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Treatment of peritrochanteric fractures with the Endovis BA cephalomedullary nail: multicenter study of 1091 patients

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Abstract Treatment of peritrochanteric fractures involves reduction and synthesis using reconstruction plates and screws, intramedullary or cephalomedullary nails, or external fixators. A new cephalomedullary nail, Endovis BA (Citieffe, Italy), made of titanium alloy implanted without reaming and is fixed with 2 cephalic screws was used to treat 1091 patients with lateral fractures of the femoral neck (AO class 31-A). The patients had a mean age of 75 years (range, 48–99 years), and 83% had one or more systemic comorbidities. Mean operative time was 35 min (range, 20–100 min), and 483 patients (44.3%) required transfusion of one or more units of blood. The nail was implanted without distal blockage in 886 patients (81.2%) and without reaming in 1081 patients (99.1%). Intra-operative complications were recorded in 28 patients (2.6%). At the 6-month follow-up, 128 patients (12%) had died from

causes unrelated to the surgery. Of the remaining 963 patients, 632 (65.6%) could walk independently, 249 (25.9%) could walk with assistance, and 82 (8.5%) could not walk. Postoperative complications were recorded in 38 patients (3.5%); most common complications were cut-out (10 cases), loss of reduction (8 cases) and prominent screws (6 cases). In conclusion the Endovis BA nail seems to be a reliable choice for the treatment of lateral fractures of the femoral neck, especially considering the short operating time and low rate of complications.

Key words Femoral neck · Peritrochanteric fractures · Intramedullary nailing

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Introduction

Peritrochanteric fractures usually arise in situations of structural weakness of bone due to osteoporosis [1]. In these patients, minor or low-energy traumas are sufficient to cause a fracture, but often fractures occur spontaneously without external cause [2]. Treatment of these fractures aims to achieve stable synthesis, allowing immediate mobilization and early weight bearing. The best treatment for femoral neck fractures is surgical, but many of these patients have systemic comorbidities (e.g. arterial hypertension, diabetes mellitus, and cardiopathy) that increase the risks associated with surgery.

Treatment of lateral femoral fractures involves reduction and synthesis using reconstruction plates and screws, elastic intramedullary nails, cephalomedullary nails or external fixators [3–8]. The most commonly used means of synthesis are cephalomedullary nails [3–8]. Here, we present the 6-month results obtained with a new cephalomedullary nail, Endovis BA, applied in the treatment of 1091 patients with lateral fractures of the femoral neck.

Materials and methods

The study enrolled consecutive patients with lateral fractures of the femoral neck, seen between August 2002 and June 2005 in 6 departments of orthopaedics and traumatology distributed throughout the Italian territory. Patients were excluded only if they could not be operated because of poor health conditions; all patients who could tolerate the operation for the lateral neck fracture were included in the study.

The preoperative examination included clinical history, assessment on the Physical Status Classification System of the American Society of Anesthesiologists (ASA) [9] evaluation on the SF-36 Medical Outcomes short form health survey, Italian version [10], and anteroposterior radiographs of the hip. Using the AO classification system [11] for fractures of the proximal femur (type 31), patients were distinguished into 3 groups:

- 31-A1. Simple peritrochanteric fractures (in two fragments with good medial contact and therefore considered stable).
- 31-A2. Multifragmentary fractures (with detachment of the lesser trochanter and posteromedial wall, and therefore with greater instability).
- 31-A3. Intertrochanteric fractures (with interruption of the medial and lateral walls and a fracture rim in inverse direction with respect to the preceding two groups).

Surgical technique

Surgical treatment consisted of fracture reduction and synthesis by intramedullary nailing using the Endovis BioAdvanced (BA) nail

(Citieffe, Calderara di Reno, Italy). Distal nail blockage was used for all intertrochanteric fractures (class 31-A3) and for some multifragmentary fractures (class 31-A2). Reaming of the intramedullary canal was generally not needed. The traditional supine position for the patient was assumed on a trauma table. Uniplanar fluoroscopy was used in all hospitals, and a small proximal incision at the greater trochanter level, under fluoroscopic control, was the first step of the surgical procedure. Once the medullary canal has been penetrated by the guide pin, a conic reamer was used to enlarge the trochanteric hole to introduce the nail. Hammering on the guide and distal reaming were usually not needed. When the nail was in place, a 35-cm calibrated drill was used through the distal 130° oblique screw-hole as an aligner to check if the position of the nail (height and anteversion with respect to the reduced neck and head of femur) was correct; this drill also allowed to calculate the length of the screws. Usually proximal screw was 5 mm shorter than the distal one. When the surgeon was satisfied with the position achieved, the first the proximal screw was introduced, then the distal screw; both are self-drilling.

