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# Is distal locking with short intramedullary nails necessary in stable pertrochanteric fractures? A prospective, multicentre, randomised study

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ABSTRACT

We investigated whether a proximal femoral nail can be implanted without a distal locking screw in AO/OTA 31-A1 and 31-A2 pertrochanteric stable femur fractures. A multicentre, randomised study was conducted in six level-two trauma centres in our area (Puglia, Italy). A total of 333 patients received their allocated intervention (162 in the locking group [LG] and 171 in the unlocking group [UG]) and 266 patients were included in the final analysis at 1 year. Our data showed no statistically significant difference between the two groups at 1-year follow-up for ability to walk, SF-36 questionnaire results, residual pain (visual analogue scale [VAS] score) and level of overall satisfaction. There were also no statistically significant differences between groups for mortality and length of hospital stay. Conversely, the UG was associated with shorter operation and fluoroscopy times, shorter surgical incision length, and less blood loss and residual thigh pain. Pertrochanteric stable fractures (31-A1, 31-A2) can be treated successfully with intramedullary nails without distal locking, reducing patient and clinical personnel radiation exposure and sanitary costs (surgery time and screws costs).



## Introduction

Osteoporosis represents a major public health problem because of the low-energy trauma and fragility fractures associated with this condition. Hip fractures have been recognised as the most serious consequence of osteoporosis because of the associated complications, which include chronic pain, disability, diminished quality of life, and premature death. Osteoporotic hip fractures are an established health problem in the West. With rising life expectancy across the globe, the number of elderly individuals is increasing in every geographical region, and it is estimated that the incidence of hip fractures will grow from 1.66 million in 1990–6.26 million by 2050 [1].

In Italy, there are 78,000 hip fractures related to osteoporosis every year, with 90% of these in patients aged over 65 years [2]. This is probably due to changing demographics and the continuous increase in life expectancy of the population and, therefore, the presence of a higher number of elderly patients [3].

Approximately 33,000 closed reduction and internal fixation and 19,000 hemiarthroplasties are performed every year in Italy in patients aged over 75 years. The cost of these procedures, added to the cost of total hip arthroplasties for femoral fractures, reaches 900 million Euros. Further costs, such as rehabilitation, home care, drugs and indirect costs for working days lost, increase the expected cost to 1800 million Euros [4].

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Both intramedullary and extramedullary implants are available for the reduction and fixation of pertrochanteric fractures; however, no gold standard has been defined. Recent studies show that the use of intramedullary nails is now more common than the use of extramedullary implants [5,6]. Intramedullary nails have shown some advantages, such as better recovery to pre-injury activity level, less blood loss, and fewer complications [7,8]. Furthermore, cephalomedullary nails may be beneficial in the treatment of unstable and subtrochanteric fractures [6,9].

A recent Cochrane Systematic Review assessed the superiority of the sliding hip screw compared with intramedullary nails for extracapsular hip fractures [10]. Internal fixation with an intramedullary system is also gaining popularity in this field.

In the United States and Europe, there has been a striking increase in the use of cephalomedullary nails, from 3% to 67% over the last 15 years, particularly among younger surgeons [5,11].

There are several types of intramedullary nails currently available; however, the limited evidence from randomised controlled trials has not shown any important differences between the varying designs of nails [10]. A nail-construct generally provides load-sharing properties while enabling immediate mobilisation [12–14]. Intramedullary nails function as internal splints that enable, or even promote, secondary bone healing [15]. These devices are designed to bear most of the load initially, and then gradually transfer it to the bone as fracture healing progresses. The load-bearing of any intramedullary nail largely depends on the fracture pattern and the reduction achieved. Reaming of the canal and distal locking enable the transmission of physiological loads to the proximal and distal ends of the nail through the screws. In the absence of interlocking screws, the implant transfers axial compaction motion along the longitudinal axis of the nail to the bone. If significant cortical contact can be attained, compressive loads will be largely supported by the bone cortices; however, if there is no cortical contact, all compressive loads will be transferred distally through the nail to the distal interlocking screws, which will resist fracture collapse and length loss until their fatigue failure or fracture healing occurs [15].

Distal locking screws were designed to improve axial and/or rotational stability; this also avoids the movement of the distal tip of the nail in cases where there is a wide canal and an undersized nail is introduced [16–18]. Few studies have looked at the utility of distal locking; in so-called stable intertrochanteric fractures, with cortical apposition, there is likely to be sufficient stability even without a distal-locking screw [19].

