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# Outcomes following total knee arthroplasty with CT-based patient-specific instrumentation

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**Abstract**

*Purpose* A 24-month prospective follow-up study was carried out to compare perioperative clinical outcomes, radiographic limb alignment, component positioning, as well as functional outcomes following total knee arthroplasty (TKA) between patient-specific instrumentation (PSI) and conventional instrumentation (CI).

*Methods* Ninety consecutive patients, satisfying the inclusion and exclusion criteria, were scheduled to undergo TKA with either PSI or CI. A CT-based PSI was used in this study, and a senior surgeon performed all surgeries. Patients were clinically and functionally assessed preoperatively, 6 and 24 months post-operatively. Perioperative outcomes were also analysed, including operating time, haemoglobin loss, the need for blood transfusion, length of hospitalisation, and radiographic features.

*Results* At 24-month follow-up, clinical and functional outcomes were comparable between the two groups. PSI performed no better than CI in restoring lower limb mechanical alignment or improving component positioning. There were no differences in operating time, haemoglobin loss, transfusion rate, or length of hospitalisation between PSI and CI.

*Conclusion* No significant clinical benefit could be demonstrated in using PSI over CI after 24 months, and routine use of PSI is not recommended in non-complicated TKA.

*Level of evidence* II.

**Keywords** Total knee arthroplasty · Patient-specific instrument · Patient-specific cutting block · Clinical and functional outcomes · Radiographic outcome

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## Introduction

Patient-specific instrumentation (PSI) is a novel technique in total knee arthroplasty (TKA) that potentially permits more accurate alignment of the components and therefore contributes to increased survivorship and satisfactory long-term outcome [4, 10, 18, 20, 27, 31]. Customised cutting blocks are fabricated for individual patient from a three-dimensional (3D) model obtained from a computed tomography (CT) or a magnetic resonance image (MRI) of the lower extremity. Additionally, PSI has been shown to decrease surgical time, allow for greater ease of use than conventional instrumentation (CI), as well as reduce blood loss and the amount of embolic fat by eliminating the use of an intramedullary femoral alignment rod [5, 21, 25].

These benefits come at the cost of increased expenses and waiting time to surgery [5, 30]. Thus, there is great scientific and practical interest in the overall advantages and reliability of PSI systems. At present, there is no consensus in the literature regarding the accuracy and reliability of PSI as many studies have shown controversial and inconsistent results of various PSI systems [7, 29, 34, 36]. As a new technique, most of the current studies have focused on perioperative or radiographic outcomes associated with PSI, while investigations focusing on clinical and functional outcome are scarce and limited by short follow-up periods. There still exists controversy over whether PSI can provide better clinical, functional, or radiographic outcomes, especially in the mid or long term.

Therefore, a 24-month follow-up study of two cohorts of patients who had undergone TKA with either PSI or CI was carried out to compare clinical and functional outcomes, radiographic alignment, and perioperative results. The authors hypothesise that TKA with PSI, compared to CI, provides patients with comparable clinical, functional, and radiographic outcomes.

## Materials and methods

Ninety consecutive patients who were scheduled for unilateral TKA during 2011 and 2012 at Singapore General Hospital were prospectively followed up for 24 months. The inclusion criteria consisted of substantial pain and loss of function due to osteoarthritis of the knee, any degree of genu varum deformity, and ≤15° of genu valgum. Patients with inflammatory arthritis, post-traumatic arthritis, a genu valgum deformity of >15°, previous knee surgery that required the removal of metallic implants, revision total knee arthroplasty, active knee joint infection, or the need for bilateral total knee arthroplasty were excluded. Patient underwent TKA with either PSI or CI after being offered both options, with the knowledge of their respective benefits and limitations. TruMatch® Personalised Solutions (DePuy Synthes, Warsaw, IN, USA), a CT-based patient-specific surgical instrumentation, was used in this study. A senior surgeon performed all surgeries. Preoperative demographic and clinical data, including age, gender, body mass index (BMI), and preoperative functional scores, were collected and compared between the two groups.

