

Patient-specific instruments for total knee arthroplasty can accurately predict the component size as used peroperative

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Abstract

Purpose Patients-specific instruments (PSI) for implantation of total knee arthroplasty (TKA) can be used to predict the implant size for both the femur and the tibia component. This study aims to determine the impact of approval of the PSI planning for TKA on the frequency of, and reason for intraoperative changes of implant sizes.

Methods The clinical records of 293 patients operated with MRI- (90.4 %) and CT-based (9.6 %) PSI were reviewed for actual used implant size. Preoperative default planning from the technician and approved planning by the operating surgeon were compared with the intraoperative implanted component size for both the femur and tibia. Intraoperative reason for not following the default sizes was outdated. Furthermore, MRI- and CT-based PSI were compared for these outcomes.

Results In 93.9 and 91.1 % for, respectively, the femur and tibia (n.s.), the surgeon planned size was implanted during surgery. The predicted size of the femur ($p < 0.00$) and the tibia ($p < 0.00$) component planned by a technician differed from the implanted component sizes in 62 (21.2 %) and 51 (17.4 %) patients, respectively. In 17 cases, the femoral component size was adapted intraoperative based on the expert opinion of the operating surgeon. In 26 cases, the tibia component was changed during the surgery because of a mediolateral overhang, sclerotic bone, medial or lateral

release, limited extension and/or fixed varus deformity. The results between the MRI- and CT-based PSI did not differ (n.s.).

Conclusions PSI is a tool to help the surgeon to achieve the best possible results during TKA. The planning made by a technician should always be validated and approved by the operating surgeon who has the ultimate responsibility regarding the operation. With PSI, the operating surgeon is able to minimize intraoperative implant size errors in advance to improve operating room efficiency with possible lowering hospital costs per procedure.

Levels of evidence III.

Keywords Patient-specific matched instruments · Patient-specific guides · Patient specific instruments · Templating · Custom-fit · Total knee arthroplasty · Guides · Implant size · Preoperative planning

Introduction

Half a decade ago, patient-specific instruments (PSI) for total knee arthroplasty (TKA) were introduced. This simplified procedure eliminates the use of intramedullary guides. Published results on PSI are contradictory. None of the studies demonstrates a significant improvement of postoperative mechanical axis alignment when compared to conventional instrumentation [16, 20]. On the other hand, preoperative digital templating appears to be accurate in predicting the implant size used in TKAs with high reproducibility when used by residents and TKA surgeons [7]. The system can predict intraoperative bony resections, component sizes, alignment, and can prevent unknown constraints during surgery (e.g. extreme implant size, special implant orders) which may improve operating room

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efficiency [8, 10]. This may result in a reduction of the overall number of surgical instruments and may reduce associated operation expenses [1, 6, 13]. However, the used preoperative imaging techniques (e.g. MRI- or CT-scan) may influence these results. CT-scans have limitations in visualizing and outlining the intra-articular cartilage [22]. Furthermore, CT-based knee models appeared to be slightly larger than the patient's bones when compared to MRI-based 3D knee models, which were slightly smaller [21]. On the other hand, it is shown that the use of CT-based PSI can reduce costs [15]. The PSI system used in this study comes with a planning tool for which suggested planning settings should be approved by the operating surgeon. If not, the guides will be manufactured based on the templates produced by a technician. This study aims to determine the impact of approval of PSI planning for TKA on the frequency of, and reason for intraoperative changes of the implant size. There are less data to support the accuracy of MRI- and CT-based PSI for TKA to preoperatively predict the component size as used during surgery. This case series study hypothesized that both MRI- and CT-based PSI can accurately predict the component size as used perioperative.

Materials and methods

A consecutive cohort ($n = 293$) of TKA patients operated between 2012 and 2013 with MRI- or CT-based PSI (Signature, Biomet, Warsaw INC) by a single experienced knee arthroplasty surgeon (NK) was included in this study. Default planning from the manufacturer and surgeon approved digital planning were compared with the actual implant size used intra-operatively for both the femur and the tibia. A total of 28 (9.6 %) patients were not eligible for MRI scans and were operated using CT-based PSI. The CT-group consisted of patients with claustrophobia ($n = 9$), patients with movement artefacts during long MRI scans ($n = 8$) and/or those with implanted electronic devices (pacemaker, neurostimulator for bladder control or cochlear implants; $n = 12$). Baseline demographics and perioperative clinical outcomes are listed in Table 1.

