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A Study to Assess Rotational Alignment of Femoral Component & Its Functional Outcome in Computerized Navigated Total Knee Arthroplasty

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ABSTRACT
Osteoarthritis of the knee is a debilitating condition that affects most of the people in the age more than 45 years. After the failure of conservative treatment to contain the pain and function of the limb, total knee Arthroplasty is the only solution that is left. The functional and clinical results of total knee Arthroplasty too depend on the proper alignment of the mechanical axis. So many advances have been done in this field to improve the mechanical axis alignment. In the present study we have evaluated the rotational alignment of femoral component and its functional outcome in computerized navigated total knee Arthroplasty using Knee Society Score and Knee Functional Score.

Key words: Total Knee Arthroplasty, Navigated, Rotational Alignment Of Femoral Component, Knee Society Score

Abbrevations: TKA (Total knee Arthroplasty), FFD (Fixed Flexion Deformity), CFA (coronal Femoral Angle), CTA (Coronal Tibial Angle), SFA (Saggital Femoral Angle), KCS (Knee Clinical Score), KFS (Knee Functional Score), PCA (Posterior Condylar Axis), TEA (Trans Epicondylar Axis)

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I. INTRODUCTION

Arthritis is one of the most frequent debilitating disease in the World, affecting millions of people.[1] Patients with unsalvageable, extremely arthritic, painful, and misshapen knees are being offered Total Knee Replacement Arthroplasty as their final therapy choice.[2,3] The rotational alignment of the femoral and tibial components is critical in determining the functional outcome of Total Knee Arthroplasty.[4] Computer navigation aid has been created to assist surgeons, with the anticipation that such systems will result in better-aligned knee replacements, with the benefits of greater function and longevity.[5] We predicted that in Total Knee Arthroplasty (TKA), optimal femoral component rotational alignment is critical for establishing a balanced knee reconstruction, and that Computerized Navigated Total Knee Arthroplasty will provide a better clinical and

- functional outcome in patients, when rotational alignment is kept within 3-5 degree of external rotation. The present study was conducted to evaluate the functional outcome and rotational alignment of femoral component in computerized navigated total knee Arthroplasty With two main Objectives: 1. To assess the accuracy (in relation to rotational alignment of femoral component) of computerized navigated Total knee Arthroplasty by radiological examination 2. To assess the functional outcome of computerized navigated total knee Arthroplasty clinically by using knee society scores.

II. MATERIALS & METHODS

The present prospective and observational study was conducted in the Department of Orthopaedics, Unique Super Speciality Center, Indore (M.P.) for a period of 12 months. We had included 30 patients undergoing total knee Arthroplasty. The sample size was calculated According to the study done by **Bhandarkar et al (2016)[6] Sample Size, n = N x/((N-1)E2 + x)** Where, N is the population size**,** r is the fraction of responses, margin of error is E for which E = Sqrt[(N - n)x/n(N-1)] & Z is the critical value for

the confidence level c. A Constant of, x = Z(c/100)2 r(100-r). By putting N=20000, r=4.23% and Z=1.96 in the above formula, we obtained a sample size of 63 at the confidence interval of 95%. Due to COVID Pandemic, We could obtain 31 patients for the present study, but for convenience of calculation, we had **finally included 30 patients** in the present study and these were used for final analysis.

Preoperative CT scan (image 2) was done to assess the alignment. The Brainlab Knee Navigation System was used (image 1). Patients were followed-up at 3rd month, 6th month and 12th month after the surgery. Knee Society Score was used for assessment of functional outcome. Serial X-rays were taken for alignment assesment.(image 3) Postoperative CT scan of the knee joint was used for final assessment of the femoral component rotation. (image 2)

III. RESULTS

The mean age of the patients was 65.83 ± 5.31 years with an equal distribution of males and females. Right side involvement was more (66.7%). Varus deformity was seen in 70% of the patients. 93.3% patients underwent total knee Arthroplasty due to osteoarthritis. There was significant improvement in the mean KCS score (table 1, figure 1) and mean KFS score (table 2, figure 2) over a period of 12 months ($p<0.05$). The combined mean KCS + KFS score also showed significant improvement ($p<0.05$) (table 3, figure 3). The rotational alignment of the femoral component (in external rotation) was achieved between 3.0 to 4.2 degree, which was excellent. The rotational alignment of femoral component (in external rotation) was graded as 3.0-3.5; 3.6-4.0 and 4.1-4.5. There were 8 patients in the 3.0-3.5 rotational alignment of femoral component group; 21 patients were in 3.6-4.0 group and 1 patient was in 4.1-4.5 group.

