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KNEE ARTHROPLASTY

Early clinical and radiological results of total knee arthroplasty using patient-specific guides in obese patients

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Abstract

Purpose Total knee arthroplasty (TKA) is a challenging procedure in patients with a high body mass index (BMI). The aim of our study was to assess the outcome and accuracy of restoration of mechanical alignment in TKA using patient-specific guides (PSG) involving patients with high BMI.

Materials and methods Patients with BMI of 30 or above were enrolled in the study. The mean age of the patients was 65.15 years. The study comprised of 46 males and 54 females. Total knee arthroplasty was planned after a pre-operative MRI and long leg x-ray films using customized PSG.

Results Of the 105 knees (100 patients) in the study, average BMI was 35.42 kg/m^2 (30–56). Twenty patients (20 %) had class III obesity ($\geq$40 kg/m^2). The average blood loss and operative time were 236.1 ml (range 50–700 ml) and 92.2 min (65–130 min), respectively. The average post-operative mechanical axis was noted to be 1.85° varus (range 4° valgus to 6° varus). Eighty-eight patients (86.27 %) had mechanical alignment within 3° of neutral. There were no adverse intraoperative events. One patient had deep infection that required a two-stage revision. The average post-operative range of motion at 1-year follow-up was 105.8° (range 80°–130°).

Conclusion Patient-specific guides technology restores the coronal mechanical axis reliably in obese patients without adversely affecting outcomes. Our short-term follow-up has shown favorable outcomes. Surgeons should use these customized jigs as a guide and adjust the size of components, alignment and rotation according to normal surgical principles.

Keywords Obesity · Patient-specific guides · Alignment

Introduction

Total knee arthroplasty (TKA) on obese patients is challenging as these patients often have co-morbidities, are relatively young and may have a poor outcome. Obesity has also found to adversely affect the post-operative mechanical alignment using standard TKA instrumentation [1].

Studies have shown that as little as 3° of mal-alignment of the mechanical axis may result in altered pressure distribution and load between compartments of the knee [2]. Component positioning may have more relevance in these patients as obesity leads to increased stresses placed on the prosthetic joint that may further accentuate abnormal loading patterns, and lead to premature failure [3, 4]. The thick soft tissue envelope in obese patients may make exposure difficult, obscure bony landmarks, and impede accurate positioning of cutting guides [5].

Studies have reported increased rates of wound complications, component loosening, and revision surgery [4, 6, 7]. Recent studies on use of patient-specific instrumentation have demonstrated statistically significant improvement in neutral mechanical alignment using patient-specific instrumentation compared to manual

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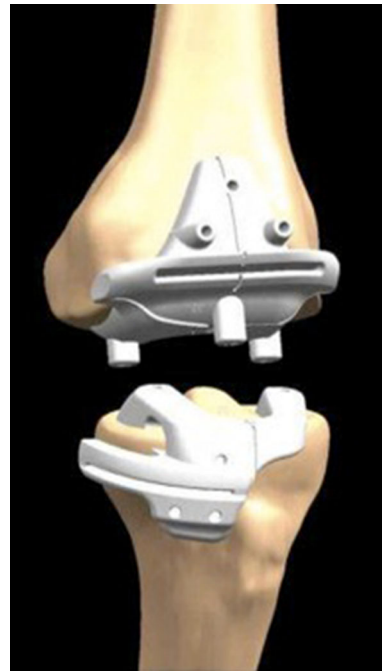   London NW1 2PG, UK

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instrumentation [8, 9]. The purpose of this study was to assess the early outcome of TKA in obese patients with a body mass index (BMI) of 30 or above using patient-specific guides (PSG). We hypothesize that the PSI technique results in satisfactory post-operative coronal alignment with good early outcomes.

Materials and methods

This prospective study included 105 knees (100 patients with 5 bilateral) (46 males, 54 females) with a BMI of 30 and above who underwent TKA by the senior surgeon (WB) using PSG between May 2010 and December 2012.

Informed consent with the option patient refusal was taken in all the patients enrolled. The inclusion criterion was patients undergoing TKA for the diagnosis of primary osteoarthritis with a BMI > 30. 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 pre-operative magnetic resonance imaging (MRI) for the generation of customized cutting blocks. Patients who refused to participate in the study were excluded. 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. They were also informed regarding the relatively new nature of the technology and absence of any long-term data on the same. All the patients who were willing to participate using the patient-specific instruments were, thus, included in the study. Pre-operative assessment included documentation of age, BMI, and deformities in the knee. All patients were asked to fill out the preop assessment form for KOOS/WOMAC scoring.

