

Original Research Article

A study of functional outcome of intertrochanteric fractures operated with intraheal proximal hip stabilizing nail-multicentric study

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ABSTRACT

Background: Modalities of fixation in intertrochanteric fractures have been a topic of debate since times immemorial. Our special aims at comparing the functional outcome of Intraheal™ proximal hip stabilizing nail (PHSN, GPC Medical Limited) fixation in 200 patients of intertrochanteric fractures.

Methods: 200 patients of intertrochanteric fracture fulfilling the inclusion criteria were included in our study. Preoperative AP and Lateral views of hip joint were taken for all patients. In post-operative period, the patients were reviewed at 2 weeks, 1 month, 3 months, 6 months, and 12 months by the operating surgeon. Functional assessment, radiological assessment of bony union and complications were evaluated in follow up period.

Results: 200 patients underwent Intraheal™ proximal hip stabilizing nail fixation. They were followed-up the patients at 2 weeks, 1, 3, 6 and at 12 months postoperatively AP and lateral pelvic X-rays were obtained at each follow-up, and implant position changes, all complications, and fixation failures were recorded. We included a total of 200 patients meeting the criteria in this study and follow up was done till 12 months postoperatively. Intra-operative complications, time of hospital stay, Varus fixation and fracture displacement were assessed.

Conclusion: Advantages noted with PHSN fixation were excellent Harris hip score, lesser screw cutout, early union rate. However, PHSN had greater incidence of anterior thigh pain at all intervals of follow-up. There were no significant local wound complications or duration of hospital stay.

Keywords: Intertrochanteric fracture, PHSN, Trauma, Elderly

INTRODUCTION

Intertrochanteric fractures are among the most commonly encountered fracture seen in the elderly age groups. Management of these fractures has significantly evolved from closed reduction with a derotation boot to arthroplasty in comminuted, unstable intertrochanteric fractures in the elderly population. Historically, unstable fracture patterns warranted operative intervention, typically utilizing intramedullary fixation. However,

modern management has emphasis on early return of function and active lifestyle leading to surgical recommendation even for stable patients. The choice of implant remains surgeon-dependent, encompassing both extramedullary and intramedullary fixation techniques. The proximal femoral nail (PFN), was introduced by the AO/ASIF group in 1998, has become a key treatment option for trochanteric fractures. Intramedullary devices, especially in unstable fractures offer biomechanical advantages over extramedullary devices due to their

shorter lever arms, which result in lesser forces being applied over the implant.^{1,2} Although early reports indicated immense benefits of the proximal femoral nail, it was still associated with complications resulting both due to design and technical/surgical issues. Earlier, generation nails included two lag screw designs. Complication such as Z effect, Reverse Z effect, difficulty in positioning two lag screws in femoral neck, implant protrusion in some cases, fractures of the femoral shaft below the tip of the device, and collapse at the fracture site.¹⁻⁹

Over the years, many of these issues have been addressed with the introduction of newer-generation cephalomedullary nails, which incorporate improvements such as modifications in the number and diameter of lag screws, changes to the proximal nail diameter, repositioning of the distal locking screw, adjustments to the curvature of long nails, the medio-lateral angle, and the addition of radiolucent instruments. The Intraheal™ proximal hip stabilizing nail (PHSN) is a modification of the proximal femoral reconstruction nail. This system provides excellent stability even in osteoporotic bones. Furthermore, with intramedullary nails, there is the advantage of early postoperative weight-bearing due to weight sharing by the nail, leading to faster functional recovery.

The primary objective of this prospective observational study is to evaluate the short-term functional and clinical outcomes of unstable intertrochanteric fractures managed with the Intraheal™ PHSN (GPC Medical Ltd.). The assessment will be conducted using the visual analog scale (VAS) and the Harris Hip Score, along with radiological evaluations of fracture union. We aim to demonstrate that this newer implant design enhances functional outcomes while minimizing complications.

