Document Cover Page

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Unstable proximal femur trans trochanteric fractures treated with dynamic hip screw with tricalcium B phosphate / hemihydrate sulfate graft scaffold
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Title: Unstable proximal femur transtrochanteric fractures treated with dynamic hip screw with tricalcium β phosphate / hemihydrate sulfate graft scaffold.

Abstract.

Transtrochanteric fractures are a frequent entity, principally in patients over 65 years old, with low bone density. Most of these fractures of the proximal femur are treated effectively with internal fixation with a dynamic hip screw (DHS), nonetheless a conditional factor in the treatment success it's in the fracture stability and in the osteoporosis, severity giving way to the most frequent complication, the loosening of the dynamic screw in the femoral head which conditions lack of bone healing. The objective of this study was to determine the utility of tricalcium β phosphate / hemihydrate sulfate graft as a scaffold to prevent loosening of the DHS compared to patients treated with a DHS without graft. Control groups were randomized and compared utilizing the Tip to-Apex distance (TAD), 19 patients were evaluated in the study group versus 17 in the control group at three different times using Student T, ANOVA and Turkey's post Hoc. Conclusion: The use of tricalcium β phosphate / hemihydrate sulfate graft as a scaffold for transtrochanteric unstable fractures proved useful to prevent loosening of the DHS

Introduction.

Transtrochanteric fractures are a frequent entity, principally in patients over 65 years old, with low bone density, Most of these fractures represent 57% of all proximal femur fractures.[1] Due to the improvements in the quality of life in elderly adults and longevity there's been an increase in the incidence rates of these fractures in adults after the age of 80 years.[2, 3].The DHS is an implant that biomechanically allows for sliding of the screw modifying interfragmentary contact and impeding fracture healing. However, despite being an excellent method of fixation, there is still a high incidence of complications in adult patients, the most common being loosening of the DHS in the femoral head. [4, 5, 6, 7, 8, 9, 10, 11, 12, 13.]

There are various studies that prove the complications of stable transtrochanteric fractures utilizing DHS as a treatment, but the number of cases on those is small. [8, 14, 15, 16] For stable fractures the DHS facilitates bone healing via compression between the fragments, this doesn't happen in unstable fractures where the DHS does not achieve adequate fixation producing a larger array of complications (4%-19%). [11,12,13]

The failure in the fixation of the screw will result in a migration of itself and a varus collapse of the proximal fragment with a loosening of the implant. Eventually there will be a bigger space with no support on the screw´s previous position, resulting in a technically demanding and complex revision surgery. [5, 6] Consequently, there is controversy whether arthroplasty replacement is preferred over osteosynthesis in patients with osteoporosis and unstable fractures, however, the risk of periprosthetic infection or increased bleeding during joint replacement surgery makes the decision to place a DHS against a prosthesis debated.

In an attempt to avoid the conditioning factors of failure in the treatment of older adults in the DHS implant, various techniques have been described that improve the dynamic screw anchorage in the femoral head and neck, as well as to maintain the fragments in a stable position. Until the fracture heals, the first is a trochanteric support plate in the shape of a racket or star, however it is difficult to obtain in our setting; 17,18. The other alternative is augmentation with the application of polymethylmethacrylate cement in the femoral neck canal, allowing its inclusion through the bone trabeculae. 19, 20, 21, 22, 23. There is still no consensus on which is the best implant or adjuvant system for unstable hip fractures.

Likewise, a measuring method has been described to evaluate the risk of short-term loosening of the DHS system in transtrochanteric fractures, this method is known as the Apex-Tip index and is defined as the distance between the tip of the screw and the apex of the femoral head on anteroposterior and lateral radiographs, obtaining a score in millimeters that allows us to know the risk of loosening of the sliding screw after fixation 14, 15, 24.

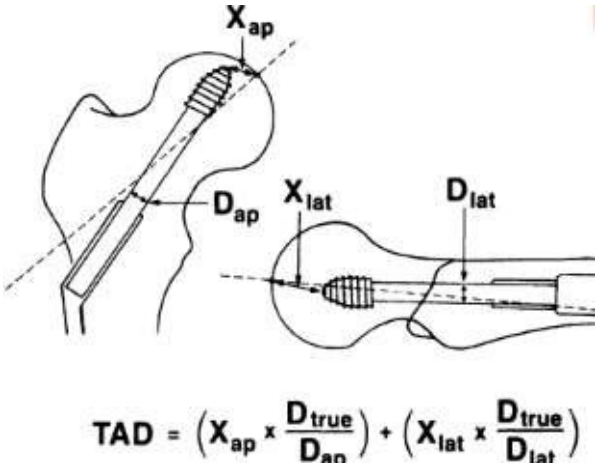


Figure 1. Apex – Tip Index = ($X_{ap} * V_{true/} D_{ap}$) + ($X_{lat} * D_{True} / V_{lat}$)

Materials and methods.

