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A prospective randomised controlled study of patient-specific cutting guides compared with conventional instrumentation in total knee replacement

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Patient-specific cutting guides (PSCGs) are designed to improve the accuracy of alignment of total knee replacement (TKR). We compared the accuracy of limb alignment and component positioning after TKR performed using PSCGs or conventional instrumentation. A total of 80 patients were randomised to undergo TKR with either of the different forms of instrumentation, and radiological outcomes and peri-operative factors such as operating time were assessed. No significant difference was observed between the groups in terms of tibiofemoral angle or femoral component alignment. Although the tibial component in the PSCGs group was measurably closer to neutral alignment than in the conventional group, the size of the difference was very small (89.8° (SD 1.2) *vs* 90.5° (SD 1.6); p = 0.030). This new technology slightly shortened the bone-cutting time by a mean of 3.6 minutes (p < 0.001) and the operating time by a mean 5.1 minutes (p = 0.019), without tangible differences in post-operative blood loss (p = 0.528) or need for blood transfusion (p = 0.789). This study demonstrated that both PSCGs and conventional instrumentation restore limb alignment and place the components with the similar accuracy. The minimal advantages of PSCGs in terms of consistency of alignment or operative time are unlikely to be clinically relevant.

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The success of total knee replacement (TKR) depends on several factors, including limb alignment, component positioning and soft-tissue balancing.[1] Accurate coronal alignment correlates with good clinical outcomes,[2,3] whereas malalignment has been associated with early loosening,[4] uneven wear of polyethylene bearings,[4] lower functional scores[5] and a higher implant failure rate.[4,6] Although computer-assisted TKR (CA-TKR) has the potential to improve alignment and reduce variation,[7] it introduces prolonged operating times, increased costs and complications arising from the guidance pins.[8,9,10]

Patient-specific cutting guides (PSCGs), which use three-dimensional (3D) imaging to capture the true anatomy of an individual's knee, have been developed. Two guides are manufactured to match the patient's distal femur and proximal tibia. These instruments subsequently determine all the cuts made in the bone, with the aim of orientating the TKR to its assumed normal axis. However, the effectiveness of PSCGs is still unclear. Ng et al[11] demonstrated that PSCGs could improve the accuracy of component positioning and reduce variation compared with conventional instruments, but these advantages were not observed by Nunley et al.[12] To our knowledge, there are no appropriately powered randomised studies evaluating this technology. We conducted a prospective, randomised, controlled trial comparing the accuracy of knee alignment and component positioning after TKR performed using PSCGs *versus* conventional instrumentation.

Patients and Methods

The study was approved by the ethics committee and institutional review board of Siriraj Hospital, Bangkok, Thailand. The trial was registered with ClinicalTrials.gov (NCT01449474) and conducted at a single centre. From January to November 2011, 80 patients undergoing unilateral posterior-stabilised TKR for the treatment of osteoarthritis (OA) were included in the study. Patients with flexion contracture > 30°, previous complex knee surgery, retained metal hardware at the hip, knee or ankle, extra-articular deformity of the knee, contraindications to MRI, and those who refused consent, were excluded (a total of six).

The primary outcome was defined as the difference in mechanical axis deviation in the coronal plane between the two types of instrumentation. Based on previous studies[13,14] the sample size was determined by a comparison of two independent groups. A mean difference of 1.4° in the mechanical axis

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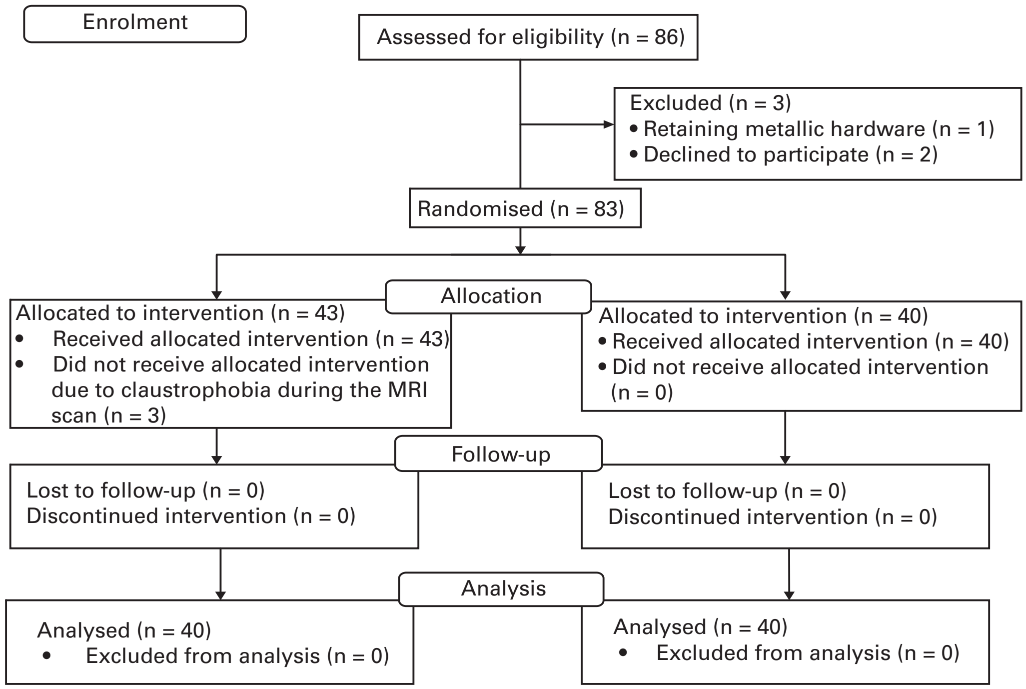

