

Patient Specific Guides in Total Knee Arthroplasty-Are They Accurate in Restoring Mechanical Alignment? A Prospective Clinical Series of 175 Cases

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ABSTRACT

BACKGROUND: Our study looked to see if patient specific guides in TKA restored mechanical alignment in patients with osteoarthritis.

MATERIALS AND METHODS: This prospective study measured the coronal alignment using long leg radiographs in 175 TKAs performed using patient specific cutting blocks. All patients underwent a posterior stabilizing TKA (Smith & Nephew GENESIS II) by the senior surgeon (WB) using Visionaire cutting blocks (based on pre-operative MRI studies).

RESULTS: The mechanical axis of the knee joint was measured using long leg radiographs taken six weeks post-operatively. There were no adverse intraoperative events. The coronal axis was restored to within 3° of neutral in 144 of 168 knees (85.7%).

CONCLUSION: We conclude that patient specific instrumentation is accurate in restoring mechanical alignment in patients undergoing TKA.

Key words: Patient specific guides; Knee; Arthroplasty; Alignment

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INTRODUCTION

Total knee arthroplasty (TKA) restore function, decrease pain and align the knee in arthritic conditions. Surgical technique and accuracy of prosthetic insertion determine long-term survival in TKA^[1]. Studies have shown poor prosthetic alignment leads to component loosening and instability, poor clinical outcomes and ultimately failure of the TKA^[2-4]. Component alignment is based on intramedullary or extramedullary devices in conventional TKA. Extramedullary devices are surgeon dependent while intramedullary jigs are unsuitable when there is abnormal bony anatomy. Furthermore, intramedullary jigs are invasive, breaching the femoral and tibial canals, increasing medullary pressure, which can lead to increased embolic events^[5,6].

Computer-assisted navigation (CAN) in TKA has been designed to improve the accuracy of implant position and alignment. Early studies showed an improvement in alignment using CAN^[7,8]. By contrast, more recent studies have shown no difference in alignment between computer-navigated and conventional TKA^[9,10]. In addition, computer-navigated surgery has been shown to have increased tourniquet and operative time^[9-11]. There have also been reports of femoral and tibial fractures from navigation pin sites^[12-14].

Patient specific instrumentation is a new technology using advanced imaging techniques to develop patient specific femoral and tibial cutting blocks based on the patient's three-dimensional anatomy. It is designed to improve mechanical alignment accuracy

while eliminating the use of extra CAN equipment. Initial studies have shown a decrease in operative time, blood loss and a reduction in instrument usage in TKA using patient specific guides^[15-17]. More recent studies have demonstrated statistically significant improvement in neutral mechanical alignment using patient specific instrumentation compared to manual instrumentation^[18-19]. The improved outcomes in coronal alignment were also reported in a review article as well as improved efficiency compared to conventional techniques^[20]. On the other side there are studies published that show no advantage of patient specific guides in either improving the coronal outliers^[20-24] or functional outcome compared to the conventional techniques^[25,26].

There is still limited data and literature looking at patient specific TKA and alignment. Initial experience with patient specific TKA with the senior surgeon of this study demonstrated a mechanical axis within 3 degrees of neutral in over 90% of patients^[21]. The purpose of this study was to confirm that patient specific instrumentation results in restoration of mechanical alignment in TKA. Additional benefits of the patient specific TKA were determined by assessment of operative time and blood loss in our cohort of patients.

MATERIALS AND METHODS

This prospective study included 162 patients (71 male, 91 female) who underwent 175 TKA done using patient specific guides. All bilateral knee replacements were performed as staged procedures. A written informed consent was taken from all the patients. The inclusion criterion was patients undergoing TKA for the diagnosis of primary osteoarthritis. Patients with history of trauma, mal-aligned femoral/tibial shafts, or prior history of surgery on the knee were also included as long as they did not have any form of hardware near the joint, which interfered with the use of a preoperative magnetic resonance imaging (MRI) for the generation of customized cutting blocks. The exclusion criterion was the refusal of the patients to participate in the study. All the patients during the study duration were offered the option of patient specific TKA and explained the perceived advantages found at the initial study^[21]. They were also informed regarding the new nature of the technology and absence of any long-term data. All the patients willing to participate using the patient specific instruments were, thus, included in the study.

