

Clinical and functional outcomes of internal fixation with intertrochanteric antegrade nail in older patients with proximal extracapsular femoral fractures

M. Galli · V. Ciriello · L. Bocchino ·
N. M. Gangemi · M. Peruzzi · E. Marzetti

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Abstract

Purpose The intertrochanteric Trigen Intertan[®] nail (Smith & Nephew, Memphis, TN) is a popular fixation device for proximal extracapsular femoral fractures (PEFFs). We evaluated clinical and functional outcomes in patients with PEFFs treated with Trigen Intertan[®] nail.

Methods In a single-site, prospective observational study, clinical and functional parameters were recorded for all patients admitted to the Emergency Department with PEFFs from June 2008 through June 2011. Patients with severe cognitive impairment, severe disability, neoplastic pathological fractures, or suffering from terminal illnesses were not eligible for the study. Fractures were classified according to the AO/OTA classification system. Preoperative physical fitness was assessed via the American Association of Anaesthetists (ASA) score. The Barthel index was used to quantify the level of physical function before fracture and at follow-up.

Results One-hundred thirty-five patients with PEFFs were eligible for inclusion during the 3-year survey (mean age 83.2 ± 9.5 years; 82 % females). Fracture type distribution was as follows: A1.1 = 18 %, A1.2 = 7 %, A1.3 = 5 %, A2.1 = 44 %, A2.2 = 21 %, A2.3 = 5 %. All patients were treated with Trigen Intertan[®] nail. Two patients experienced a fracture of the femoral shaft during the insertion of a long nail for an A2.3 fracture. Weight-bearing was allowed between the third and tenth

postoperative day depending on pain tolerance and general conditions. No loss of reduction, collapse of the femoral neck, nonunion or fixation failure were observed. Two patients died within 10 days postoperatively, and nine within 6 months after surgery. Functional status 1 month after surgery was lower than pre-fracture levels, and improved over follow-up. At 6 months, functional status was comparable to the pre-fracture level.

Conclusions Trigen Intertan[®] produces highly satisfactory clinical and functional results in older patients with PEFFs. Complete functional recovery is obtained on average 6 months after surgery.

Keywords Elderly · Hip fracture · Intertrochanteric fracture · Proximal femoral nail · Osteosynthesis · Surgical treatment

Introduction

Over the last decades, the incidence of proximal extracapsular femoral fractures (PEFFs) has increased dramatically, with significant impact on morbidity, disability, and mortality [1]. The large majority of patients with PEFFs fractures are older, comorbid people [2]. Patients hospitalized for PEFFs present high rates of morbidity, disability, and mortality (up to 32 % die within the first year after the event) [2]. The occurrence of a femoral neck fracture reduces the life expectancy by approximately 1.8 years and causes patients to spend about one-fifth of their remaining lives in long-term care [3]. Among those who survive longer than 6 months after the event, only 50 % of patients regain their pre-fracture functional status [4]; most of them are not able to resume their previous lifestyle and experience significant impact on quality of life, with relevant socioeconomic implications [5].

M. Galli · V. Ciriello · L. Bocchino · N. M. Gangemi ·
M. Peruzzi · E. Marzetti (✉)

Department of Geriatrics, Neurosciences and Orthopedics,
Institute of Orthopedics, Catholic University of the Sacred Heart
School of Medicine, Teaching Hospital "Agostino Gemelli",
Largo Agostino Gemelli 1, 00168 Rome, Italy
e-mail: emarzetti@live.com

Postoperative mortality in hip fracture patients can be significantly reduced by performing surgery early after the trauma, by reducing the operative time, and by allowing load as early as possible [6, 7]. The Trigen Intertan® intertrochanteric antegrade nail (Smith & Nephew, London, UK), a fourth-generation intramedullary nail, is an increasingly popular fixation device for PEFF treatment. This nail offers good rotational stability of the head-neck fragment and allows controlled sliding and intraoperative compression of the fracture heads. In addition, the presence of a double screw reduces the risk of cut-out or varus collapse [8, 9]. The proximal portion of the nail has a trapezoidal section (stem-like) to ensure a good metaphyseal fitting.

