The Philippine Journal of Orthopaedics

ORIGINAL ARTICLE

Evaluating Fracture Hematoma Reintroduction vs. Non-Reintroduction in Femoral Shaft Fractures: A Single-Blinded Randomized Controlled Trial

Nike Kier P. Perez, MD and Jerome David J. Sison, MD, FPOA

Department of Orthopedics, Region 1 Medical Center, Dagupan City, Pangasinan, Philippines

ABSTRACT

Background. Fracture hematoma plays a critical role in bone healing by supplying essential growth factors. However, the original hematoma is often discarded during surgery. The potential benefits of reintroducing fracture hematoma remain unclear.

Objective. This study aimed to evaluate the efficacy of fracture hematoma reintroduction in promoting bone union, reducing pain, and improving functional outcomes in patients with closed femoral shaft fractures treated with open reduction and intramedullary nailing.

Methodology. A single-blinded randomized controlled trial was conducted, enrolling 18 adult patients with closed femoral shaft fractures. Patients were randomized into two groups: hematoma reintroduction (n = 9) and non-reintroduction (n = 9). The primary outcome was time to bone union, measured using the Radiographic Union Scale in Tibial fractures (RUST). Secondary outcomes included pain (assessed using the Visual Analog Scale) and functional outcomes (evaluated with the Lower Extremity Functional Scale) at six, 12, and 24 weeks postoperatively. Statistical analysis included ANOVA and multivariable regression.

Result. At six weeks, the hematoma reintroduction group showed a significantly higher mean RUST score compared to the non-reintroduction group (p = 0.022). However, by 12 weeks (p = 0.108) and 24 weeks (p = 0.241), the difference between the groups was no longer statistically significant. Both groups demonstrated similar improvements in pain and functional outcomes over time. No complications were reported in either group.

Conclusion. While hematoma reintroduction may enhance early bone healing, the long-term outcomes in terms of bone union, pain, and function are comparable between the two treatment approaches. Hematoma reintroduction is a well-tolerated intervention, with no observed complications.

Keywords. fracture hematoma, femoral shaft fractures, intramedullary nailing, bone healing, randomized controlled trial

INTRODUCTION

Femoral shaft fractures are among the most common long bone injuries, often resulting from high-energy trauma such as motor vehicle accidents or falls from height. These fractures typically require surgical stabilization, with intramedullary nailing being the current gold standard due to its biomechanical stability and favorable outcomes in fracture healing and functional recovery.[1]

In ideal settings, minimally invasive osteosynthesis (MIO) is preferred for long bone fractures, as it preserves the soft tissue envelope and the local biologic environment. However, in many rural or resource-limited hospitals where intra-operative fluoroscopy (C-Arm) is unavailable, MIO becomes impractical. In such cases, surgeons often resort to open

ISSN 0118-3362 (Print)
eISSN 2012-3264 (Online)
Printed in the Philippines.

Received: September 19, 2025
Accepted: October 20, 2025
Published Online: November 3, 2025.
https://doi.org/10.69472/poai.2025.31

Corresponding author:
Nike Kier Passi Perez, MD
Medical Officer III, Region 1 Medical Center,
Department of Orthopedics, Barangay Pantal,
Arellano St., Dagupan City, Pangasinan, Philippines
E-mail: nikeperez14@gmail.com
ORCiD: https://orcid.org/0009-0002-1359-5472

reduction techniques, which inherently disrupt the fracture hematoma—a key component of the early healing cascade.

Fracture hematoma is rich in mesenchymal stem cells, inflammatory cytokines, and angiogenic growth factors such as VEGF and BMPs, all of which play critical roles in initiating neovascularization and endochondral ossification.[2-4] The hematoma microenvironment supports cellular recruitment, vascular invasion, and soft-callus formation, thereby accelerating bone repair.[3,5] Despite this biologic plausibility, a hematoma is often removed during open surgery because of traditional surgical practice, infection concerns, or the absence of clinical evidence supporting its reintegration.

Although animal and preclinical studies have demonstrated the benefits of preserving or reintroducing fracture hematoma, few clinical trials have evaluated these effects in humans.[2,4,6] This highlights a gap in translational research, particularly in low-resource settings where biologic preservation strategies could help compensate for limited imaging and specialized surgical tools.

