

Impact of Using Cephalomedullary Nails with and without Cement Augmentation in the Femoral Head to Avoid Cut-Out in Patients Undergoing Surgical Treatment of Transtrochanteric Fractures

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ABSTRACT

The transtrochanteric fracture of the femur is a public health problem that tends to increase with the aging of the population. One of the worst and most frequent complications of conventional treatment with fixation with a cephalomedullary nail is the cut-out effect.

Objective: *To compare the incidence of the cut-out effect of transtrochanteric femoral fracture fixation with a cephalomedullary nail with or without cement augmentation.*

Methods: *prospective randomized study. Two groups were divided with 11 patients each with transtrochanteric fractures of the proximal femur Tronzo 3,4 or 5. Group A underwent fixation with a conventional cephalomedullary nail and Group B underwent fixation with a cephalomedullary nail with cement augmentation. Both groups were evaluated by the HOOS Score at 1, 3, 6 and 12 months postoperatively.*

Result: *There were no cut-out complication in the operated cases. Patients in Group B had a better evolution in the HOOS Score with a statistical difference of $p < 0.001$.*

Keywords

NPF stem, Hip, Transtrochanteric fracture, NPF failed.

Introduction

Due to the aging of the world population and the increasing state of activity of the elderly, there is a continuous growth of osteoporotic femur fractures and their respective complications. The problems and complications related to the treatment of geriatric hip fracture are well known [1]. First, osteoporotic hip fractures mainly occur in a comorbid geriatric population, leading to high rates of perioperative morbidity and complications, and consequently to an increase in healthcare costs. These costs are mainly due to acute hospitalization needs and post-acute institutional care, as up to 20% of patients with a hip fracture will need to be institutionalized

after the fracture, as they cannot return to their pre-morbid place of residence due to functional decline. Second, osteopenic or osteoporotic bone at the fracture site can interfere with implant fixation and lead to implant failure and/or secondary fracture displacement [2].

Fractures of the intertrochanteric region of the proximal femur are some of the most common fractures encountered by an orthopedic surgeon in elderly patients due to the presence of osteoporosis and consequent bone fragility.

By 2040, the incidence is expected to have doubled in the entire world population. Intertrochanteric fractures represent approximately 45% to 50% of all hip fractures in the elderly, and

of these, 50% to 60% are classified as unstable [3].

The “gold standard” treatment for unstable transtrochanteric fractures of the proximal femur is the use of cephalomedullary nails.

The proximal femoral nail has a better clinical effect than other internal fixators in the treatment of intertrochanteric fractures, especially unstable ones. However, as the number of cases worldwide has increased, so has the incidence of cut-out-related complications. Cut-out is one of the most common complications, with an incidence of up to 3-15% as reported in the literature and an excellent alternative to avoid these cases is the application of bone cement (polymethylmethacrylate) which can potentially reduce the risk of cut-out complications and reoperations [4,5].

The use of a cephalomedullary fixation nail with increased stabilization of the screw using the injection of orthopedic cement through the screw is a great solution to increase the stability of the fixation and avoid unwanted effects.

Objective

To prove the effectiveness of using the Proximal Femoral Nail (PFN) with the injection of Orthopedic Cement in the proximal screw of the femoral head to avoid the “Cut-Out” effect in unstable Transtrochanteric fractures of the Proximal Femur.

Material and Methods

The study protocol and research were carried out in accordance with the Ethics Committee and approved via the CEP/CONEP System. It is worth mentioning that only patients who consented by signing the term were included in this study.

This pilot study was designed as a single-center prospective cohort study that included patients with Transtrochanteric Fractures of the Proximal Femur.

To characterize our study population, cases of Transtrochanteric Fractures of the Proximal Femur classified by the Tronzo Classification in Tronzo 3, 4 and 5 were defined for inclusion.

For the composition of the sample of this study, patients who underwent surgical treatment and who met the following eligibility criteria were selected.

Inclusion Criteria

All patients over 65 years of age with an unstable intertrochanteric fracture of the femur (according to Tronzo classification 3, 4 and 5) and who agreed to participate in the study through the informed consent form were included in the study.

Exclusion Criteria

Patients with stable transtrochanteric fracture of the femur (according to the Tronzo classification), patients with multiple trauma, pathological fractures, with compound fractures or who refused to participate in the study.

All surgeries were performed by surgeons previously trained for this study. The fracture was reduced on a traction table. After fracture reduction, a cephalomedullary nail (Orion Intramedullary mailing system, Biomecânica Inc.) was inserted according to the manufacturer's instructions and the use of the cement was performed by randomization of the patients, avoiding the surgeon's bias, also following the manufacturer's leaflet (Biomecânica Inc.). Patient demographics data collected were age, sex, body mass index (BMI), diabetes, tobacco use, American Society of Anesthesiologists (ASA) status. The intraoperative information recorded were operative time, intraoperative blood loss, presence of intraoperative complications such as tachycardia, rapid decrease in blood pressure or oxygen saturation, nail data and physical characteristics of the cement when used.

Statistical Analysis

Data were presented as mean ± standard deviation (SD) and analyzed using JMP Pro 14.0 (SAS Institute, Cary, NC, USA). Student's t test was used to compare the demographics, radiographic parameters, and clinical outcomes of the Cemented and Uncemented groups. Fisher's exact test was performed to analyze categorical data. p values < 0.05 were considered statistically significant.

Results

During the study period, 22 patients underwent cephalomedullary nail for intertrochanteric fractures. After randomization, the groups were divided into 11 patients with cement and 11 patients without cement. We looked at patient demographics between the two groups, and they were well balanced.

