Intermediate Term Outcomes of Navigation Assisted Total Knee Arthroplasty.

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ABSTRACT

Background: Osteoarthritis of the knee is among the most common contributing causes of global disability, prevalent in 20 to 40 % of those over 75 years of age. Total Knee Arthroplasty (TKA), today; is the final treatment option provided to patients with unsalvageable, severely arthritic, painful and deformed knees. TKA with a postoperative mechanical axis of <30 varus or valgus have better long-term survival. Despite the continuing improvement in mechanical alignment systems, it has been estimated that the error in tibial and femoral alignment of over 3° occurs in about 10% of total knee arthroplasties even when they are carried out by well-trained surgeons using the most up-to-date mechanical alignment tools. Computer Assisted TKA has shown to reduce outliers of mechanical leg axis (>3° valgus/varus deviation) compared to the conventional technique. We hypothesized that Computer Assisted Total Knee Arthroplasty will offer a good clinical and functional outcome in patients. Methods: This was a prospective study done in Department of Orthopaedics at our institute. 53 cases were taken with diagnosis of osteoarthritis of knee joint from May 2015 to June 2017. The study was prospective and observational in nature and informed consent was obtained from each patient. Clearance from scientific and ethical committee of the institute was obtained. The results of navigation assisted total knee replacements were assessed with Visual Analogue Scale, Knee society knee score and Function Score and radiologically by various component angles and Mechanical Axis Deviation. Results: Mean Mechanical Axis Deviation of 18.04° varus preoperatively (range, 15° -24°) was corrected to 0.28° varus (range 3.5° valgus- 3.3° varus) postoperatively. Mean Knee Society score improved from 2.415 (range 0-14) to 82.55 (range 50 -95), and function score from 23.40 (range, 0 -65) to 82.55(range 50-95) at minimum 12 months of follow up. The mean pre-operative VAS was 7.6 and showed linear improvement post operatively to 4.0 at 1 month, 2.37 at 3 months, 1.07 at 6 months and finally 0.64 at 12 months. The mean component angles of implants in Tibia and Femur post-operatively were measured as Coronal femoral angle - 90.025°, Sagittal femoral angle - 90.425°, Coronal tibial angle - 90.311°, Sagittal tibial angle - 88.896°. Conclusion: 60.37% excellent and 30.18% good functional outcome along with significant improvements in knee society knee scores and VAS scores was reported. This suggests that computer assisted TKA is a safe, effective and reliable method to alleviate pain and correct deformities in patients with Osteoarthritis of the knee joint. The radiological assessment done Post-operatively confirmed that, CATKA is a significantly accurate tool to correct the deformities.

Keywords: TKR, CATKR, Navigation, CATKA, TKA,

INTRODUCTION

Osteoarthritis of the knee is among the most common contributing causes of global disability, prevalent in as much as 20 to 40 % of those over 75

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Dr. Murtuza Rassiwala 73, New Saifee Nagar, Behind Digamber School, Manikbagh Road, Indore (M.P) 452014. years of age.^[1-3] OA is strongly associated with aging and heavy physical occupational activity, a required livelihood for many people living in rural communities in developing countries like ours.^[3] Total Knee Arthroplasty (TKA) today is the final treatment option provided to patients with unsalvageable, severely arthritic, painful and deformed knees. The goals of TKA surgery include adequate alignment of the prosthesis components and the Limb, stability of the knee, and attainment of sufficient range of motion, which permits adequate movement to attain improved quality of life.^[4]

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TKA usually presents excellent results, although serious complications occur in around 5% of TKA because of loosening, infection, instability, dislocation or fracture. [5] The surgeons' experience in patients' selection, soft tissue balancing, the alignment of the leg, the restoration of the joint line and also the prosthetic design are all possible factors influencing the success of TKA. [6]

The 10-year survival rate of total knee arthroplasty (TKA) has improved to approximately 95%. [7-9] TKA with a postoperative mechanical axis of <3° varus or valgus have better long-term survival. [10-15] The prosthetic loosening rate is 24% when the deviation is >3° but only 3% when less. [14] The 10-year survival rate is 90% when the deviation is <4° and decreases to 71 to 73% when the deviation is >4°. [13] Malposition may cause pain, [16] limited range of movement, [17] joint instability, [18] early polyethylene wear and implant loosening. [19] The accuracy of the conventional extra and intramedullary guiding systems may decrease in patients with obesity, a wide medullary canal or severe extra-articular deformity. [20]

Despite the continuing improvement in mechanical alignment systems, it has been estimated that the error in tibial and femoral alignment of over 3° occurs in about 10% of total knee arthroplasties even when they are carried out by well-trained surgeons using the most up-to-date mechanical alignment tools.[21] This is due to drawbacks of the conventional alignment systems. Preoperative Xray templating always carries an error of measurement. It is difficult to determine intraoperative anatomical landmarks such as the centre of the femoral head and talus. The conventional alignment tools assume a standard bone geometry which may not apply to specific patients. Finally, all mechanical alignment tools rely on direct visual inspection to confirm the accuracy of implant positioning at the end of the procedure.