METHODS

Study type

A prospective observational study was conducted. The patient included in study were operated by three senior orthopedic surgeons with over 10 years of experience in handling complex fractures. The surgeons were independently performing these surgeries at 2 hospitals- Department of Orthopedics, KK Hospital Delhi, India (Author PG, AG), DR Maternity and Nursing Home, Delhi, India (Author SC). Study was conducted after approval from the Ethical committee of both the institutes.

Study duration

The study period was from January 2021 to January 2023 with a follow up of one year for last enrolled patient at 2 weeks, 1 month, 3 months, 6 months, and 12 months. Independent radiological assessment by experienced musculoskeletal specialized radiologist of the findings recorded by surgeons in pre- and post-operative radiographs.

Study parameter

Some study parameters were, age- sex groups, types of fracture, post-operative pain, rate of union and functional scoring by Harris hip score. Complications, local and systemic

Inclusion criteria

Inclusion criteria include age 50-70 years, both male and female, unstable Intertrochanteric fractures (AO/OTA 31-A2, 31-A3). BMI<30 kg/sq.m, preinjury ambulatory status-unassisted community ambulation. Closed reduction and internal fixation by of Intraheal™ proximal hip stabilizing nail

Exclusion criteria

Patients who have history of previous hip surgery/preexisting hip pathology. Patients having deformities and pathologies of other joints of the lower limbs which have adverse effects on the functional outcome of the surgery. Patients with acute hip infection/chronic systemic infection. Polytrauma, Pathological fractures, Prolapse intervertebral disc disease (PIVD), BMI>30 kg/sq.m. Post-operative Follow-up<2 year.

Sampling technique

Patients meeting inclusion and exclusion criteria were selected after obtaining written informed consent.

Statistical analysis

In our study, all patients underwent radiographic and laboratory evaluation. Statistical analysis was performed with the SPSS, version 21 for Windows statistical software package (SPSS inc., Chicago, IL, USA). An anteroposterior and lateral view of pelvis with each hip was obtained during admission time. Skin traction was applied till pre-anaesthetic clearance.\

Mean waiting period from admission to surgery was <1 day. All patients underwent intramedullary fixation using standard techniques on a fracture table in supine position under fluoroscopic guidance. Most of the patients were discharged on 2nd post-operative day. Patients were followed up on 2 weeks, 1 month, 3 months, 6 months and 12 months after the surgery (Figure 1 a, b). They were evaluated using VAS score (Table 2), Harris Hip score (Table 4) and radiological parameters of union (Table 3) and complications (Table 5).

Closed reduction technique

The mentioned technique was used in all cases for closed reduction with fluoroscopic guidance. After anaesthesia and patient positioning on fracture table, traction is applied over the slightly abducted extremity. More abduction is required for fractures which have a Varus deformity.

Stable reduction requires in which medial and posterior cortical contact between major proximal and distal fragment in order to prevent Varus and posterior displacing forces. If adequate cortical contact is obtained as seen on the AP view, and good posterior cortical contact is seen on lateral view, fracture can be fixed in anatomic position. Reduction is generally obtained with direct traction, abduction, external rotation. Traction is most important component in reducing intertrochanteric fracture since it achieves neck shaft angle. Comminuted fractures in which lesser trochanter fragment is large displaced fragment, require more external rotation for closure of posterior defect. In comminuted fractures, it is more important to avoid internal rotation because the fracture fixed in internal rotation which is a gross functional disability.

RESULTS

In our study there are 200 patients who underwent the study included 120 males (60%) and 80 females (40%). Their age ranged from 50-70 years as per the inclusion criteria with (mean \pm SD) age of 61 ± 7.8 years. On 3rd post-operative day, the visual analogue scale (VAS) was done (Table 2). Fracture Non-union was not reported in any patient. Rate of union was 12 weeks noted in 170 patients (85%) of the patients (Table 3).

Table 1: Distribution as per Boyd and Griffin classification.

