Does the PFNA™ nail limit impaction in unstable intertrochanteric femoral fracture? A 115 case-control series

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Original article

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Fixation failure

A B S T R A C T

Introduction: Femoral neck shortening after dynamic fixation of extra-capsular fracture may impair functional results, but is rarely assessed. The present study measured impaction in stable and unstable fractures (on the Ender classification) treated by PFNA™ nail. The objectives were: 1) to validate the Ender classification to assess fracture stability; 2) to determine whether neck shortening and head purchase quality varied with stability; and 3) to determine the functional impact of femoral neck shortening.

Hypothesis: The study hypothesis was that the PFNA™ nail stabilizes unstable as well as stable fractures.

Materials and Methods: One hundred and fifteen consecutive patients, aged over 70 years, operated on for intertrochanteric fracture using the PFNA™ nail were followed up prospectively for 6 months. Multivariate analysis, including age, gender, assembly quality and body-mass index, was applied to assess the predictive power of the Ender classification with respect to femoral neck shortening. Secondly, patients were grouped according to stable versus unstable fracture (n=70 and 45, respectively), and impaction and femoral head purchase were assessed on a dedicated radiographic protocol. Functional results were assessed on Parker score.

Results: In the unstable fracture group, 3 assembly failures required revision by total hip replacement. Ender grade ≥ 2 was significantly predictive of >5 mm neck shortening. Neck shortening was greater in unstable fracture: 8.1 ± 8.4 mm (range, 4–32 mm), versus 2.5 ± 3.7 mm (range, 3–14 mm) (P=0.0004). Mean blade cut-through was 1.2 ± 2.9 mm (range, 1–12 mm) in unstable fracture, versus 0.3 ± 1.3 mm (range, 1–6 mm) (P=0.02). Mean cut-out was 2.3 ± 6 mm (range, 2–21 mm) in unstable fracture, versus 0.5 ± 2.6 mm (range, 1–8 mm) (P=0.03). Parker scores diminished comparably in the two groups, without significant difference at follow-up: 3.9 ± 2.6 (range, 0–9) in stable and 3.1 ± 1.9 (range, 0–8) in unstable fracture; reduction in Parker score showed no correlation with femoral neck shortening (r=0.013, P=0.88).

Discussion: The PFNA™ nail provides poorer stabilization of unstable compared to stable fracture. Femoral neck shortening should be taken into account in assessing internal fixation hardware performances.

Level of evidence: Level III. Prospective case-control study.

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1. Introduction

Dynamic osteosynthesis of superior femoral fracture provides fracture site impaction, to reduce shear stress on the material, and should theoretically allow immediate weight-bearing [1]. The downside is secondary neck collapse, reducing femoral lateralization. Złowodzki et al. [2], in a series of intra-capsular fractures, reported a mean 8 ± 5 mm shortening of the femoral neck, significantly impairing functional scores. The present study sought to extend this type of analysis to extra-capsular fractures, which are more often managed by dynamic osteosynthesis. In these fractures, the neck is actually intact, but impacted in the metaphysis, especially if the metaphyseal cancellous bone is osteoporotic, reducing femoral lateralization with supposedly the same functional impact as reported by Złowodzki et al. [2]. Only Oger et al. [3], to the best of our knowledge, assessed this parameter in trochanteric fracture treated by sliding screw-plate. Generally speaking, osteosynthesis failure in this type of fracture is
assessed only in terms of disassembly on Baumgaertner’s criteria [4]: i.e., by variation in the tip–apex distance between the cephalic material and the subchondral bone. The various meta-analyses on the subject failed to differentiate materials in terms of cut-out [5,6] or revision rates [5–7]. In a large-scale randomised study, Parker et al. [8] found no difference between intramedullary nailing and dynamic screwing, except in motion recovery time. Giraud et al. [9] reported a preference for sliding screw-plates, but only from the point of view of cost and blood loss.

The current study assessed pertrochanteric fracture fixation by the PFNA™ (proximal femoral nail antirotation) nail, whereby head purchase is achieved by a helical blade; disassembly was assessed on classical criteria plus femoral neck shortening, and the relation between degree of shortening and functional results at follow-up was analysed. Implant performance in terms of stabilization was compared between stable (control group) and unstable (test group) fractures, with metaphyseal cancellous bone impaction on the Ender classification [10] as criterion of bone instability. The study objectives were:

- to validate the Ender classification in the assessment of fracture instability;
- to determine whether neck shortening and head purchase quality varied with stability; and;
- to determine the functional impact of femoral neck shortening. The study hypothesis was that the PFNA™ nail stabilizes unstable as well as stable fractures.