In the CI group, the distal femur was prepared using an intramedullary rod with the femoral valgus angle set at 5°, while the proximal tibia was prepared with an extramedullary cutting jig perpendicular to the mechanical axis of the tibia. For the patients in the PSI group, they had a preoperative CT scan of the lower limb according to the manufacturer's PSI protocol. Custom cutting blocks were manufactured according to the preoperative plan formulated on the basis of 3D images, which were reviewed and approved by the surgeon. Using two anterior and two distal pins, the patient-specific femoral cutting block was placed on the distal part of the femur, where the distal femoral osteotomy was then made through the slot on the cutting block. A second femoral cutting block was attached to the distal femoral pin-site holes for the anterior and posterior condylar femoral resections. Then the tibial cutting block was positioned on the proximal tibia, with a guide rod attached to the cutting slot to ensure the alignment with the tibia. After confirming the varus/valgus position of the guide, the proximal tibial osteotomy was performed. All patients had prostheses from DePuy Synthes Sigma® Fixed Bearing Knee system (Warsaw, IN, USA), and closure of wounds was performed in a standard manner.

Primary outcomes were the clinical and functional recovery at 6 and 24 months post-operatively, which consisted of (1) range of motion (ROM), maximal flexion, and maximal extension; (2) Oxford Knee Score (OKS); (3) Knee Society Function Score (KSFS) and Knee Society Knee Score (KSKS); and (4) Short Form-36 Score (SF-36) compounded into Physical Component Score (PCS) and Mental Component Score (MCS). Staff from Orthopaedic Diagnostic Centre, which includes technicians, clinical outcome executives, and physiotherapists, who were blinded to the type of instrumentation used, performed the objective functional measurements and scoring questionnaires both preoperatively and at the follow-ups.

In addition, perioperative outcomes were also analysed to corroborate or oppose the perioperative advantages of PSI as compared to CI. The following outcomes were analysed: operating time, haemoglobin loss, the need for blood transfusion, length of hospitalisation, and radiographic features. Standing coronal long-leg radiographs taken before discharge were analysed, and the hip–knee–ankle axis (HKA, or mechanical axis, the angle subtended by the femoral and tibial mechanical axes; neutral = 180°), coronal femoral angle (CFA, the angle between the mechanical axis of the femur and the transcondylar line of the femoral component; neutral = 90°), and coronal tibial angle (CTA, the angle between the mechanical axis of the tibia and the tibial base plate; neutral = 90°) were measured. Measurements were taken to an accuracy of 0.1°. Tibial slope was also measured from the lateral knee radiographs. Two independent, blinded assessors performed the radiographic measurements using picture archiving and communication systems (PACS) with high inter-rater reliability [19].

The hospital ethics committee audited and approved the study protocol (SingHealth CIRB: 2015/2109). The study was carried out in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki.

### Statistical analysis

Power analysis was performed prior to the conduct of this study. The minimally clinically important difference of OKS was found to be five points [12]. At 24 months post-operatively, to detect a difference of five points in OKS with standard deviation of 8, a sample size of 42 patients in each arm would be required to achieve a power of 0.80. This calculation was done for a two-sided test with a type I error of 0.05. Allowing for a dropout rate of 5 % during

**Table 1** Preoperative demographic and clinical data by type of instrumentation

| | PSI ($n = 42$) | CI ($n = 48$) | $p$ value |
|---|---|---|---|
| Age (years) | 69.3 ± 7.2 | 66.8 ± 5.9 | NS |
| Gender (male/female) | 12/30 | 11/37 | NS |
| BMI (kg/m$^2$) | 26.9 ± 5.2 | 27.1 ± 4.6 | NS |
| Preoperative maximal extension | 8.5° ± 8.2° | 6.7° ± 5.0° | NS |
| Preoperative maximal flexion | 122.9° ± 13.8° | 117.7° ± 18.4° | NS |
| Preoperative range of motion | 114.4° ± 19.5° | 111.2° ± 19.8° | NS |
| Preoperative Oxford Knee Score | 26 ± 8 | 26 ± 7 | NS |
| Knee Society Function Score | 52 ± 10 | 54 ± 14 | NS |
| Knee Society Knee Score | 34 ± 16 | 39 ± 18 | NS |
| SF-36 Physical Component Score | 34 ± 9 | 30 ± 10 | NS |
| SF-36 Mental Component Score | 55 ± 9 | 52 ± 8 | NS |

