

A Comparative Study on the Efficacy of Local Infiltration of Autologous Blood versus Local Corticosteroid Infiltration for the Treatment of Chronic Lateral Epicondylitis Elbow

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Abstract: Musculoskeletal disorders are common problems in primary health care. Chronic painful tendon disorders are common in both athletic and sedentary individuals^{1,2}. Lateral epicondylitis is relatively more common among working-age individuals in the general population³. Typical signs and symptoms include pain and tenderness over the lateral epicondyle, exacerbated by resisted wrist extension and passive wrist flexion, and impaired grip strength. This study aims to find whether autologous blood provides comparable functional outcome over local steroids and hence whether it can replace steroids in treatment of tennis elbow. Patients with non traumatic elbow pain attending the Orthopaedics Out Patient Department of Jubilee Mission Medical College Hospital from January 2013 to August 2014. The participating subjects were randomly grouped into two groups [Steroid (Group A) & Autologous Blood (Group B)] according to a random number table. Pain in the subject's affected elbow was measured using Visual Analogue Score (VAS) and the functional status of their affected elbow was measured using Patient-Rated Tennis Elbow Evaluation (PRTEE) Score and Mayo Elbow Performance (MEP) score. Initially both the groups had comparable initial VAS scores. At 1 month follow up, steroid group showed a significantly greater improvement in mean VAS scores when compared to autologous blood group p value 0.001. However at 6 months follow up, steroid group showed no statistically significant difference in mean VAS scores when compared to autologous blood group, p value 0.7. Average PRTEE score and average MEP score at 6 months showed no difference statistically. From the current study we concluded that both local corticosteroid and autologous blood were equally efficacious in the treatment of chronic lateral epicondylitis of elbow.

I. Introduction

Musculoskeletal disorders are common problems in primary health care. They are the most common work-related disease, with high costs incurred from long-term disability. Chronic painful tendon disorders are common in both athletic and sedentary individuals^{1,2}. Lateral epicondylitis is relatively more common among working-age individuals in the general population³. Lateral epicondylitis has been found to be the second most frequently diagnosed musculoskeletal disorder of the upper extremities in a primary health care setting⁴

Tennis elbow or lateral epicondylitis refers to a syndrome of pain centred over the common origin of the extensor muscles of the fingers and wrist at the lateral epicondyle. Typical signs and symptoms include pain and tenderness over the lateral epicondyle, exacerbated by resisted wrist extension and passive wrist flexion, and impaired grip strength. It occurs more commonly in non-athletes than athletes and has a peak incidence in the fifth decade. The initial treatment is with rest, modification of activity and local splint. Local injection of corticosteroids comes next if the initial treatment is found to be unsatisfactory.

Another novel modality of treatment is the local administration of growth factors. These growth factors are administered in the form of autologous whole blood or platelet-rich plasma (PRP). The degranulation of the alpha-granules in the platelets releases many different growth factors that play a role in tissue regeneration processes.

II. Aims And Objectives

In the treatment area of lateral epicondylitis, there exist several different treatments, with varying side effects. Local injection of corticosteroids has been "the treatment" for tennis elbow for long. Despite its local complications it is still preferred over other treatment modalities by many orthopaedicians. But there is growing mound of evidence in the current literature which states that there is absence of an inflammatory component in lateral epicondylitis. So the treatment by local steroids need to be re-evaluated as steroid treatment is based on the premises that the major pathological factor in tennis elbow is inflammation. Moreover; studies show conflicting evidence about their efficacy and there are some complications too. In a study by Jobe and Cicotti⁵, it

was found that superficial injection of corticosteroid may result in subcutaneous atrophy and that intra tendinous injection may lead to adverse changes within the ultrastructure of the tendon. The use of autologous growth factors seems to be promising in the treatment of this disease. It is thought to lead to tendon healing through collagen regeneration and the stimulation of a well-ordered angiogenesis. It is obtained from autologous blood and is a cheap and readily available alternative to steroids. This study aims to find whether autologous blood provides comparable functional outcome over local steroids and hence whether it can replace steroids in treatment of tennis elbow.

Autologous blood was selected as the medium for injection because

1. its application is minimally traumatic
2. it has a reduced risk for immune-mediated rejection, devoid of potential complications such as hypoglycemia, skin atrophy, tendon tears
3. its application is minimally traumatic
4. it is simple to acquire and prepare, easy to carry out as outpatient procedure
5. it is inexpensive^{6,7}

III. Materials And Methods

Study design

Prospective interventional cohort study.

Study population

Patients with non traumatic elbow pain attending the Orthopaedics Out Patient Department of Jubilee Mission Medical College Hospital.

Study setting

Jubilee Mission Medical College & Research Institute, Thrissur, Kerala, India.

Duration of study

A period of 20 months from January 2013 to August 2014

Inclusion criteria

Patients between 18 - 60 years of age diagnosed of having chronic lateral epicondylitis attending the Orthopaedics Out Patient Department of Jubilee Mission Medical College Hospital.

Exclusion criteria

1. Pain less than 6 months duration
2. History of trauma
3. Patients having local infection over the lateral aspect of elbow
4. Patients who had previously taken local steroid injection or local autologous blood or PRP infiltration for the treatment of lateral epicondylitis
5. Patients with history of surgery for LE
6. Effusion of the elbow
7. Radiculopathy due to cervical spine pathology
8. Entrapment of the ulnar nerve
9. Periarticular fracture elbow

Statistics and Sample size

Based on 95% CL, and Type 1 error at 5%, calculated sample size is 100 (2 groups of 50 subjects each), randomized, computer generated random number table used. Statistical data analysis, mean $\pm$ SD (standard deviation), Percentage, Chisquare test, Non parametric statistical tools were used all statistical test the $p < 0.05$ considered as statistically significant.

IV. Methodology

All patients attending Orthopaedics Out Patient Department of JMMC & RI diagnosed of having chronic lateral epicondylitis were informed about the study and a written consent was obtained from those willing to participate in the study. Then the participating subjects were randomly grouped into two groups [Steroid (Group A) & Autologous Blood (Group B)] according to a random number table. Pain in the subject's affected elbow was measured using Visual Analogue Score (VAS) and the functional status of their affected elbow was measured using Patient-Rated Tennis Elbow Evaluation (PRTEE) Score and Mayo Elbow Performance (MEP) score.

V. Procedure

Subjects were made to lie supine. The affected elbow was thoroughly cleaned with Povidone Iodine

and Surgical Spirit and allowed to dry. The point of maximum tenderness over the common extensor origin area was identified by palpation and 2 ml (80 mg) of Methyl Prednisolone Acetate (Inj. DEPOMEDROL®) was infiltrated locally into that point of subjects belonging to Group A. Under strict aseptic precautions; 2 ml of blood was drawn from subjects belonging to Group B via venepuncture using a 21 gauge needle from the contralateral antecubital fossa and it was infiltrated locally into their affected elbow as described earlier. All the subjects were observed for 1 hour for any acute adverse effects. Following the procedure they were allowed to ice the elbow and take paracetamol as necessary, but to avoid anti-inflammatory drugs. No local anaesthetics were used. Pain in the subjects elbow was reassessed after 1 month and again at 6 months using VAS. The functional status of the subjects elbow was also reassessed along with it using PRTEE and Mayo Elbow Performance scores. Any subject complaining of breakthrough pain while under follow-up was managed by oral paracetamol only. Subjects were advised not to take any other analgesics during the study period. All injections were given by the same operator.

Diagnostic criteria

- Pain over lateral epicondyle for more than 6 months; especially during wringing movements and forced dorsiflexion of the hand.
- Tenderness over the lateral epicondyle and the common extensor origin.
- A positive "chair lifting test" or the "coffee cup test"⁸ in which the patient feels pain at the lateral epicondyle when picking up a full cup of coffee
- Positive "Mills' test"⁹ in which full pronation combined with complete
- wrist and finger flexion prevents full elbow extension or, at least, a feeling of resistance at the elbow and pain at the lateral epicondyle
- Positive "Maudsley's test"¹⁰ or the "middle-finger test", in which resisted extension of the middle finger when the elbow is fully extended and the forearm is pronated causes pain at the lateral epicondyle.

VI. Results

Age group encountered in the study ranged from 24 years to 54 years, with a mean age of 40.62 ± 10.2 in steroid injection group and 38.36 ± 9.8 in autologous blood injection group. Peak incidence at fifth decade of life was seen in steroid injection group and at fourth decade was seen in autologous blood injection group. The mean age of patients in steroid injection group was 40.62 and in autologous blood injection group was 38.36; p value= 0.15 which was not significant. Thus age of patients in both the groups was comparable.

Out of the 100 participants, 54 were males and 46 were females. In steroid injection group, Male 28 (56%) and Females 22 (44%) and autologous blood injection group, Male 26 (52%) and Females 24 (48%) patients respectively; P value > 0.05 (0.54) which is not statistically significant. Thus both the groups were comparable in terms of number of males and females in each group.

Prevalence of Diabetes Mellitus and Prevalence of Hypertension showed no significant difference between the two groups. The mean duration of symptoms in patients with lateral epicondylitis in steroid injection group and autologous blood group were 1.92 Years and 1.92 Years respectively. P value was 0.916 which means there is no significant difference between the two groups regarding mean duration of symptoms.

Initially both the groups had comparable initial VAS scores. At 1 month follow up, steroid group showed a significantly greater improvement in mean VAS scores (26.0; from 65.6 to 39.6, 39.6%) when compared to autologous blood group (7.4; from 65.2 to 57.8; 11.3%); p value 0.001. However at 6 months follow up, steroid group showed no statistically significant difference in mean VAS scores (36.0; from 65.6 to 29.6, 54.9%) when compared to autologous blood group (36.4; from 65.2 to 28.8; 55.8%); p value 0.79.

The initial mean PRTEE pain score of both the groups showed comparable initial mean PRTEE pain scores. At 1 month follow up, steroid group showed no statistically significant difference in mean PRTEE pain scores when compared to autologous blood group; p value 0.61. At 6 months follow up also, steroid group showed no statistically significant difference in mean PRTEE pain scores when compared to autologous blood group; p value 0.81.

The initial mean PRTEE score (for Functional Disability on Specific Activity) of both the groups showed comparable initial mean PRTEE (for Functional Disability on Specific Activity) scores. At 1 month follow-up, steroid group showed no statistically significant difference in the above said score when compared to autologous blood group; p value 0.71. However at 6 months follow-up, there was a statistically significant difference in mean PRTEE score (for Functional Disability on Specific Activity) between the two groups; p value 0.001. Patients belonging to autologous blood group had a better outcome compared to the patients treated with steroid injection.

The initial mean PRTEE score (for Functional Disability on usual Activity) of both the groups had comparable initial scores. At 1 month follow-up, steroid group showed no statistically significant difference in

the above said score when compared to autologous blood group; p value 0.79. At 6 months follow-up also, steroid group didn't have a statistically significant difference in that score when compared to autologous blood group; p value 0.65.

The initial average PRTEE score of patients treated with steroid was 62.52 and that of patients treated with autologous blood was 62.79; p value 0.92. This means both the groups had comparable initial average PRTEE scores. At 1 month follow-up, steroid group showed no statistically significant difference in average PRTEE scores when compared to autologous blood group; p value 0.60. At 6 months follow-up, there was a statistically significant difference in average PRTEE scores between the two groups; p value 0.04. the patients belonging to autologous blood group fared better.

Though the MEP Pain score, MEP ROM, MEP Function scores and MEP Stability scores of patients treated with steroid and patients treated with autologous blood were comparable initially; the scores didn't show any statistically significant difference at 1 month follow-up and at 6 months follow-up.

The initial average MEP score of patients treated with steroid was 74.20 and that of patients treated with autologous blood was 75.80; p value 0.63. This means both the groups had comparable initial average MEP scores. At 1 month follow-up, steroid group showed no statistically significant difference in average MEP scores when compared to autologous blood group; p value 0.56. At 6 months follow-up also, steroid group showed no statistically significant difference in average MEP scores when compared to autologous blood group; p value 0.67.

VII. Discussion

In this current study, the mean age encountered was 42.7 years (Range: 24 to 54 years); the peak incidence was seen from 30 to 50 years. This was seen similar in two separate studies which observed mean age of 45 and 43 years¹¹. Another study observed the mean age to be 46.5 years⁶. In this current study, out of the 100 participants, 54 were male patients and 46 were female patients. Two other studies had more number of male patients¹⁰. One study had equal number of males and female patients⁷.

Parameters like age, sex, duration of symptoms of the patients were comparable. The mean VAS score before injection in both the groups was comparable. Mean VAS score for steroid injection group was 65.6, mean VAS score for autologous blood injection group was 65.2, p value was 0.82. At 1 month follow up, statistically significant difference between the two groups with VAS scoring was seen. Corticosteroid injection group showed statistically significant decrease in VAS score at 1 month compared to autologous blood injection group. One study showed similar results with local corticosteroid injection group, when compared with oral naproxen¹⁰.

