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Original Research Article

A prospective comparative study of functional outcome of 28 mm versus 36 mm femoral head sizes in uncemented total hip arthroplasty

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ABSTRACT

Background: Incidence of dislocation is about 1% to 6% for primary total hip arthroplasty (THA) and 4.8% to 13% for revision THA. The diameter of the femoral head is one of the important variables under the control of a surgeon. Larger heads with modern necks improve the head-to-neck ratio, increase jump distance, reduce component impingement, instability and increase ROM. Objective were to compare the functional outcome of 28 mm versus 36 mm head sizes in uncemented THA in terms of ROM and functional status.
Methods: In this prospective comparative study conducted on 30 patients with 36 diseased hips undergoing primary THA with 28 mm and 36 mm femoral head sizes for degenerative arthritis aged between 20-70 years, in Sanjay Gandhi institute of trauma and orthopaedics, Bangalore from November 2019 to April 2021. All patients were followed up at 6, 12 and 24 weeks postoperatively and assessed for ROM and functional status using modified Harris hip score (HHS).
Results: The flexion was 9.31 degrees, extension was 4.0 degrees, adduction was 3.35 degrees, abduction was 4.31 degrees, internal rotation was 6.13 degrees, external rotation was 9.06 degrees and modified HHS was more in patients who received 36 mm femoral head as compared to the patients who received 28 mm femoral head at the end of follow up.
Conclusions: We conclude that the use of 36 mm femoral head provides better improvement in the range of motion, functional outcome, and better patient and surgeon satisfaction than 28 mm femoral head in THA.

Keywords: 28 mm vs 36 mm femoral head, 36 mm femoral head, Uncemented THA

INTRODUCTION

Total hip replacement arthroplasty is a surgical procedure, which has relieved the incapacitating pain arising from the hip joint in millions of people. THA is a remarkable surgical procedure especially in young patients that provides mobility, stability as well as better quality of life for thousands of patients throughout the world.

THR provides pain reduction and improves physical function and quality of life in most patients with end stage hip osteoarthritis.[1,7] However, Instability and dislocations after THA are the most common complications and will lead to a reduction in the quality of life and are the common cause for revision THA.[1,2] And is a major cause of dissatisfaction for both patients and surgeons.

A dislocation occurs at a rate of 1% to 6% for primary THA.[2-6] Cause of instability and dislocation after THA is multifactorial including those that are patient, surgery, and implant-related. Proper preoperative planning and assessment, attention to surgical detail, and good postoperative care will help in reducing the incidence of dislocations drastically.[1] Large size femoral head has been proposed to be one of the important variables under the surgeon's control that helps in reduction of the risk of instability, dislocation and improve impingement-free range of movements by increasing the jump distance.[1,7-9]

The reported incidence of dislocation from primary THA is 0.6% with 36 mm (large head) and 6.4% with 28 mm (standard head) femoral head size.[9,10] The femoral head size used in THA has remained relatively constant between 2012 and 2015, with 36 mm heads used in approximately 50% of the procedures performed in the USA.[10,11] The Norwegian Arthroplasty Registry found lower dislocation rates using 32-mm heads compared to 28- and 22-mm heads.[11-14]

In a range-of-motion simulation with digitized implants and virtual reality software, Barrack et al found an improvement of 8 degrees of hip flexion when head size was increased from 28 mm to 32 mm.[8,9]

Burroughs et al in an experimental range-of-motion model with head sizes larger than 32 mm, found that impingement between prosthetic components could be largely eliminated with the use of large heads.[6]

Large femoral head THA has shown to provide better hip ROM compared to 28 mm THA, and this is most likely due to a combination of a propitious prosthetic head neck diameter ratio and significantly greater total arcs of motion (approximately 20°), and optimal hip stability.[15,16]

However, some studies found no statistically significant difference in dislocation rates and range of movement between small and large diameter femoral heads.[9,10,17,16]

Since there are ambiguity and contradictions, as well as not many studies were done in India comparing "Small diameter (28 mm) femoral head and large diameter (36 mm) femoral head". We intend to take up the study to compare the influence of the use of both large and small femoral heads on the postoperative stability and range of movements following a primary THA.

Aims and objectives

The aim and objectives of the study were to compare the functional outcome of 28 mm versus 36 mm femoral head sizes in uncemented THA in terms of post operative range of movements (ROM). Post operative functional status with modified HHS. The rate of dislocations post-operatively and to record any complications peri-operatively and in early post-operative period.

METHODS

A prospective comparative cross-sectional study was conducted among 30 patients undergoing Primary Hip Arthroplasty through poster lateral approach, in the department of orthopaedics at Sanjay Gandhi institute of trauma and orthopaedics, Bangalore, from November 2019 to April 2021.

Clearance from the institutional ethics committee was obtained before the study was started. An informed, written and bilingual consent from all the patients was obtained before the study was started.

