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Research Article

Innovative Use of β-Tricalcium Phosphate/Hemihydrate Calcium Sulfate Scaffold in Unstable Hip Fractures Management: A Randomized Controlled Trial

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Abstract

Background: Unstable intertrochanteric fractures in the elderly treated with Dynamic Hip Screw (DHS) fixation are prone to failure; synthetic scaffold augmentation may improve stability and prevent loosening before bone consolidation.

Methods: Between April 2015 and June 2018, 36 patients aged 65-80 with acute unilateral non-pathological intertrochanteric fractures were randomized into two groups. The experimental group (n=19) received DHS fixation with β-Tricalcium Phosphate / Hemihydrate Calcium Sulfate graft applied in the cervico-cephalic femoral canal, while the control group (n=17) underwent conventional DHS fixation. Tip-to-Apex Distance (TAD) was measured post-operatively at 6 and 12 weeks to assess cut-out incidence. The statistical analysis included ANOVA and chi-square test to compare proportions between groups.

Results: The study group exhibited a lower average TAD increase over time compared to the control group (12 weeks TAD = 24.1 mm, 32.1 mm, respectively), indicating a statistically significant difference ($p = 0.0457$). The control group showed a higher tendency for cut-out between the baseline and 12 weeks, whereas the experimental group, maintained stability, suggesting reduced cut-out risk and improved bone healing with the experimental intervention. Additionally, the chi-square test indicated that the proportions of good prognosis were significantly higher in the experimental group at 12 weeks ($p = 0.03313$).

Conclusion: β-Tricalcium Phosphate/Hemihydrate Calcium Sulfate in DHS fixation for unstable intertrochanteric fractures demonstrates potential in reducing cut-out rates and improving implant stability.

Keywords: Intertrochanteric Fractures; Dynamic Hip Screw; B-Tricalcium Phosphate; Calcium Sulfate; Cut-Out

Introduction

Intertrochanteric femoral fractures represent a major public health challenge, particularly in elderly patients over 65 years old with low bone mineral density [1,2]. They are a primary cause of significant morbidity, functional decline and high mortality rates, with epidemiological data indicating a sustained increase in incidence as populations age and the prevalence of osteoporosis rises [3]. These fractures account for nearly half of all hip fractures and are particularly common in women, largely due to postmenopausal bone loss and changes in hip anatomy [2,3]. They most often occur after low-energy falls onto fragile, osteoporotic bone, highlighting the vulnerability of this population [2,4]. The management algorithm for these fractures is dictated by the fracture pattern complexity and, most importantly, its biomechanical stability [5]. The AO/OTA classification system is the most widely used standard for categorizing these injuries. Type 31-A1: These are stable, simple two-part fractures. The integrity of both the posteromedial cortex (calcar) and the lateral wall is preserved. This inherent stability allows the native bone to absorb physiological loads, making them ideal for load-sharing implants. Type 31-A2: These are multifragmentary fractures. While the lateral wall is typically intact, the posteromedial cortex is comminuted. The loss of this medial buttress

introduces instability and increases the risk of varus collapse. Type 31-A3: These are considered inherently unstable fractures. This group includes reverse obliquity patterns (where the fracture line runs from proximal-lateral to distal-medial) and transverse fractures [5-7]. In these patterns, dynamic compression implants can lead to fracture displacement rather than stability [8,9]. An essential determinant of instability, particularly in A2 patterns, is the competence of the lateral femoral wall (often defined as <20.5 mm thickness). In unstable patterns (A2 and A3), the critical buttress support is lost, shifting mechanical demands entirely onto the fixation construct and elevating the risk of implant failure [9].

The Dynamic Hip Screw (DHS), a sliding hip screw implant, has long been a gold standard for treatment [7,10]. Biomechanically, it allows for controlled dynamic sliding, which translates axial loads into interfragmentary compression, thereby promoting fracture healing. In stable fracture patterns (e.g., AO/OTA 31-A1), the DHS achieves high union rates, excellent functional outcomes and facilitates early mobilization [11].