2. Material and method

2.1. Patients

A single-centre comparative study recruited 142 consecutive patients, aged over 70 years, presenting with pertrochanteric extra-capsular fracture operated on between September 2010 and September 2012. After providing consent, they were included in a 6-month prospective follow-up protocol. Nineteen were lost to follow-up and 8 died: 115 complete files underwent radiologic and clinical analysis. Fractures were classified as unstable (45 patients) in case of impaction of trochanteric cancellous bone by an intact cervical spur: i.e., Ender grades 4 and 5 [10] (Fig. 1). Stable fracture (70 patients) comprised Ender grade 1 and 2 fractures in external rotation, with intact trochanteric cancellous bone able to limit cervical spur impaction. Ender grade 3 fractures were excluded, being rare and involving ligamentous instability (posterior capsular and periosteal hinge rupture), distinct from the bone instability which was the focus of the present study. The two groups (stable and unstable fracture) were comparable on the main demographic parameters (Table 1).

![Fig. 1. The first 5 grades of pertrochanteric fracture on the Ender classification. Grades 1 and 2: displacement in the form of opening in lateral rotation around the posterior capsular-periosteal hinge, with intact metaphyseal cancellous bone. Grade 3 is complete posterior capsular-periosteal hinge rupture, and not included here. Grades 4 and 5: cervical spur impaction in the greater trochanter, impacting the metaphyseal cancellous bone.](image)

<table>
<thead>
<tr>
<th>Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Grade 1: Displacement in the form of opening in lateral rotation around the posterior capsular-periosteal hinge, with intact metaphyseal cancellous bone.</td>
</tr>
<tr>
<td>2</td>
<td>Grade 2: Complete posterior capsular-periosteal hinge rupture, not included here.</td>
</tr>
<tr>
<td>3</td>
<td>Grade 3: Cervical spur impaction in the greater trochanter, impacting the metaphyseal cancellous bone.</td>
</tr>
<tr>
<td>4</td>
<td>Grade 4: Impaction of trochanteric cancellous bone by an intact cervical spur.</td>
</tr>
<tr>
<td>5</td>
<td>Grade 5: Impaction of trochanteric cancellous bone by a cervical spur.</td>
</tr>
</tbody>
</table>

Table 1

<table>
<thead>
<tr>
<th></th>
<th>Stable fracture</th>
<th>Unstable fracture</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age ± SD (years)</td>
<td>83 ± 6.7 (70–98)</td>
<td>85 ± 5.4 (70–95)</td>
<td>0.8</td>
</tr>
<tr>
<td>Sex ratio (M/F)</td>
<td>0.3</td>
<td>0.15</td>
<td>0.1</td>
</tr>
<tr>
<td>Mean BMI (± SD)</td>
<td>23.4 ± 3.4 (15–29)</td>
<td>23.3 ± 3.2 (14–28)</td>
<td>0.9</td>
</tr>
<tr>
<td>ASA score (n)</td>
<td>23.3 ± 3.2 (14–28)</td>
<td>23.3 ± 3.2 (14–28)</td>
<td>0.5</td>
</tr>
</tbody>
</table>

BMI: body-mass index; ASA: American Society of Anesthesiologists.

2.2. Surgery

Fracture fixation used the titanium PFNA™ nail (Synthes, Etupes, France). Closed reduction was performed, with the patient supine on the orthopedic table, under fluoroscopic control. The blade was impacted in the cancellous bone of the femoral head and rotation was locked by 5 mm controlled compression. Weight-bearing was resumed 2 days after surgery.

2.3. Assessment

The principal assessment criterion was femoral neck shortening due to fragment crumpling; secondary criteria were head purchase quality (blade cut-out and cut-through) and functional gain or loss on Parker score [11].