The mean KCS score in the 3.0-3.5 rotational alignment group was 81.25 ± 3.54, in the 3.6-4.0 group the mean KCS score was 79.29 ± 5.54 and in 4.1-4.5 group, the mean KCS was 70.00 ± 0.00. The mean KCS score was higher in the 3.0-3.5 group and least in the 4.1-4.5 rotational alignment of femoral component group. Of the 8 patients in the 3.0-3.5 rotational alignment of femoral component group, 3 (37.5%) patients had excellent outcome and 5 (62.5%) patients had good outcome.

Of the 21 patients in the 3.6-4.0 rotational alignment of femoral component group, 7 (33.3%) patients had excellent outcome and 14 (66.7%) patients had good outcome. The 1 (100%) patients in the 4.1-4.5 rotational alignment of femoral component group had good outcome. (table 4, figure 4) According to KCS score, 33.3% patients had "Excellent" outcome and 66.7% patients had "Good" outcome. The mean KFS score in the 3.0-3.5 rotational alignment group was 86.25 ± 5.18, in the 3.6-4.0 group the mean KFS score was 86.19 ± 4.98 and in 4.1-4.5 group, the mean KFS was 90.00 ± 0.00. The mean KFS score was higher in the 4.1-4.5 group and least in the 3.6-4.0 rotational alignment of femoral component group. Of the 8 patients in the 3.0-3.5 rotational alignment of femoral component group, 5 (62.5%) patients had excellent outcome and 3 (37.5%) patients had good outcome. Of the 21 patients in the 3.6-4.0 rotational alignment of femoral component group, 13 (61.9%) patients had excellent outcome and 8 (38.1%) patients had good outcome. The 1 (100%) patient in the 4.1-4.5 rotational alignment of femoral component group had excellent outcome.(table 5, figure 5) According to KFS, 63.3% patients had "Excellent" outcome and 36.7% patients had "Good" outcome. The KCS score showed excellent results more in males in comparison to the females ($p=0.020$). (image 4,5,6 & images 7,8,9,10 represents findings of examples of CASES 1 & 2 respectively)

Complications such as knee pain (6.7%), superficial infection (6.7%) and serous discharge (3.3%) were seen in our study.

IV. DISCUSSION

The functional results of a good total knee Arthroplasty depend on the correct positioning of the components and soft tissue balancing. Any misbalance leads to pain, restriction of the range of motion, instability and wear along with loosening of the implant. Prior to the advent of computer assisted navigation system, emphasis was placed on the correlation of limb alignment, for which well-designed instrumentation systems were developed which gave reproducible results.[7] Even after the development of many systems, mal-alignment still remains a challenge for the operating surgeon.[8]

The present study was conducted with an aim to assess the results of computer-assisted navigation for the alignment of components – femoral component in the sagittal and coronal plane and rotational alignment in external rotation in patients undergoing total knee Arthroplasty.

Mean age of the patients in our group was 65.83 ± 5.31 years with a range from 56 to 75 years. The mean age was comparable with the age reported in the studies done by **Kim et al (2007)**[10] who reported mean age in their patients to be 67.6

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years with a range from 54 to 83 years, which is comparable to our study. This age strongly correlates with the age at which there is highest prevalence of osteoarthritis. Osteoarthritis onsets between the age of 45-50 years and deterioration are seen by the age 55-60 years. The age group up to 60 years is a productive age and undergoes total knee Arthroplasty and patients with age more than 70 years do not opt for such surgeries due to associated co morbidities which make them unfit for undergoing major surgeries. In our study, there was an equal predominance of gender i.e. 50% each. While the study done by **Hsu et al (2019),**[18] **Wada et al (2016)**[14] and **Kim et al (2018)**[16] reported a female predominance in their studies. Generally, it has been seen that female gender is more prone to having osteoarthritis of knee. The reason being achieving peri menopause or menopause by the age of 45-50 years, leading to hormonal disturbance. Another important aspect is that Indian females prefer squatting position while performing household work.