However, the performance of the DHS is markedly inferior in unstable fractures (A2 and A3), which constitute 40-60% of presentations. In the absence of cortical buttressing, the DHS fails to neutralize the intense shear and varus moments, leading to a high complication rate (reported between 4% and 19%) [9,12]. The most common complication is the loosening and superior migration of the lag screw through the femoral head, a catastrophic failure known as cut-out [13]. This failure results in varus collapse, limb shortening and implant loosening, often creating a significant bone void that requires a technically demanding and complex revision surgery. A Tip-Apex Distance (TAD) greater than 25 mm is a well-established predictor of this failure (Fig. 1) [13,14].

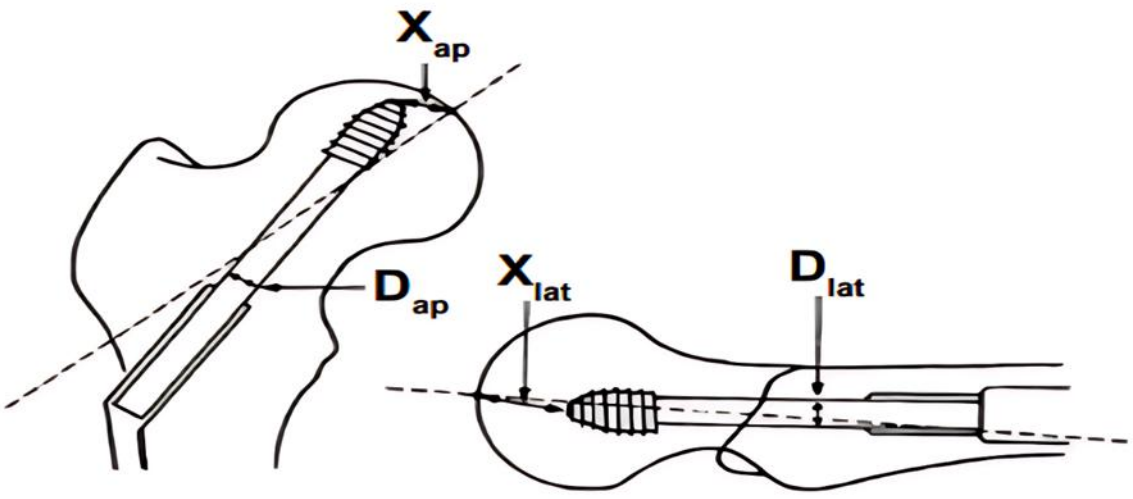

Figure 1: Apex-Tip Index = (X_{ap} * V $_{true}$/D_{ap}) + (X_{lat}*D_{True}/V_{lat}).

Although Cephalomedullary Nails (CMN) are generally recommended for unstable, comminuted or lateral wall-incompetent fractures according to international guidelines, including the AAOS 2021 recommendations, DHS can still be considered in selected cases [8-10]. To mitigate the higher risk of mechanical failure associated with DHS in poor-quality or unstable bone, various augmentation techniques such as Trochanteric Stabilization Plates (TSP) or Polymethylmethacrylate (PMMA) cement, have been proposed to enhance screw anchorage [10,15,16]. Despite these strategies, there remains no clear consensus on the optimal implant or adjuvant system for these challenging fractures [9].

The aim of this study is to evaluate the incidence of cut-out failure of the dynamic hip screw implant used alone, compared to a study group in which a tricalcium ß phosphate/hemihydrate sulfate graft scaffold is added through the cervical canal prior to placing the sliding screw, to improve implant integration and bone healing.

Methodology

Study Design

This was a randomized controlled trial with a prospective, longitudinal and experimental design.