This study aims to address that gap by evaluating the effect of fracture hematoma reintroduction during open reduction and intramedullary nailing of femoral shaft fractures. We hypothesized that reinfusing the native hematoma after fixation would promote early bone healing, replicating the biologic advantages of minimally invasive approaches without requiring specialized equipment.

To objectively assess radiographic healing, we used the Radiographic Union Score for Tibia (RUST). Although originally developed for tibial fractures, RUST has been validated as a reliable and reproducible tool for assessing union in long bones, including the femur.[7] This scoring system provides a consistent framework for evaluating healing across defined postoperative time points.

By comparing outcomes between hematoma reintroduction and standard non-reintroduction protocols, this single-blinded randomized controlled trial explores the feasibility, safety, and potential clinical value of this biologic adjunct—particularly in rural and underserved health-care environments.

METHODOLOGY

Patient enrollment, inclusion/exclusion criteria, randomization and blinding

This single-blinded randomized controlled trial was conducted at Region 1 Medical Center from January 2021 to December 2023. Adult patients presenting with closed femoral shaft fractures were screened for eligibility (Figure 1).

Inclusion criteria were adults aged 18–60 years with closed, isolated, unilateral femoral shaft fractures (AO type 32A or 32B), fit for surgery, and who presented within 21 days of injury.

Exclusion criteria included: open fractures, pathologic fractures, polytrauma, prior surgery on the same limb, significant comorbidities (e.g., uncontrolled diabetes mellitus, end-stage renal disease), and refusal to provide informed consent.

After confirming eligibility and obtaining consent, patients were randomized into two groups (hematoma reintroduction or non-reintroduction) using a block randomization method. A computer-generated sequence from the Research Randomizer tool (www.randomizer.org) was used. Allocation was concealed in sealed opaque envelopes, which were opened just before surgery. Surgeons were informed of the group assignment immediately before the procedure. The study was not registered at ClinicalTrials.gov.

To minimize potential biases, blinding was maintained throughout the evaluation. The operating surgeon was not

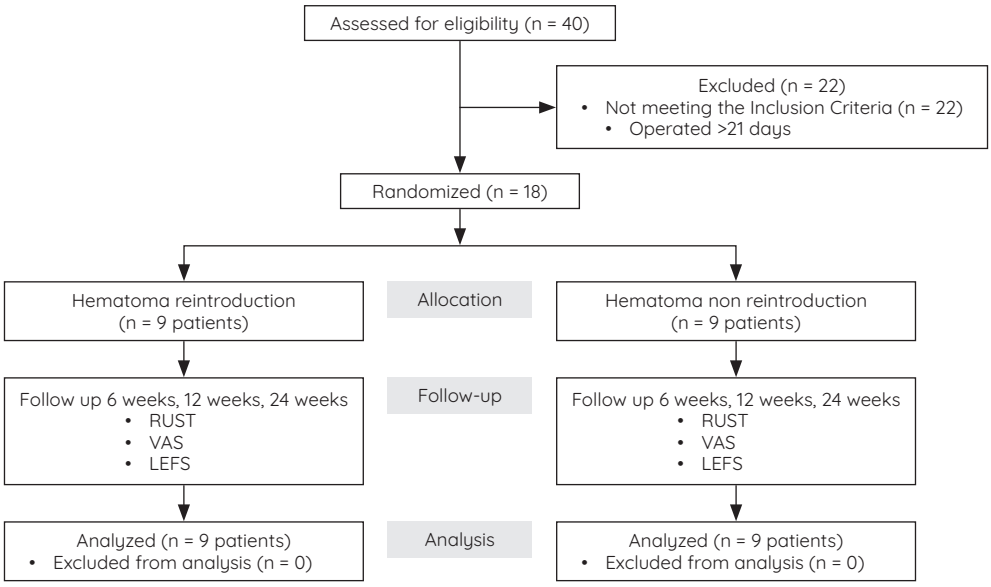

Figure 1. Flowchart of patient inclusion, randomization and follow up.

involved in postoperative outcome assessment. A separate research assistant—uninvolved in the clinical care or surgical procedure—collected follow-up data. Radiographic scoring was performed by an independent observer blinded to treatment allocation.