Computer-assisted imaging analysis technology has been widely used in the musculoskeletal joint biomechanics research in recent years. Imaging techniques can accurately reconstruct the anatomic features of the target joint and reproduce its in vivo motion characters. The data has greatly improved our understanding of normal joint function, joint injury mechanism and hence the surgical treatment.^[22]

CATKA has shown to improve the positioning of implant placement and more properly align the lower limb mechanical axis according to the desired plan.^[21] CATKA has shown to reduce outliners of mechanical leg axis (>3° valgus/varus deviation) compared to the conventional technique.^[23]

We hypothesized that Computer Assisted Total Knee Arthroplasty will offer a good clinical and functional outcome in patients. The present study aims to assess the clinical, functional and radiological outcome with Computer Assisted Total Knee Arthroplasty.

MATERIALS AND METHODS

Study population

The results of 53 Total Knee Arthroplasty that was performed during April 2015 to May 2016 having a minimum follow up of 1 year were reviewed and studied.

Study Design

Prospective Observational Study.

Inclusion Criteria

- 1. Primary osteoarthritis of the knee joint
- 2. Patient age above 45 years
- 3. Unilateral total knee arthroplasty

Exclusion Criteria

- 1. Patients with complex primary total knee arthroplasty-
 - Range Of Motion <50°,
 - Angular deformity >20°,
 - FFD $> 30^{\circ}$,
 - Neurovascular/skin diseases
- 2. Age < 45 years
- 3. Revision arthroplasty
- 4. Bilateral Total Knee Arthroplasty
- 5. Inflammatory arthritis
- 6. Latent or recent bone infection.

Outcome measures-

- 1) Clinical- Pain (VAS)
- Functional Knee society knee score and Function Score
- 3) Radiological- Confirmed intra operatively via navigation and checked on post-operative short A/P radiographs^[24]
 - a. Coronal femoral component angle
 - b. Sagittal femoral component angle
 - c. Coronal tibial component angle
 - d. Sagittal tibial component angle
 - e. Mechanical axis deviation

As knee range of motion, flexion contracture and extension lag are part of Knee Society Knee Score, their individual analysis was not attempted.

The Raster image obtained from the digital X-ray system was imported in Autocad 2008 as raster image the midline of anatomical axis of femur was drawn using linear tool and various angles were calculated by similarly drawing median lines of concerned bones. The angle calculations was automatically displayed by the software and recorded as such. The image measurement and data-recording were performed by one senior radiologist.



Image 1: Navigation System

RESULTS

The study comprised of 53 patients of total knee arthroplasty. All cases were unilateral knee replacement patients.

1) Frequency distribution of age group in the study

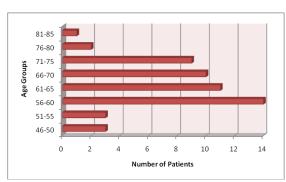


Figure 1: Frequency distribution of age group in the study

Most of the patients in this study format belong to 56-75 age groups. The minimum age of operated patient was 50, while the highest age was 85 years. The highest frequency was in the age group of 56-60 years with 26.41% incidence. Mean age was 64.35.

2) Gender Distribution of patients

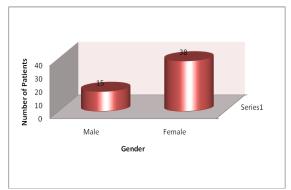


Figure 2: Gender Distribution of patients

Female had predominance in the study group. Out of 53 patients, 38 were female (71.69%) and 15 were male (28.31%).