Participants and Subjects

Between April 2015 and June 2018, a total of 39 consecutive patients with acute, non-pathological, unilateral intertrochanteric fractures, classified according to the AO system as 31A1.3, 31A2.1, 31A2.2 and 31A2.3, were enrolled. Three patients were excluded as they were lost to follow-up during the subsequent 3 months. A total of 36 participants were analyzed, with a mean age of 72 years (range: 65 to 80 years). All patients were treated with closed reduction and internal fixation using the DHS system. Before surgery procedure, patients were informed about the research objectives and provided written informed consent to participate in one of both groups (control and study group).

Data Collection

The randomization process was as follow: patients arrive at the hospital's emergency department, where they receive primary care and are subsequently hospitalized. After a clinical and radiographic evaluation, their inclusion in the study is assessed. Using the Random.org web page, it is determined whether they are assigned to the control or study group. The randomization type was single-blind, as the investigator knew which group everyone belonged to, but the patient did not. For the surgical procedure, an epidural or general anesthesia was applied the surgeries were made by the same surgeon. A fracture reduction table was used to achieve the most anatomical alignment possible. In the control group, DHS was applied and it was verified that all the sliding screws were centered on the femoral head in the usual manner. For the study group, 10 cc of geneX paste (Biocomposites, 700 Military Cutoff Road, Suite 320, Wilmington, NC 28405, USA) was applied prior to the insertion of the sliding screw [17-20]. The synthetic graft was introduced into the femoral head using an arthroscopic 5 mm cannula and a cylindrical 3 mm impactor, immediately afterwards the sliding screw was inserted and the DHS plate was fixed with 4.5 cortex screws using the conventional technique (Fig. 2).

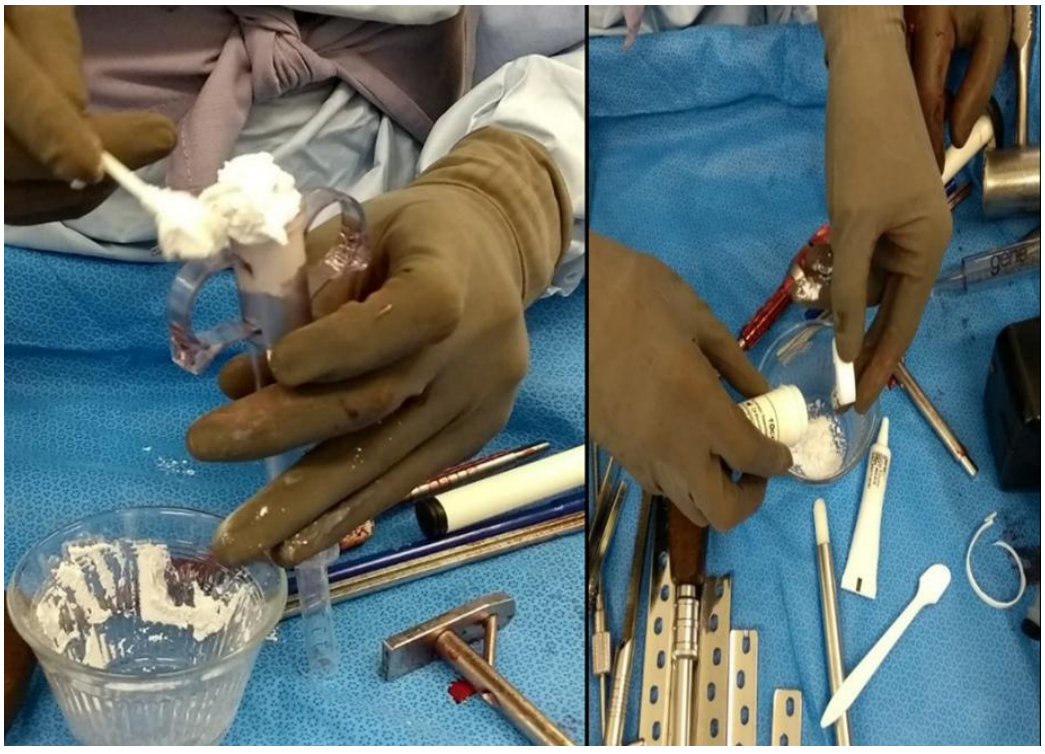

Figure 2: GeneX preparation method.