All patients in the study group underwent cemented posterior stabilizing TKA (GENESIS II SPC [LEGION Primary]. Component placement was achieved using patient-specific cutting blocks created by a single company (VISIONAIRE; Smith and Nephew, Memphis, Tenn) (Fig 1). As it took 4 weeks for the blocks to be manufactured and be available in the operating theatre, an MRI scan of the arthritic knee, along with full-length weight-bearing x-rays of the involved limb, was obtained in all patients, 4–6 weeks before the procedure. Using specialized computer software analyzing anatomical landmarks and surgeon's input (on alignment, rotation, and any additional femoral resection based on pre-operative flexion deformity), specialized cutting guides were generated for each patient. Modifications to the blocks could be made orally to the engineer or on the Internet. 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.

Fig. 1 Visionaire femoral and tibial patient-specific cutting blocks. Source https://www.smith nephew.com/patient/treatments/knee-treatments/visionaire-patient-matched-technology/

An external tibial alignment jig was used to confirm the coronal alignment before making the tibial cut (Fig 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.

The whitesides and epicondylar axis were routinely marked before using the femoral all in one cutting block. The PSI femoral jig has a marking on the superior surface that corresponds to the whitesides line as determined by the pre-operative software measurements. This is compared to
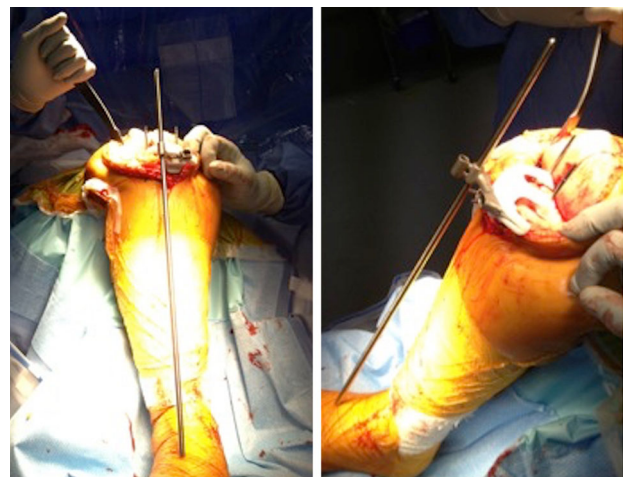
Fig. 2 External alignment rod applied onto tibial cutting block to verify alignment

the surgeon's interpretation of the whitesides line and the difference between them if any is documented in millimetres.

Intraoperatively, a record of stability of feel of all the cutting blocks was also kept. This "feel of stability" was subjective, and we tried to identify the cutting blocks that felt grossly unstable or rocking. Removal of offending osteophytes that hindered in the proper seating of the cutting blocks was performed only 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 pre-operative plan. The patella was routinely resurfaced in all the cases.

In all patients, tourniquet was deflated after dressings were applied. Negative suction drains were kept for 24 h. Skin-to-skin time and blood loss were also recorded. Blood loss was estimated by method of counting the blood-soaked mops and gauze pieces and by measuring blood lost to the suction bottles.

Our routine DVT prophylaxis included low-dose oral aspirin for 6 weeks in patients with no risk factors for DVT.

At a 6-week follow-up visit, full-length x-rays for calculating the coronal alignment of the limb were obtained. Alignment was measured as degrees of deviation from the mechanical axis (minus for varus and plus for valgus). Two independent observers assessed alignment measurements. All patients were followed-up to a period of at least 1 year. The postop KOOS/WOMAC scores were recorded at 1-year follow-up.

Results

One hundred and five knees (100 patients) were included in the study; 46 males and 54 females. Patients aged 47–91 years (mean 65.15 years) with mean BMI of 35.42 kg/m^2 (range 30–56 kg/m^2) were enrolled in the study.