In the present study, right side was more involved (66.7%) in comparison to the left side (33.3%). Study done by **Luzo et al (2014)**[13] also reported this finding. In general population, majority of the people are having right side dominance and use of right leg for many activities is done. Hence, this could be the probable reason for affection of right side.

In the present study, varus deformity is the most common deformity (70.0%), followed by FFD (20.0%) and least was valgus deformity (10.0%).

Majority of the patients in our study are having osteoarthritis (93.3%) and only 6.7% patients are having rheumatoid arthritis. **Kim et al (2018)**[16] had included all the patients of osteoarthritis in their study. The mean preoperative **KCS score** was 25.60 ± 7.22, at 3 months it was 40.17 ± 8.46, at 6 months it was 66.67 ± 7.35 and at 12 months it was 79.50 ± 5.31. There is a significant improvement in the mean KCS score over a period of 12 months ($p<0.05$).

Most of the literature available has used Knee Society Score for the evaluation of functional outcome.

Kim et al (2018)[16] in their study reported a mean Knee Society Score of 26 (range 17-39) in the navigated TKA group and it improved significantly to 93 (71-100) at the final follow-up. The results of the present study are comparable with the study done by **Kim et al (2018).**[16] (table 6). The mean preoperative KFS score was 36.00 ± 9.59, at 3 months it was 48.67 ± 7.54, at 6 months it was 72.00 ± 5.66 and at 12 months it was 86.33 ± 4.90. There is a statistically significant ($p<0.05$) improvement in the mean KFS score over a period of 12 months in the present study.

Study done by **Luzo et al (2014)**[13] also reported a significant improvement in the KFS score over a period of 6 months. The results of **Luzo et al (2014)**[13] are comparable to the results of the present study. (table 7)

The preoperative **KCS+KFS score** was 61.60 ± 12.16, at 3 months postoperative it was 88.83 ± 11.79, at 6 months postoperative it was 138.67 ± 8.89 and at 12 months postoperative it was 166.17 ± 7.15. There is statistically significant improvement in the mean KCS+KFS score over a period of 12 months. Studies done by **Spencer et al (2007)**[11] and **Decking et al (2007)**[9] also reported a significant improvement in the combined KCS + KFS scores ($p<0.05$). Our results corroborate with the results of these studies. (table 8)

In the present study, 10 (33.3%) patients had excellent final outcome and 20 (66.7%) patients had good outcome according to the KCS score. There was no patient with insufficient or poor outcome. According to KFS, 19 (63.3%) patients had excellent final outcome and 11 (36.7%) patients had good outcome. There was no patient with insufficient or poor outcome.

In the study done by **Luzo et al (2014)**[13] according to KCS score excellent results were seen in 37.8% patients, good results were seen 39.8% patients, insufficiency was seen in 12.8% patients and poor in 9.7% patients. The proportion of excellent outcome was comparable with that of **Luzo et al (2014)**[13], but in our study we obtained a high proportion of good outcome in comparison to their study (table 9). There was no patients with insufficient and poor outcome in the present study. The results of the KCS score were not dependent on the age and the side involved ($p>0.05$), but KCS score was dependent on the gender of the patients ($p=0.020$). Excellent KCS scores were more in males in comparison to the females.

The results of the KFS score were not dependent on the age, gender and the side involved ($p>0.05$). The mean femoral component coronal angle is 89.77 ± 1.11 with a range from 88 to 91.6 degrees. The mean femoral component sagittal angle is 90.21 ± 0.99 with a range from 88.5 to 91.6 degrees. The mean rotational alignment of femoral component (in external rotation) in degree is 3.69 ± 0.29 with a range from 3.0 to 4.2. All the patients were having excellent outcome with regard to rotational alignment of femoral component (in external rotation).

The study done by **Zhang et al (2011)**[12] reported a mean coronal femoral alignment of

90.34 degree. The results of our study are comparable with this study.

In the present study, there were 2 (6.7%) patients with knee pain, 1 (3.3%) patient had serous discharge and 2 (6.7%) patients had superficial infection. There are no major complications seen in our study.

According to the study done by **Vignesh et al (2021)**[17] conducted study using conventional total knee Arthroplasty. The rotation alignment of the femoral component in external rotation, in 60% patients the alignment was between 4-7 degrees, in 30% patients it was 7.1-10 degrees and in 10% patients it was 10.1-13 degrees. The mean femoral component was a mean of 4.5° (range, 2° -6°) internally rotated with reference to TEA when balanced flexion gaps were achieved in this study.

