World Journal of Orthopedics

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DOI: 10.5312/wjo.v7.i1.61

World J Orthop 2016 January 18; 7(1): 61-68
ISSN 2218-5836 (online)

ORIGINAL ARTICLE

Case Control Study

Patient specific guides for total knee arthroplasty are ready for primetime

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Author contributions: Schotanus MGM designed the study, gathered and analysed all the data, wrote the initial draft of the manuscript, managed and performed the study; Boonen B ensured the accuracy of the data and the analysis and gave critical revisions related to important intellectual content of the manuscript; Kort NP designed the study, revised the manuscript and gave final approval of the version of the article to be published.

Institutional review board statement: The study was reviewed and approved by the Institutional Review Board (METC Atrium-Orbis-Zuyd, Heerlen, the Netherlands) file name 13-N-09.

Informed consent statement: All patients gave informed consent prior to the study enrolment.

Conflict-of-interest statement: Dr. Nanne P Kort is a consultant on the PSG technique for Biomet, Europe. The other authors declare that they have no conflict of interest.

Data sharing statement: No additional data are available.

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Received: February 11, 2015
Peer-review started: February 12, 2015
First decision: June 18, 2015
Revised: October 22, 2015
Accepted: November 17, 2015
Article in press: November 25, 2015
Published online: January 18, 2016

Abstract

AIM: To present the radiological results of total knee arthroplasty (TKA) with use of patient specific matched guides (PSG) from different manufacturer in patients suffering from severe osteoarthritis of the knee joint.

METHODS: This study describes the results of 57 knees operated with 4 different PSG systems and a group operated with conventional instrumentation (*n* = 60) by a single surgeon. The PSG systems were compared with each other and subdivided into cut- and pin PSG. The biomechanical axis [hip-knee-ankle angle (HKA)], varus/valgus of the femur [frontal femoral component (FFC)] and tibia (frontal tibial component) component, flexion/extension of the femur [flexion/extension of the femur component (LFC)] and posterior slope of the tibia [lateral tibial component (LTC)] component were evaluated on long-leg standing and lateral X-rays. A percentage of > 3° deviation was seen as an outlier.

RESULTS: The inter class correlation coefficient (ICC) revealed that radiographic measurements between both assessors were reliable (ICC > 0.8). Fisher exact test was used to test differences of proportions. The percentage of outliers of the HKA-axis was comparable between both the PSG and conventional groups (12.28% *vs* 18.33%, *P* < 0.424) and the cut- and pin PSG groups (14.3% *vs* 10.3%, *P* < 1.00). The percentage of outliers of the FFC (0% *vs* 18.33%, *P* < 0.000), LFC (15.78% *vs* 58.33%, *P* < 0.000) and LTC (15.78% *vs* 41.67%, *P* < 0.033) were significant different in favour of the PSG

group. There were no significant differences regarding the outliers between the individual PSG systems and the PSG group subdivided into cut- and pin PSG.

CONCLUSION: PSG for TKA show significant less outliers compared to the conventional technique. These single surgeon results suggest that PSG are ready for primetime.

Key words: Total knee arthroplasty; Patient specific matched guides; Patient matched instruments; Single surgeon; Alignment; Conventional instruments; Cutting guides; Pin guides

Core tip: Total knee arthroplasty (TKA) is one of the most successful and commonly performed surgical procedure for the treatment of severe knee osteoarthritis with excellent 15-20 years survivorships. This article provides an analysis on patient specific matched guides (PSG) between different manufacturers and the conventional technique and between pin- and cutting guides for TKA. In addition, we compared our results with previous studies (level 1 evidence), which are generally unambiguous, and show no radiological difference. However, in this trial, we do see difference in favour of the PSG technique.