All patients in the study group underwent posterior stabilizing TKA (GENESIS II SPC [LEGION Primary]; Smith and Nephew, Sydney, Australia) that was implanted with cement. All operations were performed by the senior author (W.B.). Component placement was achieved using patient specific cutting blocks created by a single company (VISIONAIRE; Smith and Nephew, Memphis, Tenn.). As it took 4 weeks for the blocks to be manufactured and be available in the operating theatre, an MRI of the arthritic knee, along with full-length weight-bearing X-rays of the limb, was obtained in all patients 4 to 6 weeks before the procedure. The MRI and the radiographs were carried as outpatient procedures, and hence, no hospital admission was required for the patient. Using specialized computer software analyzing anatomical landmarks and surgeon's input (on alignment, rotation, and any additional femoral resection based on preoperative flexion deformity), specialized cutting guides were generated for each patient (Figure 1). The surgeon preferences were the default position for the cutting blocks and modifications could be performed during a 48 hour period before the guides were made. Modifications to the blocks could be made orally to the engineer or through an online system. The alignment was based on mechanical axis of the limb, and osteophytes were included in the plan to ensure a unique fit for each patient.

In all patients (except one patient with peripheral vascular disease), the leg was elevated and the tourniquet was inflated to 350 mm Hg, and a midline medial parapatellar approach was used. To avoid anterior femoral notching, an angel wing instrument was used just before the femoral cuts using the customized blocks. Similarly, an external tibial alignment jig was used to confirm the tibial alignment before making the tibial cut (Figure 2). Any obvious malalignment was an indication to abandon the usage of the cutting block in that case, and use the conventional tibial cutting block instead. Intraoperatively, a record of stability of feel of all the cutting blocks was also kept. This 'feel of stability' was subjective, and the senior surgeon tried to identify the cutting blocks that felt grossly unstable. Removal of osteophytes that hindered in the proper seating of the cutting blocks was performed in these cases. Ligamentous balancing was done in all patients to ensure gap equality (flexion/extension matching) and gap symmetry (collateral balance). A record was also made of any bony cut that had to be redone after the initial cut with the customized cutting block and also whether the size of the implanted component matched the preoperative plan.

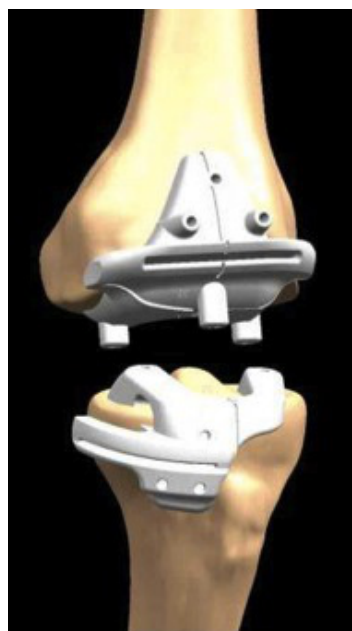


Figure 1 Schematic diagram of patient specific cutting blocks.



Figure 2 Accuracy of tibial cutting block checked by conventional extramedullary guide rod.

The tourniquet was deflated after the wound was closed and dressings were applied. Negative suction drains were used for 24 hours. As the intraoperative blood loss was negligible because of tourniquet application throughout the procedure, the drain output was taken as an estimate of the blood loss.

At the 6-week follow-up visit, full-length radiographs were obtained for calculating the coronal alignment of the knee. Alignment was measured as degrees of deviation from the mechanical axis (minus for varus and plus for valgus). Femoral and tibial alignments were measured separately as well. Two independent observers assessed alignment measurements. All data were assembled and entered by a third researcher.

RESULTS

175 TKAs (162 patients; 13 bilateral) were included in the study. There were 71 males and 91 females. The mean age of the patients was 65.5 years (range, 20-93 years). The mean BMI was 31 kg/m² (range, 20-56 kg/m²). None of the patients had neutral preoperative alignment. Preoperative varus/valgus deformities at the time of surgery included 136 patients with varus alignment (average -7.6°; range -0.4 to -30.1°) and 39 with valgus alignment (average 8.07°; range, 0.1 to 19.6°). Preoperative flexion averaged 102.9° (range, 60°-154°) and average extension loss was 5.7° (range, 0°-20°).

No adverse intraoperative events were seen with the use of patient specific guides. The mean total blood loss was 224.7 mL (50-700 mL). Only one patient had excessive blood loss (700 mL), as a tourniquet was not used. Blood loss also decreased during the trial as we introduced intravenous tranexamic acid. The mean skin-to-skin time was 91 minutes (65-130 min). A gradual reduction of operating time was observed in more recent cases, possibly because of experience and familiarity with the use of patient specific system by the whole surgical team.

One patient died on the third post-operative day following severe hypoxia secondary to a myocardial infarction. Another patient was lost to follow-up. One patient had a deep infection, which required a two-stage revision.