*PSI* patient-specific instrumentation, *CI* conventional instrumentation, *SF-36* Short Form-36, *NS* non-significant

**Table 2** Improvements of clinical and functional outcomes at 6 and 24 months post-operatively

| Variable | PSI | $p$ value[a] | CI | $p$ value[a] |
|---|---|---|---|---|
| Maximal extension | | | | |
| Pre-op | 8.5° ± 8.2° | – | 6.7° ± 5.0° | – |
| 6 months | 5.2° ± 5.5° | 0.001 | 3.8° ± 4.9° | <0.001 |
| 24 months | 0.9° ± 4.3° | <0.001 | 0.1° ± 3.6° | <0.001 |
| Maximal flexion | | | | |
| Pre-op | 122.9° ± 13.8° | – | 117.7° ± 18.4° | – |
| 6 months | 111.7° ± 17.2° | 0.001 | 115.9° ± 13.5° | NS |
| 24 months | 118.8° ± 15.6° | 0.029 | 118.0° ± 15.1° | NS |
| Range of motion | | | | |
| Pre-op | 114.4° ± 19.5° | – | 111.2° ± 19.8° | – |
| 6 months | 106.6° ± 20.1° | 0.041 | 112.1° ± 15.3° | NS |
| 24 months | 118.0° ± 17.9° | NS | 117.9° ± 17.0° | 0.043 |
| Oxford Knee Score | | | | |
| Pre-op | 26 ± 8 | – | 26 ± 7 | – |
| 6 months | 41 ± 5 | <0.001 | 40 ± 6 | <0.001 |
| 24 months | 42 ± 5 | <0.001 | 42 ± 4 | <0.001 |
| KSFS | | | | |
| Pre-op | 52 ± 10 | – | 54 ± 14 | – |
| 6 months | 68 ± 21 | <0.001 | 69 ± 16 | <0.001 |
| 24 months | 72 ± 19 | <0.001 | 77 ± 16 | <0.001 |
| KSKS | | | | |
| Pre-op | 34 ± 16 | – | 39 ± 18 | – |
| 6 months | 81 ± 16 | <0.001 | 84 ± 9 | <0.001 |
| 24 months | 86 ± 9 | <0.001 | 82 ± 11 | <0.001 |
| PCS | | | | |
| Pre-op | 34 ± 9 | – | 30 ± 10 | – |
| 6 months | 48 ± 9 | <0.001 | 47 ± 9 | <0.001 |
| 24 months | 47 ± 11 | <0.001 | 50 ± 7 | <0.001 |
| MCS | | | | |
| Pre-op | 55 ± 9 | – | 52 ± 8 | – |
| 6 months | 57 ± 8 | NS | 56 ± 11 | NS |
| 24 months | 56 ± 9 | NS | 57 ± 9 | 0.007 |

*PSI* patient-specific instrumentation, *CI* conventional instrumentation, *NS* non-significant, *KSFS* Knee Society Function Score, *KSKS* Knee Society Knee Score, *PCS* Physical Component Score, *MCS* Mental Component Score

[a] Statistical significance of each outcome measure compared to preoperative baseline

the interval between surgery and 24-month follow-up, this study was designed to include a total of 90 patients.

Statistical analyses were carried out in consultation with in-house biostatistician, using SPSS® 21.0 (IBM, Armonk, NY, USA). For preoperative demographic and clinical data, perioperative outcomes, and radiographic outcomes at 24 months post-operatively, Student's unpaired $t$ test and Pearson Chi-square test were used for continuous and categorical variables, respectively. For PSI and CI groups, the clinical and functional outcomes at 6 and 24 months post-operatively were compared with the baseline using the Student's paired $t$ test. Multivariate regression analyses were performed between the two groups for clinical and functional outcomes at 24 months post-operatively, adjusting for age, gender, and BMI. A $p$ value $< 0.05$ was considered significant.