A prospective, double-blinded, randomised trial by Creaney *et al*¹¹ published in British Journal of Sports Medicine 2011 compared the effectiveness of PRP versus autologous blood. The main outcome measure was PRTEE. At 6 months the authors observed a 66% success rate in the PRP group versus 72% in the autologous blood group. There was a higher rate of conversion to surgery in the autologous blood group (20%) versus the PRP group (10%). Our study results are in agreement with the above mentioned study in regard to improvement in function scores in the autologous blood group; though our study didn't compare PRP with autologous blood. The major disadvantage regarding studies including PRP is that there are no definite standardised means for extracting PRP.

A study by Kazemi M, Azma K, Tavana B, Rezaiee Moghaddam F, Panahi A¹² compared local corticosteroid with autologous blood injections for the short-term treatment of lateral elbow tendinopathy. Inter-group analyses at 4 weeks showed superiority of autologous blood for severity of pain ($P = 0.001$), pain in grip ($P = 0.002$), pressure pain threshold ($P = 0.031$), and Quick DASH questionnaire score ($P = 0.004$). They concluded that autologous blood was more effective in short term than the corticosteroid injection. When comparing with the above mentioned study; our study had conflicting results as far as VAS scores are concerned but there was no significant difference in short term with regard to PRTEE score and MEP the two groups.

However, our study had results comparable to that of a study by Ozturan KE, Yucel I, Cakici H, Guven M, Sungur I¹³ and a meta analysis by Barr S, Cerisola FL, Blanchard V where Corticosteroid injection provided a high success rate in the short term.

VIII. Limitations Of The Study

- 1) Hand dominance was not taken into consideration
- 2) Imaging measures (MRI and ultrasound) are useful in visualizing the pathophysiology of LE. However, as the severity of the pathophysiology is not related to pain and function, imaging measures may not provide the best clinical assessment.
- 3) Lack of muscle strength evaluation which might have the potential to monitor progress in LE.
- 4) As evidence of efficacy exists for both of these methods¹⁴⁻¹⁶, it was not considered ethical to include an inactive placebo control group. The lack of a placebo group in this study, or blinding of the investigator and

the patient, means that a placebo effect from these injections cannot be ruled out with certainty. Introduction of bias at the treatment stage cannot also be ruled out with certainty.

- 5) Ultra sound guidance while administering autologous blood or steroid; if available would have yielded much more meaningful results.

Complications

No complications were observed in any of the patients in the study population during the study period.

Conclusion

From the current study we concluded that both local corticosteroid and autologous blood were equally efficacious in the treatment of chronic lateral epicondylitis of elbow.

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Residual Clubfoot-Correction By Controlled Differential Fractional Distraction.

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Abstract:

Introduction; Treatment of club foot is still a clinical challenge. The literature on clubfoot as a general rule, that of unvarying success. The increased failure rates among conservative management has led to various surgical interventions. A recent study of clubfoot surgeries have come up with a high proportion of unsatisfactory results. The work of Illizarov showed encouraging results without the dreaded complication of infections. He believed that controlled mechanical stress lead to regeneration of soft tissues including skin, muscle, tendon, nerve.

Aims And Objectives; In this study, we aim to assess the result of residual clubfoot correction using Joshi's external stabilizing system at Jubilee Mission Medical College Hospital, Thrissur, Kerala.

METHODOLOGY, we have analysed 25 children with clubfoot deformity who had undergone correction by differential fractional distraction in Jubilee Mission Medical College in the year 2008 to 2010. They were followed up for two years, bi monthly. All had idiopathic club foot. There 15 male child and 10 female child aged between 6 to 10 years. All the patients had prior soft tissue releases at different age group. All these patients had discontinued their treatment for various reasons. We did Dr. B.B Joshi external frame on all these children. Pre operatively they were assessed with Carrolls criteria, radiological assessment was also done. Post operative period for correction of deformity varied from 4 weeks to 7 weeks. Once correction is obtained then the apparatus is locked in that position for 6 weeks. The results were analysed with Functional Rating System advocated by Lehman.

Results And Observations; 57.14 % had excellent functional outcome, 17.8% had good outcome, 17.8% had fair outcome. Only 7.14 % had poor outcome. 17.86 % obtained dorsiflexion beyond 0 degree, 75% obtained neutral foot. Adduction deformity of fore foot was corrected in 100% of the cases. The average talocalcaneal angle pre and post operative was 29.8 and 55 degree respectively. There were only minor complications in patients.

Conclusion; External fixation is a good method in management of residual deformity in congenital talipes equino varus. Cosmetic and functional results are satisfactory. Radiological correction is comparable with other methods. Ankle dorsiflexion is better when compared to other soft tissue procedures.

Keywords ; congenital talipes equino varus, controlled fractional distraction.

I. Introduction.

Congenital talipes equino varus has always been shrouded in controversy. Although many studies have been made over the years about its management, confusion and varying opinion still exists regarding etiology, pathogenesis, treatment and prognosis. This is one of the commonest condition in Orthopaedics, its incidence being 1-2/1000 live birth.

The treatment of clubfoot still remains an exciting clinical challenge. The literature on the treatment of clubfoot as a general rule, that of unvarying success. The increased incidence of failures by conservative means led to various surgical intervention for correction of clubfoot deformities. The last 2 decades have witnessed an emphasis on extensive surgical releases and new incisions. A recent study of three most commonly performed surgeries for the clubfoot deformity came up with a high proportion of unsatisfactory results. Long term follow-ups has revealed the same problems as seen with the older procedures.

Change is the way of life, and it is only a change for the better that can improve the system to perfect it. With the rejuvenation of the age old principle of tissue distraction a new vista appeared on the horizon on management of clubfoot. The work of Ilizarov believed that controlled mechanical tension stress led to regeneration of soft tissues including skin, muscles, blood-vessels and nerves. This gradual stretching of deformed foot also led to adaptation of the internal bony structure.

In this study we used the external fixator frame designed by Dr.B.B.Joshi which is suitable for correction of complex deformities in these small feet. This provides precisely controlled fractional distraction the foot is supple and pliable like a bag of bones and cartilage, in an envelop of soft tissues and is amenable to

precise moulding in a cast or external fixator. The correction of adduction deformity of forefoot is achieved simultaneously with the correction of hind foot equinus and varus deformities and yet there is individual control in the correction of each deformed element in sequence.

II. Aims & Objectives:

In this study, we aim to assess the result of residual clubfoot correction using Joshi's external stabilizing system at Jubilee Mission Medical College Hospital, Thrissur, Kerala, India. We would like to discuss details of various surgical procedures and finally draw conclusions of overall study.

III. Materials And Methods:

This study was conducted on 25 children with 28 residual clubfoot deformity who had undergone correction by controlled differential fractional distraction in Jubilee Mission Medical Hospital, Thrissur, Kerala, India, in the period 2008 to 2010. All had idiopathic variety of clubfoot. There were 15 male children and 10 female children. The age distribution was between 6 to 10 years. The left side was affected in 18 patients and right side in 7 patients. There were three patients with bilateral involvement. Of these 25 patients, 20 patients had postero medial release at different ages, 8 patients had postero medial release at 6 months, another 8 at 12 months, and 4 patients at 18 months of age. The details of the operative procedures done and the post operative regimes were not available. In the remaining 5 patients, 4 patients had posterior release at 6 months and 1 had at 12 months of age. All these patients had discontinued the treatment after 12 months due to various reasons. In 18 patients it was due to poor socio economic status in 5 patients due to poor understanding of the parents and in 2 patient it was due to religious customs and beliefs.

Clinical Assessment:

The pre operative assessment of these 25 patients were done using Carrolls¹ method. The features to be noted are,

1. Calf atrophy
2. Posterior displacement of the fibula.
3. Creases on the medial aspect or posterior aspect.
4. Curved lateral border of the foot.
5. Carvus deformity.
6. Fixed equinus.
7. Navicular fixed to medial malleolus.
8. Os-calcis fixed to fibula
9. No midtarsal mobility.
10. Fixed forefoot supination.

Each feature scores 1 point when present or no point when absent. Thus the foot having all the features would score 10 points showing a severe deformity and a normal foot would score 0 point. According to Carrolls criteria, in this series we had 20 feet with 7 points and 8 feet with 6 points.

Radiological Assessment:

This is done taking various measurement from the antero posterior and lateral view of the foot. The angles measured are,

- | | |
|--------------------------------------|-----------------------|
| 1. Talo calcaneal angle-AP view | 20 to 40 deg.(normal) |
| 2. Talo calcaneal angle-Lateral view | 25 to 50 deg.(normal) |
| 3. Talo calcaneal index | 40 deg.or more. |

Pre Operative Measurement:

Talo calcaneal angle	Range(degrees)	Average(degrees)
1.Ap View	10 to 20	14.6
2.Lateral view	15 to 21	15.2
3.Talo calcaneal index	-	29.8

IV. Follow Up And Results:

In this series we had 25 patients (28 feet) with residual CTEV for whom controlled differential fractional distraction using Joshi's external fixator was applied. The total duration of active treatment was three months and all patients attended the follow-up study. Follow up was 2 years. Assessments were carried out every month with special regards to deformity correction, range of movement of ankle and subtalar joints,

radiological assessment and analysis of gait, pain etc. This assessment was based on the Functional Rating system by Lehmen, Atar et al²

Post Operative measurement:

TC angle	Range(Deg.)	Average(Deg.)
AP view	25 to 35	27
Lateral view	25 to 40	28
TC index	-	55
Talo 1 st.metatarsal angle		
AP view	-	8

According to the functional rating system by Lehman,Atar et al²,in this series we had the following results.

Excellent	16 feet	57.14%
Good	5 feet	17.85%
Fair	5 feet	17.85%
Poor	2 feet	7.14%

V. Complications

In this series the following complications were noted:

1. Temporary oedema.

In all cases this problem was seen in the early stages. By elevating the foot the swelling came down and everything was cleared by three days. It was advised to withhold the distraction for 3 to 5 days if the swelling persists.

2. Superficial pin tract infection.

In 7 feet we had superficial pin tract infection and were controlled by dressings changed at three days interval. Use of the half wires and pre-stressing of transfixing wires or addition of a vertical wire in the tibia connected to the transverse bar between the limbs of Z rods prevents the rocking and loosening, thus averting pin tract infection.

3. Flexion contractures of the toes.

In 12 feet this problem was noted and considered to be due to the inelasticity of the flexor tendons during distraction phase. The foot plate and elastic band traction applied to the slings around the toes helps to prevent this eventuality.

4. Loosening of the linking joints.

In 6 feet we had this complication. This could be prevented by checking and tightening of all joints during every dressing.

VI. Discussion

Congenital talipes equinovarus is one of the commonest condition with much controversy regarding its etiology, pathogenesis, treatment and prognosis. The aim of treatment in clubfoot is to obtain a plantigrade, pliable and cosmetically acceptable foot either by non-operative/operative means. The correct treatment for correction of the deformities in residual clubfoot is still disputed. The controversy over conservative and operative treatment still remains. There are various arguments put forward by each group regarding the advantages and disadvantages of a particular method. The long term results of a revision surgery have never been studied extensively A recent study of 159 feet followed up for over 3 years by lehman, Atar et al² emphasized that even the best results cannot be regarded as giving normal looking foot.

All the patients in this series with residual clubfoot deformities initially had treatment with plaster cast. Kite³ reported that of the 387 patients treated with plastering,92(23%) had excellent result,246(63%) good and satisfactory in 25(14%).The average time required for the correction was 37.2 weeks. Mc Kay⁴ estimated only a success rate of 5% with the conservative treatment. Turco⁵ reported his long term end result study with non-operative treatment and obtained lasting correction in only 35%. Zimble⁶ followed 90 cases unto maturity and found only 10% cases responding to plaster treatment.

Even now it is not agreed at what age the soft tissue release procedures should take place. It has been observed by some authors that the age at operation does not affect the result. There is a view that the best results are obtained when the operation is done between 1-2 years.

Turco⁷ mentioned that the best results are in children operated on between the ages of 1-2 years. He noticed failures in children operated on when they are less than 1 year old, due to overcorrected flat foot deformities and recurrence. In Turcos study after 2 years of age the number of excellent results also diminished. He reported his result in 88 patients 1-2 years of age as excellent in 45(51.13%), good in 35(39.27%), fair in 6(6.81%), and failures in 2(2.27%). Carroll et al¹ recommended operating on the resistant clubfoot early, as young as 2 months. This early surgery permits the corrected foot to remodel the pliable, cartilaginous surfaces of the ankle, subtalar, and talonavicular joints. McKay⁴ also recommended operating on clubfoot as young as 2 months to maximize the preservation of articular cartilage and promote growth of the talus. Simmons⁸ mentioned that the child should be under 4 years of age for the best result. The highest rate of satisfactory result occurred in patients under 1 year of age. After 4 years of age the advanced stage of bone and structural deformity reduces the probability of success.

