

**“RETROSPECTIVE COMPARATIVE STUDY OF
DYNAMIC HIP SCREW FIXATION AND PROXIMAL
FEMUR NAILING IN OSTEOPOROTIC
INTERTROCHANTERIC FEMUR FRACTURES”**

Dissertation submitted to

**THE TAMILNADU DR.M.G.R.MEDICAL UNIVERSITY
CHENNAI**

*In Partial fulfillment of the Regulations
for the Award of the degree*

**M. S. DEGREE-BRANCH II
ORTHOPAEDIC SURGERY**



**MADRAS MEDICAL COLLEGE
CHENNAI**

MAY - 2020

CERTIFICATE

This is to certify that this dissertation “**RETROSPECTIVE COMPARATIVE STUDY OF DYNAMIC HIP SCREW FIXATION AND PROXIMAL FEMUR NAILING IN OSTEOPOROTIC INTERTROCHANTERIC FEMUR FRACTURES**” is a bonafide record of work done by **DR.M.SUNDAR PRAKASH**, during the period of his Post graduate study from May 2017 to May 2020 under guidance and supervision in the **INSTITUTE OF ORTHOPAEDICS AND TRAUMATOLOGY**, Madras Medical College and Rajiv Gandhi Government General Hospital, Chennai-600003, in partial fulfilment of the requirement for **M.S.ORTHOPAEDIC SURGERY BRANCH II** degree Examination of The Tamilnadu Dr. M.G.R. Medical University to be held in May 2020.

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DECLARATION

I declare that the dissertation entitled “**RETROSPECTIVE COMPARATIVE STUDY OF DYNAMIC HIP SCREW FIXATION AND PROXIMAL FEMUR NAILING IN OSTEOPOROTIC INTERTROCHANTERIC FEMUR FRACTURES**” submitted by me for the degree of M.S ORTHOPAEDICS is the record work carried out by me during the period of May 2017 to May 2020 under the guidance of **Prof.N.DEEN MUHAMMAD ISMAIL, M.S.Ortho., D.Ortho.**, Director, Professor of Orthopaedics, Institute of Orthopaedics and traumatology, Madras Medical College, Chennai. This dissertation is submitted to the Tamilnadu Dr.M.G.R. Medical University, Chennai, in partial fulfilment of the University regulations for the award of degree of M.S.ORTHOPAEDICS (BRANCH-II) examination to be held in May 2020.

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ACKNOWLEDGEMENT

I express my thanks and gratitude to our respected Dean **Prof.Dr.R.JAYANTHI, M.D., FRCP (Glasg)**., Madras Medical College, Chennai – 3 for having given permission for conducting this study and to utilize the clinical materials of this hospital.

I would like to express my sincere thanks and gratitude to our beloved chief **Prof.N.DEEN MUHAMMAD ISMAIL M.S, Ortho., D.Ortho.**, Director, Institute of Orthopaedics and Traumatology, for his valuable advice throughout this study .

My sincere thanks and gratitude to **Prof.V.SINGARAVADIVELU, M.S.Ortho., D.Ortho.**, Professor, Institute Of Orthopaedics and Traumatology, for his guidance and constant advice provided throughout this study.

My sincere thanks and guidance to **Prof.A.PANDIASELVAN, M.S.Ortho., D.Ortho.**, Professor, Institute Of Orthopaedics and Traumatology, for his valuable advice and support.

I sincerely thank **Prof.NALLI.R.UVARAJ, M.S.Ortho.D.Ortho.**, for his advice, guidance and unrelenting support during the study.

I sincerely thank **Prof.B.PASUPATHY, M.S.Ortho.D.Ortho.**, for his advice, guidance and unrelenting support during the study.

I am very much grateful to **Prof.PRABHAKARAN, M.S.Ortho., D.Ortho.**, for his unrestricted help and advice throughout the study period.

I am very much grateful to **Prof.K.VELMURUGAN, M.S.Ortho., D.Ortho.**, for his unrestricted help and advice throughout the study period.

I am deeply indebted to my beloved co-guide **Dr.NALLI R GOPINATH, DNB.Ortho. D ORTHO**, who has guided me in every aspect of this study.

I sincerely thank **Dr.S.Senthil Sailesh, Dr.P.Kannan, Dr.P.Kingsly, Dr.A.Saravanan, Dr.G.Hemanthkumar, Dr.G.Kaliraj, Dr.N.Muthalagan, Dr.R.Rajganesh, Dr.Sarathbabu Dr.D.Sureshanandhan, Dr.P.Dhanasekaran, Dr.Balasubramaniam, Dr.Srinivasan, Dr.G.Karthik, Dr.Jvaghar Jill, Dr.Jeffery Navin Raj** Assistant Professors of this department for their valuable suggestions and help during this study.

I thank all anaesthetists and staff members of the theatre and wards for their endurance during this study.

I am thankful to all my post graduate colleagues for helping me in this study. I am grateful to my family for their unconditional love, trust and support. Last but not least, My sincere thanks to all our patients, who made this study possible.

Finally I offer my sincere prayers to God Almighty!

ABSTRACT

BACKGROUND AND OBJECTIVES

Intertrochanteric fractures is one of the common most fractures of the hip especially in the older age groups with osteoporotic bones. Women are most susceptible and most common mode of injury is Trivial fall.

The aim of management of an intertrochanteric fracture is the recovery of the patient back to optimal function and prevention of future hip fractures. This led to the fact that these fractures are fixed internally. The two types of implants used for internal fixation of these fractures are DHS and PFN. Intramedullary devices like the PFN has advantage in these fractures as their lie close to the mechanical axis of the limb, and hence the rate of implant failure is lesser.

AIM OF THE STUDY

The purpose of the our study is to assess the advantages of proximal femoral nail in terms of fracture union, anatomical reduction and also the functional outcome compared to the patients treated with DHS.

MATERIALS AND METHODS

This is a retrospective study of forty patients with intertrochanteric fracture(stable and unstable) who has radiological evidence of

osteoporosis(Singh's index) treated by PFN or DHS. The results are compared for functional outcome using Modified Harris Hip score

RESULTS

Pain is significantly lesser in patients managed by PFN. The limb length discrepancies occurs at higher rate in the patients managed by DHS. In both stable and unstable intertrochanteric fractures, patients treated with PFN, had significantly better outcomes.

CONCLUSION

From our study, we consider PFN as better alternative to DHS in treatment of intertrochanteric femur fractures.

KEY WORDS

Intertrochanteric fractures, DHS, PFN.

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INTRODUCTION

Intertrochanteric fractures involve those fractures that occur in the region extending from the extra-capsular basilar neck to the region along the lesser trochanter proximal to the medullary canal. These fractures are one of the most common fractures of hip predominantly occurring in females, older than 65 years of age. Most of them are osteoporotic.¹⁻⁷

Hagino et al⁸ proposed that, risk of hip fracture in lifetime for individuals at 50 years of age as 5.6% for men and 20% for women.

Gulberg et al⁹ in 1997 estimated the incidence of hip fracture worldwide would double to 2.6million by the year 2025, and 4.5million by the year 2050.

The aim of treatment of any intertrochanteric fracture is to restore mobility safely and efficiently and restore the patient to pre-operative status.¹⁰

DHS has gained widespread acceptance in last two decade and have been extensively used for fixation. The DHS has been shown to produce good results but complications are frequent, particularly in unstable inter-trochanteric fractures.¹¹

In 1998, AO/ASIF introduced proximal femoral nail (PFN)¹² for the treatment of trochanteric fractures in recent years. The advantage of

Intra-medullary devices like the proximal femoral nail is that, it provides a more biomechanically stable construct as the placement of implant lie closer to the mechanical axis of the limb.¹³ This intramedullary implant allows weight bearing early and limb shortening was limited.¹⁴ Overall, the literature suggests that the DHS has little advantage over the PFN except cost, while the PFN achieves better intra-and post-operative results, with fewer complications, dislocations and less pain, while increasing speed of mobilization.¹⁵

So, our study is to investigate whether PFN shows significant difference than DHS fixation in the treatment of intertrochanteric fractures in terms of fracture union and functional outcome by Modified Harris Hip Score.

AIM OF THE STUDY

To compare, the management of intertrochanteric femur fractures in Osteoporotic individuals with the proximal femoral nailing and dynamic hip screw device fixation, in terms of:

- Fracture union
- Functional outcome.

REVIEW OF LITERATURE

The evolution of treatment concepts regarding pertrochanteric fractures is critical to advancing our treatment modalities.¹⁶ Initial treatment in the 1800s in England focused on the work of Pott and Cooper¹⁷ who advocated supporting thigh in a flexed position and that early mobilization of the patient was the primitive goal for the patient's survival. The second school of treatment was founded by Hugh Owen Thomas of Liverpool,¹⁸ which advocated immobilization and prolonged bed rest.

In 1902, Whitman re-evaluated the role of conservative treatment of this type of fracture and advocated reduction and stabilization with traction, abduction and internal rotation, to better restore the anatomy of hip.¹⁹

In the 1800s, Langebeck²⁰ and others had attempted internal fixation of the hip from a transtrochanteric insertion, but resulted in failure of these techniques. Lane, Lambotte, and Hey Groves were the pioneers who developed the modern principles of osteosynthesis.²¹

The real modern era of internal fixation of hip fracture began with Smith- Petersen in 1925 and his invention of the triflange nail.²² Brittain,²³ using a very low placement on the lateral cortex of the femur, treated pertrochanteric fractures with Smith-Petersen nail, presaging the later high-angle type devices.²⁴ Johansson²⁴ developed

the technique of 'blind nailing' and he is also credited with developing the first cannulated Smith-Petersen nail.

In 1930s, Henry, Lippmann, Handerson and others reported on the use of lag-screw type devices instead of nails.²⁵ Thornton²⁶ in 1937 is credited with first attachable side plate bolted to a Smith-petersen nail.

The Jewett nail a triflange nail is welded to a plate for fixation of shaft.²⁷ He was the first to advise the open reduction of the lesser trochanter with separate screws to increase the stability of the fracture. Blount²⁸ and Moore²⁹ in 1940s coined the term and concept of Blade plate. In 1944, Neufeld and Capener³⁰ developed fixed angle type nail plates.³¹

Trochanteric buttress plate were first reported by Boyd and Griffin³² in 1949 for preventing medialization with Neufeld plate in unstable fractures. The invention of sliding compression with a cannulated system of drilling and insertion was invented by Godoy-Moreira³³ and is the precursor of this class of implants in 1938. Schumpelick and Jantzen³⁴ described about a sliding cannulated system with side plate in 1952.

In 1955 to 1958, Pugh³⁵ and Massie³⁶ reported success with the application of an SHS device to minimize medial penetration of the femoral head and early fatigue failure. Their modification included a

blunt tipped cannulated screw design coupled to a forged side plate of optional length and neck angle. There was a keyed slot for rotational instability.

The desire to increase stability of unstable fracture pattern with proactive Valgus osteotomies was popularized by Dimon and Hughston,³⁷ Sarmiento and Williams,³⁸ and Harrington and Johnston³⁹ in 1960 and 1970s. These techniques have largely been abandoned.

In 1979 to 1980, Kyle et al⁴⁰ and Jensen⁴¹ described the issue of instability with sliding device.

Müller- Farber et al⁴² observed postoperative mobility is inversely proportional to sliding of the hip screw.

Rhaey et al⁴³ in 1993 reported that the cause for fixation failure was excessive sliding. Baixauli⁴⁴ et al found that postoperative pain may be due to sliding >15 mm. To overcome the complications occurred in SHS, a trochanteric supporting plate is used. It increase the stability of fracture fixation in revision surgery after a failure due to superior lag screw cutout

Gotfried⁴⁵ developed Percutaneous compression plate system which overcomes the rotational instability of the hip and minimized damage to greater trochanter and lateral wall of femur.

In the 1980 to 1990s, renewed interest in hip fracture failures led to a

new approach to fixation in the plate field, Medoff and Maes⁴⁶ introduced the biaxial compression hip screw for unstable fractures. It allows both axial compression along the shaft reminiscent of an Eggers plate as well as dynamic compression at screw-plate interface in the head. The shortcoming of biaxial compression plate is limb shortening.⁴⁷ The biaxial compression plate provides theoretical advantages for more complex intertrochanteric femur fractures.

Cephalomedullary implants are devices inserted with a closed technique and fluoroscopy control with variable length femoral geometry and proximal screw holes to permit fixation with nails or screws into the femoral head. They evolved from the Y-nail of Kuntscher⁴⁸ in 1953. The Gross-Kempf gamma nail and Russell-Taylor reconstruction nail were two new intramedullary devices designed for the hip region and coincided with the widespread adoption and popularity of closed interlocking techniques in the 1980 to 1990s.

The Gamma-Nail, the first-generation nail for treatment of these fractures, has relatively high incidence of peri-implant fracture.⁴⁹ Second generation- Gamma nail with modifications like, a reduced valgus bend to 4°, decreased distal diameter to 11 mm, and short length(180 mm) of implant decreased the stress concentration, thereby reducing the incidence of peri-implant fracture.⁵⁰

In 1996, the third- generation nails such as the proximal femoral nail (PFN) was designed by Arbeitsegmenin Schaftfur Osteo Synthes fragen(AO/ASIF).⁵¹ Its biomechanical properties like being an axial, load bearing device with a short lever arm, greater implant length, smaller and flexible distal ends and an additional antirotational screw in femoral neck may offer significant advantage over dynamic hip screw.

ANATOMY

The femur is the strongest bone in the human body being a quarter of the stature. It takes part in articulation of both hip and knee joint. Femur consists of three distinct parts:

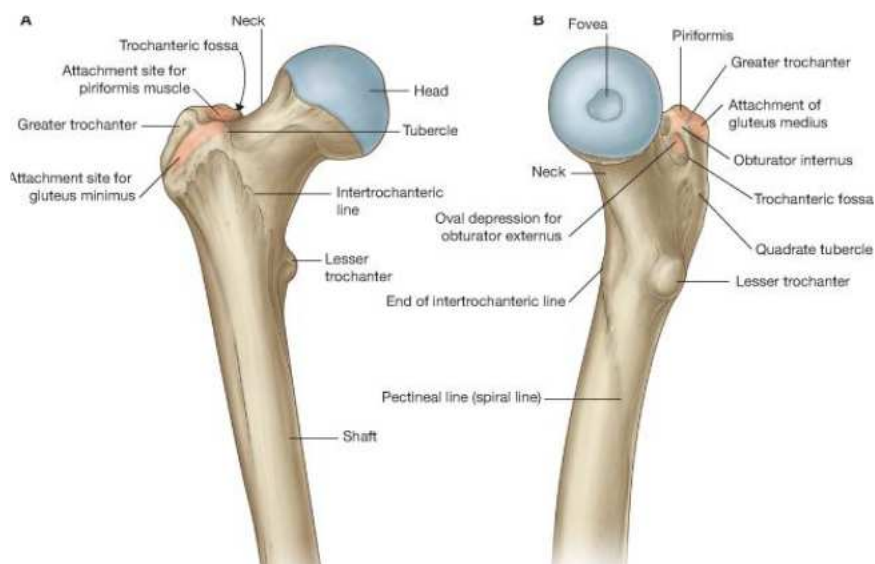
- 1) Shaft or Diaphysis, which extending from the Trochanter to flare of the femoral condyles
- 2) The proximal metaphysis consisting of articular head ,neck , greater and lesser trochanter
- 3) Distal metaphysis, a medial and lateral condyle articulating with the tibia.

Head, neck, greater trochanter and lesser trochanter constitutes the proximal femur.

The head of femur forms two thirds of a sphere and is directed medially, upward and anteriorly. The hip joint is congruous only in the weight bearing portion since head is not a perfect sphere . The neck is a stout bar of bone, which is pyramidal in shape , anteriorly flattened out. Neck – shaft angle is an angle intended by axis of shaft and neck which is about 120-130 degree. This arrangement allows greater mobility at the hip joint .. The head and neck of femur is anteverted by 10^0 - 15^0 with respect to the shaft. A broad, rough and oblique line, the intertrochanteric line, gives attachment to the iliofemoral ligament. The posterior aspect of

the neck is separated from the shaft by a prominent, rough ridge, the intertrochanteric crest. The greater trochanter is large quadrangular laterally positioned and is the traction epiphysis for the gluteus medius, which draws it superomedially and posteriorly. The lesser trochanter is a conical projection, lying posteromedially. The femoral shaft narrower in middle third, it widens to a lesser extent as it is traced upwards, and widening is well appreciated near the lower end of the bone.

