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ORIGINAL ARTICLE

How evolution of the nailing system improves results and reduces orthopedic complications: more than 2000 cases of trochanteric fractures treated with the Gamma Nail System

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Abstract

Purpose The incidence of trochanteric fractures has increased significantly during the last few decades, especially in elderly patients with osteoporosis. The dynamic/sliding hip screw and the cephalomedullary nail are the most commonly used fixation methods to treat trochanteric fractures. The improvements in the Gamma Nail System (GNS) associated with a correct surgical technique reduced the postoperative orthopedic complications. The purpose of this study was to compare the results of the different Gamma Nails.

Methods The present study is a retrospective analysis of 2144 patients treated with GNS between January 1997 and December 2011 for trochanteric fractures, classified according to AO classification method. The patients were divided into three groups according to the nailing system: 525 were treated with Standard Gamma Nail (SGN), 422 with Trochanteric Gamma Nail (TGN) and 1197 with Gamma3 Nail.

Results The overall incidence of intra-operative complications was 1.21 %; the incidence of intra-operative complications for each group was 1.71 % for SGN group, 0.47 % for TGN group and 1.25 % for Gamma3 Nail group. The overall incidence of postoperative complications was 5.48 %, and the incidence for each group was 10.73 % for SGN group, 9.92 % for TGN group and 2.92 % for Gamma3 Nail group.

Conclusion The GNS is a safe device with a low rate of intra-operative complications. The evolution of this nail system reduces postoperative complications, thus improving the results at follow-up and confirming that the Gamma3 Nail is a safe and predictable device to fix trochanteric fracture.

Keywords Trochanteric · Pertrochanteric fractures · Nail · Gamma Nail System · Cutout

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Introduction

According to the literature, 90 % of hip fractures occur in elderly patients (over 65) with osteoporosis and it is one of the most important causes of mortality and morbidity in the geriatric population [1, 2]. The incidence of trochanteric fractures has increased significantly during the last few decades becoming important in terms of social and economic issue [3–8]. The dynamic/sliding hip screw (SHS) and the cephalomedullary nail (CM) are the most commonly used fixation methods to treat trochanteric fractures. The use of CM is increasing as a fixation device for these fractures, especially for the treatment of unstable trochanteric fractures [9–14].

The Gamma Nail System (GNS), a widespread intramedullary nail, was developed in the 1980s evolving the concepts of Prof. G. Kuntscher to treat trochanteric fractures. The Standard Gamma Nail (SGN), as it was called, was first used in 1988. A modified design, the Trochanteric Gamma Nail (TGN), was introduced in 1997, and in 2003 the third-generation nail, the Gamma3 Nail, completely replaced previous versions. The SGN was 200 mm long, the proximal diameter of 17 mm, a valgus angle of 10° and two holes for the distal locking. In the last version of the nailing system, the Gamma3 Nail, there is the decrease in the length of the nail from 200 to 180 mm, the proximal diameter of 15.5 mm, a valgus angle of 4° and one hole for the distal locking. The SGN was 200 mm long, the proximal diameter of 17 mm, a valgus angle of 10° and two holes for the distal locking. The TGN was 180 mm long, a valgus angle of 4° and a single hole for the distal locking. The Gamma3 Nail is 180 mm long with a conical nail tip. The proximal diameter is 15.5 mm, it has a valgus angle of 4°, and the diameter of proximal hole for the introduction of the lag screw is 10.5 mm. The configuration of the lag screw has been changed: The thread provides a less invasive and more mechanical seal, and tapered shape makes it easier for its installation. A range of three different neck-shaft angles (120°, 125° and 130°) are available for the lag screw entry, according to the contralateral neck-shaft angle. The lag screw is secured with a small screw, named the self-retaining set screw, that allows the lag screw to slide but not rotate. The hole for the distal locking screw is oblong and thus allows to execute a static and dynamic blocking according to the fracture pattern and the diameter decreased from 6.28 to 5 mm. Furthermore, the evolution of the target device allows an easier nail introduction and the ability to use a minimally invasive technique with a proximal incision of 2.5–3 cm.

This study puts in comparison the three different models of Gamma Nail (SGN, TGN, Gamma3 Nail), assessing the percentage of consolidation and intra-operative and post-operative complications to verify whether the changes applied to the GNS have introduced any improvement in the results. These improvements associated with a correct surgical technique reduced the postoperative orthopedic complications [14–18].

