

Study on Association between Outcome of Dynamic Hip Screw Fixation in Intertrochanteric Fracture with Lateral Femoral Wall Thickness.

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I. INTRODUCTION

Trochanteric fracture are common in the elderly people. The frequency of this fracture has increased primarily due to the increasing life span and more sedentary life style brought on by urbanization and osteoporosis¹. Trochanteric fractures occur in the younger population due to high velocity trauma, where as in the elderly population it is most often due to trivial trauma.

Incidence of intertrochanteric fracture is rising because of increasing number of senior citizens with osteoporosis. By 2040 the incidence of intertrochanteric fracture is estimated to be doubled².

The trochanteric fracture can be managed by conservative method and there is usually union of the fracture. If suitable precautions are not taken the fracture undergoes malunion, leading to varus and external rotation deformity at the fracture site and shortening and limitation of hip movements³. It is also associated with complications of prolonged immobilization like bedsore, deep vein thrombosis and respiratory infection. So aim of treatment should be prevention of malunion and early mobilization. Taking all the factors into consideration surgery by internal fixation of the fracture is ideal choice.

There are various forms of internal fixation device used for trochanteric fracture. The most commonly used device is the Dynamic hip screw (DHS) with side plate assemblies. This is a collapsible fixation device which permits the proximal fragments to collapse or settle on the fixation device, seeking its own position of stability. The stability of Dynamic hip screw mainly depend on fracture pattern, osteoporosis, location of screw in femoral head and lateral femoral wall integrity⁴.

Significantly increased reoperation rate have been reported in patient who sustained postoperative lateral wall fracture (PLWF)⁵. The cause of post-operative lateral wall fracture are believed to be intra operative reaming and implant insertion through the base of this often delicate lateral wall⁶. The risk factors of post-operative lateral wall fracture have been shown to be advanced subtype of fracture classification and thinner lateral wall.

The presence of an intact lateral wall is especially important in fracture with an already comminuted posteromedial wall. It has been seen that here presence of lateral wall does not prevent excessive collapse in all case.

Pre-operative or post-operative fracture of the lateral femoral wall is the predictor for a reoperation after intertrochanteric fracture treated with dynamic hip screw.

Previous studies have shown that when the pre-operative thickness of lateral wall was less than 20.55⁷ mm the chance of post-operative lateral wall fracture is very high when fixed with dynamic hip screw alone.

Preoperative or postoperative fracture of the lateral femoral wall is the main predictor for a reoperation after an intertrochanteric fracture treated by Dynamic hip screw.

Tip apex distance (TAD) should be less than 25mm to prevent DHS cut out or failure.⁸ Which most often happens if the screw is placed too anterior or too superior. The tip apex distance is the sum of the distance from the tip of the screw to



apex of the femoral head on anterior-posterior and lateral view.

Pain following intertrochanteric fracture has been associated with delirium, depression, sleep disturbance and decreased response to intervention for other disease states. Therefore, it is important to treat and manage complaints of pain adequately during acute treatment of intertrochanteric fracture. Poorly managed postoperative pain is associated with delayed ambulation, pulmonary and urinary complications. So, patients are pre operatively managed with systemic analgesia and lower limb traction. Intraoperatively managed with nerve block. Post operatively managed with systemic analgesia, nerve block, early physical therapy.⁹

The importance of the integrity of the lateral femoral wall is increasingly being recognised in the treatment of intertrochanteric fracture (ITF). Previously, the condition of the posteromedial portion was regarded as the most important prognostic factor in the outcome of fixation using a dynamic hip screw (DHS), but recently it has been demonstrated that integrity of the lateral wall is essential for successful results. Little consideration has been given to postoperative fracture of the lateral wall, although it has been reported that it takes place in 21% of ITF following fixation in the presence of an initially intact lateral wall, with 22% of these patients undergoing re-operation, and the remainder experiencing a protracted healing period and excessive shortening¹⁰. The identification of patients at risk of a secondary lateral wall fracture would greatly improve the outcome of DHS treatment. Thickness of the lateral wall is a simple and quantifiable parameter for intra-operative evaluation of the anatomical structure. Biomechanical studies have shown that the resistance to deforming force increases with thickening of cortical bone. In this study, we investigated the reliability of lateral wall thickness as a predictor of lateral wall fracture after DHS implantation and also the functional outcome of patients.

AIMS AND OBJECTIVES

- 1) To determine intraoperatively the lateral femoral wall thickness among the study subject.
- To find out association between outcome of DHS fixation and lateral wall thickness clinically among the study subjects.
- To find out association between outcome of DHS fixation and lateral wall thickness radiologically among the study subjects.

ANATOMY OF PROXIMAL FEMUR

The femur is the longest and strongest bone of body and like all long bones consists of a shaft and two ends. It articulates at its upper end with the hip bone and at its lower end with both the patella and the tibia. The upper end of the femur comprises a head, a neck, a greater trochanter and lesser trochanter. The fracture between the greater and lesser trochanter called intertrochanteric fracture.¹¹

The greater trochanter large is quadrangular laterally positioned. The upper posterior margin overhangs the trochanteric fossa. The greater trochanter provides insertion for most of the muscles of gluteal region. The upper border of the greater trochanter gives insertion to the piriformis and the medial surface to the common tendon of obturator internus and two gemelli. The gluteus minimus is inserted into the rough impression on its anterior surface. The gluteus medious is inserted into the oblique and flattened strip on its lateral surface. The area behind the insertion is covered by the deep fibres of gluteus maximus with the trochanteric bursa interposed. The trochanteric fossa receives the insertion of the obturator externus.

The lesser trochanter is a conical eminence, which projects medially and backwards from the shaft at its junction with lower and posterior part of the neck. It gives attachment to the psoas major on its summit and iliacus at its base.





BLOOD SUPPLY VASCULAR ANASTOMOSIS OF PROXIMAL FEMUR¹³

A : Trochanteric anastomosis -

1- Superior gluteal artery.

2- Ascending brunch of lateral circumflex artery.

3- Ascending brunch of MCFA.

B : Cruciate anastomosis -

1 – Inferior gluteal artery.

2 – Ascending brunch of 1st perforator artery.





CLASSIFICATION¹⁴

AO Classification of trochanteric fracture

3 – femur

- **3** 1 proximal end segment.
- 1. 3 1 A 1 Simple pertrochanteric fracture

a) 3 1 A 1 . 1 – Isolated single trochanter fracture

- b) 3 1 A 1 . 2 2 part fracture
- c) 31A1.3 Lateral wall intact (> 20.5 mm)

2. 3 1 A 2 - Multifragmentory per trochanteric lateral wall incompetent < 20.5 mm

a) 31 A 2.2 – with 1 intermediate fragment.

- b) 3 1 A 2 .3 with 2 or more intermediate fragment.
- 3.31 A 3 Intertrochanteric (reverse oblique).
- a) 31 A 3.1 Simple oblique.
- b) 3 1 A 3 .2 Simple transverse .
- c) 3 1 A 3 .3 Wedge or multifragmentary





BOYD AND GRIFFIN CLASSIFICATION :

- Type | Type − || Type – ||| Type - |V





EVAN CLASSIFICATION : Evan type - | (stable) Evan type - ||(unstable)

Evans Classification



IMPLICATION OF FRACTURE ANATOMY¹⁵

The degree of fracture comminution directly affects the stability. Less the comminution, the more resistance is offered to the deforming forces by enhancing compression and shear resistance response. Unstable intertrochanteric fracture has four main fragments: the proximal neck, the greater trochanter, the lesser trochanter



and the proximal femoral shaft. Analysis of their pattern may help in improving fixation stability. A large posterior and posteromedial void is present; only a fragile lateral wall survives which is an extension of the femoral shaft. With breakage of this frail lateral wall the intertrochanteric fracture resembles a sub trochanteric type; this unnecessary transformation should be prevented. Lateral wall plays a major role in stabilizing and fixing an unstable intertrochanteric fracture, as it serves as a support for axial rotational and varus stability of the proximal fragments when it interlocks after impaction. Gerard et al .¹⁶ Evaluated experimental lateral wall damage and concluded that care should be taken to avoid breaking the lateral wall when drilling at its base during fracture fixation. Lateral wall fracture may occur during or after surgery. If it occurs, collapse and a long period of disability will follow. This collapse is the main contributor to postoperative morbidity¹⁷.

In fixation of a hip fracture, bone must support load: the greater this support, the lesser the load on the implant. In a comminuted fracture, stresses on the implant are greater because the bone does not support any load. Similarly, an implant bears more stresses in an intertrochanteric than in an intracapsular fixation because of the greater bending effect of hip joint forces.



Three segments along the fixation device deserve particular attention: the proximal fixation within the femoral head, the midsegment, and the distal fixation at the lateral trochanteric wall or intramedullary area. The ability to maintain reduction in these three parts is the key to unimpaired fracture healing. Furthermore. controlled fracture impaction should be provided by the fixation system to adjust for bone resorption because the more unstable a fracture is, the more ability to control impaction is required. Initially, the fracture's anatomy, the number of fragments, and the remaining bone stock determine its stability. Appropriate reduction can lower this instability, and fracture compression will further enhance stability. However, bone damage at the fracture site during or after surgery could produce secondary fracture instability.

DYNAMIC HIP SCREW

The dynamic hip screw (SHS) is a unique implant. It facilitates application of compression across the fracture line at the time of surgery; it also acts as a rail on which axial movement is feasible to achieve impaction of the fracture fragments with the passage of time. It is strong enough to withstand large bending loads and also protects the fixation against disruptive torque transmitted by the shaft in internal or external rotation. 'Dynamic' action of SHS results in reduced incidence of cut-out and of penetration of the nail into the hip joint, as opposed to static devices.³

The dynamic hip screw has two major components: a plate with a barreland a screw.

The screw has a wide shaft with coarse threads at one end. The screw shaft is hollow and narrower than the threaded end. The inside of the opposite end of the shaft has a fine thread, which facilitates application of controlled compression to the fracture; this is achieved by setting a distinctive screw

Two designs of lag screws are prevalent. In keyed dynamic hip screw system, the lag screw is captured within the plate barrel so that the screw can slide along the barrel but cannot rotate. This



mechanism theoretically maximizes the rotational stability of the femoral head and neck compared to a non-keyed system in which the lag screw can rotate within the plate barrel. Use of a keyed dynamic hip screw system, however, requires that the lag screw be oriented so that the plate can be properly positioned along the femoral shaft. The second component of a SHS is a bone plate with a barrel attached at an angle. Plate-barrel implants with angle varying between 130° and 150° are obtainable but the one with an angle between 135° and 140° is often used. The screw shaft fits the barrel of the plate and moves freely within it.



