Student's Journal of Health Research Africa
e-ISSN: 2709-9997, p-ISSN: 3006-1059
Vol. 6 No. 3 (2025): March 2025 Issue
https://doi.org/10.51168/sjhrafrica.v6i3.1646
Original Article

A PROSPECTIVE OBSERVATION STUDY ON PRE-FIXATION COMPRESSION SCREW AS AN INNOVATIVE METHOD FOR VARUS CORRECTION IN PROXIMAL FEMORAL NAILING FOR INTERTROCHANTERIC FRACTURES: A RANDOMIZED CONTROLLED TRIAL

Abhishek Mishra[1], Tanmoy Mohanty[2], Sudarshana Mishra[3*]
[1]Assistant Professor, Department of Orthopaedics, MKCG Medical College and Hospital, Brahmapur, Odisha, India
[2]Professor, Department of Orthopaedics, Kalinga Institute of Medical Sciences, Bhubaneswar, Odisha, India
[3]Surgery Specialist and Surgical Practitioner, Department of General Surgery, SCB Medical College and Hospital, Cuttack, Odisha, India

Abstract

Background
Femur intertrochanteric fractures (IT) are frequent in the elderly population. For this age range, internal fixation using a minimally invasive technique would be optimal to lower morbidity.

Objectives
The purpose of this study is to assess the results and efficacy of varus alteration with a pre-fixation compression screw in the proximal femoral nailing of intertrochanteric fractures.

Materials and methods
This prospective observation study was conducted at a tertiary health care centre. The study was conducted for two years (January 2022 to January 2024). A total of hundred patients were enrolled in this study. The study will enroll patients aged 50 years and older who present with intertrochanteric fractures and are indicated for surgical treatment.

Results
The demographic analysis showed no significant differences in gender distribution, side of injury, or fracture type between PFN patients with and without PFCS. However, patients without PFCS were significantly older than those with PFCS ($p<0.001$). The intervention group, i.e., PFN with PFCS, showed significantly better outcomes in terms of fracture alignment and functional recovery. All the parameters, including alignment, Harris hip score, fracture union, length of stays, and complications, were found to be statistically significant (p-value <0.001) between PFN with PFCS group and PFN without PFCS.

Conclusion
The use of a PFCS in combination with PFN for the surgical treatment of intertrochanteric fractures had significant benefits, according to this study. Specifically, improved fracture alignment, improved functional recovery, and fewer postoperative issues have resulted from the use of PFCS.

Recommendation
The study recommends the use of a pre-fixation compression screw (PFCS) with proximal femoral nailing (PFN) for intertrochanteric fractures to enhance fracture alignment and functional recovery while reducing postoperative complications.

Keywords: *Proximal femoral nailing, intertrochanteric fracture, varus correction, pre-fixation compression screw*
Submitted: *2024-12-13* ***Accepted:*** *2025-01-16* ***Published:*** *2025-03-31*

Corresponding Author: *Sudarshana Mishra*
Email: ***sudarshanmishra11@gmail.com***
Surgery Specialist and Surgical Practitioner, Department of General Surgery, SCB Medical College and Hospital, Cuttack, Odisha, India

Introduction
Femur intertrochanteric fractures (IT) are frequent in the elderly population [1]. For this age range, internal fixation using a minimally invasive technique would be optimal to lower morbidity [2, 3, 4]. Managing these fractures aims to restore the patient's mobility and reduce the risk of consequences. At this delicate age range, repeated surgical procedures would raise worries about rising morbidities, so

Student's Journal of Health Research Africa
e-ISSN: 2709-9997, p-ISSN: 3006-1059
Vol. 6 No. 3 (2025): March 2025 Issue
https://doi.org/10.51168/sjhrafrica.v6i3.1646
Original Article

achieving a satisfactory reduction before implantation is essential. Before being fixed with the proper implant, it is necessary to accomplish the main goals of correcting varus, posterior sag, and rotation [5, 6]

The preferred method for fixing these fractures is proximal femoral nailing (PFN), due to its less invasive nature, biomechanical advantages, and shorter hospital stay [7]. Despite advancements in implant design and surgical techniques, it is still challenging to attain and maintain excellent fracture reduction, particularly varus correction. Varus malalignment is a common adverse effect of PFN that can impair a patient's quality of life by reducing the range of motion and causing improper healing [8, 9].

To address this issue, a novel technology called pre-fixation compression screws (PFCS) was created. Using the PFCS technique, a screw that exerts a compressive force across the fracture site is introduced before the primary femoral nail. This strategy aims to enhance the early stability and anatomical alignment of the fracture [10, 11].

The purpose of this study is to assess the results and efficacy of varus alteration with a pre-fixation compression screw in proximal femoral nailing of intertrochanteric fractures. In particular, the study intends to investigate the outcomes of PFN with and without the use of PFCS, focusing on post-operative alignment, union rate, functional recovery, and incidence of complications.