Sample size

The sample size estimation will be done using the following formula:

$$N= (Z_{\frac{\alpha}{2}} + Z_{1-\beta}{}^2)/d^2$$

Where, n is the sample size, Zα/2=1.96 [For an alpha level of 5%, α=0.05], Z1-β=0.84 [For power of the study at 80%, 1-β=0.80], d is effect size or Cohen's d [d=0.51, a difference of 51% in the functional outcomes (Modified HHSs) between 2 study groups during the post-operative period to yield a statistically significant result], n=30.14

The total sample size for the present study was 30.

The present sample size was divided into 2 groups of 15 patients each.

The inclusion and exclusion criteria were as follows:

Inclusion criteria

All cases undergoing primary total hip replacement in our institute which included patients with age group >18 years of either sex and <70 years. Patient with osteoarthritis hip (primary and secondary) which affects their activities of daily living. X-ray of the patient's hip must show well established arthritic changes. Patient with AVN grade 3 and above with radiological changes of arthritis and patients willing for total hip replacement surgery and giving informed written consent were included in the study.

Exclusion criteria

Patients with failed THA, patients with septic arthritis, patients with neuropathic joints, neurological defects around hip (paralyzed abductors), presence of active foci of infection in the body and patients who are unfit for surgery due to associated medical problems and patients not willing for surgery were excluded from the study.

Patients who satisfied the inclusion criteria were included in the study. They were admitted and examined according to protocol both clinically and radiologically. Routine blood investigations, CRP, ESR, urine routine, Nasal swab for MRSA were done for all the patients. Special attention was paid to CRP and ESR and if these were abnormal, surgeries were deferred.

Trained joint replacement surgeons in the hospital provided the treatment. The patients were evaluated clinically and radiologically before surgery and at 6 weeks, 12 weeks, and 24 weeks postoperatively. All cases were assessed for the range of movements using goniometer, functional outcome by modified HHS and for dislocations

with clinical and radiological evaluation. Each case was followed minimally for 6 months.

Statistical analysis

The data will be entered in MS excel statistical package for social sciences [SPSS] for Windows version 22.0 released 2013. Armonk, NY: IBM Corp., will be used to perform statistical analyses.

Descriptive statistics

Descriptive analysis of all the explanatory and outcome parameters will be done using frequency and proportions for categorical variables, whereas in mean and SD for continuous variables.

Inferential statistics

Chi-square test was used to compare the categorical variables between 28 mm and 36 mm head groups. Mann Whitney and independent

Student t test was used to compare the mean values of continuous variables between 28 mm and 36 mm head groups. The level of significance was set at $p<0.05$.

RESULTS

The 30 patients with 36 hips with different hip conditions were treated with primary THA in the department of orthopaedics, Sanjay Gandhi institute of trauma and orthopaedics, Bangalore from November 2019 to April 2021. Out of 30 patients, maximum patients 9 (30.07%) belonged to the age group between 51-60 years of age, 7 (23.3%) patients belonged to an age group of below 30 years of age, 5 (16.7%) patients belonged to the age group 31-40 years of age, 8 (26.7%) patients belonged to age group of 41-50 years of age and 1 (3.3%) patient belonged to age group of 60 years and above. In our study, the youngest patient was 26 years old and the oldest patient was 65 years old. The mean age at the time of operation was 43.17 years. (Table 1 and Figure 1).

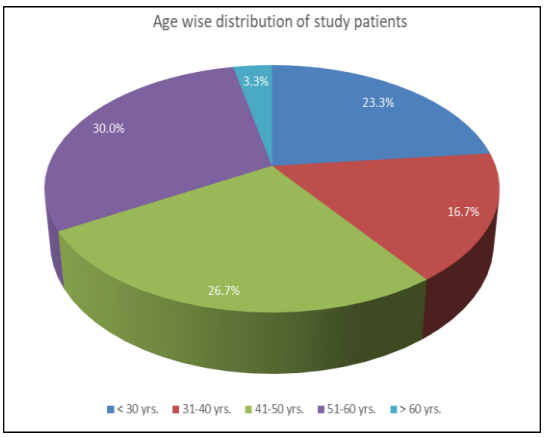

Figure 1: Age distribution.

Table 1: Distribution of femoral head size according to different age groups.

Category	28 mm head		36 mm head		P value
	N	%	N	%	
Age (Years)					
<30	2	16.7	5	27.8	
31-40	3	25.0	2	11.1	
41-50	5	41.7	3	16.7	0.11
51-60	1	8.3	8	44.4	
>60	1	8.3	0	0.	

Note: Comparison of age distribution between 28 mm and 36 mm head groups using Chi square test.

Out of 30 patients in our study, 17 (56.7%) were males and 13 (43.3%) were females, thus showing male preponderance (Figure 2).

