

# A preliminary experience with a new intramedullary nail for trochanteric fractures

Pietro Maniscalco<sup>1</sup>, Fabrizio Quattrini<sup>1</sup>, Corrado Ciatti<sup>1</sup>, Valeria Burgio, Fabrizio Rivera<sup>2</sup>, Giovanni Di Stefano<sup>3</sup>, Vito Pavone<sup>3</sup>

<sup>1</sup> Orthopedics and Traumatology Department, Guglielmo da Saliceto Hospital, Piacenza, Italy; <sup>2</sup> Orthopaedic Surgery Department, SS Annunziata Savigliano Hospital, Savigliano (CN), Italy; <sup>3</sup> Orthopedics and Traumatology Department, University of Catania, Italy

**Summary.** *Background and aim of the work:* The worldwide incidence of fractures of the proximal end of the femur is increasing as the average age of the population rises. The current surgical gold treatment standard is intramedullary nail fixation. The Authors present their experience with the D-Nail system for intertrochanteric femur fractures. *Methods:* From January 1st to February 21st 2020 (breakout of COVID-19 pandemic) 34 patients were treated with the D-Nail system: 11 with basicervical fractures, 16 with intertrochanteric stable fractures and 7 with intertrochanteric unstable fractures. In 11 cases, a single cephalic screw was used; in 23 cases, two of them were used. Distal locking was executed in 7 patients. Follow-up time ranged from 2 to 3 months. *Results:* None of the reported intra- or post-operative complication was linked to the fixation device or the surgical technique. Patients were monitored with clinical and radiological checkups using modified Harris Hip Score to accurately evaluate the fluctuations in the rehabilitation period. *Conclusion:* The main advantages of this synthesis device are the proximal hole's peculiar shape, which allows the possibility to position one or two cephalic screws on the same nail, and the silicon coating, which provides numerous biological advantages. Distal locking was executed in selected cases only, based on fracture type. Optimum treatment involves rapid execution of surgery, minimal trauma during surgery, maximum mechanical stability, and rapid weight-bearing. Although our case number is small and follow-up time brief, our results are encouraging. ([www.actabiomedica.it](http://www.actabiomedica.it))

**Key words:** Pertrochaneric fractures, Intramedullary nail, Silicon coating, D-Nail , COVID-19

## Introduction

Femoral fracture is the predominant reason for surgical procedure in the orthopaedic field (1). As the Italian population gets progressively older, we are witnessing a consequent increase in femoral fractures, to the extent that the current values are expected to triple as of 2050, constituting an ever-growing cause of mortality and morbidity (2,3). Proximal femur fractures are more common in the elderly populace because they are often due to accidental falls, while they can occur in younger people because of high-energy traumas

(i.e. traffic accidents) (4,5). Old-age-related issues like osteoporosis, malnutrition, scarce to no physical activities, neurological impairments, imbalance or asthenia elevate the risk of potential falling, thus increasing fracture risk (2,6,7).

The most important classifications of proximal femur fractures is that of the AO Foundation/Orthopaedic Trauma Association (AO/OTA) fracture classification (8) (Table 1).

To better describe fracture of the trochanteric region, we also have to use the Evans-Jensen classification (9), which divides fractures into two groups:

stable and unstable. Stable fractures are in turn split into undisplaced 2 part fractures (type IA) and displaced 2 part fractures (type IB). Unstable fractures are split into displaced 3 part fractures with posterolateral comminution (type IIA), displaced 3 part fractures with large posteromedial comminuted fragment (type IIB) and 4 part fractures (type III).

It has been demonstrated that, especially for an elderly patient with a precarious physical condition, it is crucial to swiftly intervene surgically (within 48 hours of the main trauma), thus allowing a quick functional recovery and minimising bedridden time (10-12). This way, the patient benefits with regard to both survival and quality of life, and it is also more cost-effective.