Table 1: Scores In Our Study

Scores	Pre operative	Post op 1 month	Post op 3 month	Post op 6 month	Post op 1 year
Knee society knee score (out of 100)	2.41	53.15	63.69	64.83	82.55
Knee society function score(out of 100)	23.40	38.11	55.56	68.30	82.55
Visual analogue scale(out of 10)	7.6	4	2.37	1.07	0.64

- The mean Pre-operative knee score in our group lies at 2.41 /100.
- The mean Post-operative knee scores improved gradually to 53.15 at 1 month, 63.69 at 3 months, 64.83 at 6 months and 82.55 at 12 months. This improvement was statistically significant at 95% confidence intervals when compared to the respective pre operative score.
- The mean Pre-operative function score in our study is 23.40/100.
- The Post-operative Knee Society Function Score improved to 38.11 at 1 month. The improvement was gradual to 55.56 at 3 months and then 68.30 at 6 months. The function score at 12 month was at 82.55. This improvement was statistically significant at 95% confidence intervals when compared to the respective pre operative score.
- The mean Pre-operative VAS of our study group is 7.6/10.
- Post-operatively, mean VAS values showed linear improvement in scores to 4.0 at 1 month, 2.37 at 3 months, 1.07 at 6 months and finally 0.64 at 12 months. This improvement was statistically significant at 95% confidence intervals when compared to the respective pre operative score.

Table 2: Post Operative Component Angle

Complications	
Component angles	Mean Post operative(in
	degrees)
Sagittal tibial	88.89
Sagittal femoral	90.42
Coronal tibial	90.31
Coronal femoral	90.02

Table 3: Complications

Events	Occurrence (out of 53)	
Phlebitis	Nil	
Pulmonary embolism	Nil	
Hematoma formation	Nil	
Skin necrosis	Nil	
Infection	1	
Delayed rehabilitation	2 (inclusive of patients in 5 and 7)	
Knee stiffness	1	

Post-operatively, one patient developed wound site infection, presented to us with delayed wound healing and discharging sinus. One patient reported with knee stiffness and persistent pain on knee bending. No major complications such as infection, deep vein thrombosis or pulmonary embolism were found in either group.

Pre-Operative











Image 5: Navigation Image (Intra Op)

Image 4: Navigation Image

Follow up







Image 7: Post Operative

Image 8: Post Operative



Image 2: Showing Intra Op Use Of Navigation System

DISCUSSION

This study was meant to assess the results of computer assisted navigation for the alignment and orientation of the components in total knee arthroplasty. Our study results are compared with

the results of the studies considered in the review of literature.

Mean age of the patients in our group was 64.35 years, this is comparable to the study age group in the meta analysis of Hetaimish et al (69.0 \pm 0.8) and studies of Sparmann et al (67.4) and Kim et al (67.6).[25-27] The mean age of the patients studied strongly correlates with the prevalence of osteo arthritis in Indian population.

A female preponderance in the current study (m:f=15:38) amounting to 71.69% patients correlates well with numerous studies which also report a higher incidence of knee related afflictions requiring TKA in female populations. [26-33] High gender bias in knee arthritis attributable to menopause is a possible reason for the skew in the number of patients towards females in the current study. The other aspect important particularly to the Indian population is high use of squatting position in household work and activities of daily living.

In the current study right side affection of disease is observed to be slightly more as compared to the left side (53 knees operated, 28 right side, 25 left side). This slight deviation was also found by Luzo et al in their study. [34] However a definite correlation cannot be stated as it was not investigated.

There is no general agreement in the literature about the optimal orientation of a TKA, and the critical point is that the instrumentation allows the surgeon to place the components in the orientation he or she decides. The accepted range for component orientation is also changing in the literature: between $\pm 2^{\circ}$ and $\pm 4^{\circ}$ from the optimal one. We chose the range of $\pm 3^{\circ}$ for all criteria, as this range is widely accepted in the literature and will allow easier comparison.[10-15]

On comparing Pre-operative Mechanical Axis Deviation (MAD) to various studies, 50% patients in the study group of Sparmann et al had a mechanical axis deviation of >100.[26] The study group of Lutzner et al reported a pre-operative mechanical axis deviation with mean $7.0\circ$ (-5.1 \circ to 18.60).[35] Similarly, Chang et al reported mean preoperative mechanical axis deviation of the lower extremity of 13.38° (varus 25° to valgus 10°). [28] Pang et al reported a pre-operative mean MAD at 17.1 degrees in 35 patients operated with navigation TKA.[29]

This corresponds well, though not strongly with the pre-operative mechanical axis deviation in our study group where mean is 18.040 varus, with a range of 12.500 - 200 varus angulation. All valgus knees in our study were associated inflammatory arthritis, and hence excluded.

Post-operative mechanical axis deviation in our study varied from -3.50 (valgus) to 3.30 (varus) with a mean of 0.28 degrees (varus) and a standard deviation of 1.580. On statistical analysis, the mean was found to be significant at 90% confidence interval. However, with paired t-test, at 95% CI, the

comparison of pre operative and post operative mechanical axis deviation showed significant improvements.

