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Analysis of the use of the Anti-Rotational Device in Cephalomedullary Nail and its Implications in Fractures of the Proximal Femur

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Abstract

Objective: Evaluate the influence in the position of the anti-rotational device in cephalomedullary nails and its influences on the consolidation of trochanteric fractures.

Methods: Retrospective case series comprising 58 patients with unstable trochanteric fractures that underwent osteosynthesis with cephalomedullary nail and anti-rotational device. Were analyzed the radiographs of the pelvis and ipsilateral hip osteosynthesis with 6 months postoperatively and compared to initial. The radiographic parameters used were tip-apex index (TAD), the positioning of the sliding screw in relation to the central axis of the femoral neck, the angle of reduction and fracture healing.

Results: From the 58 patients selected for initial postoperative examination, 15 (26%) died, 6 (10%) lost the thread of the treatment and 37 (64%) were reassessed. Most of them were female patients, between the ninth and tenth decade of life. It was observed that 31 (84%) fractures were consolidated, while 6 (16%) patients had their fractures not yet consolidated. The reduction angle in healed fractures was 1290 and in non-healed were 1360. In these, the position of the sliding screw was far from the central axis of femoral neck.

Conclusion: The fixation of trochanteric fractures with cephalomedullary nail with anti-rotational device is safe. The reduced fractures with valgus above 135 ° showed higher rates of nonunion. In these cases the position of the sliding screw was lower than ideal to fit the anti-rotational device, which may have affected negatively the fracture healing.

Keywords: Transtrochanteric Fractures; Post OP Complications; Pseudoarthrosis; Cefalomedular Nails; Anti-Rotational Screw

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Introduction

Transtrochanteric fractures correspond to extracapsular fractures of the proximal femur located between the trochanters [1,2]. It is a common fracture in the elderly population, usually associated with low-energy trauma. It is estimated that nine in ten intertrochanteric fractures occur in individuals over 65 years of age [3]. Currently in developed countries, one in every 1,000 inhabitants per year is affected by this type of fracture. It is estimated that in 2050 the incidence will be three times higher and the annual cost of treatment, around \$8 billion, will be doubled.3-6 Thus, they are considered a major public health problem [1,2].

The treatment is inevitably surgical, with the objective of allowing the patient early mobilization, reducing complications arising from bed confinement. Non-surgical treatment is limited to patients with comorbidities that contraindicate anesthesia, surgery, or both [1,3,7].

Due to the abundant blood supply in the trochanteric region, the rate of osteonecrosis and pseudoarthrosis are low, favoring internal fixation surgical treatment [1]. The main surgical treatment method for intertrochanteric fractures is osteosynthesis, although prosthetic replacement is occasionally indicated [3].

The determination of the fracture pattern and it's stability is fundamental to define the treatment options. Fractures that affect the postero-medial cortex, with reverse trace or subtrochanteric extension, are considered unstable [1,3]. Recently, the importance of the lateral cortex in the stability of the fracture has been recognized [8-11].

In the evolution of its treatment, intramedullary systems have been developed, aiming for greater stability in unstable fractures, where extramedullary systems are mechanically overloaded and have a biomechanical disadvantage.

Fixation with the sliding hip screw (DHS) is recommended for stable fractures. In unstable fractures, cephalomedullary implants have been recommended, as they present biomechanical superiority due to the reduction of the flexion moment on the implant, better rotational control, greater control of varus collapse and shortening, due to their more medial position compared to extramedullary devices [1,12-16].

Correct positioning of the sliding screw is vital for treatment success. The Baumgartner method corresponds to the currently most used positioning parameter [1]. Anatomical particularities of populations and factors related to the surgeon's experience are determining factors that influence the placement of these implants [16-18].

The evolution of cephalomedullary rods has allowed the improvement of models with two proximal fixation locks, associating the sliding screw in the second lock, with a smaller diameter screw, aiming the improvement of rotational stability [19].

The objetive of this study was to retrospectively evaluate the influence of the anti-rotational device positioning of cephalomedullary rods on the consolidation of unstable intertrochanteric fractures."