Various complications have been highlighted for distal locking of intramedullary nails, including loosening, breaking and subsequent peripheral injuries, and secondary femoral fractures. Increased operative time, X-ray exposure and potential stressor factors during drilling should also be taken into account [20–27]. As a result, some authors have reduced their indications for distal locking in trochanteric fractures [24–27] or they do not use it at all [12,27].

Intramedullary nailing is largely used at our institution and in this study we focused on the use of distal locking in stable fracture patterns. We performed a multicentre, randomised study to evaluate the role of distal locking of short intramedullary nails to fix stable pertrochanteric fractures (31-A1, 31-A2).

A total of 333 patients were randomly assigned to the locking group (LG; 162 patients) or the unlocking group (UG; 171 patients).

Intraoperative variables (blood loss, fluoroscopy time, surgery time) were recorded and compared between the two groups. Postoperative complications, time to union and clinical outcomes at a mean follow-up of 12 months were also investigated and compared.

Our hypothesis was that there were no differences in terms of clinical outcome and complications in stable intertrochanteric fractures treated with short locked and short unlocked cephalomedullary nails. In addition, unlocked nails were thought to be correlated with a shorter surgery time, and lower radiation exposure, blood loss and sanitary costs.

## Materials and methods

### *Ethics*

The study was approved by our regional ethics committee and our institutional board (N°BDFPSPIF). Informed consent was obtained from all patients included in the study.

### *Patients and methods*

Six level-two trauma centres in our area (Puglia, Italy) were involved in the study. A total of 579 patients in emergency departments were assessed for eligibility between April 2012 and October 2014. The inclusion criteria were the presence of an acute (treatment within 15 days from trauma) pertrochanteric stable fracture type 31-A1/31-A2 in patients aged over 65 years who were able to walk before the injury with or without crutches. Exclusion criteria were medical contraindications, medical illness or cognitive disorders precluding participation in the follow-up examination, unwillingness to participate, open fracture, bilateral fractures, pathological fracture and previous ipsilateral hip or femur surgery.

Among 579 patients assessed, 178 did not meet the inclusion criteria, 21 refused to participate in the study and 23 were treated with Dynamic Hip Screws (DHS) (Fig. 1).

Therefore, the initial patient sample comprised a total of 357 patients with pertrochanteric stable fracture. In all patients, fractures were caused by low-energy trauma, generally a fall from a standing height. Fractures were classified according to the AO/OTA classification system by the operating surgeon and the corresponding author (G.V.) together [28].

Patients were randomised to two groups according to computer-generated random numbers, which were secured in sealed envelopes. Twenty-four patients were excluded post-randomisation because of medical contraindications. A total of 333 patients were included in the final patient sample and received their allocated intervention: 162 patients were assigned to the locking group (LG) and 171 patients to the unlocking group (UG) (Fig. 1).

Thirteen different surgeons each with more than 10 years of experience performed the operations.

The Endovis BA Citieffe nail (Calderara di Reno [BO], Italy) was used in all patients [29]. This device is made of titanium alloy (Ti-6Al–4 V ELI), and is 195 mm long with a metaphyseal angle of 5°, a proximal diameter of 13 mm and a distal diameter of 10 mm. Two oblique screws with a cervico-cephalic angle of 130° were used for proximal locking, thereby preventing the rotation of the femoral head and neck. The cephalic screws are self-drilling and are available in nine different lengths (70–110 mm), with a diameter of 7.5 mm where they traverse the nail, tapering to a 6.4 mm diameter before the threads. The distal end of the nail consists of a 30-mm, 4-ray "diapason", which offers gradual reduction in stiffness and reduces stress shielding. Just proximal to the diapason, the nail is traversed orthogonally by a circular hole for the optional insertion of a "static" screw for distal blockage. This diaphyseal screw is 5 mm in diameter and is available in four different lengths (30–45 mm). Dynamic locking is not possible with this type of nail.

A standardised operative technique was used following the manufacturer's instructions. Closed reduction of the fracture was performed on the fracture table to restore the anatomical position of fragments. Uniplanar fluoroscopy was used in all cases. The first step of the surgical procedure was a small proximal incision at the

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