Surgical technique and hematoma reintroduction

All patients underwent open reduction and antegrade intramedullary nailing via a lateral approach. A standard stainless-steel femoral nail system was used in all cases, with distal and proximal locking screws. Although implant length and diameter were adjusted based on intraoperative measurements, the implant type and manufacturer were consistent across all patients.

In the hematoma reintroduction group, a target volume of 10 mL of fracture hematoma was aspirated using a sterile 14-gauge needle and 20-mL syringe immediately after fracture exposure and before irrigation. The aspirate was collected into a sterile container and reintroduced into the fracture site after definitive fixation and before wound closure. If less than 10 mL of liquid hematoma was available, visible clotted hematoma was carefully collected using sterile forceps, placed into the same 20-mL syringe, and reinjected to reach the 10 mL target volume. In the control (non-reintroduction) group, the hematoma was completely evacuated and discarded during standard irrigation, with no reinfusion (Figure 2).

Hematoma reintroduction

For patients assigned to the hematoma reintroduction group, the hematoma collected from the fracture site was kept in a sterile environment. Once the fracture was stabilized and the implants were positioned, the preserved hematoma was reintroduced into the fracture site.

Postoperative care and follow-up

All patients received the same standardized postoperative care, including antibiotics, thromboprophylaxis, and pain management. Radiographs (anteroposterior and lateral views) were taken at six, 12, and 24 weeks postoperatively. Clinical follow-up was done concurrently.

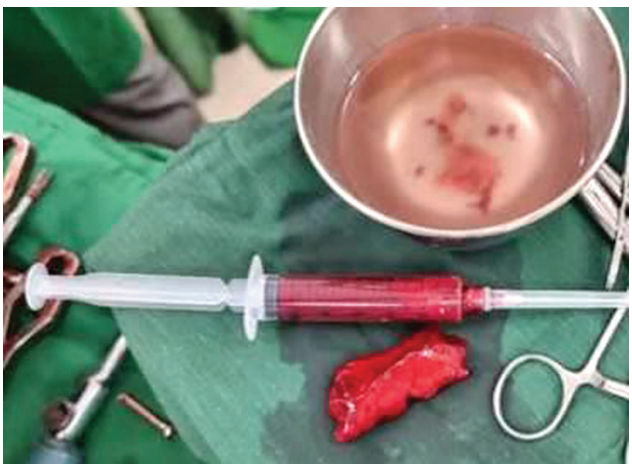

Figure 2. Sample of aspirated hematoma (10 ml) prior to reintroduction into the fracture site.

Outcome measures

The primary outcome was radiographic evidence of fracture healing, assessed using the Radiographic Union Scale in Tibial fractures (RUST). This score evaluates bridging callus on four cortices, with higher scores indicating greater union. A score of ≥9 was considered indicative of union.

Secondary outcomes included pain (measured by the Visual Analog Scale, VAS) and function (measured by the Lower Extremity Functional Scale, LEFS), both assessed at six, 12, and 24 weeks.

Sample size and statistical analysis

The study initially screened 40 patients, of whom only 18 met all inclusion criteria. This sample size was not determined by power analysis due to the exploratory nature of the trial and logistical limitations. The goal was to generate preliminary clinical data to guide future studies on fracture hematoma reintroduction.

Data were analyzed using SPSS version 25 (IBM Corp., Armonk, NY, USA). Descriptive statistics summarized baseline characteristics. One-way ANOVA was used to compare RUST, VAS, and LEFS scores between groups at each time point. Multiple linear regression was used to control for covariates such as age, fracture type, and sex. Statistical significance was set at $p < 0.05$.

Ethical considerations

The study protocol was reviewed and approved by the Institutional Review Board of Region 1 Medical Center (IRB Protocol No. 2019-012). Written informed consent was obtained from all participants before enrollment. Patient data were anonymized and stored in encrypted, password-protected files accessible only to authorized members of the research team. The study was conducted in accordance with the Declaration of Helsinki (2013 revision). The authors declare no conflicts of interest.

RESULT

A total of 18 patients were included in the study, with 9 in the hematoma reintroduction group and 9 in the non-reintroduction group. The mean age was 30.0 ± 12.18 years in the hematoma reintroduction group and 27.78 ± 6.57 years in the non-reintroduction group. Most participants were male (14 out of 18), with all four female patients belonging to the non-reintroduction group. None of the patients were smokers (Table 1).