Tibial side abnormalities that required ‘adjustments’ intra-operatively were insufficient cut, coronal (varus/valgus) mal-alignment, sagittal (abnormal slope) mal-alignment and size mismatch. The pre-operative Visionaire cutting blocks were found to be inaccurate in these cases on the tibial side (Table 1) Tibial cuts made through the patient specific guides were insufficient in 3 knees. The tibial cut had to be redone in order to remove an additional 2 mm of bone to fit the liner and balance the knee, whereas none of the femoral cuts had to be revised

10 cases (5%) required readjustment of the tibial guide using a conventional extra-medullary cutting block. The indication for use of conventional block was either coronal mal-alignment (9 cases with 8 in varus and 1 in valgus) or sagittal (slope) abnormality (1 case). 19.4% (34 patients) had tibial size ‘mismatch’. If there was any possibility of overhang with the projected tibial size, the senior surgeon downsized the tibial component.

The size of planned femoral component matched the implanted component in 93.1% (163 of 175) knees. In all cases of femoral size change, the surgeon upsized the femoral component to decrease the flexion gap to prevent excessive posterior bone loss. Tibial component mismatch was seen in 19.4% (34 of 175) knees. Post-operative flexion averaged 105.2° (range, 75°-130°). Flexion of 75° was seen only in one patient who had anticoagulant induced swelling and subsequent significant knee stiffness.

Table 1 Tibial side abnormalities.

	Number of Patients	Percentage
Insufficient Cut	3	2%
Coronal (varus/valgus) malalignment	9	5%
Sagittal (abnormal slope) malalignment	1	-
Size mis-match	34	19.40%

Table 2 Rotational profile of femoral and tibial components.

	Mean Rotation (mm)	Range (mm)
Femoral Component (Whiteside’s Line)	-0.27	-5 to +5
Tibial Component (Medial third tibial tubercle)	0.02	-5 to +5

Table 3 Effect of opposite femoral and tibial alignment on mechanical axis*.

Patient	Femoral Component Alignment	Tibial Component Alignment (degrees)	Overall Coronal Alignment (degrees)
1	1	-1	0
2	1	-4	-3
3	1	-2	-1
4	5	-1	4
5	-2	1	-1
6	4	-3	1
7	-6	2	-4

* Negative values stand for varus from neutral.

At the 6-week follow-up, the mean mechanical axis was found to be valgus 1.7° from neutral (range, 4° valgus to 9° varus). In 85.7% knees (144 of 168 knees; the long leg radiographic data was missing in 7 patients) the mechanical axis was restored to within the acceptable limit of 3° of varus/valgus from neutral.

Intraoperative rotational alignment following implantation was judged with respect to Whiteside’s line and medial third of tibial tubercle and this was then co-related with the rotation suggested by the patient specific guides. Femoral jig rotation averaged 0.27 mm of external rotation compared to Whiteside’s line (range -5 mm to +5 mm) and final tibial trial was 0.02 mm (-5 mm to + 5 mm) externally rotated compared to the initial Visionaire position (Table 2). The rotation corresponded to that dictated by the guides in all cases.

Alignment of femoral and tibial component was also measured individually to study their ‘combined’ effect on overall mechanical alignment. In 7 knees, the components were aligned in opposite directions to each other, thus reducing the abnormality of mechanical axis. The angle of mechanical axis ranged from 0 to 4 in these cases (Table 3).

DISCUSSION

The purpose of the study was to evaluate the use of patient specific guides in TKA and to see if such a technique restored a neutral mechanical axis. Previous literature has shown the importance of proper coronal alignment for a successful TKA, concluding that alignment outside 3° leads to decreased prosthetic survivorship^[4,28,31,32]. Berend found an increased risk of medial tibial bone collapse with a tibial component with greater than 3° of varus^[3]. As such, the implantation technique should minimize postoperative mechanical axis malalignment. Our results showed that the mechanical axis was restored to within 3° of neutral in 85.7% (144 of 168) knees that had undergone a TKA using patient specific instrumentation. This shows reliable accuracy of the technique,

considering that incidence of malalignment of mechanical axis can be as high as 25% using conventional techniques^[37,38].

The use of CAN in TKA has been debated. A meta-analysis by Bauwens found no statistical difference in mechanical alignment between CAN and conventional TKA^[9]. Kim supported these results in a large prospective randomized trial in 2012^[10]. CAN also comes at the expense of increased patient co-morbidities, such as tourniquet and operating time, increased instrument trays and bulky navigation equipment, and intra-operative complications. Several studies have shown fractures associated with the insertion of CAN guide pins^[12-14]. Navigation has been shown to increase surgical operating time, with a meta-analysis demonstrated a mean increase of 23% in time^[9].

Only recently have studies evaluated post-operative mechanical alignment in TKA using patient specific guides. Howell^[15] and Spencer^[33] showed good post-operative alignment with no adverse effects using the OtisKnee system while Klatt^[34] reported malalignment using the same implant guides in a study of 4 patients. Lustig^[35] concluded an unsatisfactory accuracy results in 60 cases using intra-operative computer navigation to assess the alignment with patient specific guides. However, Yaffe^[36] found the patient specific guides to be more accurate than computer navigation in predicting the femoral component size. A retrospective study by Nunley^[17] reported a similar amount of outliers comparing TKAs using patient specific and conventional instrumentation.