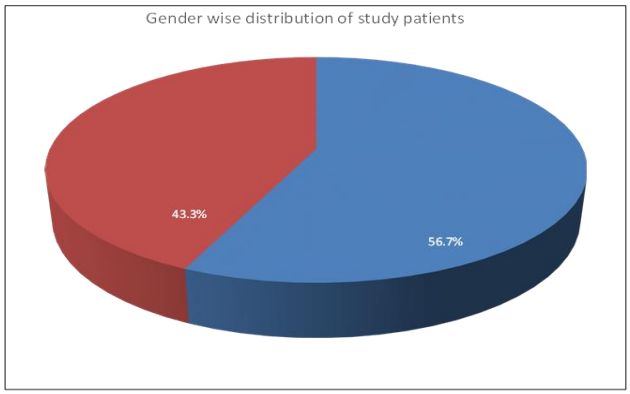

Figure 2: Gender distribution.

A thorough clinical and radiological examination was performed. All the patients were prepared and operated once the general condition was stable and the patient was fit for surgery. Out of 36 hips in our study, we have used implants from I ndus in 25 hips (2.8%), Smith and Nephew in 4 hips (13.33%), max Meril in 30 hips (83.33%) and PS medica in 1 hip (2.8%). All patients operated through a postero-lateral approach with meticulous posterior capsular and soft tissue repair. The average surgical time was 1/2 hours. The 24 (66.7%) hips operated under combined spinal-epidural anaesthesia, 11 (30.6%) hips were operated under spinal anaesthesia only and 1 (2.8%) hip suffering from ankylosing spondylitis was operated under general anaesthesia. In our study groups, no intra-operative complications were noted. Two patients from 36 mm head size group developed lengthening of the operated limb and 1 patients from 28 mm head size group developed shortening of the operated limb, which was treated with shoe-rise on the shorter side. Two patients (1 from each group) developed a superficial wound infection (SWI) which were treated with superficial wound debridement and extended the antibiotic course (Table 2). In our study 8.38 days was mean stay in the hospital for the patients with 28 mm femoral head THA and 8.30 days for the patients with 36 mm femoral head THA and there was no statistical significance with p=0.88

(Table 3). A statistically significant difference in the range of motion in all planes and modified HHS was noted in 36 mm femoral head THA group as compared to 28 mm femoral head THA. The flexion was 9.31 degrees, extension was 4.0 degrees, adduction was 3.35 degrees, abduction was 4.31 degrees, internal rotation was 6.13 degrees and external rotation was 9.06 degrees more in patients who received 36 mm femoral head as compared to the patients who received 28 mm femoral head at the end of follow up. In our study of 36 hips in 30 patients who had undergone primary THA. We have found that hips with the 36 femoral head had a range of abduction of 5.75 degrees, 5.4 degrees and 4.31 degrees more compared to 28 mm femoral head at 6 weeks, 12 weeks and 24 weeks follow-up respectively with statistically significant p=0.005 at the end of follow up. In our study of 36 hips in 30 patients who had undergone primary THA. We have found that hips with the 36 femoral head had a range of internal rotation of 6.06 degrees, 6.25 and 6.12 degrees more compared to 28 mm

femoral head at 6 weeks, 12 weeks and 24 weeks follow up respectively with statistically significant p<0.001 at the end of follow up. In our study of 36 hips in 30 patients who had undergone primary THA. We have found that hips with the 36 femoral head had a range of external rotation of 8.31^0 8.75 degrees and 9.06 degrees more compared to 28 mm femoral head at 6 weeks, 12 weeks and 24 weeks follow-up respectively with statistically significant p<0.001 at the end of follow up (Table 4).

The modified HHS was 8.54 more in patients who received 36mm femoral head as compared to the patients who received 28 mm femoral head at the end of follow up. A statistically significant difference in modified HHS was noted in 36 mm femoral head THA group as compared to 28 mm femoral head THA with same acetabular shell size. The modified HHS was 9.17 and 4.40 with acetabular shell size 50 and 52 respectively more in patients who received 36 mm femoral head as compared to the patients who received 28 mm femoral head at the end of follow. However, we have not seen any dislocations in either of the groups during our study period.

Table 2: Intra-operative and post-operative complications.

Variables	Category	28 mm head		36 mm head		P value
		N	%	N	%	
Intra-op complications	Nil	16	100	20	100	
Post-op complications	Shortening 1 cm	1	6.3	0	0.0	0.41
	Lengthening 1 cm	0	0.0	2	10	
	Superficial skin infection	1	6.3	1	5	
	Nil	14	87.5	17	85.0	

Note: Comparison of intra-op and post-op complications between 28 mm and 36 mm head groups using Chi square test.

Table 3: Duration of hospital stay in days.

Parameters	Head size	N	Mean	SD	Mean difference	P value
Hospital stays	28 mm head	16	8.38	1.78	0.08	0.88
	36 mm head	20	8.30	1.17		

Note: Comparison of mean length of hospital stay (in days) between 2 groups using independent student t test

Table 4: Comparison of mean flexion, extension, adduction, abduction, internal and external rotation between 2 groups.