Schotanus MGM, Boonen B, Kort NP. Patient specific guides for total knee arthroplasty are ready for primetime. *World J Orthop* 2016; 7(1): 61-68 Available from: URL: http://www.wjgnet.com/2218-5836/full/v7/i1/61.htm DOI: http://dx.doi.org/10.5312/wjo.v7.i1.61

INTRODUCTION

Total knee arthroplasty (TKA) has been developed significantly over the last decades. Many changes have been made to improve both survival and functioning. A good postoperative biomechanical axis is one of the key elements for a good implant survival. Malalignment is associated with poor implant survivorship[1-4]. Several studies reported results of postoperative malalignment using conventional intramedullary alignment rods in TKA[5-9]. Computer navigation was introduced to cope with malalignment and instability in conventionally placed prostheses[10]. These days, revolutionary changes within the elective knee arthroplasty have taken place due to industry driven interventions[11]. Patient specific matched guides (PSG) for TKA is a relatively new technique to align the knee prosthesis, using 3D rapid prototyped disposable cut or pin guides that fits on the native anatomy of the individual patient[12,13]. This perioperative guiding technique eliminates the use of intra- and extra medullar rods to make bony resections. Previous published results on PSG suggest this to be a good alternative to conventional instrumentation with comparable results, improved radiological outcome and reduced operation time and blood loss[7,13-23].

This prospective study on PSG between different manufacturers and conventional technique for the implantation of TKA was designed to address the following research questions: Is there a significant difference in outliers in alignment in the frontal and lateral plane between PSG and conventional TKA, secondly between the four individual different PSG systems and thirdly between cut- and pin PSG? We hypothesise that there will be fewer outliers with PSG TKA compared to conventional TKA without differences between different PSG systems and cut- and pin PSG.

MATERIALS AND METHODS

Patients were operated for TKA with PSG systems from 4 different manufactures (Table 1). In daily practice the TKA system and PSG from the company Biomet is used. Between May 2013 and April 2014, 60 consecutive patients with debilitating osteoarthritis (OA) of the knee joint, who were eligible for primary TKA were included (Figure 1). Patients who were not eligible to undergo magnetic resonance imaging (MRI) due to metal artefacts around the knee joint from previous surgery, claustrophobia, movement artefacts during MRI scanning time, pigmented villonodular synovitis, implanted electronic devices and patients that refused to consent were excluded. TKA surgery was done using PSG and consisted of guides from 4 different TKA suppliers (Table 1). The conventional TKA group consisted of 60 patients who were randomly selected from a cohort ($n \geq 500$) as a comparison group. We did not match patients (*e.g.*, body mass index, gender, age and severity of OA) to avoid selection bias.

All patients gave informed consent to participate in this prospective study and were operated by a senior knee orthopaedic surgeon (NK) with extensive experience with PSG[15,16]. Patients were not blinded to the type of alignment method used. Three patients were excluded from the study and therefore did not receive the intervention as planned. A flowchart of the study design is shown in Figure 2. There were no significant differences in baseline demographics, as summarized in Table 2.

PSG and the conventional TKA surgery are extensively described in previous published studies[15,16]. Preoperative, a virtual 3 dimensional plan was made based on the imaging protocols of the different manufacturers (Table 1). Preferred component position of the prosthesis was planned to obtain a neutral biomechanical axis [hip-knee-ankle angle (HKA)] and position of the femoral [frontal femoral component (FFC)] and tibial [frontal tibial component (FTC)] components in the frontal plane. All settings during planning in the lateral plane were similar for all PSG systems: Femoral component flexion [flexion/extension of the femur component (LFC)] and tibial component posterior slope

Table 1 Different industries with brand names, guide type, implant name and scanning modality

	Dupuy-Synthes	Smith and Nephew	Zimmer	Biomet
PSG	Trumatch	Visionaire	PSI	Signature
Guides	Cut	Cut	Pin	Pin
Implant	Sigma CR	Genesis Ⅱ	NexGen	Vanguard CR
Imaging protocol	CT[1]	MRI[2]	CT or MRI[1]	CT or MRI[1]

[1]Scan of the hip, knee and ankle join; [2]MRI of the knee joint with long leg standing X-ray. PSI: Patient-specific instrument; PSG: Patient specific matched guides; CT: Computed tomography; MRI: Magnetic resonance imaging; CR: Computed radiography.

