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**Original Article** 

# COMPARISON OF CEMENT AUGMENTATION VS NON-AUGMENTED FRACTURE FIXATION OF INTERTROCHANTERIC FEMUR FRACTURE IN ELDERLY PATIENTS

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## ABSTRACT

**Objective**: To compare the effectiveness of cement-augmented versus non-augmented fixation methods for treating intertrochanteric femur fractures.

**Methods:** This prospective study was done in a tertiary care hospital of North India on patients presenting with intertrochanteric fractures. After enrolment, the patients using the stringent selection criteria they underwent fracture reduction with and without cement augmentation. Functional assessment utilising the Harris Hip Score (HHS), Quality of life assessment and associated complications were evaluated. Follow-up was done at 6 w, 3 mo, 6 mo and until radiographic union was achieved.

**Results**: The mean duration of operation was significantly longer in Group I (59.68 min) compared to Group II (49.72 min; p<0.0001). Functional outcomes, assessed using HHS and Barthel index, showed non-significant differences between groups. However, intra-group analyses indicated significant improvements over time. Radiologically, Group II had a significantly greater mean sliding distance of the screw/blade (14.12 mm vs. 12.14 mm; p<0.00001) and higher mean varus deviation (7.16° vs. 3.15°; p<0.0001). Complications were minimal and similar in both groups, with no systemic or thromboembolic complications reported.

**Conclusion**: The study found significant differences in operative time between the two groups, but functional outcomes were comparable at all follow-up intervals. Radiological analyses revealed significant differences in screw/blade sliding and varus deviation, indicating that cement augmentation may affect biomechanical stability.

Keywords: Intertrochanteric fractures, Cement augmentation, Harris hip score, Barthel index, Sliding

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## INTRODUCTION

Intertrochanteric fracture is a subset of extra-capsular fractures of the proximal femur. It occurs in anatomical region between greater and lesser trochanters [1, 2]. These injuries are predominantly found among older adults, particularly those with osteoporosis, where low-energy mechanisms such as ground-level falls are the primary instigators. In contrast, younger individuals typically sustain these fractures due to high-energy traumas, highlighting the disparate mechanisms underlying their occurrence in different populations. Epidemiologically, studies have documented femaletomale ratio which ranges from 2:1 to 8:1, with affected patients generally older than those presenting with femoral neck fractures, thus underscoring the demographic significance of intertrochanteric falls [3, 4].

The clinical classification of intertrochanteric fractures into stable and unstable categories plays crucial role in both management strategy and prognosis. Stable fractures maintain the integrity of the posteromedial cortex, offering sufficient resistance to compressive forces post-reduction. Conversely, unstable fractures may involve complications such as comminution of the posteromedial cortex, fractures of lesser trochanter, subtrochanteric extensions, or reverse obliquity patterns, which necessitate more complex treatment approaches [5, 6].

Management of intertrochanteric femur fractures is generally stratified into nonoperative treatment and surgical intervention. Although non-operative management is infrequently indicated, it may be suitable for patients who are not able to walk or those at heightened risk of perioperative mortality. However, the associated outcomes tend to be poor, with increased complications such as pneumonia, urinary tract infections, pressure ulcers, and deep vein thrombosis [7, 8]. Surgical management, classified as urgent rather

than emergent, allows for optimisation of co morbidities, ultimately reducing morbidity and mortality rates [9].

The predominant surgical techniques include the use of sliding hip screws and intramedullary hip screws, with choice of implant significantly influenced by the fracture pattern and stability [10]. Intramedullary nailing has emerged as a preferred method for more unstable configurations and is favoured for its minimally invasive approach, which potentially reduces intraoperative blood loss. Nevertheless, concerns regarding implant failure, particularly in osteoporotic populations, necessitate the exploration of innovative augmentation techniques [11, 12]. Cement augmentation, utilising materials such as Polymethyl Methacrylate or calcium phosphate, has demonstrated promise in enhancing the mechanical stability of fixation devices, thus improving clinical outcomes [13, 14].

This study compares outcomes of cement-augmented versus non-augmented fixation techniques for intertrochanteric femur fractures in elderly patients. Through this comprehensive analysis, we seek to shed light on the complexities of managing intertrochanteric fractures and their implications for patient care and public health.

## MATERIALS AND METHODS

This study is designed as a prospective study conducted in a tertiary care hospital of North India. The trial focuses on patients presenting with unstable intertrochanteric fractures and compares the efficacy of fracture reduction with and without cement augmentation.

## Study setting

The study enrolled patients from the emergency and outpatient departments of Orthopaedics between June 2023 and May 2024. The sample size comprised all patients who met predefined selection criteria, and their participation was sanctioned by Institutional

Ethics Committee. Written informed consent was taken from all participants.