Between April 2016 and June 2018, 36 patients were registered with acute non-pathological unilateral transtrochanteric fractures between the ages of 65 and 80, with an average age of 72 years, all of whom were treated with closed reduction and internal fixation with the DHS system. Before the surgical treatment, the patients were informed of the objective of the study and they were given an informed consent, which they signed to be part of the study. The surgical procedure was performed under epidural blockade or general anesthesia by the same surgeon, a fracture reduction table was used to obtain an alignment as anatomically as possible. The DHS System was applied, and it was verified that all the sliding screws were centered on the femoral head. For the study group, prior to the introduction of the sliding screw, 10 cc of geneX [genex, 700 Military Cutoff Road, Suite 320, Wilmington, NC 28405, USA] in paste were applied and its introduction to the femoral head was completed using a cannula. 5.0 mm twin fix and a cylindrical metal impactor, immediately afterwards the sliding screw was inserted, and the DHS plate was fixed with 4.5 cortex screws using the conventional technique. Figure 4.
Both groups were evaluated by measuring the apex-tip index on an anteroposterior and lateral radiograph of the proximal femur in the immediate postoperative period and again during follow-up with the same radiographic projections at 6 and 12 weeks to compare the incidence of loosening.
Figures 2, 3

The necessary information was collected from the patients, including demographic variables and their results. Data were represented as mean and standard derivation for continuous variables or percentages for discrete variables. The p value was established before analysis at 0.05 for each test, the logistic regression analysis was analyzed to investigate interactions on independent variables and its ability to predict implant loosening. Analysis of variance (ANOVA) and Tukey's post hoc test were analyzed for multivariate statistical analysis.

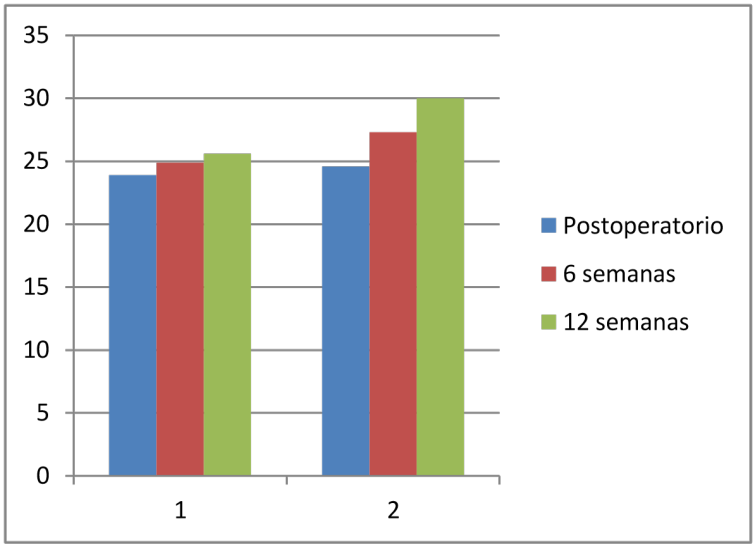
Results:

The results of the Tip – Apex Index were obtained where the average for the immediate postoperative period was 23.9 for the experimental group and 24.6 for the control group with a difference of less that 1 point. At 6 weeks the average for the experimental group was 24.9 and for the control group 27.3 where the difference increased to almost 3 point and at 12 weeks 25.6 for the experimental group and 30.0 for the control with a difference of almost 5 points.

		Tip – Apex Index					Tip – Apex Index		
Study Group	**Age**	**Postoperative**	**6 weeks**	**12 weeks**	**Control Group**	**Age**	**Postoperative**	**6 weeks**	**12 weeks**
1	78	19.75	20.2	21.1	1	70	43.5	45.3	46.7
2	70	29	31.21	30.2	2	74	25.9	27.4	30.9
3	80	21.2	22.1	22.8	3	67	23.4	25.5	28.4
4	65	52.6	52.8	53.1	4	75	29.2	32.7	34.5
5	69	30.5	30.8	31	5	78	21.3	26.7	28.1
6	77	18.1	19.2	19.5	6	72	17.8	19.6	24.7
7	68	22.67	23.5	24.2	7	72	20.8	24.2	27.1
8	74	18.5	21.2	23.8	8	80	17.2	19.9	22.5
9	67	15.5	16.2	16.7	9	68	15.8	26.9	28.5
10	75	24.1	26.8	27.1	10	65	32.6	35.2	37.8
11	79	15.3	16.2	17.8	11	69	25.4	26.8	32.9
12	67	21.9	23.2	25.1	12	79	28.2	29.1	31.5
13	72	19.5	20.7	21.5	13	70	18.5	20.5	24.6
14	74	23.6	23.9	24.5	14	77	26.7	27.5	28.7
15	65	30.5	31.2	31.9	15	66	24.1	26.9	29.4
16	66	32.5	33.1	33.4	16	76	25.1	26.9	28.1
17	79	25.4	25.8	26	17	80	23.5	24.1	26.9
18	69	17.8	18.5	19.6					
19	76	16.1	17.9	18.2					
Average:	72.1053	23.9221053	24.9742105	25.6578947	Average:	72.824	24.64706	27.364706	30.0764706