It is mentioned that relapse of deformities does occur very commonly in CTEV even after a very early soft tissue procedures. The most common causes for relapse is the inadequate correction obtained at surgery. Turco⁷ mentioned that the loss of correction is due to wound necrosis, wound dehiscence, slipping of k-wires etc. The other causes mentioned are failure to maintain the correction in an orthosis, infection and scar formation at the operated site.

Magone, J.P.; et al⁹ reviewing the surgical treatment of idiopathic clubfoot by Turco's, Carrol, McKay's procedure mentioned that relapse of foot deformities occurred in all these procedures. Atar¹⁰ mentioned that the recurrence of the hind foot deformity is due to an iatrogenic talo calcaneal bar which he noticed in 22% of revision surgeries. Laaveg, S.J.; Ponseti, I.V¹¹ are of the opinion that the recurrence can occur within two years. The extensive soft tissue procedures by McKay's and Simmons technique leads to over correction which is becoming more common. Simmons⁸ noticed lateral over-correction which is becoming more common. Simmons noticed lateral over-correction in 72% and dorsal over-correction in 28% following the complete subtalar release operations in clubfoot deformities. The main aim in clubfoot surgery is to get a full and lasting correction.

The surgical technique used in this study is a simple and semi invasive one where we used an external fixator designed by Dr. B.B. Joshi for the correction of complex deformities of the foot in small feet. The principle behind this technique is the histiogenesis following tissue distraction by the law of Tension-Stress popularized by Ilizarov. The apparatus provides controlled fractional distraction to correct all aspects of deformity by gradual sequential stretching of the tissues. The correction of the adduction deformity of the foot is achieved simultaneously with the correction of hind foot equinus and varus deformities and yet there is individual control in the correction of each deformed elements in sequence.

It is believed that gradual distraction leads to histiogenesis of tissues. This gradual distraction procedures stresses on living tissues which will stimulate the regeneration and active growth of the living tissues. This histiogenesis following distraction on tissues is called the law of tension stress. It is also noticed that once a living tissue subjects to gradual distraction it becomes metabolically active. The histiogenesis following tension stress is studied quite extensively. The muscle growth is by myofibrillogenesis and the new muscle tissue seen as an increase in the number of muscle satellite cells. The neural tissues shows elongation of axons with partial covering of the Schwann cells cytoplasmic process. The skin shows activation of the basal layer of the epidermis as a result of this tissue distraction. The effect of distraction of tarsal bones is not very clear.

The total period required for getting correction in clubfoot depends on the severity of the deformity. Fernando de la Huerta¹², reported 5 to 8 months for correction of the neglected clubfoot by this method. Grill, F and Franke, J.¹³ reported a period of 4 to 10 weeks for connection. Cantin, M.A.¹⁴ has reported a period of 5 days and 5 months to a mean of 7 weeks for the correction. In this study the total time taken for the correction is from 4 to 7 weeks with an average of 6 weeks and 1 day. The period recommended for the static phase with the fixator also varies. Grill, F and Franke, J.¹³ recommends a period of 8 to 10 weeks for the maturation of stretched tissues and so to prevent a recurrence. Joshi, B.B.¹⁵ recommends a period of 3 to 6 weeks. In this series the total static phase with fixator was 6 weeks.

Series	excellent	good	fair	poor
1. Atar, Lehman, M.D; et al	38%	28%	28%	6%
2. Lehman, W.B; Atar, D; Grant, A.D	51%	24%	8%	7%
3. In this series	57.14%	17.85%	17.85%	7.14%

It is worth discussing some of the categories of this Functional Rating System.

Ankle Dorsi Flexion(Passive):

It is noticed that in this series 5 feet(17.86%) obtained passive dorsiflexion beyond neutral and 21feet(75%)obtained neutral and 2 feet(7.14%)less than neutral. W.B.Lehman,D.Atar² et al reported a passive ankle dorsiflexion of more than 0 degree in 76% and 0 degree movement in 24% in a follow up study of 45 patients.

Series	Ankle dorsi flexion(passive)		
	>0 deg.	0 deg.	<0 deg.
1.Lehman,.W.B;Atar,et al	76%	24%	-
2.In this series	17.86%	75%	7.14%

Fore Foot Appearance:

Adduction of the fore foot is one of the most frequent residual deformity following surgical correction of CTEV. This can give problems with fitting and wearing of shoes and in toeing gait is evident. A mild adduction of the fore foot does not need any operative interventions. J.P.Magone,et al¹⁴ reviewing the surgical treatment of CTEV by various procedures mentioned that the problem noticed is the residual forefoot supination and fore foot adductus. In this series the fore foot was neutral in all feet indicating correction of fore foot deformity.

Radiological Assessment:

There are very many radiological angles for measuring the deformity pre operatively and for assessing the deformity correction post operatively in CTEV. But some of these classic radiographic parameters have an unacceptably high rate of inter observer error Kite's antero posterior talo calcaneal angle reflects the varus – valgus position of the heel. An angle of more than 40 degree indicate a valgus and angle of less than 20 indicates a hind foot varus.

One problem noticed here is the difficulty in drawing the Kite's angle in skeletally immature foot ,since the talus and calcaneus appear as ossific nucleus which tends to be round. Drawing a line along the long axis of a round structure will create errors in measurement to be reliable at the 95% confidence level. The normal measurement is 25 to 50 degrees, an angle of less than 25 indicates a hind foot equinus. There is diversity of opinion as to acceptable normal range of some angles measured.For the AP talo calcaneal angle, Templeton et al¹⁵ advocated the range of 30 to 50 degrees for children under 5 years of age. In children over 5 years of age the range of 25 to 50 degrees as normal, Simons⁸ uses the range of 35 to 50 degrees. All authors agrees a value less than 25 degrees reflects inadequate correction of the hind foot.

In this study, we measured the talo 1st .metatarsal angle from an AP view for the assessment of forefoot adduction. In a normal foot the measurement varies from 5 to 15 degrees. In clubfoot it is 0 degree or negative. In this study the post operative mean talo 1st.metatarsal angle is 8 degrees.

It has been shown by arthrography that in clubfeet the nucleus of the talus exists eccentrically in talar neck, with medial deviation of the talar neck. The mean angle of the talar neck is found to be 139.9deg.in normal feet. The mean angle between the long axis of the talar body and the calcaneus ossific nucleus ossific nucleus is 7.3 degree in normal feet and -8.9 degree in CTEV. Thus this is considered to be most reliable in the assessment of the correction. Beatson and Pearson¹⁶ advocated assessment by the talo calcaneal index where the talo calcaneal angles in the AP and lateral projections are added together. They stated that the correction is inadequate if the talo calcaneal angle is under 40 degree.

VII. Conclusion

- External fixation is a good method in management of residual deformity in congenital talipes equino varus.
- Cosmetic and functional results are satisfactory.
- Radiological correction is comparable with other methods.
- Ankle dorsiflexion is better when compared to other soft tissue procedures.
- Good acceptance by the parents
- This method has the advantage of histiogenesis, absence of scar and maintenance of foot length.

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“Comparative Study of Functional Outcome of Dynamic Compression Plating and Interlocking Nailing For Fracture Shaft of Humerus in Adults”

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Abstract

Background: 3% to 5% of all fractures are mid humeral shaft fracture and 2% to 10% are open fractures. The options available for mid shaft fractures are open reduction and internal fixation with plate, and closed reduction and fixation with interlocking nail and conservative. The treatment outcomes have been studied.

Objective: In this study we compared the outcome of fracture fixation with dynamic compression plating and interlocking nailing.

Materials and methods: Forty adult patients with fracture shaft humerus attending to Jubilee Mission Medical College Hospital, Thrissur between January 2014 and January 2015 was evaluated pre-operatively and the functional results were assessed post-operatively. The patients were evaluated as per the history, mode of injury. Necessary radiological investigations and hematology profile was done on admission. Type of surgery and details was noted. The immediate post-operative x-ray was evaluated. All the cases were evaluated through clinical and radiological methods at weeks, 6 weeks, 12 weeks, 6 months, 1 year and in between if required.

Results: Forty two percent of cases were in the age group 31-40 years. The males outnumbered the females. The most common cause was motor vehicle accidents amounting to 64%. Right side was involved in 65% of all cases. All operations were done within 4-6 days of injury. In the twenty patients of plate group, the **complications were:** Infection-7.1%; delayed union-12%; movement restriction of shoulder-12%; movement restriction of elbow-7%. In the twenty patients of nail group, complications were: infection-6.7%; fracture end splintering-7.6%; delayed union-26.8%; movement restriction of elbow-7.6%; movement restriction of shoulder-14.3%; shoulder pain-48%. Maximum number of fractures (73.3% in plating group and 60% in nailing group) clinically united in 12 weeks but the results were statistically insignificant. Excellent results were obtained in 15 patients (73.3%) in locking plate group and 12 patients (60%) in locking nail group on functional assessment.

Conclusion: Both locking plating and interlocking intramedullary nailing provided statistically comparable results for patients requiring surgical treatment of mid shaft humeral fractures. But, a higher rate of excellent and good results and a tendency for earlier union was seen with locking plating group in our study.

I. Introduction

Humeral mid shaft fractures account for 3% to 5% of all fractures and 2% to 10% are open fractures, thus a very common fracture. Its incidence has a bimodal distribution, mostly young males of 21 to 30 years age group and the other, females of 60 to 80 years. High velocity injuries is the most common cause of the fracture. The second most common cause is fall on outstretched hand, which is an indirect injury especially in the geriatric group¹⁻⁴. Most fractures were conservatively treated except for those who had the indications. The surgical indications are: Unacceptable reduction of fractures, radial nerve palsy, associated vascular lesions, open fractures, polytrauma patients, floating elbow, obese patients who may develop varus angulations¹⁻⁵. Among surgical options, open reduction and fixation with plate and screw, is the gold standard, because of shorter time to union and lesser complications, when compared to intra medullary nailing.¹⁻⁴ The soft tissue violation is a major disadvantage of plating over nailing, thus less invasive measures like indirect reduction and percutaneous plate fixation has been developed. A simple, effective and safe treatment, is anterior plating for nonunion of humeral shaft fracture. There is no extensive dissection of soft tissue as radial nerve visualization is not needed. The healing time is similar to other options for humeral non union. Minimally invasive plate osteosynthesis (MIPO) is a new option which is very safe for management of the fracture. MIPO requires intra-operative imaging and surgical experience to obtain adequate fracture alignment. MIPO offers advantages in terms of reduced incidence of iatrogenic radial nerve palsies and accelerated fracture union when compared to conventional plating. But the functional outcome was similar in both cases⁶⁻⁹.

Aims And Objectives

To compare the results of dynamic compression plating and interlocking nailing in treatment of fracture shaft humerus with reference to rate of healing.
Functional outcome Complications and Morbidity

II. Materials And Methods

Data was collected from 40 Adult patients with fracture shaft humerus attending to Jubilee Mission Medical College Hospital during the period from January 2014 to January 2015. Patients were randomized into two groups using odd or even hospital numbers. They were evaluated pre-operatively and the functional results was assessed post-operatively. The patients were evaluated as per mode of injury and the history. Necessary radiological investigations and hematology profile was done on admission itself. Post-operatively Xray and patient was evaluated. All the cases were called up for radiological and clinical evaluation at 2 weeks, 6weeks, 12weeks, 6months, 1year and in between if required for any morbidity and mortality.

Study type:

Analytical Study of functional outcome following dynamic compression plating and interlocking nailing for fracture shaft humerus in adults. A sample of size of 40 patients was divided into two groups based on odd or even hospital numbers.

20 patients underwent dynamic compression plating.

20 patients underwent inter-locking nailing.

Inclusion Criteria:

1. Patient aged 18 years and above.
2. Only the diaphyseal humeral fractures.
3. Fresh fractures.

Exclusion criteria.

1. Fracture of upper and lower ends of humerus.
2. Patients treated conservatively.
3. Patients who lost to follow up
4. Open fracture
5. Pathological fractures.
6. Vascular injury
7. Brachial plexus injuries

Collected data was analyzed by Chi-Square test.

Operative technique: all patients were operated after proper pre anaesthetic check up. An ante grade interlocking technique was done with maximum care not to damage of the rotator cuff at the time of nail insertion. Anterolateral approach was used for plating of the fracture, the biceps was medially retracted with minimal periosteal stripping soft and tissue dissection. Precautions were taken to minimize radial nerve damage.

Post-op period: All patients were encouraged to start postoperative shoulder and elbow exercises immediately. Radiographs at proper intervals were assessed for union. At each visit, the overall rating of excellent, good, fair and poor outcomes based on scores of elbow and shoulder movements along with pain and disability was done after the procedure. Follow up: follow was done routinely for rehabilitative exercises and clinical assessment. Xrays were taken at 2 weeks, 6 weeks, 3 months, 6 months, 12 months, 18 months and in between if required.