Materials and methods

The present study is a retrospective analysis of 2144 patients treated with GNS at our department between January 1997 and December 2011. Patients with poly-trauma and pathological fractures were excluded from our study. Three different generations of CM nailing including SGN, TGN and Gamma3 were applied in this study to treat trochanteric or subtrochanteric fractures according to the availability of the system at the time of treatment.

The patients were divided into three groups according to the nailing system: 525 were treated with SGN (24.49 %), 422 with TGN (19.68 %) and 1197 with Gamma3 Nail (55.83 %). The mean age of the patients was 80 years (range 32–96) for SGN group, 83 years (range 65–93) for TGN group and 82 years (range 24–104) for Gamma3 Nail (p value 0.386 with ANOVA test). Through the study group, 72.62 % (1557 patients) were female. Standard anteroposterior (AP) and lateral view radiographs of the hip were performed for all patients at the time of admission, and fractures were classified according to AO classification method. More than 90 % of the fractures were classified as 31A1 and 31A2 (Table 1).

All the patients were operated with a traction table; general and spinal anesthesia were equally common. A closed reduction, as anatomical as possible, was performed under fluoroscopy control before surgery. Flexible reamers were used to ream the femoral shaft 1.5–2 mm more than the diameter of the nail so as to facilitate the insertion of the nail and avoiding or reducing the intra-operative fractures. Osteosynthesis was performed using the CM nailing systems available at the time of surgery by a skilled surgeon, or by a resident under the supervision of the skilled surgeon, according to the standard technique. All nails were locked distally with one locking screw using the targeting device.

The postoperative rehabilitation protocol consisted of 2 days of bed rest and passive mobilization, followed by ambulation with immediate weight bearing, when permitted by the general conditions of patient and the quality of fracture reduction. Standard AP and lateral radiographs were performed postoperatively and at follow-up. The intra- and postoperative orthopedic complications were identified reviewing the surgical reports, the radiographs and the follow-up visit reports.

The intra-operative complications included intra-operative fracture, non-satisfactory fracture reduction (Fig. 1), self-retaining set screw into the soft tissue, multiple distal drilling, rupture of 3-mm ball-tipped guide wire and intra-articular protrusion of the lag screw.

Some patients (1122 patients, 52.33 %) were excluded from the postoperative complication study because of insufficient follow-up (<3 months); however, they remained included in the intra-operative complication study.

The postoperative complications were the lag screw cutout (Fig. 2), nail breakage (Fig. 3), femoral fracture, non-union, osteonecrosis (ON), surgical wound hematoma, subcutaneous lag screw protrusion, intra-articular lag screw protrusion and the lag screw exposure.

Table 1 Type of fractures according to the AO classification

	Count	%
31A1	941	43.9
31A2	1046	48.8
31A3	93	4.3
31B1	6	0.3
31B2	21	1
Missing	37	1.7
Total	2144	100

Fig. 1 A case of non-satisfactory fracture reduction

Fig. 3 A case of nail breakage

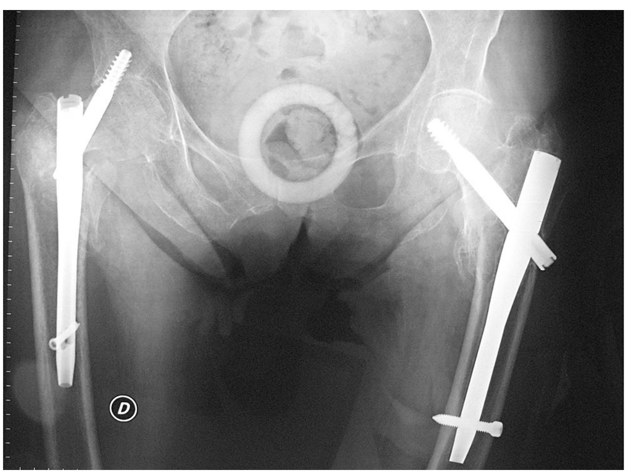

Fig. 2 A case of lag screw's cutout (40 days after surgical act)

