ISSN: 2146-8370

PROGRESS IN ORTHOPEDIC SCIENCE, 2022
VOL 8, NO. 4, PAGE 1 – 7
DOI: doi.org/10.47363/POS/2022(8)164

RESEARCH ARTICLE

Open Access

"Are Patient Specific Cutting Guides Better Alternative to Conventional Instrumentation in Primary Total Knee Arthroplasty? "-Prospective Randomized Comparative Study"

Om Baghele, Nishant D Goyal*, Navroze Kapil, Nikhil Verma, Anuj Jain and Simon Thomas

Arthroscopy and Arthroplasty fellow, Sant Parmanand Hospital and Delhi Institute of Trauma and Orthopedics New Delhi, India

ABSTRACT

Background: Patient specificicuttingiguides (PSCGs)iisirelativelyinewitechnology utilized in TKA having benefits of accurate image-guided preoperative, fewer-operative steps, less soft tissue trauma, lesser component mal-alignment, and operating time. Toidate, studies in the literature oniPSCGs have been limited and without comparative control groups. At the same time the effectiveness of PSCGs is also unclear.

Material and Method: This prospective randomized comparative study was icarried out on 70 randomly selected patients divided into two groups of 35 patients each at a tertiary care centre.iPatients with varus, intra-articular deformity were included in the study. Demographics, radiological parameters, iimplantation time,itourniquet time, post op VAS score and complications were studied in both the groups.

Observation and Results: Both the groups were statistically similar and comparable and there was no selection bias with regard to age, side, bilaterally, gender, BMI and comorbidity. The differences between mean pre-operative Femoral Mechanical Anatomical angle, Postop Lower limb alignment, VAS score, mean fall of haemoglobin were statistically insignificant whereas the difference between implantation time, tourniquet time were statistically significant.

Conclusion: PSCGs can achieve more close to neutral lower limb alignment with less number of outliers in primary TKA. It does not give any added advantage with regard to component placement. PSCGs can help to reduce the postoperative blood loss, implantation time and operative time thus can be a beneficial alternative in patients with high risk of anaesthesia.

ARTICLE HISTORY

Received October 02, 2022
Accepted October 13, 2022
Published October 28, 2022

KEYWORDS

Patient Specific Cutting Guides, Primary Total Knee Arthroplasty, Conventional Tka, Lower Limb Alignment, Mechanical Axis

Abbreviations

TKA	Total Knee Arthroplasty
PSCGs	Patient Specific Cutting Guides
MRI	Magnetic resonance Imaging
CT	Computed Tomography
HKAA	Hip Knee Ankle Angle
3D	3iDimention
ETO	Ethylene Trioxide
FMAA	Femoral Mechanical Anatomical Angle
LDFA	Lateral Distal Femoral Angle
MPTA	Medial Proximal Tibial Angle
VAS	Visual Analogue Score
SD	Standard Deviation
BMI	Body Mass Index
SPSS	Statistical Package for Social sciences

Introduction

TotaliKnee Arthroplasty (TKA) is one of the most successful and commonly performed surgical procedures in the world. The success of TKA depends on several factors, most important being limb alignment (within 3º of the mechanical axis), component positioning and soft-tissue balancing [1].iAccurate coronal alignment correlates with good clinical outcomes whereas mal-alignment of the mechanical axis by >3º has been associated with early loosening, uneven wear of polyethylene bearings, lower functional scores and a higher implant failure rate [2,3].

New Technology for TKA can ensure substantialiimprovement iniclinical efficiency oripatientioutcomes. Computer-aided navigationiforiTKAiwasidevelopeditoiimprove icomponent ialignment iand iavoid outliers [4]. However, it has not become widely used because of the high costs, increased surgical time to perform these procedures and steep learning curve [5].

During the past decade, TKA technology evolved to include patient specific cutting guides (PSCGs), which uses data obtained

Contact Nishant Goyal nishantdgoyal@gmail.com Arthroscopy and Arthroplasty fellow, Sant Parmanand Hospital and Delhi Institute of Trauma and Orthopedics New Delhi, India.

from MRI or CT or Hip Knee Ankle X-ray of the lower limb (HKA view) for the preparation of cutting jigs useful for TKA [6]. These data guides the surgeon in determining the desired positioning of the prosthetic components. This is possible because the jigs itself determines the cutting thicknesses and angles, as well as the rotations of the prosthetic components.