**Inclusion Criteria** includes patient's age ≥65 y and history of lowenergy trauma.

**Exclusion Criteria** includes Age<65 y, History of dementia, Patients with neuromuscular or musculoskeletal deficiencies limiting the ability to perform objective functional tests, Recent history of substance abuse, Active malignancy and concurrent fractures or surgical procedures that could influence postoperative outcomes.

#### Preoperative assessment

A comprehensive preoperative evaluation was conducted for all enrolled patients, including detailed history taking to ascertain the mechanism of injury and previous medical history, Comprehensive physical and systemic examinations, Clinical assessment specific to the fracture, Radiographic evaluation (X-rays) to confirm fracture site and classification, Necessary routine laboratory investigations (blood and urine tests) for anaesthetic clearance and assessment of

the general health of the patient, Computed tomography (CT) scans were conducted as warranted by clinical presentation. All findings were systematically recorded in a designated pro forma.

#### Randomisation and group allocation

Eligible patients were randomised into two groups of twenty-five each using a computer-generated sequence. Group I underwent fracture reduction with cement augmentation, while Group II received fracture reduction without cement augmentation. All surgical procedures were conducted under spinal anesthesia.

#### Surgical procedure

Following selection, patients were transported to operating room, where either epidural, spinal, or general anesthesia was administered. Upon successful induction of anesthesia, patients were positioned supine on an orthopaedic fracture table, with uninjured leg secured to a leg holder. Unlike positioning required for using DHS, it was essential to adduct ipsilateral hip to facilitate nail entry; this was achieved by tilting torso 10 to 15 degrees toward the contralateral side.





Fig. 1: Left IT femur #

Initially, closed reduction was attempted using internal rotation and longitudinal traction. In cases where closed reduction was not feasible, a mini-open approach was employed. This involved making a small longitudinal incision approximately 5 cm proximal to greater trochanter. Gluteal fascia was incised, and gluteus medius was split longitudinally to access tip of trochanter. The correct entry point for nail was determined using fluoroscopy, and a guide wire was advanced from trochanter to medulla (fig. 2).



Fig. 2: Entry site



Fig. 3: Lag screw guide wire placed close to calcar

Subsequently, a cannulated drill was used to establish an entry point for nail. After drilling the proximal femur, a nail sized at 130° and 240 mm was inserted. Under fluoroscopic guidance, lag screw guides were positioned as near to the calcar as possible on the anteroposterior radiograph and centrally on lateral radiographs (fig. 3).

Once the appropriate location was identified, measurements were recorded. A novel cement inserter device was developed based on diameter of PFNA instrumentation (fig. 4)



Fig. 4: Cement inserter device



Fig. 5: Bone cement

After obtaining necessary measurements, poly methyl methacrylate (PMMA) (fig. 5) bone cement was prepared, and using newly designed device, the cement was inserted (in doughy state) into the femoral head through predrilled screw site under fluoroscopic supervision (fig. 6).



Fig. 6: Cement inserted



Fig. 7: Screw inserted



Fig. 8: Post op x-rays



Fig. 9: Post op X-rays



Fig. 10: Post op X-rays (2nd)

Upon completion of cement insertion, the appropriately sized screw was inserted without any time delay following insertion of cement, followed by derotation screw (fig. 6,7). In none of the case we notices loss of reduction and fixation during whole of the process. The nail was statically locked distally with one screw. Postoperative management included standard prophylaxis for deep vein thrombosis, and patients were mobilised with weight-bearing as tolerated and no cement related complications were noted.

## Follow-Up and outcome measures

Patients were scheduled for follow-up assessments at 6 w, 3 mo, 6 mo, and until radiographic union was achieved. During these follow-ups, evaluations focused on: Healing of the postoperative incision and any adverse symptoms, Radiographic assessment (X-rays) to evaluate bone healing, specifically at the 3-month mark.

#### Outcome measures

Primary Outcome Measures include Functional assessment utilising HHS, Quality of life assessment, Rate of complications categorised into implant-related, systemic, and thromboembolic complications.

Secondary Outcome Measures include Re-interventions required at the fracture site during the follow-up period, Radiological outcomes, specifically measuring screw/blade migration in millimetres (mm) on AP X-rays and varus angulation in degrees as observed in the same radiographs.

#### Statistical analysis plan

The collected data were compiled and analysed using the Statistical Program for Social Sciences (SPSS) software version 20.0 (Chicago, Illinois, USA). Statistical analyses were conducted on an intention-to-treat basis.