Pre-operative varus/valgus deformities at the time of surgery included 83 patients with varus alignment (average −7.87°; range −0.4° to −21.4°) and 22 with valgus alignment (average 8.34°; range 0.5°–17.6°). There were 26 patients with coronal deformity greater or equal to 10° (20 patients with varus alignment, max −21.4°, and six with valgus alignment, max 17.6°). Pre-operative flexion averaged 102.34° (range 60°–154°) and average extension loss was 5.1° (range 0°–20°).

No adverse intraoperative events were seen with the use of PSG. The average blood loss was 236.1 ml (range 50–700 ml).

Only one patient had excessive blood loss (700 ml) as the tourniquet was not used to reduce pain. The mean skin-to-skin time was 92.2 min (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, including the scrub nurses and surgical assistants.

There were no adverse intraoperative events recorded. One patient required an arthrotomy with washout and change of liner for suspected early infection at 5 weeks post surgery.

One patient presented to us with deep infection at 6 months that required a two-stage revision. Five patients needed manipulation under anesthesia postop for unsatisfactory knee bend (<90°) at 6 weeks. One patient with calf pain at 4 days postop was found to have above knee thrombus on duplex scan that needed warfarin therapy for 6 months.

One patient died on the third post-operative day following severe hypoxia secondary to a myocardial infarction.

Tibial side abnormalities that required 'adjustments' intra-operatively were an inadequate tibial resection, coronal (varus/valgus) mal-alignment, sagittal (abnormal slope) mal-alignment and size mis-match. In other words, the pre-operative visionaire plan and/or cutting blocks were found to be inaccurate in these cases on the tibial side. Tibial cuts made through the PSG were insufficient in two knees. The tibial cut, therefore, had to be, redone 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.

Five cases (4.76 %) required readjustment of the tibial guide using conventional cutting block. The indication for use of conventional block was either coronal mal-alignment (four cases with three in varus and one in valgus) or sagittal (slope) abnormality (one case). "Adjustment" was done before the bone cut was performed.

The senior surgeon was very conservative on tibial size and would often downsize if there were any chance of overhang. The tibial peg was cemented and the senior author feels this enhances tibial fixation.

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 PSG.

Femoral and tibial component mismatch was termed when there was a difference between the jig size and the size that the surgeon decides upon intraoperatively. Femoral component size mismatch was seen in 6.66 % (seven of 105) knees. In all cases of femoral size change, the surgeon upsized the femoral component to decrease the flexion gap as he felt excessive posterior femoral bone was being excised. Tibial component mismatch was seen in

17.14 % (18 of 105) knees, ten of whom had to be upsized and eight downsized.

Post-operative flexion averaged 105.8° (range 80°–130°). At the 6-week follow-up, the mean mechanical axis was found to be 1.85° varus (range 4° valgus to 6° varus). Eighty-eight of 102 knees (86.27 %) had mechanical alignment (the long leg radiographic data was missing in three patients) restored to within the acceptable limit of 3° of varus/valgus from neutral. Of the outliers, 11 were in varus and 3 in valgus.

Alignment of femoral and tibial component was also measured individually to study their 'combined' effect on overall mechanical alignment. On the femoral side, there were four outliers (3 varus and 2 valgus) and 10 on the tibial side (8 varus and 1 valgus). The mean mechanical axis of femoral component was 1.02 and mean MA of tibial component was 1.0 indicating that both components individually were well aligned too.

There was an improvement in the pre and postop KOOS (36.6–76.2) and WOMAC scores (38.4–78.6) at 1-year follow-up.

Discussion

We undertook this study to analyze the utility of patient-specific instrumentation in obese patients, particularly focussing at the restoration of mechanical alignment.

We could achieve mechanical axis of within 3° of normal in 86.27 % of patients with mean MA of 1.85° which is comparable to other studies done by navigation group in the normal population. We feel that we could achieve good alignment in contrast to some of the other studies that have quoted increases rates of malalignment, because we used conventional techniques of verifying alignment and amount of bone cut before resection. We feel that bone resection relying entirely on the seating of the guide would lead to erroneous results. Frequent use, better training of engineers and improvement in block manufacturing techniques will improve the results further.

TKA is a challenging procedure in patients with high BMI. Pre-operative alignment and BMI are the two most important factors contributing to post-operative alignment. [10] A BMI >35 kg/m^2 was associated with strong trend toward malalignment of the components.