Type of fracture: Boyd and Griffin classification	Frequency	(%)
IT type 1	40	20.0
IT type 2	100	50.0
IT type 3	30	15.0
IT type 4	30	15.0
Total	200	100.0

Table 2: Association of pain status of patients at post-intervention with groups.

VAS score	No. of cases percentage
3	20/10.0
4	80/40.0
5	60/30.0
6	40/20.0
Total	200/100.0

Table 3: Association of rate of union between patients at post-intervention with groups.

Rate of union	No. of cases percentage
4 weeks	0/0.0
12 weeks	170/85
16 weeks	29/14.5
Total	199/99.5

Table 4: Association of functional scoring with Harris hip score at post- intervention with groups.

Functional scoring with category	No. of cases percentage
<70	Poor 10/5.0
70-80	Fair 30/15.0
80-90	Good 50/25.0
90-100	Excellent 110/55.0
Total	200/100.0

Table 5: Association of intraoperative and post-operative complications of patients with groups.

Complications	No. of cases percentage
None	178/89.0
Fracture displacement at nail insertion/Lateral greater trochanteric fracture	10/5.0
Cut out proximal screws	1/0.5
Varus mal-union, shortening<2 cm	10/5.0
Non union	1/0.5

Functional results are assessed by Harris Hip Score were assessed. As regards to complications, our study concluded good results in 70% patients with Intraheal™ proximal hip stabilizing nail (PHSN) (Table 5).

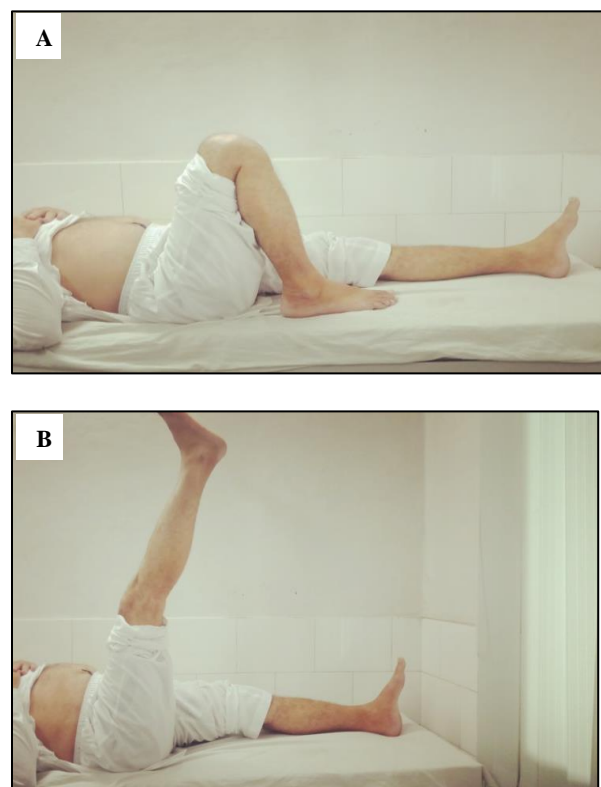


Figure 1 (A and B): Intraheal™ proximal hip stabilizing nail fixation 6 months post-op.

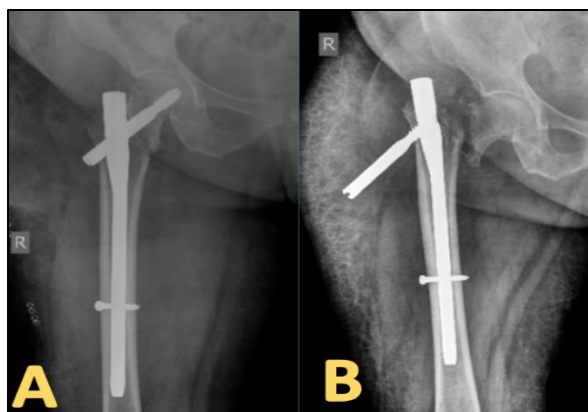


Figure 2: (A) Radiograph of patient with complication of screw back out leading to fracture displacement and non-union. Immediate post-operative X-ray and (B) screw back out and fracture displacement.

