

Long-term results of the augmented PFNA: a prospective multicenter trial

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Received: 11 September 2013
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Abstract

Background Pertrochanteric fractures are increasing and their operative treatment remains under discussion. Failures needing reoperations such as a cut-out are reported to be high and are associated with multiple factors including poor bone quality, poor fracture reduction and improper implant placement. The PFNA[®] with perforated blade offers an option for standardized cement augmentation with a PMMA cement to provide more stability to the fracture fixation. It remains unclear if the augmentation of this implant does any harm in a longer time span. This prospective multicenter study shows clinical and radiological results with this implant with a mean follow-up time of 15 months.

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Methods In 5 European clinics, 62 patients (79 % female, mean age 85.3 years) suffering from an osteoporotic pertrochanteric fracture (AO 31) were treated with the augmented PFNA[®]. The primary objectives were assessment of activities of daily living, pain and mobility. Furthermore, the X-rays were analyzed for the cortical thickness index, changes of the trabecular structure around the cement and the hip joint space.

Results The mean follow-up time was 15.3 months. We observed callus healing in all cases. The surgical complication rate was 3.2 % with no complication related to the cement augmentation. A mean volume of 3.8 ml of cement was injected and no complication was reported due to this procedure. 59.9 % reached their prefracture mobility level until follow-up. The mean hip joint space did not change significantly until follow-up and there were no signs of osteonecrosis in the follow-up X-rays. Furthermore, no blade migration was assessed.

Conclusion This study makes us believe that the standardized augmentation of the PFNA with a perforated blade is a safe method to treat pertrochanteric femoral fractures. It leads to good functional results and is not associated with cartilage or bone necrosis.

Keywords Hip fracture · Augmentation · PMMA · Cement leakage · PFNA · Cut-out · Cement augmentation · Osteoporosis · Cortical thickness index · Cement distribution · Hip joint space · Osteonecrosis · Long-term follow-up · Parker Mobility Score · Pertrochanteric fracture

Introduction

The demographic development leads to an increase of fragility hip fractures and their treatment is still under

discussion. Stable A1 fractures are regularly stabilized with a Dynamic Hip Screw [32], whereas there is an increasing trend for intramedullary devices in the treatment of unstable A2 and A3 fractures [1, 2, 26, 30, 39].

Literature shows that screw designs for the cephalic part of the implant come up with failure rates needing revision surgery of up to 16 % [2, 24, 25, 38]. Recent studies showed that the PFNA with its blade for the cephalic part of the implant is effective for pertrochanteric fracture fixation [26, 35] with low failure rates of 0.6–3.6 % [20, 26, 35]. It has to be mentioned that these investigations [20, 26, 35] were not limited to the elderly where an underlying osteoporosis could lead to even higher failure rates. Several biomechanical studies have already proven the mechanical superiority of using a blade instead of a screw in osteoporotic bone [13] and the fixation construct gets even more stable with the use of an additional augmentation with polymethylmethacrylate (PMMA) cement in fact independently of the position of the blade within the head-neck element [8–11, 33, 34]. From the clinical side, the use of an augmented blade is known to lead to good results in short time [16].

The main concerns about such a device were a potential disturbance of bone metabolism [14, 19, 37] and the induction of cartilage damage although there are several investigations rebutting this [4, 41, 43]. The current prospective multicenter trial was conducted to evaluate the long-term clinical outcome as well as the radiological results with the standardized augmentation of the PFNA. To our knowledge, this is the first investigation reporting long-term results with this device.

Materials and methods

The study was performed at five orthopedic departments starting in October 2009 and the last follow-up examination was in May 2013. The inclusion criteria were as follows: pertrochanteric fracture (AO/OTA 31A), age 65 and above, low energy trauma and signed informed consent. Patients with a pathological fracture, active malignancy or organ transplant were excluded. The ethical commission approved the study and every single patient signed the informed consent form. A total number of 110 patients have been included. 25 (22.7 %) cases were lost to follow-up due to refusal, concurrent indisposition or weakness which made an additional evaluation impossible. 23 patients died for reasons not related to the surgical procedure. The remaining 62 patients were followed up according to the study protocol. The decision to augment was made by the surgeon without using strict objective measurements.

The surgical technique is described in the first publication with this device [16].

Figure 1a–d shows a representative case of standardized cement augmentation of the perforated PFNA blade in an 82-year-old lady with an unstable pertrochanteric fracture with a 1-year follow-up X-ray.

Outcome parameters

The WHO Performance Score [28] was used to measure the quality of life before and after the fracture. It consists of five levels in which 0 means full activity without restriction and 4 means completely disabled and totally confined to bed or chair.

The Parker Mobility Score [29] was used to assess the walking ability before the accident and at the follow-up. The particular capability to walk inside, walk outside and having social contact is evaluated in 4 levels with “no difficulty”, “alone”, “with help from another person” and “not at all”. A maximum of nine points means unlimited walking ability. In addition, the use of a walking aid was documented for every patient before and after the accident.

Pain was assessed using the visual analog scale (VAS) as previously described [6] and widely known. The VAS was found to have good measurement properties for assessing pain in hip fracture patients [5].