Variables	Time (Weeks)	Groups (mm head)	N	Mean	SD	Mean diff.	P value
Comparison of mean flexion between 2 groups at different time intervals using independent student t test	6	28	16	87.19	7.3	-9.31	<0.001*
		36	20	96.5	5.87		
	12	28	16	90.63	4.43	-10.63	<0.001*
		36	20	101.25	4.55		
	24	28	16	92.19	6.57	-9.31	<0.001*
		36	20	101.5	4.62		
Comparison of mean extension between 2 groups at different time intervals using independent student t test	6	28	16	6.88	4.03	-4.13	<0.001*
		36	20	11	2.05		
	12	28	16	7.5	3.16	-4	<0.001*
		36	20	11.5	2.35		
	24	28	16	7.5	3.16	-4	<0.001*
		36	20	11.5	2.35		

Continued.

Variables	Time (Weeks)	Groups (mm head)	N	Mean	SD	Mean diff.	P value
Comparison of mean adduction between 2 groups at different time intervals using independent student t test	6	28	16	23.13	5.44	-4.88	0.002*
		36	20	28	2.99		
	12	28	16	24.38	4.79	-3.98	0.005*
		36	20	28.35	3.03		
	24	28	16	25	5.48	-3.35	0.02*
		36	20	28.35	3.03		
Comparison of mean abduction between 2 groups at different time intervals using independent student t test	6	28	16	32.5	4.83	-5.75	<0.001*
		36	20	38.25	2.45		
	12	28	16	33.13	4.43	-5.38	<0.001*
		36	20	38.5	2.35		
	24	28	16	33.44	4.73	-4.31	0.005*
		36	20	37.75	3.8		
Comparison of mean internal rotation between 2 groups at different time intervals using independent student t test	6	28	16	20.94	4.91	-6.06	<0.001*
		36	20	27	3.4		
	12	28	16	21.25	4.65	-6.25	<0.001*
		36	20	27.5	3.03		
	24	28	16	21.88	5.12	-6.13	<0.001*
		36	20	28	4.1		
Comparison of mean external rotation between 2 groups at different time intervals using independent student t test	6	28	16	27.19	5.15	-8.31	<0.001*
		36	20	35.5	3.94		
	12	28	16	28.75	5.63	-8.75	<0.001*
		36	20	37.5	3.44		
	24	28	16	28.44	6.25	-9.06	<0.001*
		36	20	37.5	3.44		

Table 5: Comparison of mean modified HHS's between 2 groups at different time intervals, and mean modified HHS scores at difference time intervals between different femoral head size for 50 acetabular shell size.

Variables	Time (Weeks)	Groups (mm head)	N	Mean	SD	Mean diff.	P value
Comparison of mean modified HHS between 2 groups at different time intervals	6	28 head	16	39.06	2.86	-7.24	<0.001*
		36 head	20	46.3	3.21		
	12	28 head	16	59.25	2.35	-8.65	<0.001*
		36 head	20	67.9	2.55		
	24	28 head	16	84.31	4.08	-8.54	<0.001*
		36 head	20	92.85	2.11		
Comparison of mean modified HHS scores at diff. time intervals b/w different femoral head size for 50 acetabular shell size	6	28	3	37	3.61	-8.83	0.003*
		36	6	45.83	2.32		
	12	28	3	59	3	-8.67	0.001*
		36	6	67.67	1.51		
	24	28	3	83.67	4.04	-9.17	0.003*
		36	6	92.83	2.32		

DISCUSSION

A prospective comparative cross-sectional study was conducted on 30 patients with 36 hips treated with primary THA for different hip conditions aged between 20-70 years during study period from November 2019 to April 2021 by the trained surgeons through poster-lateral approach with meticulous repair of short external rotators, posterior capsule and soft tissue structures in the department of orthopaedics, Sanjay Gandhi institute of trauma and orthopaedics, Bangalore. Out of 30 patients included in the study, 17 (56.7%) were males and 13 (43.3%) were females with a mean age of 43 years at the time of surgery.

In our study, a statistically significant difference in the range of motion in all planes and modified HHS was noted in 36 mm femoral head THA group as compared to 28 mm femoral head THA. The flexion was 9.31 degrees, extension was 4.0 degrees, adduction was 3.35 degrees, abduction was 4.31 degrees, internal rotation was 6.13 degrees and external rotation was 9.06 degrees more in patients who received 36 mm femoral head as compared to the patients who received 28mm femoral head at the end of follow up.

The modified HHS was 8.54 more in patients who received

36 mm femoral head as compared to the patients who received 28 mm femoral head at the end of follow up. A statistically significant difference in modified HHS was noted in 36 mm femoral head THA group as compared to 28 mm femoral head THA with same acetabular shell size. The modified HHS was 9.17 and 4.40 with acetabular shell size 50 and 52 respectively more in patients who received 36 mm femoral head as compared to the patients who received 28mm femoral head at the end of follow up.