Methods

Retrospectively, a serie of cases composed of 58 patients with preoperative radiographic diagnosis of unstable intertrochanteric fracture, submitted to osteosynthesis procedure in 2011, through cephalomedullary rod of the PF-Targon* model (BBraum, Melsungen - Germany) were analyzed. Of these patients, 15 (26%) died, 6 (10%) were lost to follow-up and 37 (64%) were reevaluated. The casuistry was evaluated regarding gender, age and fracture classification. The fractures were classified using the AO/ASIF and Tronzo classification systems. Fractures AO/ASIF 31A2 and 31A3 and Tronzo type III, III variant, IV and V (Figure 1) were considered unstable and included in this study [13].

Figure 1: Tronzo Classification.

The surgical technique used was common to all, performed by the same surgical team of the service, consisting of indirect reduction of the fracture with the aid of an orthopedic table and fixation under intraoperative fluoroscopy.

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Rods of distal diameter of 10 or 12 mm, proximal diameter of 17 mm, mediolateral angle of 6° and cervicodiafisary angle of 130° were used. The choice of implant was based on the measurement of the cervicodiafisary angle of the contralateral proximal femur.

All patients received pre and postoperative anti-thrombotic medication prophylaxis. Prophylactic antibiotic therapy with cefazolin was performed during anesthesia induction, 60 minutes before the surgical procedure, and maintained after the procedure. Postoperative pain management and physiotherapy rehabilitation were encouraged early on, evolving with the progression of walking in a stepwise manner according to tolerance.

The postoperative radiographs were analyzed by the digital image archiving system IMPAX^{*} (version 6.3.1.7501, from AGFA HealthCare N.V.). Simple radiographs of the homolateral hip and pelvis in Antero-posterior (AP) and Lateral (L) views were used, following the standardization proposed by Polesello., *et al*, performed in the immediate postoperative period and six months postoperatively [20]. For the AP view, the patient was positioned in a dorsal decubitus position with the lower limbs in internal rotation of 15^o to 20^o and the X-ray beam directed in the median line, above the pubic symphysis. In the L view, the patient was positioned in a dorsal decubitus position with 90^o flexion of the contralateral hip and the X-ray cup angled at 45^o cranially in the horizontal plane towards the affected thigh root (Figure 2).



Figure 2: Standard positioning for AP and P radiographs of the hip and pelvis.

Fractures were considered consolidated when they presented at least three intact cortices, bone callus or new trabecular bone, visualized in two orthogonal radiographic views.

To obtain the measurements, radiographs in the AP position were used, measuring the diameter of the femoral head in its largest axis, the diameter of the neck in its thinnest thickness (AB), the cervicodiafisary reduction angle, the distance between the central axis of the sliding screw and the upper edge of the anti-rotational device (Z_X) and the distance of the central axis of the sliding screw and the lower edge of the neck (X_B). The central axis of the femoral neck was determined by the neck axis at the midpoint of its thinnest thickness (AB). The distance from the tip of the screw to the apex of the femoral head (Tip Apex Distance - TAD) was evaluated in the AP and P views, according the method proposed by Baumgartner and Solbert. Figure 3 represents the reference points used for these measurements and figure 4 demonstrates the use of digital tools of the IMPAX^{*} program to obtain the aforementioned measurements.

Figure 3: Reference points for proposed measurements. AB: Diameter of the femoral neck at its narrowest point. AB': Radius of the femoral neck. X: Central axis of the sliding screw. Z: Line tangent to the upper edge of the anti-rotational device. Z_X: Distance from the screw axis to the upper edge of the anti-rotational device.

Figure 4: Digital tools in the IMPAX® program to obtain the measurements. A: Neck diameter. B: Head diameter. C: Reduction angle. D: Distance X_B. E: TAD in AP incidence. F: TAD in P incidence. G: Distance Z_X. H: Distance X_A.

The value of Z_X (15 mm) is constant and provided by the manufacturer. To ensure the reliability of the data obtained, we applied as an individual correction factor the ratio between the Z_X measurement taken in the digital radiographs and the value provided by the manufacturer.

Radiographs were repeated at six months postoperatively and it was verified whether the implant positioning had an influence on fracture consolidation.