Baier et al (2017)[15] in their study reported that 1.9% of the patients had to undergo revision surgery in the navigated total knee Arthroplasty group in a 11 year follow-up reviewed retrospectively. In our study we did not find any case who underwent revision surgery. This could be due to the fact that the duration of our study is short. (table 10)

V. CONCLUSION

We found that using computer-assisted navigation system for total knee Arthroplasty provided excellent results. The rotational alignment of femoral component in external rotation was found to be excellent. There were no major complications encountered in the present study. We conclude that computer-assisted total knee Arthroplasty should be advised for total knee Arthroplasty, which will provide excellent mechanical axis alignment and accurate rotation alignments, giving extra life to the prosthesis with better clinical and functional outcome.

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Table 1 Comparison of mean KCS score at different follow-ups (N=30)
Paired 't' test applied. P value < 0.05 was taken as statistically significant

Follow-up	No.	KCS [Mean ± SD]	't' value	P value
Preoperative	30	25.60 ± 7.22	-15.254, df=29	0.001*
Postoperative 3 months	30	40.17 ± 8.46		
Postoperative 3 months	30	40.17 ± 8.46	-18.385, df=29	0.001*
Postoperative 6 months	30	66.67 ± 7.35		
Postoperative 6 months	30	66.67 ± 7.35	-10.775, df=29	0.001*
Postoperative 12 months	30	79.50 ± 5.31		

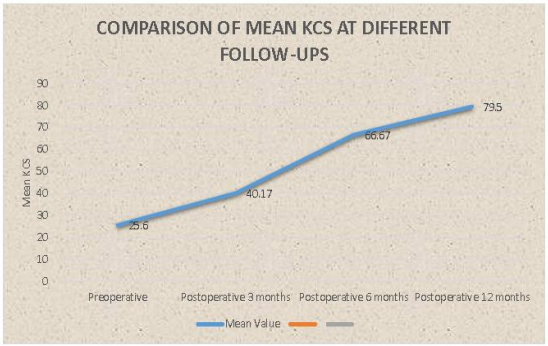

Figure 1: Line diagram showing comparison of mean KCS at different follow-ups

Table 2
Comparison of mean KFS score at different follow-ups (N=30)
Paired 't' test applied. P value < 0.05 was taken as statistically significant

Follow-up	No.	KFS [Mean ± SD]	't' value	P value
Preoperative	30	36.00 ± 9.59	-13.765, df=29	0.001*
Postoperative 3 months	30	48.67 ± 7.54		
Postoperative 3 months	30	48.67 ± 7.54	-14.959, df=29	0.001*
Postoperative 6 months	30	72.00 ± 5.66		
Postoperative 6 months	30	72.00 ± 5.66	-14.198, df=29	0.001*
Postoperative 12 months	30	86.33 ± 4.90		

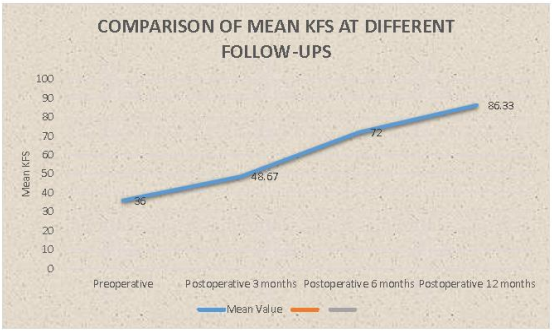

Figure 2: Line diagram showing comparison of mean KFS at different follow-ups

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Table 3
Comparison of mean KCS + KFS score at different follow-ups (N=30)
Paired 't' test applied. P value < 0.05 was taken as statistically significant

Follow-up	No.	KCS+KFS [Mean ± SD]	't' value	P value
Preoperative	30	61.60 ± 12.16	-20.473, df=29	0.001*
Postoperative 3 months	30	88.83 ± 11.79		
Postoperative 3 months	30	88.83 ± 11.79	-23.316, df=29	0.001*
Postoperative 6 months	30	138.67 ± 8.89		
Postoperative 6 months	30	138.67 ± 8.89	-18.923, df=29	0.001*
Postoperative 12 months	30	166.17 ± 7.15		