The ratio of the length of the screw within the barrel to that projecting out of the barrel also affects the ease of sliding (Fig. 6-7B). The shorter the length of the screw outside the barrel, the easier the sliding. Optimal sliding results when the tip of the screw shaft is within 1 cm or less of the platebarrel junction.

Barrels are available in standard and short lengths. A standard barrel is 38 mm long

while a short barrel measures 25 mm. A screw in barrel should be able to slide at least 10 mm to minimize the risk of fixation failure. When a fracture is stabilized with less than 10 mm of available slide. A short barrel plate is recommended when the length of inserted lag screw is 85 mm or less.¹⁵





Lag screw	Barrel			
Thread diameter	12.5 mmStandard	1	38	
mm				
Angle 135, 140	,145, 150			
Thread length	22 mm	Short	25	
mm				
Shaft diameter	8 mm	Angle	135	
Recommendation	S			
SHS dimension:				
Thread length 22	mm			
•Standard barrel	length: 38 mm			
•Recommended	sliding length 2	5 mm (min 1	0
mm)				
•Total length 22	+ 38 + 25=85 mm	L		
		1		

•The standard barrel should be used with screws 85 mm or longer

Short barrel for screws 80 mm and shorter.

II.

The coarse threaded tip of the screw should ideally lie in the central sector of the

a)Y. Gotfried¹⁸, MD conducted a study in

2004 on attenuation of the lateral trochanteric wall,

femoral head in AP and lateral X-rays. Superior and anterior sector placement is always avoided as the screw is likely to cut out from these locations. The tip of the screw should lie 5–10 mm under the subchondral bone.

The barrel is installed through a channel in the lateral femoral cortex and the screw shaft freely enters the barrel. The plate should fit the shaft without stress and is attached to it with at least four screws engaging eight cortices. The fracture should be compressed by setting a special small-diameter screw in the barrel end of the SHS after fixing the plate. The screw should be twisted to engage the fine threads inside the hollow shaft of the SHS to exert an outward pull. SHS compression screw is 36 mm long and has a hexagonal socket to fit the large hexagonal screwdriver. It is applied to achieve final fracture impaction or to maintain achieved compression intraoperatively





A Key Element in the Reconstruction of unstable Per trochanteric hip fracture evaluation of twenty four patients were included in the study : 22

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women and two men, with a median age of 74 years (range , 56 - 92 years). All patients had a period of severe post-operative disability until fracture healing.

Fracture of the lateral wall resulted in collapse in all cases. Radiologically, before the operation all fractures had an intact lateral wall. However, at follow up. The lateral wall was broken at the barrel drilling site of the compression hip screw/ dynamic hip screw, and had migrated proximally. The femoral head and neck had collapsed and the lag screw protruded laterally.

After proper statistical analysis of the finding they concluded that in all patients fracture of the lateral wall, which was intact preoperatively, was responsible for this complication. Therefore, maintaining the integrity of this structure should be a major objective in all surgical stabilization procedures for unstable pertrochanteric fractures.

b)Hsu et al.⁴ in 2013 in their study on lateral femoral wall thickness did a retrospective study on 208 patients treated with DHS and barrel plate. The results showed that fracture of the lateral wall occurred in 42 patients (20%). They found that lateral wall thickness was a reliable predictor of post-operative lateral wall fracture with a threshold value of 20.5 mm being a reliable predictor for secondary lateral wall fracture. From this they suggest that treatment with a DHS is not advisable in the presence of a lateral wall thickness is a reliable predictor of post – operative lateral wall fracture; and 3) Intertrochanteric fracture with a lateral wall thickness < 20.5mm should not be treated with a DHS alone.

c)Henrik Palm, MD et al.⁶ in 2017 - in their study on Integrity of the Lateral Femoral Wall in Intertrochanteric Hip Fractures: An Important Predictor of a reoperation. Evaluation of only 3% (five) of 168 patients with an intact lateral femoral wall post operatively underwent reoperation with six months, whereas 22% (ten) of forty - six patients with a fractured lateral femoral wall were operated on again. After proper statistical analysis of their finding they conclude that a post-operative fracture of the lateral femoral wall was found to be the main predictor for a reoperation after an Intertrochanteric fracture. Consequently, we concluded that patients with pre-operative or intraoperative fracture of the lateral femoral wall are not treated adequately with a sliding compression hip screw device, and

Intertrochanteric fractures should therefore be classified according to the integrity of the lateral femoral wall, especially in randomized trials comparing fracture implants.

d)Cheng – En Hsu et al.⁵ conclude a study in 2015 on attenuation of Trochanter stabilizing plate improves treatment outcomes in AO/OTA 31 - A2 intertrochanteric fractures with critical thin femoral lateral walls. Evaluation of in 205 patients who were treated with DHS alone. The risk factor found to be associated with PLWF was utilized to include 171 patients who were at high risk of PLWF. After proper statistical analysis of the their finding they conclude that lateral wall thickness is the main risk factor post-operative lateral wall fracture in A2 fractures treated by DHS fixation. Use of TSP in A2 fractures with critically thin lateral wall thickness of < 2.24 cm can significantly decrease the lag screw sliding distances, postoperative lateral wall fracture rate, and reoperation rate.

e) Sreejith KP et al.⁷ conclude a study in 2017 on attenuation of A Comparative Study to Assess the Preoperative Thickness of Lateral Trochanteric Wall as a Predictor of Postoperative Lateral Wall Fracture in Intertrochanteric Fracture Treated by Dynamic Hip Screw. A Radiograph based Comparative study involved 66 patients with intertrochanteric fracture treated by dynamic hip screw fixation. All patients had an intact lateral wall preoperatively and were AO/OTA 31 A1 and AO/OTA 31 A2 fractures. The mean thickness of trochanteric wall in 39 patients with A1 fracture was 27.5 mm (SD=7.17) whereas the mean thickness in A2 type fracture (27 cases) was 17.3 mm (SD=4.88).74.07% of patients with A2 type fracture developed a fracture of the lateral wall whereas only 15.38% of A1 type fracture had a fracture of lateral wall after a six months follow-up. When the lateral wall thickness is less than 20.55 mm there is significantly high chance of lateral wall getting fractured if fixed with a DHS alone.

f)Annur R. Pradeep KP ¹⁶et al. concluded in a study in 2018 on attenuation of Intraoperative lateral wall fractures during Dynamic Hip Screw fixation for intertrochanteric fractures-Incidence, causative factors and clinical outcome. The intact lateral wall plays a key role in stabilization of trochanteric fracture. Hence extreme precaution should be taken to prevent lateral wall damage during DHS fixation. This study was aimed at



evaluating the determinants of lateral wall fracture and its effect on outcome in intertrochanteric fracture femur treated with DHS. 34 (19.5%) patients had lateral wall fractures. Medialization was found in 22 out of these 34 (64.7%) patients. The mean preoperative lateral wall thickness of these patients is 19.2 mm, compared with 26.8 mm in patients with intact lateral wall (p < 0.001). Lateral wall thickness was a reliable predictor of intra operative lateral wall fracture during DHS fixation and nailing was a good option especially when lateral wall thickness is <21 mm.

g)Rakesh Kumar et al¹⁹. concluded in a study in 2015 on attenuation of THE ROLE OF LATERAL FEMORAL WALL THICKNESS IN INTERTROCHANTERIC FRACTURE. Total 48 patients (30 male & 18 female) Jan 2012 to Dec 2013. The incidence of post-operative lat. wall fracture was significantly higher in A2 fracture then in A1 fracture. The fracture of lateral wall occured in 9 patients (20%). The mean preoperative lat. wall facture was 2cm compared with 2.8cm in 39 patients without lat. Wall thickness of 22 A1 facture was 3mm which was significantly thicker than the mean of 22 mm found 26 A2 facture.

h)Dr.Kurapathi Rajesh et al.²⁰ concluded in a study in 2018 on attenuation of Assessment of lateral femoral wall thickness as a measure to predict postoperative lateral femoral wall fractures in intertrochanteric fractures treated with Dynamic Hip Screw. Thirty, intertrochanteric fractures of AO31A1 and AO31A2 type were enrolled. The mean age group is 64.3 years among which mostly were males (53%). Most of the patients (60%) had fractures on the left side of which (86%) sustained injury due to trivial fall. Out of 30 cases 12 cases (40%) were AO31A1type and 18 cases (60%) were AO31A2 type. The mean thickness was 27.9mm in AO31A1 group and 21.4mm in AO31A2 group. AO31A1 (40%) and AO31A2 (43%) achieved normal radiological union within 6 months postoperatively without any lateral femoral wall fractures in the postoperative period.The conclusion of this study is Preoperative assessment of lateral femoral wall thickness is a useful measure to predict postoperative lateral femoral wall fractures in intertrochanteric fractures treated with DHS. From this study, it is recommended that a preoperative lateral femoral wall thickness of less than 22.1 mm is the critical value below which the

lateral femoral wall fracture can occur when fixed with DHS alone.

I)Rubio-Avila et al. ²¹concluded in a study in 2013 on attenuation of Tip to apex distance in femoral intertrochanteric fractures: a systematic review. Seventeen studies were eligible for this review, four of which were included in combined analysis of dichotomous outcomes and seven in combined analysis of continuous outcomes. Patients with TAD > 25 mm had a significantly greater risk of cut-out than patients with TAD < 25 mm (RR = 12.71).

j)Pradyumna R. et al.²² concluded in a study in 2017 on attenuation of a prospective comparative study in the clinical outcome of trochanteric and subtrochanteric fracture femur with proximal femoral nail versus dynamic hip screw. A prospective study of 50 patients with intertrochanteric and subtrochanteric fracture among which 30 were treated with Proximal Femoral Nail and 20 with Dynamic Hip Screw. This study concluded that fractures of the trochanteric region of the femur need a proper selection of implant based on fracture pattern. DHS has excellent results when used on stable fractures. For unstable fractures, PFN is the implant of choice. In case of subtrochanteric fractures PFN has better results in both stable and unstable fractures compared to DHS with less failure rates and restoring better hip biomechanics.