Fig. 1

Patient flowchart.

Table I. Patient characteristics in the patient-specific cutting guide (PSCG) and conventional groups

Characteristics*	PSCG group (n = 40)	Conventional group (n = 40)	p-value
Mean age (yrs) (range)	69.5 (55 to 84)	70.3 (53 to 85)	0.641†
Female:male	34:6	36:4	0.735‡
Right:left	25:15	20:20	0.367‡
Mean weight (kg) (range)	66.2 (47.4 to 102)	65.9 (46.8 to 92.5)	0.896†
Mean height (cm) (range)	154.6 (138 to 175)	153.4 (142 to 168.6)	0.496†
Mean BMI (kg/m^2) (range)	27.7 (20.2 to 44.15)	28.0 (22 to 39.6)	0.826†
Mean ROM (°)(range)	109.3 (65 to 140)	106.3 (70 to 135)	0.438†

* BMI, body mass index; ROM, range of movement
† *t*-test
‡ chi-squared test

deviation was found between the two types of instrumentation, with a standard deviation (SD) of 2.4° and 1.7° for PSCG and conventional instrumentation, respectively. Therefore, a sample size of 36 knees per group was estimated to have sufficient power (p = 0.80) to detect a significant difference (α = 0.05, two-sided significance level). Assuming a loss-to-follow-up rate of approximately 10%, we aimed to recruit a minimum of 80 patients (40 knees per group). The patients were randomised to each treatment arm via the blocks-of-four method. The patient flow is summarised in Figure 1 and the patients included were found to be similar between the two groups (Table I).

In group 1, Custom pin guides (Patient Specific Instruments system, Zimmer, Warsaw, Indiana) were manufactured based on a pre-operative MRI scan. From the imaging data, engineers at Materialise (Leuven, Belgium) created virtual 3D models of the patient's knee and determined the mechanical axes. Using the models, the surgeon selected the appropriate size of femoral component based on anterior femoral surface referencing, and the tibial component size that avoided mediolateral overhang of the implant on the tibial plateau. Adjustments were made to ensure that the components were perpendicular to the coronal mechanical axis. We aimed to realign the knee to neutral mechanical

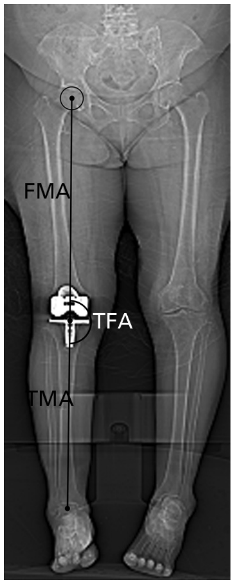

Fig. 2

Post-operative hip-to-ankle CT scout image showing the measurement of a mechanical tibiofemoral angle (TFA) formed by the femoral mechanical axis (FMA) and the tibial mechanical axis (TMA).

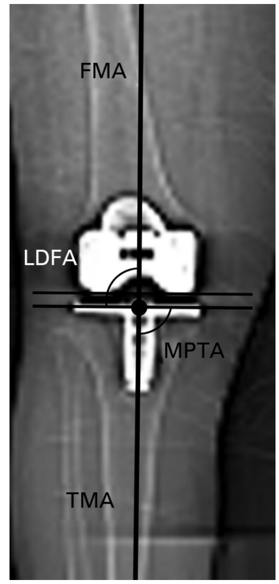

Fig. 3

CT scout image showing the measurements of the lateral distal femoral angle (LDFA) and the medial proximal tibial angle (MPTA) (FMA, femoral mechanical axis; TMA, tibial mechanical axis).

axis according to Insall's concept,[15] not a pre-arthritic alignment.[16] Rotationally the femoral component was positioned along the transepicondylar axis and the tibia aligned with the medial one-third of the tibial tubercle. The PSCGs were manufactured using rapid prototyping. The overall time required to manufacture the PSCGs was four to six weeks before surgery.