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The variables were presented in tables with absolute and relative frequency distribution. Associations were tested by Pearson's Chi-Square test. Statistical significance of the differences between the means of the quantitative variables was verified through the T-student and paired T-student test. Normality of the variables was tested by the Shapiro-Wilk test. Correlation between quantitative variables was tested by the Spearman Correlation coefficient. The analyses were carried out with a significance level of 5% (p less than 0.05).

The collected information was stored in the database developed in the Excel^{*} for Windows program, and the statistical analysis was performed using the STATA 11 SE software.

Results

Of the 58 patients selected for post-operative analysis, 15 (26%) died, 6 (10%) lost the follow-up and 37 (64%) were reevaluated and included in the study.

Regarding the classification of fractures, 19 fractures were grouped as Tronzo III (56.9%), 5 fractures as Tronzo IV (10.4%) and 13 as Tronzo V (19.8%). There were no statistically significant differences between the Tronzo classification and gender (Table 1).

Tronzo cl.	Female			Male		р	
	N	%	N	%	N	%	P
III	12	48,0%	7	58,3%	19	51,4%	0,764
IV	4	16,0%	1	8,3%	5	13,5%	
V	9	36,0%	4	33,3%	13	35,1%	
Total	25	100,0%	12	100,0%	37	100,0%	

Table 1: Association between gender and Tronzo Classification.

The majority of cases evaluated were composed of female patients (68%). The average age was 80 years, with a range between 64 and 97 years (Table 2).

Sex	№ (%)	Mean	SD	Median	Min.	Max.
Male	12 (32%)	77	6,9	76,5	68	90
Female	25 (68%)	81	8,7	80	64	97
Total	37 (100%)	80	8,4	79	64	97

Table 2: Prevalence of age, in years, according to gender.

In relation to the measures analyzed, statistically significant differences were found in measures X_B and X_A between male and female patients. In the other measures, such differences were not observed (Table 3).

Variables	Corr	Imedia	te post-op	6 month	n	
variables	Sex	Mean	SD	Mean	SD	р
Head	Fem	50,3	2,7	49,9	2,6	0,24
diameter	Male	52,8	4,4	54,6	3,7	0,06
AB distance	Fem	34,6	2,7	34,3	2,4	0,12
(neck)	Male	37,9	3,1	37,4	3,7	0,19
Reduction	Fem	131,8	9,4	129,3	5,7	0,23
angle	Male	130,8	7,0	133	6,2	0,46
AB' distance	Fem	17,3	1,3	17,1	1,2	0,12
(neck radius)	Male	18,9	1,5	18,7	1,8	0,19
Z_X distance	Fem	17,0	2,0	16,4	1,3	0,15
(implant)	Male	15,5	1,6	15,5	1,6	0,89
X_B distance	Fem	12,7	3,6	12,5	3,6	0,70
	Male	14,8	2,9	13,8	2,9	0,02
X_A distance	Fem	21,9	3,2	21,5	3,2	0,39
	Male	23,2	2,9	21,9	3,4	0,004
(X_B - X_A)	Fem	-9,7	6,3	-9,0	6,2	0,79
distance	Male	-8,5	5,0	-8,0	5,2	0,18
(AB' - X_B)	Fem	4,6	3,1	4,6	3,3	0,96
distance	Male	4,3	2,5	4,8	3,1	0,06
([AB' - Z_X] -	Fem	-1,7	2,1	-1,2	1,5	0,27
2) distance	Male	1,6	2,0	1,2	1,8	0,60
TAD	Fem	20,9	6,8	20,8	6,0	0,81
	Male	20,8	6,8	22,0	3,6	0,55

Table 3: Evaluation of the measured variables based on gender.

In the comparative evaluation of bone consolidation, it was observed that 31 (84%) fractures showed full consolidation, while 6 (16%) fractures presented as non-consolidated. In female patients, 22 (88%) fractures showed full consolidation and 3 (12%) fractures did not consolidate. In male patients, 9 (75%) fractures showed consolidation, while 3 (25%) fractures did not consolidate (Figure 5).

The rates of fracture consolidation were correlated with gender, age, and fracture classification, however, no statistical differences were identified between these data (Table 4).