Here we report clinical and functional outcomes of internal fixation with Trigen Intertan® nail in a series of elderly patients with PEFFs.

Materials and methods

Study sample

This was a single-site, prospective observational study. Analyses were conducted in 135 patients consecutively admitted to our Emergency Department for PEFFs from June 2008 through June 2011. Diagnosis was established via standard X-ray of the traumatized hip. Fractures were classified according to the AO/OTA classification system [10]. Comorbid conditions and medications were recorded using a dedicated questionnaire. Exclusion criteria were inability or unwillingness to provide informed consent, severe cognitive impairment (i.e., Mini-mental status examination ≤ 10), inability to walk before fracture, neoplastic pathological fractures, and presence of severe illnesses with an estimated life expectancy lower than 6 months. The functional status was examined via the Barthel index [11]. Standard blood analyses were performed at the admission, first postoperative day, and at discharge. The study protocol was approved by the Catholic University's Ethics Committee.

Surgery

All interventions were performed by the same orthopedic surgeon (M.G.) within 24–96 h from admission, under fluoroscopic control. Patients were placed supine on the operating table, with the lower limb in traction. A preoperative fluoroscopy in anterior-posterior and axial views was obtained to evaluate fracture alignment after the reduction maneuvers. The reduction was judged satisfactory when the main fracture fragments (i.e., cervical, trochanteric, and diaphyseal) were correctly aligned in both

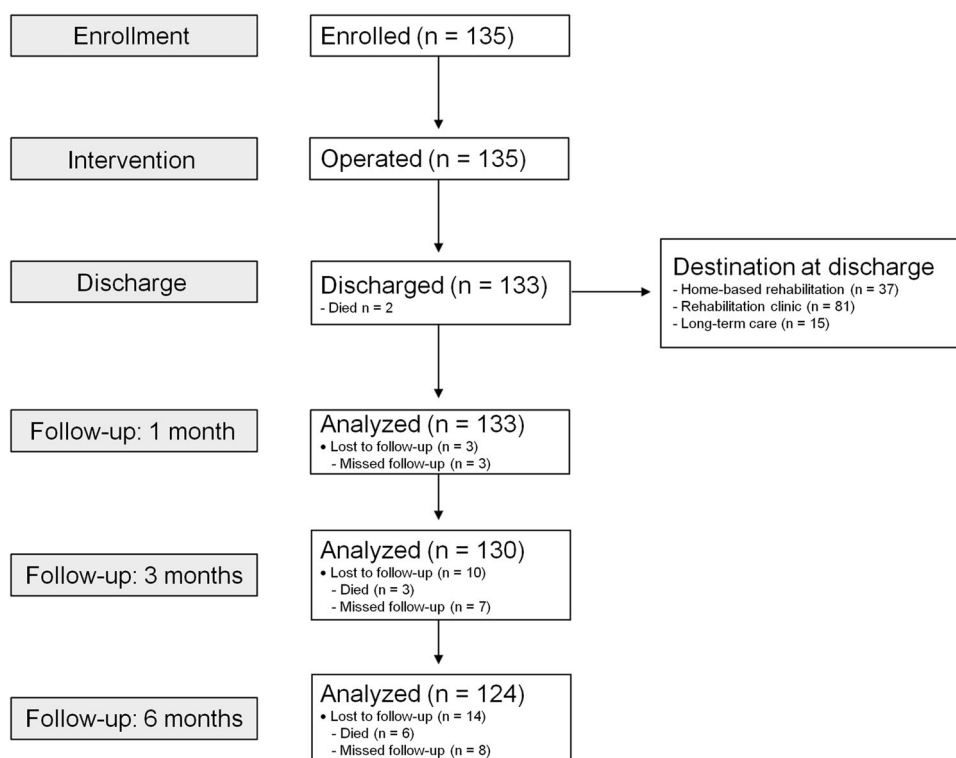
fluoroscopic views. In A2.2 and A2.3 fractures, the comminution and dislocation of intercalating fragments did not affect the overall reduction judgment. Surgery was minimally invasive in all but six cases presenting with A2.3 type fractures with muscle flaps interposed between bone fragments. Ten-mm diameter nails with cervical angle of 125° (103 cases, 76 %) or 130° (32 cases, 24 %) were used. A long nail (34–40 cm) was implanted in fractures with medial cortex comminution extended beyond the lesser trochanter (i.e., A2.2. and A2.3 fracture types; $n = 35$; 26 %). Short nails (18 cm) were used in the remaining 74 % of cases. Implant positioning differed depending on the fracture stability. In A1 and A2.1 fractures, implant positioning was obtained through the correct insertion of the proximal screws and an adequate diaphyseal filling. In these cases, fracture stability was improved due to the compression obtained through the lag mechanism and the rotative stability provided by the advantageous cross-sectional shape of the combined proximal screws. Proximal screws were placed in the posterior-inferior quadrant of the femoral head to achieve a tip-apex distance (TAD) < 24 mm (18.8 ± 2.7 mm) [12]. The position of the proximal screws in the femoral head was ascertained via fluoroscopy in anterior-posterior and axial views. In A2.2 and A2.3 fractures with severe comminution among cervical, trochanteric and diaphyseal fragments, fixation stability was obtained mainly via the correct positioning of the proximal screws, since the compression mechanism is less effective in such fracture patterns. In all cases, fixation stability was evaluated by dynamic maneuvers under fluoroscopy. All patients were administered a prophylactic intravenous shot of cephalosporins or fluoroquinolones. For a detailed description of the Trigen Intertan® nail, the reader is referred to the product page on the manufacturer's website (<http://www.smith-nephew.com/professional/products/all-products/trigen-intertan-intertrochanteric-antegrade-nail/>).