DISCUSSION

The selection of proper implants for intertrochanteric fractures is still confusing the surgeon due to high rate of post-operative complications, hip deforming forces at hip, inadequate evidence for appropriate implants etc.

PFN, AO/ASIF introduced a third-generation intramedullary nail called proximal femoral nail.^{5,11} It works on principal of controlled collapse at fracture site but because it is an intramedullary nail so it has a short lever arm, place closed to the mechanical axis of femur so it is a load sharing implant.¹¹ The advantage of this device is less requirement of soft tissue dissection. Due to addition of 6.4 mm anti-rotation screw it reduces rotation of cephalocervical fragment during surgery.^{7,11} Well documented complications are cut-out of screw cutout, fractures, varus fixation, nonunion, other implant related problems such as inability to put in anti-rotation screw (Table 5).⁵

Butler et al, conducted an extensive analysis of the Cochrane database, Medline, Scirus, and included 41 articles on intertrochanteric fractures. He concluded that age, sex, pre-fracture functioning, and cognitive impairment are related to mortality and functional outcomes. Mortality, pain, functional score, and quality of life did not differ by surgical implant class. According to Bhandari et al, this should no longer be an issue with modern implant designs and more experience, however the authors of a Cochrane review came to a different conclusion.¹⁵⁻¹⁷

Parker et al, conducted an analysis of Cochrane database, Medline, Embase and other sources, assessed all randomized control trials comparing cephalon condylar nails and extramedullary implants and concluded that gamma nail was associated with increased risk of operative and later fracture of the femur, and increased rate of reoperation. Complication of fracture fixation were more common in the intramedullary implants.¹⁷

In our study, no postoperative femoral fractures occurred. In another study using PFNA, femoral fractures were reported in two postoperative and five intraoperative cases.¹⁰ This implies that this problem of femoral fractures persists, however we did not encounter any such difficulties in our study. Still more extensive studies may be required to reach a conclusion.

Displacement of greater trochanter fracture fragments and damage to lateral cortex intra-operatively were reported in 10 cases (Table 5). It is may be due to high profile of instruments, anatomy of nail, or patient related factors such as osteoporotic bone. Cutting out is a familiar problem in intertrochanteric femoral fractures. Cut-out rates, including the Z effect, have been reported to range from 3% to 10% with the gamma nail.^{6,18,19}

In study of Vaquero et al, there is no statistical difference in the cut-out rates between the proximal femoral nail anti-rotation (PFNA) and the Gamma nail. Poor positioning of the screw, and improper fracture reduction rather than implant-related causes resulted in cut-out of screws. In our study we observed single case of screw cut-out (Figure 2A, 2B).¹⁹

Patient was ambulatory prior to surgery with no preexisting symptoms related to hip/systemic involvement. Patient had fracture following fall from bed. Till suture removal, no complication was noted, patient remained non ambulatory post-surgery. Around 6 weeks post-surgery patient came with complaint of swelling over operated hip. Patient did not experience any pain in sitting or during physiotherapy sessions. On X-ray, screw back out with fracture displacement was noted. Patient underwent only backed out screw implant removal and refused for any other operative procedure.

Ruecker et al, reported only two implant cut outs in 48 patients with intertan nail during follow up of one year. Implant cut out has been more documented in PFN.^{5,13,20} The cutout rates for PFN have been documented between 0.6-8%.^{7,21} This can be avoided by proper placement of screw and early weight bearing and mobilization (Table 5). It is a well-known fact that implant positioning and proper surgical technique play a more significant role in eliminating this problem rather than implant itself. Our results may suggest that the design of the implant also plays some role in preventing cutout.

Unstable intertrochanteric fractures of femur treated with an intramedullary device are commonly related to mild pain at the site of the fracture and in the middle thigh. Ruecker et al encountered that there is no nail impingement or thigh pain problems in patients treated for an intertrochanteric fracture using this nail.¹³ Our study documented no femoral shaft fractures in the post-operative period. Post operatively neck shaft angle was measured and compared to the normal side for assessment of correction achieved.