Fracture classification and baseline characteristics

An imbalance was noted in AO fracture types between the two groups: the hematoma reintroduction group had more AO 32A fractures (8 out of 9), while the non-reintroduction group had more AO 32B fractures (5 out of 9). AO 32A fractures are generally considered to have a more favorable prognosis than 32B wedge-type fractures, which may influence healing rates despite randomization (Table 1).

Primary outcome: fracture healing (RUST Scores)

All patients completed the 24-week follow-up and achieved radiographic union, defined as RUST ≥9. No cases of delayed union or nonunion were observed (Table 2).

At six weeks, the hematoma reintroduction group demonstrated a significantly higher mean RUST score compared to the non-reintroduction group (6.44 ± 1.24 vs. 4.89 ± 1.36; $p = 0.022$), indicating an early radiographic healing benefit (Figures 3 and 4). However, by 12 and 24 weeks, the difference between groups diminished and was no longer statistically significant, suggesting that the initial advantage did not translate into superior long-term healing outcomes (Tables 2 and 3).

Secondary outcomes: pain and functional recovery

Pain scores, assessed using the VAS, improved steadily in both groups across all time points. The hematoma reintroduction group showed slightly lower scores, though differences were not statistically significant (Table 4).

Functional outcomes, as measured by the LEFS, improved progressively over time in both groups. Scores were slightly higher in the reintroduction group at all time points (Table 4).

Complications

No complications or adverse events were reported in either group. There were no instances of implant failure throughout the study period.

Table 1. Baseline Characteristics of Participants

Baseline Characteristics	Hematoma Reintroduction (n = 9)	Hematoma Non-reintroduction (n = 9)	Total (n = 18)
Age (mean ± SD)	30.0 ± 12.18	27.78 ± 6.57	28.89 ± 9.68
Gender, n (%)			
Male	9 (64.3%)	5 (35.7%)	14
Female	0 (0%)	4 (100%)	4
Smoking status, n (%)			
Smoker	0	0	0
Non-smoker	9 (100%)	9 (100%)	18
Fracture type, n (%)			
Type 1 (AO 32A)	8 (66.7%)	4 (33.3%)	12
Type 2 (AO 32B)	1 (16.7%)	5 (83.3%)	6

Table 2. Primary Outcome—Radiographic Evidence of Bone Union Over Time

Time (Weeks)	Hematoma Reintroduction (Mean ± SD)	Hematoma Non-reintroduction (Mean ± SD)	*p*-value
6	6.44 ± 1.24	4.89 ± 1.36	0.022
12	8.86 ± 0.90	7.63 ± 1.69	0.108
24	10.60 ± 1.52	9.38 ± 1.85	0.241

Table 3. ANOVA Results for RUST Scores

Time (Weeks)	Sum of Squares	df	Mean Square	F	*p*-value
6 weeks					
Between Groups	10.889	1	10.889	6.426	0.022
Within Groups	27.111	16	1.694		
Total	38.000	17			
12 weeks					
Between Groups	5.668	1	5.668	2.979	0.108
Within Groups	24.732	13	1.902		
Total	30.400	14			
24 weeks					
Between Groups	4.617	1	4.617	1.536	0.241
Within Groups	33.075	11	3.007		
Total	37.692	12			

Table 4. Secondary Outcomes—Pain and Functional Outcomes over Time

Time (Weeks)	Pain level (VAS score)	Functional Outcomes (LEFS score)
6	5.67 ± 1.00	37.11 ± 6.88
	6.00 ± 0.50	36.22 ± 2.33
12	3.29 ± 0.49	55.57 ± 3.78
	3.88 ± 0.64	53.75 ± 2.92
24	1.40 ± 0.55	74.20 ± 3.90
	1.88 ± 0.64	72.75 ± 2.65

