



## A COMPARATIVE STUDY BETWEEN TITANIUM AND STAINLESS STEEL ALLOY MADE PROXIMAL FEMORAL NAIL IN INTERTROCHANTERIC FRACTURES OF FEMUR.

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**ABSTRACT** **Introduction :** Intertrochanteric fractures constitute one of the most common fractures of the hip. These fractures were initially treated with conservative management, but with recent advancements and techniques internal fixation with Proximal Femoral nail is considered to be the better choice. Stainless steel is a group of Iron based alloys that contains 11% chromium which prevents iron from rusting and provide heat resistant properties. Titanium alloys contains mixture of titanium and other chemical elements which have high tensile strength and provide toughness and light weight. This study was done to compare between titanium and stainless steel alloys made Proximal Femoral nail in the intertrochanteric fractures of femur. **Methodology :** This study was done randomized prospectively in the Department of Orthopedics, Trauma center, JA group of hospitals. A total of 60 patients were selected, of which 30 were treated with Titanium proximal femoral nail and rest 30 with Stainless steel proximal femoral nail. Functional outcomes were measured clinically using rise up and go test and limb length discrepancy and radiologically union was assessed at 3<sup>rd</sup> week, 6<sup>th</sup> week, 3<sup>rd</sup> month, 6<sup>th</sup> month post-operatively. **Result :** Rise up and go test and Limb length discrepancy measured in both the cases revealed similar functional outcome in both proximal femoral nails. Radiological assessment revealed better union rate with Titanium proximal femoral nail. **Conclusion :** Closed Intertrochanteric fractures treated with Titanium and Stainless steel alloy made proximal femoral nail yielded similar results.

**KEYWORDS :** Limb length discrepancy, Rise up and go test, Titanium PFN, Stainless steel PFN.

### INTRODUCTION

Intertrochanteric fractures are extracapsular fractures of the proximal femur that occur in between the greater and lesser trochanter. Intertrochanteric fractures and Per-trochanteric fractures account for 90% of the proximal femoral fractures occurring in elderly patients and also the most common fractures seen in elderly are often pathologic, usually resulting from minimal to moderate physical trauma to areas of bone significantly affected by osteoporosis like simple fall in the house<sup>[1,2]</sup>.



**Fig-1 Intertrochanteric Fracture Left Side**

Etiology may differ but trauma is the most common cause of the fractures as seen in this area. Intertrochanteric fractures account for approximately 3.40% of all fractures in adults<sup>[3]</sup>. They are result of high energy trauma and are associated with the risk of many complications and even death<sup>[4]</sup>. With increasing number of elderly patients its number is estimated to be double by 2040. Ninety percent of elderly hip fractures result from a low-energy fall<sup>[5]</sup>. There is a life-time risk of hip fractures at 50 years of age as 5.6% for men and 20% for women<sup>[6]</sup>. The incidence of proximal femoral fractures among females is two to three times higher than among males. The risk of a proximal femoral fracture doubles every ten years after age of 50<sup>[7]</sup>.

### AIMS AND OBJECTIVES

- To compare and assess the functional outcome between Titanium alloy made Proximal Femoral nail and Stainless Steel alloy made

Proximal Femoral nail in the treatment of Intertrochanteric fractures of the femur.

- To analyze the rate of union and surgical site complications between the two implants.
- To compare the versatile nature of Titanium alloy made proximal femoral nail and Stainless Steel alloy made proximal femoral nail in the treatment of Intertrochanteric fracture of femur.

### MATERIAL AND METHODS

This study was done in the Department of Orthopedics and Trauma Centre in J. A. Group of Hospitals, Gwalior (M.P.). It was longitudinal randomized prospective study, done from December 2020 to February 2022. The sample size was 60 patients divided in 2 groups (30 patients in each group) : Group A - those who were treated using titanium proximal femoral nail and Group B - those who were treated using stainless steel proximal femoral nail. Patients were treated with closed reduction and internal fixation with proximal femoral nailing by routine technique. Patients were followed up both clinically and radiologically at 3<sup>rd</sup> week, 6<sup>th</sup> week, 3<sup>rd</sup> month, and 6<sup>th</sup> month postoperatively. The implants were procured for surgery as per the existing hospital policies as these surgeries were conducted in the department routinely. Fracture pattern included for study were Intertrochanteric fractures of proximal femur.

