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No radiological and clinical advantages with patient-specific positioning guides in total knee replacement

A multicenter randomized controlled trial

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Background and purpose — Although the use of patient-specific positioning guides (PSPGs) in total knee replacement (TKR) in theory is promising, the technique has not yet proven its superiority compared with the conventional method. We compared radiological alignment and clinical outcome between TKR performed with the use of PSPGs and the conventional operation method.

Patients and methods — 3 hospitals participated in a prospective trial. 109 patients were randomized to either the conventional method or to the use of PSPGs. Postoperatively a full-length standing anteroposterior radiograph and a postoperative CT scan were taken. On the CT scan the alignments were measured for both the femoral and tibial components in the frontal, sagittal, and axial plane. The Knee injury and Osteoarthritis Outcome Score (KOOS), the Eurocol-5D-3L (Eq5D) descriptive system and visual analogue scale (VAS), a pain score (NRS), and range of motion (ROM) were recorded preoperatively, and at 3 months, 1, and 2 years. The operation time and length of hospital stay were recorded.

Results — 90 patients were available for postoperative CT measurements. A statistically significant difference was found between the conventional TKR instrumentation and the use of PSPGs for the frontal femoral (mean (SD) 0.6° (1.7) vs. –0.3° (2.2), CI 0.08 to 1.69) and tibial (–0.3° (1.5) vs. 0.9° (2.1), CI –1.98 to –0.44) component angles and for the tibial alignment in the sagittal plane (–3.8° (3.0) vs. –2.2° (2.5), CI –2.72; –0.42). The proportions of outliers were similar between the groups as well as the hip–knee–ankle angle, the KOOS sub scores, the Eq5D, pain (NRS), ROM, operation time, and length of hospital stay.

Interpretation — The use of PSPGs requires a preoperative CT scan or MRI and the guides have an additional cost. As this study was not able to prove any extra benefit of the use of PSPGs we recommend the conventional operation method for TKR.

Several studies underline the importance of alignment for long-term survival of total knee replacements (TKRs) (Berend et al. 2004, Fang et al. 2009, Ritter et al. 2011) and for better patient-related outcome scores (Choong et al. 2009, Longstaff et al. 2009). Nevertheless, with the conventional operation method and with computer assistance, considerable percentages of alignment outliers are reported (Siston et al. 2005, Yau et al. 2008, Kim et al. 2009). With the purpose of obtaining optimal alignment, patient-specific positioning guides (PSPGs) have been on the market for several years. Various names and abbreviations have been used for these guides: patient-specific instrumentation (PSI), patient-specific cutting guides (PSCG), patient-matched positioning guides (PMPG), patient-matched instrumentation (PMI), and patient-specific guides (PSG). In this article, we shall use the term patient-specific positioning guides (PSPGs) to encompass all guides. The guides represent a preoperative software plan based on CT or MRI. Several RCTs have been conducted comparing the use of PSPGs with the conventional operation method. Some studies reported better alignment (Ng et al. 2012, Daniilidis and Tibesku 2014, Macdessi et al. 2014, Schotanus et al. 2016), while others did not (Nunley et al. 2012, Chareancholvanich et al. 2013, Woolson et al. 2014, Huijbregts et al. 2016). With regard to clinical outcome most studies did not report any difference (Boonen et al. 2016, Huijbregts et al. 2016). The hypothesis of this study was that the use of PSPGs would not lead to better alignment than using conventional TKR instrumentation. Secondary endpoints were knee injury and osteoarthritis outcome score (KOOS), a health quality measurement questionnaire (Eq5D), pain, range of motion, length of hospital stay, and operation time.

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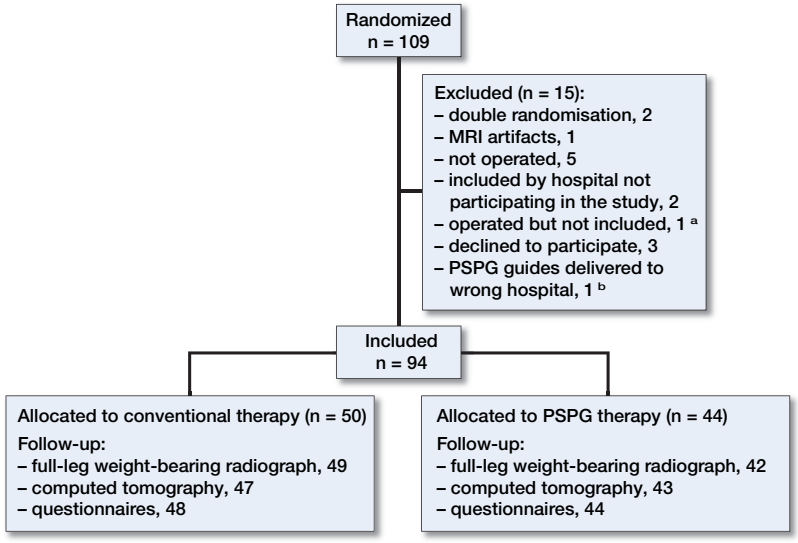