The mean age of the patients was 74 years and the mean body mass index was 25.6.

In the population studied, 14.29% of patients were classified as ASA1; 72.45% of patients classified as ASA 2 and 13.27% of patients classified as ASA 3, as we can see in figure 1.

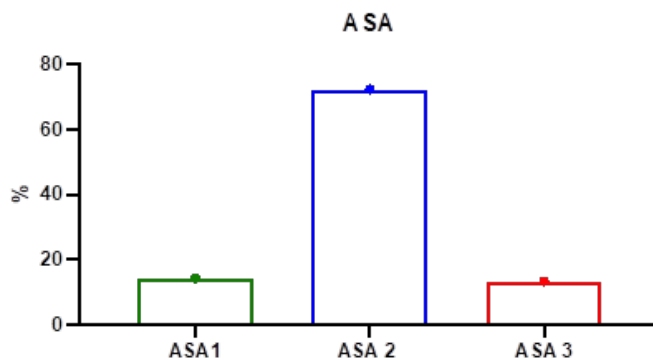


Figure 1: Distribution of patients according to the ASA classification of the American Society of Anesthesiology.

In the population studied, we had a prevalence of 21 (95.45%) of cases of Transtrochanteric Fractures of the Proximal Femur classified by the Tronzo Classification in Tronzo 3 and 1 (4.55%) of patients classified as Tronzo 5, as shown in figure 2.

The mean surgery time was 67 minutes and there were no cases in which the surgical treatment was interrupted due to the occurrence of side effects or complications.

No complications such as cut-out or cut-through were observed in any of the patients in either group.

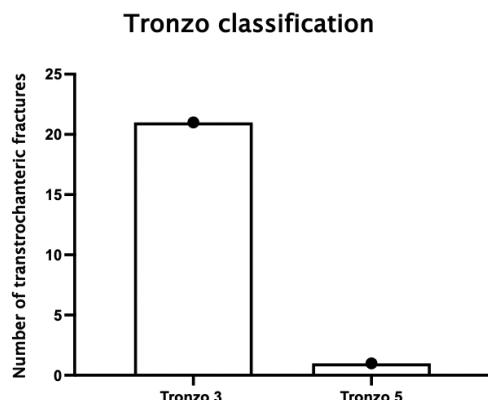


Figure 2: Cases of Transtrochanteric Fractures of the Proximal Femur classified by Tronzo.

When the Hip Disability and Osteoarthritis Outcome Score (HOOS) was applied and evaluated, there was a significant increase over time, up to 12 months of follow-up for both groups with $p < 0.05$ for time effect, with $p < 0.05$ for group-time interaction for group with cement and without cement, with the numbered scale of the Score being 23 for 1 month after surgery, 28 for 3 months after surgery, 36 for 6 months after surgery and 40 for 12 months after surgery, as we can see in figure 3 and 4.



Figure 3: Functional assessment using the HOOS Score.

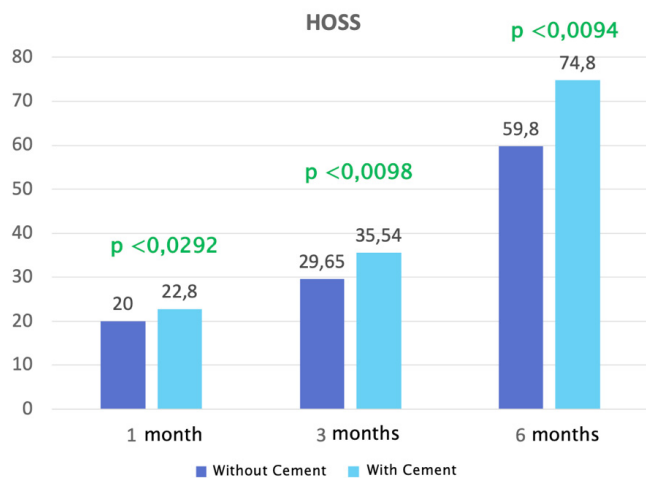


Figure 4: Functional assessment using the HOOS Score, separated by months of follow-up and treatment with or without cement.

Discussion

This study corroborates the growing evidence that selected implant augmentation in the treatment of Transtrochanteric fractures in poor bone quality adds a significant amount to bone-implant fixation. The perforated PFN blade and screw design allows for an improved and accurate injection of bone cement around the cephalic implant, effectively increasing the surface area of the bone-implant interface while minimizing the actual amount of cement needed to achieve stability.

The results of the present study agree with previous clinical and biomechanical reports demonstrating the beneficial effect of increasing cement on implant-bone anchorage by increasing shear strength.

The improved design of the cephalic implant and the meticulous application of the surgical technique have resulted in safe and acceptable clinical results.

The groups in this study, regardless of randomization, demonstrated a homogeneous pattern of cement distribution around the cephalic implants and significantly higher failure loads than the non-increased ones, with no evidence of necrosis in the cement groups.

In our study, it was demonstrated that cement augmentation can be performed safely without evidence of joint leakage, radiographic avascular necrosis of the femoral head at 12 months postoperatively.

Conclusion

There were statistical differences between the groups. The group operated with cephalomedullary nail with cement augmentation performed better in the HOOS Score than the other group.

There were no cases of Cut-Out or Cut-Through in either group. There were no cases of necrosis in the cement group of the study.

Compliance with ethical standards

Disclosure of conflict of interest

The authors declare that there are no conflicts of interest in the preparation of this manuscript.
Statement of informed consent

This document is a clinical research protocol that will be conducted in compliance with all stipulations of this protocol, current national regulations, and the guidelines established by the Document of the Americas and the ICH Good Clinical Practice Guide.

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