PSCGs has the benefits of accurate image-guided preoperative planning, fewer intra-operative steps, and reduced number of itrays used [7]. It can minimize intra-operative soft tissue trauma, icomponent mal-alignment, and operating time [8].

To date, studies in the literature on PSCGs have been limited and without comparative control groups. At the same time the effectiveness of PSCGs is also unclear [6]. Therefore, to evaluate the precision of CT guided PSCGs over conventional method, we conducted a prospective study comparing the accuracy of mechanical alignment of limb and component positioning after TKA performed using PSCGs versus conventional instrumentation. We also compared the implantation time, demographic and radiological parameters in both the groups.

Manufacturing of patient-specific jigs using 3D printing

The manufacturing of the 3D printed patient-specific jigs for TKA uses "additive manufacturing" technique in which the model is created by deposition of a powder in a layer by layer manner based on computer-aided design.

The jigs were manufactured using biocompatible materiali(nylon, polymers, or metals) which have specific characteristics.iThese jigs do not abrade when in contact with bone saws. Moreover, the material used is compatible with autoclaving, so that it can be used during the surgery.

PSCGs facilitates cutting guidesiby creating a 3-dimensional model of the knee preoperatively, using CT or MRI or HKA radiograph. With a specific software program manufacturing engineers turn 2- dimensional images into 3-dimensional representations of the knee and lower limb.

A preoperative planning with bony resections is then created and presented to the operating surgeon. Using specific software, the operator is then able to evaluate the 3D planning of the TKA with desired bony resections. During this phase, the surgeon is able to iapprove or modify the pre-operative plan, adjusting as needed the tibial and femoral bone resections. In this phase, it is also possible to accurately plan the depth and the coronal orientation of the resection,ias well as the rotation and the slope of the cuts.

After the operator's authorization, custom cutting guides that fit on the patient's anatomy are manufactured and then sent to the surgeon (Figure 1).

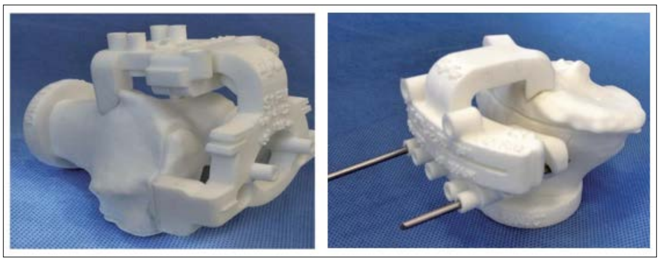

Figure 1: 3 Dimensional Pscgs for Distal Femoral and Proximal Tibia

The PSCGs femoral guides are used to determine the valgus angle, level of resection, alignment, rotation, and size of the femoral component, whereas the patient-specific tibial guides are used to determine tibial alignment, level of resection, and tibial slope and rotation. Usually, 3 to 4 weeks are required to the final production of these cutting iguides.

Duringisurgery, the PSCGs are either used directly as slotted cutting guides or for an accurate pin positioning, using standard resection instrumentation for the bone cuts. The cutting guides are used for the primary distal femoral cut and proximal tibial cut. (Figure i2) The subsequent bone cuts are achieved with standardized instrumentation.

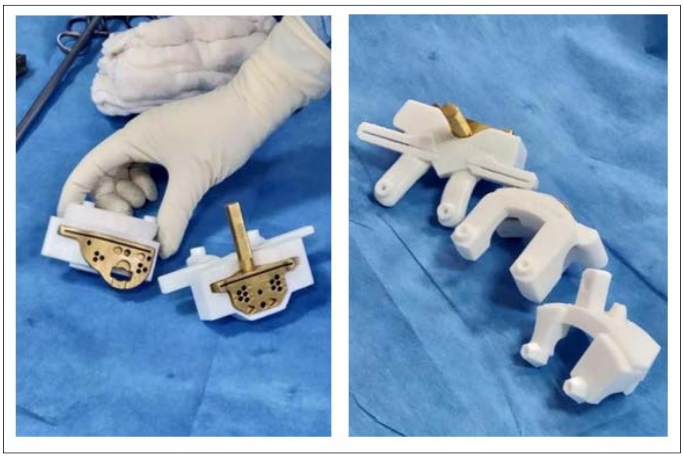

Figure 2: Pscgs Distal Femoral and Proximal Tibial Cutting Jig

If the resections do not appear well aligned or orientated from the operator's point of view, intraoperative modifications can be realized by using standard instrumentation for additional femoral and tibial cut.