Table 2 Baseline demographics per alignment method, *n* (%)

	Trumatch	Visionaire	PSI	Signature	Conventional	*P* value
Number of patients	15	13	14	15	60	
Mean age, yr (range)	72 (57-90)	72 (63-82)	69 (52-86)	68 (56-74)	65 (50-83)	0.097
Male	6 (40)	7 (54)	7 (50)	7 (47)	34 (57)	0.967
Mean BMI (range)	30 (23-36)	30 (23-37)	30 (26-36)	30 (23-38)	28 (21-37)	0.373
Severity OA						
Moderate	13 (87)	11 (85)	13 (93)	14 (93)	53 (88)	0.991
Severe	2 (13)	2 (15)	1 (7)	1 (7)	7 (12)	0.959

PSI: Patient-specific instrument; BMI: Body mass index; OA: Osteoarthritis.

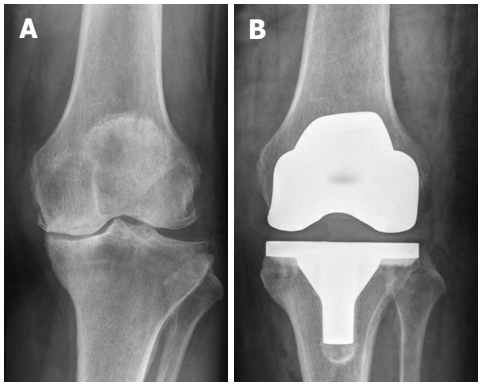

Figure 1 Anterior-posterior radiograph of a left knee of a female patient. A: Preoperative severe osteoarthritis; B: Postoperative with the Sigma CR, total knee arthroplasty (Depuy) *in situ*.

[lateral tibial component (LTC)] were set at 3°. The final approval of settings was done by the operating surgeon (NK). After approval, the disposable cut or pin guides (Table 1) for perioperative alignment were manufactured and used during surgery. A midline approach was used and a cemented prosthesis implemented in all cases (Table 1). The guides were designed to make contact with osteophytes and therefore it was not allowed to remove these prior to the bony cuts. The same procedure was performed in the conventional group, except for the standard conventional rods for femur and tibia with the same implant as the Signature group (Vanguard Complete Knee System, Biomet, Warsaw, INC). Conventional rods were used to align the position of the cutting blocks: LFC and LTC were set at 0°.

All patients received a multimodal pain protocol including spinal or general anesthesia and local infiltration analgesia without a drain and urine catheter. Postoperative procedures were the same in all TKA patients. Patients followed an enhanced recovery pathway and received subcutaneous thromboprophylaxis (Fondaparinux) once daily for 35 d, starting on the evening on the first postoperative day.

Preoperative approved planning for the femur and tibia component were compared with the postoperative achieved alignment of each component on radiographs. HKA-axis and implant position were measured with a calibrated protocol on digital images on a PACS system[15,16]. HKA angle was evaluated on standardized 1-year postoperative frontal long-leg standing X-rays. Varus/valgus position of the FFC and FTC perpendicular to the HKA angle were measured on the same frontal radiographs. Flexion/extension of the LFC, measured from the anterior femoral cortex and posterior or anterior slope of the LTC measured from the posterior cortex of the tibia, were evaluated on 1-year postoperative lateral radiographs. Deviations of > 3° between preoperative planned HKA-axis (sum of FFC and FTC) and individual components (FFC, FTC, LFC and LTC) compared to the postoperative achieved alignment on radiographs, were considered as outliers. Mean values, SD and percentages of > 3° deviation of the preoperative planned alignment and postoperative alignment were first compared between the complete PSG group and the conventional group and all PSG groups were compared with each other. A comparison between cut- and pin guides was also made (Table 1).