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Figure 5: Status of fracture consolidation after 6 months of post-operation.

	N	Cor fi	nsolidated ractures	No	n-consolidated fractures	Р
		%	N	%		
Sex	Fem	22	88,00%	3	12,00%	0,315
	Male	9	75,00%	3	25,00%	
Age	< 80 years	17	80,95%	4	19,05%	0,592
	> 80 years	14	87,50%	2	12,50%	
Tronzo	III	15	78,95%	4	21,05%	0,584
CL.	IV	4	80,00%	1	20,00%	
	V	12	92,31%	1	7,69%	

Table 4: Consolidation rates of fractures according to gender,age, and Tronzo Classification.

Comparing the measurements found in consolidated fractures with those without consolidation, statistically significant differences were observed in the angle of reduction of fractures (p = 0.01), where the average value of measurements of pseudoarthrosis fractures (136°) was greater than that of consolidated fractures (129°) (Figure 6). The other measurements did not show statistically significant differences (Figure 7).

Figure 6: Evaluation of reduction angle in consolidated and non-consolidated fractures.

Figure 7: Evaluation of measured variables in consolidated and non-consolidated fractures.

Considering the ideal positioning of the sliding screw in the center of the femoral head on the implant (Targon PF^{*}), the minimum described diameter of the femoral neck corresponds to 34 mm.21 Of the patients analyzed with minimum diameter of the femoral neck, 11 fractures presented consolidation and two did not. There was a statistically significant difference in the comparison between gender and ideal screw positioning (p = 0.008). In 20% (5) of the cases of female patients, it was possible to obtain the ideal screw positioning. In male patients, the ideal positioning was possible to obtain in 66.67% (8) of the cases (Table 5).

Neck diameter (AB)	Consoli fract	idated ures	Non-consolidated fractures			
	Fem	Male	Fem	Male		
	N (%)	N (%)	N (%)	N (%)		
< 34mm	17 (77,3)	3 (33,3)	3 (100)	1 (33,3)		
≥ 34mm	5 (22,7)	6 (66,7)	0 (0)	2 (66,7)		
TOTAL	22 (100)	9 (100)	3 (100)	3 (100)		

Table 5: Evaluation of the femoral neck diameter in consolidated and non-consolidated fractures by gender.

According to the Spearman Correlation Coefficient, there was a strong correlation between the reduction fracture angle and the positioning of the sliding screw (r = 0.92 and p = 0.007) in the nonconsolidated fractures. The greater the angle and valgus positioning of the reduction, the greater the lower distance of the screw in relation to the central axis of the neck. In consolidated fractures, this variable showed weak correlation and no statistical significance (r = 0.23 and p = 0.20). The non-consolidated fractures demonstrated an average distance of the screw with the median axis of the femoral neck (4.85mm) greater than that of consolidated fractures (3.43mm) (Table 6).

	N (0/)	Moon	CD	CI (9	95%)	Madian	Min	Max
	N (%) Mean		30	Inf. lim.	Sup. lim.	Meulali	WIIII.	Max.
Consolidated frac- tures	31 (84)	3,43	3,24	2,24	4,62	3,21	-3,16	8,97
Non-consolidated fractures	6 (16)	4,85	5,39	-0,8	10,51	6,54	-4,73	10,88

Table 6: Distance between the axis of the sliding screw and the central axis of the femoral neck.

Discussion

Proximal femur fractures have a significant socio-economic impact, with a high rate of morbidity and mortality associated. The use of cephalomedullary nails in the treatment of unstable trochanteric fractures has biomechanical advantages compared to extramedullary devices [1,12-15]. Although controversial, the use of nails has the advantage of earlier return to walking, shorter surgical time, and less intra-operative blood loss [1,3,19].

The epidemiology of trochanteric fractures shows prevalence in women and individuals in their eight decade of life, justified by the lower bone mineral density of the proximal femur in this age group [1,7,15,17,22]. The present study demonstrates epidemiology in accordance with what is found in literature. Also, the prevalence of trochanteric fractures of types III or IV of Tronzo (AO: 31 A2) is described, as evidenced in this analysis [1,17,23,24]. There was no statistically significant difference between the association of age group or fracture pattern and the gender of the patients.