A part from surgical planning, PSCGs can also be used for education and counseling of the patient and family, for better understanding the pathology and surgery which has been planned.

Material and Methods

This prospective randomized comparative study was carried out on 70 randomly selected patients at a tertiary care center of a metro city for a period of 2 years. Study have been approved by the appropriate ethical committee and have been performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki. Informed consent has been obtained from patients and full confidentiality has been maintained.CONSORT guidelines have been followed for the study.

All patients undergoing TKA for primary osteoarthritis of knee iwere included in this study. Only patients with varus, intra-articular deformity and the patients in whom deformities could be addressed by primary implants were included in the study.

Patients with secondary Osteoarthritis, with valgus deformity or with extra-articular deformity and patients not willing to give consent were excluded from the study.

Patients were divided into two groups,iA and B with 35 patients each by random allocation, using computer randomization method. Group A patients underwent TKA with PSCGs. Group B patients underwent TKA using conventional approach. Byirandom selection from lots,i58iknees in 35 patients whoiunderwent TKAiby PSCGs wereiallotted in group A and 56 knees in 35 patients who underwent TKA without PSCGs (ConventionaliTKA) were allotted in group B.

Patients allocated to group A underwent a CT scan of both lower limbs from the hip joint to ankle joint. The preoperative planning from 3D reconstructed CT scanogram images was performed using planning software (Materialise). 3Diprint of the Knee joint iwas done using the CT Scanogram and customized cutting jigs were made, one for idistal femur and one for proximal tibia. These Cutting jigs were sterilized by ETO and packed for use on the day of surgery. The cutting jigs were discarded or given to patient after the surgery.

Patients in group B underwent TKA by conventional instrumentation provided by the implant company. Allipatients underwent cemented posterior stabilized knee arthroplasty with fixed bearing insert *[Legion ® Knee Smith and Nephew or Opulent ® Knee Maxx Meril]*

In both groups single orthopedic surgeon specialized in TKA performed all the procedures. The pre-perative, post-operative protocol and operative steps were same for the groups. The patella was not resurfaced in any group.

In group A, the femoral jig was placed on distal femur without removing osteophytes. (Figure-3)iVisual confirmation of the cut was done, distal femur cut taken and jig was removed. Now the femoral preparation was completed using 4mm cutting jig. Proximal tibial jig iwas placed on the superior surface of tibia in the position which had maximal conformity.iJig was secured with pins. Now varus and valgus alignment was checked using extramedullary rod. (Figure-4) After verification proximal tibial cut was taken. Proximal tibial jig from implant company was used to broach the proximal tibia in appropriate external rotation.

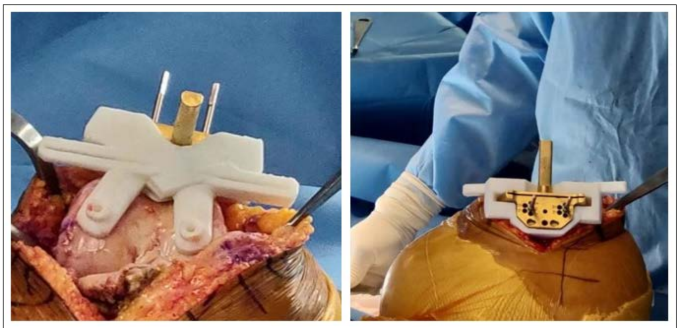

Figure 3: The Femoral Patient Specific Jig Sitting Snugly on the Distal and Anterior Femoral Cortex

Figure 4: The Tibial Patient Specific Jig Anatomically Matching the Proximal Tibial Anatomy. Varus/ Valgus Alignment Checked by Alignment Rod

In group B, standard intramedullary instrumentation was used for the femoral component.iThe tibial component was placed according to the mechanical axis using extramedullary instrumentation.