### Inclusion Criteria

Patients with Inter-trochanteric fractures of femur, Patients with complete clinical records, Age :- >40 years, Medically and surgically fit for surgery, Capability to give informed consent, Preoperative ambulatory patient.

### Exclusion Criteria

Refusal to consent, Age < 40 years, Age > 80 years, Suspected Pathological fracture, Pre-existing hip pathology, Patients who were bedridden or barely mobile bed to chair, Significant cognitive impairment.

### METHODOLOGY

Cases were operated in routine hours as per admission and availability of operation theater. Most of the cases were operated between 2<sup>nd</sup> to 10<sup>th</sup> day of admission.

After preoperative assessment cases were prepared for surgery. Under aseptic precaution and prophylactic antibiotic coverage cases were operated. Cases were operated either with Titanium alloy made proximal femoral nail or Stainless steel made Proximal Femoral nail on the basis of simple random sampling e.g. 1-3-5.. will be Stainless Steel, 2-4-6.. will be Titanium with minimum acceptable criteria for reduction including –

- Tip apex distance<sup>[23]</sup> : TAD is defined as the sum of the distances between the tip of the lag screw and the apex of the femoral head, as measured on the anterior-posterior (AP) view and on the lateral view, both distances being corrected for radiograph magnification by using the true diameter of the lag screw. TAD greater than 25mm, predictive of a higher extrusion rate.
- Screw Placement
- Screw Size
- Neck shaft angle after final fixation > 130 degree.
- Screw tip configuration : both tips should be in horizontal line.

## RESULTS

In our study, there were 30 (50%) patients were treated with Titanium alloy made Proximal Femoral Nail termed Group A, while the other 30 (50%) patients were treated with Stainless Steel alloy made Proximal Femoral nail termed Group B to assess the functional and radiological outcome between both groups in the treatment of Intertrochanteric fractures of the femur.

The Mean age was 63.03±10.10 years, among them patients were distributed across the age spectrum of 42 to 78 years. Majority of patients were in the age group 61-70 years in both the groups. The mean age in Group A was 64.70±9.21 years and in Group B mean age was 61.43±10.84 years.

In Group A, 10 (33.33%) patients were male, 20 (66.66%) patients were female. In Group B, there were 12 (40.0%) male patients, 18 (60.0%) patients were female. The preponderance of female patients in both the groups was seen 38 (63.33%).

In Group A, there were 19 (63.33%) patients who were injured due to fall on floor, 11 (36.66%) were injured due to road traffic accidents (RTA). In Group B, there were 18 (60.0%) patients were injured due to fall on floor, 12 (40.0%) were injured due to Road traffic accidents (RTA). Fall on floor was the most common mode of injury (61.66%) of both the groups followed by Road traffic accidents (38.33%).

In Group A, there were 12 (40.0%) patients who involved in left side intertrochanteric fracture, 18 (60.0%) who were involved in right side intertrochanteric fracture. In Group B there were 14 (46.7%) patients who involved in left side intertrochanteric fracture, 16 (53.3%) who were involved in right side intertrochanteric fracture.

In Group A, there were 7 (23.3%) patients who had Type I fracture, 14 (46.7%) had Type II fracture, 3 (10.0%) had Type III fracture and 6 (20.0%) had Type IV fracture. In Group B, there were 10 (33.3%) patients who had Type I fracture, 12 (40.0%) had Type II fracture, 6 (20.0%) had Type III fracture and 2 (6.7%) had Type IV fracture. Type II fracture is more common than Type 3, 4 and 1.

In our study out of 60 patients (Group A and Group B) Radiological assessment was done at 6<sup>th</sup> week, 3<sup>rd</sup> month and 6<sup>th</sup> month. In all patients bridging callus was seen at 6<sup>th</sup> week. Complete fracture union was seen at 3<sup>rd</sup> month for 29 (96.7%) in Group A and 27 (90.0%) in Group B. Complete fracture union was seen at end of 6 months in all patients.

The Rise Up and Go test (RUG) is a simple test used to assess a person's mobility and requires both static and dynamic balance.

In Group A and Group B was 33.77±1.61 seconds and 34.32±1.49 seconds respectively at 6<sup>th</sup> week. At 3<sup>rd</sup> month in Group A it was 26.79±1.80 seconds and Group B 26.43±1.90 seconds and at 6<sup>th</sup> month in Group A were 20.41±1.03 seconds and Group B it was 20.19±1.18 seconds.