Characteristics of the device

The Endovis BA nail is a new intramedullary device that was developed in conjunction with Citieffe (Calderara di Reno (BO), Italy) [12]. It is made of titanium alloy (Ti-6Al-4V ELI), is 195 mm long, and is laterally angled 5° at the proximal extremity (Fig. 1). The proximal diameter is 13 mm, while the distal diameter is 10 mm.

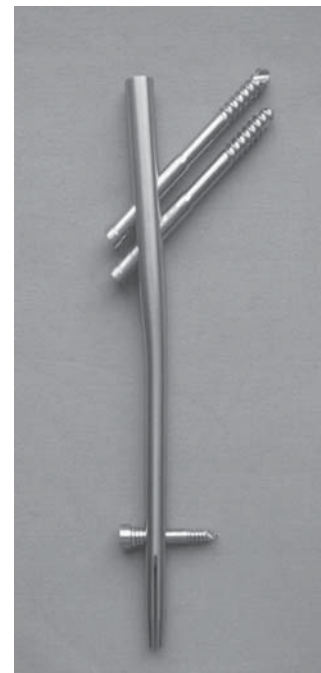


Fig. 1 The cephalomedullary Endovis BA nail, shown with the two cephalic screws and the optional diaphyseal screw in place

The proximal end of the nail is traversed diagonally by holes for two screws that form a 130° cervicodiaphyseal angle and that, when implanted, prevent rotation of femoral head and neck. These cephalic screws are available in 9 lengths (70–110 mm), have a diameter of 7.5 mm where they traverse the nail, and taper to 6.4 mm diameter before the threads. They are non-cannulated, self-drilling and self-tapping; therefore the nail can be inserted without motorized instruments such as drills. 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 hole for the optional insertion of a screw for distal blockage. This diaphyseal screw is 5 mm in diameter and is available in 4 lengths (30–45 mm). This screw was mainly used in 31-A3 lateral fractures.

Postoperative care and follow-up

Postoperatively, patients were allowed to sit upright on the second postoperative day, and to begin walking with a walker on the fourth postoperative day, if their general conditions were good. Follow-up was planned at 1, 3 and 6 months, when complete consolidation should be achieved. At each follow-up, patients were invited to return for clinical and radiographic assessment; if patients were unable to return, follow-up was performed by telephone contact with the patient or a relative. Patients were re-administered the SF-36 questionnaire at the last follow-up visit (6 months after surgery).

Results

A total of 1091 patients with lateral fractures of the femoral neck underwent intramedullary nailing using the Endovis BA nail. The patients had a mean age of 75 years and were predominantly female (Table 1). The majority of patients (83%) had one or more systemic comorbidities, resulting in an ASA physical status score of II-IV. The most common comorbidity was arterial hypertension (764 patients, 70%), followed by diabetes mellitus (436 patients, 40%) and cardiopathy (273 patients, 25%). The mean preoperative SF-36 score was 54. This low score is due to the advanced age of the population and their previous and concurrent diseases.

The mean operating time was 35 minutes (range, 20–100 min). Patients were exposed to ionizing radiation during fluoroscopic control for a mean of 45 s (range, 30–105 s). Overall, 483 patients (44.3%) required postoperative transfusion of one ($n=410$) or more units of concentrated red blood cells. The nail was implanted without distal diaphyseal blockage in 886 patients

(81.2%); distal blockage was performed in all 31-A3 fractures ($n=153$) and in 52 of the 523 multifragmentary fractures (10%) classified as 31-A2. Intramedullary reaming was necessary only in 10 patients (0.9%) with femoral canals narrower than 10 mm. Intra-operative complications were recorded in 28 patients (2.6%), and included incorrect positioning of the cephalic screws ($n=14$), diapason opening ($n=4$), guide wire deformation ($n=4$), difficulty in performing distal blockage ($n=3$) and incorrect length of cephalic screws ($n=3$). Improperly positioned screws were not removed but their positions were monitored radiographically; all healed normally. For diapason opening, the nail was replaced with better alignment in the femoral canal. Deformed wires were changed. The distal blockage turned out to be difficult, the nail was left unblocked.