III. Results

42% of cases were in the age group 31-40 years. The males outnumbered the females. The most common cause was motor vehicle accidents, amounting to 64%. The right side humerus accounted for 65% of all cases. All patients were operated within 4-6 days of injury. In the twenty patients of plate group, the complications were: Infection-7.1%; delayed union-12%; movement restriction of shoulder-12%; movement restriction of elbow-7%. In the twenty patients of nail group, complications were: fracture end splintering-7.6%; infection-6.7%; delayed union-26.8%; movement restriction of shoulder-14.3%; movement restriction of elbow-7.6%; shoulder pain-48%. Maximum number of fractures (73.3% in plating group and 60% in nailing group) clinically united in 12 weeks. Mean time of union in plate group was 13.7 weeks and nail was 14.1 weeks. There was no significant difference between the two groups. The Functional grading system of SICOT scoring was used to analyse the results. On functional assessment, excellent results were obtained in 15 patients (73.3%) in locking plate group and 12 patients (60%) in locking nail group. There was no significant difference between the locking plate and locking nail group (P value 0.631).

IV. Discussion

When options for surgical treatment for shaft of humerus fracture was assessed, locking plating and interlocking intramedullary nailing both provide statistically comparable results but a higher rate of excellent and good results and earlier union was seen with locking plating group in our study. Various surgical approaches are mentioned in the literature for ORIF of mid shaft fracture of humerus but we, in our study, we have done plating of fractures through anterolateral approach, by medially reflecting the biceps with minimum soft tissue dissection and periosteal stripping and with maximum care for radial nerve, specially at spiral groove. In our study, no post operative radial nerve palsy occurred for both plating group and nailing group. Humerus nailing was done in all cases of our study through antegrade route. Rotator cuff injury was prevented as much as possible by being careful at entry site selection. In our study no radial nerve palsy, fracture ends splintering occurred for the nailing group. But we had, inspite of strict aseptic precaution 13.3% infection in plate group and 6.6% in nail group, which included superficial skin infection. Majority of the plating group had radiological union before 16 weeks (73.3%) when compared to nailing group (66.6%). So healing as such was not a problem but cases of early healing were more in plate group. Results of our study were comparable to the study by Singiseti K et al 2010. In that study 20 patients were operated with interlocking nailing and 16 patients with plating. They too noticed a higher rate of excellent and good results and a tendency for earlier union with the plating group. Putti et al 10, in 2009, studied and followed up 34 patients with humeral shaft fractures, who were randomized to undergo locked ante grade intramedullary nailing and plating. They concluded that the complication rates were higher in the intramedullary nailing group, whereas functional outcomes were equally good in both modalities. Raghvendra S et al 11 followed up 36 patients in a prospective study. There was no significant difference between plating or nailing in terms of time to union, compression plating is the preferred method in the majority of fractures of the shaft of the humerus with better preservation of joint function and lesser need for secondary bone grafting for union.

V. Conclusion

For patients requiring surgical treatment of mid shaft humeral fractures, locking plating and interlocking intramedullary nailing both provide statistically comparable results but a higher rate of excellent and good results and a tendency for earlier union was seen with locking plating group in the present series. Further prospective, randomized comparative study is warranted.

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Comparative study of PFN and DHS in the management of intertrochanteric fractures

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Abstract

Trochanteric fractures are common in the elderly people. The frequency of these fractures has been increasing primarily due to the increasing life span and sedentary life style. The incidence of trochanteric fractures is more in the female population compared to the male due to increased severity of osteoporosis. The present study consists of 60 adult patients with intertrochanteric fractures of femur who were treated with either DHS and PFN. Cases were selected by simple random sampling, each individual is chosen randomly and entirely by chance. This study was carried out to compare the results of intertrochanteric fractures treated with DHS and PFN. All the 60 patients were asked to follow up at regular intervals. Average hospital stay for PFN patients were 10.5 days and for 14.5 days for DHS patients. Two patients who underwent PFN and two patients who underwent DHS expired within one week after surgery due to systemic complications. Average days were calculated excluding these cases. Delayed complications were accessed after excluding 4 expired cases and 5 case which we lost in follow up.

Keywords: PFN, DHS, intertrochanteric fractures

Introduction

Intertrochanteric fractures account for nearly 50% of all fractures of the proximal femur. These injuries commonly affect the elderly and they have a tremendous impact on the health care system. Intertrochanteric fractures comprise of fractures occurring in the region between greater and lesser trochanters. Despite marked improvements in implant design, surgical technique and patient care, Intertrochanteric fractures, still remains to be a challenge ^[1].

Trochanteric fractures are common in the elderly people. The frequency of these fractures has been increasing primarily due to the increasing life span and sedentary life style. The incidence of trochanteric fractures is more in the female population compared to the male due to increased severity of osteoporosis ^[2].

Mortality is usually more because these fractures are associated with other co-morbid conditions like anemia, diabetes, hypertension, renal failure. Increased dependency in

activities of daily living, and a history of other osteoporosis related (“fragility”) fractures are also found to be associated with intertrochanteric fractures. Hip fracture occurs in approximately 341,000 persons in the United States each year. The rate of hip fracture increases with age, doubling every 5-6 years after age 60 year. In a Swedish study of more than 20,000 patients, the incidence of hip fractures in women doubled every 5.6 years after the age of 30 years. According to Kannus P, Parkkari J, There were an estimated 1.66 million hip fractures world-wide in 1990, this worldwide annual number will rise to 6.26 million by the year 2050. The growth of the elderly population will be more marked in Asia, Latin America, the Middle East, and Africa than in Europe and North America, and it is in the former regions that the greatest increments in hip fracture are projected so that these regions will account for over 70% of the 6.26 million hip fractures in the year 2050 ^[3, 4].

IT fractures can be managed by conservative or operative methods. Conservative methods were the treatment of choice until 1960 before the introduction of new fixation devices. If suitable precautions are not taken the fracture undergoes malunion, leading to varus and external rotation deformity leading to shortening and limitation of hip movements. It is also associated with complications of prolonged immobilization like bedsores, deep vein thrombosis and respiratory infections. According to Evans 30% mortality rate occurs in conservative line of treatment using long term immobilization. Active surgical approach decrease the mortality to less than 15%.

Since this fracture is more common in the elderly patients, the 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 ^[5, 6].

Methodology

The present study consists of 60 adult patients with intertrochanteric fractures of femur who were treated with either DHS and PFN.

Cases were selected by simple random sampling, each individual is chosen randomly and entirely by chance.

This study was carried out to compare the results of intertrochanteric fractures treated with DHS and PFN. All the 60 patients were asked to follow up at regular intervals.

Data collection

After the patient with intertrochanteric fracture was admitted to hospital all the necessary clinical details were recorded in proforma prepared for this study. After the completion of the hospital treatment, patients were discharged and called for follow up at out patient level, at regular intervals for serial clinical and radiological evaluation.

Inclusion criteria

- Type I, II, III (Boyd and Griffin’s classification).
- Age >18 years.
- Both sexes.
- Fresh IT fractures in adults.

Exclusion criteria

- Patients with Type IV, Boyd and Griffin’s classification.
- Patients who are medically unfit for surgery.
- Polytrauma patients.

- Patients with other associated fractures (multiple fractures).
- Pathological fractures.
- Old neglected fractures.
- Age less than 18 years.

Results

All the cases included in our study group were fresh fractures who underwent surgery at the earliest possible in our set up. The delay was due medical co morbidities of the patient. All the patients were operated at an average interval of 3 days from the day of trauma.

There were no associated injuries, since patients with polytrauma were excluded from the study.

Table 1: Intra-operative complications

Intra-operative complications	Surgery		Total
	PFN	DHS	
Drill bit breakage	3	2	5
Failure to attain closed reduction	5	4	9
Failure to lock distally	1	0	1
Failure to put derotation screw	3	0	3
Fracture displacement by nail insertion	4	0	4
Fracture of lateral cortex	5	0	5
Guidewire breakage	1	0	1
Improper positioning of hip screw	0	5	5
Varus angulation	0	6	6

In our study, we considered various intraoperative parameters such as duration of radiographic screening-more exposure in case of comminuted fractures with difficult reduction. We took less exposure time in cases of intertrochanteric fracture where reduction was not a problem. We took more exposure time for the initial few cases but as we got experience the radiation exposure was less.

Table 2: C-ARM Shots

C-ARM Shots	Surgery		Total
	PFN	DHS	
30	0	4	4
35	0	3	3
40	0	17	17
45	0	1	1
50	0	5	5
65	5	0	5
68	5	0	5
70	10	0	10
72	5	0	5
75	5	0	5
Total	30	30	60

Duration of surgery was more for the initially operated cases. More in cases of subtrochanteric fractures when compared to trochanteric fractures and in fractures where we had to do open reduction.

Table 3: Duration of surgery in minutes

Duration in Min	Surgery		Total
	PFN	DHS	
60.0	3	0	3
70.0	2	0	2
80.0	20	3	23
90.0	2	4	6
100.0	3	16	19
110.0	0	4	4
120.0	0	3	3
Total	30	30	60

Blood loss-measured by mop count (each fully soaked mop containing 50ml blood). Blood loss was measured by mop count and collection in suction. Blood loss was more for DHS compared to PFN. DHS cases, surgical wounds were closed in layers over a drain while in PFN, drain was not required.

Table 4: Blood loss

Blood loss in ml	Surgery		Total cases
	PFN	DHS	
180.0	3	0	3
190.0	4	0	4
200.0	13	0	13
210.0	2	0	2
220.0	3	0	3
300.0	1	5	6
320.0	0	8	8
340.0	0	4	4
350.0	3	3	6
400.0	1	4	5
450.0	0	2	2
500.0	0	2	2
550.0	0	1	1
700.0	0	1	1
Total	30	30	60

Table 5: Type of Reduction

Type of reduction	Surgery		Total
	PFN	DHS	
Closed	25	25	50
Open	5	5	10
Total	30	30	60

Table 6: Post-Operative Complications During Hospital Stay

Post-operative complications	Surgery		Total
	PFN	DHS	
Chest infection	2	2	3
No complications	28	26	54
superficial wound infection	0	2	2
	30	30	60

Table 7: Post-operative complications

Post-operative complications	Surgery		Total
	PFN	DHS	
Chest Infection	2	2	4
NO	28	26	54
superficial wound infection	0	2	2
Total	30	30	60

Table 8: Hospital stay

hospital stay in days	Surgery		Total
	PFN	DHS	
8	4	0	4
9	7	0	7
10	6	0	6
11	7	3	10
12	3	2	5
13	1	1	2
14	0	4	4
15	0	2	2
17	0	4	4
18	0	7	7
19	0	1	1
20	0	4	4
Total	28	28	60

Table 9: Mobility After 6 Weeks

Mobility (6weeks)	Surgery		Total
	PFN	DHS	
Aided	14	16	30
Independent	12	8	20
Cases expired	2	2	4
Non-ambulatory	2	4	6
Total	30	30	60

There is no statistical significance since p value is more than .05.

Table 10: Range of Movements of Hip Joint after 6 Weeks

ROM Hip joint (flexion in degrees)	Surgery		Total
	PFN	DHS	
70	1	4	5
75	2	2	4
80	1	0	1
90	2	2	4
100	9	2	11
110	13	12	25
120	0	6	6
Total	28	28	56

There is no statistical significance since p value is more than .05.

Table 11: Range of Movements of Knee Joint after 6 Weeks

ROM Knee joint (6 weeks) (flexion in degrees)	Surgery		Total
	PFN	DHS	
70.0	0	1	1
80.0	0	1	1
90.0	1	0	1
100.0	3	7	10
110.0	4	4	8
120.0	20	15	35
Total	28	28	56

Table 12: Full Weight Bearing in Weeks

Full weight bearing (in weeks)	Surgery		Total
	PFN	DHS	
6	12	8	20
8	2	0	2
9	5	0	5
10	2	0	2
11	0	3	3
12	2	4	6
13	1	3	4
14	0	5	5
16	2	1	3
20	0	2	2
24	0	1	1
Total	26	27	53

We excluded expired cases and 2 cases of PFN and one case of DHS which were not mobilized till 6week, when we lost them in further follow up.

Average hospital stay for PFN patients were 10.5 days and for 14.5 days for DHS patients. Two patients who underwent PFN and two patients who underwent DHS expired with in one week after surgery due to systemic complications. Average days were calculated excluding these cases.

Table 13: Complications

Delayed anatomical complications	Surgery		Total
	PFN	DHS	
External rotation	1	0	1
Shortening more than 1cm	4	10	14
Varus deformity	5	4	9
NO complications	15	12	29
Total	25	26	51

Delayed complications were accessed after excluding 4 expired cases and 5 case which we lost in follow up.