An MRI- or CT-scan was used to generate a computerized three-dimensional (3D) joint reconstruction (default), planned by a technician. This 3D default template enables the surgeon to preoperatively plan the knee replacement using digital planning software (SOMS, Biomet, Warsaw INC) to determine the component sizes and alignment for each patient-specific case. Preoperative default templates from the technician and templates approved by operating surgeon (NK) were compared with the intraoperative implanted component size for both the femur and tibia.

Table 1 Patient baseline demographics and perioperative clinical outcome

	PSI cohort ($n = 293$)
Median age, years (range)	70.1 (43.8–88.9)
Male, n (%)	121 (41.2)
Right, n (%)	152 (51.9)
Mean BMI, (range)	29 (20–47)
ASA I/II/III, n	99/177/17
MRI-based guide, n (%)	265 (90.4)

The size of the actual components and polyethylene insert used intraoperatively was recorded. The amount of patients for which the template size was equal to the intraoperative placed implant was calculated for the following groups: surgeon vs. operation room (OR) (identical size, deviation of 1 size, deviation of >1 size), technician vs. OR (identical size, deviation of 1 size, deviation of >1 size) and surgeon vs. technician (identical size, deviation of 1 size, deviation of >1 size).

When a component size differed, the operative record was checked for the reason not using the approved component size. Furthermore, MRI- and CT-based PSI were compared for these outcomes.

This study was validated and approved by the Independent Review Board (METC Atrium-Orbis-Zuyd Heerlen, the Netherlands; IRB-nr.14N50) and registered online at the Dutch Trial Register (www.trialregister.nl).

Statistical analysis

Statistical Package for the Social Sciences Statistics Software version 17.0 for Windows (SPSS, Inc., Chicago, Illinois) was used to test any difference of proportions (Fisher exact test).

A post hoc power analysis was done in order to check if this study had sufficient statistical power to detect a treatment effect. P value was considered to be statistically significant at $P \leq 0.05$ for all analyses.

Results

The proportion of templates approved by the surgeon correctly predicted the size of the femoral (n.s.) and tibial (n.s.) components in 276 (93.9 %) and 267 (91.1 %) patients, respectively. Femoral ($p < 0.00$) and tibial ($p < 0.00$) component sizes predicted by the planning made by the technician differed from the implanted component sizes in 62 (21.2 %) and 51 (17.4 %) patients, respectively. There were no conversions from PSI procedures to conventional instrumentation in this study.

The planned component size of the femur from both the technician and operating surgeon was different from the implanted component sizes in two patients. In 29 patients (femur, $n = 13$ and tibia, $n = 16$), the planned size from the technician and the operating surgeon was similar but differed from the implanted size. In 12 other patients, the size for the femur ($n = 2$) and tibia ($n = 10$) estimated by the technician and the implanted size were comparable.

In 17 patients, the femoral component size was adapted peroperatively, based on the expert opinion of the operating surgeon. In 12 patients, the tibial component was changed during the surgery to prevent possible irritation of the capsule and collateral ligaments because of a mediolateral overhang. In 13 other patients, the implant sizes changed, because of sclerotic bone, medial or lateral release, limited extension, fixed varus deformity, and for one patient because of minor medial overhang (<3 mm). For 16 patients, the planning of the technician and surgeon were similar but different from the actual implanted size, and in 10 patients, the planning of the technician was similar to the actual implanted size.

Postoperative radiographs showed that the perioperative adjustments for implant sizes were correct and justified. The amount and percentage of differences in planned implant sizes provided by the technician and operating surgeon compared to the actual implanted sizes (OR) are summarized in Table 2.