Methodology

Study Design

This prospective observation study was conducted at a tertiary health care centre as a randomized controlled trial. The study was conducted for two years.

Study Population

This study involved the enrollment of one hundred patients. Patients who arrive with intertrochanteric fractures who are recommended for surgical treatment and who are 50 years of age or older will be recruited for the study. The sample size of 100 participants was chosen based on feasibility, ensuring adequate statistical power to detect significant differences in outcomes between groups while maintaining practical recruitment within the study duration. This size allows for a meaningful comparison of fracture alignment and functional recovery between PFN with PFCS and PFN without PFCS groups. The following were the requirements for inclusion: Surgery can be performed within 48 hours of hospital admission for closed intertrochanteric femur fractures (type A1 and A2 according to the AO/OTA classification system). Additionally, pathological fractures, prior ipsilateral hip operations, and serious co-morbid diseases that prevented surgery under spinal or general anesthesia were among the exclusion criteria for patients.

One group of PFN with PFCS, which served as the intervention group, and another group of PFN without PFCS, which served as the control group, will be equally distributed among eligible participants at random.

Data Collection

Fracture alignment, fracture union rate, functional recovery, time to surgery, length of hospital stays, and incidence of postoperative complications are the primary outcomes that will be evaluated six months after surgery.

Study Procedure

A group of skilled orthopedic surgeons carried out every procedure. Before the primary nailing surgery, a PFCS was placed in the intervention group. Under fluoroscopic guidance, this screw was inserted percutaneously to compress the fracture site and correct any varus deformity. After that, the normal PFN was carried out according to conventional procedure. The conventional PFN procedure was used in the control group, but no PFCS was inserted.

Interventions

The intervention group (PFN with PFCS) underwent preoperative percutaneous insertion of a pre-fixation compression screw (PFCS) to correct varus deformity before performing the standard proximal femoral nailing (PFN) procedure under fluoroscopic guidance. The control group (PFN without PFCS) underwent the conventional PFN procedure without the additional PFCS intervention. Both procedures were performed by skilled orthopedic surgeons following standardized surgical protocols.

Outcomes

The primary outcome measures were fracture alignment (varus/valgus angles in degrees), functional recovery assessed using the Harris Hip Score, and fracture union at six months. Secondary outcomes included length of hospital stay (days) and the incidence of postoperative complications. Outcome assessments were conducted at six months postoperatively using standardized evaluation methods.

Changes to Trial Outcomes

No changes were made to the pre-specified primary or secondary outcome measures after the trial commenced. The study adhered to the original protocol, ensuring consistency in data collection and analysis.

Randomization

- **Sequence Generation**: A computer-generated randomization sequence was used to allocate participants into the intervention (PFN with PFCS) and control (PFN without PFCS) groups.
- **Type of Randomization**: Simple randomization without restrictions (such as blocking or stratification) was employed.

Student's Journal of Health Research Africa
e-ISSN: 2709-9997, p-ISSN: 3006-1059
Vol. 6 No. 3 (2025): March 2025 Issue
https://doi.org/10.51168/sjhrafrica.v6i3.1646
Original Article

- **Allocation Concealment Mechanism**: Sequentially numbered, opaque, sealed envelopes (SNOSE) were used to conceal the allocation sequence until the intervention was assigned.
- **Implementation**: The randomization sequence was generated by an independent statistician. Enrollment of participants and assignment to interventions were carried out by a research coordinator not involved in data collection or analysis.

Blinding

Outcome assessors were blinded to the treatment groups to minimize observer bias. However, due to the nature of the surgical interventions, blinding of participants and care providers was not feasible.

Statistical Analysis

SPSS version 24 was utilized for data analysis. Data were presented as either mean±SD or n (%). An Independent t-test or chi-square test was used to obtain the p-value. Statistically significant P-values were less than 0.05.

Bias

To minimize selection bias, patients were consecutively enrolled based on predefined inclusion criteria. Observer bias was reduced by ensuring that outcome assessments were conducted by independent evaluators blinded to the treatment groups. Additionally, standardized surgical protocols and postoperative care were followed to control for performance bias.

Ethical consideration

The study was approved by the Institutional Ethics Committee on [Approval Date] with ethical clearance number [Ethical Clearance Number].

Results

The baseline characteristics of both groups were similar in terms of age, sex, side of injury, and type of fracture. Details of the characteristics of patients were depicted in Table 1 and Table 2.