In the largest study to date by Ng^[19], 85.6% of cases had a post-operative coronal alignment less than or equal to 3° from neutral in 569 TKAs performed using patient specific guides. A review article also concluded patient specific instrumentation improves accuracy in mechanical alignment in TKA^[20]. Our results expand our initial publication by Bal^[27] showing a restoration of mechanical axis in the majority of patients.

The outcome of Patient specific guides is similar to other studies^[15,33]. The majority of the cutting blocks had a stable fit, and sizes of the implanted components matched the preoperative plan in most knees. These results were similar to our findings in our pilot study^[27]. Furthermore, it was found after the bony cuts that majority of these knees were well balanced, and there was limited need for soft tissue balancing. The tibial guide was readjusted in 10 of the 175 cases because of perceived abnormal alignment using an external guide (Table 1). This finding was similar to the study by Howell, who found 3 of 48 tibial guides and 3 of 48 femoral guides with an incorrect fit. The misaligned guides were attributed to by MRI technician error^[15]. We believe with increased training of MRI technicians over time, the patient specific cutting guides will become even more accurate in the future.

This study also attempted to measure the rotation of the implanted components. This was performed intraoperatively by clinical observation. The femoral component was referenced to Whiteside's line while the tibial component was referenced to the medial third of the tibial tubercle. When compared to the patient specific guide in 145 cases, there was a difference of 0.27 mm of the femoral component and 0.02 mm of the tibial component. Thus, rotational alignment correlated accurately to the pre-operative plan.

We believe that patient specific guides in TKA offers many potential benefits over conventional techniques. It allows the surgeon to individualize each patient and reduce the incidence of alignment outliers. Because the sizes of the components are known prior to surgery, there is decreased requirement of instrument trays or bulky navigation computers in the operating room. In addition, the cutting blocks are patient specific and, hence, disposable. In our study, only 2 trays were required (3 if resurfacing the patella)

instead of the standard 10-12 trays used in a conventional TKA. This not only shortens the setup time but also decreases the turn over time between cases because of the decreased need of cleaning and sterilizing instruments. This can be particularly beneficial in hospitals with limited sterilization equipment and help allow more cases to be accomplished in the same period. Ast^[20] also highlighted the improved efficiency with patient specific guides in their review article. All these factors might theoretically add to the cost-effectiveness of the procedure and offset, to some extent, the increased expenditure of MRI scans borne by the patients. However, our study falls short of a cost-benefit analysis using patient specific guides.

Unlike the conventional TKA, the patient specific TKA does not require the use of intramedullary alignment rods. Because the system is noninvasive, it has the potential to reduce the incidence of fat embolism and possibly decrease blood loss and recovery time^[37,38]. We postulate decreased blood loss occurs because invasive intramedullary guides do not breach the intramedullary canal during the operation, which also could decrease operative time.

There are several limitations of our study. Mechanical alignment was measured using long limb radiographs, which can be subject to inter-observer variability. Ideally, computed tomography (CT) should be used to assess post-op mechanical alignment and rotation of implants for accurate assessment. However, we believed the excessive radiation exposure due to a CT did not justify its use. This was one of the reasons behind choosing a system that relies on preoperative MRI and long-leg radiographs (and not whole-leg CT scan) for generating the customized cutting blocks. Use of MRI for postoperative evaluation is not cost-effective, and there are inherent problems of accuracy (as compared with CT) with implanted hardware.

This study was only a prospective case series with no randomization of patients and the absence of comparison with non-patient specific TKAs. However, we believe a postoperative mechanical alignment of 1.7°, with 85.7% of cases within 3° neutral, is comparable, if not improved, over conventional TKA results. This study contributes to the literature, considering the relatively new nature of the technology and limited published data on the subject. This study did not evaluate the long-term functional outcome and survival of TKAs using patient specific technology. Although it is the long-term outcome that is most important for assessing a new technology, this was not the aim of our current study. Larger studies with multiple surgeons may provide more information and reproducibility of results. Nevertheless, the study established the safety of patient specific TKA in osteoarthritis and can be used as a basis for designing future studies.

CONCLUSION

Patient specific technology in TKA was found to be as accurate in restoring the postoperative mechanical alignment. In all cases, patient specific guides require a rather detailed and careful input from the operating surgeon. The option of using external guides should always be available to the surgeon if necessary. Advancements in techniques and MRI scan interpretation for the guides may improve accuracy further. Surgeons should continue to use their judgment in accepting or rejecting the preoperative 'patient specific' plans. Patient specific guides 'customize' TKA and give encouraging results. It can be safely used in most of the cases of osteoarthritis and should be considered as an alternative to conventional and computer-assisted techniques of TKA.

Ethical approval

The study has been carried out with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.”

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