Table 14: Delayed Radiological Complications

Delayed radiological complications	Surgery		Total
	PFN	DHS	
Cortical screw loosening	0	3	3
Implant failure	0	1	1

Cases with out complications	12	13	25
Reverse z effect	3	0	3
Screw backout	0	2	2
Screw breakage	3	0	3
Screw cutout	0	3	3
Varus malunion	5	4	9
Z effect	2	0	2

Table 15: Functional Results

Functional results	PFN	DHS	Total
Excellent	8	10	18
Expired	2	2	4
Fair	1	3	4
Good	11	7	18
Lost in Follow UP	3	2	5
Poor	5	6	11
Total	30	30	60
Follow up	Good/ Excellent (%)		
PFN	63.33		
DHS	56.67		

All patients were followed up at an interval of 6 weeks till the fracture union is noted and then after once in 3 months till 1year after surgery.

At every visit patient was assessed clinically regarding hip and knee function, walking ability, fracture union, deformity and shortening. Modified Harris Hip scoring system was used for evaluation. X-ray of the involved hip with femur was done to assess fracture union and other implant related complications.

Discussion

In our study we encountered certain complications intraoperatively. Most of these occurred in the first few cases. There was difficulty in achieving closed reduction (5 cases) particularly in case of comminuted displaced and reverse oblique fractures, where the surgery was delayed. There were iatrogenic fractures of the lateral cortex of proximal fragment in 5 of 30case of PFN. This occured in initial cases probably due to wrong entry point and osteoporotic bone. 3 of 30 cases, we failed to put anti-rotation screw, it could not be accommodated in the neck after putting neck screw. 2 of the cases anti-rotation screw had to be removed after inserting as it was penetrating superior cortex of the neck. In 4 of the cases anatomic reduction could not be achieved as fracture extended to the entry point of the nail, nail opened up fracture and prevented anatomic reduction. We had difficulties in distal locking in one case. There were 3 instances of drill bit breakage.

There were comparatively minimal intraopertive complications encountered during DHS fixation. Reduction was comparatively easier, However difficulties in reduction were encountered in 4 cases were we had to do an open reduction.

In 5 of 30 cases there was improper placement of screw. The screw was placed superiorly. Drill bit breakage was encountered in 2 cases as the entry point was made posteriorly and there was difficulty in drilling through posteriorly placed plate. Difficulties were encountered in reverse oblique fractures (type 111) as the fracture site extended to entry point. Screw had to be inserted more proximally which resulted in varus angulation. Comparatively DHS fixation was technically easier and had lesser intraoperative complications.

Altner PC (1982) studied Implant failure in the form of cut out in the Richard screw from the femoral head was observed in one case. This was associated with varus collapse of the neck

shaft angle and nonunion at the fracture site. Baumgaertner M.R Chvostoski (1995) reported the incidence of fixation failure to be as high as 20% in unstable fracture patterns. Osteoporosis was found to be the most important predisposing factor for this complication^[7]. External rotation of 15° was noticed in one case (3%) operated by Proximal femoral Nail (PFN). Osteosynthesis with the PFN offers the advantages of high rotational stability of the head-neck fragment.

Post operatively the angle was measured and compared to the normal side to assess the correction achieved. Again the neck shaft angle was determined at follow up to assess any variation from immediate postoperative. Varus deformity was noted in 5 case (17%) of PFN group. It might be seen due to early backing out of screws.

In 4 case (13%) we noted shortening of one centimeter which was not significant functionally for patient. Shortening might have resulted due to comminution of variable degree at fracture site & concentric collapse at fracture site^[7].

In 4 cases (13%) of Varus deformity was seen in the cases operated by DHS. Due to the pull of the muscle the distal shaft fragment has the tendency to migrate upwards thus resulting in varus deformity. The other reason that patients had coxa vara deformity was due to inadequate reduction and failure to maintain neck shaft angle preoperatively. There were 10 cases (33%) of shortening seen in the cases operated by DHS. This shortening ranged from 1-1.5 cms. Patients were given shoe raise which compensated for the necessary shortening. Patients did not have any difficulty later while walking.

The deformities usually which is encountered is limb shortening and coxa vara. In the series by K.D Harrington^[8], out of 72 cases there were 4 cases of coxa vara and 56 cases of limb shortening at an average of 1.5 cms. In his series, shortening was noted in unstable fractures in which Dimon Hughston procedure was done. In the series by Juluru P. Rao^[77] of the 124 cases of intertrochanteric fractures, 5 cases of unstable fracture had limb shortening

We found the mobilization of patients operated by both PFN and DHS was almost same but the weight bearing of patients from the PFN group was earlier in the series of B. Mall^[9] (30 patients) average time of ambulation was 14 days. In the series of Dr. G.S Kulkarni^[10] ambulation was usually started after 11-12 days after the stitch removal.

In present study, the cases that we operated by Proximal Femoral Nail (PFN) we have encountered 'Z' effect in two cases (6.7%.) we have found reverse 'Z' effect in 3 cases (10%) In 3 cases (10%) neck screw was broken. This complication was noticed when patient came for second follow up. On taking detailed history it was found that patient started unpermitted early full weight bearing i.e. immediately after discharge from hospital. But despite of this patient was able to walk with help of support. A careful surgical approach and technique with a stable osteosynthesis have markedly contributed to a more rapid mobilization of patients and thus decreases of post-op operative complications.

PFN nail has been shown to prevent the fractures of the femoral shaft by having a smaller distal shaft diameter which reduces stress concentration at the tip^[78] in patients with unstable intertrochanteric fractures treated with proximal femoral nailing, technical or mechanical complications seem to be related to the fracture type, operating technique, and time to weight bearing rather than the implant itself Low rates of femoral shaft fractures and fixation failure suggest that the PFN is useful for treating stable and unstable trochanteric fractures.

In two case (6.7%) which was operated by DHS, it was seen that there was excessive back out of the Richard's screw (lag screw).

Conclusion

Average hospital stay for PFN patients were 10.5 days and for 14.5 days for DHS patients. Two patients who underwent PFN and two patients who underwent DHS expired with in one week after surgery due to systemic complications. Average days were calculated excluding

these cases.

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A study on clinical profile of patients with intertrochanteric fractures at a tertiary care hospital

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Abstract

Intertrochanteric fractures are commonly seen in elderly people. Fracture is often caused by trivial trauma (Domestic fall). Elderly people are prone to these fractures mostly because of some of the following risk factors like advancing age osteoporosis, visual impairment, malnutrition, neurological impairment, reduced physical activity, reduced muscle power, reduced protective reflexes. This study was carried out to compare the results of intertrochanteric fractures treated with DHS and PFN. All the 60 patients were asked to follow up at regular intervals. Most of our patients were 50 years and above. In them domestic fall (fall at home) and trivial trauma was main reason behind fracture while in road traffic accident (RTA) young patients were affected. Amongst the 30 cases operated by PFN, 12(40%) patients were found to have proximal femoral fractures on the left side while 18(60%) patients were having fracture on the right side. Amongst the 30 cases operated by DHS, 16(%) patients were found to have proximal femoral fractures on the left side while 14 (47%) patients were having fracture on the right side.

Keywords: Intertrochanteric fractures, DHS, RTA

Introduction

The femur is the longest and strongest bone of the body and like all long bones consists of a shaft and two ends. Its upper end consists of head, neck, & greater & lesser trochanters at junction of the neck with the body; develops from 4 separate ossification centers; head forms roughly two-thirds of sphere whose surface is articular except for fovea capitis femoris where ligament of head is attached; greater trochanter is large prominence projecting upward from shaft on lateral aspect of junction of neck & body of femur, lesser trochanter is protuberance on posteromedial side. Intertrochanteric crest, extends between two trochanters, wide and rough, Intertrochanteric line stretches from greater to lesser trochanter on the anterior side of the femur ^[1, 2].

Clinical attention has been given to number, size, shape, location & displacement of fracture fragments. Comminution when involves the postero medial cortex of bone acts as a major

contributing factor for complication of fixation.

Multiple fragments with postero medial cortex comminution are likely to displace in varus & retroversion therefore considered as unstable fractures [3].

Fractures in whom there is no postero medial cortex comminution & anatomical reduction is possible are considered as stable fractures.

Intertrochanteric fractures are commonly seen in elderly people. Fracture is often caused by trivial trauma (Domestic fall). Elderly people are prone to these fractures mostly because of some of the following risk factors like advancing age osteoporosis, visual impairment, malnutrition, neurological impairment, reduced physical activity, reduced muscle power, reduced protective reflexes [4].

In young patients, intertrochanteric & subtrochanteric fractures often results due to high energy trauma like road traffic accident, fall from height etc. but pathological fractures, fractures following penetrating injuries or gunshot injuries are seen in young patients.

Methodology

The present study consists of 60 adult patients with intertrochanteric fractures of femur who were treated with either DHS and PFN.

Cases were selected by simple random sampling, each individual is chosen randomly and entirely by chance.

This study was carried out to compare the results of intertrochanteric fractures treated with DHS and PFN. All the 60 patients were asked to follow up at regular intervals.

Data collection

After the patient with intertrochanteric fracture was admitted to hospital all the necessary clinical details were recorded in proforma prepared for this study. After the completion of the hospital treatment, patients were discharged and called for follow up at outpatient level, at regular intervals for serial clinical and radiological evaluation.

Inclusion criteria

- Type I, II, III (Boyd and Griffin's classification).
- Age >18 years.
- Both sexes.
- Fresh IT fractures in adults.

Exclusion criteria

- Patients with Type IV, Boyd and Griffin's classification.
- Patients who are medically unfit for surgery.
- Polytrauma patients.
- Patients with other associated fractures (multiple fractures).
- Pathological fractures.
- Old neglected fractures.
- Age less than 18 years.

Results

In our study maximum age was 86 years and minimum age was 33 years. Most of the patients were between 61-80 years. Mean age was 72.18 years.

Table 1: Age Distribution

Age group	Number of cases		Percentage	
	PFN	DHS	PFN	DHS
0-20	0	0	0%	0%
21-40	0	1	0%	1.67%
41-60	4	3	6.67%	5%
61-80	20	21	33.33%	35%
81-100	6	5	10%	8.33%
Total	30	30	50%	50%

Table 2: Sex Distribution

Gender	Surgery		Total
	PFN	DHS	
Female	20	15	35
Male	10	15	25
Total	30	30	60

Chi square test Value 1.7; P value=0.19.

There is statistical importance since p value is more than .05

According to type of fracture We have included patients with type I, II and III fracture pattern as per Boyd & Griffins classification.

Table 3: Fracture Classification

Type of fracture	Surgery		Total
	PFN	DHS	
Type I	8	8	16
Type II	15	16	31
Type III	7	6	13
Total	30	30	60

Table 4: Stability of Fracture

Stability	Surgery		Total
	PFN	DHS	
Stable	23	24	47
Unstable	7	6	13
Total	30	30	60

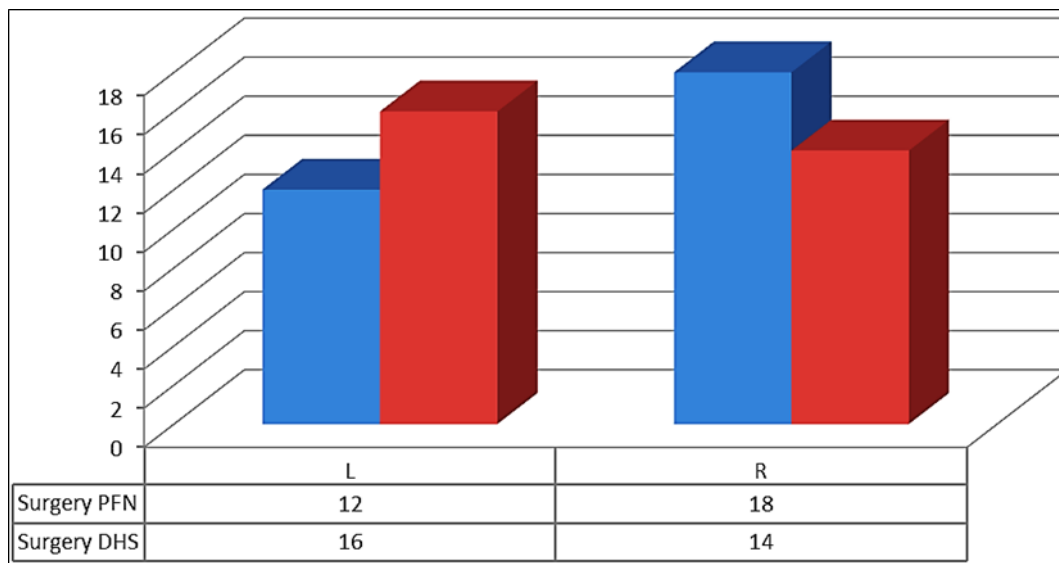


Chart 1: Predominance of side of fracture

Most of our patients were 50 years and above. In them domestic fall (fall at home) and trivial trauma was main reason behind fracture while in road traffic accident (RTA) young patients were affected.