According to the Limb Length Discrepancy (LLD) in Group A and Group B was 12.60±2.35 mm and 12.45±1.80 mm respectively at 3<sup>rd</sup> week. At 3<sup>rd</sup> month it was 14.10±2.76mm in Group A and 15.30±2.05 mm in Group B and at 6<sup>th</sup> month in Group A it was 14.10±2.76 mm and in Group B it was 15.30±2.05 mm. 20 patients in Group A and 19 patients in Group B had no limb length discrepancy at 3<sup>rd</sup> week, 3<sup>rd</sup> month and 6<sup>th</sup> month.

When internal fixation is performed, toe touch was permitted next day and partial weight-bearing was permitted from 21<sup>st</sup> day, and after 6<sup>th</sup> week full weight-bearing was permitted. Partial weight-bearing allows you to place half of your weight on the operated extremity. Use a scale to see how much pressure is on affected leg when half of weight is placed on it. Early full weight bearing mobilization with walker

support helped in achieving a good outcome in both nail groups.

In our study 100% patients in both the groups has shown partial weight bearing after 3<sup>rd</sup> week. On 6<sup>th</sup> week in Group A 93.3% and in Group B 90.0% patients has shown complete weight bearing. Both groups of patients had shown good recovery.

The average blood loss in Group A was 273.67±22.28ml and in Group B was 274.17±21.33ml.

The average surgery duration in Group A was 52.53±14.19 mins with the maximum and minimum duration being 75 mins and 30 mins respectively. The average duration of surgery in Group B was 55.40±9.57 mins with the maximum and minimum duration being 79 mins and 34 mins respectively.

The average duration between trauma and surgery in Group A was 3.30±0.877 days and in Group B it was 3.33±0.884 days. Surgery was done in less than 4 days for 61.7% of cases and more than 4 days for 38.3% of cases.

In Group A, 3 (10.0%) patients had undergone Z effect and rest 27 patients had no complications. In Group B Implant breakage & varus collapse, surgical site infections and Z effect was seen i.e. 3 (10.0%) respectively and rest 27 patients had no complications.

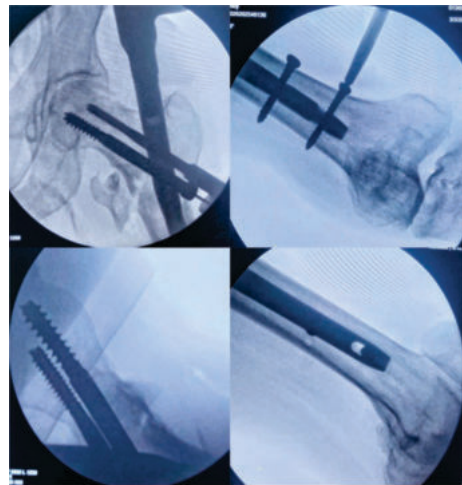


Fig-2  
Fluoroscopic control Images (AP and Lateral view)



Fig-3 Complications A) Screw Back out (Z effect) in Titanium PFN B) Implant failure (Varus collapse) in Stainless Steel PFN

## DISCUSSION

Intertrochanteric femur fractures constitute one of the most common fractures of the hip. The incidence of fractures in the trochanteric region has risen with the increasing numbers of elderly persons with osteoporosis<sup>[8]</sup>. Such patients generally have poor bone quality, thus requiring a fixation device that provides maximum stability and minimises surgical complications. Although many number of different implants are available for fixation but the ideal implant for the treatment of intertrochanteric fractures is still a matter for discussion in India.

In our study, there were 30 (50%) patients who were treated Titanium alloy made Proximal Femoral nail in Group A, while the other 30 (50%) were treated Stainless steel alloy made Proximal Femoral nail Group B.

The mean age of the patients was  $63.03 \pm 10.10$  years among them patients were distributed across the age spectrum of 42 to 78 years. Maximum patients were in age group 61-70 years in both the groups. The mean age in Group A was  $64.70 \pm 9.21$  years and in Group B mean age was  $61.43 \pm 10.84$  years. The association was found to be statistically not significant ( $p > 0.05$ ) which shows the age of both groups are comparable.

In Group A, 10 (33.33%) patients were male and 20 (66.66%) patients were female. In Group B, there were 12 (40.0%) patients were male and 18 (60.0%) patients were female. The preponderance of female patients in both the groups was seen 38 (63.33%). Females are more commonly affected than males due to post-menopausal osteoporosis. In a study conducted by Chang KP, et al. in 229 hip fractures, with an increase in age, there was an increase in the incidence rates of hip fractures in both male and female patients. Even then, the most striking difference in incidence between sexes [116 (women) and 0 (men) per 100,000 person-years] was seen in the 60-64 years age group. The association found to be statistically significant ( $p < 0.05$ ) which shows the gender of both groups are not comparable<sup>[9]</sup>.