At inclusion, fractures were classified as Ender grade 1, 2, 4 or 5 by a single observer (PM). Patients were assessed radiologically on postoperative day 2, before resumption of weight-bearing (reference postoperative radiography), then at 6 months. AP hip views were obtained at each point with neck anteversion neutralized by internal rotation until the two medial edges of the greater trochanter were superimposed. Reduction quality and material positioning were assessed on early postoperative radiographs. Ideally, the angle between neck and diaphysis should show less than 10° difference with respect to the contralateral side and the cervical blade should be in the inferior third of the neck on AP view and in the mid-third on lateral view, with the tip of the blade centered in the femoral head on both views (Figs. 2 and 3).

Concordance and reproducibility of the Ender classification were tested by 3 observers (MH, AP, PM) reading 20 radiographs twice at 1 month’s interval. For reproducibility, the Kappa coefficient was calculated on the Cohen test [12]. The interobserver concordance coefficient was calculated on the Fleiss test [13]. Coefficients were interpreted following Landis and Koch [14].

Radiographic measurements were taken retrospectively by an observer blind to the fracture classification (MH). Neck shortening...
was assessed by comparing the radiograph at last follow-up (at 6 months or before revision surgery) and the early postoperative views. Image enlargement was controlled using the (known) length of the helical blade on AP view. Neck impaction in the metaphysis was assessed by the distance between the proximal end of the blade and the nail. Head purchase was assessed by two parameters: blade protrusion (“cut-through”) into the femoral head, measured as the axial distance of the blade tip from the subchondral bone, and “cut-out”, measured as the perpendicular distance to the screw axis between the tip of the blade and the subchondral bone (Fig. 2). Total femoral neck shortening was calculated as the sum of blade cut-through into the head and neck impaction in the metaphysis. Measurements were made on digitized radiographs using PACS software (Carestream Health Inc., Rochester, NY, USA). Variations in Parker score [11] were calculated as the difference between preoperative and 6-month values.

2.4. Statistics

To reveal a mean difference of 5 ± 5 mm on the principal assessment criterion of neck shortening, at least 25 patients were required per group to achieve 90% power. A 5 mm threshold was selected as being liable to affect quality of life scores, according to Zlowodzki et al. [15], and as being greater than the precision of measurements from digitized radiographs subject to moderate variations in view, estimated by Massin et al. [16] as of the order of 1 mm.

Factors associated with >5 mm shortening were analysed on univariate and multivariate logistic regression and expressed as odds ratios (OR) with 95% confidence intervals (95% CI). The significance threshold for univariate analysis was set at 20%. All such variables identified in the study were included in the final multivariate model after analysis of interaction with Ender grade; the significance threshold for multivariate analysis was set at 5%. In case of positive interaction, the variable was forced in the multivariate model. Statistical analysis was performed by two investigators (TD and CE) on R software, 3.02 (R Foundation for Statistical Computing, Vienna, Austria).

3. Results

Intra-observer concordance for Ender classification was strong, but inter-observer reproducibility was weak (Table 2). For a risk of >5 mm neck shortening, observer assessment of assembly quality as being inadequate showed significant predictive value (OR = 3.27; 95% CI, 1.4–7.7; P = 0.007), as did Ender grade 4 or 5 (respectively, OR = 5.18; 95% CI, 1.7–16.0 (P = 0.004); and OR = 5.00; 95% CI, 1.3–18.8 (P = 0.017)). Ender grade >2 showed highly significant predictive value for >5 mm neck shortening. There was an interaction between Ender grade >2 and gender, the impact of Ender grade on shortening being weaker in male than in female subjects (Table 3).

Table 2  
Kappa coefficient for intra-observer concordance (lines 1 and 2) and inter-observer reproducibility (line 3).

<table>
<thead>
<tr>
<th></th>
<th>Observer 1</th>
<th>Observer 2</th>
<th>Observer 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reproducibility (±SD)</td>
<td>0.37 ± 0.14</td>
<td>0.35 ± 0.14</td>
<td>0.33 ± 0.15</td>
</tr>
<tr>
<td>Weighted Cohen’s κ</td>
<td>0.76</td>
<td>0.68</td>
<td>0.86</td>
</tr>
<tr>
<td>Concordance (Fleiss)</td>
<td>0.34 ± 0.06</td>
<td>95% CI: 0.21–0.38</td>
<td></td>
</tr>
</tbody>
</table>

Table 3  
Univariate analysis of predictive value of the Ender classification (grade >2) for >5 mm femoral neck shortening according to gender.

