A newly designed locked intramedullary nail for trochanteric hip fractures fixation: Results of the first 100 Trochanteric™ implantations

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Summary

Introduction. — Internal fixation continues to be the surgical treatment of choice for trochanteric region hip fractures. Intramedullary nailing is the updated version of the Küntscher Y nail and provides stable osteosynthesis of trochanteric hip fractures, classically achieved by closed reduction.

Material and methods. — We report on our experience (which started in 2003), using a new fixation device featuring a metaphyseal antegrade nail locked with two cephalic screws and comprising a diaphyseal distal locking. Between April 2003 and September 2006, the first 100 patients who sustained an extracapsular intertrochanteric hip fracture and indicated for internal fixation were prospectively enrolled in this single-center study.

Results. — Eighty-six patients (mean age 80.3) were reviewed at 6 months (nine had died, three had failure and two were lost to follow-up) and reported a satisfactory functional outcome (mean Merle d’Aubigné score was 16 and mean Harris Hip score was 90). Union was achieved within a mean delay of 3 months (median 102 days 1/2) in a good anatomical position (mean medialization was 1.86 — ranging from −16 to 0 mm, and mean shortening was 1.72 mm — ranging from 0 to 24 mm). Functional recovery was satisfactory with a mean Parker score of 7.52. Total operating time was shortened and good fracture stabilization allowed early weight bearing.

Discussion. — Classically, such intertrochanteric fractures can be managed either with a dynamic screw-plate type fixation or with an intramedullary nailing device locked through a single cephalic screw and finally, in rare cases, with a hip arthroplasty supplemented with some sort of fixation. Most published clinical studies of screw-plate fixations have generally reported satisfactory results except for unstable fractures associated with a calcar area lesion. Screw-nail
fixations featuring a single cephalic screw should be used in these latter fracture patterns. We believe this new implant design will significantly enhance the anatomical result and functional outcome of these fractures; all this is expected to bring about an earlier recovery of patient’s walking ability.

Conclusion. — This original intramedullary nailing system provides reliable internal fixation means for intertrochanteric fractures since it combines the advantage of a closed reduction procedure with a more stable biomechanical construct.

Level of evidence: Level IV. Therapeutic prospective study.

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Introduction

Trochanteric fractures account for 60% of all proximal femoral fractures and occur in more than 90 out of 100 000 people [1—2]. The majority of these fractures occur in patients over 65 years of age, and most commonly affect female (three out of four cases), while reporting an increasing incidence due to the ageing of the population and correlated bone fragility and osteoporosis [3]. Moreover, basicervical and upper subtrochanteric fractures have raised this incidence rate since they require the same surgical treatment which is classically screw-plate osteosynthesis or antegrade centromedullary nailing [4]. Unstable fractures are biomechanically much more challenging when the calcar is damaged, thus compromising the strength of some surgical constructs [5]. We report on the results of a proximal antegrade centromedullary screw-nail osteosynthesis (Trochanteric™), in a continuous monocenter series involving the first 100 implantations. The purpose of the present study was to evaluate the perioperative morbidity as well as the short-term clinical and anatomical outcome.

Material and methods

We conducted a continuous, monocenter, prospective study, between April 2003 and September 2006, in the first 100 patients admitted to the emergency unit who sustained trochanteric fracture treated by Trochanteric™ nail osteosynthesis (Smith & Nephew™; Memphis, Tennessee, USA). This fixation device comprises a titanium centromedullary nail of 150 or 200 mm length and 10 or 11.5 mm diameter, held by two sliding cephalic screws of 6.4 mm and one or two 5 mm distal locking screws (one static and one dynamic hole) (Fig. 1). Preoperative evaluation included: Age, gender, score of the American Society of Anesthesiology (ASA) [6], Charnley’s classification grade [7] and the injured hip.

The fracture pattern was classified according to Ender and Weidner [8] (Fig. 2). Our study criteria were perioperative morbidity (number of packed red blood cells, complications and early deaths), short-term, three-month and eventually six-month-results depending on fracture healing. Hip function was clinically scored with the Postel-Merle d’Aubigné (PMA) [9] and Harris (HHS) [10] scales and radiographically assessed based on time to fracture healing and quality of union and impact on the proximal femur architecture (femoral lateralization and impaction) were investigated by measurement of radiographic indexes with magnification correction in the very early postoperative period and at fracture healing (Fig. 3). Restoration of patient’s functional autonomy was evaluated using the Parker et al. rating system [11] (Table 1) at the last follow-up.