In group 2, conventional instrumentation was used in the form of an intramedullary femoral rod with the cut in 5° of valgus, which is our normal practice.[17] The proximal tibia was cut perpendicular to the mechanical axis of the limb using an extramedullary guided rod.

All patients received a cemented NexGen LPS-Flex fixed-bearing prosthesis without patellar resurfacing (Zimmer) performed by the same experienced knee surgeon (KC) using a minimally invasive approach. In group 1, PSCGs were placed over the articular surfaces in order to orientate the pins that determined the seating position of the standard cutting blocks used for the preparation of the femoral and tibial surfaces. This technology allowed the surgeon to cut the femur first. In group 2, bone preparation was performed in the normal manner in the axial orientation described above. The rest of the TKR was subsequently performed in the same way for both groups. Soft-tissue balancing was performed after all the trial components were put in place. The exposed femoral canal in group 2 was filled with a bone plug before implantation of the cemented prosthesis.

At the end of the operation a drain was placed intra-articularly and retained for 48 hours after surgery. All patients were mobilised under the direction of a physiotherapist on the first post-operative day.

Anteroposterior hip-to-ankle CT scanograms, with the patella orientated straight ahead and centred over the femoral condyles, were evaluated at four weeks post-operatively. Two independent blinded investigators (RN and CP) measured the radiological parameters using the digital tools of the picture archiving and communication system (PACS). The mechanical tibiofemoral angle (TFA), defined as the angle formed by the femoral and tibial mechanical axes of the lower limb (FMA and TMA), was measured (Fig. 2). Deviations of the TFA were recorded as positive if varus, and as negative if valgus. The lateral distal femoral angle (LDFA), formed by a line connecting the distal femoral component surface and the FMA (Fig. 3), the medial proximal tibial angle (MPTA), formed by a line connecting the tibial base plate surface and the TMA (Fig. 3), were measured. Deviations of both component alignments were noted as positive if the LDFA or MPTA was < 90° (valgus position) and as negative if > 90° (varus position).

The bone cutting time was defined as the time elapsed between the placing of the distal femoral jig (in group 1) or the insertion of the intramedullary femoral guided rod (in group 2) and when the trial component placement was completed. Skin-to-skin operative time was also recorded. The length of the skin incision, amount of blood loss, required units of transfused blood, post-operative complications and length of hospital stay were noted.

Table II. Peri-operative data in the patient-specific cutting guide (PSCG) and conventional groups

Characteristic (mean, range)	PSCG group (n = 40)	Conventional group (n = 40)	p-value
Skin incision (cm)	11.5 (9 to 14)	11.3 (10 to 15)	0.339*
Bone-cutting time (min)	16.2 (12 to 22)	19.8 (15 to 25)	< 0.001*
Operative time (min)	62.9 (45 to 80)	68.0 (50 to 90)	0.019*
Blood loss (ml)	614.8 (220 to 1170)	581.8 (210 to 1160)	0.528*
Patients requiring blood transfusion (n, %)	8 (*20*)	10 (*25*)	0.789†
Length of stay (days)	5.0 (4 to 9)	5.2 (1 to 7)	0.385*

* *t*-test
† chi-squared test

Table III. Radiological measurements and assessment of outliers in the patient-specific cutting guide (PSCG) and conventional groups

Radiological assessment*	PSCG group (n = 40)	Conventional group (n = 40)	p-value
Mean pre-operative TFA (°) (range)	168.7 (160 to 188)	168.4 (160 to 186)	0.852†
Mean (SD) post-operative angle (°)			
TFA	179.7 (176 to 183)	179.7 (176 to 184)	1.000†
LDFA	90.1 (87 to 93)	89.9 (85 to 94)	0.078†
MPTA	89.8 (87 to 93)	90.5 (87 to 94)	0.030†
Outliers > ±3° (n, %)			
Tibiofemoral alignment	1 (*2.5*)	3 (*7.5*)	0.615‡
Femoral component	-	7 (*17.5*)	0.012‡
Tibial component	-	1 (*2.5*)	1.000‡
Outliers > ±2° (n, %)			
Tibiofemoral alignment	7 (*17.5*)	12 (*30.0*)	0.293‡
Femoral component	2 (*5.0*)	13 (*33.5*)	0.004‡
Tibial component	2 (*5.0*)	6 (*15.0*)	0.263‡