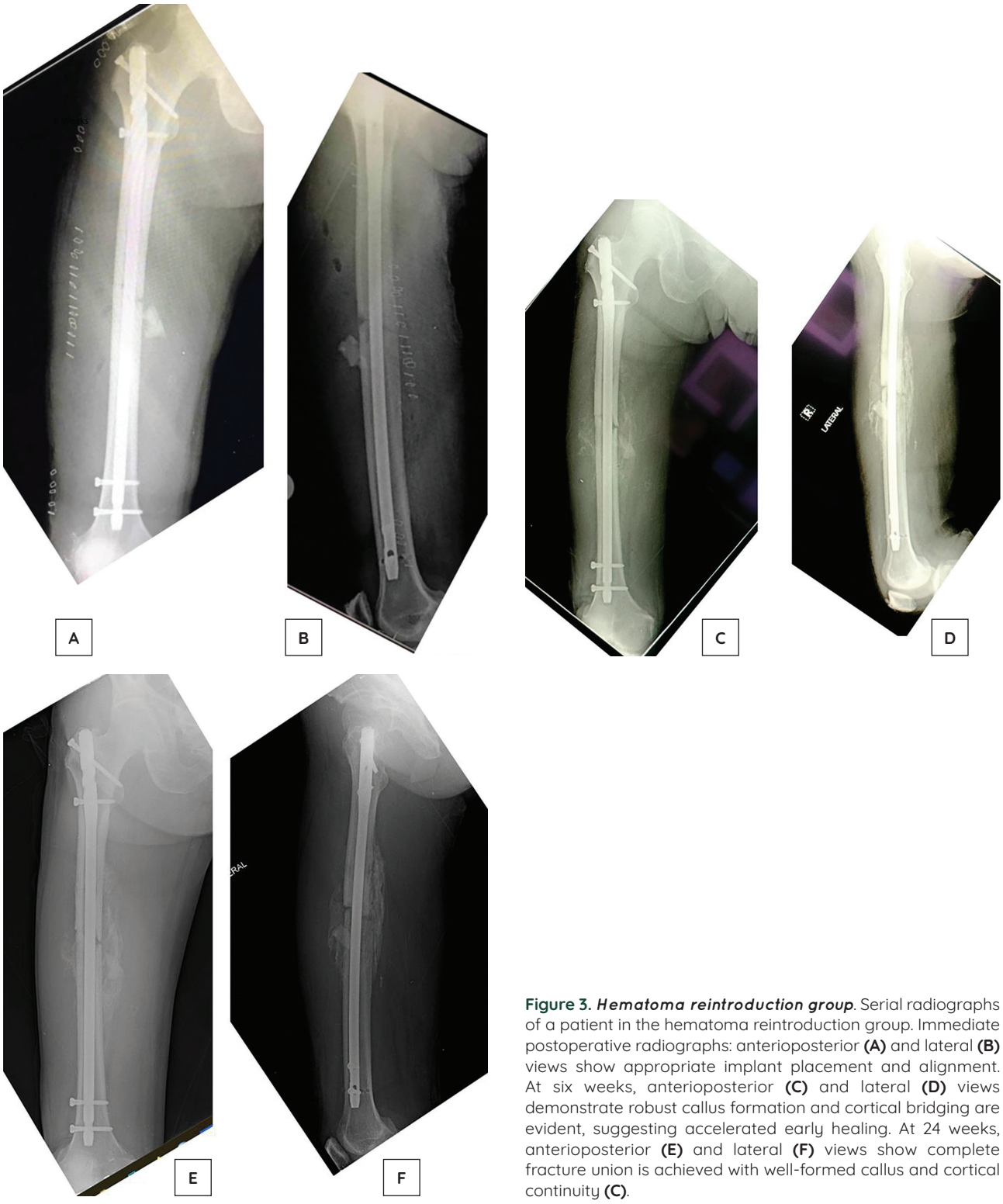

Figure 3. ***Hematoma reintroduction group***. Serial radiographs of a patient in the hematoma reintroduction group. Immediate postoperative radiographs: anterioposterior **(A)** and lateral **(B)** views show appropriate implant placement and alignment. At six weeks, anterioposterior **(C)** and lateral **(D)** views demonstrate robust callus formation and cortical bridging are evident, suggesting accelerated early healing. At 24 weeks, anterioposterior **(E)** and lateral **(F)** views show complete fracture union is achieved with well-formed callus and cortical continuity **(C)**.