Figure 1. Flow chart.
[a] This patient was randomized, but the surgeon was not aware of this inclusion and therefore this patient was not followed up in this study.
[b] There were no guides available on the day of surgery and it seemed that the guides were delivered to another hospital. The surgeon operated using the conventional method and unfortunately without following up this patient according to the study protocol.

Table 1. Demographics

Factor	Conventional	PSPG
Number of patients	50	44
Men/women ratio	18/32	14/30
Age (years) mean (SD)	64 (6.9)	67 (8.8)
BMI, mean (SD)	29 (4.6)	31 (4.9)
ASA grade, no of patients		
1	4	3
2	37	34
3	9	6
4	0	1

Patients and methods

From September 2011 to January 2014 109 patients with symptomatic knee osteoarthritis were included. 94 patients were operated with TKRs and were available for follow up (Figure 1, Table 1). 3 hospitals participated in this study (Oslo University Hospital, Betanien Hospital Skien and Telemark Hospital Skien).

Inclusion criteria for the study were patients with symptomatic knee osteoarthritis. Patients could only be included for a unilateral arthroplasty. Contra-indications were: marked bone loss, which could preclude adequate fixation of the device, non-cooperative subjects, neurologic and muscular disorders, severe vascular insufficiency of the affected limb, severe instability or deformity of the ligaments and/or surrounding soft tissue, which may preclude stability of the device, rheumatoid arthritis, and other systemic diseases and known metal allergy.

Randomization

After receiving written consent block randomization was obtained by variable block sizes. Patients were randomized to either TKR with the conventional operation method (control group) or to TKR with PSPG assistance (study group). All patients were referred for a preoperative MRI (according to the Signature™ scanning protocol; Signature MRI Inc, Monrovia, CA, USA) so that they did not know which type of operation they would receive.

Sample size calculation

A sample size calculation was performed for the frontal mechanical alignment. The standard deviation was set at 2.4 based on previous studies (Mullaji et al. 2007, Spencer et al. 2009). With an effect size of 1.5 degrees a sample size of 41 knees per group was needed to achieve a power of 0.8 and significance level of 0.05. A power analysis was also performed for the secondary outcome, the Knee injury and Osteoarthritis Outcome Score (KOOS). In order to detect a difference of 10 units in KOOS with common standard deviation equal to 20, a strength calculation showed that we needed to include 63 patients in each group to achieve a force of 80% and a significance level 0.05.

Operative procedure

In both groups, the aim was to achieve neutral mechanical alignment in the coronal plane. A standard medial parapatellar approach was used. A tourniquet was applied during the entire operation until the skin was closed. A Vanguard Cruciate Retaining Total Knee (Vanguard Complete Knee System, Biomet Inc, Warsaw, IN, USA) was cemented with Reobtain Bone cement R (Biomet Inc, Warsaw, IN, USA) in all cases. Orthopedic surgeons specialized in TKR performed the vast majority of operations; in 3 cases a resident, under guidance of a knee surgeon, performed the procedure. For the control group, standard intramedullary instrumentation was used for the femoral component. The femoral rotational axis was defined using Whiteside's line, the epicondyle axis, and posterior condylar axis. The tibial component was placed according to the mechanical axis using extramedullary instrumentation.

For the study group, the preoperative planning from 3D reconstructed MRI images was performed using planning software (Materialise NV, Leuven, Belgium). The femoral component was set at 3 degrees of flexion. The surgical epicondylar axis obtained from 3D MRI reconstructed images was used to set femoral rotational reference. The tibial component was planned according to the ideal mechanical axis and with 3 degrees of posterior slope. Intraoperatively, the PSPGs were placed on the femur and tibia guiding the bone

resection. The aim was to use the PSPG for setting the rotation of the tibial tray. However, in cases where the surgeon intraoperatively assessed that another tray size was more suitable, the planned one was discarded and the extra-medullary guiding system was then used to align the tibial tray in the axial plane and measure the appropriate size. In both groups, 5000 IE dalteparin was given subcutaneously on the day of surgery and daily for 2 weeks postoperatively. Cephalotin 2 g was given intravenously 20–30 minutes prior to surgery. Thereafter 3 doses of 2 g cephalotin were administered on the day of surgery. Postoperative mobilization was started at day 0 with active exercises and ambulation in both groups. Operation time and the length of stay in hospital were documented.