* TFA, mechanical tibiofemoral angle; LDFA, lateral distal femoral angle; MPTA, medial proximal tibial angle
† *t*-test
‡ chi-squared

Statistical analysis. The data were analysed using SPSS v13.0 (SPSS Inc., Chicago, Illinois). Quantitative data were presented as mean and SD. The differences in the results were analysed using the unpaired Student's *t*-test and the chi-squared test. Spearman's rank and point-biserial correlations were used to examine the relationship between body mass index (BMI) and post-operative alignment. Statistical significance was set at a p-value < 0.05. The reliability of measuring the alignment variables was tested by studying 20 random radiographs by the two observers (interobserver reliability) on two separate occasions two weeks apart (intra-observer reliability) and expressed as an intraclass correlation coefficient (ICC).

Results

The peri-operative results were similar for both groups, including skin incision length, blood loss, blood transfusion rates and length of hospital stay (Table II). No femoral notching and no other PSCG-related adverse events or complications were detected in the study. The use of PSCGs had slightly smaller mean bone-cutting and operative times than the conventional instrumentation (Table II).

The two independent assessors showed the intra- and interobserver reliability, with the ICCs more than 0.75 for measurement of all radiological values. The lowest ICC (0.789) was observed in TFA angle measurement.

There were no significant differences in pre-operative TFA, post-operative FTA or LDFA between the groups (Table III). Nevertheless, a significant difference was demonstrated in post-operative MPTA. The proportion of patients with a TFA and MPTA of either ±3° or ±2° variation from the target value was comparable between the groups but there were significantly fewer outliers of the LDFA in the PSCG group. The distributions of alignment deviations are shown in Figure 4. On subgroup analysis there was no correlation between BMI and any post-operative alignments or outliers (Table IV).

Discussion

Coronal malalignment in excess of ±3° is associated with decreased functional outcomes and implant longevity.[4-6] Although CAS-TKR can improve the accuracy of post-operative alignment, outliers still occur.[8,14,18] Likewise, for the newly introduced PSCGs there are only a limited

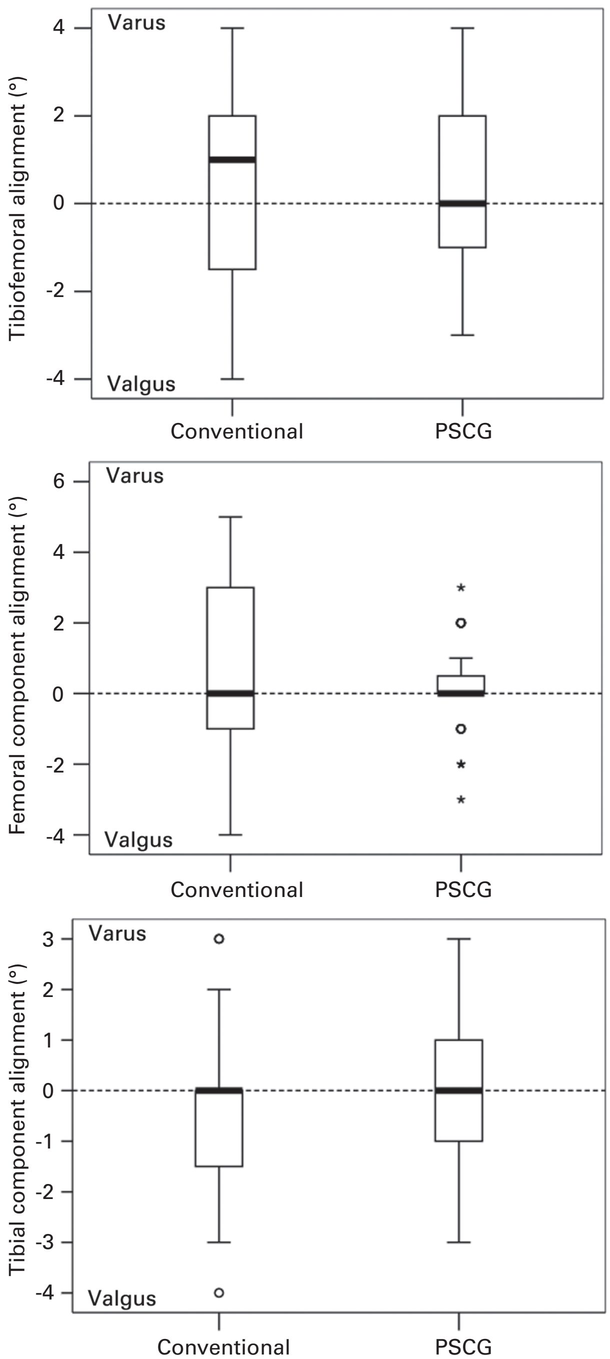

Fig. 4

Box plots showing the outlier distributions of tibiofemoral, femoral component and tibial component alignments compared between patient-specific cutting guide group (PSCG) and conventional instrumentation. The boxes denote the median and interquartile range (IQR), whiskers denote the range of data, * denote values > 1.5 × IQR and ° values > 3 × IQR from the median.