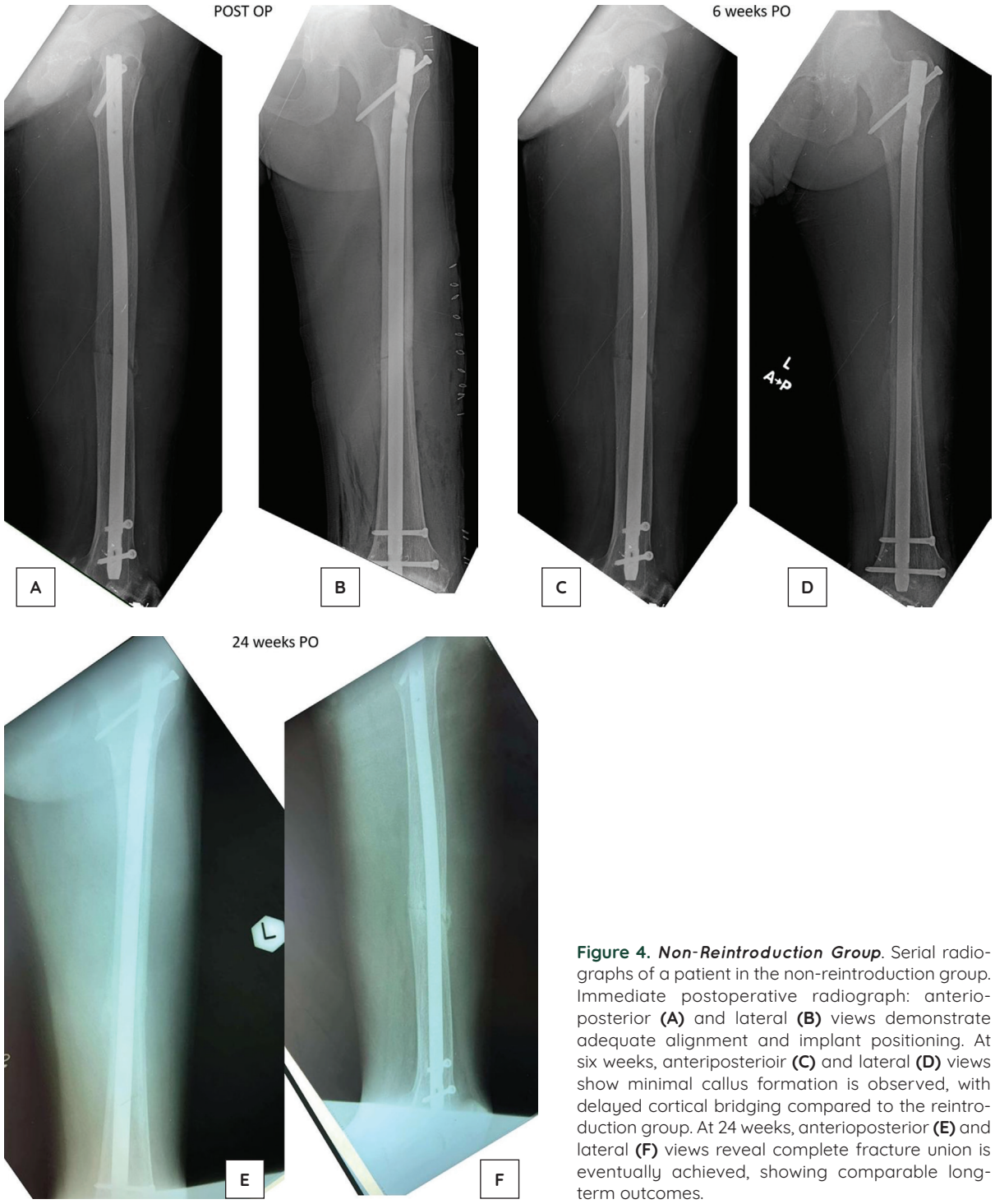

Figure 4. ***Non-Reintroduction Group***. Serial radiographs of a patient in the non-reintroduction group. Immediate postoperative radiograph: anterioposterior **(A)** and lateral **(B)** views demonstrate adequate alignment and implant positioning. At six weeks, anteriposterioir **(C)** and lateral **(D)** views show minimal callus formation is observed, with delayed cortical bridging compared to the reintroduction group. At 24 weeks, anterioposterior **(E)** and lateral **(F)** views reveal complete fracture union is eventually achieved, showing comparable long-term outcomes.