Radiological Parameters

All patients underwent digital X-ray Bilateral Knees standing AP, lateral and Hip iKnee Ankle (HKA) view preoperatively.

Single observer measured the preoperative hip–knee–ankle Angle (HKAA) and Femoral Mechanical Anatomical Axis (FMAA) from the full leg weight-bearing radiograph in both the groups. Patients in groupiA also underwent CT scannogram of the leg preoperatively. In this group, the Mechanical and Anatomical axis of Femur drawn on the CT scan using software (Materialise) and FMAA were calculated using same software.

Post operatively HKA view was taken in both the groups. HKAA, Lateral Distal Femoral Angle i(LDFA) and Medial Proximal Tibia Angle (MPTA) were measured in both groups.

During surgery Implantation time and total tourniquet time was noted in both theigroups. Implantation time was defined at the time from tourniquet inflation to the time iof final cementation of the implants. Tourniquet was inflated just before incision and deflated just after staples were applied.iThe tourniquet time is the time for which tourniquet inflated. Patients retained gravity assisted drain for a period of 24 hrs. The blood collected in drains in both groups was measured.

The VASiscores of both groups were recorded.iThe post-operative medication and rehabilitation protocol was same for both the groups.

Sample Size

Comparing the results of the conventional method and PSCGs, Pfitzner et al. report a statistically significant difference of outliers (± 3 degrees) to the HKA, reporting values of 57 and 93% respectively; Drnek et al. report similar values, 73 and 93%; Heyse et al. values of 77 and 98%; Daniilidis et al. 79 and 91% with statistical significance ($P < 0.05$)[33-36]. Assuming these values as reference, the minimum required sample size at 5% level of significance and 80% power is obtained 78 [9-12].

Hence, we proposed to collect a sample size of 35 in each groups.

Statistical Method

Means (SD) were given for variables and numbers with percentages were presented for categorical variables. Student's t-test for 2 independent samples was used ifor the estimation of differences in radiological component angles, age, BMI, and operation time etc. Differences in distributions of categorical variables between the groups were examined by using Pearson's chi-square test. A p-value < 0.05 will be considered statistically significant. IBM Statistical Package for Social sciences (SPSS) iversion 16.0 was used for statistical analysis.

Observation and Results

The observation and results are discussed with respect demographics, radiological Parameters, implantation time,itourniquet time, post op VAS score and complications as follows.

The mean age in group A was 63.34 (Range i49-72) years and in group B was 63.63 (Range 46-75)iyears. To check the homogeneity on the basis of age, chi-square test and t-test was applied. Both the groups were statistically similar and comparable (p>0.05) and there was no selection bias with regard to age, side, bilaterally, gender, BMI and comorbidity.

The mean pre-operative Femoral Mechanical Anatomical angle (FMAA) measured manually on X ray HKA view was 6.12 and on CT scan software was 5.87 in Group A.iTheidifference was not statisticallyisignificant (p ivalue>0.05). The FMAA in group A was 6.38 and in igroup B was 6.19. There was no statistically significant difference in FMAA between two groups (P value > 0.05).

The mean Hip-Knee-Ankle Angle (HKAA) in post-operative patients was 3.68 in group iA and 4.46 in group B.iThere was no statistically significant difference between two groups regarding lower limb alignment measured on HKA X-ray (P value >0.05).

The Mean LDFA and MPTA were 90.59 and 99.71 in group A whereas 90.36 and 89.69 in group B. There was no statistically isignificant difference between both groups (P value >0.05). Outliers were defined as follows: more than ± 3 degrees from neutral alignment for the KAA; more than 90 ± 3 degrees for the LDFA and MPTA. 23 out of 58 (39.65%) in group A were outliers and 36 out of 56 (64.28%) in group B were outliers. There was statistically significant difference in HKAA outliers (P value <0.05). But there was no statistically significant difference in LDFA andiMPTA outliersi(P value>i0.05).

The mean tourniquet time and implantation time in Group A was 54.58 min and 26.75 min whereas in group B it was 61.37 min and 35.03 min respectively. These idifferences were statistically significant between both groups (Pivalue <0.05).i(Table-1) This signified that operating time and implantation time were shorter in group A than in group B.