There was varus deformity noted in 10 cases (5%) patients. It may be due to inadequate reduction and failure to maintain neck shaft angle preoperatively or due to early backing out of screws. There was one case of non-union reported in our study, patient with screw back out had developed fracture displacement and non-union with shortening. Patient was not willing for operative intervention. Preoperative planning, implant size and optimal placement of implant i.e. placement of proximal screws in central and inferior quadrant of femoral head confirmed on AP and Lateral views are some of the probable important things which minimizes the complications.

Fracture healing was assessed on clinical and radiological evidence of fracture union (Table 2). In our study average fracture union was 12 weeks (Table 3). Functional outcome was assessed by the modified Harris hip scoring system. In our study good to excellent results were seen in 80% of the cases (Table 4).

Excessive shortening of the neck (>5 mm) may cause weakening of gluteus medius strength and limit the movement of the hip joint. Starting from guide wire insertion, reaming, nailing and locking the fracture has to be fully kept reduced to avoid shortening. Although in our study, ten cases show shortening, likewise Varus collapse. The number of patients was too small to allow comprehensive evaluation of the usefulness or the incidences of complications (Table 5), and thus, we suggest that a large prospective study should be done to see the incidence of all complications.

CONCLUSION

In a background of rising incidence of intertrochanteric fractures in the elderly, our study aimed at studying the outcome of intertrochanteric fractures treated with Intraheal™ proximal hip stabilizing nail (PHSN, GPC Medical Limited). Most patients had good to excellent outcome with PHSN. Intraheal™ proximal hip stabilizing nail has got a good outcome but long-term studies with bigger sample size need to be done to study the outcomes and complications and also comparative study needs to be done with other implants available for fixation intertrochanteric fractures.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

REFERENCES

1. Papasimos S, Koutsojannis CM, Panagopoulos A, Megas P, Lambiris E. A randomised comparison of AMBI, TGN and PFN for treatment of unstable trochanteric fractures. Archives of Orthopaedic and Trauma Surg. 2005;125(7):462-68.

2. Haynes RC, Pöll RG, Miles AW, Weston RB. Failure of femoral head fixation: a cadaveric. 1997.
3. analysis of lag screw cut-out with the gamma locking nail and AO dynamic hip screw. Injury. 1997;28(5-6):337-41.
4. Butt MS, Krikler SJ, Nafie S, Ali MS. Comparison of dynamic hip screw and gamma nail: a prospective, randomized, controlled trial. Injury. 1995;26(9):615-8.
5. Kubiak EN, Bong M, Park SS, Kummer F, Egol K, Koval KJ. Intramedullary fixation of unstable intertrochanteric hip fractures: one or two lagscrews. J Ortho T. 2004;18(1):12-7.
6. Boldin C, Seibert FJ, Fankhauser F, Peicha G, Grechenig W, Szyszkowitz R. The proximal femoral nail (PFN)-a minimal invasive treatment of unstable proximal femoral fractures: a prospective study of 55 patients with a follow-up of 15 months. Acta Orthopaedica Scandinavica. 2003;74(1):53-8.
7. Tyllianakis M, Panagopoulos A, Papadopoulos A, Papasimos S, Mousafir K. Treatment of extracapsular hip fractures with the proximal femoral nail (PFN): long term results in 45 patients. Acta orthopaedica belgica. 2004;70(5):444-54.
8. Al-Yassari G, Langstaff RJ, Jones JW, Al-Lami M. The AO/ASIF proximal femoral nail (PFN) for the treatment of unstable trochanteric femoral fracture. Injury. 2002;33(5):395-99.
9. Huang ZY, Liu XW, Su JC. Dynamic hip screws vs. proximal femur nail in treatment of intertrochanteric fractures in patients age over 70 years old. Shanghai Med J. 2010;33(11):1042.
10. Pavelka T, Matejka J, Cervenková H. Complications of internal fixation by a short proximal femoral nail. Acta chirurgiae orthopaedicae et traumatologiae Cechoslovaca. 2005;72(6): 344-54.
11. Matre K, Vinje T, Havelin LI, Gjertsen JE, Furnes O, Espehaug B, Kjellefold SH, Fevang JM. TRIGEN INTERTAN intramedullary nail versus sliding hip screw: a prospective, randomized multi-center study on pain, function, and complications in 684 patients with an intertrochanteric or sub trochanteric fracture and one year of follow-up. JBJS. 2013;95(3):200-8.
12. Mereddy P, Kamath S, Ramakrishnan M, Malik H, Donnachie N. The AO/ASIF proximal femoral nail antirotation (PFNA): a new design for the treatment of unstable proximal femoral fractures. Injury. 2009; 40(4):428-32.
13. Chawla S, Gupta M, Grover V, Garima. Functional and clinical evaluation of intramedullary osteosynthesis with Intraheal™ proximal femoral nail, advanced in unstable peri trochanteric fractures. Int J Orthop Sci. 2021;7(4):92-6.
14. Ruecker AH, Rupprecht M, Gruber M, Gebauer M, Barvencik F, Briem D, Rueger JM. The treatment of intertrochanteric fractures: results using an intramedullary nail with integrated cephalocervical screws and linear compression. J Ortho Tra. 2009;23(1):22-30.