The results of the PSI group subdivided into MRI- and CT-based PSI did not differ between the planning made by the technician, operating surgeon and the actual implanted

Table 2 Amount and percentage of identical sized in approved templates (Surgeon) and default templates (Technician) compared to the used size used peroperative (OR) and agreement between the surgeon and technician

Identical sizes	Femur ($n = 293$)	Tibia ($n = 293$)
Surgeon vs. OR, n (%)	276 (93.9)	267 (91.1)
Upsized, n (%)	4 (1.4)	5 (1.7)
Downsized, n (%)	13 (4.4)	21 (7.1)
Error of 1 size, n (%)	15 (5.1)	25 (8.5)
Error of >1 size, n (%)	2 (0.7)	1 (0.3)
Technician vs. OR, n (%)	231 (78.8)	242 (82.6)
Upsized, n (%)	5 (1.7)	33 (11.3)
Downsized, n (%)	57 (19.5)	18 (6.1)
Error of 1 size, n (%)	56 (19.1)	46 (15.7)
Error of >1 size, n (%)	6 (2.0)	5 (1.7)
Surgeon vs. technician, n (%)	243 (82.9)	248 (84.6)
Upsized, n (%)	3 (1.0)	38 (13.0)
Downsized, n (%)	47 (16.0)	7 (2.4)
Error of 1 size, n (%)	49 (16.7)	41 (14.0)
Error of >1 size, n (%)	1 (0.3)	4 (1.4)

Table 3 Amount and percentage of differences in approved templates (Surgeon) and default templates (Technician) compared to the actual used size perioperative (OR) and between the surgeon and technician when the PSI group is subdivided into MRI- and CT-based PSI for both femur and tibia size

Identical Femur size	MRI ($n = 265$)	CT ($n = 28$)	P value
Surgeon vs. OR, n (%)	252 (95.1)	24 (85.7)	n.s.
Technician vs. OR, n (%)	212 (80.0)	19 (67.9)	n.s.
Surgeon vs. Technician, n (%)	219 (82.6)	24 (85.7)	n.s.
Identical tibia size			
Surgeon vs. OR, n (%)	240 (90.6)	27 (96.4)	n.s.
Technician vs. OR, n (%)	222 (83.8)	20 (71.4)	n.s.
Surgeon vs. technician, n (%)	227 (85.7)	21 (75.0)	n.s.

Table 4 Amount and percentage of the used size of inlay

Inlay size	Amount ($n = 293$)
10	96 (32.8 %)
12	148 (50.5 %)
14	42 (14.3 %)
16	7 (2.4 %)

size. These results and the results of the inlay sizes are summarized in Tables 3 and 4, respectively.

A post hoc power analysis revealed that there was sufficient statistical power ($1-\beta = 0.98$) to detect a treatment effect when comparing the outcomes between the surgeon and technician. The power was not sufficient regarding the comparison between MRI- and CT-based PSI for the femur ($1-\beta = 0.05$) and tibia ($1-\beta = 0.35$) component.

Discussion

The most important finding of the present study was that the predicted femoral and tibial component size in primary TKA with PSI, preoperatively approved by the operating surgeon, results in a more accurate prediction of the actual size of the femoral and tibial components used during surgery as compared to the planning settings made by a technician.

Digital preoperative planning can accurately predict the component sizes and therefore minimize the number of surgical trays used peroperatively [5, 10, 11, 18]. However, results on this topic are inconclusive [11, 18]. Only a few papers studied the accuracy of planning component size with the use of PSI for TKA (Table 5). The results in the literature on the topic of size prediction vary with authors, reporting good accuracy of the PSI to predict component

Table 5 Literature overview on templating total knee arthroplasty. Approved templates (Surgeon) and default templates (Technician) compared to the actual used size perioperative (OR) for both femur and tibia size

Author(s)	N	Template	Surgeon-OR correct femur/Tibia component	Technician-OR Correct Femur/Tibia component
Boonen et al. [2]	40	PSI, signature (MRI)	95 %/90 %	80.0 %/72.5 %
Boonen et al. [4]	200	PSI, signature (MRI)	88.0 %/70.5 %	78.5 %/59.0 %
Hsu et al. [7]	48	2D Digital templating software ^a	TKA 54 %	NA
Issa et al. [8]	89	PSI, shapematch ^b (MRI)	95.5 %/93.0 %	NA
Kniesel et al. [9]	94	2D digital templating software ^c	With reference ball 52 % Without reference ball 33 %	NA
Levine et al. [10]	176	2D digital templating software ^d	66 %/58.5 %	NA
Miller and Purtill [12]	50	2D digital templating software	64 %/60 %	NA
Pietsch et al. [14]	50	PSI ^e (MRI)	100 %/84 %	84 %/38 %
Stronach et al. [19]	66	PSI, signature (MRI)	23 %/47 %	NA
Current study	293	PSI, signature (MRI and CT)	93.9 %/91.1 %	78.8 %/82.6 %

^a OrthoView LLC Jacksonville, Florida

^b Stryker Orthopedics, Mahwah, NJ

^c Medi-Cad AP-X-rays, Hectec GmbH; Niederviehbach, Germany

^d Advanced Case Plan, Stryker Imaging, Flower Mound, Texas

^e Patient-Specific Instruments, Zimmer, Warsaw, USA

size [18] and others reporting frequent intraoperative directed changes [10, 14].