Table 1: Comparison of TT, IT Drain Output between Two Groups

	Group A (PSCGs TKA)	Group B (CONVENTIONAL TKA)	P value
TT	54.58±6.82	61.37±5.34	<0.0001
IT	26.75±3.53	35.03±4.28	<0.0001
Drain	43.98±30.33	78.77±24.13	<0.0001

The mean drain output in Group A was 43.98 mL and in group B was 78.77 ml. The mean drain output in group A was less compared to group B. This difference was statistically significant (P value < 0.05). The mean pre-operative, post-op hemoglobin and mean fall of hemoglobin postoperatively were shown in Table-2, the values of which are statistically insignificant.

Table 2: Comparison of Hemoglobin Fall between Two Groups

Hb(Mean ± SD)	Pre	Post	Mean Drop	P value
Group A (PSCGs)	12.6±1.19	10.71±1.08	-1.53	>0.05
Group B (Conventional TKA)	12.24±1.06	11.18±1.29	-1.42	>0.05
P value	>0.05	>0.05		

VASiscore was compared between group A and group B pre-operatively, on POD1 and at the time of discharge. There was no statistically significant difference in pain score between both groups at any point of time. In our study there was no evidence of postoperative complications like infection, pulmonary embolism in both the groups. I

Discussion

PSCGs for TKA is a relatively new technique to align the knee prosthesis,iusing 3D rapid prototyped disposable cut or pin guides that fits on the native anatomy of the individual patient [13].iThis perioperative guiding technique eliminates the use of intra and extra imedullary rods to make bony resections. It has been proven that conventional intramedullary alignment rods in TKA can cause postoperative mal-alignment [14].

Age, Gender, Side & BMI

Our study showed that the majority of population undergoing TKA were obese (BMI>30) elderly females (age >60 years), operated bilaterally at the same time. This is because Osteoarthritis is more common in old age. In females,imenopause interferes with hormone level causing osteoarthritis.iThis results are in co ordinance with studies of Souza J et al, Singh J et al,iKulkarni et al [15-17].

Pre-operative FMAA

FMA is an angle between femoral anatomical and mechanical axis. On the femoral side, the mechanical iand anatomical axes do not match each other, and hence the distal femoral cut has to be itaken concerning the femoral valgus angle axis which may vary among patients. Traditionally, the cuts have been made by keeping the femoral valgus angle fixed for all.iHowever, there may be differences in femoral anatomy like variations in the neck-ishaft angle, femoral bowing which can lead to different FMA.

Vaishya et al.isaid that advantages of the PSCGs in femoral valgus prediction may help to improve outcomes of replacement surgeons. In our study there was no significant difference in preoperative FMA angle in both groups A and B [18].

Comparison of FMAA

Deakin et al, and Barkados et al, concluded that mechanical axis cannot be restored in total knee arthroplasty with a fixed valgus resection angle. Hence FMA angle should be individualized as there was a statistically significant difference between males and females. Theoretically, ithere is a direct positive correlation between the femoral offset and the femoral valgus iangle. Since there is a higher hip offset in female; they tend to have higher femoral valgus angles. The changes in the femoral valgus angles would affect the overall mechanical axis as well [19,20].

Iniour study there was no statistically significant difference inipostoperative FMAA between two groups. That means valgus angle iprediction by both PSCGs and conventional technique was comparable.

Post-op lower limb alignment on HKA view

Insall et al,idescribed that the mechanical alignment is the widest method used to asses post-op lower limb alignment after TKA for its high reproducibility and easiness [1]. It requires an initial distal femoral and tibial cut perpendicular to the mechanical axes of femur and tibia respectively.iPurpose of this alignment is to create and even load distribution ion the new joint line.iThe knee joint aligned thorough the ianatomical alignment may be loaded more medially with a medial tibial plateau fixation ifailure. He also promoted the femoral component positioning at 3° of external rotation iin order to balance flexion and extension gaps.

Comparison between various studies about postoperative lower limb alignment measured on HKA view after TKA in shown in Table-3.