DISCUSSION

This study evaluated the effects of fracture hematoma reintroduction on the healing of closed femoral shaft fractures treated with open reduction and intramedullary nailing. The primary outcome, as measured by RUST scores, showed a statistically significant advantage in the hematoma reintroduction group at six weeks. This supports the hypothesis that fracture hematoma, when reinfused into the fracture site, contributes to early bone healing. However, the difference diminished over time and became statistically insignificant at 12 and 24 weeks, suggesting that while early callus formation may be enhanced, long-term union is ultimately comparable between treatment groups.

Secondary outcomes, including pain (VAS) and functional recovery (LEFS), followed similar trajectories. Both groups showed progressive improvement in pain and mobility, with no significant difference at any time point. These findings suggest that while hematoma reintroduction may accelerate early radiographic healing, it does not appear to provide sustained advantages in long-term patient-reported outcomes.

The Radiographic Union Score for Tibia (RUST), although originally developed for tibial fractures, has been validated in long bone healing, including femoral shaft fractures. Litrenta et al demonstrated high interobserver reliability of RUST and modified RUST when applied to metadiaphyseal femoral fractures, supporting its use in this study.[3]

The biological rationale for hematoma preservation lies in its composition of mesenchymal stem cells, cytokines, and osteoinductive growth factors such as VEGF and BMPs.[2,4,6] These elements are central to initiating angiogenesis, inflammation, and osteogenesis—the first steps of fracture healing. Marsell and Einhorn described the hematoma as a "biologic burst" that stimulates vascular invasion, soft callus formation, and cortical bridging.[2] Preserving or reintroducing this biologic material has been shown to enhance bone regeneration in preclinical models,[4,8] and our findings suggest this benefit may translate clinically during the early healing phase.

This study also carries relevance for surgical decision-making in resource-limited environments. In many rural hospitals where intraoperative fluoroscopy is unavailable, minimally invasive osteosynthesis (MIO) is impractical, compelling surgeons to perform open reduction. This approach disrupts the biological environment of the fracture site. Hematoma reintroduction offers a low-cost, biologically sound adjunct to mitigate this disruption without extending operative time or requiring specialized equipment.[1,9,10] Furthermore, in health systems where financial hardship often delays orthopedic care,[9] cost-effective interventions that improve early healing can help reduce the burden on both patients and hospitals.

No complications or adverse events were recorded in either group, demonstrating that hematoma reintroduction is a safe adjunct to internal fixation. This finding helps address concerns about possible contamination or immunologic reaction associated with reinfusion of biologic material.[5,7]

Despite these promising results, this study has several limitations. The small sample size limits the power to detect subtle differences and increases the risk of type II error. As a pilot trial, the aim was to generate preliminary data for future large-scale studies. Additionally, an imbalance in fracture patterns between groups (more AO 32A fractures in the hematoma group and more 32B in the control group) may have influenced early results despite randomization. Multivariable regression was used to control for this, but residual confounding remains possible.

In summary, fracture hematoma reintroduction appears to be a safe, biologically rational, and cost-effective technique that promotes earlier radiographic healing. While long-term outcomes were similar, the early healing benefit may have practical implications in patients requiring early mobilization and in low-resource environments where delayed union has significant functional and economic consequences. Larger, stratified studies are warranted to confirm these findings.

CONCLUSION

This randomized controlled trial is among the first to clinically evaluate the effect of fracture hematoma reintroduction on femoral shaft fracture healing in humans. Our findings indicate that reinfusing the native fracture hematoma during open reduction and intramedullary nailing may promote faster radiographic healing in the early postoperative period. However, this early benefit was not sustained at later time points, with comparable outcomes in bone union, pain reduction, and functional recovery observed between the hematoma and non-reintroduction groups by 12 and 24 weeks.

In rural or resource-limited hospitals where fluoroscopy is unavailable and MIO is impractical, open reduction remains necessary. Hematoma reintroduction may help restore the biologic potential lost during surgical exposure, offering a biologically sound, low-cost adjunct without requiring additional instruments or time.[1,9,10]

This technique was found to be safe, with no adverse events or implant failures. It may offer added value in enhancing early healing, reducing the risk of delayed union, and decreasing long-term patient costs—particularly relevant in low-resource settings where economic hardship limits access to prolonged postoperative care.[9] Further large-scale studies are warranted to validate these findings and identify patient groups that may benefit most from this biologically augmented approach to fracture management.