Both groups were evaluated by measuring the Tip-Apex Distance (TAD) on anteroposterior and lateral radiographs of the proximal femur immediately postoperatively and during follow-up at 6 and 12 weeks to compare the incidence of loosening (Fig. 3-6).

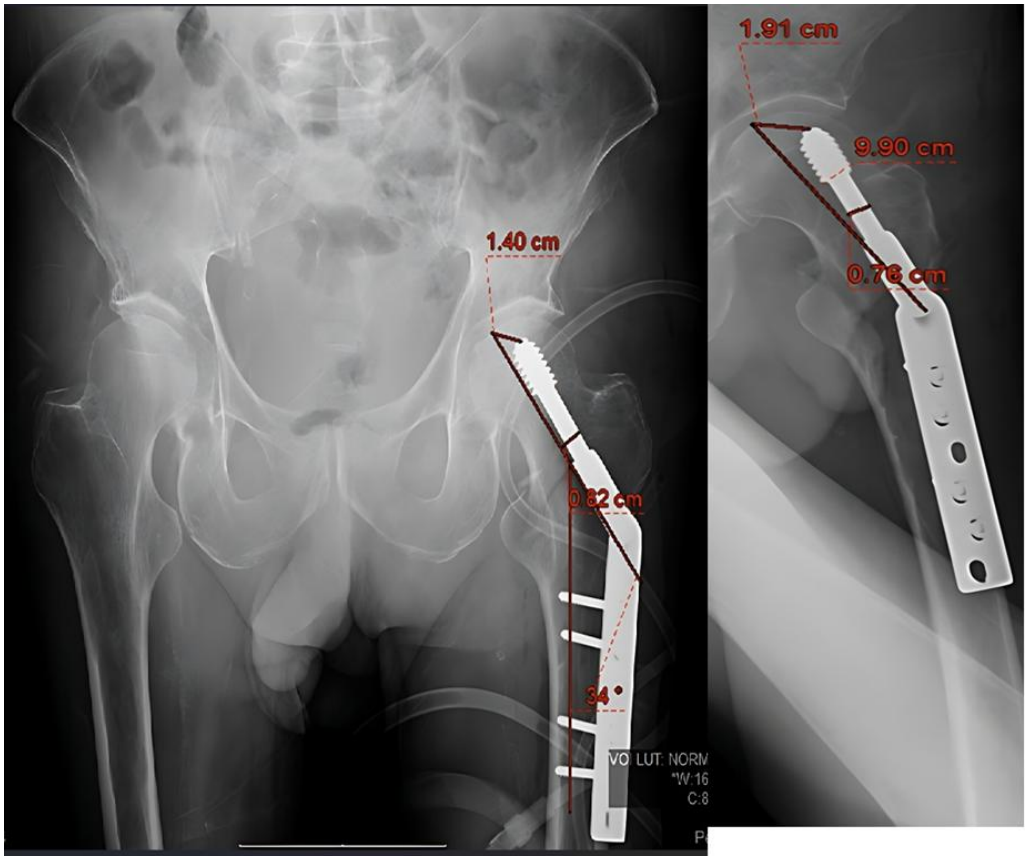

Figure 3: X-ray showing TAD measurements in anteroposterior and axial views.