The "cutout" consists of the extrusion of the lag screw from the femoral head by more than 1 mm as a consequence of the collapse of the neck-shaft angle into varus [19]. Different types of cutout were observed, according to the primary position of the lag screw, the migration and the approximate penetration point in the femoral head [20, 21]. In the article [22] is described this type of divisione of the femorale head to describe the correct position of the lag screw on the sagittal plane: The femoral head was divided into four zones on the AP view and three zones on the lateral view [22]. Inferiorly in the AP plane and centrally in the axial plane are considered the best positions of the lag screw [23–26]. An additional measurement was to assess the position of the lag screw by means of tip–apex distance (TAD) which represents both the position and depth of a screw in t he femoral neck and head [27]. The TAD is a sum of the distance, in millimeters, from the tip of the lag screw to the apex of the femoral head, measured on AP and lateral X-ray view; a TAD more than 25 mm [27, 28] / 30 mm [23] was demonstrated to be an important factor for cutout in stable and unstable fractures [19, 21, 28, 29]. The "varus consolidation" or "varus malunion" is defined the neck-shaft angle is more than 10° of varus relative to the contralateral side [30]. "Non-union" is considered as no sign of bone healing and callus formation with consistent pain 6 months postoperatively. The osteonecrosis occurs in 0.5–1 % of the cases; it is a painful hip condition associated with limitation of range of hip motion and radiologic signs of collapse of femoral head [31]. In addition, results which were derived from the ancient generations of SGN were separately compared with the results of the patients treated with Gamma3 Nail, using Fisher's exact test.

Results

Intra-operative complications

Of all 2144 patients of our study, 525 were treated with SGN (24.49 %), 422 with TGN (19.68 %) and 1197 with Gamma3 Nail (55.83 %).

Table 2 Number of intra-operative complications

Intra-operative complications	All	SGN (525)	TGN (422)	Gamma3 (1197)
Femoral fracture	2	2		
Non-satisfactory reduction	8	3	2	3
Distal locking screw outside	7	3		4
Loss of self-retaining set screw	3			3
Multiple distal drilling (diameter 4.2 mm)	4			4
Rupture of 3-mm ball-tipped guide wire	1	1		
Intra-articular protrusion of the lag screw	1			1

Table 3 Treatment of the intra-operative complications

Treatment intra-operative complications	SGN (525 patients)	TGN (422 patients)	Gamma3 Nail (1197 patients)
Femoral fracture	2 1 Gamma long nail 1 Non-weight bearing	/	/
Non-satisfactory reduction	3 2 Partial weight bearing 1 Shorter lag screw	2 1 Revision with TGN Nail 1 Shorter lag screw	3 1 Revision with Gamma3 Nail 2 Lost to follow-up
Distal locking screw outside	3 3 Revision of the screw	/	4 4 Revision of the screw
Multiple distal drilling (diameter 4.2 mm)	/	/	4 4 Partial weight bearing
Loss of self-retaining set screw	/	/	3 3 Screw removal
Intra-articular protrusion of the lag screw	/	/	1 Asymptomatic
Rupture of 3-mm ball-tipped guide wire	1 Asymptomatic	/	/

The intra-operative complications for each group are given in Table 2.

The overall incidence of intra-operative complications was 1.21 %, in particular: 1.71 % (9 of 525 patients) for SGN group, 0.47 % (2 of 422 patients) for TGN group and 1.25 % (15 of 1197 patients) for the group treated with Gamma3 Nail: SGN versus Gamma3 $p = 0.5045$ and TGN versus Gamma3 $p = 0.2664$: Both are not statistically significant.

The treatment of the intra-operative complications is given in Table 3.

Postoperative complications

Of all 2144 patients of our study, only 1022 had a sufficient follow-up: 205 patients with SGN (20.06 %), 131 with TGN (12.82 %) and 686 with Gamma3 (67.12 %). A total of 1122 patients were excluded: 876 patients were completely lost to the follow-up and 246 patients were evaluated only once after discharge, approximately 35–40 days after surgery.

The mean follow-up of this study is 4 months (range 3–48 months).

The postoperative complications for each group are compared in Table 4.

The overall incidence of postoperative complications was 5.48 % (56 of 1022 patients), in particular: 10.73 % (22 of 205 patients) for SGN group, 9.92 % (13 of 131 patients) for TGN group and 2.92 % (20 of 686 patients) for Gamma3 Nail group.