## Results

There were 42 patients who underwent TKA with PSI and 48 patients with CI. Preoperative demographic and clinical features of patients from both groups are presented in Table 1, and there existed no significant differences between the two groups. In the PSI group, there was one case in which tibial cutting block was abandoned in view of excessive valgus of the proximal tibia cutting block, one case which required recut of the tibial surface to increase the flexion/extension gap, and one case in which tibial component was down-sized due to excessive overhang. No 30-day mortality or revision was observed in either group.

Table 2 details the clinical and functional improvements at 6 and 24 months post-operatively for both groups. Overall, the range of motion was maintained

**Table 3** Clinical and functional outcomes at 24 months post-operatively and changes from preoperative baseline by type of instrumentation

| Variable | PSI | CI | Adjusted *p* value[a] |
|---|---|---|---|
| Oxford Knee Score | | | |
| Pre-op | 26 ± 8 | 26 ± 7 | NS |
| 24 months | 42 ± 5 | 42 ± 4 | NS |
| Change | 16 ± 7 | 16 ± 8 | NS |
| KSFS | | | |
| Pre-op | 52 ± 10 | 54 ± 14 | NS |
| 24 months | 72 ± 19 | 77 ± 16 | NS |
| Change | 20 ± 17 | 23 ± 18 | NS |
| KSKS | | | |
| Pre-op | 34 ± 16 | 39 ± 18 | NS |
| 24 months | 86 ± 9 | 82 ± 11 | NS |
| Change | 52 ± 18 | 43 ± 21 | NS |
| PCS | | | |
| Pre-op | 34 ± 9 | 30 ± 10 | NS |
| 24 months | 47 ± 11 | 50 ± 7 | NS |
| Change | 13 ± 12 | 20 ± 13 | NS |
| MCS | | | |
| Pre-op | 55 ± 9 | 52 ± 8 | NS |
| 24 months | 56 ± 9 | 57 ± 9 | NS |
| Change | 1 ± 9 | 5 ± 9 | NS |

*PSI* patient-specific instrumentation, *CI* conventional instrumentation, *NS* non-significant, *KSFS* Knee Society Function Score, *KSKS* Knee Society Knee Score, *PCS* Physical Component Score, *MCS* Mental Component Score

[a] Statistical significance adjusted for differences in age, gender, and BMI between the two groups

for PSI group and marginally improved for CI group at 24 months post-operatively. At 6 and 24 months post-operatively, there were similarly significant improvements in the mean scores of OKS, KSFS, KSKS, and PCS of the SF-36 Health Survey for both groups. At 24 months post-operatively, no significant differences were detected between PSI and CI groups in all clinical and functional outcomes after adjusting for differences in age, gender, and BMI, as shown in Table 3.

Perioperatively, operating time, haemoglobin loss, transfusion rate and length of hospitalisation were similar between PSI and CI groups, as shown in Table 4. Radiographic results showed that the lower limb mechanical alignment and coronal component positioning were satisfactory and comparable between the two groups.

## Discussion

The most important finding of the current study is that patients had significant clinical and functional improvements post-operatively for both PSI and CI groups, but there existed no significant differences between the two groups at 24 months post-operatively. This is one of few studies on PSI functional outcomes that have followed up patients for at least 24 months; therefore, it provides further clinical insights into choosing surgical instruments when planning knee arthroplasty in non-complicated cases.

There are few clinical outcome studies comparing PSI and CI in TKA, most of which have shown insignificant difference between the two groups, and follow-up periods were less than 1 year [1, 2, 25, 37, 38, 40]. Conversely, Yaffe et al. [39] found that PSI was associated with a statistically significant improvement in functional scores when compared to conventional TKA at 6-month follow up. Anderl et al. [3] using another CT-based PSI also reported subtle clinical differences between PSI and CI at 2 years after TKA. A similar study conducted by the authors also showed that OKS, KSFS, KSKS, and SF-36 Score were comparable between PSI and CI groups at 2 years post-operatively, but an MRI-based PSI system was studied [8].