Table 3: Comparison of Post-Op Mechanical Axis on Hka View in Patient Specific Instrument Group Vs Conventional Instrument Group in Various Studies

Studies	Comparison
Abane L et al.	Comparable in both groups
Chareancholvanich K et al.	Comparable in both groups
Huijbregts, HJ et al.	More accurate mechanical alignment in patient specific instrument groups But statically insignificant
Noble et al.	More accurate mechanical alignment in patient specific instrument groups which is more near to the neutral (+/- 0.3 degrees), But statically insignificant
Sassoon et al.	No reliable improvement using patient specific instruments
Our study	No statistically significant difference between two groups , comparable to results of previous studies.

Component Alignment

Coronal mal-alignment in excess of ±3°iis associated with decreased functional outcomes and implant longevity [2,3]. Thienpont et al. In their meta-analysis concluded ithat PSCGs does not improve the accuracy of components alignment in TKA compared iwith CI.iWhereas, Howell et al.isuggested that inaccuracy in component placement in PSCGs group might be caused by technical errors induced by malaligned MRI or CT scan [21,22].

Iniour study, there was no significant difference in both femoral and tibial component alignment with respect to their mechanical axis in both the groups.

Outliers

In our study we found that both PSCGs and conventional instrumentation restore limb iand component alignment with a similar degree of accuracy. But there was significantly ilower numbers of outliers in PSCGs group in our study. These results are contrast to the study of Abane L et al. Van Leeuwen JAMJ et al.iand Chen et al.iwho reported more outliers in the PSPG group. However Ng VY et al [7]. Concluded PSCGs system helped the surgeon toiplace components closer to a neutral axis than conventional instruments resulting in lesser number of outliers [23,24].

Tourniquet time [Surgical time] and Implantation Time

Itiisiaicommon idea that PSCGs could theoretically shorten operating time, especially for less experienced surgeons.

In a randomized controlled trial, Hamilton et al. Demonstrated that PSCGs do not shorten surgical time in comparison with traditional cutting jigs surgery. However Bali et al. and Boonen et al. Showed different iresults [25-27].

Accurate placement of femoral and tibial jigs may need experience because of difference in conformity between jigs and bones. According to Sassoon iet iali there is decisive evidence exists to support that PSCGs requires fewer surgical trays, but they suggested that PSCGs does not clearly decrease the operative time [22].

In our study, the operating time and implantation time were shorter with TKA using PSCGs. This is because in PSCGs instrumentation there was ino need of intramedullary jig insertion.

BloodiLoss and Hemoglobin Drop

Rodientry hole has been considered a source of iperi and postoperative oozing resulting in an increased blood loss after conventional TKA.iHowever well performed conventional TKA with bone plugging of the femoral hole and extra-medullary tibial alignment can be considered as a blood sparing surgery that reduces hidden blood loss [28]. PSCGs do not violate intra-medullary canal as intra-medullary rod is not necessary to set the correct alignment, thus reducing the blood loss. Our study showed the similar results with significantly less blood loss in PSCGs group.iHowever, mean postop hemoglobin drop in both the groups in our study were not statistically significant.

VAS Score

In our study,iVisual Analogue Score (VAS) was the main tool to measure the post- operative pain in patients who underwent TKA. Kotela A et al, and Birla VP et al. observed significantly lesser pain postoperatively in PSCGs group compared to Conventional group [29,30].

Iniour study, there was no significant difference in pain score between both groups at any point of time. VAS score was high on POD1 in both the groups and there was marked decrease in VAS score seen on the day ofidischarge. There was a statistically significantireduction iin VAS score on day of discharge as compared to POD1 in both the groups [31-34].

Complications

Iniour study there was no evidence of postoperative icomplications like infection,ipulmonary embolism in both the groups.

Conclusion

Onithe basis of above findings we conclude that, PSCGs can achieve more close to neutral lower limb alignment with less number of outliers in primary TKA. However, it doesinot give any added advantage with regard to component placement.iPSCGs can help to reduce the postoperative blood loss, implantation time and operative time as intra-medullary reaming of femoral canal is not necessary in it. It also reduces the number of steps required to complete the TKA.

Recommendations

Thus we recommend that PSCGs should be considered as better alternative in patients with high risk for anaesthesia as it reduces operative time and postoperative blood loss and at the same time help to achieve accurate lower limb alignment. We also recommend the use of iPSCGs in patients with extra-articular deformities or in patients with retained hardware where using intra-medullary alignment jig placement is not possible.

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