Ethical approval

This study was approved by the institutional review board (IRB Atrium-Orbis Zuyd Heerlen, the Netherlands;

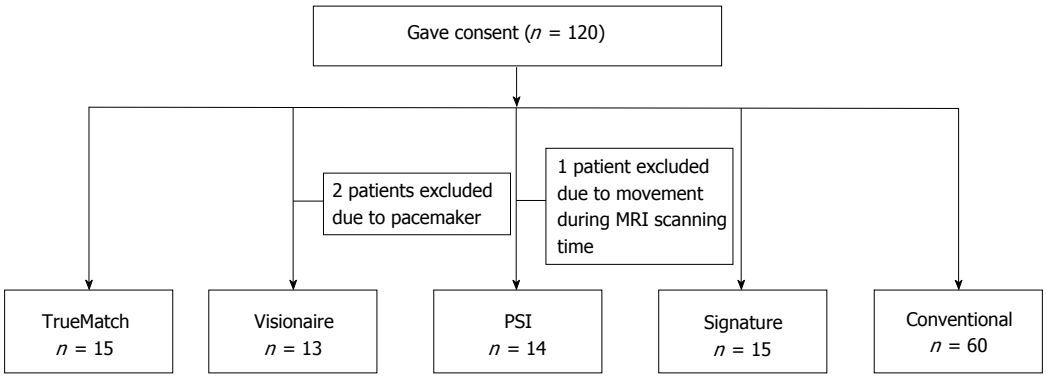

Figure 2 Flowchart study design. PSI: Patient-specific instrument; MRI: Magnetic resonance imaging.

Table 3 Inter observer correlation coefficients

	HKA	FFC	FTC	LFC	LTC
Inter CC	0.811	0.879	0.883	0.850	0.943

HKA: Hip-knee-ankle angle; FFC: Frontal femoral component; FTC: Frontal tibial component; LFC: Flexion/extension of the femur component; LTC: Lateral tibial component; CC: Class correlation coefficient.

IRB-nr.13N09), registered online at the Dutch Trial Register (NTR4739) and was performed in compliance with the Helsinki Declaration of 1975, as revised in 2000. All patients were informed and they consented to providing data for anonymous use.

Statistical analysis

Statistical Package for the Social Sciences V17.0 (SPSS, Inc., Chicago, IL) for Windows was used. All radiographic evaluation was performed once for each radiograph, performed by 2 independent assessors (MS and SH). Inter class correlation coefficient (ICC) was calculated to check for inter observer reliability. An ICC ≥ 0.7 was considered as good correlation. Statistically significant differences for radiographs were analyzed with a one-way ANOVA. The Bonferroni method for correcting for multiple comparisons was used to reduce the chances of obtaining false-positive results (type Ⅰ errors). Fisher exact test was used to test differences of proportions. *P*-value was considered to be statistically significant at $P \leq 0.05$ for all statistical analyses.

RESULTS

Of the 120 patients included, 3 patients could not be scanned with MRI and were operated with use of computed tomography (CT)-based PSG (Signature, Biomet). Baseline demographics are shown in Table 2. All guides fitted well during the time of operation, there were no conversions to conventional instrumentation. All radiographic measurements of both observers were reliable and ICC's were excellent (Table 3).

With regard to the individual components, percentage of outliers of the FFC ($P < 0.000$), LFC ($P < 0.000$) and LTC ($P < 0.05$) were significantly different in favour of the PSG group (Table 4). Regarding the individual different PSG systems, the mean (SD) HKA-axis ($P < 0.000$), the FFC ($P < 0.000$) and LTC ($P < 0.000$) alignment were significantly different (Table 5). The PSG group subdivided into cut- and pin PSG showed significant difference regarding the mean FFC ($P < 0.022$) and the LTC ($P < 0.009$) alignment (Table 6).

Table 4 Mean (SD) values and amount of patients and percentages of outliers of > 3° deviation of the planned alignment and postoperative alignment compared between the patient specific matched guides and the conventional group, *n* (%)

Outliers	PSG	Conventional	*P* value
HKA outliers	7 (12.28)	11 (18.33)	0.424
Mean (SD)	179.49 (2.24)	178.54 (2.27)	0.015
FFC outliers	0 (0)	11 (18.33)	0.000
Mean (SD)	89.44 (1.73)	88.03 (1.73)	0.000
FTC outliers	1 (1.75)	0 (0)	1.000
Mean (SD)	89.87 (1.32)	90.37 (1.38)	0.058
LFC outliers	9 (15.78)	35 (58.33)	0.000
Mean (SD)	86.09 (2.86)	86.04 (3.14)	0.314
LTC outliers	9 (15.78)	25 (41.67)	0.033
Mean (SD)	92.86 (2.64)	87.43 (2.63)	0.000

PSG: Patient specific matched guides; HKA: Hip-knee-ankle angle; FFC: Frontal femoral component; FTC: Frontal tibial component; LFC: Flexion/extension of the femur component; LTC: Lateral tibial component.