Radiological measurements

A full leg weight-bearing radiograph and a computed tomography (CT) scan according to the Perth protocol (Chauhan et al. 2004) were planned 3 months postoperatively. 2 orthopedic surgeons measured the postoperative hip–knee–ankle (HKA) from the full leg weight-bearing radiograph using IMPAX software v6.4.5024 (AGFA Healthcare, Mortsel, Belgium). The HKA angle was determined by the angle between a line from the center of the hip to the center of the knee and a line from the center of the knee to the center of the ankle. The aim in both groups was to achieve neutral alignment (180°). HKA angles greater and lower than 180° indicated respectively valgus and varus. Outliers were defined as a deviation of more than 3° from the neutral axis.

Multi-slice CT scanners (Philips Brilliance 2.6 |Philips Healthcare (Cleveland) Inc., USA] and Siemens Emotion Somatom 6 [Forcheim, Germany])) were used for the postoperative CT scan according to the Perth protocol. Independent radiographers performed each component angle measurement once by using a standard workstation and software. Both radiographers had previous training and experience with the measurements from a former study where the following measurement protocols were used (Leeuwen et al. 2015).

The frontal femoral component angle (FFCA) was measured between a line from the femoral head center to the deepest point of the femoral notch and a line parallel to the distal femoral condyles. The frontal tibial component angle (FTCA) was defined as the angle between a line from the center of the plateau to the center of the talus and a line parallel to the tibial tray. The sagittal femoral component angle (SFCA) was obtained from a line from the center of the femoral head to the deepest point of the notch, and a line across the posterior flange of the component. The tibial slope (sagittal tibial component angle—STCA) was defined as the angle between a line from the center of the tibial plateau to the ankle, and a line parallel to the tibial tray. The axial femoral component angle (AFCA) was the angle between a line through the surgical epicondylar axis, and a line across the posterior condyles. 90 degrees were subtracted from the angle measurements in the coronal and sagittal planes. The angle measurements in the coronal plane were performed on the lateral side, which resulted in positive and negative values representing respectively varus and valgus. In the sagittal plane, positive values indicated an anterior slope and negative values indicated a posterior slope. For the tibial component angle in the sagittal plane, 3° were added to the CT measurements for the PSPG group as the PSPG was planned with 3° of flexion and the conventional method aimed for neutral alignment. Positive and negative angle values in the axial plane represented respectively external and internal rotation of the femoral component. Outliers were defined as a deviation of more than 3° from the planned alignment in all planes.

Clinical scoring

At inclusion, after 3 months, and at the 1- and 2-year follow up, patients were asked to fill in a KOOS, a health quality measurement questionnaire (Brooks 1996) (the EQ-5D-3L descriptive system and the EQ visual analogue scale (EQ VAS)) and a pain score (the numeric 11-point pain rating scale (NRS-11): a numeric rating scale from 0–10 where 0 represents no pain and 10 the worst possible pain). At the same intervals, the range of motion (ROM) of the operated knee was recorded. For the EQ-5D-3L the EQ-5D levels were dichotomized into "no problems" (level 1 scores) and "problems" (level 2 and 3 scores) as described in the EQ-5D-3L User Guide (version 5.1, April 2015, p. 12) as level 3 scores were expected to be very low.

Statistics

Means (SD) were given for continuous variables and numbers with percentages were presented for categorical variables. Student's t-test for 2 independent samples was used for the estimation of differences in radiological component angles, age, BMI, and operation time. Differences in distributions of categorical variables between the groups were examined by using Pearson's chi-square test. A mixed effect model for linear and logistic regression was used to fit 4 continuous (KOOS, Eq5D VAS, NRS pain, and ROM) and binary data points (Eq5D descriptive) per patient, respectively. In the mixed-effect models, time and group variables and interaction time x group were fixed; patient ID and identity covariance structure were random variables. The significance level was set at 0.05. The analyses were performed with SPSS@ version 23 (IBM Corp, Armonk, NY, USA) and STATA® version 14 (StataCorp LP, College Station, TX, USA).