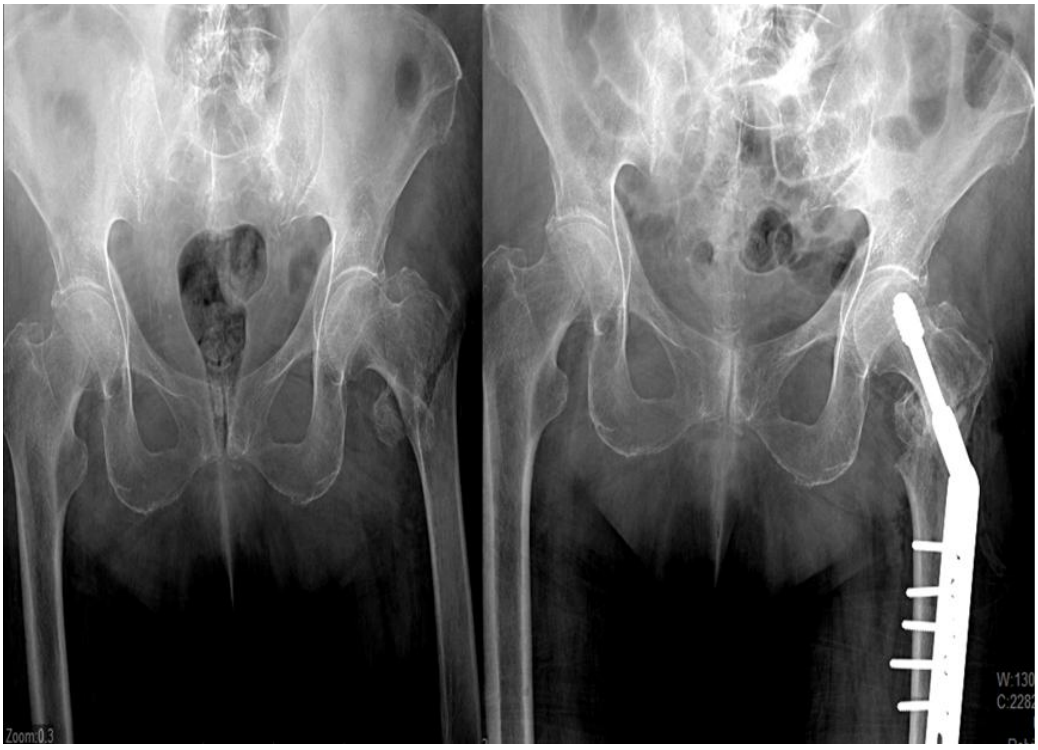

Figure 4: a) X-ray shows unstable fracture; b) Postoperative image.