Obesity also leads to increases short-term complications as wound healing problems and greater risk of infection. In a single-center analysis of 7181 primary hip and knee arthroplasties, Jamsen and colleagues [11] demonstrated that the infection rate increased from 0.37 % in patients with a normal BMI to 4.66 % in the morbidly obese group. A study of 60 patients with an average BMI of 39.9, demonstrated almost twice the risk (11.6 vs. 6.6 %) of in hospital wound problems as well as three times the rate of deep infections after TKA compared to controls (5.0 vs. 1.6 %) [12].

A higher prevalence of patellofemoral symptoms in obese patients were found in a study of 257 knee arthroplasties in 182 patients at a mean of 4 years (range 2–7 years) postoperatively [13]. Other studies reported similar findings in relation to patellofemoral pain [14, 15]. Common risk factors for venous thromboembolism in orthopedic patients are obesity, prolonged immobilization, history of deep vein thrombosis (DVT), delayed post-operative ambulation, and female sex [16, 17].

Studies have reported post-operative mechanical alignment in TKA using PSG. One of them has shown 85.6 % of cases had a post-operative coronal alignment less than or equal to 3 % from neutral in 569 TKAs performed using PSG (Signature Personalized Patient Care system; Biomet Inc, Warsaw, IN) [9].

Others have shown good post-operative alignment with no adverse effects using the OtisKnee system (OtisMed Inc., Hayward, CA) [18, 19].

A study reported a cohort of 260 patients operated using PSG ($n = 115$), navigation ($n = 53$) or conventional instrumentation ($n = 92$) [20]. Post-operative CT imaging was used to compare alignment between the three groups. In PSG and navigation groups, the post-operative hip-knee angle (HKA) was within 3° of neutral alignment in 91.3 and 90.7 % of patients, respectively. This compared to 80.4 % of patients in the conventional group ($p = 0.02$). They concluded that the use of PSG resulted in similar alignment accuracy to navigation surgery and superior alignment to conventional surgery with significantly shorter operative times.

A case series of 60 patients reported intraoperative computer navigation to evaluate the accuracy of the cutting blocks (Smith and Nephew Visionaire) in the coronal and sagittal planes for the tibia, as well as rotational plane for the femur [21]. The patient-specific cutting blocks (PSCB) would have placed 79.3 % of the sample within ±3° of the pre-operative plan in the coronal plane, while the rotational and sagittal alignment results within ±3° were 77.2 and 54.5 %, respectively. They concluded that the Visionaire PSCB system achieved unacceptable accuracy when assessed by computer navigation.

Study evaluated component alignment of 48 knees operated either with standard instrumentation (26 knees) or patient-specific cutting blocks (22 knees) [25]. At 6-month follow-up, there were no significant improvement in clinical outcomes or knee component alignment among the two groups. They concluded that the group treated with patient-specific cutting blocks had a significantly higher prevalence of malalignment in terms of tibial component slope than the knees treated with standard instruments.

Recent studies that have focused on the rotational profile in PSI knees. One such study detailed a post-operative MRI in 94 patients of TKA of which 46 operations were performed using PSI and 48 using conventional instrumentation [23]. Deviation more than 3 were considered outliers. There were significantly more outliers in the conventional (22.9 %) group than in the PSI group (2.2 %, $p = 0.003$) and they concluded that PSI technique could lead to better femoral rotational profile. A more recent study by the same authors has reiterated the use of PSI in significantly reducing outliers of optimal rotational tibial component alignment in TKA [24].

Another series studied rotational profile of 40 patients operated by the PSI or conventional technique (20 in each group) [25]. They found no significant difference of femoral rotation between the two groups but they found that the internal rotation of tibial component was less in the PSI (8°) compared to the standard group (15°).

This study is not without shortcomings such as lack of post-operative long leg sagittal films to study the tibial slope and assessment of rotational profile by CT scan. It would be interesting to trend long-term follow-up of these patients with reference to aseptic loosening and patellofemoral issues and comparison with a control group would be an added advantage.

Conclusion

PSG technology reliably restores the mechanical axis in obese patients. Immediate post-operative and early results at 1-year follow-up in our series are encouraging. The erroneous tibial bone cut error that we would have otherwise obtained in some cases with the use of jigs can be promptly minimized by checking with the alignment guides in all cases. Surgeons should use these customized jigs as a guide and adjust the size of components, alignment and rotation according to normal surgical principles.

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