Improved accuracy of component positioning is one of the main potential advantages of PSI. Neutral mechanical limb alignment and accurate coronal component positioning are also primary intraoperative goals for satisfactory long-term outcome after TKA [14, 18, 27]. The recent literature has revealed controversial results regarding mechanical alignment. Anderl et al. [3] concluded that CT-based PSI, compared with CI, improves accuracy of mechanical alignment restoration and 3D component positioning in primary TKA. Pfitzner et al. [24] compared two types of PSI systems using different imaging modalities and found that PSI increased accuracy compared with CI and that MRI-based PSI was more accurate compared with CT-based PSI regarding coronal mechanical limb axis. A better performance was also observed in the MRI-based system than in the CT-based system by Ensini et al. [13] Most other studies have failed to

**Table 4** Perioperative clinical and radiographic outcomes by type of instrumentation

| | PSI | CI | *p* value |
|---|---|---|---|
| Operating time, min | 85 ± 25 | 87 ± 26 | NS |
| Haemoglobin loss, g/dL | 2.6 ± 0.9 | 2.3 ± 0.9 | NS |
| Blood transfusion, % | 9.5 | 10.4 | NS |
| Length of hospitalisation, d | 6.1 ± 5.1 | 6.3 ± 4.6 | NS |
| Hip–knee–ankle axis | 177.9° ± 3.9° | 177.8° ± 3.1° | NS |
| Coronal femoral angle | 91.8° ± 1.9° | 92.7° ± 2.3° | NS |
| Coronal tibial angle | 91.0° ± 1.6° | 90.3° ± 1.6° | NS |
| Tibial slope angle | 1.9° ± 2.0° | 2.0° ± 1.4° | NS |

*PSI* patient-specific instrumentation, *CI* conventional instrumentation, *NS* non-significant prove the expected superiority of PSI in restoring neutral mechanical limb alignment and component positioning, or have found even higher prevalence of malalignment with PSI compared to CI [1, 5, 6, 9, 15, 17, 22, 23, 28, 32, 35, 37, 39, 40]. Using the same PSI as this study, Woolson et al. [38] also found no significant improvements in knee component alignment in patients treated with PSI as compared with those treated with CI by using 3D CT data. Findings from the current study agree with most of the recent literature, which shows no significant difference of PSI in improving the accuracy of limb alignment and component positioning compared to CI.

The other postulated advantages of PSI are reduction in operating time and less blood loss. While some studies have validated such advantages [5, 6, 11, 15, 21, 25, 26, 31] associated with PSI, conflicting results have been reported in others [1, 16, 33, 37, 38]. Both Pietsch et al. [25] and Chotanaphuti et al. [11] have failed to observe a lesser haemoglobin loss or lower transfusion rate with PSI, though blood drainage was reduced. In this study, no significant advantages have been demonstrated in the PSI group regarding the operating time, haemoglobin loss, transfusion rate, or length of hospitalisation. Although PSI can reduce the amount of trays and instruments required and therefore leads to higher operating room turnover rates, the clinical significance may remain subtle. In addition, these advantages may not translate into socio-economic benefits due to the intrinsic costs of preoperative imaging and production of the patient-specific guides, and the 6-week additional time required for manufacturing of the patient-specific guides [21, 30].

There are a few limitations to this study. Randomisation was not performed; nevertheless, all patients were counselled regarding the choice of the two types of surgical instruments, and there were no differences in patients' preoperative demographic and clinical data between the two groups. Another limitation is that long-leg radiographs were used to measure the mechanical axis and component alignment in the coronal views, and lateral knee radiographs, instead of sagittal long-leg radiographs, were used to measure the tibial slope. There is a lack of accurate radiographic data in the sagittal plane, including femoral component rotation angle. In this study, the authors emphasised more on coronal component alignment because it predicted functional outcomes, earlier loosening, and polyethylene wear [14].

## Conclusion

In summary, CT-based PSI and CI showed comparable clinical and functional outcomes at 24 months after TKA. There were no significant differences between the two types of instruments in achieving alignment restoration, component positioning, and perioperative clinical outcomes in terms of operating time and blood loss. Thus, routine clinical use of PSI in non-complicated cases of TKA is not recommended in view of the additional cost and waiting time. Future larger-scale randomised studies are crucial to provide further evidence in the long term.

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