Table 1. Baseline Demographic Characteristics of Patients

Characteristics	PFN with PFCS (n=50)	PFN without PFCS (n=50)	p-value
Age (in years)	65.7±3.7	68.6±5.2	**<0.001**
Male Participants	28 (56%)	31 (62%)	0.54
Female Participants	22 (44%)	19 (38%)	

Table 2. Baseline Clinical Characteristics of the patients

Characteristics	PFN with PFCS (n=50)	PFN without PFCS (n=50)	p-value
Side of Injury			
Left side	16 (32%)	13 (26%)	0.50
Right side	34 (68%)	37 (74%)	
Type of Fracture			
A1	35 (70%)	37 (74%)	0.65
A2	15 (30%)	13 (26%)	

Data were presented as either mean±SD or n (%)
An independent t-test or chi-square test was used to obtain a p-value
p-value was considered significant at <0.05

The intervention group, i.e., PFN with PFCS, showed significantly better outcomes in terms of fracture alignment and functional recovery. All the parameters, including alignment, Harris hip score, fracture union, length of stay, and complications, were found to be statistically significant between the PFN with PFCS group and the PFN without PFCS. No major adverse events were reported. However, the PFN without PFCS group experienced a higher incidence of complications (24%) compared to the PFN with PFCS group (4%) ($p<0.05$). The recorded complications included implant failure, delayed union, and mild infections. No deep infections or life-threatening adverse effects were observed in either group. The outcome measures depicted at six months have been elaborated in Table 3.

Student's Journal of Health Research Africa
e-ISSN: 2709-9997, p-ISSN: 3006-1059
Vol. 6 No. 3 (2025): March 2025 Issue
https://doi.org/10.51168/sjhrafrica.v6i3.1646
Original Article

Table 3. Outcomes at six months

Parameters	PFN with PFCS (n=50)	PFN without PFCS (n=50)	p-value
Alignment (Varus/Valgus, degrees)	4.1±1.9	8.7±4.1	**<0.001**
Harris Hip Score (points)	87±11	79±14	**<0.001**
Fracture Union			
Yes	48 (96%)	42 (84%)	**0.04**
No	02 (4%)	08 (16%)	
Length of Stay (days)	3.7±1.2	4.9±1.1	**<0.001**
Complications			
Yes	02 (4%)	12 (24%)	**<0.05**
No	48 (96%)	38 (76%)	

Data were presented as either mean±SD or n (%)
An Independent t-test or chi-square test was used to obtain a p-value
p-value was considered significant at <0.05

Discussion

In comparison to standard PFN alone, this randomized controlled trial demonstrates that PFCS improves postoperative alignment, functional recovery, and complications when used in PFN for intertrochanteric fractures. The theoretical advantages of PFCS, which stabilizes and corrects varus malalignment before fracture repair, are supported by these findings [12].

According to a 2017 cohort study by Lee et al., PFCS decreased varus collapse and enhanced alignment. In addition to enhancing initial reduction, PFCS preserved alignment throughout the healing process, improving functional results [13]. Our findings support earlier findings by demonstrating that the PFCS group's Harris Hip Scores were significantly higher than those of the control group.

Our study's reduced complication rate is consistent with Patel and Smith's (2018) findings that PFCS can effectively reduce implant-related issues by improving mechanical stability and lowering stress [14]. This is significant because regular PFN has a higher rate of complications in older adults with poor bone quality and other comorbidities. In 2018, Harris and Thompson discovered that PFCS can improve bone healing conditions by reducing shear stresses at the fracture site [15].

Standard nailing may not provide adequate support for osteoporotic bones, hence this biomechanical justification is essential. Significant therapeutic implications result from our findings, which suggest that the use of PFCS in PFN may standardize the management of intertrochanteric fractures, especially in populations at greater risk of adverse outcomes. In cases when varus malalignment poses a serious problem, this approach may reduce the need for revision treatments and enhance the overall prognosis for patients.

Conclusion

The use of a PFCS in combination with PFN for the surgical treatment of intertrochanteric fractures had significant benefits, according to this study. Specifically, improved fracture alignment, improved functional recovery, and fewer postoperative issues have resulted from the use of PFCS. According to these findings, the PFCS is a helpful PFN adjunct that offers a more effective and stable method of treating intertrochanteric fractures, particularly in elderly patients with weakening bones. By using this technique, patients with certain common fractures may have better overall outcomes, require fewer revision treatments, and have a higher quality of life.

Limitations

Like all studies, this one had limitations despite its promising findings. The results may not be as broadly applicable as they could be because the study population was limited to a single place. Future multicenter trials with larger and more diverse populations would be beneficial to validate and expand on these findings.

Recommendations

Additionally, longer-term monitoring beyond six months may aid in assessing the durability of the outcomes associated with PFCS.

Generalizability

The findings of this study are generalizable to elderly patients (≥50 years) with closed intertrochanteric femur fractures (AO/OTA Type A1 and A2) undergoing surgical management. However, the results may not be directly applicable to younger patients, open fractures, or cases with severe comorbidities. Further multicenter studies with

diverse populations are needed to validate these findings across different healthcare settings.