Tip – Apex Index

	Grupo Experimental	Grupo control
Postquirurgico	23.9	24.6
6 semanas	24.9	27.3
12 semanas	25.6	30



Statistical analysis

The experimental group was compared against the control group at three different times using Student's t - test. In the immediate postoperative period (0 weeks) the value of t was -0.27803. The p value was 0.391; not finding a statistically significant difference for both groups with a $p < 0.05$. At 6 weeks the value of t was -0.95573 and the value of p was 0.17, not finding a significant difference for $p < 0.05$. However, at 12 weeks the t value was -1.84694 with a p value of 0.36737 for a $p < 0.05$ finding a significant difference between both groups. For the control group, the results were analyzed using ANOVA with a p of 0.04 and a Turkey's post Hoc of 0.035 between the immediate postoperative period and the 3-month evaluation. In both tests a significant difference is found.

Discussion.

Transtrochanteric fractures are one of the most frequent bone entities found in elderly patients over 65 years of age, who will also have some degree of osteoporosis. The objective of the study was to determine the utility of the absorbable graft of tricalcium ß phosphate / calcium sulfate hemihydrate paste at the time of the placement of the DHS to prevent loosening of this in unstable transtrochanteric fractures of the proximal femur compared to conventional DHS system placement.

In the control group to whom the resorbable graft of tricalcium ß phosphate / calcium sulfate hemihydrate was not applied, we found a tendency to loosen mainly between 6 and 12 weeks, essential time for bone consolidation. For the experimental group, no significant difference in implant loosening was found between the postoperative period and 3 months, resulting in a lower probability of loosening for the group of patients treated with absorbable graft of β-tricalcium phosphate / calcium sulfate hemihydrate.

There is still controversy regarding the decision between osteosynthesis or joint replacement treatment when facing an unstable transtrochanteric fracture, when placing an osteosynthesis implant with a high technical requirement due to the type of fracture and bone conditions inherent to the patient, the risk of loosening is high increasing the

likelihood of a revision surgery. For this reason, some surgeons prefer to perform a first-instance primary hip replacement to avoid this scenario. In this study we were able to demonstrate the first study comparison of closed reduction and internal fixation with the DHS system associated with resorbable tricalcium ß phosphate / calcium sulfate hemihydrate graft against closed reduction internal fixation with the conventional DHS system placement method in unstable transtorchanteric fractures, however more studies to confirm that the use of resorbable tricalcium ß phosphate / calcium sulfate hemihydrate graft is useful to decrease the complications of osteosynthesis in unstable transtrochanteric fractures. Without a doubt, this is a step in the right direction to decide to perform osteosynthesis instead of joint replacement as the first treatment option.

Conclusion.

The application of tricalcium ß phosphate / calcium sulfate hemihydrate pastes as a graft for the treatment of unstable transtrochanteric fractures with the DHS sliding screw has better results avoiding to a greater extent the loosening of the implant during bone healing.

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INFORMED CONSENT

Title of research: Unstable proximal femur trans trochanteric fractures treated with dynamic hip screw with tricalcium B phosphate / hemihydrate sulfate graft scaffold.

1. The purpose of this study is to analyze radiographic measurements in patients with hip fractures treated with surgery with or without added Calcium Sulfate Scaffold (GeneX)
2. Upon accepting to enter the study, surgical treatment will be performed according to the fracture presented. The surgery consists of fixing the fracture line with osteosynthesis material (DHS system), after which X-rays of the injury will be taken at 6 and 12 weeks.
3. We expect to have 40 participants for this study, who must be between 65 and 80 years old, with an unstable hip fracture and who undergo surgical treatment with the DHS system, they must have a follow-up of at least 12 weeks and two X-rays at 6 and 12 weeks.
4. Potential risk and discomforts: The risks in this study are specific to the surgical treatment to which it will undergo unwanted fracture, no union fracture, soft tissue infection, osteomyelitis, dislodging of osteosynthesis material, bleeding, unwanted fracture, limb shortening affected, limitation of movement or ambulation, pulmonary thromboembolism, sepsis, and death. For the application of calcium sulfate, you could present heterotopic ossification which means, extra bone formation.
5. Potential benefits: Restore function of the affected limb, return to daily activities, promote the healing of the fracture.
6. Confidentiality: All the information collected in this study will be encrypted to protect the identity of each participant, the researcher will securely maintain the files and data collected electronically.
7. The decision to participate in this study is completely voluntary, if you do not wish to participate in this study, the care, services, or benefits to which you are entitled will not be affected.
8. If you decide to participate in this study, you can withdraw or withdraw at any time without retaliation.
9. This study is at no cost to participants.

I voluntarily agree to participate in this research program
□ **Yes**
□ **No**
I understand that I will be given a copy of this signed Consent Form.

Name of Participant (print): _____ Signature: _____ Date:_____.

Name of Witness (print): _____ Signature: _____ Date: _____.

25. Person Obtaining Consent: _____Signature: