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Conventional Vs Pin-less Navigation Technique in Total Knee Replacement in Western Indian Population

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1. Introduction

Knee osteoarthritis represents a major health issue.Total knee replacement (TKR) has been established as standard therapy for severe osteoarthritis. Restoration of the mechanical axis is a main objective in TKR, as it is attributed to good long-term results.The success of this procedure as measured by pain relief, improved function, greater patient satisfaction, and implant longevity is predicated on a number of factors. These include prosthetic factors such as implant size, tribology, geometry, alignment, and position; patient factors including size, weight, activity, the existence of medical comorbidities, psychological, and physiological response to joint surgery; and surgical factors including surgical skill and experience, duration of surgery, appropriate preparation, and implantation of the prosthesis. The longevity of total knee prosthesis depends mostly on the correct alignment (Frontal, Sagittal&Axial) of the prosthetic components, soft tissue balancing & restoring the mechanical axis of lower limb (1). Recently, there has been greater focus on surgical technique and its relationship to implant performance and survival (2)**.** In addition, greater attention is being paid to reducing surgical trauma through less invasive surgery and better implant positioning through computer-assisted surgery (CAS) (3).

Numerous radiological and clinical studies have proven that computer-assisted total knee replacements (CAS-TKR) are more precise regarding limb alignment reconstruction as well as implant position compared to the conventional technique. In spite of its valuable advantages, the navigation technique is still not used as routine. (4) Main limitations are higher costs and additional time required for the surgical procedure.(5,6)Further disadvantages are a prolonged training curve for new users (7,8) and morbidity due to the placement of bony reference arrays such as fractures and infections (9,10)

The use of computer-assisted navigation is increasingly favored by Orthopaedics surgeons in total knee arthroplasty (TKA) because of reported advantages in literature including increased precision of individual component placement, (11)correlation with better knee function and quality of life (12) as well as a reduced number of outliers in obtaining neutral mechanical alignment.(13) Initial navigated systems used separate femoral and tibial diaphysis reference tracker pins which resulted in the occurrence of tracker pin-associated complications(14)In addition to a longer duration of surgery. (15) Pinless navigation systems were thus developed to harness the advantages in mechanical alignment of a computer-navigated TKA while essentially eliminating tracker pin-associated complications. The differences in surgical setup between a pinned versus painless computer-assisted surgery (CAS) setup in TKA surgery.The current literature comparing pinless-navigated TKA with CAS with conventional TKA revealed improved lower limb alignment and placement of componentswithout significant difference in early post-operative function and range of movement although a longer duration of surgery was required. (16, 17, 18)

Total knee replacement (TKR) surgery has become a commonly performed and highly successful surgical procedure. Recent innovations have improved both early and long term results. Navigation is the most significant advance in instrumentation for total knee replacement over the last decade.

Although systemic reviews of TKA with CAS assisted by tracker pins have revealed no difference in clinical outcomes when compared to conventional TKA, there is a paucity of data describing the clinical outcomes in patients who underwent TKA with CAS using pinlessnavigation. The purpose of this study was to compare the clinical function, alignment, and survivorship of the component in primary total knee replacement (TKR) using navigation versus conventional surgical technique at 1- and 2-year follow-up.

2. Materials & Methods

The patients included had osteoarthritis, Rheumatoid Arthritis or Ankylosing Spondylitis of the knee. All the patients were operated on by adult reconstruction surgeon trained in Conventional TKR & navigated TKR. A total of 16 patients met the inclusion criteria and were screened for enrolment in thestudy; all of them provided informed consent, all patients were randomized. After giving informed consent, 16 patients were randomized to undergo a navigated or conventional procedure. Unilateral as well as bilateral knees were included in this study. The assignment of the knee to navigation or not was done randomly and in which 12 knees were operated by computed assisted pinlessnavigation and remaining 15 knees were operated by conventional method of total knee replacement. Randomization was based on a permutation algorithm without stratification and administered by a certified medical biometrician (FK) by means of SAS software. Nine men and seven women were enrolled in the study. At the time of the index arthroplasty, the mean age of these patients was 61.5 years (range 40 to 80 years). The mean duration of follow-up was 3 years (range 3 months to 3 years). Clinical and radiographic follow-up examinations of the patients were performed with the rating system of the Knee Society score at 3 months, 6 months, 1 year and 2 yrs after the operation.