Most patients with intertrochanteric fractures have considerable osteopenia. The quality of bone for the purchase of implant within the femoral head and neck is less than desirable. It is important that the internal fixation devices are placed in the part of the head and neck where the quality of bone is good. Ward, proposed the trabecular system of the proximal femur. The orientation of the trabeculae lies along the lines of weight bearing, with thicker trabeculae extending from the calcar and passing superiorly into the weight-bearing dome of the femoral head. There are five groups of trabeculae, namely the primary compressive, secondary compressive, primary tensile, secondary tensile and the greater trochanter groups.



Fig(1)- Anatomy of proximal femur

TRABECULAR PATTERN AND INDEX OF OSTEOPENIA⁵²

1. Principal Compressive Group

It is triangularly configured vertically oriented trabecular system extending from femoral neck to medial cortex of the head of femur.

2. Principal Tensile Group

It forms an arc extends from inferior aspect below fovea to lateral margin of greater trochanter traversing femoral head to superior cortex of neck.

4. Secondary Compressive Group

It has a fan like configuration extending from greater trochanter to calcar and lesser trochanter.

5. Secondary Tensile Group

Oriented along the lines of stress in the lateral proximal femur.

3. Greater Trochanter trabeculae

Confined to greater trochanter along the lines of stress.

WARD's triangle is a region formed between primary and secondary trabeculae.

The bone of poorest quality is in the anterosuperior aspect of the head and neck. The primary compression trabeculae are most strongest and persistent trabeculae. The primary tension trabeculae prevent the varus collapse of primary compression trabeculae.

SINGH AND MAINI INDEX⁵³

It is classified into six grades and used to quantify the bone density of femoral neck on radiology.

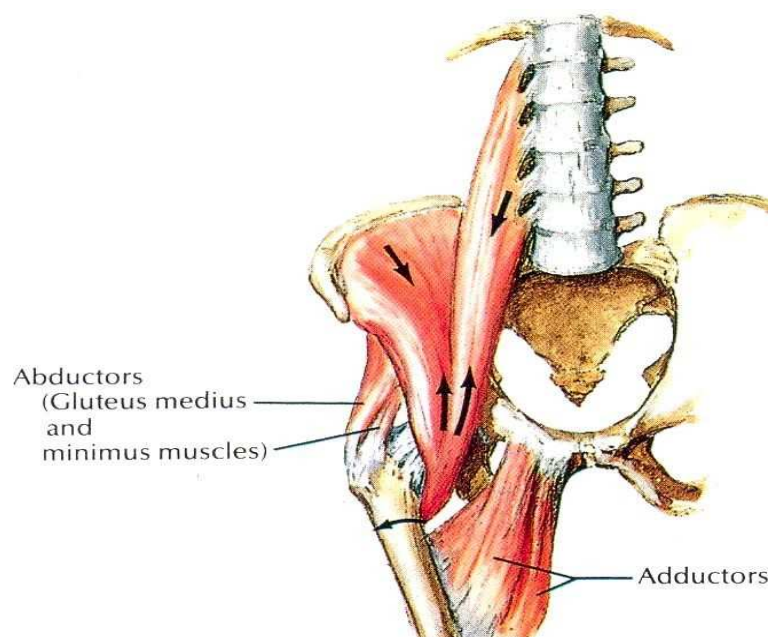
Grade 6 represents all trabeculae of normal thickness. The grade 5 is represents the loss of trabeculae at the region of Ward's triangle. Grade 4 shows thinned out principle tensile trabeculae without the loss of continuity. In grade 3 principle tensile trabeculae are thinned and breakage in continuity is present. Primary compression trabeculae alone is present ,other trabeculae nearly resorbed in Grade 2. In grade 1 only primary compression trabeculae are visible and are thinned.

Grade 1,2,3 are considered as osteoporotic whereas grade 4,5,6 are the normal variants. Since osteoporosis cannot be assessed from the fractured bone, the intact opposite hip is evaluated for osteoporosis on initial radiograph at the time of injury.

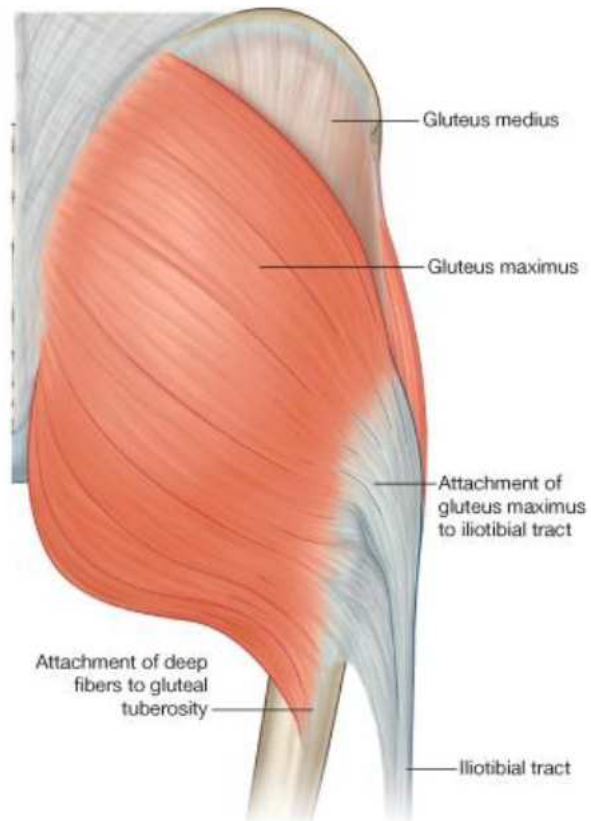
MUSCLE ACTIONS IN FRACTURES OF THE HIP

The gluteus medius, the principal abductor and internal rotator of the hip, is relaxed by the proximal displacement in the intertrochanteric fractures. The external rotators produce deformity when the opposing internal rotators, primarily the gluteus medius, are inactivated by loss of the fulcrum normally provided by the fixation of the femur to the pelvis at the hip. This effect must be considered during the reduction of the fractures.

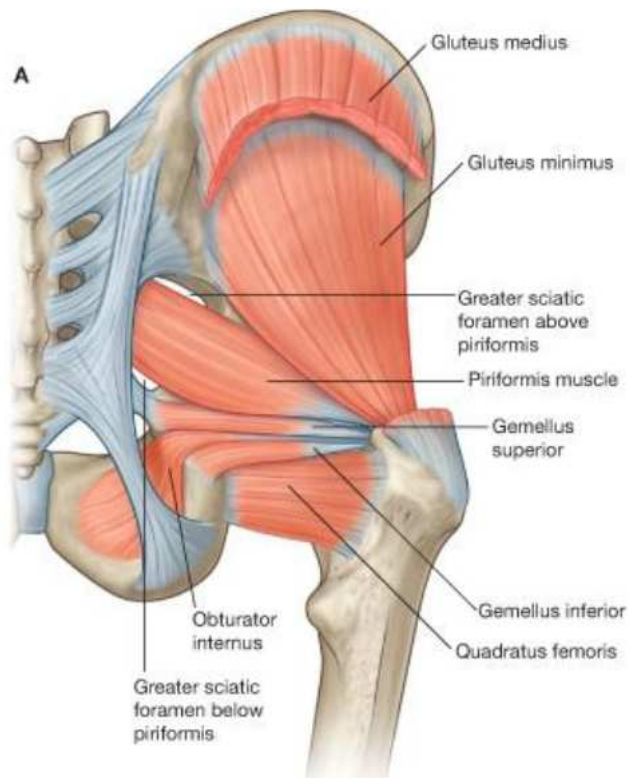
The iliopsoas, attached to the lesser trochanter, contributes to the upward displacement of the distal fragment and to the external rotation and flexion of the limb. In Intertrochanteric hip fractures, the adductors, unopposed by the abductors, adduct and shorten the extremity.



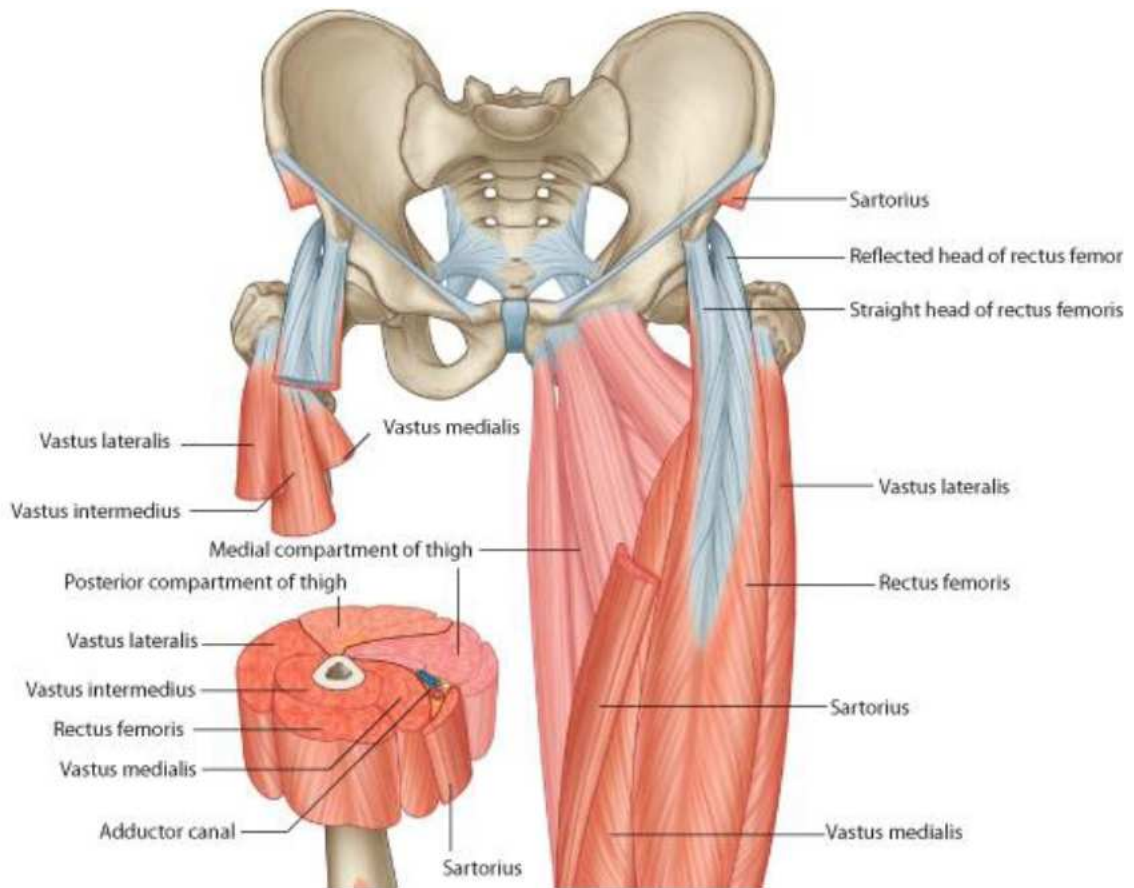
Fig(2-)-Muscle forces acting on the proximal femur



Fig(3) Posterior view of hip



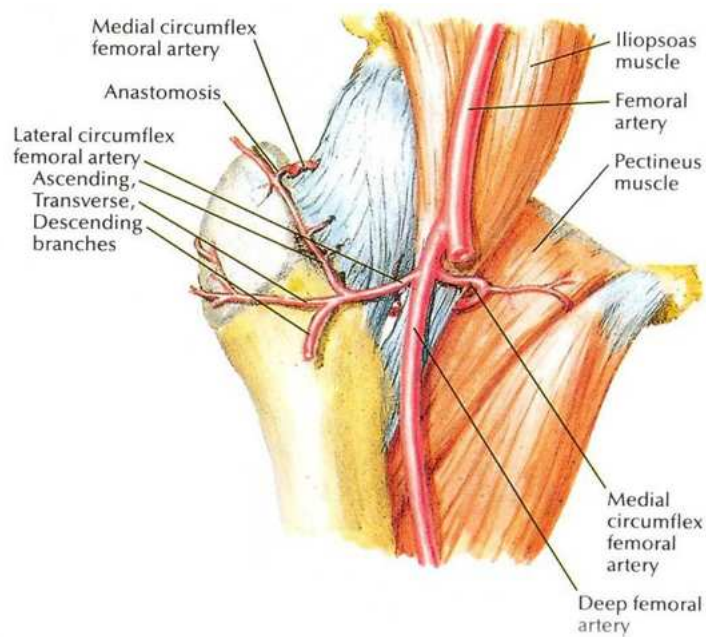
Fig(4) Posterior view of hip



Fig(5-)Anterior view of hip

VASCULAR SUPPLY OF THE PROXIMAL FEMUR

The blood supply of the proximal part of the femur arise primarily from the lateral and medial circumflex femoral arteries - branches of Profunda Femoris artery. They form an extra-capsular ring around the base of neck of femur.



Fig(6)-Vascular supply of the proximal femur

The metaphysis of the femur is supplied mainly by the superior and inferior metaphyseal vessels and lateral epiphyseal artery. The ascending cervical branches of retinacular vessels is divided into lateral, medial, anterior and posterior groups. The lateral vessels being the most important vessels supplying proximal femur. The lateral weight bearing portion of the femoral head is supplied by lateral epiphyseal group of arteries. These epiphyseal arteries forms anastomosis with artery of ligamentum teres and metaphyseal arteries.

MECHANISM OF INJURY

Low-energy falls from a standing height account for approximately 90% of community hip fractures in patients over 50 years of age with a higher proportion of females. Cummings and Nevitt⁵⁴ noted that neither increasing incidence of fall nor age-related osteoporosis explains the increase in hip fractures. They hypothesized the cause a hip fracture:

- (a) The faller must be oriented to impact near the hip
- (b) Protective responses must fail
- (c) Less energy is absorbed by the soft tissues around the hip than that necessary to prevent fracture
- (d) The residual energy of the fall applied to proximal femur must exceed its strength.

Indirect forces, including the pull of iliopsoas muscle on the lesser trochanter and the abductors on the greater trochanter have also been incriminated for intertrochanteric fracture. Other modes of injury may be either road traffic accidents or a fall from height. In the immediate post-traumatic stage of these fractures, the patient presents with physical findings like externally rotated and shortened extremity.

RADIOGRAPHIC EVALUATION

An anteroposterior and a cross table lateral view of the hip are usually taken to study the fracture geometry and to allow visualization of the trabecular pattern of the proximal femur which is an important clue in estimating bone quality and also for preoperative planning.

Singh and group⁵⁵ proposed an index for grading the degree of osteoporosis present in the proximal femur based upon radiographic appearance of the trabecular pattern.

Laros and Moore⁵⁶ found that patients with Singh grade 3 or lower had an increased incidence of complications of fixation. Subtrochanteric extension or possibility of pathological fracture requires full length femoral AP and LAT radiographs for implant length selection. Therefore both AP and LAT views of affected femur to knee are required with special attention to femoral bow and medullary canal diameter. Traction views with internal rotation may be of benefit preoperatively as an aid in the selection of definitive internal fixation.

CLASSIFICATION

In 1822, Astley Cooper⁵⁷ described the first classification of hip fracture:

Intracapsular or Extracapsular fractures with main complication of non-union and avascular necrosis in the first and malunion with coxa vara in the second.

In 1949, Boyd and Griffin⁵⁸ classified intertrochanteric fractures based on treatment recommendation.

In 1949, Evans⁵⁹ provided a simple classification based on the presence of mechanical instability as related to detachments from the lesser or greater trochanter. He recognized stable fractures as having an intact or reducible posteromedial buttress which prevents varus collapse.

In 1979 to 1980, Kyle et al⁶⁰ and Jensen,⁶¹ both reported independently on a revision of the Evans classification incorporating the lateral radiographic view indicating posteromedial fracture component and its relation to stability with sliding fixation system. Kyle et al. showed increased rate of deformity and collapse with increasing instability classification. Jensen et al. related the ability to reduce the fracture and secondary displacement risk with the use of a sliding hip screw type device in classification system.

Gotfried and Kulkarni et al.⁶² have developed a treatment –based classification derived from a modification of the Evans and Jensen

classification primarily to focus on the stability of the lateral wall as a buttress to minimize medialization and uncontrolled collapse after SHS fixation.