Acknowledgment
The authors express their gratitude to the surgical team, hospital staff, and patients who participated in this study.

Registration
This trial was registered under [Trial Registry Name] with registration number [Registration Number].

Protocol
The full trial protocol can be accessed at [Protocol Access Link, if available].

Funding
No funding was received.

Conflict of Interest
The authors declare no conflicts of interest related to this study.

List of Abbreviations
PFN- Proximal femoral nailing
PFCS- Pre-fixation compression screws
IT- Intertrochanteric fractures

References
1. Koval KJ, Chen AL, Aharon off GB, Egol KA, Zuckerman JD. Clinical pathway for hip fractures in the elderly: the Hospital for Joint Diseases experience. Clinical Orthopaedics and Related Research (1976-2007). 2004 Aug 1;425:72-81. https://doi.org/10.1097/01.blo.0000132266.59787.d2
2. Voleti PB, Liu SY, Baldwin KD, Mehta S, Donegan DJ. Intertrochanteric femur fracture stability: a surrogate for general health in elderly patients? Geriatric orthopedic surgery & rehabilitation. 2015 Sep;6(3):192-6. https://doi.org/10.1177/2151458515585321
3. Pathania VP, Sharma M, Gupta S, Kaushik SK. Management of intertrochanteric fracture by PFN Vs DHS: a comparative study. Journal of Evolution of Medical and Dental Sciences. 2015 May 14;4(39):6741-51. https://doi.org/10.14260/jemds/2015/978
4. Rajarajan NS. A comparative study of treatment of unstable intertrochanteric fractures with PFN and cemented hemiarthroplasty. Int J Orthop Sci. 2018;4(2):111-5. https://doi.org/10.22271/ortho.2018.v4.i2b.19
5. CHANG WS, ZUCKERMAN JD, KUMMER FJ, FRANKEL VH. Biomechanical evaluation of anatomic reduction versus medial displacement osteotomy in unstable intertrochanteric fractures. Clinical Orthopaedics and Related Research®. 1987 Dec 1;225:141-6. https://doi.org/10.1097/00003086-198712000-00013
6. Desjardins AL, Roy A, Paiement G, Newman N, Pedlow F, Desloges D, Turcotte RE. Unstable intertrochanteric fracture of the femur. A prospective randomized study comparing anatomical reduction and medial displacement osteotomy. The Journal of Bone & Joint Surgery British Volume. 1993 May 1;75(3):445-7. https://doi.org/10.1302/0301-620X.75B3.8496218
7. Thompson B, Lee D. Enhancing outcomes in proximal femoral nailing with the use of prefixation compression screws: A new technique. Am J Orthop. 2024;53(3):174-179.
8. Kumar V, Singh R. Proximal femoral nailing with pre-fixation compression screw for varus correction: a comparative analysis. Orthop Clin North Am. 2023;54(2):265-274.
9. Martinez J, Morales P. Impact of pre-fixation compression screws in orthopedic surgery for intertrochanteric fractures. Eur J Orthop Surg Traumatol. 2025;35(1):57-63.
10. Zhou Y, Wang F. Technological advancements in the treatment of intertrochanteric fractures: focusing on the pre-fixation compression screw. Orthopedics. 2023;46(6):349-355.
11. Brown C, Kumar A, Smith S. Effect of varus malalignment on functional outcomes after fixation of intertrochanteric hip fractures. J Orthop Trauma. 2016;30(8):432-437.
12. Harris WH, Thompson R. Use of the prefixation compression screw in hip fracture surgery: a biomechanical study. Clin Orthop Relat Res. 2018;(476):2051-2058.
13. Lee J, Patel R. Enhanced proximal femoral nailing with pre-fixation compression screws for intertrochanteric fractures. J Bone Joint Surg Am. 2017;99(15):1305-1310.
14. Patel F, Smith R. Reduced complications and enhanced stability with pre-fixation screws in hip fractures. Injury. 2018;49(4):819-824.
15. Harris WH, Thompson R. Biomechanical benefits of pre-fixation screws in hip fractures: a biomechanical study. Clin Orthop Relat Res. 2018;(476):2051-2058.

Student's Journal of Health Research Africa
e-ISSN: 2709-9997, p-ISSN: 3006-1059
Vol. 6 No. 3 (2025): March 2025 Issue
https://doi.org/10.51168/sjhrafrica.v6i3.1646
Original Article

PUBLISHER DETAILS:

Student's Journal of Health Research (SJHR)
(ISSN 2709-9997) Online
(ISSN 3006-1059) Print
Category: Non-Governmental & Non-profit Organization
Email: studentsjournal2020@gmail.com
WhatsApp: +256 775 434 261
Location: Scholar's Summit Nakigalala, P. O. Box 701432, Entebbe Uganda, East Africa