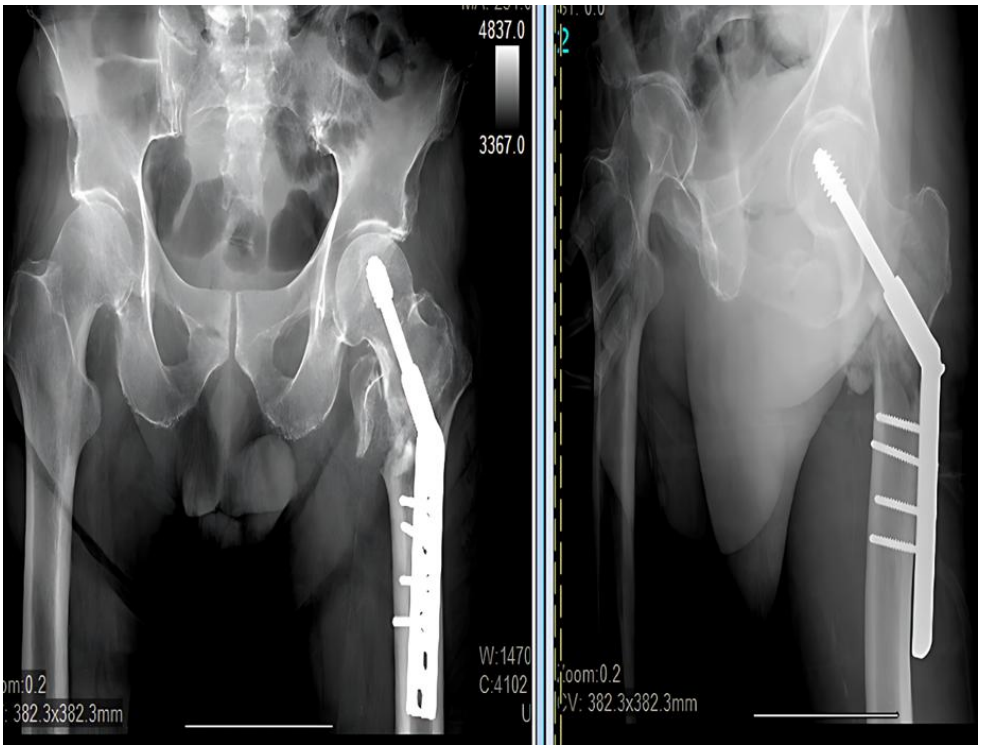

Figure 5: a) X-ray post-op; b) X-ray after 3 months follow-up.

Figure 6: Xray showing implant loosening in the control group.

Data Analysis

All data, including demographic variables and outcomes, were collected from clinical and radiographic records. Data were presented as mean ± standard deviation for continuous variables and as percentages for categorical variables. A p-value of 0.05 was set as the threshold for statistical significance. Logistic regression analysis was performed to investigate interactions among independent variables and their ability to predict implant loosening. Analysis of variance (ANOVA) and Tukey's post hoc test were used for multivariate statistical analysis in accordance with the registered study protocol (ClinicalTrials.gov Identifier: NCT05091359).

Results

A total of 36 patients were evaluated, 17 in the Control group and 19 in the Experimental group. The age range of them was 65 to 80 years, with a mean age of 72 years. For the Control group, the mean TAD at Baseline was 27.8 mm, at 6 weeks it was 29.6 mm and at 12 weeks it was 32.1 mm. For the Experimental group, the mean TAD at Baseline was 24.5 mm, at 6 weeks it was 23.8 mm and at 12 weeks it was 24.1 mm (Table 1).

Group	Age	TAD Basal			TAD 6 weeks			TAD 12 weeks		
	mean	mean	SD ±	CI 95%	mean	SD ±	CI 95%	mean	SD ±	CI 95%
Control n (17)	72.8	30.1	3.2	[27.9, 32.3]	28.9	4.1	[25.8, 32.0]	30.1	3.2	[27.9, 32.3]
Study n (19)	72.1	25.7	3.8	[23.3, 28.1]	27.2	4.3	[24.1, 30.3]	25.7	3.8	[23.3, 28.1]

Table 1: Demographics and TAD measures over time.

Statistical Analyses

An ANOVA test was used to compare TAD values at different time points within each group, followed by a Post-Hoc Tukey HSD test. Both groups were assessed at Baseline (day of surgery), 6 weeks and 12 weeks. In the Experimental group, ANOVA showed no significant change over time ($p = 0.819$), indicating that TAD values remained stable. In the Control group, ANOVA revealed a statistically significant change over time ($p = 0.0457$), with the Tukey HSD test identifying a significant difference between Baseline and 12 weeks ($p = 0.035$), suggesting an increase in TAD over the follow-up period. A chi-square test was used to compare the proportions of TAD <25 mm between groups, yielding p-values of 0.5427 at Baseline, 0.09095 at 6 weeks and 0.03313 at 12 weeks, indicating a significantly higher proportion of cases exceeding the 25 mm threshold in the Control group at 12 weeks (Fig. 7).