After surgery, 982 patients (90%) were able to sit upright on the second postoperative day; the other patients sat upright as soon as their general conditions allowed. Patients began walking with the assistance of a walker a mean of 4 days after surgery, and were discharged from hospital on the eighth postoperative day on average; there were no deaths during hospitalization.

No patient was lost to follow-up during the 6-month postoperative period, although 305 patients (28%) were unable to return for a clinical visit and were assessed by telephone. In the 6-month interval, 128 patients (12%) had died from causes unrelated to the procedure. Of the remaining 963 patients, 632 (65.6%) could walk independently, 249 (25.9%) could walk with assistance, and 82 (8.5%) could not walk. All but nine fractures had healed.

Femoral shortening of less than 2 cm was found in 59 of 274 patients treated in 2 centers. This leg length dis-

Table 1 Clinical characteristics of 1091 patients with lateral fractures of the femoral neck (AO class 31-A)

Age, years ^a	75 (48–99)
Male, n (%)	382 (35)
ASA physical status score, n (%)	
I. Normal health	185 (17)
II. Mild systemic disease	273 (25)
III. Severe systemic disease	578 (53)
IV. Severe systemic disease that is a constant threat to life	55 (5)
SF-36 score ^a	54 (20–75) SD 17.88
AO fracture classification, n (%)	
31-A1 Pterochanteric, simple	415 (38)
31-A2 Multifragmentary	523 (48)
31-A3 Intertrochanteric	153 (14)

^a Values are mean (range)

Table 2 Complications recorded in the 6-month follow-up period, for 1091 patients treated by intramedullary nailing of lateral fractures of the femoral neck. Values are number (percentage) of patients

Cut-out (perforation of screw through femoral head)	10 (0.92)
Loss of reduction	8 (0.73)
Excessive sliding of cephalic screws with subcutaneous prominence	6 (0.55)
Diaphyseal fracture beyond the nail ^a	4 (0.37)
Delayed consolidation	3 (0.27)
Pseudoarthrosis	2 (0.18)
Cephalic screw breakage	2 (0.18)
Nail breakage	2 (0.18)
Avascular necrosis of femoral head	1 (0.09)

^a One spontaneous and three traumatic fractures

crepancy was considered related to compaction of the fracture zone and thus a part of the healing process, rather than a complication.

During the 6-month follow-up, the mean SF-36 score was 48 (range, 20–65). This decrease is statistically significant (Wilcoxon's test, $p=0.018$). We assume that this reduction was due to the worsening of their walking capabilities.

Postoperative complications were observed in 38 patients (3.5%) at clinical follow-up (Table 2). Complications directly associated with the surgical method (delayed consolidation, pseudoarthrosis, implant breakage) were registered in only 9 cases (0.8%). The 3 cases of delayed consolidation and the 2 cases of cephalic screw breakage occurred in patients in whom distal blockage had been performed. In the cases of delayed consolidation, removal of the distal block was sufficient to promote healing, suggesting that blockage on the diaphysis permits monoaxial compaction of the fracture, while a multiaxial compaction is sometimes necessary.

Discussion

In this prospective multicenter study, the Endovis BA cephalomedullary nail was used successfully to treat more than one thousand elderly patients, with low rates of intra-operative and postoperative complications. Six months were considered a proper time to evaluate the efficacy of the nail, since if this kind of fracture does not heal over this period, probably it will not anymore.

Boriani et al. [13] employed the Gamma nail (Stryker, Kalamazoo, USA) in treating 1181 patients with lateral fractures of the femoral neck. In this 1994 study, the rate of intra-operative complications was 1.8%. Diaphyseal fractures occurred in 1.1% of cases, cephalic screw cut-out in 2.2%, nail breakage in 0.4% and infection in 0.3%.