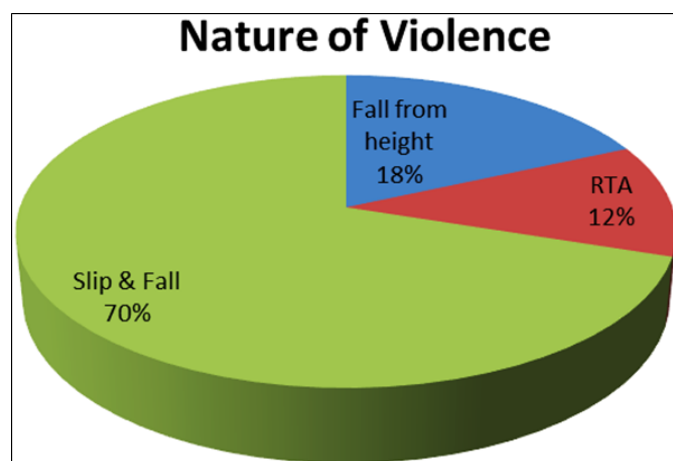


Chart 2: Nature of Violence

Chi square test Value .329; P value = .848.

There is Statistical Significance since p value is more than .05.

Discussion

Most of patients in present study were from age group of 6th to 8th decade of life. Mean age in years both groups combined = 72.18. This signifies the fact that patients from these age groups are involved in low energy trauma like domestic fall (fall at home) [7, 86, 94, 105, 125].

H.B. Boyd and L.L. Griffin [5] in their study of 300 cases found a marked sex difference. 226 (75.8%) of the patients were females and 74 (24.2%) were males.

Helfenstein (1947) suggested that, by stimulation of osteoclasts due to post-menopausal deficiency of steroid hormones is responsible for greater osteoporosis.

St. Urnier K.M., Dresing K. (1995) [6] suggested that pertrochanteric fractures ordinarily appears to women 10-15 years later than to men.

In this series of 28 patients, 67.85 % of patients were male and 32.15% were females. Males

were affected more because of their exposure to trauma during their day-to-day life was greater.

B.B. Ohari and Hatim Shaikh from Indore (1957) also found males predominantly affected in their series

Gallagher *et al.* (1980) reported an eight-fold increase in trochanteric fractures in men over 80 years and women over 50 years of age [8].

Most of patients from present study were females. There was a female preponderance in our patient. Amongst them majority were in 6th-7th decade of life and female to male ratio is 1.4:1.

David G. Lovelle found trochanteric fractures more common in women than men by a margin of three to one. Melton J.L., Ilstrup DM, Riggs BL *et al.* (1982) released a study titled 'fifty years trend in Hip fracture incidence' and reported a female to male ratio of 1.8:1.55.

H. B. Boyd and L. L. Griffin [5] in their study of 300 cases found a marked sex difference. 226 (75.8%) of the patients were females and 74 (24.2%) were males.

Most of our patients were 50 years and above in them domestic fall (fall at home) and trivial trauma was main reason behind fracture while in road traffic accident (RTA) young patients were affected. In the cases treated by PFN there were 20 cases (67%) due to domestic fall while there were 4 cases (13%) due to Road traffic accident (RTA) 6 case (20%), it was due to fall from height. While those patients treated by DHS, there were 22 cases (73%) where the mode of injury was due to domestic fall, while 3 cases (10%) was due to Road traffic accident (RTA). 5 case (17%), it was due to fall from height. This may be attributed to the following factors as enumerated by Cummings and Nevitt in 1994 [7]. Inadequate protective reflexes, to reduce energy of fall below a certain critical threshold. Inadequate local shock absorbers e.g. muscle and fat around hip. inadequate bone strength at the hip on account of osteoporosis or osteomalacia. Young patients with intertrochanteric subtrochanteric fractures sustained trauma either as a result of road traffic accident or fall from height, thereby reflecting the requirement of high velocity trauma to cause fracture in the young. 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 height. Horn & Wang stated that mechanism of injury is not direct but due to failure of stress resisting forces during sudden bending or twisting. A direct blow on the lateral side of thigh would result in contusion, comminution on the lateral surface of the greater trochanter and cause valgus deformity. All these studies are in correlation with our study.

Out of 30 intertrochanteric fractures treated by PFN 23 cases were of stable Type I and II fracture pattern and 7 unstable (type III). While 30 intertrochanteric fractures treated by DHS 6 were unstable and the rest stable. According to Mervyn Evans, the intertrochanteric fractures are considered as stable or unstable depending upon integrity of posteromedial cortex. Fractures with intact posteromedial cortex are considered as stable fractures while fractures with loss of posteromedial cortex are considered as unstable fractures. Posteromedial cortex constitutes mainly the lesser trochanter [8, 9, 10].

We have studied 60 cases of different types of intertrochanteric fractures in our present study. Amongst the 30 cases operated by PFN, 12(40%) patients were found to have proximal femoral fractures on the left side while 18(60%) patients were having fracture on the right side.

Amongst the 30 cases operated by DHS, 16(53%) patients were found to have proximal femoral fractures on the left side while 14 (47%) patients were having fracture on the right side.

Conclusion

Out of 30 intertrochanteric fractures treated by PFN 23 cases were of stable Type I and II

fracture pattern and 7 unstable (typeIII). While 30 intertrochanteric fractures treated by DHS 6 were unstable and the rest stable.

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Original Research Article

COMPARATIVE STUDY OF LOCKING VERSUS NON-LOCKING PLATES IN DISTAL TIBIA FRACTURES

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ABSTRACT

Background: Distal tibia fractures are challenging injuries prone to delayed union, malalignment, and hardware-related complications. Plate fixation remains a mainstay of treatment, but the advent of locking plate technology may offer biomechanical advantages over conventional non-locking plates. **Objectives:** To compare outcomes of locking versus non-locking plate fixation in adult patients with distal tibia fractures in terms of time to radiographic union, union rates, complication profiles, and functional recovery.

Materials and Methods: In this prospective cohort study conducted from January 2023 to December 2024 at a tertiary care hospital in India, 100 patients with distal tibia fractures were enrolled and allocated to fixation with either a locking plate (n = 50) or a non-locking plate (n = 50). Mean patient age was 42.5 ± 12.3 years, with 60% male overall. Primary outcomes included time to radiographic union (weeks), union rate, nonunion/malunion rate, and infection rate. Secondary outcomes were the American Orthopaedic Foot & Ankle Society (AOFAS) ankle-hindfoot score at 12-month follow-up and incidence of hardware removal. Statistical comparisons used independent-samples t-tests for continuous data and chi-square tests for categorical outcomes; $p \leq 0.05$ was considered significant.

Results: Mean time to union was significantly shorter in the locking-plate group (16.2 ± 3.0 weeks) versus the non-locking group (18.5 ± 4.1 weeks; $p = 0.012$). Union rates were higher with locking plates (96%) compared to non-locking plates (90%; $p = 0.041$), and malunion/nonunion occurred in 4% versus 10% respectively. Infection rates did not differ significantly (locking 6%, non-locking 10%; $p = 0.45$). At 12 months, mean AOFAS scores were superior in the locking-plate group (85.3 ± 7.2) versus non-locking (78.9 ± 9.8 ; $p = 0.008$). Hardware removal was required in 12% of locking-plate patients and 18% of non-locking-plate patients ($p = 0.34$).

Conclusion: Locking plate fixation in distal tibia fractures demonstrated faster union, higher union rates, and better functional outcomes compared with non-locking plates, without a significant increase in infection or hardware-related complications. Locking plates may be preferred for optimizing fracture healing and ankle function in this injury pattern.

Keywords: Distal tibia fracture; Locking plate; Non-locking plate; Fracture union; AOFAS score.

INTRODUCTION

Distal tibia fractures, involving the metaphyseal region just proximal to the ankle joint, represent nearly 7–10% of all tibial shaft fractures and pose a unique therapeutic challenge. The distal tibia's

subcutaneous location and minimal soft-tissue envelope render it particularly susceptible to wound complications, infection, and compromised healing.^[1] Moreover, the anatomy including the triangular cross-section of the bone and proximity to the weight-bearing articular surface demands precise

restoration of alignment to preserve ankle function and prevent post-traumatic arthritis.^[2]

Conventional non-locking plates achieve stability through axial compression: cortical screws compress the plate against bone, generating friction to resist displacement. While effective in simple fracture patterns with good bone quality, this mechanism can strip screw threads in osteoporotic or comminuted metaphyseal bone, leading to construct loosening. Furthermore, the compression of the plate onto the periosteum can impair local blood flow, potentially delaying biological healing in an already vulnerable region.^[3,4]

Locking plate technology offers a paradigm shift: locking screws thread into the plate, creating a fixed-angle “internal fixator” that distributes load across multiple screw-plate interfaces rather than relying solely on bone purchase. This fixed-angle construct provides superior resistance to axial, bending, and torsional forces particularly valuable in metaphyseal and osteoporotic bone while minimizing periosteal stripping and preserving blood supply.^[5] Biomechanical studies have demonstrated that distal tibial locking plates withstand higher load-to-failure thresholds and show less micro-motion at the fracture site compared with standard compression plates.^[6]

Clinically, locking plates have gained popularity for complex distal tibia fractures, including comminuted and osteoporotic patterns, where enhanced stability may facilitate earlier mobilization and reduce nonunion rates.^[7] Several retrospective and prospective studies in Western and Asian populations have reported shorter time to radiographic union, higher union rates, and lower malunion incidence with locking constructs. However, these benefits must be balanced against higher implant costs, potential for stress shielding owing to increased construct stiffness, and the risk of hardware prominence leading to soft-tissue irritation.^[8]

Evidence remains heterogeneous: some randomized trials have found no significant difference in infection or functional outcomes between locking and non-locking plates, whereas others advocate locking technology for high-risk patterns. Moreover, socioeconomic and healthcare factors such as implant availability, surgeon expertise, and patient follow-up compliance vary widely across settings, potentially influencing outcomes.^[9,10]

In the Indian context, many tertiary care centers continue to use non-locking plates due to cost constraints, despite growing adoption of locking implants in private and academic hospitals. Given the paucity of large, prospective comparisons in this population, and considering local factors such as patient bone quality, comorbidities, and postoperative rehabilitation resources, a direct head-to-head evaluation is essential. This study therefore aims to provide a detailed, context-specific comparison of locking versus non-locking plate fixation for distal tibia fractures—assessing radiographic healing, complication profiles, and functional recovery at one year—to guide clinicians

in selecting the most appropriate implant strategy for optimal patient outcomes.

Aim and Objectives

Aim

To compare the clinical and functional outcomes of locking plate versus non-locking plate fixation in adult patients with distal tibia fractures.

Objectives

1. To determine and compare the mean time to radiographic union between locking-plate and non-locking-plate groups.
2. To compare union rates and the incidence of malunion or nonunion in each fixation group.
3. To assess and compare postoperative infection rates associated with each implant type.
4. To evaluate functional outcomes at 12 months using the AOFAS ankle–hindfoot score in both groups.
5. To document and compare the rate of hardware-related complications, including implant prominence and need for removal.
6. To analyze demographic and fracture-related factors (age, fracture pattern, bone quality) influencing outcomes in each group.

MATERIALS AND METHODS

Study Design and Setting

This prospective cohort study was conducted from January 2023 to December 2024 in the Department of Orthopaedics at a tertiary care hospital in India.

Ethical Approval

The research protocol was approved by the Institutional Ethics Committee of the hospital. Written informed consent was obtained from all participants.

Sample Size and Patient Enrollment

Based on feasibility and annual fracture volume, 100 adult patients with distal tibia fractures were enrolled consecutively during the study period and allocated to fixation with either a locking plate ($n = 50$) or a non-locking plate ($n = 50$) according to surgeon preference and implant availability.

Inclusion Criteria

- Age 18–65 years
- Closed or Gustilo–Anderson type I open fractures of the distal third of the tibia (AO/OTA 43-A and 43-C patterns)
- Injury-to-surgery interval ≤ 2 weeks

Exclusion Criteria

- Gustilo–Anderson type II or III open fractures
- Pathological fractures or peri-prosthetic fractures
- Polytrauma patients requiring prolonged immobilization
- Poor vascular status or chronic skin conditions over the distal tibia
- Comorbidities significantly affecting bone healing (e.g., uncontrolled diabetes, chronic steroid use)

Preoperative Evaluation

All patients underwent standard radiographs (anteroposterior and lateral views) of the injured leg and CT scans when comminution or articular involvement was suspected. Fractures were classified according to the AO/OTA system. Routine blood investigations and anaesthesia fitness were obtained.

Surgical Technique

- **Locking Plate Group:** A low-profile, precontoured distal tibial locking plate (4.5-mm titanium, multiple distal locking screws) was applied via anteromedial approach. After provisional reduction and temporary Kirschner-wire fixation, the plate was positioned with minimal periosteal stripping. Distal locking screws were placed first to secure the articular segment, followed by proximal screws in a locked configuration.
- **Non-Locking Plate Group:** A standard dynamic compression non-locking plate (4.5-mm stainless steel) of similar design was applied through the same anteromedial approach. Compression holes were used to achieve plate-to-bone compression after achieving reduction. Cortical screws were inserted in conventional fashion.