ACKNOWLEDGMENTS

The authors to express my sincere gratitude to Dr. Emelito V. Ritumalta, MD, for his continuous support and guidance as the departmental head throughout this study. His general support was instrumental in the successful completion of this research.

Special thanks to Dr. Jerome Sison for his valuable assistance during the course of the study and for his technical and professional insights that greatly contributed to the research.

I would also like to acknowledge my own efforts in providing both technical help and writing assistance, which were essential in executing and presenting this work.

Finally, I extend my heartfelt appreciation to the patients who participated in this study and to the dedicated staff at Region 1 Medical Center, whose cooperation made this research possible.

STATEMENT OF AUTHORSHIP

All authors certified fulfillment of ICMJE authorship criteria.

CREDIT AUTHOR STATEMENT

NKPP: Conceptualization, Methodology, Software, Validation, Formal analysis, Investigation, Resources, Data Curation, Writing – original draft preparation, Writing – review and editing, Visualization, Project administration, Funding acquisition; **JDJS:** Conceptualization, Methodology, Validation, Formal analysis, Writing – review and editing, Supervision, Project administration.

DATA AVAILABILITY STATEMENT

Datasets generated and analyzed are included in the published article.

AUTHOR DISCLOSURE

The authors declared no conflict of interest.

FUNDING SOURCE

None.

REFERENCES

1. Rockwood CA Jr, Green DP, Bucholz RW, Heckman JD, Court-Brown CM, Tornetta P III. Rockwood and Green's Fractures in Adults, 8th ed. Philadelphia, PA: Wolters Kluwer Health; 2015.
2. Marsell R, Einhorn TA. The biology of fracture healing. Injury. 2011;42(6):551-5. PMID: 21489527 PMCID: PMC3105171 DOI: 10.1016/j.injury.2011.03.031
3. Litrenta J, Tornetta P 3rd, Mehta S, et al. Determination of radiographic healing: an assessment of consistency using RUST and Modified RUST in metadiaphyseal fractures. J Orthop Trauma. 2015;29(11):516-20. PMID: 26165265 DOI: 10.1097/BOT.0000000000000390
4. Dimitriou R, Tsiridis E, Giannoudis PV. Current concepts of molecular aspects of bone healing. Injury. 2005;36(12):1392-404. PMID: 16102764 DOI: 10.1016/j.injury.2005.07.019
5. Giannoudis PV, Einhorn TA, Marsh D. Fracture healing: the diamond concept. Injury. 2007;38(Suppl 4):S3-6. PMID: 18224731 DOI: 10.1016/s0020-1383(08)70003-2
6. Street J, Bao M, deGuzman L, et al. Vascular endothelial growth factor stimulates bone repair by promoting angiogenesis and bone turnover. Proc Natl Acad Sci U S A. 2002;99(15):9656-61. PMID: 12118119 PMCID: PMC124965 DOI: 10.1073/pnas.152324099
7. Einhorn TA, Gerstenfeld LC. Fracture healing: mechanisms and interventions. Nat Rev Rheumatol. 2015;11(1):45-54. PMID: 25266456 PMCID: PMC4464690 DOI: 10.1038/nrrheum.2014.164
8. Gerstenfeld LC, Cullinane DM, Barnes GL, Graves DT, Einhorn TA. Fracture healing as a post-natal developmental process: molecular, spatial, and temporal aspects of its regulation. J Cell Biochem. 2003;88(5):873-84. PMID: 12616527 DOI: 10.1002/jcb.10435
9. Obayemi JE, Card EB, Shirima O, Premkumar A, Massawe H, Sheth NP. Hospitalized for poverty: orthopaedic discharge delays due to financial hardship in a tertiary hospital in Northern Tanzania. Glob Health Res Policy. 2022;7(1):31. PMID: 36050802 PMCID: PMC9438232 DOI: 10.1186/s41256-022-00265-z
10. Claes L, Recknagel S, Ignatius A. Fracture healing under healthy and inflammatory conditions. Nat Rev Rheumatol. 2012;8(3):133-43. PMID: 22293759 DOI: 10.1038/nrrheum.2012.1