According to the Fisher exact test, the p value for SGN versus Gamma3 is 0.0001 and the p value for TGN versus Gamma3 Nail is 0.0015: both considered extremely statistically significant.

The treatment of the postoperative complications is given in Table 5.

According to the literature, one of the most common complications of the nail systems is the lag screw cutout [20, 21, 27]. In our study, it represents the most frequent complication; the total incidence was 1.86 % (19 cases of 1022). All cases of cutout were evaluated: In eight cases, TAD was >25 mm; in five cases, the lag screw had a

Table 4 Number of postoperative complications for each group

Postoperative complications	All	SGN	TGN	Gamma3
Surgical wound hematoma	3	3		
Fractures (under the nail)	11	3	3	5
Non-union	4	1	1	2
Lag screw cutout	19	6	6	7
Nail breakage	2	1		1
Osteonecrosis (AVN)	2		1	1
Lag screw protrusion into soft tissue	8	7		1
Intra-articular lag screw protrusion	5	1	1	3
Lag screw exposure through skin decubitus	1		1	

Table 5 Treatment of the postoperative complications

Treatment postoperative complications	SGN (205 patients)	TGN (131 patients)	Gamma3 Nail (686 patients)
Cutout	6* (*shown in Table 6)	6* (*shown in Table 6)	7* (*shown in the Table 6)
Femoral fracture	3 3 Gamma long nail	3 3 Gamma long nail	5 4 Gamma long nail 1 Plate and screws
Nail breakage	1 (*non-union fracture healed after nail breakage)	/	1 (*non-union fracture: nail removal + plate and screws)
Lag screw protrusion into soft tissue	7 4 Asymptomatic 3 Revision with a smaller screw	/	1 Asymptomatic
Lag screw through the joint line	1 Asymptomatic	1 Asymptomatic	3 2 Hemiarthroplasty 1 Total hip arthroplasty
Non-union	1 (*associated with nail breakage)	1 1 Dynamization of the distal screw	2 1 Hemiarthroplasty (*associated with nail breakage)
Osteonecrosis (ON)	/	1 1 Hemiarthroplasty	1 1 Hemiarthroplasty
Lag screw exposure through skin decubitus	/	1 Nail removal + antibiotics	/
Surgical wound hematoma	3 3 Hematoma drained	/	/

central-superior position in the anteroposterior view; and in six cases, the lag screw was anterior in the lateral view. It was observed in six cases of SGN group (2.92 %), in six cases of TGN group (4.58 %), and in seven cases of Gamma3 group (1.02 %): p value for SGN versus Gamma3 Nail is 0.0893: not statistically significant; p value for TGN versus Gamma3 Nail is 0.0114: statistically significant.

The average time of screw cutout is 10 weeks (range 40 days to 22 weeks). In ten cases, the lag screw migrated anteriorly superiorly, in seven cases migrated posteriorly superiorly, and central cutout (along the lag screw axis) occurred in two patients. Table 6 summarizes the treatment of the lag screws cutout.

Of the 205 patients treated with SGN, fracture healing was achieved in 196 cases, without need for any further intervention; of the nine patients treated, six patients maintained the original nail and changed the cephalic lag screw. Of the 131 patients treated with TGN, fracture healing was achieved in 122 cases without any further intervention; of nine patients treated, five patients maintained the original nail and changed the cephalic lag screw. Of the 686 patients treated with Gamma3 Nail, fracture

Table 6 Treatment of the lag screws cutout

Treatment	SGN	TGN	Gamma3
No treatment (varus malunion)	4	2	3
Nail removal + hemiarthroplasty	2	3	2[a]
Nail removal + hip arthroplasty			1[b]
Lag screw removal		1	1

[a] In one case, there was a hemiarthroplasty dislocation, so total hip arthroplasty was implanted

[b] During the surgery, a periprosthetic fracture occurred and it was treated with a revision femoral stem and cerclages

Table 7 Fracture healing without need for any further intervention

Nail	Fracture healing	%
SGN	196 of 205	95.60
TGN	122 of 131	93.12
Gamma3	673 of 686	98.10

healing was achieved in 677 cases without any further intervention; of the patients treated, four patients maintained the original nail changing the cephalic lag screw.

Therefore, considering only the surgical act required for an improper surgical technique (the lag screw cutout, painful subcutaneous lag screw protrusion), and considering "healed" only the fracture consolidated with the original nail without any further intervention, the number and percentage of healed fractures at the last follow-up (mean follow-up 4 months) are shown in Table 7.