MATERIALS AND METHODS

- <u>Study population:</u> The patients who were included in the study were comprised of people from various part of west Bengal especially from Kolkata and surrounding districts. They belonged to the any age group.
- <u>Inclusion</u> criteria –Patient with AO/ OTA 31 A1 (A1) and AO/OTA 31 – A2 (A2) – intertrochanteric fracture medically fit to undergo surgery
- Exclusion criteria :

a)Non traumatic fracture
b)Previous fracture in intertrochanteric region.
c)Fixation other than DHS.
d)Partial fracture reduction TAD > 25 mm

- <u>Study period</u> : 1 yr.
- <u>Sample size</u>: 30



- <u>Sample design:</u> convenience sampling
- <u>Study design</u>: Prospective study.

III. METHODOLOGY

1- <u>Preoperative evaluation :</u>

a)Before the surgery , a pre – operative assessment was done of the planned DHS patient. Pre – operative X-ray both hip + upper $\frac{1}{2}$ femur – anterior - posterior view + lateral X-ray of the injured hip in neutral position were taken for all patients assessed for categorization as per AO / OTA classification

b) Detailed history taking and clinical examination were done to assess comorbidity of the patient – smoking, diabetes, hypertension, heart disease, kidney disease, chronic obstructive pulmonary disease, cardio vascular disease or any other systemic pathology

2- Consent and counselling

A detailed discussion regarding the operative procedure of dynamic hip screw and its probable

complication and informed consent was taken from patient. Patient was also counselled for postoperative rehabilitation protocol.

3-pre operative investigations

Investigations after taking written informed consent a) X - Ray both Hip + Upper ½ of femur AP view (neutral position)

b) Blood for = Hb%, TC, DC, ESR,

Na+, k+

Urea,Creatinine,PT/INR Liver function test, Lipid profile, FBS/PPBS, HIV,

HBsAg, HCV, chest x ray, electrocardiogram, Echocardiography.

4-<u>Intraoperative estimation of lateral wall thickness</u> Fracture fixation was done in a conventional manner using a DHS according to the manufacture's instruction on a fracture table under fluoroscopic control. No other fixation device was used except for the DHS and barrel plate.



In this procedure, after exposure of the proximal guide wire insertion site, a guide wire was slowly progressed under fluoroscopic control up to the fracture site using a 135-degree angle guide with power drill. The angle guide was taken out and another identical guide wire kept adjacent to the previously inserted guide wire, was measured on scale in millimeter and it was taken as lateral femoral wall thickness in millimeter.

5- operative procedure²³

A) Patient was placed supine and spinal anesthesia was given. Placed firmly in fracture table and raising contralateral leg up 90 degree used thigh holder. The extremity was scrubbed with savlon and betadine, painted with antiseptic solution (Betadine 10%) and draping with hip isolation drape. A second-generationcephalosporin antibiotics (cefuroxime) was routinely given intravenously (after proper sensitivity testing) just prior to making incision and repeated 6 hours after completion of surgery



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b) exposure :

A straight lateral incision was made two finger beneath below the vastus ridge to the point 5 -7 cm distally.



Dissected down to the iliotibial band then incise the fascia lata and placed a retractor to retract the vastus lateralis anteriorly.



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C) placement of guide wire and measurement

Used image intensification to confirm the placement of 135-degree DHS angle guide pin under image intensification. The must be lie along the axis of the femoral neck and center of the femoral head in both anterior-posterior and lateral views. DHS angle guide pin is stop to reach the fracture site and measured the lateral wall thickness from the entry point. Another anteversion guide pin is placed parallel to the DHS guide pin.

d) Measurement of lag screw

Slide the direct measurement device (DMD) over the guide pin to determine the guide pin insertion depth. Calculate the reaming depth, tapping depth and lag screw length subtract 10 mm from the DMD reading

E) Method of fixation

The lag screw placement was done in center to the femoral head in both anterior-posterior and lateral view in image intensification. Place the DHS

Barrel plate and fixed to the femur with 4.5 mm cortical screw

F) Closure

Thorough lavage was done with normal saline and closes with layer

5)Post-operative rehabilitation

All the exercise – a) Static quadriceps drill

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b) Hamstring drillc) Bed side knee bendingd) Ankle range of motion exercisee) Walk with walking frame

Were resumed after 48 -72 hours of operation under supervision of physiotherapist. All patient were mobilized according to comorbidity of the patient and surgeon choice. Post operatively walk with a walking frame or crutches. 1st dressing was changed on day -3 of the operation and stitches off on day -14 after operation in their first follow up visit. Patient was follow up at the interval of 2weeks, 1 month, 2 month, 3 month and 6month.

6) Outcome measurement method

a) Clinical evaluation:-

Follow up was based on axial alignment, range of motion, joint stability and muscle atrophy, local finding, gait, stance, limb length discrepancy and subjective symptom.

b) Functional evaluation:-

Results obtain at follow up was by means of Short form -36 (SF-36) score and Visual analogue scale (VAS)

1) Short form -36 :-The SF-36 has eight scaled score, the score was weighted sums of the questions in each section. Score range form 0 - 100, Low score – more disability, High score – less disability.

Section:- Vitality, Physical functioning, Bodily pain, General health perception, Physical role



functioning, Emotional role functioning, Social role functioning, Mental health.

2) Visual analogue scale:-

The visual analogue scale (VAS) is commonly used as the outcome measure for such studies. It is usually presented as a 100-mm horizontal line on which the patient's pain intensity is represented by a point between the extremes of "no pain at all" and "worst pain imaginable." Its simplicity, reliability, and validity, as well as its ratio scale properties, make the VAS the optimal tool for describing pain severity or intensity. Absolute values of pain on a 0–10 scale naturally grouped into three categories: 1–4 (mild pain), 5 or 6 (moderate pain) and 7–10 (severe pain).

c) Radiological evaluation

Post-operative x-ray was taken (x-ray both hip + upper ½ femur) with both the lower limb in neutral position on operative day. Follow up at 1 month, 2 month, 3 month and 6 month also include lateral radiography of the affected hip in addition to the AP view for assessment of the TAD and screw collapse. The following step were taken

- Femoral head centre located on AP and Lateral x –ray. Line joining it to the centre of femoral neck width was extended to cut the head articular surface at the apex.
- 2) Distance between the tip of the Richard screw to the apex of the femoral head was measured in both AP and Lateral view, summed get the TAD
- 3) Any difference in TAD and angle between initial and subsequent x-rays was taken as measurement of migration of screw inside the head
- 4) The difference in length of Richard screw as measured from the end of DHS barrel plate up to the tip of screw in initial and subsequent xrays was taken as amount of collapse.

IV. RESULTS AND ANALYSIS

All data for patients were collected and tabulated in a master chart in Microsoft Office Excel 2016 Spreadsheet. Statistical analysis was done using IBM SPSS ver. 25. The quantitative data were tested for normality using Shapiro-Wilk test. Severe collapse was defined as greater than 2 cm of post op collapse. The critical value of Lateral Wall Thickness for predicting severe collapse at 6 months post op was found using ROC curve analysis and using Youden's index. Mean and Standard deviation of normal variables were calculated and compared among the AO subtypes using ANOVA with pairwise test and between lateral wall thickness more than and less than the critical value using student's unpaired t-test. Median and interquartile range for non-normal data were calculated and compared among AO subtypes as well as lateral wall thickness groups using Kruskal-Wallis test. All qualitative data were compared between the groups using chi-square test. Pearson correlation was calculated using lateral wall thickness as independent predictor of Post-op collapse, VAS score reduction and SF-36 score at each follow up. Mixed model analysis using repeated measures compound symmetry with time as fixed effect was done for comparing post op collapse and sf-36 scores among the AO subtypes. Serial correlation of post op collapse and sf-36 score was calculated by repeated measures correlation.

Statistical significance was defined at P<.05.

I. Demographic data

a. **Age:** age was found to follow normal distribution according to Shapiro-Wilk test (Fig. 1). Minimum age was 45 years and maximum 92 years. Maximum no of patients belonged to 60-70 years age.





Figure 1 Histogram and normal plot for age in years

Table 1. mean and standard deviation of age in males and females.								
Sex	count	Mean(years)	Standard	95%LCL	95%UCL	P-value		
			deviation(years)					
female	18	72.2	12.2	66.2	78.3	0.24		
male	12	67.7	8.7	62.2	73.2			
total	30	70.4	11.1	66.3	73.5			

able 1. mean and standard deviation o	of age	in male	s and	females
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The average age was 70.4±11.1 years with females (72.2± 12.2) and males (67.7±8.7) having no significant difference in unpaired t-test(P>0.05). (table 1, fig2)





Figure 2 box plot of age in females and males

AO classification	Count	Mean(years)	Standard Deviation	Lower 95% CL Mean	Upper 95% CL Mean	P- value
1.3	15	68.3	7.5	64.1	72.4	0.23
2.2	6	67.5	16.6	50	85	
2.3	9	75.9	10.8	67.6	84.2	
Total	30	70.4	11	66.3	74.5	

Table 2	mean	age	among	the		subtypes
I able 2	mean	age	among	une	AU	sublybes

There was no significant difference in age among the AO groups in one-way ANOVA test allowing for unequal variances. (p>0.05).(table 2, figure 3).





Figure 3 box plot of age among the AO subtypes

Degree of collapse	Count	Mean	Standard Deviation	Lower 95% CL Mean	Upper 95% CL Mean	p-value
mild	4	65.3	4.1	58.7	71.8	0.13
moderate	12	72.9	10.2	66.5	79.4	
severe	14	69.7	12.8	62.3	77.1	

Table 3 comparison of age in the different degree of collapse groups

An ANOVA test assuming unequal variances showed no difference in average age between patients with mild, moderate or severe post op collapse(p>.05). (table 3, figure 4).