**Table 1.** AO Foundation/Orthopaedic Trauma Association (AO/OTA) fracture classification

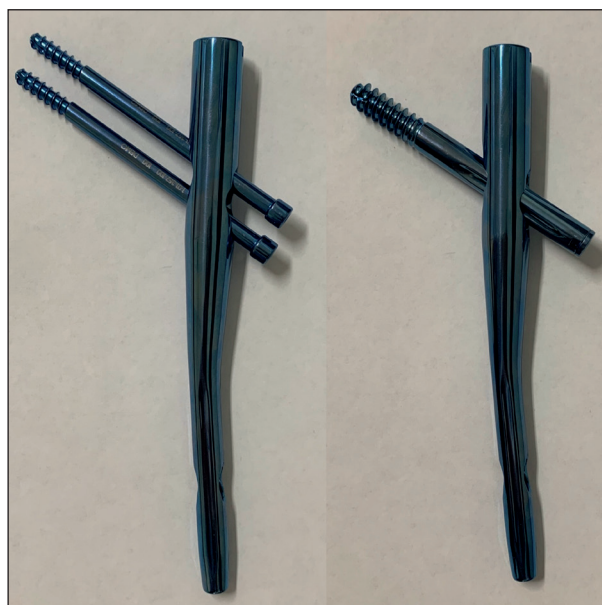
Trochanteric region fractures (31A):	
o	Simple pertrochanteric (31A1), subsequently divided into isolated single trochanter (31A1.1), 2-part (31A1.2), lateral wall intact (>20.5mm) (31A1.3)
o	Multifragmentary pertrochanteric lateral wall incompetent ( $\leq 20.5$ mm) (31A2), subsequently divided, provided each of them has 1 intermediate fragment (31A2.2) or 2 or more intermediate fragments (31A2.3)
o	Intertrochanteric reverse obliquity (31A3), subsequently divided into simple oblique (31A3.1), simple transverse (31A3.2) and wedge or multifragmentary (31A3.3)
Neck fractures (31B):	
o	Subcapital (31B1), subsequently divided into valgus impacted (31B1.1), non-displaced (31B1.2) and displaced (31B1.3)
o	Transcervical (31B2), subsequently divided into simple (31B2.1), multifragmentary (31B2.2) and shear 31B2.3)
o	Basicervical (31B3)
Head fractures (31C):	
o	Split (31C1), subsequently divided into avulsion of ligamentum teres (31C1.1), intrafoveal (31C1.2) and suprafoveal (31C1.3)
o	Depression (31C2), subsequently divided into chondral lesion (31C2.1), depression impaction (31C2.2) and split depression (31C2.3)

Currently, intramedullary nailing is the most employed synthesis method in this type of fracture (13,14). Over time, there has been an ongoing evolution of surgical techniques and tool collections, which have brought about a reduction in complication and mortality rates (15-17).

The authors present their experience with the D-Nail system for intertrochanteric femur fractures. This particular synthesis device differs from others currently on the market for two main reasons: it has a particular silicon coating, and it gives the possibility to place one or two cephalic screws on the same nail (Figure 1).

## Methods

We analyzed 34 lateral femoral fracture cases that were treated at the Orthopedics and Traumatology Department of the Guglielmo da Saliceto Hospital in Piacenza from January 1st to February 21st 2020. The series is comprised of 19 females (55.9%) and 15 males (44.1%), with an average age of  $78.1 \pm 7.9$  (range, 67–87) years, females averaging 78.5 years, males averaging 77.5 years. The fractures were basicervical in 11 cases, stable pertrochanteric in 16 cases and unstable pertrochanteric in 7 cases.

