Lo SCALPELLO (2021) 35:151-156
doi number: 10.36149/0390-5276-220

Positioning a navigation-guided cephalic screw standard gamma 3 nail in intertrochanteric fractures: preliminary experience

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Summary

Objective. Hip fractures in elderly people occur in up to 18% of women and 6% of men, with almost 50% located at lateral proximal femur. Surgical treatment prevents complications secondary to immobilization. Intramedullary fixation has the advantages of reduced blood loss and shorter surgical time. The rate of complications rate is around 20%, represented by screw jamming, refractures, implant breakage, or its medial migration, although the most common is cut-out. As a general consensus, a tip-apex-distance (TAD) of > 25 mm and incorrect cephalic screw position are predictive factors of cut-out.
Methods. The aim of this study is to evaluate the incidence of cut-out in patients treated with intramedullary nail fixation associated with a computer-guided system to place the cephalic screw. We present a small case series of 10 patients.
Results. Interventions were performed heterogeneously by different surgeons. Mean TAD was 13.3 mm. Positioning resulted on average 2 mm lower and 1 mm anterior than planned by the system. At a mean follow-up time of 6.5 months, there were no cut-outs.
Conclusions. Further studies with longer follow-up are needed, but preliminary results showed that a navigation system for cephalic screw positioning can be helpful in intramedullary fixation of proximal lateral femur fractures to prevent cut-out.

Key words: hip fractures, cut-out, tip-apex distance, cephalic screw positioning, navigation system

Received: August 19, 2021
Accepted: December 14, 2021

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How to cite this article: Lana D, Mobilia G, Ortolani A, et al. Positioning a navigation-guided cephalic screw standard gamma 3 nail in intertrochanteric fractures: preliminary experience. Lo Scalpello Journal 2021;35:151-156. https://doi.org/10.36149/0390-5276-220

Introduction

Hip fractures are the most common fractures in elderly patients affected by osteoporosis, and are increasing with the increasing aging of the population in the last few decades, with an incidence of around 18% in women and 6% in men [1]. In particular, lateral fractures of the proximal femur reach about 50% of all hip fractures [2].
Treatment of inter- and pertrochanteric fractures is surgical, except for patients who are not eligible to undergo surgery due to severe comorbidities. The aim of surgical treatment is to prevent complications secondary to prolonged immobilization through immediate weight bearing and speedy recovery using stable fixation.

The main treatment of osteosynthesis involves the use of intramedullary or extramedullary implants.
Recent studies recommend that intramedullary nail should be preferred to extramedullary fixation systems, which allow good fracture reduction but at the same time require opening of the fracture with higher blood loss, higher risk of infection, and pseudarthrosis. On the other hand, the use of an intramedullary nail is associated with shorter surgical time, less blood loss, and early weight bearing, which allows faster healing time [3,4].
Nowadays, intramedullary nail is the gold standard for lateral proximal femur fractures [5]. Prospective studies have also highlighted its superiority in terms of reducing the rate of intra and post-operative complications (especially cut-out and refracture) compared to previous systems [6].
Over the years several fixation systems have been introduced. The Gamma Nail entered clinical use in 1988 for the treatment of trochanteric hip fractures; at present, Gamma Nail (Stryker trauma Gmbh Schönkirchen, Germany), which has reached now its third generation of development, is widespread with more than one million patients treated since the introduction of the implant [6]. However, even the new designs are not free from complications, which occur in about 20% of cases [7]. The principal mechanical complications are represented by screw jamming, refractures, nail breakage, and medial implant migration, but the most common is still cut-out which complicates about 1.5% of cases resulting in outwarding of the cephalic screw from the femoral head [8,9].
The tip-to-apex distance (TAD) index and screw position are the main factors that must be considered to avoid cut-out.
According to the most recent literature, the measurement of the TAD (the sum of the distance between the proximal edge of the femoral head and the apex of the cephalic screw, acquired through intra-operative radiographs in AP and lateral views) represents the most reliable parameter in predicting the risk of cut-out, together with the correct position of the screw in the center of the femoral neck; several studies have reported that TAD values < 25 mm are associated with a reduced risk of cut-out (Fig. 1A); various authors have shown that a distance > 25 mm is a strong predictor of cut-out [10,11]. Other authors have also reported a higher percentage of cut-out when the screw was placed superiorly and posteriorly [12].
The TAD can be calculated intraoperatively by measuring the distance from the tip of the guide-pin to the apex of the femoral head in antero-posterior (AP) and lateral fluoroscopic images [12]. (Fig. 1B)
The position of pin can be evaluated intraoperatively through a lateral view obtained with a brilliance widener, subdividing the head of the femur in nine sections according to the method of Cleveland [13](Fig. 2).
Recently, a new reference point for determining the apex has been advocated: calcar-referred tip-to-apex distance (calTAD) in which the femoral head apex is referenced to the femoral calcar and not the center of the neck [14].