#### RESULTS

## Demographic and clinical characteristics

The study evaluated a total of fifty patients diagnosed with unstable intertrochanteric fractures, distributed into two groups: Group I (n=25) received fracture reduction with cement augmentation, while Group II (n=25) underwent standard fracture reduction without cement augmentation.

The mean age of participants in Group I was  $71.80\pm6.88$  y (range, 65-89 y), compared to  $71.36\pm7.39$  y (range, 65-89 y) in Group II. Statistical analysis revealed no significant difference in age between the two groups (p = 0.8284). Gender distribution showed that Group I consisted of 14 females (56%) and 11 males (44%), whereas Group

II included 7 females (28%) and 18 males (72%). The difference in gender distribution was statistically significant (p = 0.0448).

Co morbidities were present in 23 patients (92%) in Group I and 22 patients (88%) in Group II, with no statistically significant difference observed (p = 0.6373).

#### Operative time

The mean operative time was significantly longer in Group I at  $59.68\pm7.25$  min (range, 42-78 min) compared to  $49.72\pm6.15$  min (range, 40-62 min) in Group II. This difference was statistically significant (p<0.0001).

#### **Functional outcomes**

At 6 w postoperatively, the mean Harris Hip Score (HHS) for Group I was  $50.80\pm20.38$  (range, 18-88) and for Group II was  $50.68\pm19.95$  (range, 18-84), indicating no significant difference between the two groups (p = 0.9833). At the 3-month follow-up, the mean HHS in Group I was  $56.72\pm18.87$  (range, 25-85) and in Group II was  $53.24\pm19.37$  (range, 24-87), again showing no significant difference (p = 0.5230). At 6 mo, patients in Group I had a mean HHS of  $57.24\pm18.21$  (range, 27-87), while Group II had a mean HHS of  $55.12\pm16.90$  (range, 30-84) (p = 0.6716). Upon complete union, the mean HHS was  $60.48\pm17.26$  (range, 31-88) for Group I and  $56.00\pm17.51$  (range, 32-85) for Group II; the difference remained statistically non-significant (p = 0.3669).

Intra-group comparisons of the HHS indicated that the differences were statistically nonsignificant in both groups (p>0.05).

## Quality of life assessment

The Barthel index scores at 6 w postoperatively revealed a mean of 62.68±9.72 (range, 26-75) for Group I and 61.08±9.45 (range, 30-73) for Group II (p = 0.5579; non-significant). At 3 mo, the scores were 75.64±11.03 (range, 33-87) for Group I and 72.92±10.88 (range, 36-82) for Group II (p = 0.3843). At the 6-month mark, patients in Group I exhibited a mean Barthel index of 81.12±9.89 (range, 39-89) compared to 81.68±11.61 (range, 39-90) for Group II (p = 0.8551). Upon complete union, the mean Barthel index scores were 81.56±8.61 (range, 43-89) in Group I and 83.76±11.29 (range, 42-91) in Group II (p = 0.4424), indicating no significant difference.

However, intra-group analyses of the Barthel index indicated highly significant differences over time for both groups (p<0.00001).

## Complications

Complications related to fractures or implants were noted in one patient (4%) in each group. Importantly, there were no reported cases of systemic or thromboembolic complications in either group throughout the study period.

Table 1: Baseline characteristics of patients

Patients	Group I	Group II	Significance level
Age	71.80±6.88 y	71.36±7.39 y	0.8284 (NS)
Gender	Male (44%) Female (56%)	Male (72%) Female (28%)	0.0448 (NS)
Operative time (Minutes)	59.68±7.25	49.72±6.15	<0.0001 (HS)
Co morbidities	92%	88%	0.6373 (NS)

Table 2: Comparison of outcomes

	Timelines	Group I	Group II	Significance level (Inter-group)
Harris Hip score	6 w	50.80±20.38	50.68±19.95	0.9833 (NS)
	3 mo	56.72±18.87	53.24±19.37	0.5230 (NS)
	6 mo	57.24±18.21	55.12±16.90	0.6716 (NS)
	At complete union	60.48±17.26	56.0±17.51	0.3669 (NS)
	p-Value (Intra-group)	0.3290 (NS)	0.7492 (NS)	
	6 w	62.68±9.72	61.08±9.45	0.5579 (NS)
Barthel index	3 mo	75.64±11.03	72.92±10.88	0.3843 (NS)
	6 mo	81.12±9.89	81.68±11.61	0.8551 (NS)
	At complete union	81.56±8.61	83.76±11.29	0.4424 (NS)
	p-Value (Intra-group)	<0.00001 (HS)	<0.00001 (HS)	
Sliding distance (mm)		12.14±1.27	14.12±1.28	<0.0001 (HS)
Varus deviation		4.46°±1.21	7.16°±1.44°	<0.0001 (HS)

<sup>\*</sup>ANOVA test applied

#### Radiological outcomes

The mean sliding distance of the screw/blade was significantly greater in Group II at  $14.12\pm1.28$  mm (range, 12.22-16.78 mm) compared to  $12.14\pm1.27$  mm (range, 10.32-14.54 mm) in Group I, yielding a highly significant difference (p<0.00001).