The default template for both the femur and tibia size when templated by a technician was different compared to the approved size for both femur and tibia components. Therefore, the default templates should always be validated digitally and approved by the operating surgeon [14, 19] to minimize intraoperative implant size error. With PSI's, the operating surgeon is able to recognize abnormal implant sizes preoperatively [8, 10]. These abnormal sizes can be delivered in advance to improve operating room efficiency [10]. This may result in a reduction of the overall number of instruments and surgical trays necessary (reduction from 9 to 3 trays) and therefore decrease expenses associated with sterilization of instruments, storage, staff time and setup time for the operating room [1, 6, 13]. In addition, less instrumentation could help to improve tray and operating room turnover which allows more cases to be completed and thereby lowering hospital costs per procedure [10].

Potential differences in component sizes could not be explained by the use of different imaging techniques, i.e. MRI- vs. CT-based templates [8]. Both MRI- and CT-based PSI's showed comparable percentages of correctly predicted intraoperative implant sizes. Early experiences with MRI-based PSI's for TKA showed outcomes similar to this study [3, 4]. However, this study was not in line with a case controlled study showing that the actual femoral and tibial component sizes were statistically significantly different from the default size [2]. More recently, a RCT comparing

MRI- with CT-based PSI's for TKA, both from the same manufacturer, found no significant differences regarding the perioperative changes for both implant components [17].

The results of this study are in line with other studies using PSI (Table 5) and superior compared to conventional two-dimensional (2D) templating (Table 5). When using conventional 2D templates, the implant size and component alignment are templated in two planes: anterior-posterior and lateral [7, 9, 10, 12]. With PSI's, the surgeon is able to plan from multiple views in a virtual 3D design of the knee joint. PSI also includes more visual options: planning of bony resection, implant alignment (e.g. rotation, varus–valgus, slope and flexion–extension) and an overall view of the planned biomechanical axis. Despite the fact that all the default settings from the technician were approved, Stronach et al. [19] found worse outcome regarding the planned femoral and tibial component size (Table 5).

This study found excellent results in predicting the exact implant size when a surgeon approves the preoperative planning with minimal intraoperative changes.

Although well designed, this study does have some limitations. First, this study shows planning data only. Patient-reported outcome measures and functional and radiological outcomes are not described. Second, the present study was not randomized to compare conventional TKA with PSI TKA. Third, only one PSI system was from one manufacturer was used which might have affected the outcome. Therefore, our results could be inapplicable for other PSI designs from other manufacturers. Fourthly, because of

the small number of patients in the CT-group, a type II error cannot be ruled out. Finally, in the current study, all patients were operated by one experienced knee surgeon who probably has less to learn from such an assisting tool than low-volume surgeons or residents [6]. This could raise questions about the general applicability.

This study showed that PSI is able to minimize intraoperative implant size errors in advance to improve operating room efficiency with possible lowering hospital costs per procedure [1, 6, 8, 10], while none of the previous studies using PSI demonstrates a significant improvement of post-operative mechanical axis alignment when comparing PSI with conventional instrumentation [16, 20].

Conclusion

Despite the retrospective nature of this study, this study provided valuable information regarding the potential ability to preoperatively predict the perioperative component sizes. PSI is a tool to help the surgeon to achieve the best possible results during TKA. The planning made by a technician should always be validated and approved by the operating surgeon who has ultimate responsibility regarding the operation.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest. One author (NK) is a paid consultant for Zimmer-Biomet.

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Ethical approval For this type of study formal consent is not required.

Informed consent For this type of study formal consent is not required.