Results (Tables 2—4)

One hundred patients (70% of females) with a mean age of 80.3 years (range 51 to 99) and a median ASA score of 2.29 were included in this series (Table 2). Preoperative functional status was graded 64A, 10B and 26C according to Charnley’s classification. Right hip was fractured in 55% of cases, and fracture pattern was classified according to Ender’s system (Table 3) Fracture reduction was performed intra-operatively on a traction table under fluoroscopy guidance, and was recorded as anatomic in 85 cases with direct approach to the fracture site for cerclage wiring in two cases and considered as acceptable for the remainder. Surgery was performed via a lateral supratrochanteric approach with two counter skin-incisions positioned for screwing and drainage with single Jost-Redon suction drain. The mean operative duration was 44 minutes (range 20 to 80 minutes) with perioperative blood loss requiring transfusion of 71 packed red

Figure 1 Short Trochanteric™ nail on the left (150 mm) and long on the right (200 mm).
Table 1  Parker’s functional autonomy scoring [11].

<table>
<thead>
<tr>
<th>Parker’s score</th>
<th>Yes, with no difficulty and aid</th>
<th>Yes, with technical aid (stick . . .)</th>
<th>Yes, with personal assistance</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does the patient walk at home?</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Does the patient walk out of his home?</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Does the patient go shopping?</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
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</table>

blood cells in 27 patients (0 to 4 blood bags) up to the end of the hospital stay of mean length 14 days (range 7 to 32 days). Patients could get to a bedside chair the day after surgery while weight bearing and walking practice with support were initiated from the second postoperative day in 90 cases (Fig. 4). The overall incidence of immediate postoperative complications was low considering the impaired conditions of many patients: five delayed unions of which no deep infection, one deep-vein thrombosis of the lower limbs and one digestive bleeding. Nine patients died within the first postoperative month. Three female patients had failure before the third week: (a) two femoral shaft fractures at the tip of the nail, secondary to an undetected intraoperative shaft fracture. This complication required revision
Table 2 Patient’s physical status according to the ASA scale (American Society of Anesthesiology) [6].

<table>
<thead>
<tr>
<th>ASA score</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>100 patients</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>16</td>
<td>47</td>
<td>31</td>
<td>6</td>
<td></td>
</tr>
</tbody>
</table>

 Patients were reviewed at three and six months. Nine of them died, three patients with mechanical failures were excluded from the study and two female patients were lost to follow-up. Eighty-six patients were thus assessed from a thorough clinical and radiographic examination. Hip function was clinically scored using the PMA (mean score 16, range 10 to 18) and Harris Hip (mean score 90, range 41 to 100) scales (Fig. 6). Anatomical outcome was quantified with postoperative radiographic index measurements and at fracture healing. These measurements revealed a mean loss of lateralization (L) of 1.86 mm (range —16 to 0) and a mean vertical impaction (I) of 1.72 mm (range 0 to 24) (Fig. 3). The sum of these two indexes (L + I) reflected the amount of posttraumatic malunion (Table 4). Consolidation was achieved in all cases with a mean time to union of 102 1/2 days (range 45 to 180) with a maximum of six months. Two patients required nail dynamisation by distal static screw removal around the second postoperative month. At the last follow-up, mean Parker score was 7.52 (range 3 to 9) and anatomical outcome was satisfactory with only five malunions greater or equal to 10 mm (Table 4). Nail diameter did not further influence anatomical results, however a more aggressive reaming was generally necessary to accommodate the larger diameter nail. Hardware removal was performed at two years in a 55-year-old female patient.

Discussion

Osteosynthesis is the most common surgical treatment for trochanteric hip fractures due to the development of newer specific implants [3]. Moreover, we believe intramedullary nailing is the most favourable treatment option in the management of such fractures. During the 1930s, the Smith-Petersen and Moore nailing systems were the first osteosynthesis devices to be used, followed by the STACA nail-plate and Muller AO blade-plate devices during the 1950s; then was developed the Kuntscher "Y" nail and from 1964 the Ender’s nail [1]. From 1980, dynamic hip screw-plates were introduced, of which the DHS (Dynamic Hip Screw, Synthes™); then the dynamic screw-nail systems such as the Gamma (Stryker™) nail from 1990 [12]. These newer generation fixation devices provide a safer construct and allow earlier weight-bearing. A malunion may occur combining lower limb shortening and reduced lateralization of the hip joint commonly resulting in limping. Throughout a series of 82 patients (84 fractures), Oger et al. [2] report a mean impaction of 10.3 mm and a malunion in 4.8%, thus requiring the need for another fixation device in subtrochanteric fractures (graded 6 to 8 according to Ender). Centromedullary implants are intended for use in any trochanteric fracture, including unstable ones subsequent to a calcar spur lesion, and result in a lower risk of screw penetration within the femoral neck. However, newer implant-related complications are observed such as migration or back-out of the cephalic screw and femoral fracture around the tip of the nail [1,3]. Kempf et al. [12] evaluate the use of the Gamma nail in 121 patients, and report a 100% union rate at 2.7 months with occurrence

![Figure 5](image-url) Clinical case 85, left hip (Ender 7): A preoperative view, B Day 15, C and D hardware disassembling, after revision to DHS and cerclage wiring.