This was compared with the following studies

Table 4: Comparison of MAD with other studies

Study	Year of study	Number of patients	Post-Operative Mechanical Axis Deviation
Lutzner et.al. ^[35]	2008	40	1.5°
Chang et al ^[28]	2005	50	1.89°
Pang et al ^[29]	2009	35	0.4°

On comparing Pre-operative knee scores with various studies available in literature, Pang et al reported Pre-op knee scores of 32.90 in a study of 35 patients. ^[29] Luzo et al, in a study of 200 patients reported the pre-operative KSS at a mean of 44.13. ^[34] Lutzner et al studied 40 patients with navigation TKA and reported a pre-operative knee score at 36.50. ^[35]

The mean in our group lies at a mere 2.415 as compared to the above study. This difference is due to the gross deformities (as evident in pre-operative mechanical deviation) and pain encountered (as evidenced by VAS scores, discussed elsewhere) in the study population.

Similarly, Pre-operative function score in our study is 23.40. Pang et al in their study report a function score Pre-operatively at 39.10.^[29] Lutzner et al studied 40 patients with navigation TKA and reported a pre-operative function score at 52.50.^[35] While these scores are not comparable to the scores recorded in our study, they clearly indicate the gross differences in the decision to undergo TKA. A knee score of 2.415 should logically be associated with a comparable function score (low expected), while in the present study a function score of 23.4 directs towards a larger pain bearing either due to psychological aversion or financial dependence in later years of life.

Very few studies are available where VAS has been utilized for evaluating post-operative pain in TKA patients. Mean Pre-operative VAS of our study group is 7.6 in 53 patients, as compared to a VAS (pain at movement) 7.1 in a group of 69 patients in the study of Lundblad et al.^[36] This shows that patients in our study group presented at a slightly advanced stage of the disease, although with a raised threshold for pain tolerance.

The present study by utilising VAS Postoperatively shows the linear improvement in scores (R squared=0.9) from pre-operative stage to 12 month post-operative stage. However, with paired t-test, at 95% CI, the comparison of pre operative and post operative (1, 3, 6 and 12 months) VAS scores showed significant improvements.

Table 5: Comparison of VAS with other study

Duration	Mean VAS (out of 10) in our study N=53	Mean VAS Lundblad et.al. study N= 69
Pre-operative	7.6	7.1
Post-operative 1 month	4.0	-
Post-operative 3 month	2.377	-
Post-operative 6 month	1.075	-
Post-operative 12 month	0.642	-
Post-operative 18 month	-	34% - no pain 66%- pain with movement, out of which 24% had pain at rest and movement

In the literature review, the Knee Society Knee Score has been generally utilised as a decision making criteria or as an assessment tool to find correlation between pre-operative values and post-operative outcomes.^[29,32,34]

However, in our study we have used this Knee Society Knee Score as a benchmarking tool for comparing Pre-and post-operative results of navigation assisted TKA. On statistical analysis, Knee Scores showed significant improvement with 95% CI on 1,6 and 12 months, while at 3 months, the scores were significantly improved with 90% CI. However, with paired t-test, at 95% CI, the comparison of pre operative and post operative (1, 3, 6 and 12 months) knee scores showed significant improvements.

Table 6: KSS in our study

Duration	Mean knee society knee	
	score(out of 100)	
Pre-operative	2.396	
Post-operative 1 month	53.151	
Post-operative 3 month	63.698	
Post-operative 6 month	64.830	
Post-operative 12	82.55	
month		

Table 7: Table Showing Comparison of Function Score in Our Study with Luzo et al. [34]

Duration	Mean Knee Society Function Scores (Out Of 100) In Our Study. N=53	Study By Luzo Et al.[34] N=200
Pre-operative	23.40	44.13
1 month post- operative	38.11	-
3 months post- operative	55.56	-
6 months post- operative	68.30	76.85
12 months post- operative	82.55	-

Although Luzo et.al. followed up a study group of 200 patients at 6 months post operatively with function score and reported the mean to be 76.85

(minimum of 30 and maximum of 100). [34] Before the operation, 97% of the patients presented poor or insufficient functional KSS; after the operation, 77.6% presented good or excellent functional KSS. At 3 and 12 months post operatively, function scores were significantly improved with 95% CI, whereas at 1 and 6 months, the scores showed improvement with 90% CI. However, with paired t-test, at 95% CI, the comparison of pre operative and post operative (1, 3, 6 and 12 months) function scores showed significant improvements.