Ethics, registration, funding, and potential conflicts of interest

Ethical approval was obtained from both the Regional Committee for Medical and Health Research Ethics (REC West 2010/2056) and the institutional review board at Oslo University Hospital (2011/7613). All patients gave both oral and written consent to participate. The trial is registered at ClinicalTrials.gov (NCT01696552). No financial funding or other

support from companies has been received for this study and no competing interests are declared.

Results

Demographic data

Demographic data were similar between the groups (Table 1).

Radiological measurements

Full leg weight-bearing radiograph: The mean (SD) postoperative HKA angle in the conventional group was 180° (3.1) and 179° (3.0) in the PSPG group. In the conventional group 11/49 were identified as outliers versus 11/42 in the PSPG group.

Table 2. Postoperative component angles and HKA expressed as mean (SD) (range)

	Conventional	PSPG	Difference Mean	95% CI
Femoral component angle				
Frontal	0.6 (1.7) (–3.6 to 3.9)	–0.3 (2.2) (–5.4 to 5.2)	0.9	0.08 to 1.69
Sagittal	–5.3 (4.0) (–16.6 to 3.8)	–6.5 (4.3) (–15.4 to 4.7)	1.2	–0.55 to 2.95
Axial	–1.1 (2.1) (–8.0 to 3.6)	–1.3 (1.7) (–7.8 to 1.5)	0.2	–0.66 to 0.97
Tibial component angle				
Frontal	–0.3 (1.5) (–3.9 to 2.6)	0.9 (2.1) (–4.6 to 5.2)	–1.2	–1.98 to –0.44
Sagittal	–3.8 (3.0) (–14.8 to 3.5)	–2.2 (2.5) (–7.0 to 3.5)	–1.6	–2.72 to –0.42
HKA	180 (3.1) (172 to 188)	179 (3.0) (171 to 186)	1	–0.68 to 1.89

Positive values for the frontal femoral component angle and the frontal tibial component angle and the hip–knee–ankle angle (HKA) represent varus and negative values represent valgus, while the positive and negative values for sagittal femoral component angle and sagittal tibial component angle represent respectively extension and flexion. Negative values indicate that the axial femoral component angle is internally rotated, while positive values indicate external rotation. In order to compare the planned PSPG with 3° of flexion with the aimed neutral alignment with the conventional method, 3° were added to measurements of the sagittal tibial component angle.

CT: A significant difference between the conventional and PSPG group was found for the frontal femoral (mean (SD) 0.6° (1.7) vs. –0.3° (2.2), CI 0.08 to 1.69) and tibial (–0.3° (1.5) vs. 0.9° (2.1), CI –1.98 to –0.44) component angles (Table 2). In the PSPG group a trend with higher proportions of outliers was found for the sagittal femoral component angle (p = 0.08) and the frontal tibial component angle (p = 0.08) (Table 3). For the tibial component angle in the sagittal plane a significant difference was found between the groups (–3.8° (3.0) vs. –2.2° (2.5), CI –2.72; –0.42) (Table 2), but there was no difference in the proportion of outliers (Table 3).

Table 3. Outliers [a]

Factor	Conventional	PSPG	p-value [b]
Femoral component angle			
Frontal	4/47	7/43	0.3
Sagittal	23/47	29/43	0.08
Axial	7/47	5/43	0.7
Tibial component angle			
Frontal	3/47	8/43	0.08
Sagittal	26/47	17/43	0.1
Hip–knee–ankle angle	11/49	11/42	0.7

[a] Defined as more than 3 degrees deviation from operative plan.
[b] Pearson's chi-square test.

Perioperative data

No statistically significant differences were found for the operation time and the length of stay between the groups (Table 4, see Supplementary data).

Clinical outcome

The KOOS, Eq5D, the NRS pain score, and ROM were similar between the groups (Tables 5–9, see Supplementary data).

Discussion

We found a difference between the conventional TKR instrumentation and the use of PSPGs for the femoral and tibial component alignment in the frontal plane and for the tibial alignment in the sagittal plane. We did not find a significant difference in the proportions of outliers between the 2 groups.

Mechanical axis: Noble et al. (2012) included 29 patients in a RCT and found a better mechanical axis in the PSPG group; however, Chen et al. (2014) reported more outliers in the PSPG group. The difference between the groups in our study was not statistically significant, concurring with most other RCTs reporting similar rates of outliers in the overall coronal plane between the PSPG method and the conventional operation method (Boonen et al. 2013, Chareancholvanich et al. 2013, Hamilton et al. 2013, Parratte et al. 2013, Roh et al. 2013, Chotanaphuti et al. 2014, Kotela and Kotela 2014, Victor et al. 2014, Woolson et al. 2014, Huijbregts et al. 2016).