Figure 4 box plot of age in the collapse groups

b. Sex: there were 18 females and 12 males in the study. (table 3, figure4)							
Sex	Count	Percentage					
Female(f)	18	60.0%					
Male(m)	12	40.0%					
Grand Total	30	100.0%					

).	Sex: there w	vere 18 females	and 12 males	in the study.	(table 3, figure4)
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Table 4 Sex distribution in study group





Figure 5 pie -chart of sex distribution

AO classification	Sex		Total	P value
	f	m		
1.3	7	8	15	0.27
2.2	5	1	6	
2.3	6	3	9	
Total	18	12	30	

Table 5 distribution of males and	females among the AO	subgroups
-----------------------------------	----------------------	-----------

There was no significant difference (p>0.05) in the distribution of males and females among the AO subgroups. (Table 5).

c. Side of injury:14 patients had fracture on left side and 16 patients on right side. (table 6, figure 6)

radie o blae of milar, m me patients		Table	6	side	of	in	jury	in	the	patients
--------------------------------------	--	-------	---	------	----	----	------	----	-----	----------

Side	Count
Left(lt)	14
Right(rt)	16
Grand Total	30





Figure 6 pie chart showing side of injury

d. **Mode of injury:**80% of patients had domestic fall and 20% sustained road traffic accident. (table 7, figure7)

rable / mode of injury in the patients				
Mode of injury	Count			
domestic fall	24			
RTA	6			
Grand Total	30			





Figure 7pie chart showing mode of injury



Comorbidities: 13 patients had 2 or more comorbidities while 4 had none. Most of the patients had e. hypertension and diabetes mellitus. (Table 8)

Disease	count
Diabetes mellitus	11
hypertension	22
anaemia	1
hypothyroid	4
Coronary artery disease	1
Pulmonary obstructive disease	1
none	4

Table 8 count of patient's coexisting medical condition

f. Smoking or alcohol addiction: 17% of patients had history of smoking or alcoholism. (Table 9, figure 8).

Table 9 count of patients with addiction history					
Smoking/alcohol intake Count					
No	25				
yes	5				
Grand Total	30				



Figure 8 pie-chart showing count of addiction

II. Operative and fracture characteristic:

a. AO subtype of fracture: 15 cases were of AO31A1.3, 6 of 2.2 and 9 of 2.3 subtypes. (Table 10, Figure 9)

AO Subtype	Count	Percentage	
1.3	15	50%	
2.2	6	20%	
2.3	9	30%	
Grand Total	30	100%	

Table 10 count of AO subtypes





Figure 9 Pie chart of distribution of AO subtypes

b. **Date of operation from injury date**: average time to surgery was 7.5±7 days from day of injury and ranged from 0 to 31 days. (Table 11, figure 10).

Table 11 mean time to surgery nominifury								
Mean(days)	Standard Deviation	Lower Mean	95%	CL	Upper Mean	95%	CL	
7.5	7	4.9			10.1			

Table 11 mean time to surgery from injury







c. **Type of reduction**: most (83%) of the patients went closed reduction of the fracture. Only one patient went DimonHugston osteotomy. (Table 12, figure 11). Most of the patients who

required open reduction belonged to 2.3 AO subtype or had operation later than 5 days from injury.

Table 12. type of reduction done.					
Type of reduction	Count				
closed	25				
DimonHugston	1				
open	4				
Grand Total	30				

Table 12. type of reduction done.





Figure 11 pie -chart of type of reduction applied

d. Lateral wall thickness: Shapiro-Wilk test showed normal distribution of Lateral wall thickness. (Figure 12)





AO classification vs Lateral wall thickness: the average lateral wall thickness was 20.1±4.7 mm. the lateral wall thickness was compared among the AO subtypes using one -way ANOVA with equal

variance and the result was significant(p<0.001). pairwise test showed significant difference between all the subtypes. (Table 13, figure 13).

AO subtype	Count	Mean(mm)	Standard Deviation	Lower95%CL Mean	Upper95%CL Mean	P value
1.3	15	23.5	3.5	21.6	25.5	<.001



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2.2	6	16.3	2.7	13.5	19.2	
2.3	9	16.8	3.1	14.4	19.1	
Total	30	20.1	4.7	18.3	21.8	



Figure 13 Box plot of lateral wall thickness vs AO classification.

e. **Tip-Apex distance:** Shapiro-Wilk test showed normality assumption was valid for this variable. (Figure 14).





Figure 14. Histogram and Normality plot for Tip-apex distance

All patients had TAD<25mm with range from10 mm to 24 mm. the mean TAD was 16.4±3.3 mm with 95% LCL= 15.1mm and 95% UCL=17.6mm.



Pre-operative VAS score: this variable did not satisfy normality. (Figure 15) a.

Figure 15 histogram and normality plot for pre op VAS

The median score was 8.5 with minimum score 6, maximum score 10 and IQR=2.3. Pre-op VAS vs AO subtype: Kruskal Wallis test showed no significant difference in pre op VAS score among the AO subtypes(p>.05).(table 14, figure 16).

AO subtype	Median	Minimum	Maximum	Interquartile Range
1.3	9	6	10	1
2.2	7.5	6	10	1.8

Table 14 me	dian nra or	score among	۸0	cubtypec
Table 14 me	and pre of	b score among	AU	subtypes

III.

Pain score:



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b. Post-op VAS score: it was normally distributed. (Figure 17)





Figure 17.histogram and normal plot for post op VAS

Mean post op VAS score was 3 ± 1.9 . the post op VAS score was not significantly different between those who underwent closed or open reduction (Table 15, figure 18).

type of reduction	Count	Mean	Standard Deviation	Lower 95% CL Mean	Upper 95% CL Mean	P value
closed	25	2.9	1.9	2.1	3.7	0.59
DimonHugston	1	5				
open	4	3	2.4	-0.9	6.9	
Total	30	3	1.9	2.3	3.7	

Table 15. post op VAS in closed and open reduction groups





Figure 18. box plot of post op VAS vs reduction method

One-way ANOVA showed no significant difference in post op VAS score between the AO subtypes. (Table 16, figure 19)

AO subtype	Count	Mean	Standard Deviation	Lower 95% CL Mean	Upper 95% CL Mean	P value			
1.3	15	6.2	1.8	5.2	7.2	0.23			
2.2	6	4.2	1.7	2.4	6				
2.3	9	4.4	1.4	3.3	5.5				
Total	30	5.3	1.9	4.6	6				

Table 16	post op	VAS in	AO	subtypes
----------	---------	--------	----	----------







Post op vs pre-op VAS score: there was weakly positive correlation between post op and pre op VAS score which was significant (Pearson r=0.41,

p=0.02). paired t test showed significant difference(p<.001) in pre and post op VAS scores (Figure 20).







There was moderate negative correlation between post op VAS and lateral wall thickness (Pearson r=-.52) which was found significant(p=0.003). (Figure 21)



Figure 21 post op vas vs lateral wall thickness









Reduction in VAS score was not significantly different among the open and closed reduction groups(p=0.71) (table 17, figure 23).

type of reduction	Count	Mean	Standard Deviation	Lower 95% CL Mean	Upper 95% CL Mean	P value
closed	25	5.2	1.9	4.4	6	0.71
dimonhugston	1	4				
open	4	5.8	1.7	3	8.5	
Total	30	5.3	1.9	4.6	6	





Figure 23reduction in VAS vs type of reduction

There was significant difference in reduction in VAS score among the AO subgroups. (Table 18, figure 24)

AO subtype	Count	Mean	Standard Deviation	Lower 95% CL Mean	Upper 95% CL Mean	P value
1.3	15	2.4	1.8	1.4	3.4	0.017
2.2	6	3.5	2.3	1.1	5.9	

Table 18 reduction in VAS score among AO subtypes



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Figure 24 Reduction in VAS score among AO subtypes

There was significant moderate positive correlation between lateral wall thickness and reduction in VAS score. (r=0.68, p<0.001) (figure 25)







Post op VAS and Reduction in VAS did not correlate significantly with time of surgery post injury. (r=-0.4, p=.052 and r=0.3, p=0.98 respectively).

IV. Outcome variables:

a. Radiological

i. Post- op collapse:

A mixed model analysis of amount of Post op collapse using compound symmetry for repeated measures, time and AO subtype as fixed effects was carried out. There was significant difference among the AO subtypes across the follow up period(p=.009). Within group difference was significant across follow up(p=.004) and between group (p<.001). Pairwise comparison showed significant difference between AO 1.3 and both 2.2 and 2.3 at 6 months. However, difference was not significant at 1 month or 3 months and between AO 2.2 and 2.3. (table 19, figure 26)

AO subtype	Follow u	P value					
	1 month		3 months		6 months		
	mean	SD	mean	SD	Mean	SD	
1.3	5.9	4	8.9	5.5	14.3	7.1	.004
Pairwise 1.3-2.2	.18		.32		<.001		
2.2	10.2	8.9	15.7	9.1	26.8	7.6	
Pairwise 2.2-2.3	.69		.6		.83		
2.3	8.8	6.1	11.8	7.2	26.1	5.6	
Pairwise 1.3-2.3	.29		.08		<.001		
Total	7.9	5.9	11.8	7.2	20.3	9	

Table 19 mixed model for AO subtype and follow up vs collapse





Figure 26 line plot of collapse in AO subtypes by time

Within the various groups, collapse at 6 months was significant compared to both 1 and 3 months, but no within group difference was found at 3 months compared to 1 month post op. (table 20, figure 27)

Follow up time	AO subtype	P value					
	1.3		2.2		2.3		
	mean	SD	mean	SD	Mean	SD	
1month	5.9	4	10.2	8.9	8.8	6.1	<.001
Pairwise 1-3 months	.63	1	.37	1	.19	1	
3 months	8.9	5.5	15.7	9.1	13.9	7.3	
Pairwise 3-6	.002		<.001		<.001		
months							
6 months	14.3	7.1	26.8	7.6	26.1	5.6	
Pairwise 1-6 months	<.001		<.001		<.001		

Table 20 mixed model of follow up vs collapse among AO subtypes




Figure 27line plot of collapse at follow up by AO subtypes

Post-op Collapse vs Lateral wall thickness: post op collapse at 6 months was found to have strong negative correlation with lateral wall thickness(r=-.79) which was significant(p<.001). (Figure 28)





Grouped Scatter of collapse(mm) by Lateral wall thickness(mm) by time

Lateral wall thickness(mm)

Figure 28 scatterplot of collapse vs lateral wall thickness at different follow up

ii. Total and percent collapse at 6 months vs AO classification and Lateral wall thickness:

AO subtypes (table 21, figure 29). Pairwise test showed significantly more collapse in 2.2 and 2.3 compared to 1.3.

