patient after the TKR surgery. **c**: Measurement of the femoral coronal angle (FCA). **d**: Measurement of the tibial coronal angle (TCA).

Table 1
Demographics and variables of the patients by groups (M/F: male/female, R/L: right/left, mFTA: mechanical femorotibial angle, FCA: femoral coronal angle, TCA: tibial coronal angle).

Group	Sex (M/F)	Side (R/L)	Age	Preoperative mFTA	Postoperative mFTA	Postoperative FCA	Postoperative TCA
PSI instrumentation group	5/15	10/10	68.6 SD 8.57	11.7 SD 4.4	2.09 SD 1.26	89.60 SD 1.96	89.80 SD 1.44
Standard instrumentation group	4/16	9/11	70.4 SD 7.05	11.1 SD 6.3	2.84 SD 2.19	88.30 SD 2.05	89.4 SD 2.39

by a couple of rough points which creates bias on the results as well as the interpretation.

Firstly, not all PSI are designed with the same design rationale in mind. It is known that many factors in the design phase may have impact on the PSI's post production success. Some PSIs are known to only mark the joint surfaces with pins which are then used to fit TKR set's regular guides to make bone cuts whereas others provide actual patient specific cutting blocks to make some or all the bone

Table 2
The counts and ratios of the outlier values for mechanical femorotibial angle (mFTA) by groups.

			Groups	
			PSI Operated Group I	Conventionally Operated Group II
Outlier Value	NO	Count	19	13
		% within Groups	95%	65%
	YES	Count	1	7
		% within Groups	5%	35%
Total		Count	20	20
		% within Groups	100%	100%

Table 3
The counts and ratios of the outlier values for any TKR component by groups.

			Groups	
			PSI Operated Group I	Conventionally Operated Group II
Outlier Value	NO	Count	38	29
		% within Groups	95%	72.5%
	YES	Count	2	11
		% within Groups	5%	27.5%
Total		Count	40	40
		% within Groups	100%	100%

cuts required to fit the implants in the joint. The PSI designs which only mark the joint with pins and carry on with the TKR set's regular cutting guides seem to offer numerous advantages like complete control over implant size and implant's coronal, sagittal and rotational alignment. However, it may as well be its weak side considering any error in any phase may affect all related aspects. On the other hand, simpler PSI design paradigms focusing mainly on coronal and sagittal alignment may prove to be more effective in obtaining ideal alignment. Furthermore, these systems offer increased flexibility at the time of surgery for rotational and size related issues which are better decided during the surgery. The PSI system we used for this study only dictates the coronal and sagittal positioning of the implants. The rotational alignment and final implant sizes are decided upon surgery with the TKR set's conventional instruments. We felt more comfortable with this flexibility provided by the PSI during the surgery. Yet our feeling about the PSI system's design paradigms and their actual influences on the surgery have to be addressed by the research community. Further research is needed to evaluate the influences of different design rationales on the surgical experience and the resulting accuracy.

Next the precision issue of MRI and CT based PSIs comes into question. Literature is getting richer for research investigating these two radiological methods to produce PSIs. A quick sweep of the current literature seems to be slightly favoring MRI over CT based PSIs for both anatomy matching and alignment related accuracy.[22,23] The technical comparison of both radiological methods favor CT for better bone-soft tissue contrast and resolution which in theory makes CT a better candidate for 3D model generation.[24] Yet, CT based PSIs comes with the necessity of meticulous cartilage removal from the areas of PSI contact for accurate fit since they are designed to fit bony surfaces rather than the cartilage. Technically, once proper cartilage removal from appropriate joint surfaces is guaranteed the CT based PSI should perform as good as MRI based ones. On the other hand, advances in MRI technology may soon help the MRI based designs gain superiority in this field as well. Nevertheless, unlike the research published in the introductory phase of the PSI technology the newer research on PSIs seem to be favoring PSIs over standard instrumentation, including the CT derived ones.[10,15,19] Our study provides new data on this issue favoring a CT based PSI system over standard instrumentation which is consistent with the current literature.

Another important issue to discuss is the learning curve needed to adopt to the PSI system which is often overlooked. Extreme confidence on the PSI with the belief that it has no potential for error, along with lack of any previous surgical experience with PSI may have plagued some of the research in the literature, exacerbating the debate on it. This we believe might have especially played a role in the early research regarding the PSI. The recent research reporting better results with the use of PSIs might be indicative of the fact that a good understanding of the PSI system and some experience might be necessary for obtaining good results with the PSI. A recent study by De Gori and colleagues have defined a prominent learning curve for usage of PSI by an experienced surgeon who never performed PSI based TKRs.[25] Whereas another study investigating the learning curve required for PSIs by Chinnappa and colleagues defined the learning curve to be minimal and not statistically significant.[26] We believe that even though the instructions for PSI usage are very simple, overlooking these simple requirements will result in poor anatomical matching and thus poor alignment.

Finally, although the PSI systems carry much of surgical decision making to the computer design phase wrong implementations in the design phase will undoubtedly result in poor alignment. The review by Lachiewics and Henderson indicates that some PSI producing companies do perform better regarding the anatomy matching performance of the PSI and the resultant postsurgical alignment.[27] This may be a proof that the design rationale of the PSI may play a role for its precision. Yet, there is no study which has investigated the role of design rationale for different PSIs.

The strong side of our study is that it provides new data on the controversial field of PSIs and presents it with a through discussion of the design rationale of the PSIs, which we believe is a very important aspect to the debate. It is among the few studies in its field which have investigated mechanical alignment with conventional mechanical parameters such as mFTA, FCA and TCA as well as the outlier counts of malalignment beyond 3°, which as demonstrated in our study has potential to create another perspective to the role of PSIs in TKR. While providing additional data for PSIs' role in TKR our study has its own limitations as well. Firstly, as only being a prospective cohort study, it lacks the power of a randomized prospective study. Next, although being acceptable having twenty patients in each group is another limitation. Another limitation of our study is that it does not provide any data regarding role of PSIs on sagittal alignment of the knee. Finally, our findings do not help to make assumptions on the longevity of the TKR since there is no follow-up of the patients.

Conclusions

In this study the PSI group demonstrated significantly fewer outlier values for postoperative knee alignment when compared to the standard instrument group. On the other hand, our series did not reveal significant difference for mFTA, FCA and TCA. Our findings support that PSI may improve TKR alignment by improving ratio of the outlier patients with marked malalignment.

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