Postoperative management and follow-up

Low-molecular-weight heparin at standard doses was started 6 h postoperatively and administered for 35 days. Folate, vitamin B12, and iron supplementation were prescribed unless contraindicated. All patients were allowed to load on the operated limb between the third and tenth postoperative day. Clinical, functional and radiographic controls were performed at 1, 3 and 6 months after surgery.

Statistical analysis

Data of continuous variables are presented as mean $\pm$ standard deviation (SD). For all variables, normality of data was ascertained by the Kolmogorov–

Fig. 1 Flowchart of the study

Smirnov's test. Changes of laboratory and functional parameters across time-points were assessed via analysis of variance (ANOVA) for repeated measures with Tukey's post hoc test when needed. Missing data at follow-up were managed according to the last-observation-carried-forward (LOCF) method. Statistical analysis was performed using the SPSS v.13.0 software (SPSS Inc.; Chicago, IL).

Results

The flowchart of the study is depicted in Fig. 1. Demographic and clinical characteristics of the study sample on admission are summarized in Table 1. The average surgical time was 36.8 ± 10.5 min (range 30–70 min). Anesthesia was epidural in 99 cases (73 %) and general in 36 cases (27 %). Satisfactory fracture reduction and fixation were achieved in all patients. Intra-operative complications occurred in two cases and consisted of fracture of the femoral shaft during the insertion of a long nail for type A2.3 fractures. The average intraoperative blood loss was 209.6 ± 53.4 mL (range 80–310 mL), which is lower than that reported with other fixation devices [13]. Weight bearing to tolerance was allowed starting from the third postoperative day. In general, patients with type A1 and A2.1 fractures were able to tolerate full weight-bearing

Table 1 Demographic and clinical characteristics of the study sample ($n = 135$) on admission