Discussion and conclusion

A proximal femoral fracture is the most common reason for admission to an orthopedic ward. The primary goals of treatments are to achieve faster assisted ambulation and to reduce hospitalization and morbidity. The factors with the greatest impact on the treatment efficacy are the timely reduction and fixation of the fracture, the type of fixation device used, and early postoperative mobilization and full weight bearing [32, 33].

The dynamic/sliding hip screw and the cephalomedullary nail are currently the most acceptable fixation methods to treat trochanteric fractures [9–13, 20]. In the literature, most of the studies describe the different types of CM or compare the use of CM with the extramedullary device (SHS) used for the treatment of trochanteric fractures, or describe the results of the older generation of nail of the GNS [34–38].

The causes of fixation failure of a CM may be multifactorial: patient's age and bone quality, comorbidity, type of fracture, quality of fracture reduction and surgical technique, in particular the position and the size of the lag screw [20, 21, 24, 39].

The most common complication of GNS is the lag screw cutout [19–21, 28, 29]. Several studies have shown that the incidence of cutout for different sliding hip screws and intra-medullary nails ranges from 0 to 16.5 % in the recent studies, while in older ones it ranges from 17.5 to 20 % [40–48]. An unstable and complex fracture pattern, non-anatomical reduction and non-optimal position of the lag screw were considered critical factors for the cutout complication, and their combination was strongly predictive [21]. The optimal position of the lag screw has been widely discussed in the literature: A central-posterior placement of the lag screw in the lateral radiographic view and a central-inferior position in the anteroposterior radiographic view are recommended by most authors because they maximize the biomechanical stiffness and load to failure of the fixation [19, 21, 24, 28, 29]. The low percentage of cutout registered in our study, 1.85 % (19 cases of 1022), probably depends on the surgeon experience; the intra-medullary nails were implanted by a skilled surgeon or by a resident under the supervision of the skilled surgeon according to standard technique. Therefore, we think that the lower rate of cutout, especially with the Gamma3 Nail, is related to the improvement in the lag screw design, with a very low insertion torque and an excellent grip in the cancellous bone [20].

The other complications are the delayed union/non-union, the varus malunion and the nail breakage. The varus malunion, when the neck-shaft angles are more than 10° of varus relative to the contralateral side, contributes to implant failure and causes deficit in gait with compromised abductor strength, so it is correlated with poor functional outcomes [30]. The nail breakage has become rare due to the material strength and mechanical advantage [49]. The most common cause of breakage is metal fatigue caused by excessive dynamic stress in delayed union or non-union fractures or the shortening of the end of the lag screw outside the lateral femur resulting in a longer lever arm [50, 51]. The critical zone is around the insertion hole for the lag screw where forces come from the femoral neck to the diaphyseal nail [49]. In our study, only two cases of nail breakage occurred (one of TGN group and one of Gamma3 Nail); both of them were associated with non-union fracture.

Another complication is the femoral shaft fracture: The incidence has reduced in the Gamma3 Nail compared with SGN and TGN; many studies show higher numbers of femoral shaft fracture for the ancient version of Gamma Nail, up to 17 % for SGN [52–54], up to 4. 5 % for TGN [16, 38, 39, 43, 47] and <1 % for Gamma3 Nail [55, 56]. This trend is due to the design modification, such as the length, the valgus curvature and the distal diameter [16, 57–60]. In our study, there were four cases of multiple distal drilling of lateral cortex for the introduction of the distal screw which weakened the lateral cortex and increase the risk for this condition. We believe that the target device needs to be replaced or repaired after 30–40 surgical acts.

This study puts in comparison the three different models of Gamma Nail (SGN, TGN and Gamma3 Nail), assessing the percentage of consolidation and intra-operative and postoperative complications to verify whether the changes applied to the GNS have introduced any improvement in the results.

We believe that the results of this retrospective study show that the Gamma Nailing System is a safe device with a low rate of intra-operative complications. According to the achieved results, the evolution of this nail system reduces the postoperative complications, thus improving the results at follow-up and confirming that the Gamma3 Nail is a safe and predictable device to fix the trochanteric fracture.

Compliance with ethical standards

Conflict of interest The authors do not have any conflict of interest.

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