DISCUSSION

This industry driven technology proved to be safe, reproducible and easy to use. This leads to a commercial success compared to other computer-assisted technologies[11]. Although, published results on PSG are contrasted, even on level Ⅰ studies. Seven level Ⅰ studies compared conventional instrumentation with PSG and compared different PSG manufacturers. None of them had measured a significant difference in outliers of HKA axis (Table 7). However, Pfitzner *et al*[24], recently published results comparing conventional instrumentation with CT and MRI based PSG from 2 different manufacturers, and between both PSG groups. They found a significant difference regarding the outliers in HKA-axis between MRI based PSG (Visionaire; 7%) and conventional instruments (43%), but no significant difference between

Table 5 Mean (SD) values and amount of patients and percentages of outliers of > 3° deviation of the planned alignment and postoperative alignment compared between the patient specific matched guides groups, *n* (%)

	Trumatch	Visionaire	PSI	Signature	*P* value
HKA outliers	3 (20.00)	1 (7.69)	2 (14.28)	1 (6.66)	0.819
Mean (SD)	178.5 (2.3)	181.3 (1.6)	180.6 (1.6)	177.9 (1.8)	0.000
FFC outliers	0	0	0	0	1.000
Mean (SD)	89.9 (1.6)	90.1 (1.5)	89.9 (1.2)	87.9 (1.8)	0.000
FTC outliers	0	0	1 (7.14)	0	1.000
Mean (SD)	89.3 (1.4)	90.0 (1.2)	89.9 (1.6)	90.6 (1.3)	0.081
LFC outliers	2 (13.33)	2 (15.38)	1 (7.14)	4 (26.66)	0.663
Mean (SD)	85.7 (1.6)	85.4 (2.1)	87.4 (1.9)	85.8 (4.5)	0.307
LTC outliers	2 (13.33)	4 (30.76)	2 (14.28)	1 (6.66)	0.594
Mean (SD)	92.7 (2.4)	91.2 (3.0)	94.8 (1.2)	92.8 (2.7)	0.000

PSI: Patient-specific instrument; HKA: Hip-knee-ankle angle; FFC: Frontal femoral component; FTC: Frontal tibial component; LFC: Flexion/extension of the femur component; LTC: Lateral tibial component.

Table 6 Mean (SD) values and amount of patients and percentages of outliers of > 3° deviation of the planned alignment and postoperative alignment compared between the cut (*n* = 28, Trumatch and Visionaire) and pin (*n* = 29, patient-specific instrument and signature) patient specific matched guides group, *n* (%)

	Cut PSG	Pin PSG	*P* value
HKA outliers	4 (14.3)	3 (10.3)	1.000
Mean (SD)	179.9 (2.4)	179.3 (2.2)	0.342
FFC outliers	0	0	1.000
Mean (SD)	90.0 (1.5)	89.6 (1.8)	0.022
FTC outliers	0	1 (3.4)	1.000
Mean (SD)	89.6 (1.3)	90.2 (1.5)	0.115
LFC outliers	4 (14.3)	5 (17.2)	1.000
Mean (SD)	85.6 (1.8)	86.6 (3.5)	0.184
LTC outliers	6 (21.4)	3 (10.3)	0.477
Mean (SD)	92.0 (2.7)	93.8 (2.3)	0.009

PSG: Patient specific matched guides; HKA: Hip-knee-ankle angle; FFC: Frontal femoral component; FTC: Frontal tibial component; LFC: Flexion/extension of the femur component; LTC: Lateral tibial component.