However, we have not seen any dislocations in either of the groups for which we think the credit goes to the experience of the operating surgeons, improved posterior capsule and soft tissue repair and the use of elevated acetabular liners.

Singh et al conducted a retrospective study on head size and dislocation rate in primary hip arthroplasty and followed 317 primary THA's performed in 281 patients between January 2006 and December 2009 with 36 mm (group A) and 28 mm (group B) diameter femoral head through postero-lateral approach.[10,11] Their study showed that there was no statistically significant difference in the average range of motion between the two groups. However, in group A, there was 1 dislocation out of a total of 163 (rate of dislocation0.6%) whereas in group B there were 10 dislocations out of 154 hips (rate of dislocation 6.4%).

Howie et al conducted a randomized control trial study of 644 patients from September 2001 to June 2007 and found the incidence of dislocation within one year after primary hip arthroplasty was 5 times lower in patients with 36 mm articulation (0.8%) than in those with 28 mm articulation (4.4%).[18]

Amlie et al conducted a retrospective cohort study in 2572 primary THA's performed through posterolateral approach with a 28 mm or 32 mm diameter femoral head in the period of study from February 2002 to July 2009. They found dislocation in 49 hips (3.1%) with 28 mm femoral head and in 4 hips (0.4%) with a 32 mm femoral head.[3]

However, Magee et al conducted a retrospective study on effect of femoral head diameter on risk of dislocation after primary hip arthroplasty and followed 527 total hip arthroplasties in 469 patients between January 2001 to August 2010 with femoral head sizes ranging from 28 to 44 mm performed by a single surgeon (Aaron A Hofmann) in department of orthopaedics at University of Utah, USA using posterior approach in all patients. The patients were followed at defined intervals but there was found no statistically significant association between the risk of dislocation and femoral head size.[1]

Min Wokim et al conducted a study involving 543 patients who underwent primary THA and revision hip arthroplasty using the postero-lateral approach in the author's hospital from January 2000 to December 2014 and were followed for a minimum of 6 months. Primary hip arthroplasty was performed in 407 cases and revision hip arthroplasty was performed on 136 patients. A 28-mm diameter femoral head was used in 367 cases and femoral heads size larger than 32 mm were used in 176 cases. Dislocation occurred in 36 hips (9.8%) in the 28- mm head size group and 16 hips (9.1%) in the group with greater than 32-mm head size which they also found statistically insignificant. They concluded that patient-related risk factors have a greater impact on dislocations rather than head size. Recent trend changing towards the use of large femoral heads as American joint replacement registry (3rd) 2016 annual report data shows that femoral head size of 36 mm has remained relatively constant between 2012 and 2015, and was used in approximately 50% of the total hip arthroplasties performed because of increased stability with large femoral heads.[3,10,11]

Lavigne et al conducted a cohort study between February 2006 and May 2007 on 165 patients undergoing primary THA through posterior approach under age of <65 years and found that LDH-THA offers better hip ROM compared to 28 mm THA, which is most likely due to a combination of a favourable prosthetic head neck diameter ratio and optimal hip stability and significantly greater total arcs of motion (approximately 20°), mostly due to an increase of hip flexion and external rotation.

Sultan et al demonstrated that there was an average was an increase of 8.1° in the amount of IR needed to cause posterior dislocation in patients with 32 mm head when compared with patients receiving a 28-mm head and Similarly in the group of patients receiving the 32-mm head, average 8.9° increase in the amount of IR was necessary to cause posterior dislocation.[20]

Burroughs et al conducted an in vitro experimental study in orthopedic biomechanics and biomaterials laboratory, Massachusetts general, hospital, Boston, Mass in 2002 and studied the effect of larger femoral head sizes for THA on the type of impingement, range of motion (ROM), and joint stability using an anatomic full-size hip model (anatomic Goniometer) and a novel anatomic dislocation simulator with 28, 32, 38, and 44 mm femoral heads.[6] They observed that the 38-mm and 44-mm head virtually eliminate component to component impingement. Whereas, component to component impingement occurred in 60% of all cases tested with the 28-mm head and 47% of the cases tested with the 32-mm head. Femoral heads of 38-mm and 44-mm had an advantage in pure flexion of about 120 versus the 28-mm head with a skirt, and advantage of about 70 versus the 32-mm head with a skirt. And an increase in femoral-head size led to an increase in the amount of translation required to produce a dislocation (jump distance).[13,15]

Barrack et al in a ROM simulation with digitized implants and virtual reality software, found an improvement of 8 degrees of hip flexion when head size was increased from 28 to 32.[8] Whereas, Bartz et al reported only very small gains in movement before impingement when the head size increased from 22 to 28 mm and no significant increase

between 28- and 32-mm heads.[21] However, Amstutz et al reported an improvement in ROM with a 32 mm diameter head compared to a 22 mm diameter design due to a greater head-neck ratio (1.98 vs 1.74).