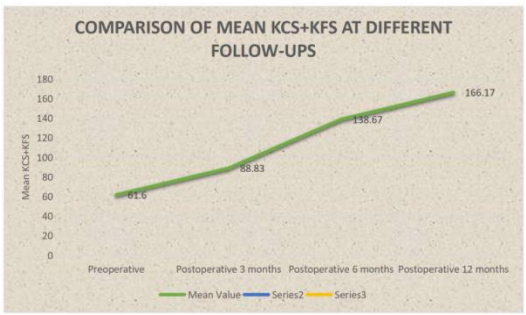

Figure 3: Line diagram showing comparison of mean KCS + KFS at different follow-ups

Table 4
Comparison of KCS in relation to rotational alignment of femoral component (in external rotation) (N=30)

Rotational Alignment of femoral component (in external rotation)	No.	KCS [Mean ± SD]	Excellent	Good
3.0-3.5	8	81.25 ± 3.54	3 (37.5%)	5 (62.5%)
3.6-4.0	21	79.29 ± 5.54	7 (33.3%)	14 (66.7%)
4.1-4.5	1	70.00 ± 0.00	0 (0.0%)	1 (100.0%)

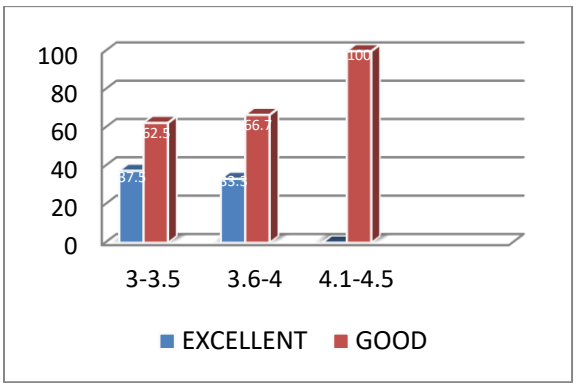

Figure 4: Percentage Of Patients Vs Rotational Alignment Showing Outcomes Of Knee Clinical Score

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Table 5

Comparison of KFS in relation to rotational alignment of femoral component (in external rotation) (N=30)

Rotational Alignment of femoral component (in external rotation)	No.	KFS [Mean ± SD]	Excellent	Good
3.0-3.5	8	86.25 ± 5.18	5 (62.5%)	3 (37.5%)
3.6-4.0	21	86.19 ± 4.98	13 (61.9%)	8 (38.1%)
4.1-4.5	1	90.00 ± 0.00	1 (100.0%)	0 (0.0%)

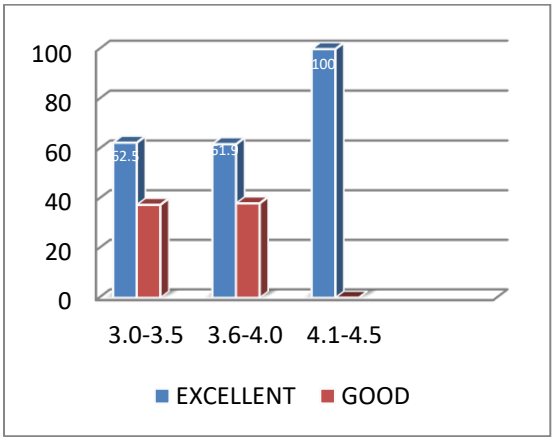

Figure 5: Percentage Of Patients Vs Rotational Alignment Showing Outcomes Of Knee Functional Score

Table 6

Comparison of KSS score in our study with Kim et al (2018)[15]

Duration	Present Study Mean knee society score (out of 100)	Kim et al (2018)
Pre-operative	25.60 ± 7.22	26 (17-39)
Post-operative 3 month	40.17 ± 8.46	
Post-operative 6 month	66.67 ± 7.35	
Post-operative 12 months	79.50 ± 5.31	93 (71-100)

Table 7

Comparison of function score in our study with Luzo et al[12]

Duration	Mean Knee Society Function Scores (Out Of 100) In Our Study N=30	Study by Luzo et al N=200
Pre-operative	36.00 ± 9.59	44.13
3 months post-operative	48.67 ± 7.54	-
6 months post-operative	72.00 ± 5.66	76.85
12 months post-operative	86.33 ± 4.90	-

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Table 8 Comparison of KCS+KFS combined score in our study with Spencer et al (2007)[10] & Decking et al (2007)[8]