Age (years)	83.2 ± 9.5
Sex (female)	111 (82)
Number of comorbid conditions ^a	1.9 ± 2.0
Number of medications	4.7 ± 2.8
AO/OTA class	
31-A1.1	24 (18)
31-A1.2	10 (7)
31-A1.3	7 (5)
31-A2.1	59 (44)
31-A2.2	28 (21)
31-A2.3	7 (5)
Side of fracture (right)	71 (53)
ASA score	
1	3 (2)
2	43 (32)
3	89 (66)
4	0 (0)
5	0 (0)
6	0 (0)

^a Includes hypertension, congestive heart failure, coronary artery disease, atrial fibrillation, chronic obstructive pulmonary disease, diabetes mellitus, cerebrovascular disease, Alzheimer's disease, Parkinson's disease, osteoarthritis, blindness, deafness, dizziness

Data are presented as mean $\pm$ SD or number (%)

3 days after surgery, while those with type A2.2 and A2.3 fractures usually started to bear load between 4 and 10 days after surgery. Major postoperative complications included cardiogenic pulmonary edema (two cases), pulmonary thromboembolism (three cases), cut-out of the cephalic screws for severe osteoporosis, as evaluated by the Singh's index [14], or incorrect intra-operative screw positioning (three cases). The overall postoperative mortality was 8 % ($n = 11$). Two patients died of multiple organ failure within the ninth postoperative day, whilst nine died within 6 months after surgery. Radiographic controls performed over the 6-month follow-up showed a satisfactory reduction of fracture in all cases, with no varus collapse of the head and neck. No cases of nonunion or peri-implant fractures were observed.

After surgery, hemoglobin levels were significantly lower than those determined on admission, and increased thereafter

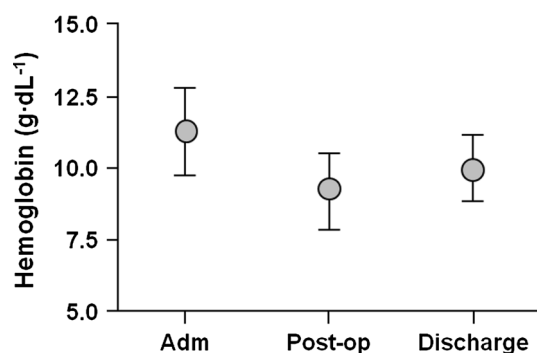
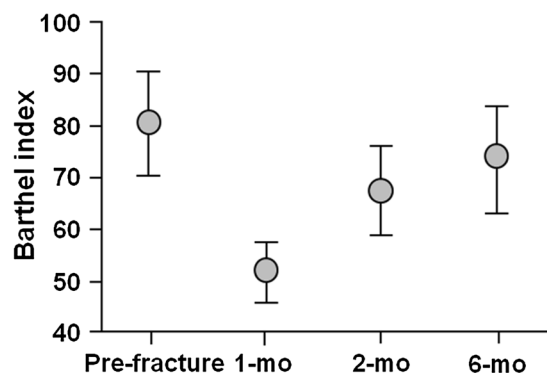


Fig. 2 Hemoglobin levels from admission to discharge. Adm, admission, post-op, 1 day after surgery; discharge. * $p < 0.0001$ vs. admission; § $p < 0.0001$ vs. discharge

Fig. 3 Changes in the Barthel index from pre-fracture to 6 months after surgery. Tukey's post hoc comparisons with mean differences and 95 % confidence intervals (CI) are presented in the table



Comparison	Mean difference	q	P value	95% C.I.
Pre-fracture vs. 1-mo	28.58	38.24	$P < 0.001$	25.83 – 31.33
Pre-fracture vs. 2-mo	13.05	17.46	$P < 0.001$	10.30 – 15.80
Pre-fracture vs. 6-mo	6.333	8.474	$P < 0.001$	3.585 – 9.082
1-mo vs. 2-mo	-15.53	20.77	$P < 0.001$	-18.27 – -12.78
1-mo vs. 6-mo	-22.24	29.76	$P < 0.001$	-24.99 – -19.50
2-mo vs. 6-mo	-6.719	8.990	$P < 0.001$	-9.467 – -3.970

(Fig. 2). Postoperative blood transfusion was needed in 24 % of patients ($n = 33$). The functional status, evaluated by the Barthel index, dropped significantly from pre-fracture to 1 month postoperatively. Over 6 months of follow-up, the Barthel index increased progressively (Fig. 3). It should be noted that the difference between pre-event and 6-month scores, although being statistically significant, was smaller than 15 points, which corresponds to the minimal clinically important difference (MCID) for the tool [15].