CT based PSG and conventional instruments, neither between both PSG systems[24]. This was contrary to what Victor *et al*[25] found. They compared 4 different PSG systems with the conventional technique, operated by 4 surgeons, with more significant outliers for the FTC and LTC in favour of the intra- and extramedular technique (Table 7). Even between the 4 different PSG systems, percentages of outliers of > 3° deviation of the planned HKA and LFC angle were significantly different, ranging from 6% to 45% and 20% to 82%, respectively[25] (Table 7). Published level I percentages of outliers in the frontal and lateral plane for individual components for both femur and tibia vary and are inconclusive. Outliers of the FFC for the PSG are comparable or less than the conventional intramedular technique. Only 2 authors published significant differences in favour of the MRI based PSG[17,24]. This was in contrast to the FTC (Table 7). Most of the outcomes are comparable, however, 2 articles published significant better outcome with extramedular rods[25,26]. Only Ng *et al*[22] found significant better outcome with MRI based PSG for the tibia. Level I results are very remarkable in regard to the LTC. These were significantly better with PSG than with conventional instrumentation (Table 7). Most notable are the significant differences that have been found with CT based PSG, which scored poorer outcome regarding to LTC outliers, ranging from 21% to 65%[19,25-27] (Table 7). A possible explanation for these outcomes can be the limitations in visualization and outlining of intra-articular cartilage in CT based 3D models[28-31]. Another explanation, based on our experience, is that CT based guides were more difficult to place on the bony surface compared to MRI based guides. Nevertheless, we did not reveal a significant difference between the MRI and CT PSG surgeries for HKA-axis and individual components for the different planes.

There may be some concerns regarding our radiological measurements. A wide variety of different analyses in the literature are used to objectively determine the postoperative position for both the femur and tibia implants (Table 7). Despite a good ICC for the evaluation of the frontal and lateral position of both femur and tibia implants, rotational alignment was not examined. Most of the literature use long-standing radiographs, except for 1 paper which used scout CT scan[17] and two used full-leg CT scans[22,27]. Postoperative evaluation on 3D-CT have shown to be a valuable tool to measure position and orientation of both the femur and tibia components and it is more accurate with significantly better femoral rotation alignment after use of PSG[18,22,32]. Unfortunately, a postoperative 3D-CT is not routinely performed in our clinic. On the other hand, plane radiographs are generally applicable for everyone.

This single surgeon experience with different PSG manufacturers could raise questions about the general applicability. We had the opportunity to use different types of PSG and implants. Based on the experience with TKA, the use of PSG and a possible learning curve, implementation of a new implant system may be a

Table 7 Published level I studies with significant percentage of outliers of > 3° deviation between the patient specific matched guides and conventional intramedular and/or extramedular alignment method for hip-knee-ankle angle axis, frontal femoral component, frontal tibial component, flexion/extension of the femur component, lateral tibial component and axial rotation of the femur and/or tibia component controlled with postoperative X-ray (long-leg standing and/or lateral X-rays) and/or computed tomography

Outliers (%) > 3° deviation	PSG system	Modality	Conventional femur/tibia	Control	Sample size (PSG/conventional)	Significant outliers (%) (PSG/conventional)
Boonen *et al*[16]	Signature	MRI	Intra	X-ray	90/90	LFC (49/65)[1]
Chareancholvanich *et al*[17]	PSI	MRI	Intra/Extra	X-ray and CT	40/40	FFC (0/18)[1]
Chotanaphuti *et al*[18]	TruMatch	CT	Intra/Extra	X-ray and CT	40/40	NA
Hamilton *et al*[19]	TruMatch	Scout CT	Intra/Extra	X-ray	26/26	LTC (65/50)[2]
Ng *et al*[22] [Outliers (%) > 2° deviation]	PSI	MRI	Intra	CT	51/27	FTC (27/67)[2], Femoral rotation (16/67)[2], Tibial rotation (22/95)[2]
Pfitzner *et al*[24]	TruMatch	CT	Intra/Extra	X-ray and CT	(30/30)/30	HKA (30/7/43)[2]
	Visionaire	MRI + X-ray				FTC (13/3/23)[1]
						Femoral rotation (1/13 /50)[1]
Victor *et al*[25]	Signature	MRI, CT	Intra/Extra	X-ray and CT	(16/16/16/16)/64	FTC (15/3)[1]
	TruMatch	MRI + X-ray				LTC (21/3)[2]
	Visionaire	MRI				HKA (6/25/45/19)[1,3]
	PSI					LFC (62/20/20/56)[2,3]
Kotela *et al*[26]	Signature	CT	Intra/Extra	X-ray	49/46	FTC (39/20)[1]
Woolson *et al*[27]	TruMatch	CT	Intra/Extra	CT	22/26	LTC (32/8)[1]
Current study	Signature	MRI	Intra	X-ray	(15/13/14/15)/60	FFC (022)[2]
	TruMatch	CT				LFC (16/67)[2]
	Visionaire	MRI + X-ray				LTC (16/42)[1]
	PSI	MRI				