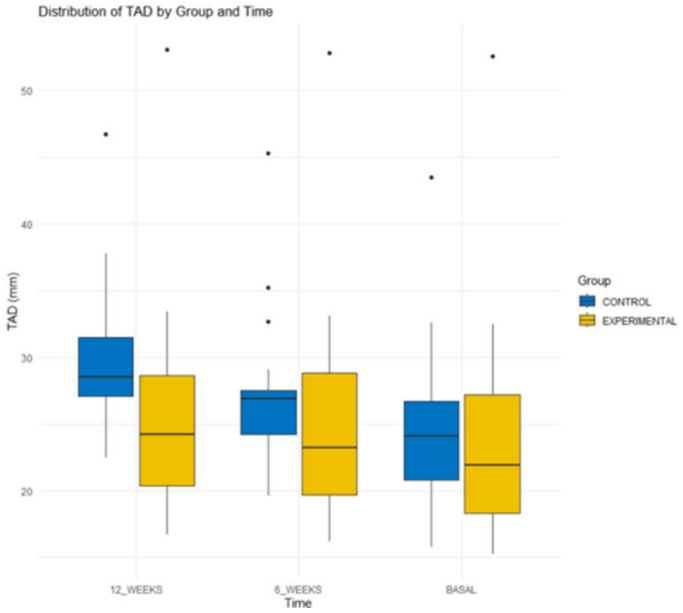

Figure 7: Box-Plot TAD distribution by group and time.

Discussion

Key Findings

According to the results, the TAD analysis across baseline, 6-week and 12-week time points revealed a significant difference in the Control group but not in the Experimental group, indicating greater DHS displacement in the Control group between baseline and the 3-month follow-up. Additionally, the proportion of good prognoses (TAD < 25 mm) was significantly higher in the Experimental group at 12 weeks. The Tip-Apex Distance (TAD) index remains a validated measure to assess the risk of short-term DHS loosening [13,21,22].

Clinical Context and Challenges

There is still no consensus on the optimal implant or adjuvant system for unstable hip fractures [23]. Osteosynthesis implants require high technical precision due to fracture type and patient bone conditions and they carry a significant risk of loosening, increasing the likelihood of revision surgery. For this reason, some surgeons prefer primary hip replacement as a first-line treatment to avoid such complications [24-26].

Novelty of the Approach

The present analysis reports the first comparison of closed reduction and internal fixation using the DHS system combined with a resorbable β-tricalcium phosphate/calcium sulfate hemihydrate scaffold versus conventional DHS placement in unstable intertrochanteric fractures [12,17,20].

Limitations and Future Directions

Despite limitations such as the small sample size and the lack of a multicenter design involving multiple surgeons, this research provides an initial approach to improving and selecting more efficient surgical methods, particularly for this highly prevalent condition.

Clinical Implications

Additionally, the observed improvement in outcomes indicates that supplementing osteosynthesis with an osteoconductive and resorbable biomaterial may broaden the applicability of DHS in the management of complex intertrochanteric fracture patterns. However, further randomized controlled trials with extended follow-up and direct comparisons with cephalon-medullary nails are necessary to validate these results and to more clearly establish the role of biomaterial augmentation in unstable hip fractures.

Conclusion

The use of a synthetic tricalcium β-phosphate/calcium sulfate hemihydrate graft in DHS fixation for unstable intertrochanteric fractures has been shown to reduce cut-out rates by improving implant stability.

Conflict of Interest Statement

The authors declare that there are no conflicts of interest that could have influenced the design, execution, authorship or publication of this randomized clinical trial.

Informed Consent Statement

Written informed consent was obtained from all participants prior to their inclusion in this study, in accordance with ethical guidelines and institutional standards.

Authors' Contributions

All authors contributed equally to the conception, design, data collection, analysis and writing of this manuscript. Each author has reviewed and approved the final version for publication.

Financial Disclosure

No financial support or funding was received for the design, conduct, analysis, writing, editing or publication of this manuscript.

Consent for Publication

Informed consent for publication was obtained from the patient(s) involved in this clinical trial, as documented in the manuscript.

Ethical Statement

This study was conducted in accordance with the principles outlined in the Declaration of Helsinki and applicable national regulations. The protocol was reviewed and determined to be exempt from formal IRB approval, as it did not meet the criteria for human subject research under federal guidelines.

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