3. Surgical Procedure

Patients were randomized to undergo TKA using a computer guidance system (CAS) or a conventionalapproach (CONV). A modular, total condylar knee arthroplasty prosthesis.Computer-Assisted Technique. A non x-ray – based navigation system (I- Assist, Zimmer) was used. Medial para-patellar approach was used in both the groups.At the commencement of the procedure, the mechanical axis of the lower limb is procured using the navigation system and the severity of the deformity is calculated and visualized using a "morphing" algorithm to create a virtual image of the lower limb on the computer display. Of note, the anatomical axis of the femur was determined by the computer as passing from the center of femoral rotation through to a point at the center of the intercondylar notch. The mechanical axis of the tibia was from the center of the anterior cruciate ligament origin on the tibial plateau to the midpoint between the medial margin of the medial malleolus and the lateral margin of the lateral malleolus. The epicondylar axis was determined by a line joining the prominence of the lateral epicondyle and the fossa distal to the medial epicondyle. The bone cuts are then navigated, and the size, orientation, and alignment of the prosthesis were assigned by the computer algorithm. Fine tuning and alteration of the computer's recommendation may be made at any stage, as deemed appropriate by the surgeon. Precutand post cut readings were collected. All bone cuts were navigated, except for the patella.

Conventional Technique:
A standard system of intramedullary and extra medullary guides wasused to align the femoral and tibial components, respectively, in the conventionalknee arthroplasty group.

Radiological Evaluations were done using both lower limb X-ray scanogram. The mechanical axis was defined as the angle between a line from center of the hip to the center of the tibial tray, and a line from the latter position to the mid-point of the ankle joint, and was assessed on the full-length standing radiograph. That of the femoral component was defined by a line through the centre of both femoral fixation pegs. The trans-epicondylar axis was measured from the sulcus of the medial epicondyle to the most prominent point of the lateral epicondyle. The angle between these two lines was assessed. The rotational alignment of the tibial component was defined as a line along the posterior border of the tibial stem from which a perpendicular line was drawn through the rotational center of the tibial tray. The tibial tubercle was divided into three parts anda line was drawn from the lateral border of the medial third to the center of the tibial tray. The angle between these two lines was measured and defined rotation.

4. Statistical Analysis

The study analysis was based on a two-sample Wilcoxon test at the 5% significance level to compare the distribution of the primary endpoint between the treatment samples. The results of this confirmatory test were summarized interms of a p-value. The calculation of sample size originallyapplied a two-sample t-test analysis, but as soon as statisticaloutliers were observed in at least one of the treatmentsamples a Wilcoxon test was used instead. The evaluation of the primary endpoint was based on the distribution of the medians and quartiles within the treatment samples as recorded on box plots. In order to allowcomparison with graphical presentations of data in the literature, histograms of this data were also prepared.

Table 1: Distribution of patient according to Gender

Gender	Group N		Group C	
	No	%	No	%
Male	10	83.3%	04	26.7%
Female	02	16.7%	11	73.3%
Total	12	100%	15	100%

Table 2: Comparison of Gender & mean age in Groups

	Group N	Group C
Gender : Male / Female	10/02	04/11
Age (in years): Mean±SD	60.83±12.14	62.20±10.61
Affected side : Right/Left	05/07	08/07

Table 3: Distribution of patient according to Diagnosis

	Group N		Group C	
	No	%	No	%
Ankylosing Spondilitis	02	16.7%	00	00%
Osteo-Arthrtis	09	75.0%	08	53.3%
Rheumatoid-Arthritis	01	8.3%	07	46.7%
Total	12	100%	15	100%

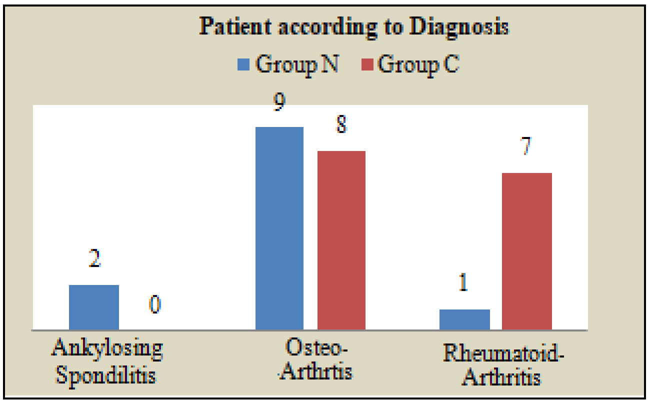

Table 4: Co-morbidities in patient:

	Group N		Group C	
	No	%	No	%
DM	02	16.7%	04	26.7%
HTN	06	50.0%	13	86.7%
IHD	05	41.7%	02	13.4%
Other	03	25.0%	12	80.0%
Total	12	100%	15	100%

Table 5: Radiological correction Pre and Post Op:

	Group N		Group C	
	Pre Mean±SD	Post Mean ±SD	Pre Mean±SD	Post Mean±SD
Valgus	7.75±2.22	00	5.56±0.58	2.67±0.58
Mean Diff.	7.75#		2.89#	
Varus	17.25±10.69	4.25±2.19	17.91±6.	2.17±2.48
Mean Diff.	13.0#		15.74#	