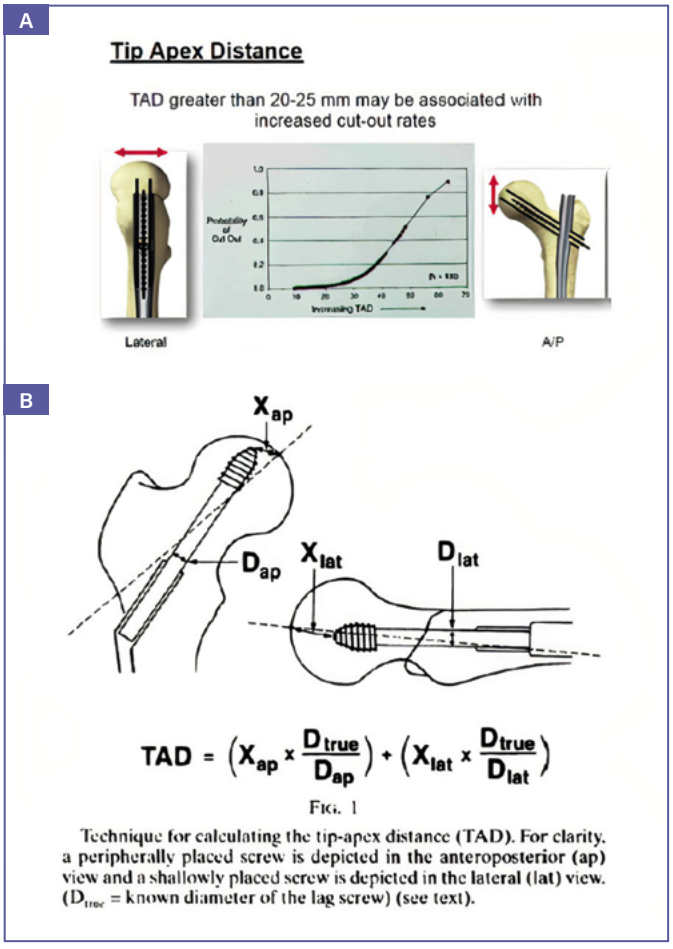

FIG. 1
Technique for calculating the tip-apex distance (TAD). For clarity, a peripherally placed screw is depicted in the anteroposterior (ap) view and a shallowly placed screw is depicted in the lateral (lat) view. (D_{true} = known diameter of the lag screw) (see text).

Figure 1. Image illustrating how to calculate Tip-to-Apex-Distance and its correlation with cut-out incidence.

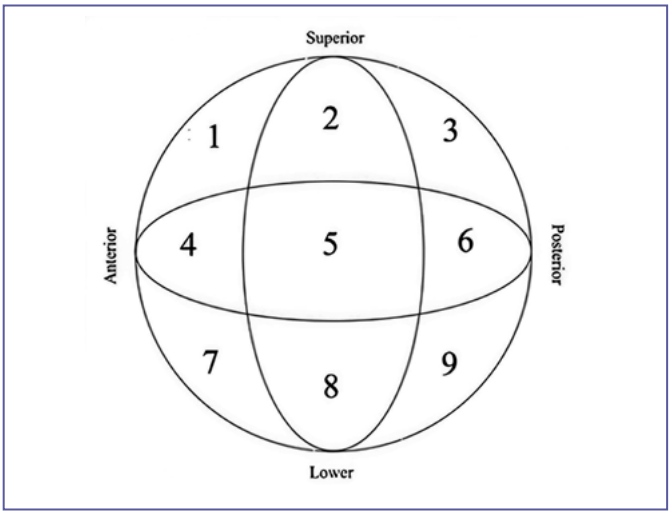

Figure 2. Schematic subdivision of femoral head according to the method proposed by Cleveland.