Duration	KCS + KFS combined (out of 200) In our study, N=30	KCS+KFS combined (out of 200) Spencer et al N= 32	KCS+KFS combined (out of 200) Decking et al N= 27
Pre-operative	61.60 ± 12.16	72.3	96.1
Post-operative 3 months	88.83 ± 11.79	125.2	-
Post-operative 6 months	138.67 ± 8.89	149.1	-
Post-operative 12 months	166.17 ± 7.15	153.5	176.2

Table 9 Post-operative function score grading as compared to the study group of Luzo et al[12]

Grading (Out of 100)	KCS Score % of Patients in Our Study N = 30	KFS Score % of Patients in Our Study N = 30	% of Patients in Luzo et al study N = 200
Excellent (> 84)	33.3%	63.3%	37.8%
Good (70-84)	66.7%	36.7%	39.8%
Insufficient (60-69)	0.00%	0.0%	12.8%
Poor (<60)	0.00%	0.0%	9.7%

Table 10 Comparison of mean component angles in our study with other studies

Angles (mean)	Our study N=30	Zhang et al N=32	Vignesh et al N=20
CFA	90.02 ± 1.23	90.34	
SFA	90.04 ± 1.07	NA	
Rotational alignment of femoral component (in external rotation)	3.69 ± 0.29		4.5 (range, 2-6)

IMAGE 1
Brainlab Navigation System

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IMAGE 2
Measurements For Rotational Alignment Of Femoral Component

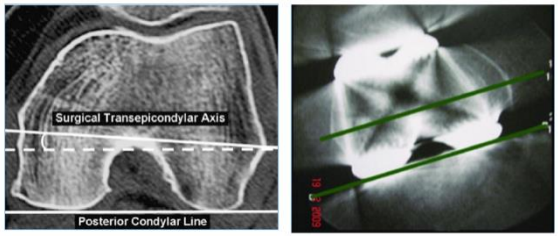

IMAGE 3
Evaluation of the coronal and sagittal alignment of the components

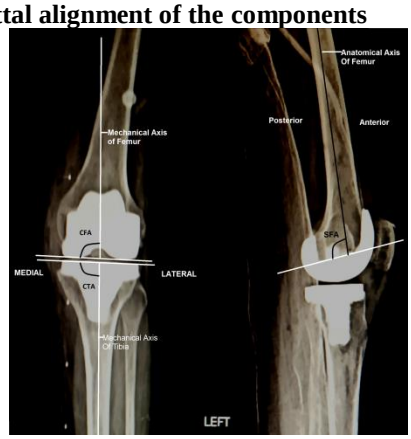

IMAGE 4
CASE 1

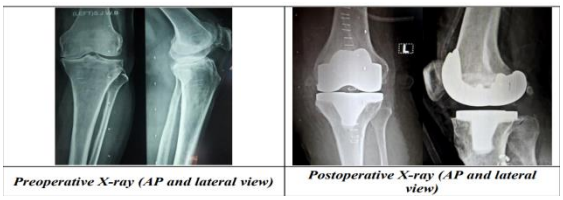

IMAGE 5
CASE 1

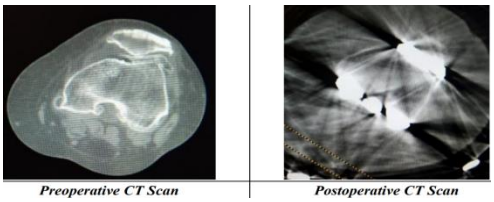

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IMAGE 6
CASE 1


Images Showing Functional outcome 1 Year Post Surgery Follow up

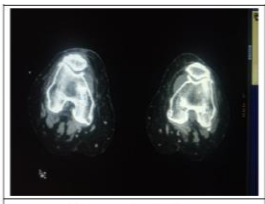
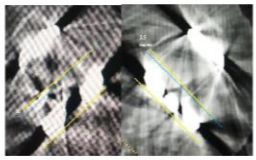
IMAGE 7
CASE 2


Preoperative X-ray (AP view) | *Preoperative X-ray (Lateral view)*

IMAGE 8
CASE 2


Postoperative X-ray (AP view) | *Postoperative X-ray (Lateral view)*

IMAGE 9
CASE 2

Preoperative CT Scan | *Postoperative CT Scan*

IMAGE 10
CASE 2


Functional Outcome