15. Qin H, An Z. Therapeutic evaluation of femoral intertrochanteric fractures by Inter Tan. *Zhongguo xiu fu chong jian wai ke za zhi=Zhongguo xiu fu chongjian waike zazhi. Chinese J Reparative and Constructive Surg*. 2010;24(12):1424-7.
16. Butler M, Forte ML, Joglekar SB, Swiontkowski MF, Kane RL. Evidence summary: systematic review of surgical treatments for geriatric hip fractures. *J Bone and Joint Surg*. 2011;93(12): 1104-15.
17. Bhandari M, Schemitsch E, Jönsson A, Zlowodzki M, Haidukewych GJ. Gamma nails revisited: gamma nails versus compression hip screws in the management of intertrochanteric fractures of the hip: a meta-analysis. *J Orthop Tra*. 2009;23(6):460-4.
18. Parker MJ, Handoll HH. Gamma and other cephalon condylic intramedullary nails versus extramedullary implants for extracapsular hip fractures in adults. *The Cochrane Library*. 2010;8:45-9.
19. Albareda J, Laderiga A, Palanca D, Paniagua L, Seral F. Complications and technical problems with the gamma nail. *International Orthopaedics*. 1996;20(1): 47-50.
20. Parker MJ, Pryor GA. Gamma versus DHS nailing for extracapsular femoral fractures. *International Orthopaedics*. 1996;20(3):163-8.
21. Vaquero J, Munoz J, Prat S, Ramirez C, Aguado HJ, Moreno E, Perez MD. Proximal femoral nail antirotation versus gamma3 nail for intramedullary nailing of unstable trochanteric fractures. A randomised comparative study. *Injury*. 2012;43:47-54.
22. Ballal MS, Emms N, Ramakrishnan M, Thomas G. Proximal femoral nail failures in extracapsular fractures of the hip. *J Orthop Surg*. 2008;16(2):146-9.
23. Min WK, Kim SY, Kim TK, Lee KB, Cho MR, HaYC, Koo KH. Proximal femoral nail for the treatment of reverse obliquity intertrochanteric fractures compared with gamma nail. *J Trauma Acute Care Surg*. 2007;63(5):1054-60.
24. Yu W, Zhang X, Zhu X, Hu J, Liu Y. A retrospective analysis of the Inter Tan nail and proximal femoral nail anti-rotation-Asia in the treatment of unstable intertrochanteric femur fractures in the elderly. *J Ortho Surg Res*. 2016;11(1):10.

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