Discussion

The present study reports clinical and functional outcomes in a relatively large sample of older patients with PEFFs treated by internal fixation with Trigen Intertan® intertrochanteric antegrade nail.

Numerous fixation means are available for the treatment of PEFFs. Screw-plate systems such as the dynamic hip screw (DHS) are typically used in stable fractures [16, 17]. This fixation device offers a good reduction, but requires greater surgical exposure and longer operative time [18]. Intramedullary nails are especially useful in unstable fractures characterized by medial column collapse [19, 20]. Most of these devices are based on a single central lag screw to synthesize the femoral head and neck or a screw-blade (spiral blade) [21]. Other nails have a system with two independent screws, but they can produce the so-called Z effect [22]. In such devices, the screws are not locked with each other and can freely slide along the nail. This may lead to varus collapse of the femoral head and neck and cut-out of the upper screw [22]. In contrast, the Trigen

Intertan[®] nail is provided with two interlocked cephalic screws that increase the overall section area, reducing the risk of rotational dislocation of the head and avoiding the Z effect. Indeed, these screws are tightened to one another, allowing intraoperative controlled compression of the fracture fragments, which can be perceived through the manual feedback while tightening the lag screw and measured directly by observing the graduated scale on the screwdriver. These features increase the stability and promote fracture healing [9, 22–24].

In our study, we recorded very few complications: three cases of cephalic screw cut-out due to severe osteoporosis or incorrect intraoperative screw positioning, and two cases of intraoperative diaphyseal fractures. In contrast to what is usually observed with single-screw devices, no clinically relevant inequality between the two limbs was observed in our series [25].

The functional status measured by the Barthel index dropped during the first month postoperatively, and increased thereafter. It is noteworthy that 6 months after surgery, the Barthel index was comparable to the pre-event score. Indeed, the mean difference between pre-fracture and 6-month scores was 8.5 points, which, although statistically significant, is below the MCID for the tool (i.e., 15 points) [15].

Limitations of the study

The absence of comparison with other fixation devices and the relatively short period of follow-up are the main limitations of the study. However, since most of the patients with PEFFS referred to our medical center were treated with Trigen Intertan[®] nail, no meaningful comparisons between this and other fixation devices were possible during the study time-frame. As for the length of follow-up, 6 months postoperatively, the Barthel index appeared to be stable and the difference between pre-event and final scores was below the MCID. Although a longer follow-up period could have increased the significance of the study, the absence of relevant clinical differences in physical performance after 6 months relative to the pre-fractural status obviated the need for longer periods of observation. In addition, since a large number of patients admitted to our center live out of region, a longer observation would have been hampered by a significant rate of losses at follow-up, therefore impeding meaningful analyses.

Conclusion

In our series, the use of antegrade intertrochanteric Trigen Intertan[®] nail for PEFFS provided satisfactory clinical and

functional results. Fracture healing was obtained in most cases, with a very low incidence of complications. Over 6 months of follow-up, most patients recovered a physical function level similar to the pre-fracture status. These results, together with the reduced intraoperative blood loss, support the use of Trigen Intertan[®] as a first-line option for the treatment of older patients with PEFFs.

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Conflict of interest M. Galli, V. Ciriello, L. Bocchino, N. M. Gangemi, M. Peruzzi and E. Marzetti declare that they have no conflict of interest.

Compliance with Ethics Guidelines The study protocol was approved by the Catholic University's Ethics Committee. Informed consent was obtained from all patients for being included in the study.

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