Boyd and Griffin Classification of Intertrochanteric Fractures⁶³

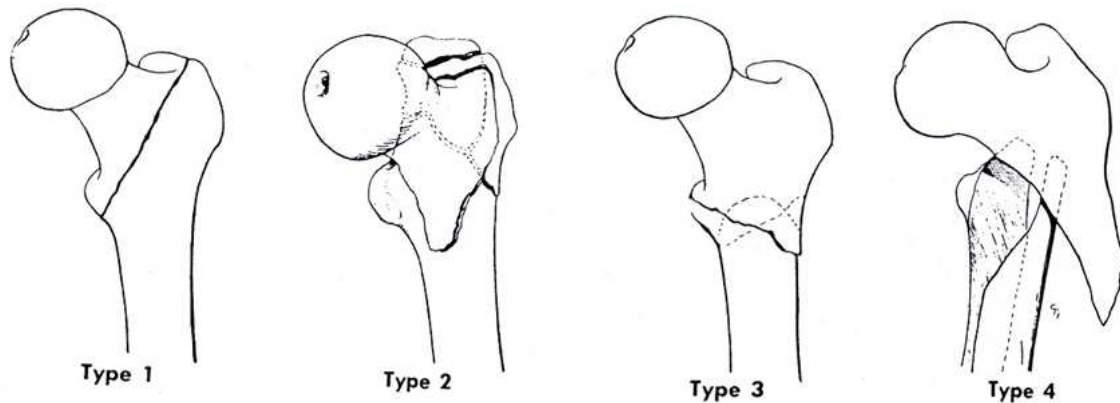


Fig (7)-Boyd and Griffin classification

Type 1 : Fractures that extend along the intertrochanteric line from the greater to the lesser trochanter.

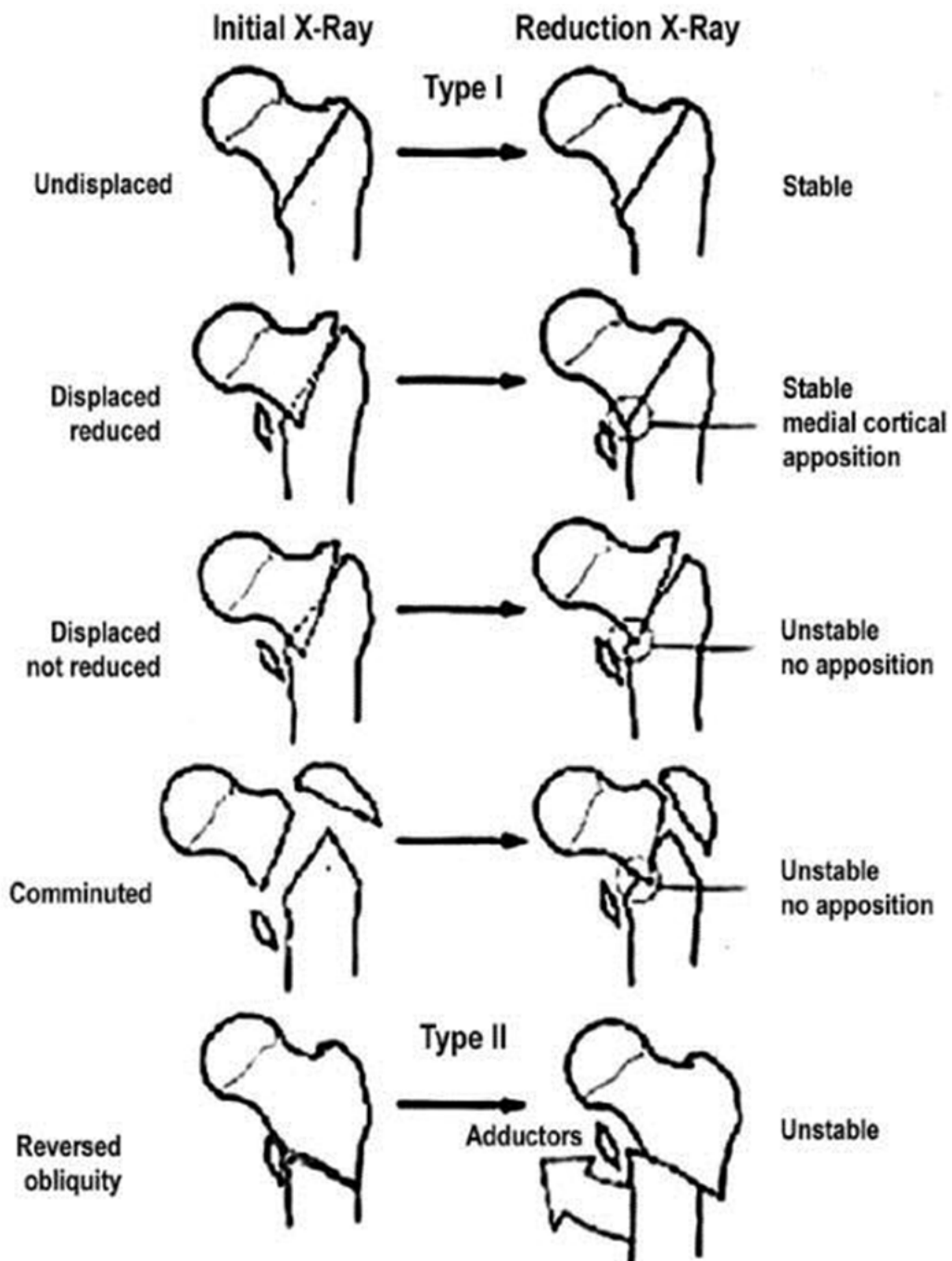
Type 2 : Comminuted fractures, the main fracture being along the intertrochanteric line(Posteromedial comminution).

Type 3 : Fractures that are basically subtrochanteric with at least one fractures passing across the proximal end of the shaft just distal to or at the lesser trochanter. The fracture line runs from superomedial to inferolateral (termed reverse obliquity by Wright).

Type 4 :Subtrochanteric with intertrochanteric extension with fracture lying in at least two planes.

Evans Classification of Intertrochanteric Fractures⁶⁴

Evans was the first to classify trochanteric fractures based upon their inherent stability. His classification scheme recognized two basic fracture types.



Fig(8)-Evans classification

Type I - Fracture line along the intertrochanteric line

Type II – Reverse oblique fracture

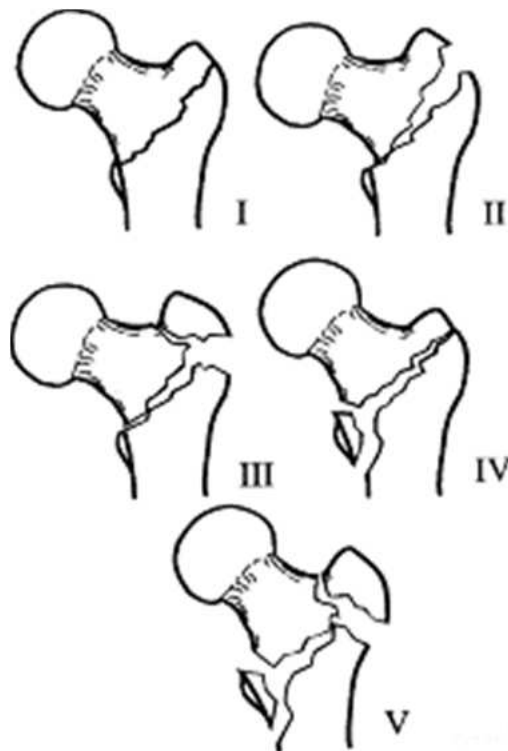
Type I fractures are further divided into four subtypes based upon their inherent stability.

The first two subtypes are stable because posteromedial cortical opposition exists or can be restored by reduction.

The second two subtypes are inherently unstable and have a marked tendency to collapse into varus owing to discontinuity of the posteromedial cortex.

Type II fractures include reverse obliquity of the fracture line which allows medial displacement of the shaft due to the unopposed pull of adductors, hence are unstable.

Jensen and Michaelsen's modification of Evans Classification⁶⁵



Fig(9) Jensen and Michaelsen's classification

Type I: Two- fragment fracture without displacement, stable.

Type II: Two-fragment fracture with displacement, stable.

Type III: Three- fragment fracture with displacement of the greater trochanter (lacks lateral support), unstable.

Type IV: Three- fragment fracture with displacement of the lesser trochanter or the medial cortex (lacks medial support), unstable.

Type V: Four-fragment fracture including the greater and the lesser trochanter or the medial cortex (lacking lateral and medial support).

BIOMECHANICS OF HIP JOINT

The goal of fixation in any fracture is to achieve union of the fracture with restoration of the normal anatomy and to re-establish the normal force vector acting along the bone.

Normal activities load the hip area with bending torsional and axial forces. These loads are resisted by the large dimension, greater peripheral substance and large cortical surface of the greater trochanter. This region also resists the tension generated by the major muscle groups attached here. At the same time its protrusions act as beam or lever arms for the attached muscles. The intertrochanteric trabecular bone pattern resists the constantly changing combination of forces acting on the hip. There are large stresses on the head and neck of the femur due to two forces: the abductor muscle force and the hip joint reaction force.⁶⁶ Gluteus medius muscle contributes axial compressive load along the neck of femur. Consequently a hip joint reaction of equal magnitude acts in opposite direction. To be in equilibrium, the joint reaction force must be equal to muscle force plus body weight. Bending forces develop in femoral neck and shaft in response to the forces acting through the head. Femoral neck must withstand all these forces since neck is offset in relation to shaft of femur.

Even when the structural integrity of the hip has been restored, the major muscle forces continue to test the stability of the fracture

fixation.⁶⁷

The implant has to stabilize the fracture and carry loads without any deformation, until osseous healing take place. During weight bearing, the reaction force passes along the medial trabeculations of the neck of femur. Any disruption in the structural continuity of the proximal end of the femur will alter the reaction force exerted through the femoral shaft and also the abductor force between the pelvis and greater trochanter exerted by the abductor muscles.

A sliding device with a screw-plate angle closest to the combined force vector allows optimum sliding and impaction. Kyle et al⁶⁸ described that closer the nail - plate angle to the resultant vector of the forces around the hip, more will be the force available for impaction of fracture. A device that is placed at a lower angle has lesser force acting parallel to the sliding axis and more force is acting perpendicular to the sliding axis. This perpendicular force tends to jam or bend the device, thus preventing impaction of fracture. So the implant is placed at an angle as high as possible.⁶⁹

Jacobs et al⁷⁰ states the sliding hip screw acts as a lateral tension band in stable fractures, transmitting forces through the medial cortex. This allows impaction of the surfaces in unstable fracture patterns, thereby decreasing the bending moment, avoiding cutout from the femoral head and shortening the lever arm.

Fixation of unstable fractures with DHS is associated with displacement of the fracture, leading to medialization of the femoral shaft and lateralization of the greater trochanter resulting in shortening of the extremity. The biomechanics of the hip is altered since lever arm of abductor is also shortened.⁷¹

Parker et al⁷² described that medialization of the femoral shaft by greater than one-third of the diameter of shaft of femur is associated with a sevenfold increase in fixation failure .

Adams et al⁷³ explains that, the shorter lever arm of intramedullary devices provides more load sharing and allow lesser collapse of the fracture hence decreases the tensile strain on the implant and hence mechanical failure of the implant is reduced. Intramedullary fixation devices provide three point fixation and controlled impaction.

Geriatric population usually consists of weak, osteoporotic bone, so, intramedullary devices carry an advantage by not having to depend on plate fixation with bone screws purchasing a compromised lateral cortex.

MATERIAL AND METHODS

The study was conducted in **RAJIV GANDHI GOVERNMENT GENERAL HOSPITAL, MADRAS MEDICAL COLLEGE, INSTITUTE OF ORTHOPAEDICS AND TRAUMATOLOGY, CHENNAI-3**. It was a **RETROSPECTIVE COMPARATIVE STUDY**. The study included 40 elderly osteoporotic patients of intertrochanteric fractures of femur managed by Proximal Femoral nail (20 cases) and Dynamic Hip Screw(20 cases).

Study includes intertrochanteric fracture of any type of Boyd and Griffin's classification. Patients from age group 40 years and above to 90years were included in the study. In all the patients along with personal data, mode of trauma, type of fracture, type of surgery, follow up examination including hip joint examination were considered. Functional outcome is assessed by **HARRIS HIP SCORE(Modified)**.⁷⁴

INCLUSION CRITERIA

- Intertrochanteric femur fractures(Stable and Unstable)- proven Osteoporotic with radiological evidence (SINGH'S INDEX) of contralateral hip.
- Age 40-90 years

EXCLUSION CRITERIA

- Pathological fractures of the hip other than osteoporosis.

- Age <40years and >90 years
- Patients those could not be contacted once involved in the study.

The fractures were fixed with either DHS or PFN. Of the 40 patients taken into the study, 20 were treated with dynamic hip screw fixation and 20 with proximal femoral nailing.

DESCRIPTION OF PROCEDURES:

Lambotte⁷⁵ described the four components of surgical treatment of fractures at the turn of the 20th century. Exposure, Reduction, Provisional Fixation, Definitive Fixation. These steps are universal in application independent of device.

POSITIONING:

Move the patient to the fracture table after anaesthesia is complete. A supine position with unaffected side flexed and abducted, affected side with foot traction, knee extension. The operative leg is raised to approx 20-30 degree of flexion and traction is given in line with the body to avoid varus positioning of hip.

REDUCTION:

The closed reduction of fracture by traction in neutral position, slight internal or external rotation. Reduction is checked anteroposterior and lateral views on the image intensifier and also look for postero-

medial continuity. The objectives of reduction is to correct varus and rotational deformities.

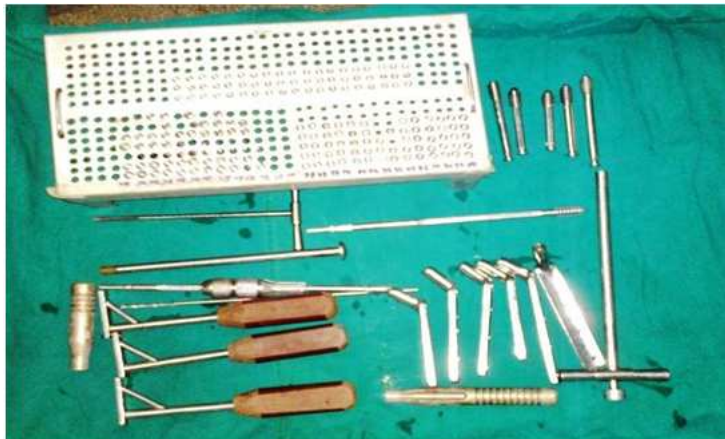
METHOD OF FIXATION

A. Dynamic Hip Screw Fixation:

Skin incision is made distal to GT along the shaft of femur laterally . Tensor fascia lata is split followed by the vastus lateralis muscle along its attachment to femur using L shaped incision. Lateral surface of proximal femur is cleared by periosteal elevator. Using the 135 degree angle guide, 2cm below the trochanteric flare is chosen as point of entry under radiographic control. A threaded guide wire of 2.5mm is inserted into the center or inferior part of the neck in AP view and centre or slightly posterior in lateral view. The length of the guide pin lying outside is measured using an external measuring device to determine required the length of the screw.

The triple reamer for the screw(8mm), the barrel (13mm) and the barrel plate junction, is set to the length already measured and reaming is done around the guide wire under image intensifier. With a screw lock tap, threads are cut into the bone followed by insertion of the lag screw of appropriate length. This allows 5mm of compression. In osteoporotic bone, tap 1-2 cm less allowing the screw to engage into sub articular bone. Side plate is advanced into lag screw and fixed with cortical screws. Traction is released and 19mm compression screw is applied.

A suction drain is inserted and layered closure done.



Fig(10)- Implants and Instrumentation



Fig(11)- Patient position on fracture table



Fig(12)- Skin incision



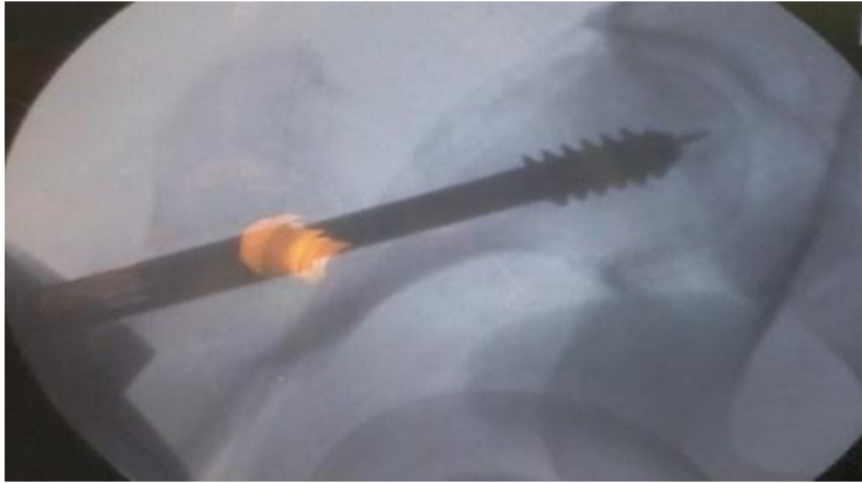
Fig(13)-IT band incised



Fig(14)-Guide pin with 135 degree angle guide



Fig(15)Triple Reaming



Fig(16)Hip screw insertion



Fig(17)-Barrel Plate fixation



Fig(18)-Compression Screw insertion

B. Proximal femur nailing

A slightly curved lateral incision of 3-5 cm extending proximally from the tip of greater trochanter is made. The fascia is incised but the gluteus medius fibers are not dissected, as the approach is designed to minimize soft tissue damage. A nail system with a targeting guide and trocar system helps protect the gluteus medius.