<table>
<thead>
<tr>
<th>Ender grade &gt;2</th>
<th>n</th>
<th>OR</th>
<th>95% CI</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>25</td>
<td>0.69</td>
<td>0.1–4.72</td>
<td>0.70</td>
</tr>
<tr>
<td>Female</td>
<td>20</td>
<td>5.91</td>
<td>2.37–14.76</td>
<td>0.0001</td>
</tr>
<tr>
<td>Total</td>
<td>45</td>
<td>3.9</td>
<td>1.77–8.58</td>
<td>0.001</td>
</tr>
</tbody>
</table>

95% CI: 95% confidence interval; OR: odds ratio.
Table 4
Multivariate analysis of intrinsic predictive values of various variables for >5 mm femoral neck shortening. Model adjusted on interaction between Ender classification and gender. Age and BMI expressed as categoric variables around median (respectively, 85 years and 25).

<table>
<thead>
<tr>
<th>OR</th>
<th>95% CI</th>
<th>( P ) value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td>2.4</td>
<td>0.74–7.75</td>
</tr>
<tr>
<td>Faulty assembly</td>
<td>3.01</td>
<td>1.13–8.02</td>
</tr>
<tr>
<td>Ender grade &gt;2</td>
<td>4.96</td>
<td>1.93–12.75</td>
</tr>
<tr>
<td>Age ( \geq ) 85 years</td>
<td>1.3</td>
<td>0.53–3.05</td>
</tr>
<tr>
<td>BMI 20–25</td>
<td>0.84</td>
<td>0.26–2.7</td>
</tr>
<tr>
<td>BMI ( \geq ) 25</td>
<td>0.67</td>
<td>0.2–2.28</td>
</tr>
</tbody>
</table>

BMI: body-mass index; 95% CI: 95% confidence interval; OR: odds ratio.

Table 5

<table>
<thead>
<tr>
<th>Mean Parker score ± SD (range)</th>
<th>Stable fracture</th>
<th>Unstable fracture</th>
<th>( P )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preoperative</td>
<td>6.1 ± 3.1 (1–9)</td>
<td>4.8 ± 2.6 (1–9)</td>
<td>0.02</td>
</tr>
<tr>
<td>6 months</td>
<td>3.9 ± 2.6 (0–9)</td>
<td>3.1 ± 1.9 (0–8)</td>
<td>0.07</td>
</tr>
<tr>
<td>Deterioration (%)</td>
<td>34.1 ± 34.1 (0–70)</td>
<td>35.4 ± 33.1 (0–70)</td>
<td>0.8</td>
</tr>
</tbody>
</table>

On multivariate analysis, 2 variables (Ender grade >2 and observer assessment of assembly quality as inadequate) showed significant independent predictive value for >5 mm shortening (Table 4). Osteosynthesis malpositioning according to the study criteria was more frequent in unstable (45%) than stable fracture (21%) (\( P < 0.001 \)).

Overall shortening was significantly greater in unstable fracture: 8.1 ± 8.4 mm (range, 4–32 mm), versus 2.4 ± 4 mm (range, 0–14 mm) in stable fracture (\( P = 0.0004 \)). Mean cut-through was 1.2 ± 2.9 mm (range, 1–12 mm) in unstable versus 0.3 ± 1.3 mm (range, 1–6 mm) in stable fracture (\( P = 0.02 \)), and mean cut-out respectively 2.3 ± 6.0 mm (range, 2–21 mm) versus 0.5 ± 2.6 mm (range, 1–8 mm) (\( P = 0.03 \)).

Parker scores were significantly lower in unstable fracture at baseline, then fell considerably, showing no significant difference between groups at follow-up (Table 5). Reduction in Parker score did not correlate with degree of shortening (\( r = 0.013; P = 0.88 \)).

Disassembly for mechanical reasons (cut-out or cut-through) occurred only in the unstable fracture group (\( n = 3 \); i.e., 4%; \( P = 0.05 \)), requiring revision by total hip replacement within 3 months (Fig. 4). One of these 3 failures occurred despite initially satisfactory reduction and assembly. There were 3 cases of revision surgery not involving mechanical factors:

- in the stable fracture group, 1 evacuation of postoperative hematoma and 1 extension of osteosynthesis due to diaphyseal fracture on the primary nail (in both cases, head purchase was maintained despite unsatisfactory initial assembly on the study criteria); and,
- in the unstable fracture group, 1 simple lavage for surgery site infection.