5. Results

The patients in the computer-assisted and conventionalstudy did differin their demographic data andpre-operative varus or valgus malalignment. The meanKSS was higher in the navigated group (90.33±3.02), but this was not of statistical significance as compared toconventional group (89.73±5.69). The operative time was significantly longer in thenavigated group, with a median duration of 89.41 +/- 12.33 minutescompared with 81.60 +- 11.88 minutes for theconventional technique.The Navigated group showed no significant difference from Conventional group in case of drain collected post 24 hrs and 48 hrs of surgery. The navigated group of patients stayed in hospital for mean time of 6.08±2.46 days whereas conventional group of patient stayed in hospital for mean time of 6.00±1.77 days which did not significantly differ from the previous group.Valgus in preoperative Navigated group of patient (7.75±2.22) changed significantly post operatively (0.00). Similarly, Valgus in preoperative conventional group of patient (5.56±0.58) changed significantly post operatively (2.67±0.58). But interestingly valgus correction in navigated group was more than conventional group and which was statistically significant (P=0.0034)(P value <0.05).

Varus malalignment in preoperative navigated group (17.25±10.69) significantly improved post operatively which was (4.25±2.19). Varus malalignment in preoperative conventional group (17.91±6) had significant change post operatively (2.17±2.48). Again interestingly varus correction was better by conventional technique than navigation technique which was statistically significant.(P= 0.0023)

6. Discussion & Conclusions

Our data did not demonstrate statistically significant difference in clinical function or rotational and functional alignment and survivorship of the components between the knees that underwent computer navigated total knee arthroplasty and those that underwent conventional total knee arthroplasty, preoperatively or at the time of the final follow-up. Post operative deformity correction by navigation technique was betterin valgus knee. But the drawback of this study is small sample size. Large sample size is required to attribute results of this study to larger population&come to conclusion. Also pinless navigation is surface navigation it doesn't give idea about rotational alignment as precisely as the pinned navigation. Rotational alignment of implants and exact position of implant was not assessed as post operative CT scan was not done.

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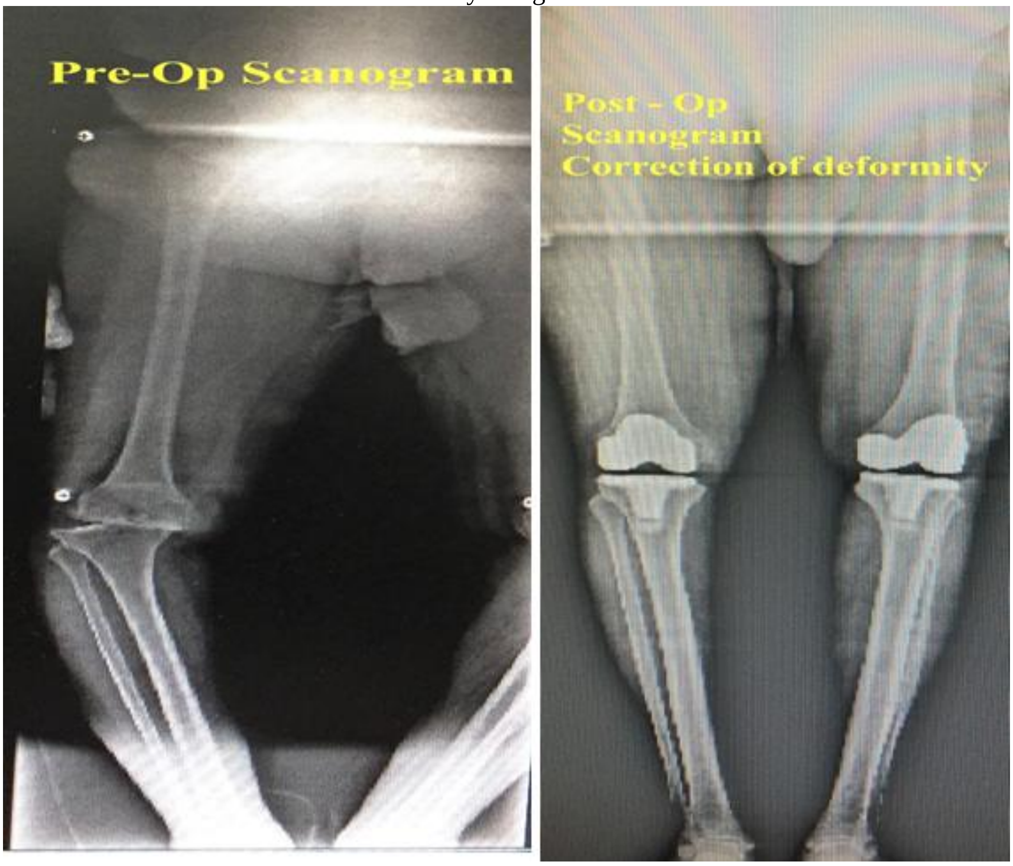
Varus Knee by Conventional method

Valgus Knee by Conventional Method

Varus knee by navigation method



Valgus Knee by Navigation Method