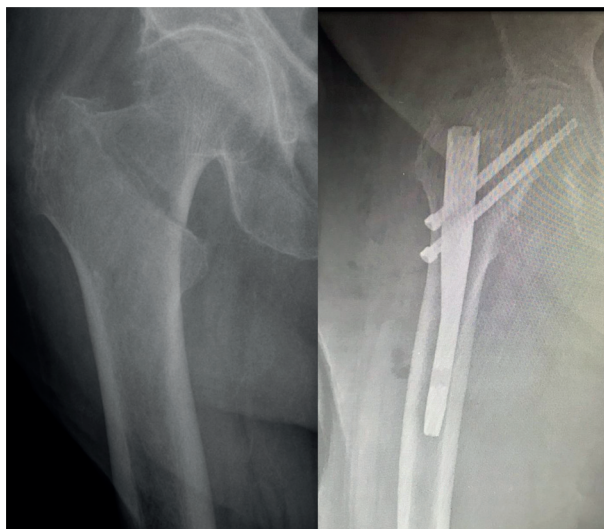


**Figure 1.** D Nail

Twenty-one patients (61.8%) were operated within 48 hours from the main trauma. For the other 13 patients (38.2%), we had to wait longer because of antiaggregating treatment (2 patients in treatment with Clopidogrel, 5.9% of total patients, 15.4% of delay) or anticoagulating treatment (18) (4 patients in treatment with Warfarin, 11.8% of total patients, 30.8% of delay; 1 patient with Acenocumarol, 2.9% of total patients, 7.7% of delay), trauma close to the weekend (4 cases, 11.8% of total patients, 30.8% of delay), and full operating room (2 cases, 5.9% of total patients, 15.4% of delay).

In all cases, the fracture was treated using D-Nail (Medgal Sp. Z o.o., Ksiezyo Polonia). This is a 170mm long, 130° wide intramedullary nail, made of silicon coating (Si-DLC) titanium alloy. Its main feature is its peculiar versatility, thanks to its three-circled hole situated in the proximal part, which can host a 10mm cephalic screw or two 6mm cephalic screws. Distal locking can be static or dynamic, depending on the screw's positioning inside of the single hole present on the nail's extremity.

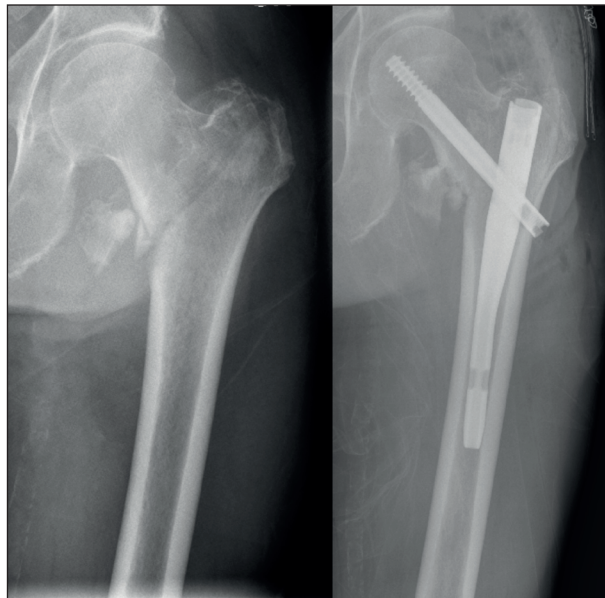
We locked the nail with two cephalic screws in the 11 basicervical fractures. In 23 cases, we used a lone cephalic screw to treat both stable and unstable pertrochanteric fractures. A distal locking screw was positioned in 7 pertrochanteric fractures, because of comminution of the great trochanter, presence of a large posterome-