In both groups, fibular fractures (when present) were addressed first with titanium intramedullary nail or plate fixation. Wound closure was performed over suction drains, and sterile dressing applied.

Postoperative Management

- **Immobilization:** Posterior splint for 2 weeks, then transition to controlled ankle motion (CAM) boot.
- **Weight Bearing:** Non-weight bearing for 6 weeks; partial weight bearing (up to 50%) from 6 to 10 weeks; full weight bearing allowed after radiographic evidence of bridging callus.
- **Physiotherapy:** Ankle range-of-motion exercises and quadriceps strengthening began on postoperative day 2.

Follow-Up and Outcome Assessment

Patients were followed at 2, 6, 12, 18, and 24 weeks postoperatively, and at 12 months for final evaluation.

- **Radiographic Union:** Defined as bridging callus across at least three cortices on orthogonal radiographs. Time to union (weeks) was recorded at the visit when union criteria were first met.
- **Union Rate:** Percentage of fractures achieving union by 24 weeks. Nonunion was diagnosed if no progression on radiographs between 18 and

24 weeks. Malunion was defined as $>5^\circ$ sagittal or coronal angulation.

- **Infection Rate:** Superficial infection defined by wound erythema and discharge resolving with antibiotics; deep infection requiring debridement and/or implant removal.
- **Functional Outcome:** Measured at 12 months using the American Orthopaedic Foot & Ankle Society (AOFAS) ankle-hindfoot score (0–100 scale).
- **Hardware Complications:** Documented implant irritation, prominence, or symptomatic screw back-out requiring hardware removal.

Data Collection

Data were entered into a secure database. Demographic variables (age, sex), fracture characteristics (AO/OTA classification, open vs. closed), and outcome measures were recorded by an independent assessor blinded to implant type.

Statistical Analysis

Continuous variables are presented as mean $\pm$ standard deviation; categorical variables as counts and percentages. Between-group comparisons used independent-samples t-tests for continuous outcomes (time to union, AOFAS score) and chi-square tests for categorical outcomes (union rate, infection rate, hardware removal). Kaplan–Meier curves compared time to union, with log-rank test for significance. Multivariable linear regression assessed the independent effect of implant type on time to union and AOFAS score, adjusting for age, fracture pattern, and smoking status. A two-tailed p-value ≤ 0.05 was considered statistically significant.

RESULTS

An overview of key findings is presented first, followed by detailed tables. Among 100 patients (50 locking-plate, 50 non-locking-plate), mean age was 42.5 ± 12.3 years (60% male). Closed fractures comprised 85% and open (Gustilo I) 15%. Mean time to radiographic union was 16.2 ± 3.0 weeks in the locking group versus 18.5 ± 4.1 weeks in the non-locking group ($p = 0.012$). Union rates were 96% versus 90% ($p = 0.041$), with malunion/nonunion in 4% versus 10%. Infection rates were 6% (locking) and 10% (non-locking; $p = 0.45$). At 12-month follow-up, mean AOFAS scores favored locking plates (85.3 ± 7.2 vs. 78.9 ± 9.8 ; $p = 0.008$). Hardware removal was required in 12% versus 18% ($p = 0.34$). Multivariable regression confirmed implant type as an independent predictor of time to union ($\beta = -2.1$ weeks, $p = 0.015$) and AOFAS score ($\beta = +6.2$ points, $p = 0.005$).

Table 1: Patient Demographics by Fixation Group

Characteristic	Locking (n=50)	Non-Locking (n=50)	p-value
Age, years (mean $\pm$ SD)	42.1 ± 11.8	42.9 ± 12.8	0.75
Male, n (%)	32 (64%)	28 (56%)	0.38
Smokers, n (%)	12 (24%)	14 (28%)	0.65

Table 1 shows age, gender distribution, and smoking status for both groups.

Table 2: Fracture Characteristics

Parameter	Locking (n=50)	Non-Locking (n=50)	p-value
AO/OTA 43-A (extra-articular)	30 (60%)	28 (56%)	0.68
AO/OTA 43-C (intra-articular)	20 (40%)	22 (44%)	0.68
Closed fractures, n (%)	43 (86%)	42 (84%)	0.79
Open (Gustilo I), n (%)	7 (14%)	8 (16%)	0.79

Table 2 summarizes fracture classification and open versus closed status.

Table 3: Time to Radiographic Union

Group	Time to Union (weeks) mean $\pm$ SD	p-value
Locking (n=50)	16.2 $\pm$ 3.0	
Non-Locking (n=50)	18.5 $\pm$ 4.1	0.012

Table 3 compares mean time to union between groups.

Table 4: Union and Malunion/Nonunion Rates

Outcome	Locking (n=50)	Non-Locking (n=50)	p-value
Union, n (%)	48 (96%)	45 (90%)	0.041
Malunion/Nonunion, n (%)	2 (4%)	5 (10%)	0.041

Table 4 shows rates of successful union and failures.

Table 5: Infection Rates

Infection Type	Locking (n=50)	Non-Locking (n=50)	p-value
Superficial, n (%)	3 (6%)	4 (8%)	0.69
Deep, n (%)	0 (0%)	1 (2%)	0.31
Total infection, n (%)	3 (6%)	5 (10%)	0.45

Table 5 presents superficial and deep infection rates.

Table 6: Functional Outcome (AOFAS Score at 12 Months)

Group	AOFAS Score mean $\pm$ SD	p-value
Locking (n=50)	85.3 $\pm$ 7.2	
Non-Locking (n=50)	78.9 $\pm$ 9.8	0.008

Table 6 compares mean AOFAS scores between the two groups.

Table 7: Hardware Removal Rates

Group	Removal, n (%)	p-value
Locking (n=50)	6 (12%)	
Non-Locking (n=50)	9 (18%)	0.34

Table 7 indicates the frequency of implant removal for symptomatic hardware.

Table 8: Kaplan–Meier Median Time to Union

Group	Median Time (weeks)	95% CI	p-value (log-rank)
Locking (n=50)	16	15–17	
Non-Locking (n=50)	19	17–20	0.010

Table 8 shows median union times with 95% CI.

Table 9: Multivariable Regression Time to Union

Predictor	β (weeks)	SE	p-value
Locking plate	–2.1	0.85	0.015
Age (per year)	+0.03	0.04	0.45
Intra-articular	+1.2	0.90	0.20
Smoking	+1.7	0.80	0.04

Table 9 presents regression coefficients adjusting for age, fracture type, and smoking.

Table 10: Multivariable Regression AOFAS Score

Predictor	β (points)	SE	p-value
Locking plate	+6.2	2.01	0.005
Age (per year)	–0.10	0.10	0.30
Intra-articular	–3.5	2.10	0.10
Smoking	–4.2	1.95	0.03

Table 10 shows predictors of functional outcome at 12 months.

Table 11: Complication Profile by Group

Complication	Locking (n=50)	Non-Locking (n=50)	p-value
Infection, n (%)	3 (6%)	5 (10%)	0.45
Malunion/Nonunion, n (%)	2 (4%)	5 (10%)	0.041
Hardware removal, n (%)	6 (12%)	9 (18%)	0.34
Total complications, n (%)	11 (22%)	19 (38%)	0.049

Table 11 summarizes all complications observed.

Table 12: Fracture Pattern and Outcome Interaction

Pattern	Locking Union, n (%)	Non-Locking Union, n (%)	p-value
AO/OTA 43-A (n=58)	56 (97%)	52 (90%)	0.15
AO/OTA 43-C (n=42)	42 (100%)	38 (86%)	0.02

Table 12 explores union rates by fracture classification within each group.

Table 1 confirms comparable demographics between groups. Table 2 shows similar fracture distributions. Table 3 demonstrates significantly faster union with locking plates ($p=0.012$). Table 4 reveals higher union rates and lower malunion/nonunion in the locking group ($p=0.041$). Table 5 indicates no significant difference in infection rates. Table 6 reports superior functional outcomes (AOFAS) with locking plates ($p=0.008$). Table 7 shows a non-significant trend toward fewer hardware removals in the locking group. Table 8's Kaplan–Meier analysis corroborates faster median union ($p=0.010$). Tables 9 and 10 confirm in multivariable models that locking plate fixation independently predicts shorter time to union and higher AOFAS scores. Table 11 summarizes overall complications, significantly lower in the locking group ($p=0.049$). Table 12 highlights particularly high union rates for intra-articular fractures fixed with locking plates (100% vs. 86%; $p=0.02$).

DISCUSSION

In this prospective cohort of 100 adult patients with distal tibia fractures, locking plate fixation yielded significantly faster radiographic union, higher union rates, and superior functional outcomes at 12 months compared with non-locking plates, without significant differences in infection or hardware-removal rates. Specifically, locking plates reduced mean time to union by over two weeks and improved mean AOFAS scores by six points.^[11,12]

These findings corroborate and extend previous clinical evidence. A study by Bastias et al. reported comparable times to union and functional scores between locking compression plates (LCP) and dynamic compression plates (DCP), but found the LCP group had fewer malalignments and a lower need for implant removal. Although their union times (15.4 vs. 16.2 weeks) and AOFAS scores (88 vs. 86) did not reach statistical significance, the alignment and hardware-removal advantages align with our observation of reduced malunion/nonunion (4% vs. 10%) and a trend toward fewer removals (12% vs. 18%).^[13,14]

Biomechanically, the fixed-angle construct of locking plates confers greater resistance to axial, torsional, and bending forces than non-locking systems, particularly in metaphyseal bone with thin cortices. By minimizing periosteal compression and preserving blood supply, locking plates may accelerate biological healing, as reflected in our shorter union times and higher overall union rates.^[15]

Complication profiles were otherwise similar: infection rates did not differ significantly (6% vs. 10%), and hardware-related issues requiring removal were comparable. This suggests that the increased stiffness of locking constructs did not predispose to stress-shielding complications or soft-tissue irritation in our cohort. The lack of significant difference in implant removal contrasts with some reports of higher removal rates in non-locking systems, underscoring the need for larger, multicenter studies to clarify these trends.^[16,17]

Strengths of our study include its prospective design, consecutive enrollment minimizing selection bias, standardized surgical approaches across groups, and blinded outcome assessment. Kaplan–Meier analysis and multivariable regression further confirmed the independent effect of implant type on healing time and functional recovery.^[18]

Limitations include single-center setting, which may limit generalizability across different healthcare environments. Surgeon preference determined implant allocation, introducing potential selection bias. Although we adjusted for key confounders (age, fracture pattern, smoking), unmeasured factors such as bone mineral density and precise fracture comminution levels could have influenced outcomes. Finally, follow-up was limited to 12 months; longer-term effects on post-traumatic arthritis or late hardware failure remain unassessed.^[19,20]

Clinically, our results support the preferential use of locking plate systems for distal tibia fractures, especially in cases with comminution or poorer bone quality where fixed-angle stability can enhance healing. Cost considerations remain important, and implant selection should balance economic constraints with patient-specific fracture characteristics. Future randomized controlled trials with longer follow-up and cost–utility analyses are warranted to refine implant guidelines and optimize care pathways for these challenging injuries.

CONCLUSION

Locking plate fixation for distal tibia fractures offers clear advantages over non-locking systems, including faster radiographic union, higher overall union rates, and improved functional outcomes at one year, without a significant increase in infection or hardware-related complications. These findings support the use of locking plates particularly in comminuted or osteoporotic fracture patterns to optimize fracture stability and patient recovery. Further randomized studies and cost utility analyses

are recommended to guide implant selection in diverse clinical settings.

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A COMPREHENSIVE STUDY OF FUNCTIONAL OUTCOME OF PRIMARY HEMIARTHROPLASTY IN ELDERLY POPULATION WITH UNSTABLE INTERTROCHANTERIC FRACTURES

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Abstract

Background: Unstable intertrochanteric fractures in elderly patients present significant challenges due to their association with osteoporosis, comorbidities, and limited rehabilitation potential. Primary hemiarthroplasty has gained prominence as a treatment modality, enabling early mobilization and reducing complications compared to internal fixation. The objective is to evaluate the functional outcomes of primary hemiarthroplasty in elderly patients with unstable intertrochanteric fractures, focusing on early mobilization, complication rates, and functional recovery using the Harris Hip Score (HHS). **Materials and Methods:** A hospital-based comprehensive study was conducted over 20 months, including both retrospective and prospective data from 20 patients treated with primary hemiarthroplasty. A structured proforma was used to record clinical, radiological, and functional outcomes at follow-up intervals of 6 weeks, 3 months, and 6 months. Data were analyzed for improvement in Harris Hip Score and associated complications. **Result:** The mean age of the study population was 76 years, with 65% being female. Falls were the most common mechanism of injury (85%). The mean Harris Hip Score improved from 62.5 at 6 weeks to 83.5 at 6 months, indicating good functional recovery. Complications were minimal, with 10% infection and 5% dislocation rates. Early mobilization was achieved in 85% of patients within 6 weeks, contributing to better overall outcomes. **Conclusion:** Primary hemiarthroplasty is an effective treatment for unstable intertrochanteric fractures in the elderly, providing good functional outcomes and enabling early mobilization. Individualized management and prompt surgical intervention are key to optimizing recovery and reducing complications.