Materials and methods

The aim of the present study is to evaluate the effectiveness of a standard fixation system using a Gamma3 medullary nail for lateral proximal femur fractures associated with a navigated system to guide the surgeon in correct positioning of the cephalic screw, and thus reduce the risk of failures. This study was approved by the Ethics Committee "Area Vasta Emilia Centro" (CE-AVEC) of the Medical University of Bologna.

Surgical technique

The new ADAPT navigation system proposed by Stryker is a software-based instrumentation designed to assist the surgeon in correct alignment, length determination, and cephalic screw positioning, thus providing information needed to locate the planned correct nail position.

The system allows the surgeon to visualize, adjust, and refine the TAD intraoperatively via software measurements and ensure the accuracy demanded.

With the aid of augmented reality, the system projects 3D measurements on the patient's radiographs, obtained in the operating room with an image intensifier, by the simple addition of a mask connected to the nail introduction system, in constant communication with a further support hooked to the image intensifier. This allows spatial identification in real time of the position of the proximal femoral epiphysis and of the nail, and guides the surgeon in the insertion and correct positioning on both AP and axial views of the cephalic screw. It directly provides the measurement in mm of how much the current positioning of the screw differs from that planned by the system on the basis of the calculated optimal TAD Index (Fig. 3). The ADAPT tablet can be covered with a tarp for use in the sterile operating field and has a wheeled stand that can be accommodated in the position preferred by the surgeon. Once completely charged, the tablet requires only one cable to connect to the arc to C, eliminating the presence of additional cables on the floor of the operative room. The touchscreen allows intraoperative adjustments, including adjustment of the femoral head contour (Fig. 3).

The system offers additional guidance for distal locking screw in long nails.

Each phase of the surgical procedure was documented by providing a surgical report of the single case treated with all relevant intraoperative measurements and images that can offer a better flow of information in the postoperative phase (Fig. 4).

This system was designed to reduce the high complication rate of cut-out, the most frequent among the mechanical complications of intramedullary nail osteosynthesis, which results in outwarding of the cephalic screw from the proximal edge of the femoral head with consequent joint irritation, pain, functional impairment, and need for further intervention.

Additional aims were to reduce radiation exposure and surgical time.

Figure 3. By the simple addition of a mask connected to the nail introduction system, in constant communication with a further support hooked to the image intensifier, the system allows to spatial identification of real time position of the proximal femoral epiphysis and of the nail, guiding the surgeon in the insertion and correct positioning both on AP and axial views of the cephalic screw directly providing the measurement in mm of how much the current positioning of the screw differs from that planned by the system on the basis of the calculated optimal TAD Index.

Kuhl and Beimel demonstrated a mean TAD value reduction and less TAD variability in addition to a significant reduction of radiation exposure (mean reduction 12.6 seconds) and surgical times (mean reduction time 4 minutes) using this novel computer assisted surgery system [15].

We present a short case series of the first 10 patients treated from October 2020 to January 2021 at our Operative Unit in Carlo Alberto Pizzardi Maggiore Hospital in Bologna.

TAD and calcar-referred TAD (CalTAD) were measured on immediate postoperative radiographs through the help of a house picture archiving and communication system (PACS) tool. Fracture callus healing and appearance of cut-out were evaluated on follow-up radiographs.