References

- Barrack RL, Ruh EL, Williams BM et al (2012) Patient specific cutting blocks are currently of no proven value. *J Bone Joint Surg* 94(Suppl A):95–99
- Boonen B, Schotanus MG, Kort NP (2012) Preliminary experience with the patient-specific templating total knee arthroplasty. *Acta Orthop* 83(4):387–393
- Boonen B, Schotanus MG, Kerens B et al (2013) Intra-operative results and radiological outcome of conventional and patient-specific surgery in total knee arthroplasty: a multicenter randomised controlled trial. *Knee Surg Sports Traumatol Arthrosc* 21(10):2206–2212
- Boonen B, Schrandt DE, Schotanus MGM et al (2015) Patient Specific Guides in total Knee Arthroplasty: A two year Follow up of the first two hundred consecutive cases performed By a single Surgeon. *JCRMM* (1):1–10
- Del Gaizo D, Soileau ES, Lachiewicz PF (2009) Value of pre-operative templating for primary total knee arthroplasty. *J Knee Surg* 22(4):284–293
- Hamilton WG, Parks NL, Saxena A (2013) Patient-specific instrumentation does not shorten surgical time: a prospective, randomized trial. *J Arthroplasty* 28(8 Suppl):96–100
- Hsu AR, Kim JD, Bhatia S, Levine BR (2012) Effect of training level on accuracy of digital templating in primary total hip and knee arthroplasty. *Orthopedics* 35(2):e179–e183
- Issa K, Rifai A, McGrath MS et al (2013) Reliability of templating with patient-specific instrumentation in total knee arthroplasty. *J Knee Surg* 26:429–434
- Kniesel B, Konstantinidis L, Hirschmüller A et al (2014) Digital templating in total knee and hip replacement: an analysis of planning accuracy. *Int Orthop* 38(4):733–739
- Levine B, Fabi D, Deirmengian C (2010) Digital templating in primary total hip and knee arthroplasty. *Orthopedics* 33(11):797
- Lorio R, Siegel J, Specht LM et al (2009) A comparison of acetate vs digital templating for preoperative planning of total hip arthroplasty: is digital templating accurate and safe? *J Arthroplasty* 24(2):175–179
- Miller AG, Purtill JJ (2012) Accuracy of digital templating in total knee arthroplasty. *Am J Orthop (Belle Mead NJ)* 41(11):510–512
- Nunley RM, Ellison BS, Ruh EL et al (2012) Are patient-specific cutting blocks cost-effective for total knee arthroplasty? *Orthop Relat Res* 470(3):889–894
- Pietsch M, Djahani O, Hohegger M et al (2013) Patient-specific total knee arthroplasty: the importance of planning by the surgeon. *Knee Surg Sports Traumatol Arthrosc* 21(10):2220–2226
- Rubin LE, Murgu KT (2013) Brief report: total knee arthroplasty performed with patient-specific, pre-operative CT-guided navigation. *R I Med J* 96(3):34–37
- Sassoon A, Nam D, Nunley R, Barrack R (2015) Systematic review of patient-specific instrumentation in total knee arthroplasty: new but not improved. *Clin Orthop Relat Res* 473:151–158
- Schotanus MGM, Sollie R, van Haaren EH et al (2016) Radiological discrepancy between MRI- and CT-based patient-specific matched guides for total knee arthroplasty from the same manufacturer: a randomised controlled trial. *Bone Joint J* 98-B(6):786–792
- Specht LM, Levitz S, Iorio R et al (2007) A comparison of acetate and digital templating for total knee arthroplasty. *Clin Orthop Relat Res* 464:179–183
- Stronach BM, Pelt CE, Erickson J, Peters CL (2013) Patient-specific total knee arthroplasty required frequent surgeon-directed changes. *Clin Orthop Relat Res* 471(1):169–174
- Thienpont E, Schwab PE, Fennema P (2014) A systematic review and meta-analysis of patient-specific instrumentation for improving alignment of the components in total knee replacement. *Bone Joint J* 96-B(8):1052–1061
- White D, Chelule KL, Seedhom BB (2008) Accuracy of MRI vs CT imaging with particular reference to patient specific templates for total knee replacement surgery. *Int J Med Robot* 4(3):224–231
- Winder J, Bibb R (2005) Medical rapid prototyping technologies: state of the art and current limitations for application in oral and maxillofacial surgery. *J Oral Maxillofac Surg* 63:1006–1015