The authors concluded that many complications were due to surgical errors. In 2000, Ingman [14] described the outcomes obtained with an original stainless steel nail (13 mm proximal diameter, 11 mm distal diameter) used to treat 159 peritrochanteric fractures. Like Endovis BA, this nail has two cephalic screws (6.5 mm diameter) and a single distal screw. Postoperative complications were lateral prominence of the screws (2.4% of cases), cut-out (1.2%), pseudoarthrosis (0.6%) and infection (1.2%). Average operating time with this new screw was only 38 min. Sailer et al. [15] used the Gamma nail to treat 96 patients in the period 1992–1996. In a retrospective analysis, the authors reported healing in 97% of patients at 1 year, but complications due to technical errors in 18% of patients. Rebuzzi et al. [16] retrospectively evaluated the results obtained in 981 patients with peritrochanteric fractures, treated at 5 centers with the intramedullary hip screw nail (Smith and Nephew Richards, Memphis, USA). They observed a low overall rate of complications requiring reoperation (1.7%). Fogagnolo et al. [17] used the AO-ASIF proximal femoral nail to treat 47 fractures in 46 patients. Intra-operative complications were observed in 23.4% of patients, mostly due to problems with distal blockage and fracture of the lateral wall of the greater trochanter. The reoperation rate was 19.1%. Postoperative complications included cut-out in 10% of cases and nail breakage in 0.6%. Recently, Hesse and Gächter [18] analyzed the main complications associated with use of the Gamma nail, in 498 peritrochanteric fractures. The most frequent complication was trochanteric pain (6% of cases), followed by cut-out (3.8%) and stem breakage (1.4%). Finally, Alvarez et al. [19] analyzed the causes of implant breakage in a series of patients treated with the Gamma nail. In the period 1990–2002, a total of 843 nails were implanted and breakage was reported in 5 cases (0.6%). All breaks were found in the proximal portion, where the cephalic screw traverses the nail. The authors attributed delayed consolidation to nail breakage, and

commented that the implant becomes excessively rigid when blocked distally. They suggested to “dynamize” the construct by removing the distal screw, in cases of delayed consolidation.

The Endovis BA nail represents an advance in cephalomedullary implants for treating lateral fractures of the femoral neck. The nail has the mechanical advantages inherent to all intramedullary implants. Moreover, its short length should improve bending, thereby helping to reduce the rate of complications associated with these implants. The use of titanium alloy, which has a modulus of elasticity approximately half that of stainless steel, provides greater flexibility. Compared to intra-medullary nails with a single cephalic screw, the Endovis BA nail uses two cephalic screws to reduce chances of femoral head rotation; this also permits a reduction in the nail’s diameter and encumbrance.

In conclusion the system seems to offer several advantages:

- Small diameter of the nail and of the two screws, which allows less removal of trochanteric cancellous bone.
- All the screws are self-drilling, self-taping and with double pitch. These technical choices reduce the need to use motorized instruments make the tools very simple: one box with ten instruments all together. Moreover the nail is available in a unique measure,

which ought to help scrub-nurses, stockage and administration.

- The smaller caliber allows implantation without reaming in most cases, and therefore reduces the operating time and exposure to radiation.

Disadvantages are the limited indications, as its restricted length does not allow this nail to be used for sub-trochanteric fractures.

Complications associated with intramedullary nailing of femoral neck fractures include cut-out, femoral neck or head rotation, diaphyseal fracture during nail insertion, and diaphyseal fracture beyond the nail due to stress shielding [13–19]. Often these complications are associated with a large nail diameter, elevated modulus of elasticity (rigidity), and the presence of a single cephalic screw. Nails of large dimensions are responsible for intra-operative fractures, especially in femurs with an excess of procurvatum typical of elderly bones. This observation was first made by Boriani et al. [20] in 1996, when they noted fewer complications using Gamma nails narrower than recommended (11 mm diameter).

In conclusion, our experience with the Endovis BA cephalomedullary nail is positive, especially considering the short operating time and the low rate of postoperative complications, compared to those reported for other cephalomedullary implants [13–19].

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