Average Total collapse at 6 months was 20.3±9 mm which was significantly different across the

		1 4010 21	mean total co	mapse by mo subtyp		
AO	Count	Mean total	Standard	Lower 95% CL	Upper 95% CL	P value
subtype		collapse(mm)	Deviation	Mean	Mean	
1.3	15	14.3	7.1	10.4	18.2	0.00018
2.2	6	26.8	7.6	18.9	34.8	
2.3	9	26.1	5.6	21.8	30.4	
Total	30	20.3	9	17	23.7	

Table 21 mean total collapse by AO subtypes







Mean percent collapse was 40.7±17.9 % which was significantly different across the AO subtypes with AO 2.2 and 2.3 having greater than 50% collapse. (table 22, figure 30)

AO subtype	Count	Mean	Standard Deviation	Lower 95% CL Mean	Upper Mean	95%	CL	P value
1.3	15	27.4	15.6	18.8	36.1			0.00006
2.2	6	55	5.5	49.3	60.7			
2.3	9	53.3	7.6	47.5	59.1			
Total	30	40.7	17.9	34	47.4			

Fable 22	Percent	collanse	hv	AO	subtype	
	1 0100110	conapse	υ,		bact, pe	

-





Figure 30Boxplot of percent collapse by AO subtype

Both the total collapse and percent collapse correlated strongly negative with Lateral wall thickness with Pearson r = -0.7992 (p<.001) and -0.8891 (p<.001) respectively. (Figure 31 and 32).



Figure 31 Scatterplot of Total collapse vs Lateral wall thickness





Figure 32 scatterplot of percent collapse vs lateral wall thickness

iii. Degree of collapse:

14 No of cases had severe collapse and 16 had mild-moderate collapse. (Table 23, figure 33)

Degree of collapse	Count
mild	4
moderate	12
severe	14
Grand Total	30

Table 23 distribution of degree of collapse





Figure 33pie chart showing distribution of degree of collapse

The AO subtypes varied significantly regarding the no of cases with severe post op collapse with Chisquare=10.1, p=.04. (Table 24, figure 34). All cases in AO 2.2 and 2.3 had moderate to severe collapse

	Table .	24 distribution of degi	tee of conapse by AO	subtypes
degree of	AO subtype			Total
collapse	1.3	2.2	2.3	
mild	4	0	0	4
moderate	8	2	2	12
severe	3	4	7	14
Total	15	6	9	30

Table 24 distribution of degree of collapse by AO subtypes





Figure 34 Multiple bar chart of distribution of degree of collapse by AO subtype

Lateral wall thickness by degree of collapse: The mean thickness was 28mm in those with mild collapse, 20.4mm in moderate collapse and 17.5 mm in severe collapse. (Table 25, figure 35). Difference was highly significant between the groups.

Degree of	Mean	Standard	Lower	Upper	P value
collapse		Deviation	95% CL	95% CL	
			Mean	Mean	
mild	28	2.9	23.3	32.7	0.00003
moderate	20.4	3.8	18	22.8	
severe	17.5	2.9	15.8	19.2	

Table 25 Mean Lateral wall thickness in different collapse groups







Degree of Collapse vs Lateral wall thickness: ROC curve was plotted for sensitivity vs 100specificity to find out critical value of Lateral wall thickness for predicting severe post-operative 

Figure 36 ROC curve for Predicting collapse as function of Lateral wall thickness



iv. Medialization vs lateral wall thickness Amount of medialization of shaft correlated significantly(p=0.0035) with lateral wall thickness measurement and Pearson r=-0.5156 which was moderately negative. (Figure 37)



Figure 37 scatterplot of medialization and lateral wall thickness

Medialization vs total collapse: weakly positive correlation was found between medialization and total collapse at 6 months, r = 0.3797, and was significant p = 0.0385. (figure 38)





Figure 38 scatterplot of medialization vs total collapse in mm

Medialization vs AO classification: average post op medialization was 4.7 ± 5.7 mm. Medialization was significantly different among the AO subtypes 2.2 and 2.3 compared to 1.3(One -way ANOVA, p=0.036).(table 26, figure 39)

AO	Count	Mean	Standard	Lower 95% CL	Upper 95% CL	P value
subtype			Deviation	Mean	Mean	
1.3	15	2.1	4.1	-0.1	4.4	0.036
2.2	6	6.7	6.5	-0.2	13.5	
2.3	9	7.8	6.2	3	12.5	
Total	30	4.7	5.7	2.6	6.9	

Table 26 medialization by AO subtype





Figure 39box plot of medialization by AO subtype

b. Functional outcome

i. SF-36 score:

Mean Sf-36 score was 73.2±12.6.

Mixed model analysis for comparing SF-36 score among different AO subtypes at different follow up was done using repeated measures compound symmetry and REML. Overall there was significant difference among the AO subtypes at all follow up(p<.001).

Pairwise, there was significant difference in Sf-36 score between 1.3 and 2.3 groups at 4 and 6 months and between 1.3 and 2.2 at 6 months. Difference was not significant between groups before 4 months and between 2.2 and 23 at any follow up. (Table 27, figure 40)

AO sub	Pairwi se p	SF-36 so	core									P value
typ e	value	2 weeks		1 month	l	2 mon	ths	3 month	ıs	6 month	S	
		mean	SD	mean	SD	mea n	SD	mean	SD	mean	SD	
1.3		40.6	4.9	52.1	10. 4	63.4	10	75.6	8	81.8	6.3	<.001

Table 27 between group difference of sf-36 score at follow up



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	1.3-2.2	0.37		0.43		.22		.06		.008		
2.2		33	5.4	38	4.5	44.5	8.8	50.8	10.2	63.8	11. 2	
	2.2-2.3	0.77		0.53		.6	-	.78		.06		
2.3		33.6	6.6	37.9	6	44.2	6.6	55	10.3	65.1	12. 2	
	1.3-2.3	0.11		0.06		.3		.04		.016		
tota 1		37	6.5	45	10. 9	53.9	13	64.5	14.4	73.2	12. 6	

Means Plot of sf_36_score by Ao_classification



Figure 40 line chart of sf-36 score of AO subtypes at follow up

Pairwise within group comparison showed significant increase in sf-36 score at 1month compared to 2 weeks in 1.3. All the three subtypes

showed significantly increased Sf-36 scores beyond 2 months compared to baseline. (Table 28, figure 41)

Table 28 sf-36 score	pairwise	comparison	among AO	subtypes at	t follow up
	F	r r r r r r			· · · · · · · · · · · · · · · · · · ·

Follow up	Pairwise p	AO sub	type					Р
	value	1.3		2.2		2.3		value
		mean	SD	mean	SD	mean	SD	.023
2 weeks		40.6	4.9	33	5.4	33.6	6.6	

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1 months		52.1	10.4	38	4.5	37.9	6
	2 weeks- 1	0.017		0.19		.13	
	months						
2 months		63.4	10	44.5	8.8	44.2	6.6
	2 weeks-	<.001		<.001		<.001	
	2months						
3 months		75.6	8.0	50.8	10.2	55	10.3
	2 weeks- 3	<.001		<.001		<.001	
	months						
6 months		81.8	6.3	63.8	11.2	65.1	12.2
	2 weeks- 6	<.001		<.001		<.001	
	months						



Figure 41 line plot of sf-36 score for AO subtypes

Sf-36 score at 6 months was significantly strongly correlated with lateral wall thickness, r=0.79, p<.001. (Figure 42)





Figure 42 scatterplot of sf-36 at 6 months vs lateral wall thickness

There was significant correlation between sf-36 score and lateral wall thickness at all times and was strongest at 3 months. (Table 29, figure 43)

time	Pearson r	р
2 weeks	0.46	0.009
1 month	0.7	<.001
2months	0.79	<.001
3 months	0.84	<.001
6 months	0.79	<.001

Table 29 correlation coefficient and significance between sf-36 and lateral wall thickness at follow up







c.

ii. Complication: there were two cut out of screw (6.6%) which occurred in AO 2.2 and 2.3 with lateral wall thickness 17mm and 10mm respectively. There was no neurovascular or wound complication.

i. SF-36 score vs Post op collapse Sf-36 score had weak negative correlation with post op collapse at 1 months r=-0.1230, which was non-significant 0.5174) (figure44). (p=

Clinico-radiological correlation



Figure 44 scatterplot of sf 36 vs collapse at 1months post op

Sf-36 score had weak negative correlation with collapse at 3 months, r=-0.4638, which was significant (p= 0.0098) (figure 45).





Figure 45 scatterplot of sf-36 score vs collapse at 3 months post op

Sf-36 score was moderately correlated with collapse at 6 months, r=-0.5694, and it was found significant (p=0.0010) (figure 46).





ii. SF-36 score vs percent collapse



Sf-36 score at 6 months had strong negative was significant(p<.001) (figure 47). correlation with percent collapse, r=-0.7141, which



Figure 47 scatterplot of sf-36 score vs percent collapse at 6 months

iii. SF-36 vs degree of collapse

Sf-36 score at 6 months was significantly different among those with severe and mild-moderate collapse (table 30, figure 48)

				, , , , , , , , , , , , , , , , , , , ,	· · · · · · · · · · · · · · · · · · ·	
Degree of	Count	Mean	Standard	Lower 95%	Upper 95% CL	P value
collapse			Deviation	CL Mean	Mean	
mild	4	89	2.3	85.3	92.7	0.01453
moderate	12	72.8	13.9	63.9	81.6	
severe	14	69.1	9.7	63.5	74.7	
Total	30	73.2	12.6	68.5	77.9	

Table 30 mean Sf- 36 score at 6 months by degree of collapse





Figure 48 boxplot of sf-36 score at 6 months by degree of collapse

iv. SF-36 score vs medialization

Sf-36 score had weakly negative correlation with medialization, r=-0.4014, which was significant(p=0.0279) (figure 49).