Table 3 Fractures distribution (100) according to Ender’s classification.

<table>
<thead>
<tr>
<th>Type 1</th>
<th>Type 2</th>
<th>Type 3</th>
<th>Type 4</th>
<th>Type 5</th>
<th>Type 6</th>
<th>Type 7&amp;7’</th>
<th>Type 8&amp;8’</th>
</tr>
</thead>
<tbody>
<tr>
<td>13</td>
<td>27</td>
<td>23</td>
<td>3</td>
<td>1</td>
<td>1</td>
<td>28</td>
<td>4</td>
</tr>
</tbody>
</table>
of 13 malunions (10.8%) and screw back-out with articular effraction in six cases (4.9%). Several prospective randomised studies have been conducted to compare the screw-plate with the screw-nail fixation: (a) Giraud et al. [4] compare the results of the DHS plate fixation versus the Targon PF nail (Aesculap™) in 60 intratrochanteric fractures and show no remarkable differences in outcomes. However the small size sample provides insufficient evidence to confirm these results; (b) a Swedish study conducted by Pajarinen et al. [13] in 108 patients, reports a similar operating time with a lower incidence of blood loss in the DHS group and a lower rate of infections and femoral neck shortening in the Gamma nail group thus resulting in a better functional recovery. Saarenpää et al. [5] have conducted a prospective study in a series of 58 elderly patients who sustained a subtrochanteric fracture and treated with Gamma nail or DHS. Through their results, the Gamma nail appears to be the most favourable fixation method to address fractures with internal cortical comminution of lesser trochanter. Nuber et al. [14] also advocate the use of the Proximal Femoral Nail, Synthes™ (PFN™) rather than DHS, combined with trochanter stabilization plate for fixation of unstable trochanteric fractures. The PFN offers a shorter operating time and hospital stay, reduces the need for revision surgery and enhances indolence at six-month-follow-up. Gadegone and Salphale [15] have conducted a prospective study in 100 consecutive patients managed by PFN™ fixation for unstable trochanteric fractures in 64%. Fracture healing was achieved in 99%, mean time to union was four and a half months, anatomical reconstruction was observed in 86% and an incidence of only 12% postoperative complications was encountered of which three migrations of the cephalic screw into the hip joint. The DHS revealed quite disappointing in the management of trochanteric fractures in the elderly population often related to poor anatomical outcome thus inducing a lameness and a persistent weakness of the gluteus medius. We thus rapidly turned to the Gamma nail and PFN to address these fractures. These fixation devices demonstrated a higher mechanical strength since a second locking screw was inserted into the femoral neck thus preventing rotational displacement of the femoral neck by eccentric effect. However, we find the use of the PFN to be technically challenging since its large diameter requires the need for a 17 mm reaming on the one hand and due to the size of both cephalic screws (11 and 6.5 mm) on the other hand. Since 2003, we have thus been preferring the use of the nail which features a maximum diameter of only 11.5 mm and two 6.4 mm cephalic screws; its proven mechanical strength reinforces our keen interest in this fixation device. Our results are similar to those of the reference Gamma nail and superior to the DHS when taking into account all types of trochanteric fractures. The operating time was short and most fractures were treated by closed procedure, thus rapidly decreasing the incidence of perioperative blood loss (73% of patients did not require blood transfusion). All patients could get in a bedside chair on the second postoperative day and early weight-bearing was delayed in only 10 cases. Only three early mechanical failures were observed; no deep infection was found; mortality rate was 9% at three months which is low if considering the age of patients. All 86 patients were reviewed at six month-follow-up and approximately 90% of

Table 4

<table>
<thead>
<tr>
<th>Criteria</th>
<th>ASA</th>
<th>Age (year)</th>
<th>ASA</th>
<th>Age (year)</th>
<th>ASA</th>
<th>Age (year)</th>
<th>ASA</th>
<th>Age (year)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transfusion (Packed Bl. Cells)</td>
<td>0.71</td>
<td>2.29</td>
<td>1.4</td>
<td>0.4 CG</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Consolidation (days)</td>
<td>102.5</td>
<td>16</td>
<td>10</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Parker</td>
<td>7.52</td>
<td>3.9</td>
<td>4.1</td>
<td>0.29</td>
<td></td>
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</tr>
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</table>

them reported a satisfactory PMA and HHS score (good or very good).

**Conclusion**

We consider the Trochanteric™ nail as a reliable fixation device which offers the advantage of a closed procedure with a more stable biomechanical construct for all trochanteric, cervicotomyrochanteric and upper subtrochanteric fractures. In the face of the good clinical and anatomical results as well as the low morbidity rate demonstrated throughout our study, we find use of this implant to be of particular interest and perfectly adapted in primary surgery for both elderly and young patients.

**References**