In Group A, 19 (63.33%) patients were injured due to fall on floor, 11 (36.66%) were injured due to road traffic accidents (RTA). In Group B, 18 (60.0%) patients were injured due to fall on floor, 12 (40.0%) patients injured due to road traffic accidents (RTA). Fall on floor was the most common mode of injury (61.66%) in both groups followed by road traffic accidents (RTA) (38.33%). The above association was statistically significant. ( $p < 0.05$ ). In another study conducted in 2016 by Dr. Punit J. Tank, Dr. Rajesh A. Solanki, Dr. Harshadkumar A. Patel, Dr. Nirav Rathi, Dr. Janak Mistry, Dr. Hireen B. Bhabhore it was seen majority of the intertrochanteric fractures occurred following trivial trauma like domestic fall in bathroom or fall on floor<sup>[10]</sup>.

Distribution according to Side of injury in Group A, there were 12 (40.0%) patients who had left side fracture, 18 (60.0%) who had right side fracture. In Group B, there were 14 (46.7%) patients who had left side fracture, 16 (53.3%) who had right side fracture. In 2011 Fakoor m et al did a study in which 253 cases ( $M=182, F=71$ ) were included. One hundred forty-six (57.7%) cases had right involvement and 107 (42.3%) of cases had left side involvement<sup>[11]</sup>.

The Intertrochanteric fracture classification used Boyd & Griffin classification Group A, there were 7 (23.3%) patients who had Type I fracture, 14 (46.7%) had Type II fracture, 3 (10.0%) had Type III fracture and 6 (20.0%) had Type IV fracture. In Group B, there were 12 (40.0%) patients who had Type I fracture, 10 (33.3%) had Type II fracture, 6 (20.0%) had Type III fracture and 2 (6.7%) had Type IV fracture. Type II fracture is more common than Types III, Type IV fractures.

Radiological outcome assessment was done postoperatively of 60 patients (Group A and Group B) with X-rays done at 6<sup>th</sup> weeks, 3<sup>rd</sup> month and 6<sup>th</sup> month. For all patients bridging callus was seen at 6<sup>th</sup> week. Complete fracture union was seen at 3<sup>rd</sup> month for 29 (96.7%) in Group A and 22 (73.3%) in Group B. Complete fracture union was seen at end of 6<sup>th</sup> month for all patients.

The Rise Up and Go test (RUG) in Group A and Group B was  $33.77 \pm 1.49$  seconds and  $34.32 \pm 1.49$  seconds respectively at 6<sup>th</sup> week. This difference in mean in patients was more in Group B with statistically significant difference ( $P < 0.05$ ). Similarly, at 3<sup>rd</sup> month & 6<sup>th</sup> month patients in Group A showed similar outcome compared to Group B with statistically insignificant difference ( $P > 0.05$ ). Those operated with Titanium PFN showed similar functional outcome and recovered simultaneously.

The Limb Length Discrepancy (LLD) in Group A and Group B was  $12.60 \pm 2.35$  mm and  $12.45 \pm 1.80$  mm respectively at 3<sup>rd</sup> week. At 3<sup>rd</sup> month it was  $14.10 \pm 2.76$  mm in Group A and  $15.30 \pm 2.05$  mm in Group B and at 6<sup>th</sup> month in Group A it was  $14.10 \pm 2.76$  mm and in Group B it was  $15.30 \pm 2.05$  mm. 20 patients in Group A and 19 patients in Group B had no limb length discrepancy at 3<sup>rd</sup> week, 3<sup>rd</sup> month and 6<sup>th</sup> month.

Weight bearing after 6<sup>th</sup> week when internal fixation is performed, partial weight-bearing is recommended from 21<sup>st</sup> day, and after 6<sup>th</sup> week full weight-bearing is allowed. Partial weight-bearing allows you to place half of your weight on the operated extremity. Begin by using a scale to see how much pressure is on affected leg when half of weight is placed on it. Early full weight bearing mobilization with

walker support helped in achieving a good outcome in both nail groups.