Figure 49 scatterplot of SF-36 score vs Medialization at 6 months post op

v. SF-36 score vs Age

SF-36 scores at 6 months were weakly correlated with age(r=-.23) and it was non significant (p=0.15) (Figure 50)





Figure 50 Scatterplot of SF-36 at 6 months vs Age of patient



PHOTOGRAPHS



Pre-operative and intraoperative xray of patient with AO31A1 fracture



Fracture fixed with DHS after anatomical reduction





Fracture united in good position and

Straight Leg Raise on fractured side







Pre-operative and postoperative x ray of patient with AO31A2 with thin lateral wall





X ray at 6 month of above patient showing severe collapse

Severely comminuted lateral wall fracture



Post-operative x ray of above patient fixed with DHS at 3 month with severe

Failure of fixation with screw cut out in above patient



V. DISCUSSION

Surgical treatment for intertrochanteric fracture has been in practice since decades²⁴. Today, Dynamic hip screw is the time-tested implant of choice for stable intertrochanteric fractures. The aim of surgical management of intertrochanteric fractures is stable internal fixation as early as possible to promote early pain free mobilization of the patient and preventing the complications associated with prolonged immobilization like bed sores, deep vein thrombosis and co-morbid problems like cardiovascular, renal and respiratory problems which are further aggravated due to recumbence and immobilization. Previously the condition of the posteromedial part of the proximal femur was considered as the most important prognostic factor in the outcome of fixation using DHS¹⁷. DHS works on the principle of controlled concentric collapse. When the support from the medial wall is good and lateral femoral wall does not suffer the problem of excessive fracture collapse. It was only recently; the importance of the presence of an intact lateral trochanteric wall is being recognized. In fractures internally fixed with a DHS, the lateral wall provides a buttress on the outer side preventing the fracture from excessive collapse. Literature review shows, lateral femoral wall thickness measurement prior to surgery is predictive of lateral femoral wall fractures when DHS is used.^{5,19}It is therefore necessary to find out which ITF are likely to develop fracture in the lateral wall in the post- operative period. Understanding this will help us to select the correct implant and method of fixation necessary⁶.

The importance of lateral wall integrity in ITF following DHS fixation was first noted by Parker²⁵. He observed that femoral medialization was strongly associated with DHS fixation failure and femoral medialization was more common if there was lateral wall fracture at the site of insertion of the lag screw.

Gotfried Y^{18} in 2004 had reported that, presence of the lateral wall on the preoperative radiograph should be a major factor in determining the internal fixation device used for fracture stabilization. The presence of an intact lateral wall is especially important in fractures with an already comminuted posteromedial wall. It has been seen that mere presence of lateral wall does not prevent excessive collapse in all case. Certain fractures with initial intact lateral wall develop lateral wall fracture in the postoperative period. It has been reported to occur in about 21% of fractures fixed with DHS alone. Studies shows that these patients with post-operative lateral wall fracture after fixation with DHS, experience a protracted healing period and excessive shortening. Henrik Palm et al.⁶ in his study in 2007 reported that preoperative or postoperative fracture of the lateral femoral wall is the main predictor for a reoperation after an intertrochanteric fracture treated by DHS⁶.

AGE DISTRIBUTION

Most of the patients in this study belonged to the age group of 6th to 8th decades. Mean age in years was 72.2. Majority of cases were in age group 60-70 years and belonged to AO31A2.3 type. When we compare our study with other available studies, the mean age was 78 years in the study by Hsu et al⁵. The mean age was 64.3 years in study done by Rajesh et al. ²⁶ while in another study by Rakesh Kumar¹⁹ the mean age was 60 years and is comparable to our study. Mean age was not significantly different in Females and males, across AO subtypes and degree of collapse.

SEX DISTRIBUTION

Most of patients in the present study were females (60%). There was female preponderance in our study as they are more likely to suffer from post-menopausal osteoporosis leading to fracture in low energy trauma. When we compare our study with other available studies, the sex distribution in the study by Hsu et al⁵ was 103(49.5%) males and 105(50.5%) females which is comparable to our study. In a major study by Rakesh Kumar¹⁹, 30(62.5%) were males and 18(37.5%) were females while in the study by Rajesh et al²⁶, there were 53% male. Sex distribution was not different across the AO subtypes by chi-square test.

SIDE DISTRIBUTION

In this study majority cases (53%) sustained injuries on their right side. 47% cases sustained injuries on left side. When compared with other similar studies, right side was affected in 97 cases (46.6%) and left side was affected in 111 cases (53.4%) in the study by Hsu et al⁵. In the study by Rajesh et al²⁶, right side was affected in 60% cases and left side was affected in 40% cases. In the study by Barton et al²⁷, right side was



affected in 4 cases(44%) and left side was affected in 62 cases(56%). The difference from other study, while not being significant, might be explained by lack of random sampling.

MODE OF INJURY

In this study, majority of cases (80%) were due to trivial fall at home which may be attributed to the inherent weakness of the bones in the elderly due to osteoporosis .20% of cases were due to RTA. The following factors as enumerated by Cummings and Nevitt in 1994 may be associated with the injury mechanism during fall i.e., the faller must be oriented to impact near the hip, protective reflexes must fail, local soft tissues must absorb less energy than necessary to prevent fracture and the residual energy the fall applied to the proximal femur must exceed its strength. Kenneth J Koval and Joseph D Zuckerman (1996) observed that 90% of hip fractures in the elderly result from a simple fall. Hip fractures in young adults were observed to result most often with high energy trauma such as motor vehicular accidents or a fall from height²⁸. When compared with study by Chandra et al²⁹ RTA / high velocity injury was the mode of injury in 6 cases (20%) and fall / low velocity injury was the cause in 24 cases (80%) which is comparable to our study.

COMORBIDITIES

Hypertension and Diabetes Mellitus were the most common comorbidity in our patients which is associated with age and osteoporosis. In the study by Setiobudi et al³⁰, Diabetes mellitus and Hypertension were the most common medical conditions among patients of intertrochanteric fracture(32.8% and 64% respectively). Other co morbidities were IHD, CVA, Parkinson's and renal impairment.

17% of our patients had history of alcoholism or smoking.

TIME TO SURGERY

Most of the patients underwent fracture fixation within 10 days (mean 7.5 days) of their injury date. In the study by Setiobudi et al^{30} , waiting time to surgery was 5.73 days.

CASE DISTRIBUTION

In our series, 15 cases (50%) were AO31A2 type (20% 2.2 and 30% 2.3 subtype) and

15 cases (50%) were AO31A1 type. In the study by Rajesh et al²⁶ Majority of the cases(60%) belonged to type AO31A2. When compared with other similar studies available, 97 cases (46.6%) were AO31A1 type and 111 cases (53.4%) were AO31A2 type in the study by Hsu et al⁵ and 22 cases (45.8%) were AO31A21 and 26 cases (54.2%) were AO31A2 type in the study by Rakesh Kumar¹⁹.

TYPE OF REDUCTION

83% of the patients needed only closed reduction while 14% had open reduction and 1 patient with highly unstable fracture pattern underwent DimonHugston procedure.

Reduction of the intertrochanteric fracture may be carried out either by open or closed means. In either circumstance the objective is to achieve a stable reduction, be it anatomical or nonanatomical in configuration. If the fracture is severely comminuted, anatomical reduction even by open reduction may be difficult, in such circumstances non-anatomic but stable reduction obtained by elective medial displacement of the femoral shaft has been used by Dimon Hugston³¹ to achieve stability followed by internal rotation.

Chang compared the result of compression hip screw fixation with anatomic reduction versus fixation with medial displacement and found that in four parts intertrochanteric fracture, anatomic reduction with dynamic hip screw, regardless of the presence of a posteromedial fragments, provided significantly higher compression across the calcar region and significantly lower tensile strain on the plate than did medial displacement osteotomy. In the study by Nageshwar et al³², anatomical reduction was done in 31 (77.5%) patients, DimonHughston osteotomy in only 9 (22.5%) cases. There was no significant difference in healing of the fractures between these two methods.

LATERAL WALL THICKNESS

The intraoperative mean lateral femoral wall thickness was 20 mm with a range of 10mm to 32mm. The mean thickness in subtype 1.3 was 23.5mm with a range of 17mm to 32mm. The remaining 15 patients had AO31A2.2 and 2.3 fractures with a mean lateral wall thickness of 16.3mm and 16.8mm respectively. The mean lateral wall thickness was 28 mm in patients with mild post-operative <1cm collapse which was



significantly higher than those with moderate (1-2cm) and severe(>2cm) collapse- 20.4 and 17.5 mm respectively. When compared to other available studies the mean lateral femoral wall thickness in the study by Rakesh Kumar¹⁹ was 20mm in those with lateral femoral wall fractures and 28mm in those without lateral femoral wall fractures. The mean lateral femoral wall thickness in the study by Hsu et at ⁵was 18.4mm in those with lateral femoral wall fractures and 27mm in those without lateral femoral wall fractures which is comparable to our study. In the radiological study by Rajesh et al ²⁶, mean preoperative lateral femoral wall thickness was 27.9 mm with range of 13.2mm to 39mm. Mean thickness in their study was 18.1mm in patients having post-operative lateral wall fracture compared to 26.1mm for patients not having lateral wall fracture. Only 3 patients in AO31A1 group in our study suffer severe collapse in the postoperative period. This may be due to the thicker lateral wall which might have reduced the occurrence of lateral wall fractures in presence of an intact medial wall. While the collapse occurred due to presence of fractured medial wall. This may be due the well opposed fracture surfaces and a stable fixation supported by the intact medial buttress and lateral femoral wall. The patients in AO31A2 group might have suffered lateral femoral wall fractures in the postoperative period leading to severe collapse due to the thinner lateral wall in this group (mean thickness is 18mm) in presence of medial wall comminution where the buttressing effect from the medial wall is lost and lead to more load acting on the lateral femoral wall on weight bearing. This hypothesis is similar to the findings of Barton et al^{27} . According to them, in patients with stable fractures with an intact posteromedial buttress, the load is shared between the implant and the calcar femoral; however, in patients with unstable fractures, the entire load is transmitted through the implant because of the loss of this posteromedial support. But, as the implant is fixed on the lateral femoral wall, the same load acts through this anatomically important structure in the proximal femur, which has more chances of getting fractured when the thickness is less and when the medical buttressing support is lacking. Among 11 patients AO31A2 group with severe collapse of postoperatively, there was lateral displacement of fracture fragments, excessive sliding of the screw

within the barrel leading to collapse at fracture site, lateral ⁵displacement of the proximal fragment and medialisation of the shaft leading to Varus at fracture site. 2 patients had fracture collapse with Varus angulations and screw cut out.