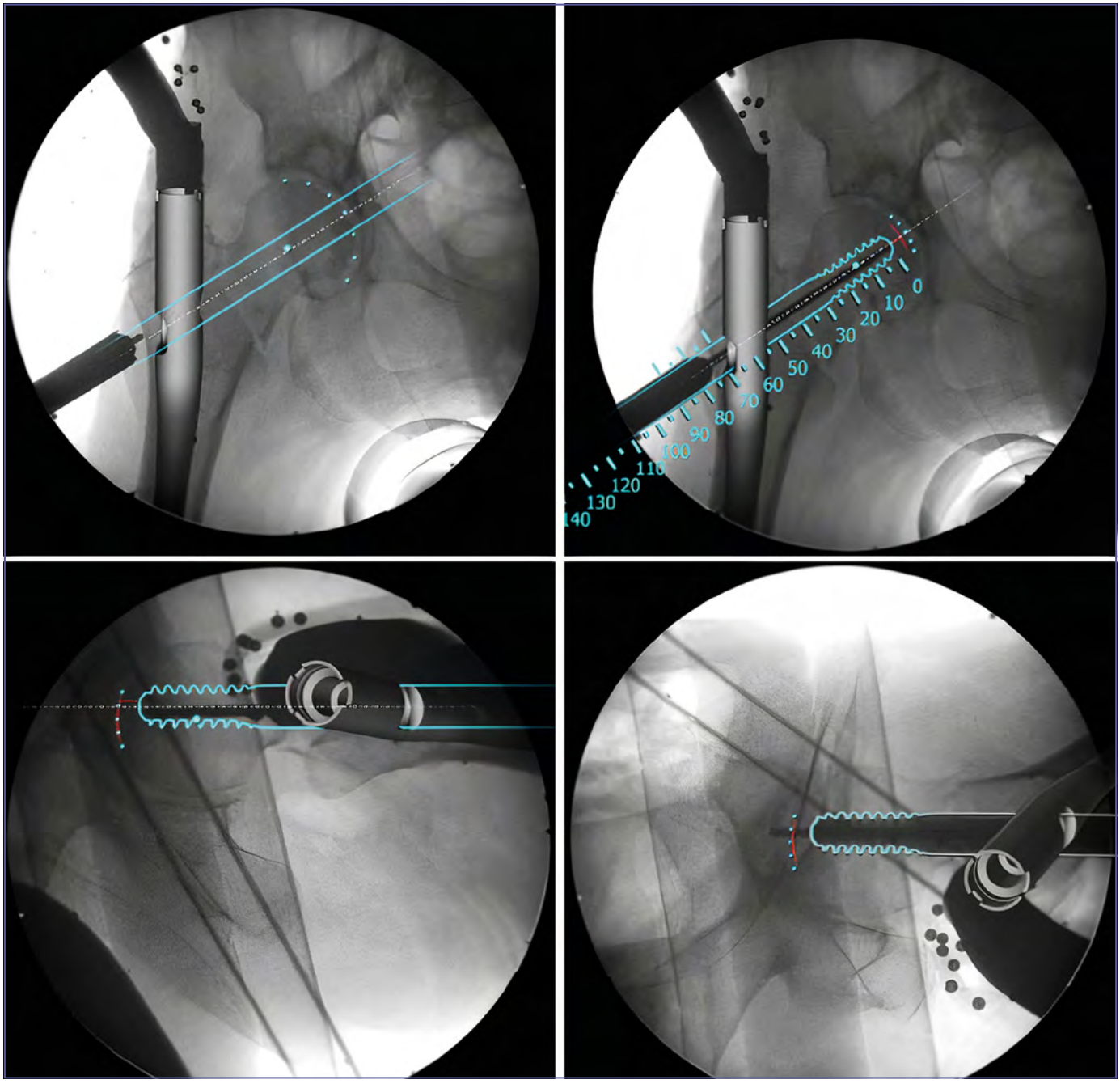

Figure 4. AP and axial views showing real time position of the nail and expected cephalic screw position, directly providing the measurement in mm of how much the current positioning of the screw differs from that planned by the system on the basis of the calculated optimal TAD Index.

Results

The mean age of the first 10 cases treated was 82 years. Nine patients were female, and the left and right side were equally involved. The fractures were classified according to AO Classification (Tab. I). In 9 of 10 cases, a short intramedullary nail (180 mm) was implanted, and in one case a long nail (360 mm). The interventions were performed heterogeneously by 8 different surgeons. The average TAD value obtained was 13.3 mm. Positioning was on average 2 mm lower in the AP view than that planned by the system, while 1 mm anterior in axial projection.

Table I. Preliminary results on ten patients treated with computer-assisted cephalic screw position associated to Gamma3 Nail osteosynthesis.