Moreover, the mean varus deviation was significantly higher in Group II at  $8.03^{\circ}\pm0.60^{\circ}$  (range,  $7.02\text{-}9.34^{\circ}$ ) compared to  $4.10^{\circ}\pm0.59^{\circ}$  (range,  $3.80\text{-}5.20^{\circ}$ ) in Group I, with this difference also being statistically highly significant (p<0.0001).

#### DISCUSSION

In our study, the outcomes of cement augmentation versus non-augmentation in unstable intertrochanteric fractures in elderly patients was evaluated. The demographic profile of the participants revealed a similar age distribution between the two groups(p = 0.8284; non-significant). However, the gender distribution indicated a notable preponderance of males in Group II and a predominance of females in Group I (p = 0.0448; significant). This finding mirrors reports from Ahmed RM (2024) [15] and Fidan F  $et\ al.\ (2022)\ [16]$ , which highlight the typical demographic characteristics (The age ranged from 44 to 90 y, with a mean age of 73) associated with hip fracture cases.

Co-morbidities were prevalent in both groups, affecting 92% of patients in Group I and 88% in Group II (p = 0.6373; non-significant). These rates are in line with findings from Kulachote N et al. (2020) [17], suggesting that patients with complex medical histories are frequently encountered in this demographic.

Our study found a significant difference in operative time, with Group I demonstrating a longer mean duration (59.68±7.25 min) compared to Group II (49.72±6.15 min), indicating a considerable impact of cement augmentation on surgical time (p<0.0001). These findings contrast with previous studies, such as those by Mochizuki Y *et al.* (2022) [18], which also noted no significant difference in operative times between augmented and non-augmented groups.

Functional assessments, including HHS and Barthel Index, revealed no significant differences at different follow-ups postoperatively, despite both groups showing improvement over time. The intragroup comparisons for both HHS and Barthel Index demonstrated statistically significant improvements (p<0.00001), supporting the efficacy of surgical intervention for enhancing mobility and independence, regardless of the augmentation approach. These results are similar to findings from Keppler AM *et al.* (2021) [19] and Kammerlander C *et al.* (2018) [20], who also documented comparable outcomes between surgical techniques.

Radiological outcomes further emphasised the advantages of cement augmentation. The significant differences in mean sliding distance of the screw/blade (12.14 mm in Group I vs. 14.12 mm in Group II; p<0.00001) and varus deviation (4.46° in Group I vs. 7.16° in Group II; p<0.0001) underscore the enhanced stability afforded by augmentation. These findings are consistent with reports of reduced sliding distances and varus collapsein augmented groups, such as those documented by Kim SJ et al. (2018) [21] and Mattsson P et al. (2004) [22], indicating potential implications for improved structural integrity and reduced risk for re-fracture or complications.

Regarding postoperative complications, the incidence of fracture or implant-related complications was low and equivalent between the two groups (4% each). This compares favourably with the higher complication rates reported by Ahmed RM (2024) [15] and Kim SJ *et al.* (2018) [21], suggesting that cement augmentation may lead to fewer complications in certain contexts when compared to other studies. Aligning with this study, Stramazzo l *et al.* (2021) observed no significant complications [13].

This study's limitations include its relatively short follow-up duration, small sample size, and the region-specific nature of data collected, which may limit generalisability. Additionally, selection bias was a concern, as only mobilised patients prior to fracture were included, potentially excluding those with higher degrees of osteoporosis who might benefit from PFNA augmentation.

#### CONCLUSION

The findings from this study demonstrate that while operative time differed significantly between the two groups, functional outcomes as measured by HHS and Barthel index scores were statistically comparable at all follow-up intervals. Radiological analyses indicated significant differences in screw/blade sliding and varus deviation, suggesting a potential impact of cement augmentation on biomechanical stability. Future multi-centric studies with larger sample sizes will enhance the robustness of the findings and allow for broader application of the results to diverse patient populations.

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None

## PATIENT CONSENT

Written informed consent has been obtained from the patient or guardian for participation and publication.

#### ETHICAL APPROVAL AND CONSENT

Approval was taken from the relevant ethics committee and written informed consent was taken from each patient to publish his details while maintaining confidentiality.

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Nil

#### **AUTHORS CONTRIBUTIONS**

All authors have contributed equally

#### **CONFLICTS OF INTERESTS**

Declared none

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