Russell et al described the surgical approach for a minimally invasive nail insertion based on three components of proximal femoral preparation: (1)precision portal placement (2)trajectory control (3)portal preservation.

Under fluoroscopic guidance, an entry point is made medial to the tip of the GT with a curved awl. A 3.2mm threaded guide pin is inserted with the tissue protection pin centering sleeve, beyond the fracture site. The position of the pin is checked on both AP and lateral view on image intensifier. Serial reaming done with 1mm increments until 1mm more than the selected nail size is reached and proximal femur entry point is widened. The mediolateral angle of 6degree allows easy insertion of the nail. The nail is then assembled to the jig and passed through the guide wire and pushed by rocking movements across the fracture site and terminal position is hammered.

Once the proximal femoral nail is inserted at desired level, reaming of head and neck for the cannulated hip screw, which is 8mm in diameter

is done. Under radiographic guidance, the hip screw is inserted into inferior half of the neck within 5-10mm from the subchondral bone of the femoral head. The cannulated stabilization screw of 6.4mm in diameter was then inserted into the proximal port of the nail under image intensifier guidance. Distal locking is performed using two cortical screws.



Fig(19)-Implants and Instruments



Fig(20)-Positioning and drapping



Fig(21)-Skin incision



Fig(22)-Entry portal with AWL



Fig(23)-Nail insertion



Fig(24)-Proximal guide wire insertion



Fig(25)-Proximal screw insertion



Fig(26)-Distal lock application

COMPLICATIONS

MORTALITY

Fractures of the proximal femur are an important cause of mortality and morbidity in all ages, especially elderly groups. Epidemiologic studies have shown that these fractures are associated with increased risk of mortality for 6 to 12 months after the injury.⁷⁶ An increased risk of mortality after hip fractures is associated with elderly age,⁷⁷ male sex,⁷⁸ poor compliance of systemic diseases,⁷⁹ operative management in patients with coexisting medical complications,⁸⁰ and also due to postoperative complications.⁸¹

Sernbo et al⁸² reported that one year mortality rates after internal fixation of intertrochanteric fractures is 35% among men and 20% among women.

Jensen et al⁸³ reported that 10% of hospital mortality rate is associated with intertrochanteric fractures.

WOUND INFECTION

Infection occurs in 1% to 2% of cases which can be minimized by preoperative prophylactic antibiotics, usually a 1st generation cephalosporins. If infection does occur, it can be life threatening and standard care involves isolation and sensitivity testing of causative bacteria and appropriate IV antibiotics.

Edwards et al⁸⁴ reported a 1.2% rate of deep wound infection and 1.1%

superficial wound infection in a series of 3000 cases. Most cases were due to *Staphylococcus aureus* and MRSA. The 1-year mortality in the total series was 30% and is increased to 50% in those who developed an infection. If infection is superficial, oral antibiotics for 7-10 days are suggested and if deep infection occurs, urgent formal surgical debridement and irrigation is required.

Wu et al⁸⁵ reviewed their experience with 23 peritrochanteric osteomyelitis cases and presented a two-staged treatment protocol. They used external fixator after radical debridement in 1st stage followed by reconstruction in 2nd stage.

PRESSURE SORES

Agarwal et al⁸⁶ reported 20 % rate of pressure sores in hip fractures.

Versluis⁸⁷ studied mortality in elderly patients with pressure sore operated for hip fractures is about 27%. The detection of pressure sore in early stage, such as localized erythema or discoloration, alerts the need for change in position.⁸⁸

THROMBOEMBOLISM

Fisher et al⁸⁹ studied the incidence of a venous thromboembolic event in the no-treatment group was 12% and in mechanical compression group 4%.

Low molecular weight heparin have been found to be safe to prevent thromboembolism in patients with hip fractures. Fondaparinux

prophylaxis from 1-4 weeks was reported as well tolerated and significantly reduced delayed venous thrombotic events from 35% to 1.4%. Based on these findings, 4-week fondaparinux treatment may become the standard thrombo-prophylaxis after hip surgery.⁹⁰

IMPLANT MALFUNCTION

Implant malfunction or failure is estimated to occur in approximately 5% of cases, usually from implant fatigue failure, femoral head medial penetration, screw cutout, shaft fixation failure with broken screws and disassembly of the device components.

The most common mode of fixation failure is the screw cut of osteoporotic bone and penetration of implant through the head or neck of the femur, causing varus collapse of the fracture.

Parker et al⁹¹ analyzed fixation failure in trochanteric fractures treated with SHS. Femoral medialization was more common in fractures particularly if there was comminution of the lateral femoral cortex at the site of insertion of lag screw. Femoral medialization was strongly associated with fixation failure, with a seven-fold increase in risk of failure if medialization of more than one third of the shaft width occurred. Loss of construct stability is one of the frequent complications manifested by collapse of the screw and varus migration of the femoral head construct with final cutout failure in most severe cases. A centre-centre position of lag screw minimizes cutout.

Baumgaertner et al⁹² reported the tip-apex distance. It is the sum of distance from the apex of femoral head and tip of the head fixation device. A summation of less than 25mm of the distance on AP and lateral radiographs is correlated with reduced cutout in a single head fixation device.

Gotfried and Palm et al⁹³ identified the significance of lateral wall fracture at point of insertion of hip screw. It requires reattachment of GT with a buttress plate techniques.

Clawson⁹⁴ stated that fixation failure rates of 5.2% and 11.5%, respectively, occurs in stable and unstable fractures.

OTHER COMPLICATIONS:

- 1) Non-union: Non union of pertrochanteric fractures with previous internal fixation is reported to affect 1% of older patients. If non- union does occur, the rate of success after implant exit, re-nailing in a more valgus position with cancellous bone graft has been reported to be 90 per cent.
- 2) Avascular necrosis: Aseptic necrosis is reported to be as low as around 0.8 per cent.
- 3) Stress fracture of femoral neck.

RESULTS

The results of treatment of intertrochanteric fractures by Dynamic hip screw and Proximal femur nailing were assessed by HARRIS HIP SCORE system. According to needs of the Indian patients, this system is modified by replacing “put on shoes and socks” by “squatting” and in place of “sitting” by “cross legged sitting”

Harris HIP evaluation (Modified).

1. PAIN

- None or ignores the pain
- Slight, Occasional, no compromise in activities
- Mild pain, no effect on average activities, Rarely moderate pain with unusual activity, may take aspirin
- Moderate pain, tolerable but makes concessions to pain
- Totally disabled, crippled, pain in bed, bedridden

2. LIMP

- None
- Slight
- Moderate
- Severe

3. SUPPORT

- None
- Cane for long walks
- Cane most of the time
- One crutch
- Two canes
- Two crutches
- Not able to walk

4. DISTANCE WALKED

- Unlimited
- Six blocks
- Two or Three blocks
- Indoors only
- Bed to chair

5. STAIRS

- Normally without using a railing
- Normally with a railing
- In any manner
- Un able to do stairs

6. SQUATTING

- With ease

- With difficulty
- Unable

7. CROSS LEGGED SITTING

- With ease
- With difficulty
- Unable

8. ENTER PUBLIC TRANSPORTATION

- Yes
- No

9. Absence of all Deformities (All yes = 4, less than 4 =0)

- Less than 30 fixed flexion contracture Yes No
- Less than 10 fixed adduction Yes No
- Less than 10 fixed internal rotation in extension Yes No
- Leg length discrepancy less than 3.2 cm Yes No

10. Range of motion (In degrees)

- Flexion
- Adduction
- Abduction
- External rotation
- Internal rotation

Range of Motion Scale

- 211-300
- 161-210
- 101-160
- 61-100
- 31-60
- 0-30

Range of Motion Score _____

Total Harris HIP Score _____

Result

- 0 -69 Poor
- 70-79 Fair
- 80-89 Good
- 90-100 Excellent

Trochanteric fractures are classified according to Boyd and Griffin classification.

The collected data were analyzed with IBM.SPSS statistics software 23.0 version. To find the significance in categorical data Chi-Square test was used similarly if the expected cell frequency is less than 5 in 2×2 tables then the Fisher's Exact was used. In both the above statistical tools the probability value 0.05 is considered as significant level.

Table (1) Fig(28)- Age distribution

Age	Frequency	Percent
Upto 50 yrs	5	12.5
51 - 55 yrs	7	17.5
56 - 60 yrs	9	22.5
61 - 65 yrs	6	15.0
66 - 70 yrs	9	22.5
Above 70 yrs	4	10.0
Total	40	100.0

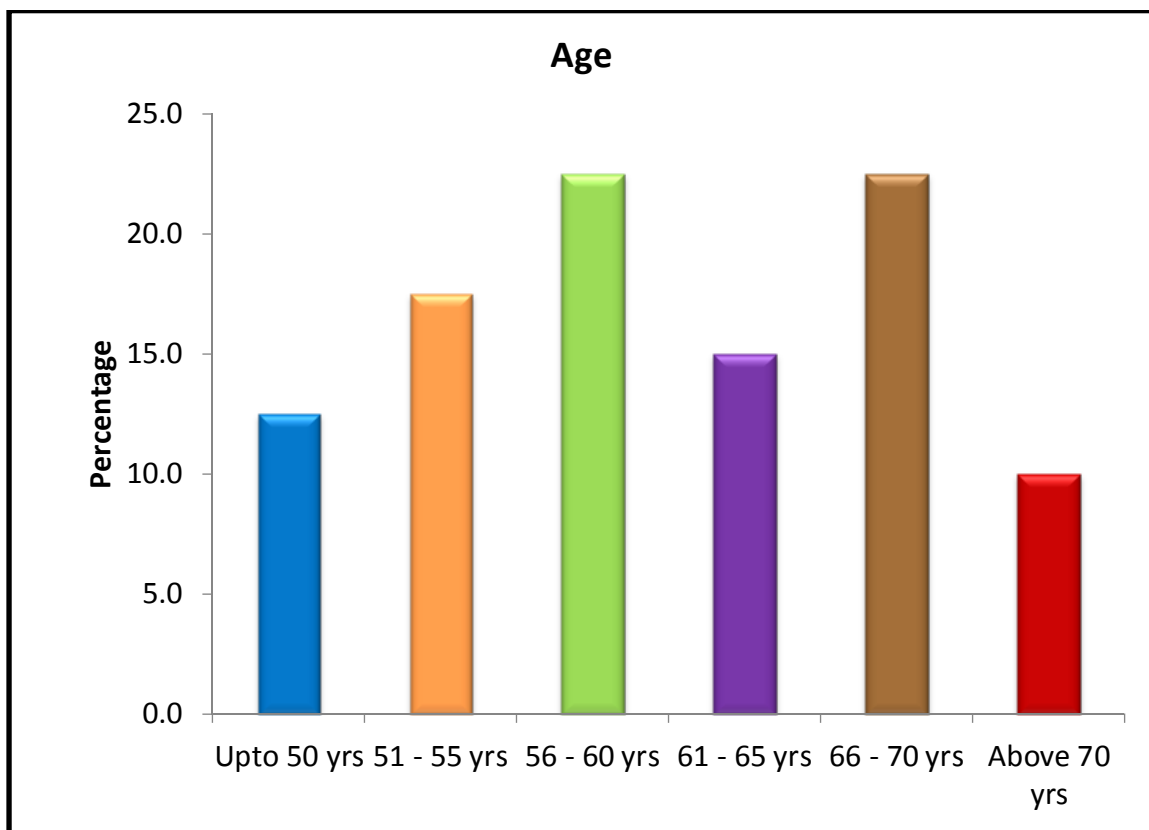
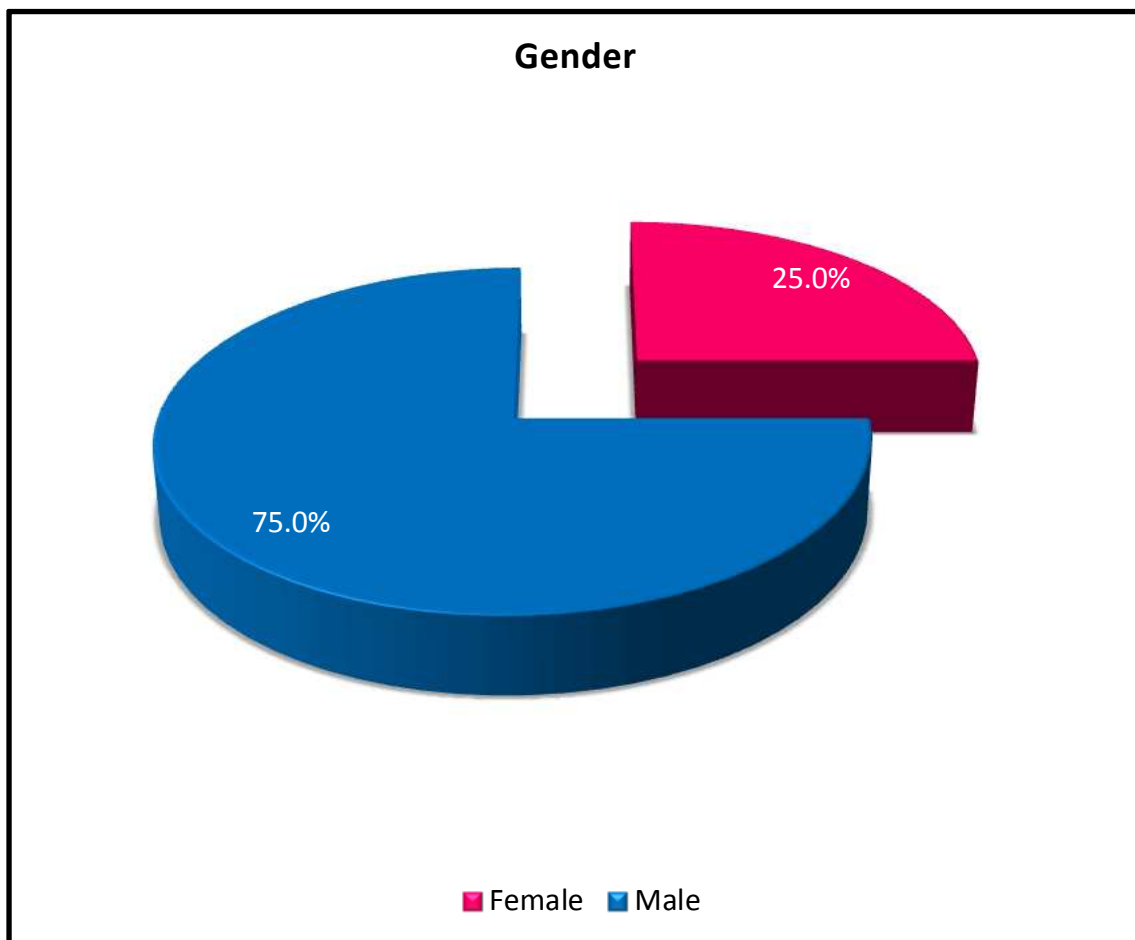