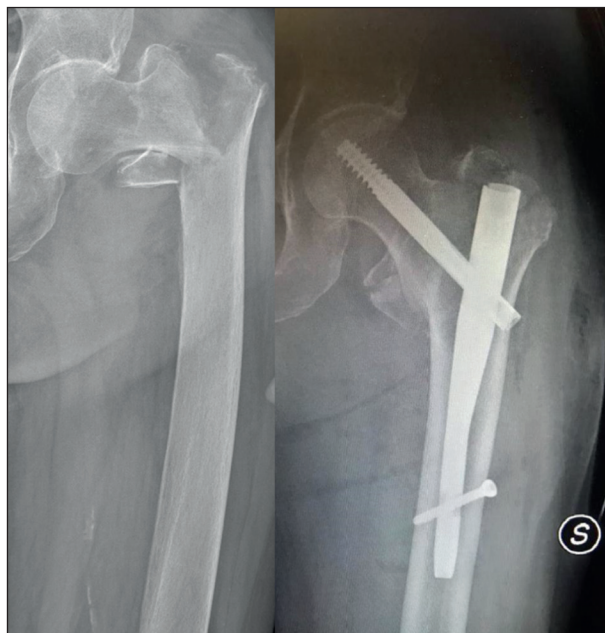
**Figure 2.** Basicervical fracture, two cephalic screws fixation without distal locking

dial fragment which crossed the small trochanter's line or wide intramedullary canal (Figures 2,3,4).

After surgery, all patients underwent x rays control and began their customized rehabilitation protocol. From the first day after surgery, muscle strengthening



**Figure 3.** Stable pertrochanteric fracture, one cephalic screw fixation without distal locking



**Figure 4.** Unstable pertrochanteric fracture, one cephalic screw fixation with distal locking



exercises and range of motion (ROM) recovery exercises were performed, both actively and passively. Starting from day two or three (depending on the patient's condition), full load and crutch walking were allowed.

Patients were clinically and radiological followed at 15, 30 and 60 days from surgery. Stitches were removed during the first post operative month. To monitor the evolution of post-operative rehabilitation, we calculated the modified Harris Hip Score (mHHS) for every patient during follow up .

## Results

Despite the limited number of cases and the absence of a complete follow-up, the initial results are very encouraging. None of the reported intra- or post-operative complication was linked to the fixation device or the surgical technique. Quali complicate? . Patients were monitored with clinical and radiological checkups, using the modified Harris Hip Score to evaluate the fluctuations in the rehabilitation period even more accurately. No patients in the cohort reported intraoperative complication. Mean surgery duration was 43.6 minutes (range, 35–53). Blood loss during surgery procedure was 130ml on average, so no drainage application was needed. All patients began rehab on the following day, starting with active/passive on the first day to an orthostatic state on the second/third day. In 6 cases, the patient needed a blood transfusion due to post-haemorrhagic anaemia. Mean post-operative hospitalization time was 6.8 days (range, 5 – 9). After their stay, 21 patients (61.8%) were transferred to a long-term hospitalization ward, while 13 patients (38.2%) went home. Due to the outbreak of the COVID-19 pandemic, the long-term hospitalization ward stopped the access, and consequently the patients who were still hospitalized in our department (9 patients, 26.5%) were sent home.

All patients arrived at their 15-day post-surgery follow up in a stretcher or a wheelchair. Wounds showed no signs of inflammation, and stitches were removed right away in all cases. Patients showed ROM improvement compared to the hospitalization period. No complications were found. The mean mHHS was 31.7 (range, 15 - 49).

At the 30-day post-surgery checkup, 26 patients (76.5%) were walking autonomously, although needing specific aids (elbow crutches), while 8 patients (23.5%) were not walking autonomously yet. Radiography showed that fractures were completely consolidated. Surgical wounds were all satisfactorily healed, with no signs of inflammation. Regarding joint functionality, 23 patients (67.6%) recovered a good amount of ROM, almost equalling pre-op values, while 11 patients (32.3%) had a worse ROM than before suffering the trauma. No complications were found. Mean mHHS was 45.8 (range, 37 - 57).

At the 60 days post-op checkup, 9 patients (26.4%) were walking without crutches, 2 of whom (5.8%) were walking aided by an elbow crutch or a walking stick. Radiographic images did not detect any significant variations since the latest checkup. Surgical wounds were free from inflammation. Joint functionality was good, with ROM equaling pre-trauma values in the majority of patients. Only 3 patients (8.8%) still have a slower recovery and struggled to obtain maximum degrees of movement. No complications were found. The mean mHHS was 67.2 (range, 59 - 89).