The morbidity and mortality of trochanteric fractures are related to the involvement of elderly patients, with multiple comorbidities and a high risk of post-operative complications [25]. The mortality rate in trochanteric fractures ranges between 6 and 11% in the first month and 14 and 36% over the first year [14]. In this analysis, a mortality rate of 26% was found during the six-month follow-up period."

Kaplan., *et al.* demonstrated in their meta-analysis the average time of consolidation of the trochanteric fractures of four months, regardless of the device used [3] Bridle., *et al.* reported that consolidation occurred in an average period of six months. According to Crawford., *et al.* the consolidation rate was 89% in patients treated with cephalomedullary nails. In this sample, there was a consolidation rate of 84% in the six-month period. Comparing the consolidation rate of fractures and the gender of patients, differently from the description in the literature, it was noted a higher prevalence of pseudarthrosis in male patients, although this comparison did not show statistically significant difference. It is known that in the treatment of trochanteric fractures, there are inherent characteristics of the fracture, not modifiable, and surgeon-dependent characteristics, such as fracture reduction, surgical technique and choice or implant positioning.

Regarding the pattern of fracture, it was found that the types of fractures Tronzo III, IV or V did not influence the rates of consolidation, which contradicts the literature, where it has usually been described worst results for consolidation of fractures Tronzo V (AO: 31 A3) [27].

The proximal femur's anatomical characteristics have shown importance in the positioning of the sliding screw or anti-rotational device in the femoral neck [21]. In the presented case series, 35% of the evaluated patients had a femoral neck diameter within the recommended range (> 34 mm) for the correct positioning of the used implant (Targon PF^{*}), with the sliding screw associated with the use of the anti-rotational device in the mid-axis of the neck. The concurrent use of the anti-rotational device tends to position the sliding screw in a lower location in relation to the midline of the femoral neck, particularly in patients with a short femoral neck and head [20,21]. In consolidated fractures, the inferior dislocation of the sliding hip screw in relation to the mid-axis of the neck was 3.43mm. In non-consolidated fractures, this dislocation was 4.85mm.

Although originally described for the DHS screw osteosynthesis technique, the Baumgaertner index can also be used for the adequate positioning of the sliding screw in cephalomedullary nails [1,13]. In nails with double proximal fixation, there is a difficulty in positioning the sliding screw in the center of the femoral head, in the AP incidence. The positioning of the screws in the P position is not influenced, due to its parallelism. However, despite the frequent occurrence of the inferior positioning of the sliding screw in relation to the mid-axis of the femoral neck, no statistically significant relationship was found between the TAD and the consolidation rates. In addition, no significant variation was found when comparing the TAD in the immediate postoperative period and six months. In this analysis, there were no cases of cut-out or "Z-effect" complications.

In relation to the fracture reduction angle, literature demonstrates the association of post-operative complications with inadequate reduction, primarily in varus.26 In this study, the mean fracture reduction angle found was 130.5° with a standard deviation of 6.06°, in line with what is described in literature [1,24]. No varus reduction was observed.

Some authors advocate for valgus reduction as an alternative to anatomical reduction for unstable fractures, with the goal of increasing the forces that cause screw compression and simultaneously reducing the flexor moment on the implant, compensating for shortening and favoring inter-fragmentary compression [28]. However, such benefits were not consistent in this study, as in nonconsolidated fractures, the mean angle of fracture reduction was 136.17°. In these cases, the eccentric positioning of the sliding screw in a more inferior position on the femoral neck may have hindered the compression of this screw, compromising fracture impaction. Furthermore, the presence of the anti-rotational device may have been an additional factor that limited compression and favored non-consolidation.

Conclusion

The osteosynthesis of unstable trochanteric fractures with the use of cephalomedullary nail associated with an anti-rotational device has proven to be safe, with high levels of consolidation and low rates of biomechanical complications. The cases of pseudoarthrosis observed in this study are related to a reduction angle of more than 135 degrees in valgus and with the inferior positioning of the sliding screw, in relation to the central axis of the femoral neck.

"The authors declare no conflicts of interest in the conduct of this work".

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