Table (2)Fig(29)- Sex distribution

Sex	Frequency	Percent
Female	10	25.0
Male	30	75.0
Total	40	100.0

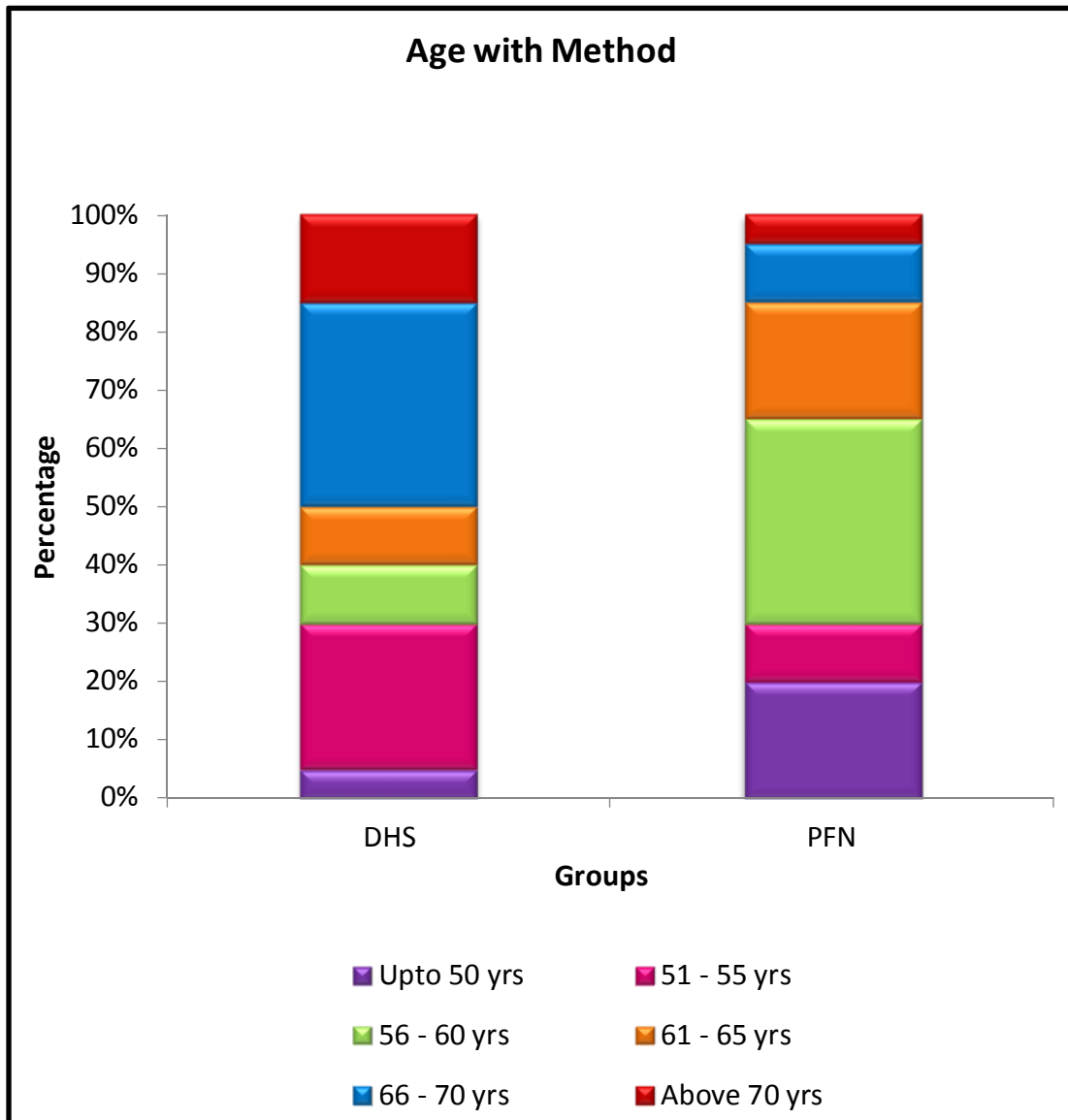


The most common age group involved in the study was 56-70yrs and is male predominance.

Table (3)- Age distribution with Method of fixation

Comparison between Age with Method							
			Method		Total	χ^2 - value	P-value
			DHS	PFN			
AGE	Upto 50 yrs	Count	1	4	5	10.308	0.067 #
		%	5.0%	20.0%	12.5%		
	51 - 55 yrs	Count	5	2	7		
		%	25.0%	10.0%	17.5%		
	56 - 60 yrs	Count	2	7	9		
		%	10.0%	35.0%	22.5%		
	61 - 65 yrs	Count	2	4	6		
		%	10.0%	20.0%	15.0%		
	66 - 70 yrs	Count	7	2	9		
		%	35.0%	10.0%	22.5%		
	Above 70 yrs	Count	3	1	4		
		%	15.0%	5.0%	10.0%		
	Total	Count	20	20	40		
		%	100.0%	100.0%	100.0%		
# No Statistical Significance at P>0.05 level							

Fig(30)- Age distribution and Method of fixation



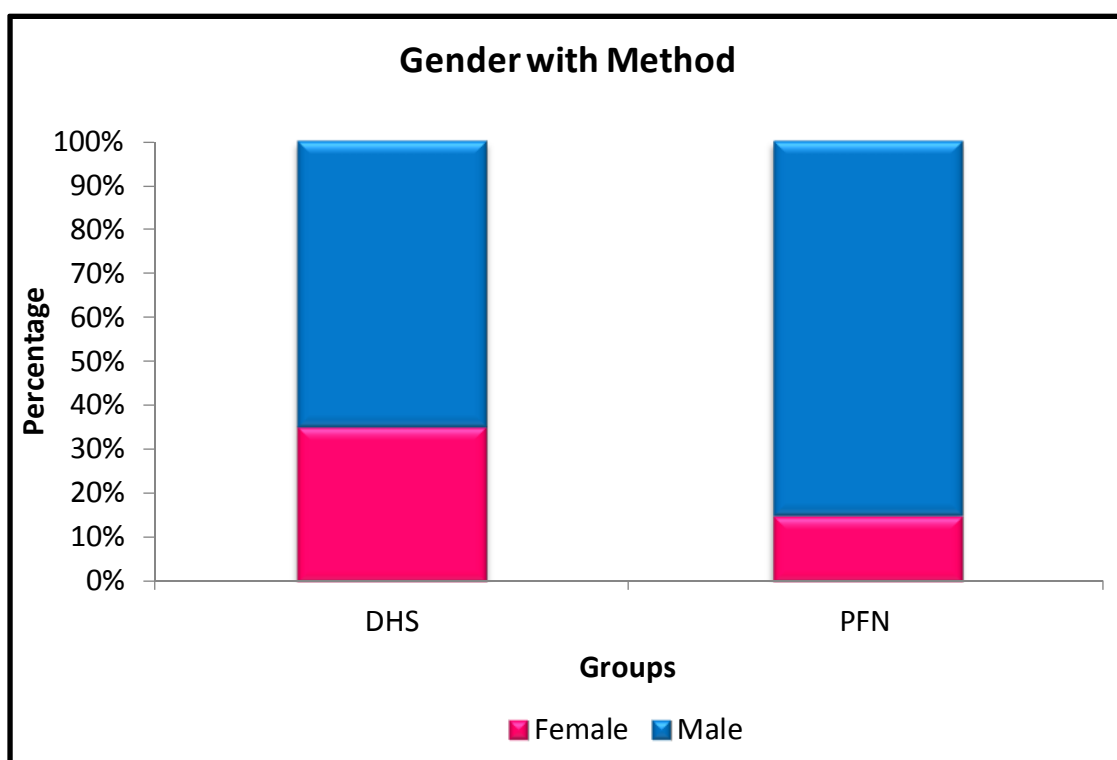
DHS was commonly done in age group 66-70yrs and PFN in age groups 56-60yrs and 66-70yrs.

Table(4)- Gender distribution and Method of fixation

Comparison between Gender with Method							
			Method		Total	χ^2 - value	P- value
			DHS	PFN			
Sex	Female	Count	7	3	10	2.133	0.273 #
		%	35.0%	15.0%	25.0%		
	Male	Count	13	17	30		
		%	65.0%	85.0%	75.0%		
Total		Count	20	20	40		
		%	100.0%	100.0%	100.0%		

No Statistical Significance at P>0.05 level

Fig (31)- Gender distribution and Method of fixation



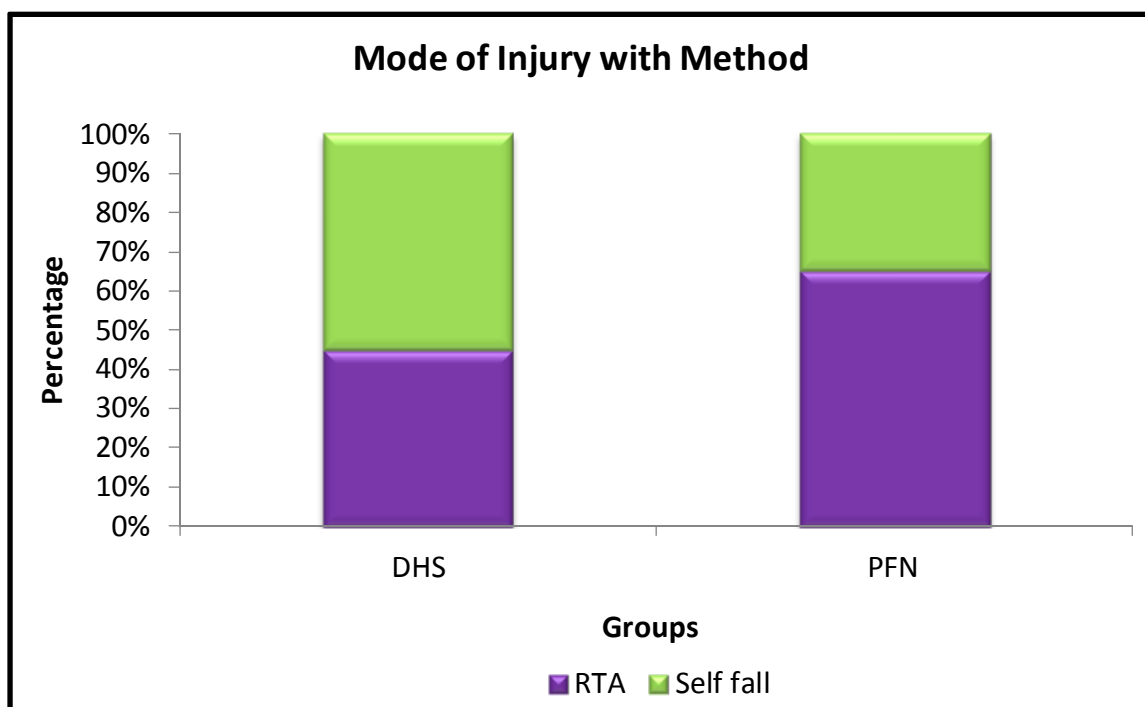
Both DHS and PFN are most commonly done in Male patients in the study.

Table (5)- Comparing mode of injury and method of fixation

Comparison between Mode of Injury with Method							
			Method		Total	χ^2 -value	P-value
			DHS	PFN			
Mode Of Injury	RTA	Count	9	13	22	1.616	0.341 #
		%	45.0%	65.0%	55.0%		
	Self fall	Count	11	7	18		
		%	55.0%	35.0%	45.0%		
Total		Count	20	20	40		
		%	100.0%	100.0%	100.0%		

No Statistical Significance at P>0.05 level

Fig (32)- Comparing mode of injury and method of fixation



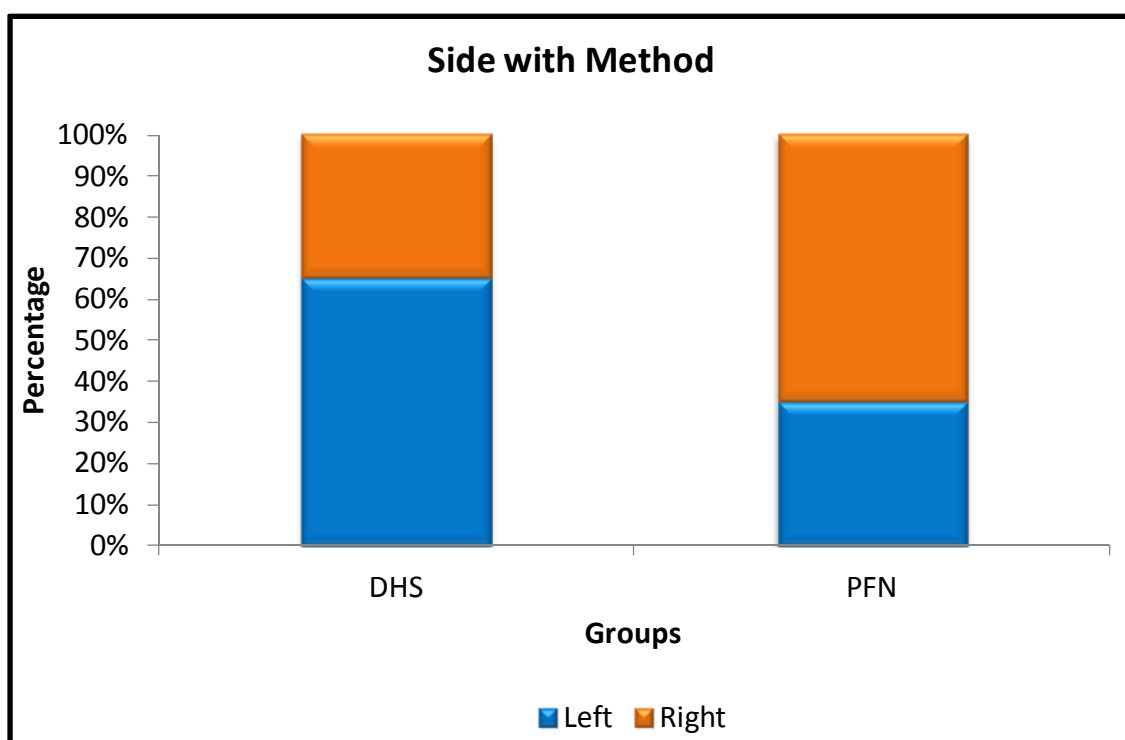
RTA is the most common mode of injury and is fixed commonly with PFN and in case of self-fall DHS is the done commonly.

Table (5)- Comparison of side of fracture and method of fixation

Comparison between Side with Method							
			Method		Total	χ^2 - value	P-value
			DHS	PFN			
SIDE	Left	Count	13	7	20	3.600	0.113 #
		%	65.0%	35.0%	50.0%		
	Right	Count	7	13	20		
		%	35.0%	65.0%	50.0%		
Total		Count	20	20	40		
		%	100.0%	100.0%	100.0%		

No Statistical Significance at P>0.05 level

Fig(33) Comparison of side of fracture and method of fixation



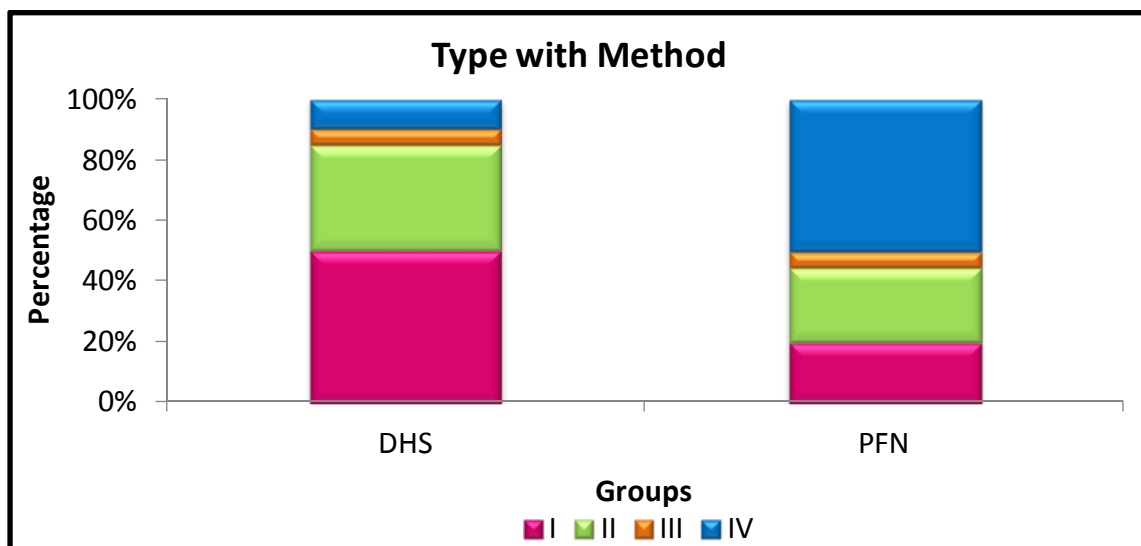
Fracture is equally distributed on both sides. Left sides are mostly fixed with DHS and right sides mostly by PFN.

Table (6)- Comparison of type of fracture and method of fixation

Comparison between Type with Method							
			Method		Total	χ^2 - value	P-value
			DHS	PFN			
Type	I	Count	10	4	14	8.238	0.041 *
		%	50.0%	20.0%	35.0%		
	II	Count	7	5	12		
		%	35.0%	25.0%	30.0%		
	III	Count	1	1	2		
		%	5.0%	5.0%	5.0%		
	IV	Count	2	10	12		
		%	10.0%	50.0%	30.0%		
Total		Count	20	20	40		
		%	100.0%	100.0%	100.0%		

*** Statistical Significance at P < 0.05 level**

Fig(34)-Comparison of type of fracture and method of fixation



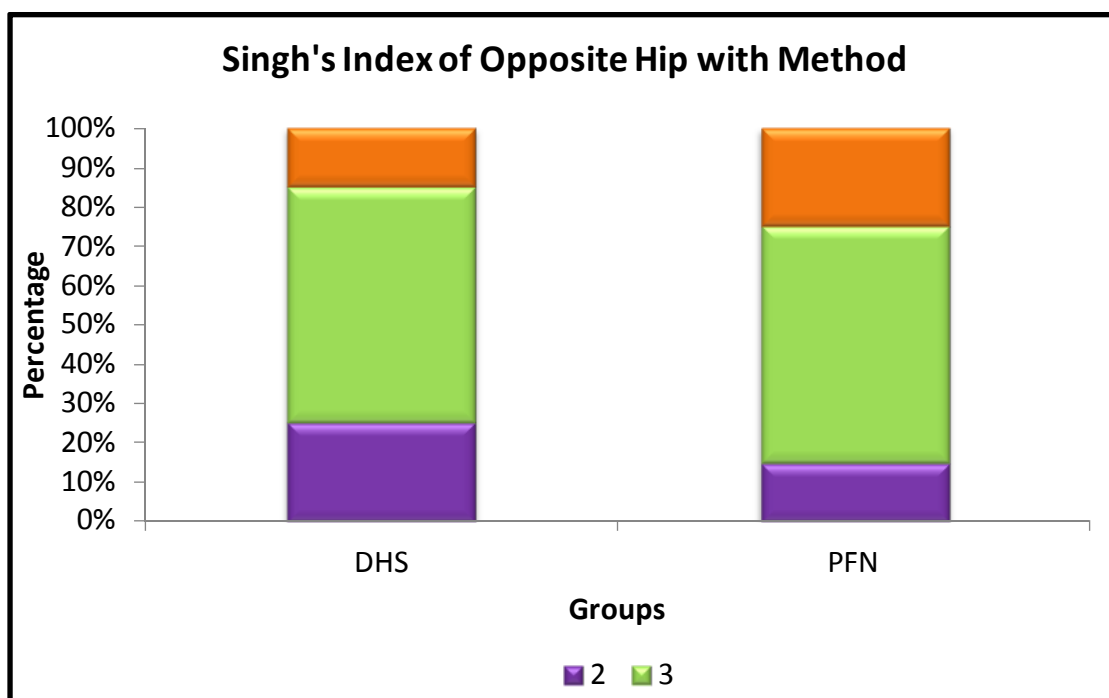
Type I fracture is most common among the individuals and is fixed with DHS mostly where as type IV fractures are mostly fixed with PFN was statistically significant.

Table (6)Comparing Singh's index and method of fixation

Comparison between Singh's Index of Opposite Hip with Method						χ^2 - value	P-value
		Method		Total			
		DHS	PFN				
Singh's Index Of Opposite Hip	2	Count	5	3	8	1.000	0.607 #
		%	25.0%	15.0%	20.0%		
	3	Count	12	12	24		
		%	60.0%	60.0%	60.0%		
	4	Count	3	5	8		
		%	15.0%	25.0%	20.0%		
Total		Count	20	20	40		
		%	100.0%	100.0%	100.0%		

No Statistical Significance at P>0.05 level

Fig (35)Comparing Singh's index and method of fixation



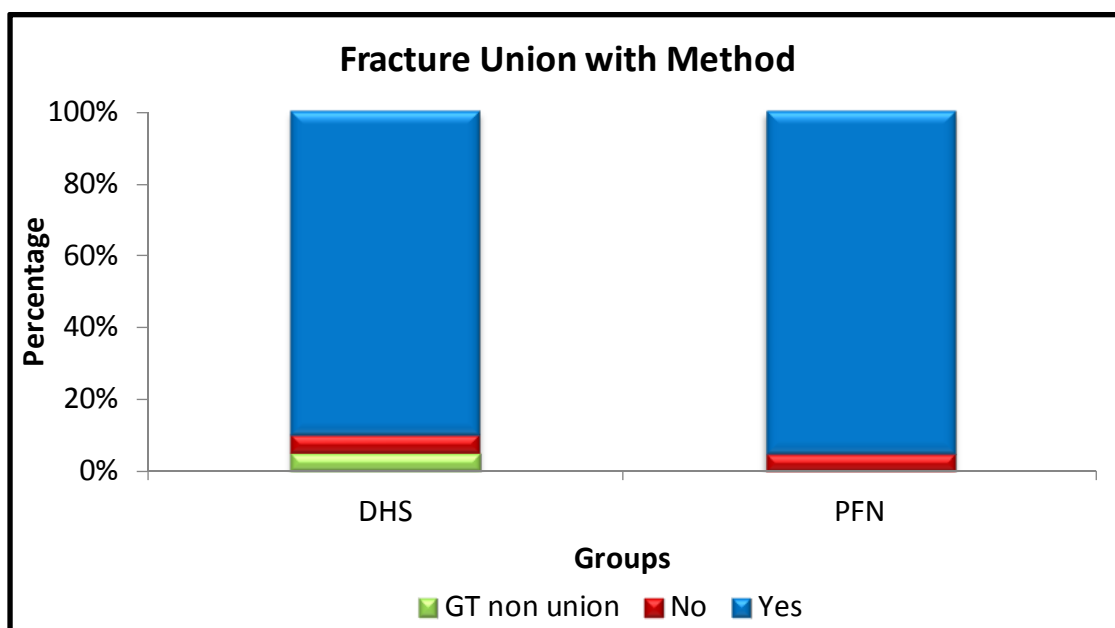
Grade III Singh's index is most common radiological type in osteoporosis and are equally fixed with DHS and PFN.

Table (7) Comparing method of fixation and fracture union

Comparison between Fracture Union with Method							
			Method		Total	χ^2 - value	P-value
			DHS	PFN			
Fracture Union	GT non union	Count	1	0	1	1.027	0.598 #
		%	5.0%	0.0%	2.5%		
	No	Count	1	1	2		
		%	5.0%	5.0%	5.0%		
	Yes	Count	18	19	37		
		%	90.0%	95.0%	92.5%		
Total		Count	20	20	40		
		%	100.0%	100.0%	100.0%		

No Statistical Significance at P>0.05 level

Fig (36) Comparing method of fixation and fracture union



Fractures fixed with either DHS or PFN, fracture united in most of the cases.

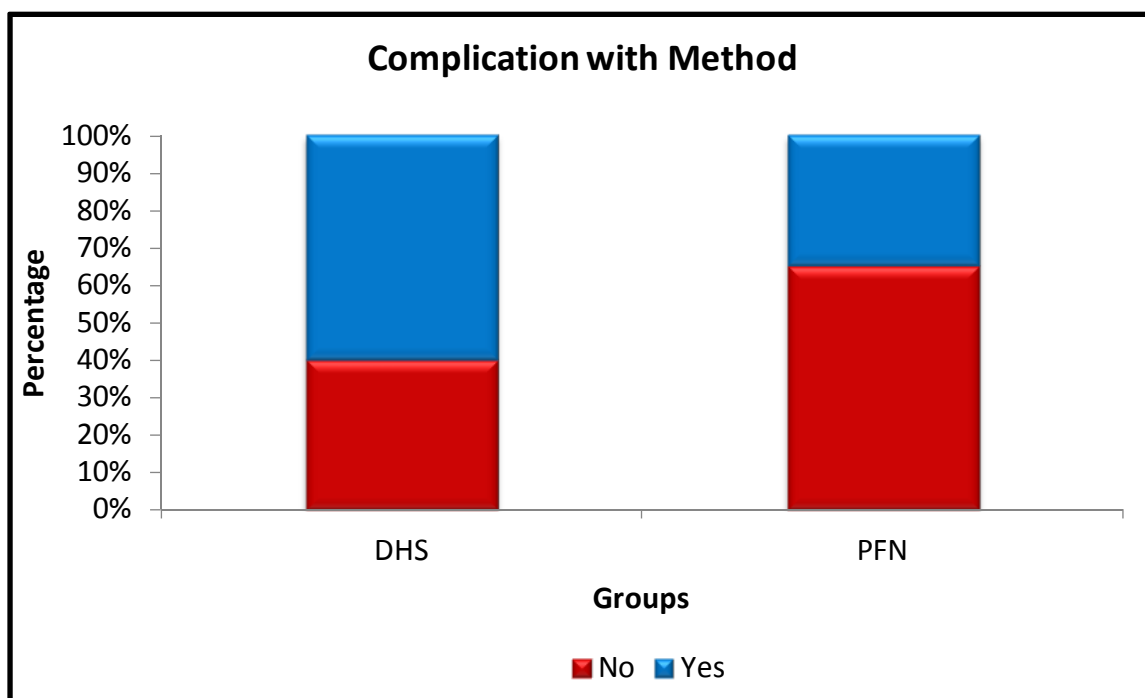
Though there is time variation in period of union, most of the cases fracture united well either fixed with DHS or PFN.

Table (8)Comparing method of fixation and complication

Comparison between Complication with Method							
			Method		Total	χ^2 - value	P-value
			DHS	PFN			
Complication	No	Count	8	13	21	2.506	0.205 #
		%	40.0%	65.0%	52.5%		
	Yes	Count	12	7	19		
		%	60.0%	35.0%	47.5%		
Total		Count	20	20	40		
		%	100.0%	100.0%	100.0%		

No Statistical Significance at P>0.05 level

Fig (37)Comparing method of fixation and complication



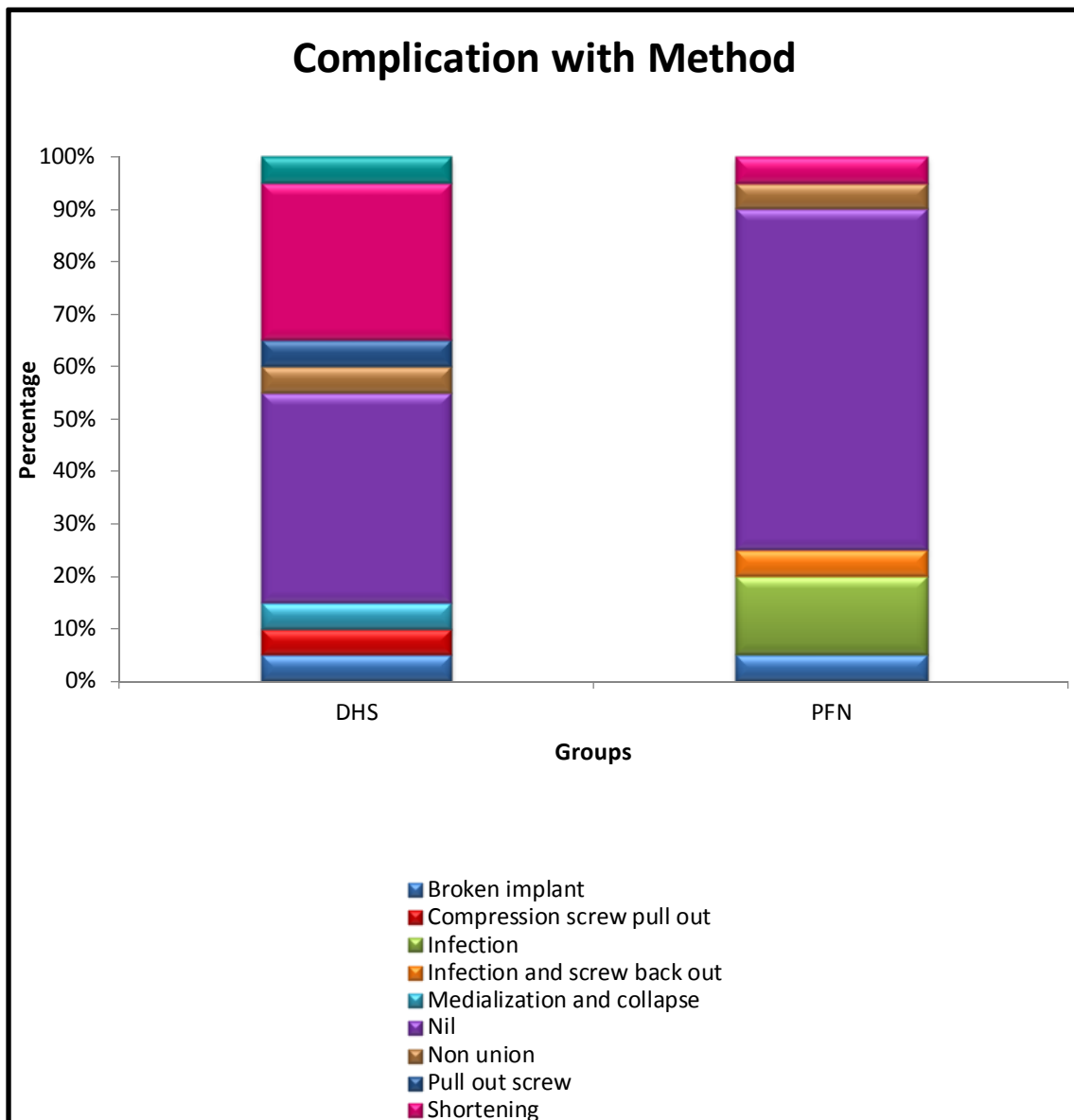
Though complication rate is common with DHS , the difference is not statistically significant.

Table (9) Postoperative Complications

Comparison between Complication with Method							
			Method		Total	χ^2 - value	P-value
			DHS	PFN			
Complication	Broken implant	Count	1	1	2	12.762	0.174 #
		%	5.0%	5.0%	5.0%		
	Compression screw pull out	Count	1	0	1		
		%	5.0%	0.0%	2.5%		
	Infection	Count	0	3	3		
		%	0.0%	15.0%	7.5%		
	Infection and screw back out	Count	0	1	1		
		%	0.0%	5.0%	2.5%		
	Medialization and collapse	Count	1	0	1		
		%	5.0%	0.0%	2.5%		
	Nil	Count	8	13	21		
		%	40.0%	65.0%	52.5%		
	Non union	Count	1	1	2		
		%	5.0%	5.0%	5.0%		
	Pull out screw	Count	1	0	1		
		%	5.0%	0.0%	2.5%		
	Shortening	Count	6	1	7		
		%	30.0%	5.0%	17.5%		
	Varus collapse and back out of screw	Count	1	0	1		
		%	5.0%	0.0%	2.5%		
Total	Count	20	20	40			
	%	100.0%	100.0%	100.0%			

No Statistical Significance at P>0.05 level

Fig (38) Postoperative Complications



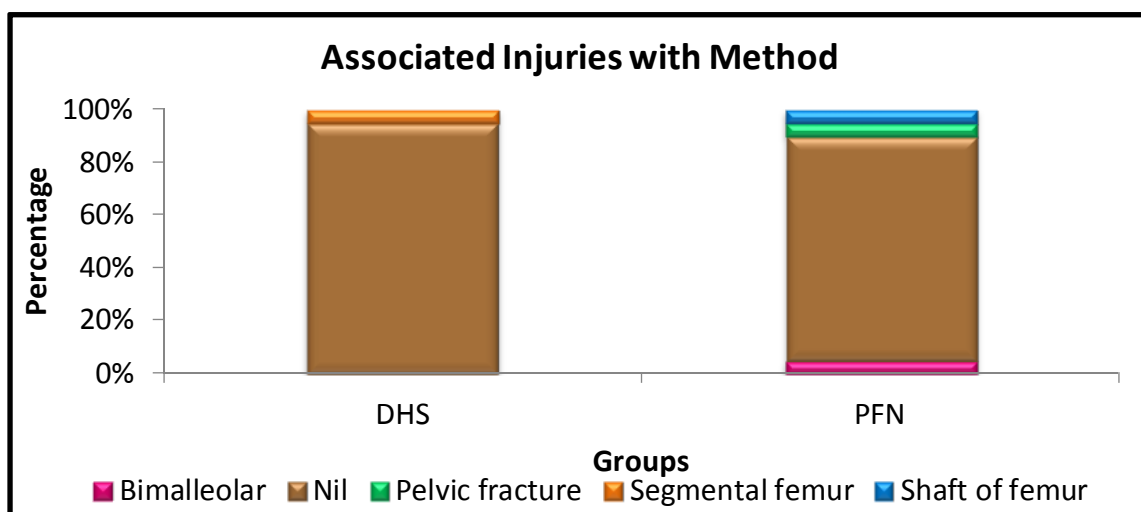
In this study limb shortening was found to be the most common complication of fractures fixed with DHS, while in fractures fixed with PFN 3 cases out of 20 cases got infected.