In our study a gradual, but definitive improvement is noticed throughout, viz, pre-operative, one month, three month, six month and twelve months stage. The study moderately correlates with the study of Luzo et.al. at six months post-operative stage.

Grading was done for Post-operative function scores and compared with the data of Luzo et al:

Table 8: Post Op. Function Score Grading as Compared to the Study Group of Luzo et al [34]

Grading (out of 100)	% of patient study. N= 53	Luzo et al study.N=200		
	6 months 12 month		6 month	
	post- post-		post-	
	operative operative		operative	
Excellent	0	60.37	37.8	
(>84)				
Good (70-84)	47.16	30.18	39.8	
Insufficient	50.94	7.54	12.8	
(60-69)				
Poor (<60)	1.88	1.88	9.7	

Table 9: Showing Comparison of Combined KSS and FS with other studies.

Duration	KS + FS combined(out of 200) In our study, N=53	KS+FS combined (out of 200) Spencer et.al. N= 32	KS+FS combined (out of 200) Decking et.al. N= 27
Pre-operative	25.79	72.3	96.1
Post-operative 1 month	91.26	-	-
Post-operative 3 months	119.25	125.2	-
Post-operative 6months	133.13	149.1	-
Post-operative 12 months	165.10	153.5	176.2

A straight comparison between our study and Luzo et al, reveals no excellent scores in our case while 37.8% patients reported excellent functional KSS. Insufficiencies contributed to about 50% patients in our study, while Luzo et al reported 12.8% patients. The percentages of patients in good category were comparable in both the studies. However, at 12 months, post-operative level, function scores grossly improved yielding 60.37% patients in excellent category, while 30.18% patients reported good outcomes.

Spencer et.al and Decking et.al. followed up patients with Knee Society Knee Score and Knee Society Function Scores combined, i.e. out of 200.^[30,37] we attempted comparison between our data and theirs

Our study presented with a low Pre-operative score (discussed earlier). However, Post-operative scores were highly correlated with the other studies as shown above.

On comparing the component angles with various studies, [28,29,38] following data was obtained:

A comparison of component angles with other published studies revealed very similar outcomes. This implies that, with the ideal orientation of implants via navigation system, clinical outcomes also improve.

Table 10: Showing comparison of Mean Component Angles in our study with other studies.

Angles (mean)	Our study N=53	Zhang et.al. N=32	Chang et.al. N=50	Pang et al N=35
CFA	90.025	90.34	89.54	89.9
SFA	90.425	NA	86.82	89.2
CTA	90.311	90.04	89.61	89.5
STA	88.896	NA	90.17	88.3

Post-operatively, one patient developed wound site infection, presented to us with delayed wound healing and discharging sinus. This was managed with debridement and secondary wound closure, leading to delayed rehabilitation.

One patient reported with knee stiffness and persistent pain on knee bending requiring prolonged physiotherapy support.

No major complications such as infection, deep vein thrombosis or pulmonary embolism were found in either group.

Surgeons' acceptance was high in this study. The software user's interface is friendly. There is no need for an additional technician to be present in the operating room, and the whole procedure can be performed by the conventional operating team. No navigated procedure had to be interrupted.

CONCLUSION

In this prospective study, fifty three patients were operated and followed up for computer assisted TKA at Unique Super Specialty Centre, Indore, M.P., from April 2015 to May 2017. 60.37% excellent and 30.18% good functional outcome along with significant improvements in knee society knee scores and VAS scores was reported. This suggests that computer assisted TKA is a safe, effective and reliable method to alleviate pain and correct deformities in patients with Osteoarthritis of the knee joint. The radiological assessment done Post-operatively confirmed that, CATKA is a significantly accurate tool to correct the deformities.

The advantage of navigation technology is in the potential for precise control of every step of the procedure and the possibility to define landmarks kinematically. The navigation system is a definite aid for optimal alignment and gap balancing during TKA and especially simulation of the ligamentous stability prior to any resection.

The follow-up of the navigated TKA is currently insufficient to know if clinical outcome or survival rates will be improved over long term. Yet, over a minimum follow up period of 12 months we report excellent to good functional outcomes in most of the cases with no revision required and no implant related complications.

Limitations

- 1) The study was observational; thus, it is difficult to apply its conclusions directly to clinical practice.
- 2) We evaluated outcomes after a short duration of follow up, that is, only 12 months. Thus, this study evaluated only correlations.
- We included patients with primary osteo arthritis of knee in our study, excluding deformities caused due to rheumatoid arthritis, Post-traumatic arthritis and extra-articular deformities as well.
- 4) The number of patients included in the present study was less hence the results of the study cannot be extrapolated to the general population.

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