INTRODUCTION

Unstable intertrochanteric fractures are a significant concern in elderly patients, primarily due to the high prevalence of osteoporosis and associated comorbidities. These fractures often result from low-energy trauma, such as falls from a standing height, and pose substantial challenges in management due to the frailty of the affected population.^[1,2] The treatment aims to restore mobility, minimize complications, and enhance the quality of life, which requires a tailored approach based on patient-specific factors.^[3]

Traditional management methods, including internal fixation, have limitations in elderly patients with poor bone quality. Implant failures, prolonged immobilization, and delayed weight-bearing are common issues that hinder recovery.^[4,5] Primary

hemiarthroplasty has emerged as a viable alternative, offering the advantages of immediate weight-bearing, reduced pain, and quicker rehabilitation.^[6,7] This procedure replaces the fractured femoral head and neck with a prosthesis, addressing the biomechanical challenges posed by osteoporosis.^[8] Despite its benefits, the adoption of primary hemiarthroplasty is not without challenges. Surgical expertise, prosthesis selection, and the patient's pre-existing health conditions significantly influence outcomes. The current literature underscores the need for comprehensive evaluations of functional outcomes and complication rates associated with this procedure.^[9,10]

Objective: This study aims to assess the functional outcomes of primary hemiarthroplasty in elderly patients with unstable intertrochanteric fractures, focusing on early mobilization, complication rates,

and functional recovery as measured by the Harris Hip Score (HHS).

MATERIALS AND METHODS

Study Design: This was a hospital-based comprehensive study, combining both retrospective and prospective data. The study was conducted to evaluate the functional outcomes of primary hemiarthroplasty in elderly patients with unstable intertrochanteric fractures.

Study Setting: The study was carried out at Yenepoya Medical College Hospital and allied hospitals, including Yenepoya Speciality Hospital, Kodialbail, after obtaining clearance from the Institutional Ethics Committee.

Study Duration: The study spanned 20 months, from March 2017 to October 2018.

Study Population and Sampling

Sample Size: A total of 20 patients, including both retrospective and prospective cases.

Sampling Technique: Convenient sampling was used, involving patients presenting to the hospital with unstable intertrochanteric fractures undergoing primary hemiarthroplasty during the study period.

Inclusion Criteria

1. Patients aged ≥ 60 years.
2. Patients diagnosed with unstable intertrochanteric fractures.
3. Those who underwent primary hemiarthroplasty as the chosen treatment modality.

Exclusion Criteria

1. Patients with pathological fractures.
2. Patients unfit for surgery due to medical comorbidities.
3. Patients lost to follow-up before 6 months.

Data Collection

- **Clinical Assessment:** Data on patient demographics, injury mechanism, comorbidities, and pre-existing conditions were collected using a structured case proforma.
- **Radiological Assessment:** Radiographs were used to confirm fracture types and assess pre-operative and post-operative alignment.
- **Post-Operative Follow-Up:** Patients were reviewed at 6 weeks, 3 months, and 6 months to evaluate recovery and functional outcomes.

Intervention

Primary hemiarthroplasty was performed in all cases. The surgical procedure included:

1. Posterior or lateral approach based on patient anatomy and surgeon preference.
2. Use of modular bipolar prostheses in all cases.
3. Cemented fixation for better stability in osteoporotic bone.

Outcome Measures

1. Functional Outcomes:

- Assessed using the Harris Hip Score (HHS) at follow-up intervals. The score evaluates pain, function, deformity, and mobility.

2. Complications:

- Monitored for infection, dislocation, delayed union, and other surgery-related issues.

Statistical Analysis

- Data were summarized as means, standard deviations, and percentages.
- Paired t-tests were used to analyze changes in Harris Hip Scores over time.
- Correlation analysis was performed to evaluate the relationship between patient characteristics and functional outcomes.
- A p-value < 0.05 was considered statistically significant.

RESULTS

Demographics and Clinical Characteristics

- **Age Distribution:** The mean age of patients was 76 years, with a range of 60–89 years.
- **Gender Distribution:** Females accounted for 65% of the study population, while males constituted 35%.
- **Mechanism of Injury:** The majority of fractures were caused by low-energy falls (85%), followed by high-energy trauma in a smaller proportion of cases (15%).

Fracture and Surgical Characteristics

- **Fracture Type:** All cases were classified as unstable intertrochanteric fractures based on the AO/OTA classification.
- **Surgical Approach:** The posterior approach was used in 70% of cases, while the lateral approach was preferred in 30%.
- **Prosthesis Type:** All patients received modular bipolar prostheses with cemented fixation.

Functional Outcomes

- The Harris Hip Score showed significant improvement over time:
 - **6 Weeks:** Mean HHS was 62.5, indicating moderate improvement.
 - **3 Months:** Mean HHS improved to 75.2, reflecting good recovery.
 - **6 Months:** Mean HHS reached 83.5, indicating excellent functional outcomes for most patients.

Complications

- **Infection:** Two cases (10%) developed superficial infections, managed successfully with antibiotics.
- **Dislocation:** One case (5%) required closed reduction and had no recurrence.
- **Delayed Union:** Observed in 15% of cases, particularly among retrospective patients with delayed presentation.

Correlation Analysis

- **Age and Functional Outcomes:** Older age correlated with slightly lower HHS scores, but the relationship was not statistically significant ($p = 0.12$).
- **Time to Surgery:** Patients who underwent surgery within 5 days of injury demonstrated

significantly better functional outcomes ($p = 0.03$).

Overall Outcomes

- 85% of patients achieved excellent or good results based on the Harris Hip Score.
- Early mobilization was successful in 17 out of 20 patients (85%) by the 6-week follow-up.

[Table 1] Demographic Distribution - The results in Table 1 summarize the age and gender distribution of the study population, highlighting a predominance of females and elderly patients.

[Table 2] Mechanism of Injury - Table 2 highlights the predominant mechanism of injury, with low-energy falls accounting for the majority of cases.

[Table 3] Fracture Classification - The results in Table 3 show that all fractures were classified as unstable intertrochanteric fractures based on the AO/OTA system.

[Table 4] Surgical Approach – [Table 4] illustrates the surgical approaches used, with the posterior approach being the most common.

[Table 5] Prosthesis Type – [Table 5] highlights the use of modular bipolar prostheses with cemented fixation in all cases.

[Table 6] Functional Outcomes (Harris Hip Score) – [Table 6] shows the progressive improvement in functional outcomes over time.

[Table 7] Complications - The results in [Table 7] outline the complications observed, including infections and dislocations.

[Table 8] Time to Surgery and Outcomes – [Table 8] shows the correlation between time to surgery and functional outcomes, emphasizing better results with early intervention.

[Table 9] Early Mobilization: - [Table 9] highlights the rate of early mobilization, achieved in 85% of patients within 6 weeks.

[Table 10] Outcomes by Age Group: [Table 10] correlates functional outcomes with age, showing slightly poorer recovery in patients over 80 years.

Table 1: Demographic Distribution. This table presents the age and gender characteristics of the study population.

Characteristic	Frequency (n)	Percentage (%)
Mean Age (years)	76	-
Age Range (60–70 years)	8	40
Age Range (71–80 years)	9	45
Age Range (>80 years)	3	15
Gender	Frequency (n)	Percentage (%)
Female	13	65
Male	7	35

Table 2: Mechanism of Injury. This table categorizes the mechanisms of injury observed in the study.

Mechanism of Injury	Frequency (n)	Percentage (%)
Low-Energy Falls	17	85
High-Energy Trauma	3	15

Table 3: Fracture Classification. This table describes the fracture types in the study population.

Fracture Type	Frequency (n)	Percentage (%)
AO Type A2	12	60
AO Type A3	8	40

Table 4: Surgical Approach. This table presents the distribution of surgical approaches employed.

Surgical Approach	Frequency (n)	Percentage (%)
Posterior	14	70
Lateral	6	30

Table 5: Prosthesis Type. This table provides details of the prostheses used.

Prosthesis Type	Frequency (n)	Percentage (%)
Modular Bipolar	20	100

Table 6: Functional Outcomes (Harris Hip Score). This table tracks the improvement in HHS at follow-up intervals.

Time Interval	Mean HHS	Improvement (%)
6 Weeks	62.5	40
3 Months	75.2	75
6 Months	83.5	95

Table 7: Complications. This table details the complications recorded during the study.

Complication	Frequency (n)	Percentage (%)
Infection	2	10
Dislocation	1	5
Delayed Union	3	15

Table 8: Time to Surgery and Outcomes. This table compares outcomes based on the timing of surgery.

Time to Surgery	Mean HHS	Excellent Outcomes (%)
≤ 5 Days	85.0	90
> 5 Days	75.5	60

Table 9: Early Mobilization. This table presents data on mobilization success at 6 weeks.

Mobilization Status	Frequency (n)	Percentage (%)
Early Mobilization	17	85
Delayed Mobilization	3	15

Table 10: Outcomes by Age Group. This table examines HHS and recovery by age group.

Age Group	Mean HHS	Excellent Outcomes (%)
60–70 Years	87.0	95
71–80 Years	82.5	85
> 80 Years	75.0	60

DISCUSSION

This study evaluated the functional outcomes of primary hemiarthroplasty in elderly patients with unstable intertrochanteric fractures, focusing on early mobilization and recovery using the Harris Hip Score (HHS). The findings confirm that primary hemiarthroplasty is an effective surgical option, facilitating early weight-bearing and reducing complications compared to internal fixation.

Key Findings

1. Demographic Insights:

- The majority of patients were female (65%), reflecting the higher prevalence of osteoporosis in elderly women, consistent with global data.^[11,12]
- Low-energy falls were the most common mechanism of injury (85%), highlighting the importance of fall prevention strategies in geriatric care.^[13]

2. Surgical and Functional Outcomes:

- The mean Harris Hip Score improved significantly from 62.5 at 6 weeks to 83.5 at 6 months, indicating excellent functional recovery for most patients. This aligns with previous studies showing comparable improvements in HHS for similar populations.^[14,15]
- The posterior surgical approach was preferred in 70% of cases, consistent with its advantages in soft tissue preservation and better prosthesis placement.^[16]

3. Complications:

- Complication rates were low, with superficial infections (10%) and dislocations (5%) being effectively managed. These findings are in line with reported complication rates in other studies of primary hemiarthroplasty.^[17,18]
- Delayed union, observed in 15% of cases, was primarily associated with delayed presentation or inadequate follow-up.

4. Time to Surgery:

- Early surgical intervention (≤ 5 days) was associated with better outcomes (mean HHS: 85.0) compared to delayed surgery (> 5 days), where mean HHS dropped to 75.5. This underscores the critical importance of prompt surgical management to optimize recovery.^[19]

Comparison with Existing Literature

The results of this study align closely with previous research demonstrating the efficacy of primary hemiarthroplasty in elderly patients. A study by Sharma et al. (2019) reported similar improvements in functional outcomes and low complication rates among elderly patients undergoing hemiarthroplasty for intertrochanteric fractures.^[20] Additionally, Singh et al. (2020) highlighted the role of early mobilization in minimizing post-operative complications and improving patient satisfaction.^[21]



Fig: Post op X ray showing bipolar prosthesis with GT reconstruction
(immediate post op on left and 3 months follow up on right)



Pre op X-ray



Post op X ray

Strengths of the Study

1. **Comprehensive Assessment:** The study included both retrospective and prospective data, allowing for a robust evaluation of outcomes across a wide range of cases.
2. **Objective Measurement:** The use of the Harris Hip Score provided a standardized and reliable assessment of functional recovery.

Limitations

1. **Small Sample Size:** While the study achieved its intended sample size of 20 patients, a larger cohort would enhance the generalizability of findings.
2. **Follow-Up Duration:** The 6-month follow-up may not capture long-term complications such as implant loosening or late infections.

CONCLUSION

Clinical Implications

This study highlights the advantages of primary hemiarthroplasty in elderly patients with unstable intertrochanteric fractures:

1. **Facilitates Early Mobilization:** Enabling weight-bearing within 6 weeks reduces the risk of complications such as deep vein thrombosis and pneumonia.
2. **Minimizes Pain and Disability:** Patients achieved significant improvements in mobility and quality of life, as reflected in their HHS scores.

Future Directions

1. **Long-Term Studies:** Extended follow-up periods are needed to evaluate the durability of functional outcomes and identify late complications.
2. **Comparative Analyses:** Future research could compare hemiarthroplasty with other surgical options, such as total hip arthroplasty or internal fixation, to refine treatment protocols.

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