Table (10) Associated injuries

Comparison between Associated Injuries with Method								
			Method		Total	χ^2 - value	P-value	
			DHS	PFN				
Associated Injuries	Bimalleolar	Count	0	1	1	4.111	0.391 #	
		%	0.0%	5.0%	2.5%			
	Nil	Count	19	17	36			
		%	95.0%	85.0%	90.0%			
	Pelvic fracture	Count	0	1	1			
		%	0.0%	5.0%	2.5%			
	Segmental femur	Count	1	0	1			
		%	5.0%	0.0%	2.5%			
	Shaft of femur	Count	0	1	1			
		%	0.0%	5.0%	2.5%			
	Total		Count	20	20			40
			%	100.0%	100.0%			100.0%

No Statistical Significance at P>0.05 level

Fig(39) Associated injuries



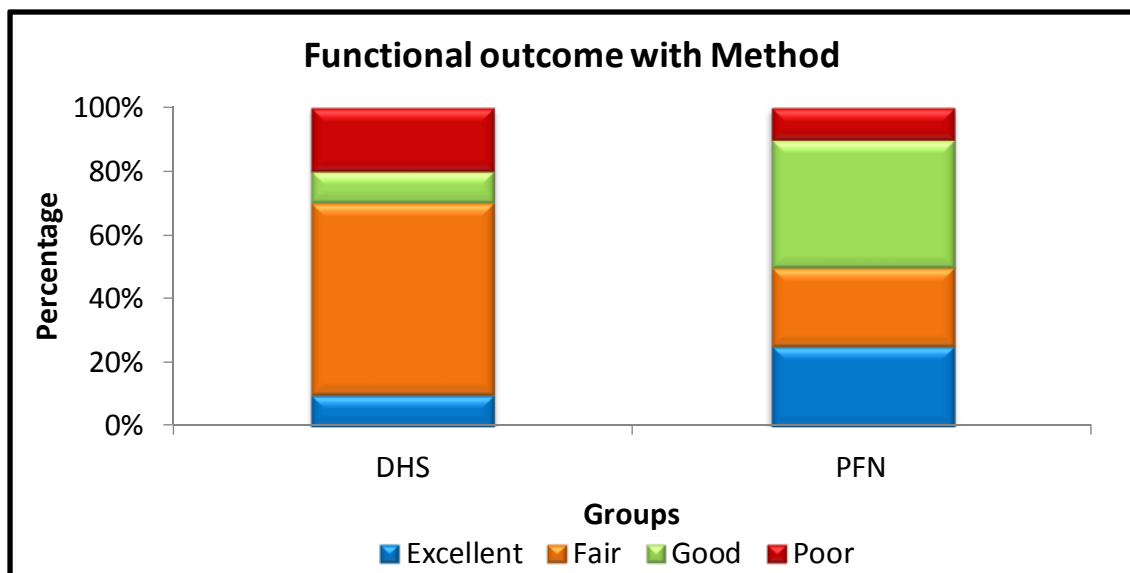
Associated fractures are more common with RTA or high velocity injuries and most common was shaft of femur fractures and few cases of pelvic fractures are reported.

Table (11) Comparing functional outcome by method of fixation

Comparison between functional outcome with Method							
			Method		Total	χ^2 - value	P-value
			DHS	PFN			
Functional Outcome	Excellent	Count	2	5	7	8.435	0.038 *
		%	10.0%	25.0%	17.5%		
	Good	Count	2	8	10		
		%	10.0%	40.0%	25.0%		
	Fair	Count	12	5	17		
		%	60.0%	25.0%	42.5%		
	Poor	Count	4	2	6		
		%	20.0%	10.0%	15.0%		
Total		Count	20	20	40		
		%	100.0%	100.0%	100.0%		

* Statistical Significance at P < 0.05 level

Fig(40)-Comparing functional outcome by method of fixation



Functional outcome depends upon the method of fixation since the difference was statistically significant. Patients operated with PFN has better functional recovery than the patients operated with DHS for intertrochanteric femur fractures.

DISCUSSION

Intertrochanteric fractures of femur is always considered to be challenge by Orthopaedic surgeons not only for obtaining fracture union but also for achieving optimal functional recovery. As suggested by Koral & Zuckermann(1994),⁹⁵ Boyd & Anderson(1961) and Weise & Schivals(2001)⁹⁶ better chance of functional recovery is achieved by Operative treatment by internal fixation. The aim of the study was to compare the functional outcome of intertrochanteric fractures in osteoporotic patients treated by dynamic hip screw fixation and the proximal femoral nail. Our study consists of 40 osteoporotic patients with intertrochanteric fractures out of which 20 was operated with DHS and 20 with PFN.

Most of the patients involved in the study were between 50years to 70years of age with 80years being the maximum and 45 years being the minimum. Mean age of the patients treated by PFN is 62.5 years and by DHS is 65 years.

Gallaghar et al⁹⁷ reported that there is eight fold increase in intertrochanteric femur fractures in men over 80 years and women over age of 50 years. Hence the study supports that intertrochanteric fractures are more common in individuals with poor bone stock. An attempt was made to find the degree of Osteoporosis by Singh's index but it involves high inter-observer variability and less accurate as said by Koot et al.⁹⁸

Since Singh's index was most easy and quick method of detecting osteoporosis in this Retrospective study, it was used.

Prabhoo Tanay Ramchandra⁹⁹ in his study reported that average age of occurrence of these fractures were 5th -7th decade.

Harrington & Johnston, Hunter, Zickel, Lasikin et al, Hall & Ainscow, Kuderna et al, Cuthbert & Howat, Saudan, Poigenfurst & Schnabl, Tyllioksi et al, Lubbelee A, Sadowski C reports higher age at presentation of fracture.¹⁰⁰⁻¹⁰⁹

Cleaveland & Thompson , Murray & Frew ,Boyd & Griffin, Scott, Evans, Wade & Campbell, Sarmiento , Gupta RC all these studies reports that incidence of intertrochanteric fractures were between 5th - 7th decades.¹¹⁰

Hence age distribution in our study correlates with other studies.

In our study there were 30 males and 10 females showing male predominance.

Pathik vala et al,¹¹¹ in their study out of 30 patients 53% were males and 47% were females showing male predominance with trivial fall being the most common mode of injury.

Manoj kumar et al¹¹² reported male predominance of the intertrochanteric fractures in their study . Sachin yadav et ¹¹³ reported male preponderance in their study attributed to high number of RTA cases involved in the study.

David G. Lovelle reported that intertrochanteric fractures were more common in women than men(3:1).

Melton J.L., Riggs BL et al , Ilstrup DM (1982)¹¹⁴ published a study titled 'fifty years trend in Hip fracture incidence' and found that female to male ratio of 1.8:1.

Heyse – Moore et al, Kuderna et al, Laskin et al reported female preponderance in their study.¹¹⁵⁻¹¹⁷

Dahl et al¹¹⁸ showed 65% of patients were females, and reported that incidence is high after menopause since they are prone for osteoporosis.

Cleveland et al , H. B. Boyd and L. L. Griffin, Helfenstein in their study reported female preponderance had given specific explanations.^{119,120}

St. Urnier K.M., Dresing K.(1995) , B. B. Ohari and Hatim Shaikh , Murrey & Frew supports our study being male predominance.¹²¹

Hagino et al¹²² reported a lifetime risk of hip fractures at 50 years of age for men is 5.6% and for women is 20%.

Sex distribution in our study correlates with some study as its attributed to higher number RTA cases involved in the study.

There were 22 patients with RTA as mode of injury and 18 patients with self fall in our study.

Sachin yadav et al¹¹³ reported RTA as the most common mode of trauma.

Cummings and Nevitt¹²³ in 1994 attributed to mode of injury, as domestic fall and trivial trauma was main cause behind the fracture in Osteoporotic individuals whereas RTA in young individuals.

Cyril jonnes et al¹²⁴ reported that trivial trauma being the most common mode of injury followed by RTA. Hence in our study there is no significant difference between the mode of injury in case of intertrochanteric femur fractures.

Regarding the side of fracture, 50% of the fractures were on the left side and 50% on the right side showing no significant difference. This was favored by Pathik Vala et al¹¹¹, Cyril Jonnes et al¹²⁴ in their studies.

We have classified intertrochanteric fractures by Boyd and Griffin classification system in which Type I was the most common type, occurring in about 14 patients, followed by Type II and Type IV with 12 patients each and Type III being the least common occurring in 2 patients.

Jacobs and coworker (1980)¹²⁵ reported that incidence of unstable intertrochanteric fractures is in increasing trend.

Among 14 cases of Type I fractures 10 were fixed with DHS and 4 with PFN, whereas in 12 cases of Type IV fractures 10 were fixed with PFN. Hence in these two types there was significant difference in the method of fixation. In Type II and Type III fractures method of fixation was equally shared between DHS and PFN and there was no significant difference exist.

The main inclusion criteria of the study was Osteoporotic fractures. Cummings

SR et al¹²⁶ reported that intertrochanteric fractures are common most fractures of hip especially in Osteoporotic bone. Osteoporosis was evaluated by Singh's index of the opposite normal hip at the time of injury. Since this was a retrospective study, only data which can be useful in calculating Osteoporosis is the Singh's index. In our study, about 60% of the patients fall into Grade III Osteoporosis and 20% has Grade II and remaining 20% of the patients has Osteopenia.

In about 20 cases fixed with DHS, 12(60%) cases have Osteoporosis of Grade III and 5 (25%)cases have Grade II Osteoporosis, whereas among 20 cases fixed with PFN, 12(60%) cases have Grade III Osteoporosis and 5(25%) has Grade IV Osteopenia. Therefore from our study it is found that there was no significant difference between method of fixation and Grade of Osteoporosis.

Ranjeetesh K et al¹²⁷ in their study reported that PFN is better tolerated in older patients with Osteoporotic bone .

Muzzafar N et al¹²⁸ found that DHS in Osteoporotic bone is associated with more complications.

Huang X et al¹²⁹ in their meta-analysis found that PFN and DHS fixation shows same effectiveness in Osteoporotic bone.

Parker et al¹³⁰ analyzed comparable results in both the implants.

Zhang K et al¹³¹ found PFN fixation had significantly lesser intra-operative complications in Osteoporotic fractures.

In this Retrospective study, though the time of fracture union cannot be assessed accurately, union of the fracture can be evaluated. Maximum period of follow-up was 5 years and minimum was 1 ½ years. Among 20 cases fixed with DHS, in 18 cases fracture has united well while in 1 case there was Greater trochanter non-union and in other case fracture has not united. Whereas in 20 cases fixed with PFN, 19 cases achieved fracture union and 1 case shows non-union.

Hemant Sharma et al¹³² reported that there was no significant time difference between union of two groups.

Sanjay Mulay , Fazil Gouri et al¹³³ in their study reported that 2% of the fractures fixed with DHS went for non-union.

Pathik Vala et al¹¹¹ described that fractures fixed with PFN, almost all cases united well whereas in DHS fixation, 8 out of 15 cases had solid union , 6 patients had varus collapse at fracture site, 1 case went for non-union.

Kevin D. Harrington , Juluru- P. Rao , Luis A. Flores , B. Mall all these studies reported fracture union in 12- 20 weeks.¹³⁴⁻¹³⁷

Ventakesh Gupta SK et al¹³⁸ reported no statistically significant difference between the two groups in terms of fracture union.

Hence our study correlates with others regarding the fracture union that PFN fixation had lesser rate of non-union though this was not statistically significant.

In present study series we have 4 patients with associated injuries like bimalleolar ankle fracture in 1 case, a case of pelvic fracture and 2 cases of shaft

of femur fracture. In shaft of femur fracture, 1 case had segmental fracture of femur at supracondylar region for which plating was done and another case of shaft of femur, long PFN was done. Pelvic fracture was fixed with plating which bimalleolar fracture was fixed with medial malleolus screw and fibular plating. Functional outcome of these patients were affected compared to those patients having isolated intertrochanteric fractures. Patient with Segmental femur fracture has stiff knee and pelvic fracture patient was bed ridden.

Prabhoo Tanay Ramchandra⁹⁹ in his study reported that distal radius fractures and calcaneum fractures are the most common associated fractures . Distal radius fractures were attributed to Osteoporotic individuals. Associated fractures are more commonly attributed to mode of injury(RTA) being the cause.

The operative management of intertrochanteric femur fractures are still associated with failures. Multiple deforming forces due to high stress concentration, high post-operative complications conflicts regarding the selection of implant. According to the Literature the incidence of post-operative infection in intertrochanteric femur fractures varies between 1.7% to 16.9%. In our study, 4 patients managed with PFN developed infection, inspite of which fracture united. Implant exit was done in 2 patients. In a case of DHS fixation, implant was broken at plate barrel junction. In a patient, fracture fixed with PFN, compression screw was broken.

Shortening of the limb occurred in 6 patients out of 20 patients fixed with DHS, and no patient with PFN had shortening.

Head screw back out was present in 2 patients fixed with DHS. Medialization and varus collapse occurred in 2 patients with DHS.

Hence in our study, complication rate with DHS is about 60% and with that of PFN is 35%.

A Bodoky, U Neff, F Harder, M Heberer advocated two dose of cephalosporin antibiotics for reducing wound infections which is given preoperatively in hip surgeries.¹³⁹

Verley GW, Milner SA (1995) proposed that in those patients where drain was kept had better wound healing and reduced rate of infection.¹⁴⁰

Saudan et al, PAN et al, Papisimos et al, Pajainen et al, Shen et al in their studies provided post-operative infection rate. 6 out of 254 fractures treated with PFN and 7 out of 273 fractures treated by DHS got infected. This indicates insignificantly higher rate of infection in DHS group.¹⁴¹⁻¹⁴⁵

Ujjwal Sinha et al in their study reported that PFN group had higher complication. There was no case of infection in DHS group while one case of PFN got infected.¹⁴⁶

K Harish, Sravya Teja Paleti et al proposed in their study that one case of PFN had infected and none of DHS patients got infected.¹⁴⁷

Xiao Huang et al, Liu et al, Saudan et al all these studies had wound complication rate higher with PFN group. There was no statistical heterogeneity between the two groups.¹⁴⁸⁻¹⁵⁰

Baumagaertner & Chrostowski¹⁵¹ studied the incidence of implant failure in unstable fractures as high as 20%. Osteoporosis being the predisposing factor.

Hemant Sharma et al¹³² reported implant failure due to lag screw cut through in 2 cases with DHS implant which resulted in varus collapse and non-union.

O'Brien et al¹⁵² concluded that no difference existed between DHS and PFN in terms of fixation failure, varus collapse.

Boldin et al, Nuber et al¹⁵³ reported that the incidence of medialization of the shaft is lesser in PFN group.

Pathik Vala et al¹¹¹ reported two patients with PFN implant had cephalic screw backing out and one patient with DHS implant had varus malunion due to excessive collapse.

Ujjwal Sinha et al¹⁴⁶ observed varus deformity and screw cut out in 30% of patients with PFN and 10% in DHS. Z effect was noted in 10% of PFN group.

Madson et al¹⁵⁴ found that there is no statistically significant difference between intramedullary and extramedullary implants in terms of femoral head cutout.

Pajarinen et al, Papasimos et al, Saudan et al¹⁴¹⁻¹⁴⁵, Zhao et al¹⁵⁵ gives data on lag screw cutout rate. It was reported in 7 out of 253 fractures managed by DHS and 5 out of 205 fractures treated by PFN. Meta-analysis shows an insignificant higher rate of lag screw cut-out in DHS individuals.

Hardy et al¹⁵⁶ studied sliding of both groups with radiographs 1year post-

operatively and found an average of 4.3mm in PFN whereas 6.9mm in DHS. Average limb shortening in DHS was 9.33mm while in PFN it was 4.72mm.

Kyle et al, Kuntscher GA reported increased forces are required for sliding in intramedullary devices. Thus the nail offers physical block to shortening of fracture fragments which explains lesser shortening in PFN groups.¹⁵⁷

Karn NK et al found that varus angulation, external mal-rotation and shortening was common in DHS.¹⁵⁸

Sanjay Mulay et al¹³³ observed shortening of extremity in 24% in DHS group compared to 10% in PFN group.

Keirui Zhang et al, Sheg Zhang et al in their meta-analysis demonstrated PFN a better choice of implant than DHS in the treatment of intertrochanteric fractures in elderly patients.¹⁵⁹

Pajarinen et al¹⁶⁰ found that there was no difference in peri- and post-operative outcome between the two groups.

Ujjwal Sinha et al¹⁴⁶ conclude that functional outcome of stable as well as unstable intertrochanteric fractures fixed with either PFN or DHS are similar.

Manoj kumar et al¹¹² concluded that there was no difference in functional outcome of intertrochanteric fractures treated with DHS or PFN. DHS is used for stable fractures whereas PFN in unstable fractures.

K Harish et al¹⁴⁷ consider PFN is better alternative to DHS in intertrochanteric

femur fractures.

Xiao Huang et al¹⁴¹ shown that PFN and DHS are equally effective in management of intertrochanteric fractures.

Kukla et al¹⁶¹ & Ahrengart et al¹⁶² reported better functional outcome in unstable intertrochanteric fractures treated by PFN compared to DHS.