In our study 100% patients after 3<sup>rd</sup> week were partial weight bearing supported. In 6<sup>th</sup> week in Group A 100% and in Group B 83.3% patients were complete weight bearing supported. Both group of patients has shown good recovery. The difference among Weight bearing in both groups showed statistically significance ( $p < 0.05$ ).

We encountered intra-operative difficulty in finding entry point if the greater trochanter was broken. Post-operative infection was seen in 1 patient in the Stainless Steel alloy made PFN group and needed change of antibiotics and dressings. He was suffering from DM Type II.

Reduction was considered as "good" if the cortical congruence at the calcar region was restored, and if the displacement between the fragments did not exceed 2 mm in any projection. The ideal position for the screw in the femoral neck for the PFN was designed as being central on the lateral radiograph and central or inferior on the AP radiograph.

Use of long IM nails has gained popularity with a number of orthopaedic surgeons worldwide. Several authors have reported on the usefulness and effectiveness of long IM nails in managing proximal hip fractures<sup>[12]</sup>. Reported union rates range from 95% to 100%, which is consistent with our results.

No significant difference was found in the trauma to surgery time, operative time and the image intensifier time for both the groups. No intra-operative femoral fracture was observed in our study, due to pre-operative selection of nail of appropriate diameter.

The mean duration of hospitalization for the Group A (Titanium PFN) was 7.23 days (5-12 days) and Group B (Stainless Steel PFN) 7.95 days (5-13 days), with resulting no significant difference. No intra-operative complications were noted.

There were no cases of post-operatively DVT/thromboembolism. In Group A, 3 (10.0%) patients had undergone Z effect and rest 27 patients had no complications. In Group B Implant breakage & varus collapse, surgical site infections and Z effect were seen i.e. 3 (10.0%) respectively and rest 27 patients had no complications.

Clinically both groups had almost equal residual hip pain, the Group A (Titanium PFN) patients were more satisfied as compared to Group B (Stainless Steel PFN) and had better walking ability after fracture treatment, which could be attributed to accurate implant position, more stable fixation and lower rate of varus malalignments.

The average duration between trauma and surgery in Group A was 3.30 days and in Group B it was 3.33 days. Surgery of most of the patients 61.7% was done in less than 4 days and more than 4 days for 38.3% of cases. All the patients were mobilized early to prevent complications and improve functional outcome.

In our study Group A (Titanium PFN) the average operative duration was 52.53 minutes with the longest duration being 88 minutes and the shortest being 35 minutes. In Group B (Stainless steel PFN) the average operative duration was 55.40 minutes with longest duration being 78 minutes and shortest being 34 minutes which is close to as compared to the study of Morihara (77 minutes)<sup>[13]</sup>. The average intra operative blood loss in our study was 274 ml, which is quite less as compared to the study of Pajarinen et al (320ml). The average time for radiological union was 12 weeks<sup>[14]</sup>.

The Titanium alloy made Proximal Femoral nail seems currently to be the optimal implant, especially in very old, severely osteoporotic patients with unstable intertrochanteric fractures. Intramedullary nailing with the PFN has distinct advantages like shorter operating time and lesser blood loss for unstable trochanteric fractures. Early mobilization and weight bearing is allowed in patients treated with PFN thereby decreasing the incidence of bedsores, uremia and hypostatic pneumonia. The incidence of perioperative and postoperative femoral shaft fractures in PFN can be reduced by good preoperative planning and correct technique, adequate reaming of the femoral canal, insertion of implant by hand and meticulous placement of distal locking screws. We also noted that the use of Titanium alloy made Proximal Femoral nail gave the advantage of doing an MRI if the need arises. Based on these results of it was concluded that proximal

femoral titanium nail is a very useful device in high-energy comminuted proximal femoral fractures with minimal complications and the implant provided bio-mechanically stable fixation in all age groups.

The choice of implant should be done preoperatively by evaluating fracture pattern and bone quality and age, to achieve accurate implant position, stable fixation, thereby reducing risk of malalignments.

### CONCLUSION

As per the result of our study we came to the conclusion that closed reduction with Proximal Femoral Titanium nail fixation for proximal femoral fractures has advantages in terms of lower incidences of Implant failure and Surgical site infection. Additionally using a Titanium nail also gives the added advantage to carry out MRI of the patient if the need ever arises.

In our study we also found that chances of Z effect are higher in Titanium Proximal Femoral nail. The risk of implant breakage is higher in Stainless Steel Proximal Femoral nail. However this difference could not be established for clinical significance and it requires further large scale study.

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