4. Discussion

The Ender classification is of predictive value for the degree of femoral neck shortening after osteosynthesis of pertrochanteric fracture. The PFNA™ nail was less effective in stabilizing unstable fractures: in Ender grade >2 fracture, neck length was less well conserved after reduction and femoral head purchase was poorer. Reduction stability was closely bound to initial assembly quality.

The present study involved certain limitations. Firstly, the loss-to-follow-up rate was high (19 patients and 8 known deaths), but matched the early mortality rate generally reported for this pathology in this age-group [17,18]. Secondly, there was an error margin in measurements around the metal implants on digitized radiographs, but of the order of a millimetre [16] and thus too low to be of clinical relevance so long as variation in angle of view is restricted, as was the aim of the study design. Thirdly, impaction was underestimated, as comparison was with postoperative values on radiographs taken 2 days post-surgery. Zlowodzki et al. [15] described a more realistic design, with the contralateral neck as reference, thereby taking into account the initial impaction liable to occur as soon as the patient awakens, well before control radiography. Fourthly, there was performance bias due to the multiplicity of surgeons, which may explain the non-negligible rate of imperfect assembly; multivariate analysis, indeed, showed that assembly quality was predictive of success. Fifthly, the Ender classification shows poor concordance, but this is also the case of the alternative classifications, both X-ray and CT [19]; however, classification was performed by the last author (PM) and was strongly predictive of secondary displacement, giving it a certain validity in the assessment of bone stability. And finally, the lack of randomisation would not seem to have led to selection bias, as the demographic data for the test and control groups were comparable.

Fig. 4. An 85 year-old female patient with a: unstable pertrochanteric fracture; b: managed by PFNA™ nail with imperfect blade centering on lateral view; c: early disassembly with fracture impaction and blade cut-out from the femoral head.

In extra-capsular fracture in the present series, shortening exceeded 5 mm in 50 cases (43.5%). Mechanically, this reduces the lever arm of the gluteal muscles [20], inducing limp [21]. These results are difficult to compare with those of Oger et al. [3], who used a different fracture classification; for grades 2 and 3, they reported 10.5 mm impaction, which is greater than in the present stable fracture group, suggesting that their screw-plate was less effective than the PFNA™ nail. Grouping grades 4 and 5 together as unstable fracture, as in the present study, correlates better with fracture stability, as these grades are predictive of considerable shortening.

The present surgical revision rate was comparable to those of other series using similar osteosynthesis techniques (gamma nail or derivatives). Parker et al. [8] reported 2 cut-outs and 1 cut-through in 215 cases. According to Simmermacher et al. [22], the helical blade, forcibly impacted in the cancellous bone [23], reduces the risk of cut-out; their series, however, showed less resistance to cut-through, as confirmed by Frei et al. [24]. As with other types of material, the blade must be positioned with precision in the femoral head; Herman et al. [25] demonstrated that blade positioning outside of the safe area (inferior quarter of the neck on AP view) increased cut-out risk by 30%. In the present series, imperfect assembly was more frequent in unstable fracture, and seemed to be less well tolerated inasmuch as there were no cases of disassembly in the stable fracture group despite some imperfect fixations. Unstable fracture thus requires greater surgical expertise.

Functional impact of femoral neck shortening was not demonstrated on Parker score. The present deterioration in Parker score was greater than reported by Soucanye de Landevoisin et al. [26] using the same material in a comparable population, possibly due to a higher rate of complications in the present series. Parker score seems less sensitive than the SF-36 score, because it does not include other parameters with a significant functional impact such as mental health, social and occupational life, and pain; however, previous functional status, considered to be the essential predictive factor for functional outcome by Tonetti et al. [27], was taken into account, results being expressed as pre- to postoperative differential.

5. Conclusion

The PFNA™ nail provided fixation of pertrochanteric fracture with a success rate close to those reported for other material. Imperfect assembly in certain cases probably affected fixation quality in unstable fracture. It will be important, in future assessments, to measure femoral neck shortening, which is a more sensitive parameter than the classical failure criteria based on tip- apex distance, reflecting the quality of head purchase.

Disclosure of interest

Philippe Massin is a consultant with the manufacturer DePuy/Synthes, receiving fees unrelated to the present study. The other authors declare that they have no conflicts of interest concerning this article.

References