Hemant Sharma et al¹³² stated that the functional outcome was significantly better in PFN than DHS which was attributed to lesser post-operative pain.

Neritan Myderrizi¹⁶³ in their study found that PFN group has better outcome in unstable and Osteoporotic intertrochanteric fractures.

In our study functional outcome was measured by HARRIS HIP SCORE (Modified). Functional outcome was excellent in 25% , good in 40% , fair in 25% and poor in 10% of PFN group whereas DHS group shows excellent in 10%, good in 10%, fair in 60% , poor in 20%. From our study the heterogeneity tests indicates statistical evidence of heterogeneity ($P < 0.05$). Data indicates that there was significant difference in the functional outcome of intertrochanteric fractures in osteoporotic individuals treated by Proximal femoral nailing group in our study.

CONCLUSION

In the present study carried out in RAJIV GANDHI GOVERNMENT GENERAL HOSPITAL, MADRAS MEDICAL COLLEGE, CHENNAI, in the INSTITUTE OF ORTHOPAEDICS AND TRAUMATOLOGY, 40 cases of Intertrochanteric femur fractures of Osteoporotic individuals were included. There were 20 patients operated by **Dynamic hip screw(DHS)** and 20 patients operated by **Proximal femoral Nail(PFN)**.

Mechanical advantages in PFN, is the shaft fixation is closer to the centre of rotation of the hip, gives a **shorter lever arm** and a **lesser bending movement** on the device, gives a biomechanically sound fixation.

Incidence of **deformity & mal-rotation** is found to be lower in PFN fixation since it has higher **rotational stability**.

Non-union of intertrochanteric fracture may occur in few cases of DHS fixation, causing **varus collapse** and **screw cut out** through femoral head which is rare in PFN.

We conclude that in the treatment of intertrochanteric fractures in osteoporotic individuals, Proximal femur nailing have significantly better functional outcome compared to Dynamic hip screw fixation.

CASE ILLUSTRATIONS

DYNAMIC HIP SCREW FIXATION

CASE – 1



Fig (41)- Pre op xray



Fig(42)- Immediate post op



Fig(43)- 2years post op



Fig(44)- Hip flexion



Fig(45)-Squatting



Fig(46)-Standing

CASE - 2



Fig(47)-Pre op xray



Fig(48)-Immediate post op



Fig(49)-2years post op



Fig(50)- Standing



Fig(51) HIP- External rotation



Fig(52)- HIP- Flexion

CASE -3



Fig(53)-Pre-op xray



Fig(54)-Immediate post op



Fig(55)-2years post-op



Fig(56)-Hip flexion



Fig(57)-Sitting cross legged



Fig(58)-Squat

PROXIMAL FEMUR NAILING

CASE-4



Fig(59)- Pre-op xray



Fig(60) -Immediate post op



Fig(61)- 2years post-op



Fig(62) Standing



Fig(63) Squatting



Fig(64) Hip flexion

CASE -5



Fig(65)- Pre op xray



Fig(66)-Immediate post-op



Fig(67)-1 year postop



Fig(68)- Hip flexion



Fig(69)-Sitting cross legged



Fig(70)-Squatting

CASE-6



Fig(71)- Pre op xray



Fig(72)- Immediate post op



Fig(73)-1 year post-op



Fig(74)- Hip flexion



Fig(75)-Standing



Fig(76)-Abduction

MASTER CHART

S.No	Name	Age/ Sex	IP no	Mode of injury	Side	Type	Singh's index of opposite hip	Method of fixation	Follow up	Fracture union	Complication	Associated injuries	Harris hip score	Remarks
1	Mr.Pandiyan	65/M	13685	RTA	Right	II	3	DHS	4yrs	Yes	Shortening	NIL	74	FAIR
2	Mrs.Dhanalakshmi	60/F	85516	Self fall	Left	II	3	DHS	4yrs	Yes	Shortening	NIL	70	FAIR
3	Mrs.Jayammal	70/F	65471	Self fall	Right	I	3	DHS	3yrs	Yes	Compression screw pull out	NIL	55	POOR
4	Mrs.Kantha	54/F	34561	RTA	Right	II	3	DHS	2yrs	Yes	Pull out screw	NIL	42	POOR
5	Mrs.Sarojammal	80/F	19783	Self fall	Left	I	2	DHS	2 ½ yrs	Yes	Nil	NIL	71	FAIR
6	Mr.Aiyalu	66/M	26467	RTA	Left	III	2	DHS	3yrs	Yes	Shortening	NIL	79	FAIR
7	Mr.Muniyan	51/M	2229	RTA	Right	I	4	DHS	2yrs	Yes	Shortening	Segmental femur #	75	FAIR
8	Mr.Dheena	52/M	89149	RTA	Right	I	3	DHS	2yrs	Yes	Nil	NIL	89	GOOD
9	Mr.Dharman	70/M	10264	Self fall	Left	II	3	DHS	2yrs	GT non union	Varus collapse and back out of screw	NIL	75	FAIR
10	Mr.Krishnasamy	56/M	19874	RTA	Left	I	3	DHS	1 ½ yrs	Yes	NIL	NIL	88	GOOD
11	Mr.Muthu	55/M	28974	RTA	Left	I	4	DHS	2yrs	Yes	Nil	Nil	74	FAIR
12	Mr.Rajamanikam	75/M	75968	Self fall	Left	I	2	DHS	2yrs	Yes	Nil	Nil	74	FAIR
13	Mrs.Pavayammal	70/F	20451	Self fall	Left	I	3	DHS	3yrs	Yes	Nil	Nil	72	FAIR

S.No	Name	Age/ Sex	IP no	Mode of injury	Side	Type	Singh's index of opposite hip	Method of fixation	Follow up	Fracture union	Complication	Associated injuries	Harris hip score	Remarks
14	Mr.Ponraj	66/M	10049	Self fall	Left	II	3	DHS	2yrs	Yes	Broken implant	Nil	75	FAIR
15	Mr.Murugan	52/M	39037	RTA	Left	I	3	DHS	1 ½ yrs	Yes	Nil	Nil	96	EXCELLENT
16	Mr.Sarathy	50/M	41352	RTA	Left	I	4	DHS	1 ½ yrs	No	Non union	Nil	79	FAIR
17	Mr.Sukumar	65/M	29377	Self fall	Left	II	3	DHS	1 ½ yrs	Yes	Shortening	Nil	96	EXCELLENT
18	Mrs.Rakkammal	70/F	25215	Self fall	Right	IV	2	DHS	3yrs	Yes	Shortening	Nil	53	POOR
19	Mrs.Angammal	70/F	11636	Self fall	Right	IV	3	DHS	2yrs	Yes	Nil	Nil	72	FAIR
20	Mr.Munusamy	80/M	42383	Self fall	Left	II	2	DHS	1 ½ yrs	YES	Medialization and collapse	Nil	62	POOR
21	Mr.Mani	62/M	10290	RTA	Left	II	3	PFN	4yrs	Yes	Nil	Nil	96	EXCELLENT
22	Mr.Venkatesan	52/M	12751	RTA	Right	IV	3	PFN	5yrs	Yes	Infection	Nil	75	FAIR
23	Mr.Gundumalli	51/M	49880	RTA	Right	IV	4	PFN	1 ½ yrs	Yes	Nil	Bimalleolar #	89	GOOD
24	Mr.Munusamy	60/M	19934	RTA	Left	I	3	PFN	3yrs	Yes	Infection and screw back out	Nil	77	FAIR
25	Mr.Jayagopi	60/M	27282	Self fall	Right	IV	2	PFN	3yrs	Yes	Nil	Nil	94	EXCELLENT
26	Mrs.Kalaivani	45/F	96651	RTA	Left	IV	4	PFN	2yrs	Yes	Nil	Nil	81	GOOD
27	Mr.Anwar basha	80/M	23550	Self fall	Left	II	2	PFN	3yrs	Yes	Broken implant	Nil	84	GOOD
28	Mr.Raju	60/M	12934	RTA	Right	IV	3	PFN	2yrs	Yes	Nil	Nil	93	EXCELLENT

S.No	Name	Age/ Sex	IP no	Mode of injury	Side	Type	Singh's index of opposite hip	Method of fixation	Follow up	Fracture union	Complication	Associated injuries	Harris hip score	Remarks
29	Mr.Solomon	64/M	29989	RTA	Right	I	3	PFN	3yrs	Yes	Nil	Shaft of femur #	83	good
30	Mr.Munusamy	70/M	56434	Self fall	Right	I	3	PFN	1 ½ yrs	Yes	Nil	Nil	92	EXCELLENT
31	Mr.Syed	50/M	81091	RTA	Left	IV	4	PFN	1 ½ yrs	No	Non union	Nil	83	GOOD
32	Mr.Kalaimani	60/M	11939	RTA	Left	IV	3	PFN	2yrs	Yes	Infection	Pelvic fracture	46	POOR
33	Mr.Saroja	70/F	12836	Self fall	Right	II	2	PFN	1 ½ yrs	Yes	Nil	Nil	75	FAIR
34	Mr.Ulaganathan	50/M	14524	RTA	Right	IV	4	PFN	4yrs	Yes	infection	Nil	82	GOOD
35	Mr.Sekar	50/M	99663	RTA	Left	I	4	PFN	1 ½ yrs	Yes	Nil	Nil	48	POOR
36	Mrs .Viruthammal	65/F	7190	Self fall	Right	III	3	PFN	2 ½ yrs	Yes	Nil	Nil	87	GOOD
37	Mr.Samynathan	60/M	12457	Self fall	Right	II	3	PFN	2yrs	Yes	Nil	Nil	78	FAIR
38	Mr.Kathiravan	58/M	86913	RTA	Right	IV	3	PFN	2yrs	Yes	Nil	Nil	92	EXCELLENT
39	Mr.Sulaiman	56/M	3589	RTA	Right	II	3	PFN	2yrs	Yes	Nil	Nil	86	GOOD
40	Mr.Munusamy	65/M	11114	Self fall	Right	IV	3	PFN	3yrs	Yes	Shortening	Nil	77	FAIR

KEY TO MASTER CHART

SEX	:	M- Male F-Female
MODE OF INJURY	:	RTA – Road Traffic Accidents
TYPE(Boyd & Griffin)	:	I - Type I II - Type II III - Type III IV -Type IV
SINGH’S INDEX OF OPPOSITE HIP	:	Grade 1 to 6
METHOD OF FIXATION	:	DHS- Dynamic hip screw PFN-Proximal femur nail
FOLLOW UP	:	YRS- Years
COMPLICATIONS	:	GT- Greater trochanter
ASSOCIATED FRACTURES	:	#- Fracture
HARRIS HIP SCORE	:	0 – 100
REMARKS	:	0 -69 Poor 70-79 Fair 80-89 Good 90-100 Excellent

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**ANNEXURE
PATIENT CONSENT FORM**

Study Detail: **“RETROSPECTIVE COMPARATIVE STUDY OF DYNAMIC HIP SCREW AND PROXIMAL FEMUR NAILING IN OSTEOPOROTIC INTERTROCHANTERIC FEMUR FRACTURES”**

Study Centre: Rajiv Gandhi Government General Hospital, Chennai.

- Patient’s Name :
- Patient’s Age :
- In Patient’s Number :

Patient may check () these boxes

I confirm that I have understood the purpose of procedure for the above study. I have the opportunity to ask question and all my questions and doubts have been answered to my complete satisfaction.

I understand that my participation in the study is voluntary and that I am free to withdraw at any time without giving reason, without my legal rights being affected.

I understand that sponsor of the clinical study, others working on the sponsor’s behalf, the Ethics committee and the regulatory authorities will not need my permission to look at my health records, both in respect of current study and any further research that may be conducted in relation to it, even if I withdraw from the study I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published, unless as required under the law. I agree not to restrict the use of any data or results that arise from this study.

I agree to take part in the above study and to comply with the instructions given during the study and faithfully cooperate with the study team and to immediately inform the study staff if I suffer from any deterioration in my health or well being or any unexpected or unusual symptoms.

I hereby, give consent to participate in this study

I hereby give permission to undergo complete clinical examination and diagnostic tests including hematological, biochemical, radiological tests and to undergo treatment.

Signature/thumb impression
of the patient

Signature of Investigator

Patient’s Name and Address

Study Investigator’s Name
(Dr.M.SUNDAR PRAKASH)

INFORMATION TO PARTICIPANTS

Investigator : DR.M.SUNDAR PRAKASH

Name of the participant :

Title : “RETROSPECTIVE COMPARATIVE STUDY OF DYNAMIC HIP SCREW AND PROXIMAL FEMUR NAILING IN OSTEOPOROTIC INTERTROCHANTERIC FEMUR FRACTURES”

You are invited to take part in this research study. We have got approval from the IEC. He/she is asked to participate because he/she satisfies the eligibility criteria. We want to assess and compare the functional outcome of dynamic hip screw and proximal femur nailing in osteoporotic intertrochanteric femur fractures treatment.

- What is the purpose of the research?

The Purpose of this study is to assess and compare the functional outcome of dynamic hip screw and proximal femur nailing in osteoporotic intertrochanteric femur fractures management.

- Study design: Retrospective study
- Discomfort and Risks

This type of techniques has been shown well tolerated in previous studies, and if you do not want to participate you will have alternative of setting the standard protocol and your safety is our prime concern.

Signature of the Investigator
(Dr.M.SUNDAR PRAKASH)

Signature/ Thumb impression of
Patient's attendant

Urkund Analysis Result

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Instances where selected sources appear:

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PLAGIARISM CERTIFICATE

This is to certify that this dissertation work titled **“RETROSPECTIVE COMPARATIVE STUDY OF DYNAMIC HIP SCREW FIXATION AND PROXIMAL FEMUR NAILING IN OSTEOPOROTIC INTERTROCHANTERIC FEMUR FRACTURES”** of the candidate **DR.M.SUNDAR PRAKASH** with Registration Number **221712009** for the award of degree in **M.S.** in the branch of **ORTHOPAEDICS**. I personally verified the urkund.com website for the purpose of plagiarism Check. I found that the uploaded thesis file contains from introduction to conclusion pages and result shows **9 percentage of plagiarism** in the dissertation.

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**INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE, CHENNAI 600 003**

EC Reg.No.ECR/270/Inst./TN/2013
Telephone No.044 25305301
Fax: 011 25363970

CERTIFICATE OF APPROVAL

To
Dr.M.Sundar Prakash
PG in M.S. Orthopaedics
Institute of Orthopaedics and Traumatology
Madras Medical College
Chennai

Dear Dr.M.Sundar Prakash,

The Institutional Ethics Committee has considered your request and approved your study titled "**RETROSPECTIVE COMPARATIVE STUDY OF DYNAMIC HIP SCREW AND PROXIMAL FEMUR NAILING IN OSTEOPOROTIC INTERTROCHANTERIC FEMUR FRACTURES**" - NO.06042018

The following members of Ethics Committee were present in the meeting held on **03.04.2018** conducted at Madras Medical College, Chennai 3

- | | |
|---|----------------------|
| 1. Prof.P.V.Jayashankar | : Chairperson |
| 2. Prof.R.Jayanthi,MD.,FRCP(Glasg) Dean,MMC,Ch-3 | : Deputy Chairperson |
| 3. Prof.Sudha Seshayyan,MD., Vice Principal,MMC,Ch-3 | : Member Secretary |
| 4. Prof.N.Gopalakrishnan,MD,Director,Inst.of Nephrology,MMC,Ch | : Member |
| 5. Prof.S.Mayilvahanan,MD,Director,Inst. of Int.Med,MMC, Ch-3 | : Member |
| 6. Prof.A.Pandiya Raj,Director, Inst. of Gen.Surgery,MMC | : Member |
| 7. Prof.Shanthy Gunasingh, Director, Inst.of Social Obstetrics,KGH | : Member |
| 8. Prof.Remam Chandramohan,Prof.of Paediatrics,ICH,Chennai | : Member |
| 9. Prof. Susila, Director, Inst. of Pharmacology,MMC,Ch-3 | : Member |
| 10.Prof.K.Ramadevi,MD., Director, Inst. of Bio-Chemistry,MMC,Ch-3 | : Member |
| 11.Prof.Bharathi Vidya Jayanthi,Director, Inst. of Pathology,MMC,Ch-3 | : Member |
| 12.Thiru S.Govindasamy, BA.,BL,High Court,Chennai | : Lawyer |
| 13.Tmt.Arnold Saulina, MA.,MSW., | : Social Scientist |
| 14.Thiru K.Ranjith, Ch- 91 | : Lay Person |

We approve the proposal to be conducted in its presented form.

The Institutional Ethics Committee expects to be informed about the progress of the study and SAE occurring in the course of the study, any changes in the protocol and patients information/informed consent and asks to be provided a copy of the final report.


Member Secretary - Ethics Committee