number of clinical studies supporting benefits, in particular increased accuracy, in implant placement.[11-13,19-22]

Klatt et al[20] initially reported on the potential for malalignment when using PSCGs, and Howell et al[21] suggested that inaccuracy might be caused by technical errors induced

Table IV. Subgroup analysis of the correlation between body mass index (BMI) and post-operative alignments or outliers

BMI *versus*...	r	p-value
Tibiofemoral angle (TFA)*		
Pre-operative	0.084	0.459
Post-operative	0.113	0.317
Lateral distal femoral angle (LDFA)*	0.117	0.303
Medial proximal tibial angle (MPTA)*	0.022	0.847
Outliers > ±2° from target value†		
TFA	0.023	0.840
Femoral alignment	0.026	0.816
Tibial alignment	0.029	0.799
Outliers > ±3° from target value†		
TFA	0.088	0.438
Femoral alignment	0.050	0.662
Tibial alignment	0.084	0.456

* Spearman's rank correlation
† point-biserial correlation

by malaligned MRI. Spencer et al[13] reported that the alignment accuracy of PSCGs was comparable with that of conventional and CAS-TKR, but those authors aimed to realign the knee to its pre-arthritic alignment,[16] not a notionally neutral mechanical axis.[15] All these previous studies were small and lacked any controls.

Based on the mechanical axis of alignment,[15] Ng et al[11] reported a series of 569 TKRs performed with PSCGs and 155 performed with conventional instrumentation. They concluded that PSCGs could assist in achieving a neutral mechanical axis with a reduction in outliers with a deviation of more than 3° from 22% to 9% ($p = 0.018$). It was also felt that this system helped the surgeon to place components closer to a neutral axis than conventional instruments. On the other hand, Nunley et al[12] were unable to demonstrate any effect of PSCGs in reducing mechanical axis outliers.

Recently, Noble et al[22] in a prospective randomised study, showed that post-operative mechanical alignment in the PSCGs group was closer to neutral than in the standard group (1.7° *vs* 2.8°; $p = 0.03$). They also claimed significant reductions in the duration of hospital stay, operating time, length of the incision and number of instrument trays used in the PSCGs group. However, their study was a preliminary report that required a larger sample size for detailed analysis.

From the results of our appropriately powered study, TKRs using PSCGs could restore limb alignment and assist in placing the components with accuracy comparable to that of conventional instrumentation. However, femoral component outliers still occurred. We routinely used the extramedullary tibial guide when performing conventional TKR and in our hands the PSCG technique produced little advantage over this widely accepted technique.

Although the PSCGs group showed measurable reductions in bone-cutting and operating times, the improvements were very small and unlikely to be clinically relevant. No shortening of incision length was associated with PSCGs in our study. Although penetration of the intramedullary canal is not necessary when using PSCGs, there were no significant differences in post-operative blood loss and blood transfusion in the study. However, we did routinely close the femoral canal with bone after the intramedullary guide was removed. It is worth reflecting on the fact that all our cases were operated on by the same experienced surgeon and the alignment does not appear to vary much, irrespective of how the bone surfaces were cut. These differences might be more apparent in the hands of less experienced surgeons.

In terms of limitations, our trial focused only on the coronal plane. Although the rotational plane is very important and could be evaluated by CT, our assessment was limited by resources. We also recognise that the aim of optimising the accuracy of alignment is to improve functional outcomes. However, this report does not include functional scoring systems or patient satisfaction because the follow-up period was very short.

Regardless of whether this technology is found to be acceptable in the future, we find that both PSCGs and conventional instrumentation restore limb and component alignment with a similar degree of accuracy. Any of the small measurable advantages of PSCGs we observed are unlikely to be clinically relevant. Although a cost-effectiveness analysis was not included, we agree with previous such studies[23-25] that the routine use of custom cutting blocks for TKR will not be cost-effective unless it results in a significantly reduced revision rate and improved patient-reported outcomes. Future studies are needed to determine the longer-term functional benefits after TKRs performed using this new and not inexpensive technology.

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