Hammerberg et al conducted a prospective study on 94 uncemented primary total hip arthroplasties in 84 patients (47 men and 37 women) operated through posterior approach in 2003 with average age of 65.1±9.8 years and mean follow up of 3.6±0.7 years and found that there was no statistical difference in range of motion in relation to head size between 28-mm, 32- mm, and 38-mm, 44-mm. However, they also found that there was no difference in linear wear with increasing femoral head size.[23]

Cho et al from department of orthopaedic surgery, Daegu catholic university college of medicine, Korea did a review study on using large femoral heads in THA in 2016 and their study showed femoral head sizes larger than 32 mm offer multiple advantages in physical function and activity levels of patients by improving hip stability, decreasing dislocations rates, increasing range of motion (ROM).[11]

Limitations

The limitation of the study is the small sample size. A larger randomised controlled study should be designed and conducted.

CONCLUSION

Based on our experience and results, we conclude that THA is an excellent procedure in the management of most of the end-stage diseases of the hip joint. The 36 mm femoral heads in total hip replacement can be used with an advantage of better improvement in the arc of motion hence better functional outcome and better patient and surgeon satisfaction as compared to use of conventional/standard femoral heads in THA. The postero-lateral approach is a safe and effective approach for THA. As we already know that cause for dislocation after THA is multifactorial. But dislocations after primary THA can be reduced significantly with operating surgeon's experience, meticulous posterior capsular and soft tissue repair along with the use of elevated acetabular liners. However, because of short period of study and less number of subjects longer study is required to make definitive conclusions.

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Ethical approval: The study was approved by the institutional ethics committee

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APPENDIX

Case 1 (right 36 mm and left 28 mm head)

X-rays

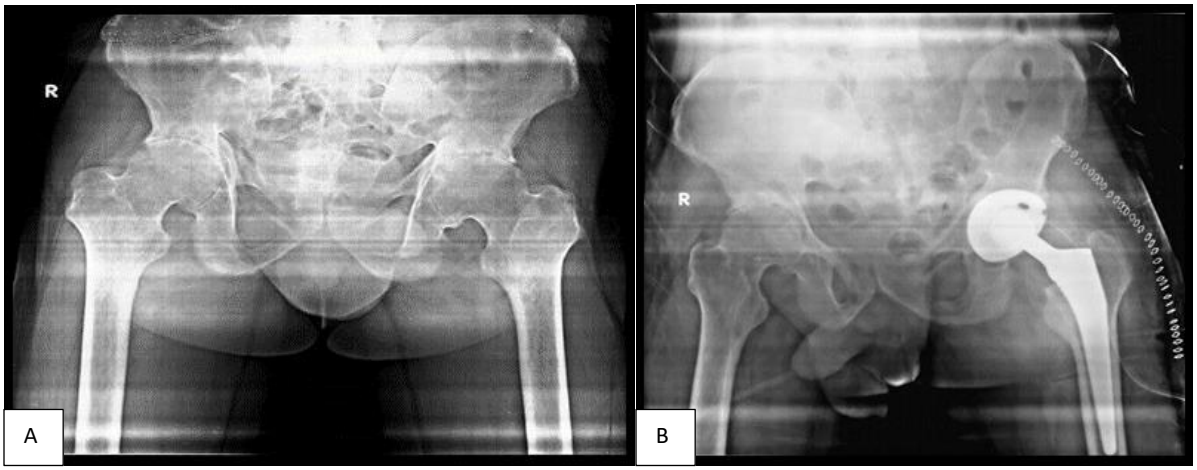

Figure 1 (A and B): Pre-op and immediate post op.

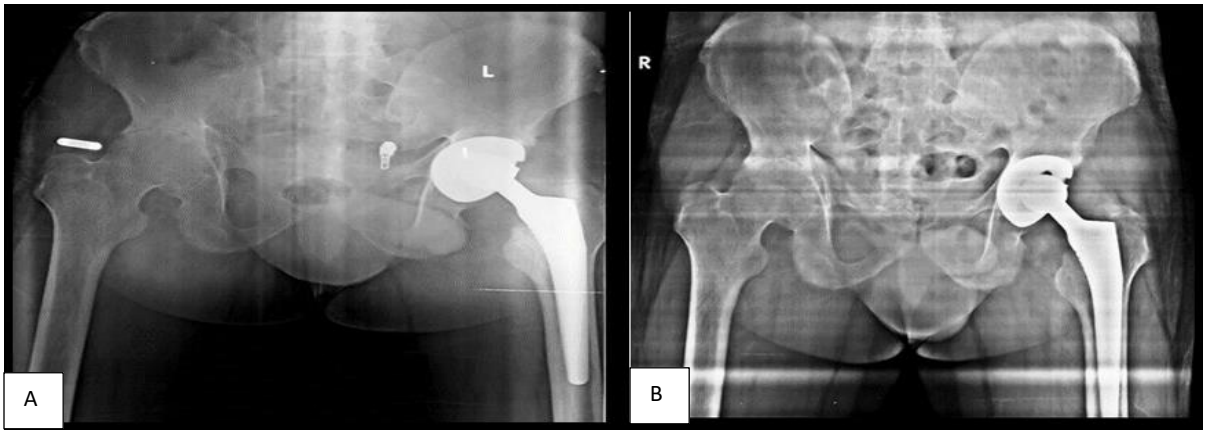

Figure 2 (A and B): 6 weeks post op and 12 weeks post op.