Patient ID	Age	Sex	Date of surgery	Side	Fracture type	Nail type	LAG screw position AP	LAG screw position Ax	TAD mm	CalTAD mm	Total shots	ADAPT shots	Time of application min	Follow-up months	Cut-out
1	79	M	16/10/2020	Left	31A2.1	180 125°	3 mm sup	2 mm post	12.23	17.6	37	22	38	11	NO
2	80	F	20/10/2020	Left	31A3.2	180 125°	1 mm sup	2 mm post	10.72	18.4	24	22	19	8	NO
3	87	F	26/10/2020	Left	31A2.1	180 125°	2 mm inf	1 mm ant	11.3	18.5	30	24	23	8.5	NO
4	78	F	27/10/2020	Right	31A3.1	360 125°	3 mm sup	4 mm ant	14.32	19.5	52	33	43	2	NO
5	87	F	03/11/2020	Left	31A2.1	180 125°	3 mm sup	1 mm ant	15.1	21.1	58	51	29	9	NO
6	90	F	13/11/2020	Left	31A1.2	180 125°	8 mm inf	3 mm ant	15.85	12.8	35	30	23	NA	NO
7	79	F	09/01/2021	Right	31A1.1	180 125°	2 mm inf	1 mm ant	8.42	16.9	33	17	28	NA	NO
8	81	F	19/01/2021	Right	31A1.1	180 125°	2 mm sup	1 mm ant	10.61	15.2	70	29	31	5	NO
9	78	F	21/01/2021	Right	31A1.2	180 125°	8 mm inf	3 mm ant	19.1	25.9	64	28	52	2	NO
10	79	F	21/01/2021	Right	31A1.2	180 125°	7 mm inf	4 mm ant	15.31	23.2	70	40	45	5.5	NO
Mean	82						2 mm inf	1 mm ant	13.3	18.9	47	29	33	6.5	

Legenda: NA: Not applicable; AP: antero-posterior; Ax: Axial; TAD: Tip-to-Apex-Distance; CalTAd: Calcar Tip-to-Apex-Distance; sup: superior; inf: inferior; post: posterior; ant: anterior.

The mean CalTAD value measured on post-operative radiographs was 18.9 mm.

On average, 47 shots were needed (24-70), of which 29 (17-51) were successful with the ADAPT system and an average of 18 failed shots (2-41). The mean application time of the system was 32 minutes for Gamma3 short nail (19-52 minutes) and in the case of Gamma3 long nail it was 43 minutes (Tab. I).

In two cases, follow-up evaluation was not available. At a mean follow-up of 6.5 months (2-11 months), none of the 8 patients evaluated presented signs of cut-out at radiographic images and all cases demonstrated fracture healing.

Discussion

The prevalence of cut-out complications in our series was of 0% (0 cases) in line with other recent larger series. In the past, the incidence of cut-out with different compression hip screws and intramedullary nails reached values up to 20% [16]. Cut-out is considered a multifactorial event that can be affected by different variables such age, bone quality, fracture pattern, quality of reduction, cephalic screw position and length, and implant design [10].There is no clear consensus on either the relationships between all these factors or on the relative importance of each.

The optimal position of the lag screw has been widely discussed in the literature, particularly the aspect of central or inferior placement of the screw in the femoral head as seen on the AP view [17,18-20]. In the literature there is wide consensus about the central position of the screw in a lateral view, although it is still not possible to define the ideal position on the AP view with two main ideas supporting this thesis: the deep central placement and the inferior placement [10,11-19,21].

Kuzyk et al. described a biomechanical study in which inferior placement of a cephalic screw gave the highest axial and torsional stiffness; similar results were obtained by Goffin et al. in a finite elements study in which they suggested that inferior middle and inferior posterior placement should be preferred [20,22]. Even the technique of Gamma3 Nail detailed by Taglang suggested AP placement in the inferior part of the neck [6]. Some authors suggested that the inferior placement of the lag screw causes a TAD increase compared with the central placement. This increase is due to the fact that the lag screw is not directed towards the apex of the femoral head [21-23].

Our research has some limitations: the first is the limited number of patients treated and the short period of follow-up. Second, a potential limitation of our research concerns the cephalic screw position, which was estimated on two radiographic views and not on CT scans; however, these latter are not routinely necessary after surgery. Nevertheless, this is one of the first studies from a single Institution with a single implant.

Conclusions

Our results confirm that TAD index is an important predictor of cut-out. Our study, even if preliminary, showed that a navigation system can be helpful in cephalic screw positioning for surgeons performing intramedullary fixation of proximal lateral femur fractures to prevent cut-out. Nevertheless, this is only a preliminary evaluation and further studies with longer follow-up periods are needed.

Ethical consideration

All procedures described in the study involving human beings were implemented in compliance with the ethical rules established by the 1975 Helsinki Declaration and subsequent amendments. Informed consent was obtained from all patients included in the study.

Author contributions

The Authors collaborated equally to the work.

Acknowledgement

Thanks to Stryker company for providing data and digital materials, including technical illustrations.

Funding

None.

Conflict of interest

All Authors declare there are no conflict of interest or source of funding for this study.

Human and animal rights

For this type of retrospective analysis, the inclusion of any declaration relating to the studies carried out on humans and animals is not required.

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