Component alignment: Several RCTs did not report any difference in component placement between the conventional and PSPG method (Parratte et al. 2013, Roh et al. 2013, Chen et al. 2014). We found a trend with higher proportion of outliers in the PSPG group for the femoral component angle in the sagittal plane (29/43 vs. 23/47, p = 0.08), similar to the findings by Boonen et al. (2013) who reported a significant difference between the PSPG and conventional methods. In the PSPG group a trend with a higher proportion of outliers was also found for the frontal tibial component angle (8/43 vs. 3/47, p = 0.08), concurrent with the findings of 2 other studies (Kotela and Kotela 2014, Victor et al. 2014). Fewer outliers were registered in the PSPG group for the tibial slope, like the findings of Hamilton et al. (2013). However, this difference was not significant (p = 0.1) in our study. Several studies have shown significantly more outliers in the PSPG group for the

tibial slope (Victor et al. 2014, Woolson et al. 2014, Huijbregts et al. 2016).

Surgical time was similar between the groups in our study, as also reported in other RCTs (Chen et al. 2014, Woolson et al. 2014, Huijbregts et al. 2016). 2 RCTs found longer operation time with the PSPG method (Hamilton et al. 2013, Roh et al. 2013), whereas other studies have reported shorter operation time (Noble et al. 2012, Boonen et al. 2013, Chareancholvanich et al. 2013, Chotanaphuti et al. 2014).

Although we did not measure the planning time, the following time-consuming steps should be considered: uploading of the MRI files, downloading the original plan, followed by checking the planning and approval. This process took on average about 10 minutes.

All KOOS sub-scores, the pain score, and the Eq5D were similar between the groups. Boonen et al. (2016) did not show a significant difference between the conventional and PSPG operation method when using the Oxford Knee score and did not find a difference for the pain scores and Eq5D either. Woolson et al. (2014) did not report any significant difference in ROM between the 2 operation methods, consistent with our findings. We found a similar length of stay to that found in other RCTs (Boonen et al. 2013, Chareancholvanich et al. 2013, Woolson et al. 2014), although Noble et al. reported shorter hospital stay with the use of PSPGs (Noble et al. 2012).

Our findings concur with other published RCTs as regards both alignment and PROMs. The use of PSPGs involves the need for a preoperative MRI, which implies the use of extra diagnostic resources and an extra cost, in addition to the cost of the PSPG equipment. PSPGs might be beneficial in cases where intramedullary rods cannot be used, for example after malunions. Further studies would be required to investigate other indications for the use of PSPGs.

There are limitations to our study. First, the preoperative plans based on an MRI were compared with postoperative CT measurements. Theoretically it would have been possible to use a preoperative plan from a CT scan, but this would have led to a bigger overall radiation exposure. Second, the total number of included patients was lower than planned (1 center withdrew from the study). Therefore, the study was underpowered for the KOOS as we calculated a need for 63 patients in each group. However, the study was sufficiently powered for radiological alignment. Third, our study did not compare tibial component alignment in the axial plane between the groups. The reason for this was our experience from a previous study where we had to change the intraoperative tibial size compared with the preoperative plan in 40% of cases. In these 40% the tibial rotation was found by using the conventional extra-medullary guide (Leeuwen et al. 2015). Therefore, in this study we did not record the number of cases in which we had to change intraoperative tibial size. Fourth, we assessed no interobserver agreement. 2 radiographers performed the CT alignment measurements once, and in a previous study we found good interobserver agreement between the same radiographers for the same measurements (Leeuwen et al. 2015). Fifth, the data of this study were based on only one type of PSPG and the findings should therefore not be generalized for other PSPG systems.

The strengths of our study were the multicenter randomized study design and the fact that different surgeons performed the procedures. Before the study start all surgeons were already familiar with the PSPG technique, which ruled out a bias due to a learning curve.

In summary, we could not prove a clear benefit with regard to radiological alignment and/or clinical outcome with the use of PSPGs in patients with knee osteoarthritis. Therefore, we recommend the conventional operation method for TKR.

Supplementary data

Tables 4–9 are available as supplementary data in the online version of this article, http://dx.doi.org/ 10.1080/17453674.2017.1393732

All authors were involved in study design, data interpretation, statistical analysis, and in writing of the manuscript. The department of Biostatistics and Epidemiology, UiO, Oslo verified the statistical analysis.

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