[1]Statistically significant different, $P \leq 0.05$; [2]Statistically significant different, $P \leq 0.005$; [3]Outliers > 3° deviation between the different PSG groups. NA: Not applicable for outliers; PSG: Patient specific matched guides; PSI: Patient-specific instrument; CT: Computed tomography; MRI: Magnetic resonance imaging; Intra: Intramedular; Extra: Extramedular; HKA: Hip-knee-ankle angle; FFC: Frontal femoral component; FTC: Frontal tibial component; LFC: Flexion/extension of the femur component; LTC: Lateral tibial component.

potential bias in the outcome[25]. However, research is mostly performed by high-volume surgeons who probably easier adapt to a new surgical technique than low-volume surgeons or residents. PSG could be an added value in less experienced surgeons due to their simplicity[19]. On the other hand, we evaluated cut and pin PSG from different manufacturers with less outliers compared to the conventional group.

Our primary goal was to investigate the accuracy of alignment between conventional and PSG and between different PSG systems compared with published level I evidence. A comparison on perioperative and clinical outcome were not made, although there is a trend towards significant shorter operating time[16-18] and blood loss[16] with surgeries performed with PSG. However, published results on component sizing are inconclusive to come up with a statement[18,19,27].

Finally, even though this study was a consecutive series compared with a historical cohort and not a randomized trial, a potential criticism was the sample size and power of this study.

The present study illustrates that this simplified surgical technique for TKA is safe and effective with acceptable radiological outcome. The PSG group shows significantly less outliers compared to the conventional technique. Whether these differences are clinically relevant is questionable and should be investigated on the long term. Based on these single surgeon results, we conclude that PSG are ready for prime time.

ACKNOWLEDGMENTS

The authors want to thank Stef van Hoef for his work in measuring the alignment on digital long-leg standing and lateral radiographs. We also thank Dr. Rob Sollie from Flinders Medical Centre Adelaide, Australia, who served as external reader, and for his comments that greatly improved the manuscript.

COMMENTS

Background

Patients with knee osteoarthritis often results in debilitating function of the knee joint warranting a total knee arthroplasty (TKA). This study aims to present the radiological results of TKA with use of patient specific matched guides (PSG) from different manufacturer in patients suffering from severe osteoarthritis of the knee joint.

Research frontiers

Patients suffering from osteoarthritis of the knee joint can be operated with use of PSG for TKA from different manufacturer. TKA with PSG has concerns regarding accurate implant alignment and the long term survival of the TKA compared to the conventional instrumentation.

Innovations and breakthroughs

In this study, PSG for TKA from different manufacturer restored good biomechanical axis and individual implant alignment in patients suffering from moderate to severe osteoarthritis of the knee joint compared to conventional alignment.

Applications

To summarize, PSG from different manufacturer can be an added value in daily

TKA practice in patients suffering from moderate to severe osteoarthritis of the knee joint compared to the conventional instrumentation for TKA.

Peer-review

The authors compared the accuracy of TKA using patient-specific instruments (PSIs) with that of TKA using the conventional technique. In addition, they compared the accuracy of 4 different manufactured PSI TKAs. In conclusion, TKA using PSIs was more accurate than TKA using the conventional method, and no difference in accuracy was found between the 4 different manufactured PSI TKAs. Regarding the PSI TKA that was recently developed, more research studies, including precision, cost, operation time, blood loss, radiation exposure, and long-term survival, should be conducted in order to examine if it confers more benefits to patients than the conventional TKA. The manuscript could add new information on PSI TKA regarding its accuracy.

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P- Reviewer: Anand A, Ohishi T
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