TIP APEX DISTANCE

All patients in our study had TAD<25mm with range from 10mm to 24mm(mean16.4mm). In the study by Barton et al.²⁷, there were 9% patients with TAD>25 mm 2 out of them had screw cut out. The importance of the position of the screw within the femoral head has been recognised since the earliest reports of clinical results associated with use of the sliding hip screw. The tip-apex distance summation of measurements represents on radiographs made in two orthogonal projections, not the physical distance from the tip of the screw to the apex of the three-dimensional femoral head. In their study, Baumgaertner et al.⁸ recommended a TAD \leq 25 mm to prevent failure by cut out. In a systematic review done by Rubio-Avila et al²¹, they assessed the effect of TAD on incidence of cut-out and confirmed TAD>25mm results in significantly greater risk of cut-out(Relative Risk=12.71). We have included patients with TAD<25mm to rule out its effect on cut out.

THRESHOLD VALUE:

In this study, a threshold value or cut-off point of 21mm was taken based on ROC curve. This is the minimum thickness below which the severe collapse (and post-operative lateral wall fracture) would occur when treated with DHS. When compared with other available studies, the cut-off point was taken at 20.5mm in the study by Hsu et al⁵ and Rakesh Kumar¹⁹. A difference of 0.5 was noted compared to other studies which is not significant considering in this study we measured intraoperatively at 1mm resolution. In the study by Rajesh et al²⁶, they found 22.1mm as cut-off. This may be attributed to the difference in the values of the thickness of the lateral femoral wall in each case and also the small sample size in that study. In the study by Sreejith et al⁷, they found cut off of 20.55 mm to predict lateral wall fracture. In the study done by Pradeep et al¹⁶, they found 21mm as the threshold of lateral wall thickness predicting lateral wall fracture which is comparable to our study.



PAIN ASSESSMENT

Pain is an important criterion for the evaluation of intertrochanteric fractures. Following surgery pain in the hip joint may be due to mechanical complications like screw cut out, joint penetration or infection, or due to avascular necrosis of the femoral head or secondary osteoarthritis of the hip joint.

Median pre-operative VAS was 8.5(range 6 to 10) and was not different across the AO subtypes.

Mean Post-operative VAS was 3 an did not differ significantly between those who underwent open vs closed reduction or between AO subtypes. Postoperative VAS was weakly correlated to pre-op VAS and lateral wall thickness.

Mean reduction in VAS score was 5.3. Reduction was not correlated with pre-operative VAS, type of reduction or time to surgery but was different across AO subtypes and had moderately positive correlation with lateral wall thickness.

In the study done by Chandra et al.²⁹, three patients had pain at end of six months, out of which one had cut out. In the Malcom L. Ecker et al³³series, 79% showed no pain, 18% had mild pain and 1% had moderate pain.

OUTCOME RADIOLOGICAL POST-OPERATIVE COLLAPSE

The mean collapse was 7.9mm at 1 months which increased to 11.8mm at 3 months and 20.3mm at 6 months. Collapse was significantly more in AO31A2 compared to AO31A1 at 6 months (26mm vs 14mm). Within each group the collapse was significantly increased at 6 months compared to 1 months and 3 months.

Amount of post-operative collapse at 6 months was strongly negatively correlated to Intraoperative lateral wall thickness measurement.

Total and percent collapse were significantly different in the AO subtypes with >50% collapse in AO31A2 compared to around 27% in AO31A1.

Total and percent collapse also were found to have strong negative correlation with lateral wall thickness. For a dynamic device to work without excessive collapse, a majority of bone along the femur's circumference should remain intact and in contact. The well known regions which provide effective bony support and load transfer between the main proximal and shaft fragments include the posteromedial calcar, the lateral wall and the anteromedial region. As such severe angulation, medialization of the proximal fragment and lateral wall fractures result in a loss of bony support, and excessive fracture collapse.

In the Chandra et al. ²⁹ study, 80% patients had no shortening and 20% had shortening of 1.5-2 cm at 6 months due to fracture collapse. In the study by Fang et al³⁴, they identified risk factors for increased collapse as increasing age, female sex, A2 fracture class, increased operative duration, poor reduction quality and TAD>25mm.

Medialization as assessed at 6 months on the post-operative skiagram. The average was 4.7mm for all patients with AO31A2 having significantly more medialization of 7mm compared to AO31A1(2mm). Medialization was moderately correlated to lateral wall thickness and amount of final collapse. This might be explained by dependence on intactness of medial buttress in addition to lateral wall. In the study by Pradeep et al^{16} , medialization was not seen in any patient with intact lateral wall, whereas 64.7% patients with lateral wall fracture had medialisation with 26.5% having > 1/3rd medialisation.

Most extracapsular fractures show no medialization. This is because the fracture lines run obliquely between the trochanters and while some collapse can occur at the fracture site, medial displacement is prevented by the intact bone of the superior-lateral part of the distal fragment resting against the proximal fragment. The fracture pattern that was the most reliable predictor of the occurrence of medialization was comminution of the lateral femoral cortex at the site of insertion of the lag screw. These fracture patterns signify a lack of lateral bony support to oppose the strong pull of the adductor muscles on the distal fragment, thereby allowing the distal fragment to displace medially.

Although specific fracture types were associated with medialization, it was not possible to predict medialisation with complete certainty. The reason for this may be due to changes in the fracture configuration occurring at the time of



surgery. If the lateral femoral cortex is weak, it may fracture at the time of reaming for the SHS lag screw or occasionally further comminution of the fracture may occur in the postoperative period, which results in medialisation.

FUNCTIONAL OUTCOME

Mean SF-36 score was 37 at 2 weeks post op and increased to 73.2 at 6 months post op in a log-linear fashion. The increase was significant at 2months compared to baseline. There was significant difference in SF-36 score among the AO subtypes at 3- and 6-months post op.

In the study by Pradeep et al¹⁶, they found only 44% patients with lateral wall fracture had fair to good outcome with mean Harris Hip score of 65.8 compared to 92% fair to good outcome in patients with intact lateral wall with 73.1 mean HHS. This is comparable to our study.

There was strong correlation of SF-36 score and lateral wall thickness beyond 1 month. The lateral wall prevents fracture collapse and shortening thereby giving stability and pain free mobility to patient.

SF-36 score was weakly correlated to post op collapse at 1 month and 3 months but moderately correlated to collapse at 6 months. It was strongly negatively correlated to percentage of final collapse. The mean SF-36 score was 89 among those with mild collapse compared to 69 among those with severe collapse. This difference was significant. SF-36 score had weak inverse relation to medialisation at 6 months.

In our study SF-36 scores at 6 months were not correlated to Age of patient. This might have been due to majority of patients in elderly age group and small sample size.

Chandra et al.²⁹ assessed functional results in DHS with Babhulkar's criteria. They had 20% excellent, 43.3% good and 33.3% poor results.

In osteoporotic hip fractures, fracture collapse is deliberately allowed by commonly used implants to improve dynamic contact and healing. The muscle lever arm is, however, compromised by shortening. In the study by Fang et al³⁴, they found more patients unable to maintain their premorbid walking function(34.2% for mild collapse, 33.3% for moderate collapse and 62.8% for severe collapse, p=0.028). They also identified predictors of better outcome in terms of walking ability were younger age, higher MMSE and MBI marks, better

premorbid walking status, less fracture collapse, and optimal lag screw position. They found fracture collapse did not affect survival of patient. This well compares to the strong inverse correlation found in our study between SF-36 score and percentage of collapse.

In the study by Gausden et al.³⁵, they found significant correlation between increased shortening and decreased cadence, increased double support time, decreased step length, and increased single support asymmetry during gait analysis. However, they did not find any significant association of shortening with Harris Hip score, VAS and SF-36 score. This might have been due to only 2 of their patients out of 72 having >2 cm shortening.

FAILURES NOTED

In this study, out of 15 cases of AO31A2, 2 patients (6.6%) had failure due to excessive collapse and cut out of head screw. No failures were noted in AO31A2 without severe collapse and in AO31A1 group. When compared with other available studies, failure in the study by Hsu et al⁵ was seen in 19 patients (49%) out of 39 patients of AO31A2 with lateral femoral wall fractures and 6 patients (8.3%) out of 72 patients of AO31A2 without lateral wall fractures and 2 patients (2.1%) out of 94 AO31A1 fractures without lateral femoral wall fractures. The difference in the results may be attributed to the small sample size in this study. The low failure rate in AO31A1 group may be as a result of the posteromedial section of the femur preventing excessive sliding of the screw and proximal fragment. In AO31A2 fractures with a lateral femoral wall fracture after implantation with DHS, the screw and the proximal fragment slide laterally and there is no structure block this movement. Further stress on the femoral head will cause screw penetration or loosening. This suggests that, an intact posteromedial femoral section provides an important support in the event of lateral wall fracture in treatment with DHS. In the absence of a stable posteromedial section, the thickness of the lateral femoral wall plays an important role in treatment outcome with DHS. In the study by Rajesh et al,²⁶ 5 cases of AO31A2 with lateral wall fractures, 1 patient(20%) had failure due to excessive collapse with implant loosening and nonunion and an associated infection. They found no failures in AO31A2 without lateral femoral wall



fractures and in AO31A1 group. In the study by Barton et al.²⁷ there was 2% rate of screw cut out in DHS.

Merits of this study:

- An assessment of the lateral femoral wall thickness was done intraoperatively using a simple method. It is likely more accurate than pre-operative radiologic assessment at fixed distance due to variability in the proximal femoral geometry and dimension among the patient population.
- Lateral femoral wall thickness is a easily quantifiable parameter. Measures can be taken to prevent postoperative lateral femoral wall fractures by this assessment and fracture fixation augmented where necessary.
- Cost effective
- Relation of various clinical and radiological parameters and pain scores was done.
- Limitations of this study:
- The main limitation of this study is having a smaller number of cases included in each group. Postoperative lateral femoral wall fracture and severe collapse were not noted in AO31A1 group may be due to the small sample size.
- The measurement is two dimensional using anteroposterior and lateral radiographs. So, chances of missing fractures not seen in these views which can be better visualized on a CT scan.
- Operations were not performed by a single surgeon and the operative skills of surgeons may have been different and could have affected the treatment outcome.
- Follow-up duration (6 months) was relatively short. Thus, reoperation rate may have been underestimated.
- Confounding effects of bone density and mental status of the patient have not been included.