## Discussion

These fractures have a very high incidence in the elderly population, and they often result in negative consequences on these patients' daily activities: 20% of them completely lose motor autonomy, and only 30-40% of them manage to recover previous functionality (19).

Although the sliding hip screw and plate has been the gold standard for many years, intramedullary nailing is becoming the preferred solution for most orthopaedic surgeons (14).

The choice of putting our trust in this new type of osteosynthesis device was based on two factors: the nail's shape and the innovative material with which it is manufactured.

As to its shape, the main peculiarity is the proximal hole, comprised of three circles, to host a 10mm screw or two 6mm screws. This allows surgeons to decide whether to fixate the nail with one or two screws

even during the operation, so it is possible to edit pre-operative planning without needing intramedullary nail removal.

The Authors suggest the use of two screws in basicervical fractures: one in pertrochanteric stable without distal locking, one in pertrochanteric unstable with distal locking. In the case of subtrochanteric fractures, we prefer to use a long nail.

As to coating, the incorporation of other elements into the DLC matrix can provide important enhancement of the biological properties of the device (20,21,22) and can be applied for any orthopaedic implants that substitute bones (20). Specifically, silicon brings some important benefits: it reduces the surface energy of DLC, preventing bacterial adhesion and, as a result, reduces the chances of having a post-operative infection (23); it increases hemocompatibility (24-26) and biocompatibility (27-29), decreasing the risk of adverse tissue reactions (inflammation, irritation, allergy); it improves the interaction of DLC with bone cells, promoting adhesion and proliferation of osteoblasts (30) (increasing osteointegration and consequently the bone healing process); it corrects surface energy by favouring the attachment of endothelial cells (27); and finally, it's not cytotoxic (27).

We decided to employ distal locking in only 7 cases where there was lateral wall comminution, presence of a large posteromedial fragment which crossed the small trochanter's line, or the intramedullary canal was wide. The choice to proceed with distal locking only in these cases is in line with many articles in the scope of present literature (31-33).

By evaluating post-operative tendencies of patients operated with this method of synthesis, we can confirm the benefits of the nail's mechanical and biological characteristics; we observed that the fractures consolidated as soon as 30 days after surgery in all cases and that the intramedullary nail integrates perfectly. Moreover, no post-op complications, infections or inflammatory episodes were detected in the surgical wound. For the evaluation of the post-operative course, we used the modified Harris Hip Score, which proved useful in lateral femur fractures (34). Mean mHHS progressively increased, from 31.7 fifteen days after surgery, to 45.8 thirty days after surgery, and finally settling to 67.2 sixty days after surgery.

## Conclusions

The treatment of choice for osteosynthesis of fractures of the trochanteric region is the second generation of intramedullary nail. Based on the data in our possession, employment of the intramedullary D-Nail for lateral femoral fracture treatment is safe and reliable. We did not detect any post-operative complication in any of the examined cases. The analyzed timespan is brief, and it would be useful for this study to go further, to increase the number of properly analyzed cases and to extend clinical and radiological imaging follow-up. There could be an assessment of whether or not the silicon coating affects biological integration and mechanical nail sealing. Unique advantage of a intertrochanteric fixation by a 10mm screw or two 6mm screws offers to surgeon a better approach to different types of fractures. For this reason and thanks to encouraging primary results we believe that D-Nail can be considered a good solution for this type of fractures.

**Conflicts of interest:** Each author declares that he or she has no commercial associations (e.g. consultancies, stock ownership, equity interest, patent/licensing arrangement etc.) that might pose a conflict of interest in connection with the submitted article.

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Correspondence:

Prof. Pietro Maniscalco

Guglielmo da Saliceto Hospital

Via Taverna 49, Piacenza, Italy

E-mail: P.Maniscalco@ausl.pc.it