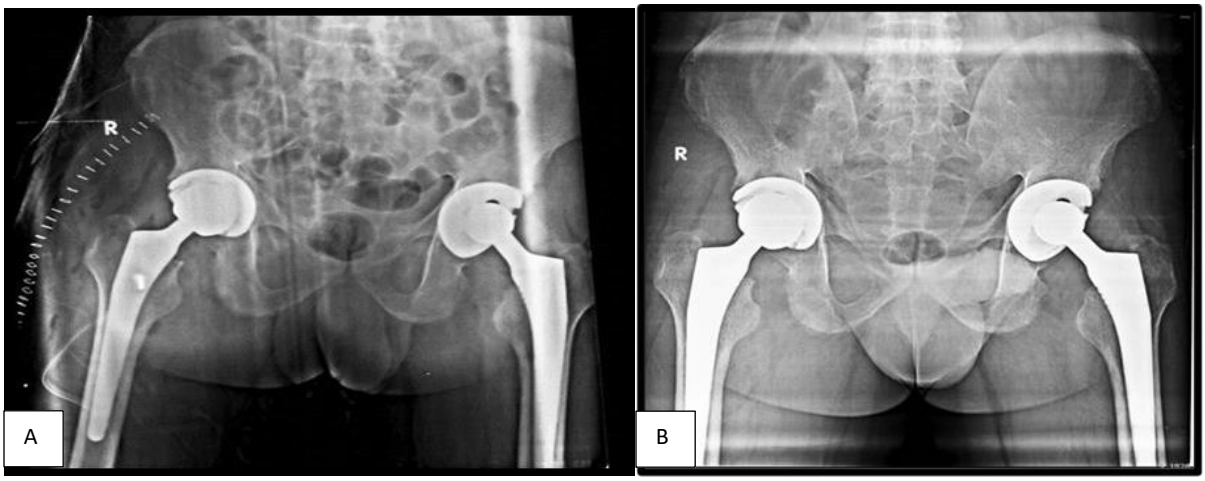

Figure 3 (A and B): Immediate post op (Rt) 24 weeks (Lt) 24 weeks (Rt) 48 weeks (Lt).

Clinical photos

Figure 4 (A-C): standing, SLRT right and SLRT left.

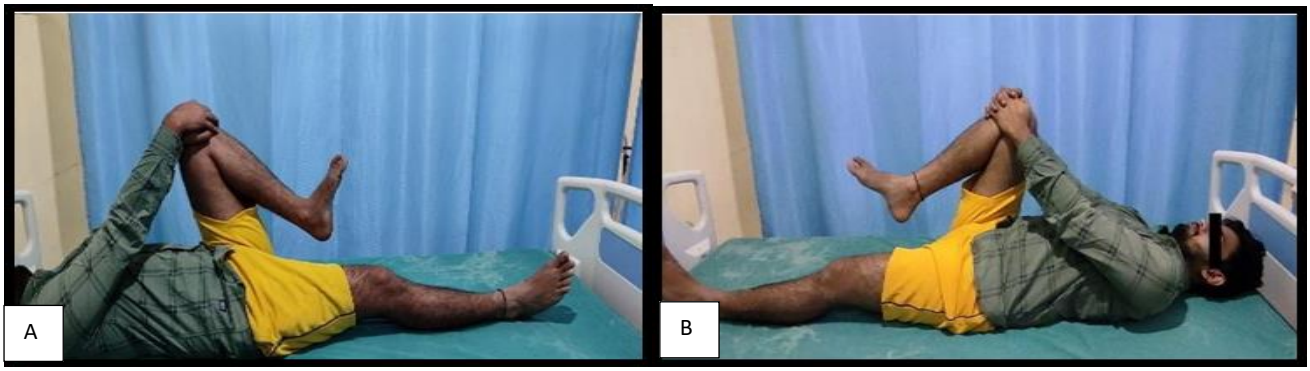

Figure 5 (A and B): Flexion left and right.