VI. SUMMARY

The best treatment for per trochanteric fractures remains controversial. DHS is widely used for this fracture, but fixation failure and poor outcomes occur due to collapse and loss of fixation. In this study we evaluated the relation between intraoperative measurement of the thickness of lateral femoral wall to functional and radiological

outcome of patient. 30 patients (18 females and 12 males) having AO31A1(15 patients) and AO31A2(15 patients) were included in the study. There mean age was 70.4 years (range 45-92 years). 53% patients had right side fracture and 47% on left side. Most of them (80%) had domestic fall. The patients were operated at mean 7.5 days from injury (range 0-31 days). 83% had open reduction and only 1 case required DimonHughston Their lateral procedure. wall thickness measurement was done intra operatively at screw insertion site using a simple procedure with mean thickness being 20 mm which was different across AO subtypes. All patients had TAD<25 mm and were ambulated full weight bearing 48 hrs post operatively. There was significant reduction in VAS score of patients post operatively which did not differ among reduction method. But reduction was moderately correlated to lateral wall thickness and differed among AO subtypes. All patients were followed up for 6 months. Collapse at fracture site was assessed at 1, 3 and 6 months and was found to differ significantly between the AO subtypes. Amount of collapse had strong negative correlation with lateral wall thickness. 40% patients had severe collapse and 60% mild-moderate collapse. A cutoff value of 21mm was calculated based on Receiver operator characteristic analysis to predict severe post op collapse and poor functional outcome. More medialisation was found in those with severe collapse and AO31A2. SF-36 scoring was assessed at 2 weeks, 1 months, 2months, 3 and 6 months. The scores were significantly less among AO31A2 and those having severe collapse. Scores improved significantly at 2-6 months compared to 2 weeks. SF-36 score had strong positive correlation to Lateral wall thickness.

VII. CONCLUSIONS

- There is increased failure rate in AO31A2 with postoperative lateral femoral wall fracture group due to thin preoperative lateral femoral wall thickness and being treated by DHS fixation.
- By measuring the intraoperative lateral wall thickness in AO31A1 and AO31A2 fractures, one can expect the chances of lateral femoral wall fractures in the postoperative period if DHS is used.
- If the intraoperative lateral wall thickness is less than 21mm, the surgeon may consider



using additional buttressing with TSP or an intramedullary implant like PFN to reduce the chances of postoperative lateral

femoral wall fractures and its complication.

• Increased collapse adversely affects patient's functional outcome.

VIII. RECOMMENDATIONS

- Trochanteric lateral wall is an important structure for the stability of intertrochanteric fracture. Its intactness adds greatly to the stability of the fixation construct.
- The thickness of lateral wall has to be assessed and if found less than 21 mm, DHS in isolation is not an ideal implant for fixation.
- DHS has to be augmented with a trochanteric support plate for thin lateral wall or intramedullary fixation should be done.
- In fractures with initial intact lateral wall of adequate thickness, if planning for DHS, great care has to be taken during surgery so as not to break the lateral wall.
- A larger study is recommended to substantiate this hypothesis.

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ANNEXURE



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ABBREVIATIONS

DHS- Dynamic Hip screw DMD- Depth measurement device LWT- Lateral wall thickness AP- anteroposterior LAT- lateral PLWF- Postoperative lateral wall fracture ITF- intertrochanteric fracture

Consent Forms

INFORMED CONSENT FORM

Name of the Principal Investigator _____

Telephone No _____

I have received the information sheet on the above study and have read and / or understood the written information.

I have been given the chance to discuss the study and ask questions.

I consent to take part in the study and I am aware that my participation is voluntary.

I understand that I may withdraw at any time without this affecting my future care.

I understand that the information collected about me from my participation in this research and sections of any of my medical notes may be looked at by responsible persons (ethics committee members / regulatory authorities). I give access to these individuals to have access to my records.

I understand I will receive a copy of the patient information sheet and the informed consent form.

Signature / Thumb Impression of subject

Date of signature

Printed name of the subject in capitals

Signature / Thumb Impression of legally accepted representative

Date of signature

<<p><<The legally acceptable representative signature should be added if the subject is a minor or is unable to sign for themselves. The relationship between the subject and the legally acceptable representative should be stated. The impartial witness signature should be added if the subject / legally acceptable representative is unable to read or write and consent should be obtained in his presence. >>

Printed name of legally acceptable representative in capitals

Relationship of legally accepted representative to subject in capitals

Signature of the person conducting the informed consent discussion

Date of signature



Printed name of the person conducting the informed consent discussion in capitals

Signature of impartial witness

Date of signature

Printed name of the impartial witness in capitals

ত পত্ৰ

এহ গবেষণায় উদ্দেশ্য এবং পদ্ধতি সম্পর্কে গবেষক আমাকে বিস্তারিতভাবে য্যাখ্যা করেছেন। আমি বেচ্ছায় এই গবেষণায় যোগদান করছি এবং আমার ইচ্ছানুসারে প্রয়োজনানুগ এই গবেষণার কাজ থেকে নিজেকে প্রত্যাহার করতে পারি। আমি এই সম্বন্ধে অবহিত যে গবেষকও আমার গবেষণায় বোগদানের বিষয়ে যে কোন সিদ্ধান্ত গ্রহণ করতে পারেন।আমি এই গবেষণায় অংশগ্রহনের দ্ধন্য কোনো পারিশ্রমিকের দাবিদার হব না এবং আমাকে এই সম্বতিপত্রের একটি প্রতিলিপি দেওয়া হবে।

অতএব আমি এই গবেষণার অংশগ্রহণ করার পূর্ণ সন্থতি দিলাম এবং এই গবেষণার উদ্দেশ্য সঞ্চলীকরণের মন্য গবেষককে সর্বান্যকভাবে সহযোগিতার সন্মতি দিলাম।

অংশগ্রহণকারীর নাম শাক্ষর -তারিশ – সাক্ষীৰ নাম -তারিশ -গবেষকের ডারিশ



<u>रोगी अनुमती पत्र</u>

रोगी का नाम उम्र रजिस्ट्रेशन विभाग (वॉर्ड) शय्या नंबर पत्ता

मुख्य ांश

मुझे इस अनुसंधान के सारे विधि आंर इससे संबंधित प्रभाव के बारे में अच्छो तरए से सूचित कर दियाग या है। मैं इस अनुसंधंन में शामिल हाने को स्वेच्छा से अनुमात दे रहा / रही हूँ। मैं अपनी इच्छानुसार कभी भी इस अनुसंधान से अलग हो सकता / सकती हूँ और इससे मेरी चिकित्सा पर कोई असर नहीं पड़ेगा।

साक्षी का हस्ताक्षर / अंगूठे का निशान

नाम एवं पता

दिनांक

रोगी का इस्ताक्षर / अंगूठे का निशान नाम एंव पता दिनांक

डॉक्टर का हस्ताक्षर दिनांक

VAS score:



SF-36 scoring³⁶



Medical Outcomes Study Questionnaire Short Form 36 Health Survey

This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. Thank you for completing this survey! For each of the following questions, please circle the number that best describes your answer.

1. In general, would you say your health	
is:	
Excellent	1
Very good	2
Good	3
Fair	4
Poor	5
2. Compared to one year ago,	
Much better now than one year ago	1
Somewhat better now than one year ago	2
About the same	3
Somewhat worse now than one year ago	4
Much worse now than one year ago	5

3. The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much? (Circle One Number on Each Line)

	Yes, Limited a Lot (1)	Yes, Limited a Little (2)	No, Not limited at All (3)
a. Vigorous activities , such as running, lifting heavy objects, participating in strenuous sports	1	2	3
b. Moderate activities , such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	1	2	3
c. Lifting or carrying groceries	1	2	3
d. Climbing several flights of stairs	1	2	3
e. Climbing one flight of stairs	1	2	3
f. Bending, kneeling, or stooping	1	2	3



g. Walking more than a mile	1	2	3
h. Walking several blocks	1	2	3
i. Walking one block	1	2	3
j. Bathing or dressing yourself	1	2	3

4. During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of your physical health**? (Circle One Number on Each Line)

	Yes (1)	No (2)
a. Cut down the amount of time you spent on work or other activities	1	2
b. Accomplished less than you would like	1	2
c. Were limited in the kind of work or other activities	1	2
d. Had difficulty performing the work or other activities (for example, it took extra effort)	1	2

5. During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** (such as feeling depressed or anxious)?

(Circle One Number on Each Line)

	Yes	No
a. Cut down the amount of time you spent on work or other activities	1	2
b. Accomplished less than you would like	1	2
c. Didn't do work or other activities as carefully as usual	1	2

6. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	
Not at all	1
Slightly	2
Moderately	3
Quite a bit	4
Extremely	5



7. How much bodily pain have you had during the past 4 weeks?	
None	1
Very mild	2
Mild	3
Moderate	4
Severe	5
Very severe	6
8. During the past 4 weeks, how much did pain interfere with	
your normal work (including both work outside the home and	
housework)?	
Not at all	1
A little bit	2
Moderately	3
Quite a bit	4
Extremely	5

These questions are about how you feel and how things have been with you **during the past 4 weeks**. For each question, please give the one answer that comes closest to the way you have been feeling. (Circle One Number on Each Line)

9.	How much	of the	time	during	the	past 4	weeks	1
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	All of the Time	Most of the Time	A Good Bit of the Time	Some of the Time	A Little of the Time	None of the Time
a. Did you feel full of pep?	1	2	3	4	5	6
b. Have you been a very nervous person?	1	2	3	4	5	6
c. Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6
d. Have you felt calm and peaceful?	1	2	3	4	5	6
e. Did you have a lot of energy?	1	2	3	4	5	6



	All of the Time	Most of the Time	A Good Bit of the Time	Some of the Time	A Little of the Time	None of the Time
f. Have you felt	1	2	3	4	5	6
downhearted and blue?						
g. Did you feel worn out?	1	2	3	4	5	6
h. Have you been a happy	1	2	3	4	5	6
person?						
i. Did you feel tired?	1	2	3	4	5	6

10. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)? (Circle One Number)	
All of the time	1
Most of the time	2
Some of the time	3
A little of the time	4
None of the time	5

11. How TRUE or FALSE is each of the following statements for you. (Circle One Number on Each Line)

	Definitely True	Mostly True	Don't Know	Mostly False	Definitely False
a. I seem to get sick a little	1	2	3	4	5
easier than other people	C				
b. I am as healthy as anybody I know	1	2	3	4	5
c. I expect my health to get worse	1	2	3	4	5
d. My health is excellent	1	2	3	4	5