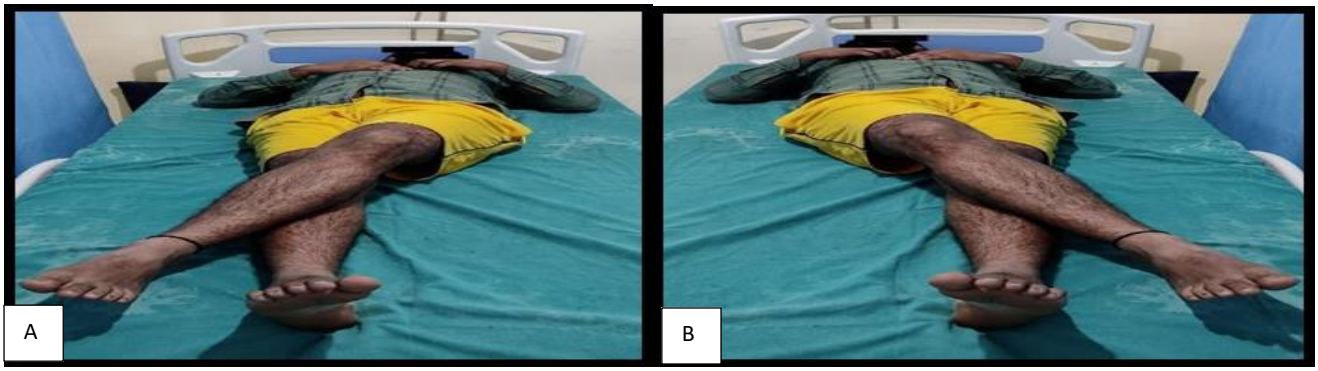

Figure 6 (A and B): Adduction left and right.

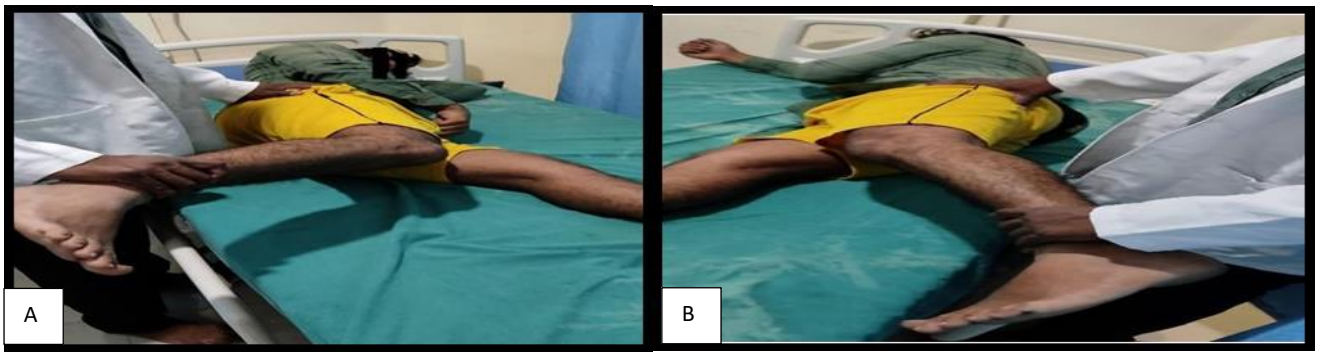

Figure 7 (A and B): Extension right and left.

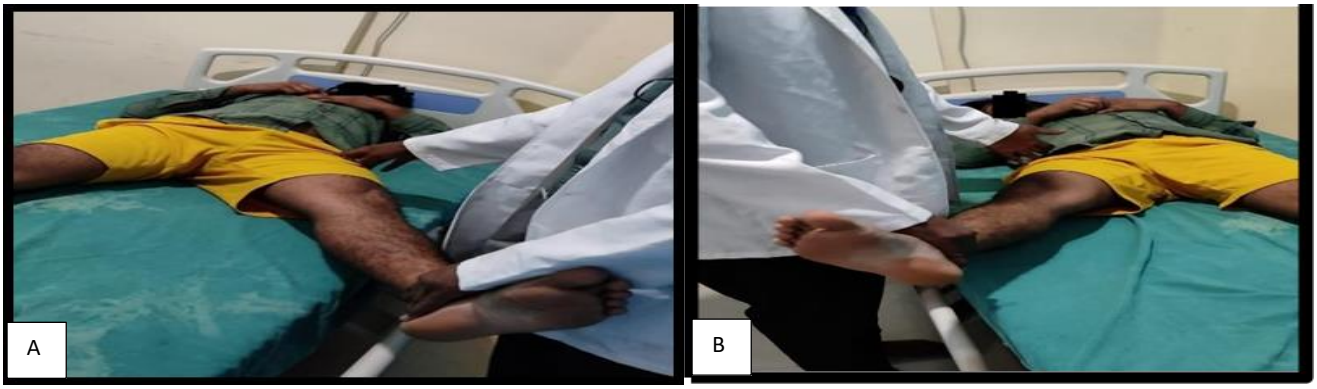

Figure 8 (A and B): Abduction left and right.

Figure 9 (A and B): External rotation and internal rotation.