The fracture pattern was assessed and classified as AO. The cortical thickness index [7] was assessed in the preoperative and in the follow-up X-rays. The cortical thickness index shows a significant positive correlation with the T-Score of the femoral neck [31] and was therefore used to classify the local bone quality in our study population. A cortical thickness index lower than 0.40 (lateral film) and 0.50 (ap film) has been described as a threshold for osteoporosis where all measured femora had a lower local bone mineral density than 2.5 standard deviations below the peak bone mass which is the WHO definition of osteoporosis [31].

On the postoperative X-rays, we evaluated the quality of fracture reduction as anatomic (no displacement), near-anatomic (<3 mm displacement or 5°–10° varus/valgus and/or anteversion/retroversion) or non-anatomic (>3 mm displacement or >10° varus/valgus and/or anteversion/retroversion) [20, 39]. The amount of injected cement was documented, and on the follow-up X-rays, signs of fracture healing were assessed. The lateral blade migration was measured as previously described [12, 42].

On the preoperative and follow-up X-rays, the hip joint space was measured as the distance of the femoral head and the acetabulum in three defined positions in the antero-posterior X-ray to assess a potential cartilage damage due to the procedure (Fig. 2). Furthermore, the presence of signs of a head necrosis by means of sclerosis or subchondral collapse was assessed in the follow-up X-rays by one of the authors (HD).

Fig. 1 **a** An 82-year-old female patient with an unstable fracture 31 A2 at her left side after a simple fall in the nursing care home. Intraoperative image intensifier picture after closed reduction and internal fixation with the PFNA and standardized cement augmentation of the PFNA blade in ap (**b**) and lateral (**c**) views. **d** Follow-up X-rax after 1 year shows a well-healed fracture and no signs of osteonecrosis of the femoral head



Fig. 2 The measure of the hip joint space in three different positions

Intraoperative complications included any unforeseen event during the augmentation such as perforation with the guide wire into the hip joint and cement leakage. Potential postoperative complications were cutting out of the blade from the femoral head, cutting through the blade centrally, any unexpected blade migration, loosening of the blade, implant breakage, infection, additional fracture or bone-healing disturbances and any other general complication within the follow-up period.

Statistical analysis

SPSS 20 (SPSS Inc., Chicago, IL) was used for statistical analysis. All baseline and follow-up parameters were described using standard descriptive statistics. Metric scaled data are reported as arithmetic mean and categorical data as absolute frequency and percentage distribution. Depending on the distribution form, a *t* test for independent

variables or a nonparametric Mann–Whitney U test was used. The Kolmogorov–Smirnov test was used to assess the distribution form. A Chi-square test or a Fisher's exact test was used to analyze categorical data. The probability level was set as $p < 0.05$.

Results

To test the long-term effects of standardized cement augmentation, 62 patients were analyzed. The mean time to follow-up was 15.3 months (365–887 days). The demographics are shown in Table 1. Associated injuries were not noted. The majority of the patients sustained an unstable pertrochanteric fracture (A2/3; 83.9 %). The mean Parker Score was 5.1 before and 4.6 at follow-up. 59.6 % of our patients reached their prefracture mobility level within the follow-up time. The mean WHO Performance Score was 2 before the fracture occurred and again 2 at follow-up, whereas 70.1 % reached their prefracture WHO Performance Score again. Table 2 shows the main functional outcome parameters split up for the single fracture types.

The mean VAS at follow-up was 0.5. All patients were osteoporotic, whereas the mean cortical thickness index (CTI AX) was 0.44 at the time of the fracture and dropped non-significantly ($p = 0.86$) to 0.42 at follow-up.

The follow-up X-rays showed an anatomic reduction in 59.7 %, whereas in 24.2 %, the reduction was near-anatomic and in 1.6 % non-anatomic. An open reduction was necessary in three cases, whereas in 2 cases subtrochanteric

cerclage wires were used to stabilize the reduction and were not removed.

There was one patient with a postoperative haematoma and one patient with a superficial wound infection both requiring a reoperation. One patient had a postoperative pneumonia and two patients a urinary tract infection which required antibiotic treatment. The presence of any of these complications was found to have a significantly negative effect ($p = 0.026$) on the Parker Mobility Score at follow-up.

There was no intraoperative complication reported. In the present study, a mean volume of 3.8 ml (3–6) cement was injected. In all cases, a leakage test was done to detect a perforation into the hip joint and no intraarticular cement was observed.

At follow-up, all fractures were healed. No sign of osteonecrosis of the femoral head or lysis around the cement could be detected. According to the above-mentioned method, the mean joint space showed no significant difference at follow-up ($p = 0.44$) which is shown in the boxplot in Fig. 3. There was no implant migration (e.g., migration of the blade related to the femoral head) measurable. Lateral blade migration averaged 5.2 mm. Lateral blade migration was not found to be associated with fracture type ($p = 0.86$) nor with implant position ($p = 0.17$), fracture reduction ($p = 0.45$) or Parker Score at follow-up ($p = 0.89$). We did not find any unexpected blade migration such as a cut-out, implant loosening or implant breakage within the study period.

Discussion

The PFNA was widely described to be a reliable implant to fix pertrochanteric fractures [18, 20, 26, 35] and the

Table 1 The baseline characteristics of the study population

	All ($n = 62$)	%
Age, mean	85.3	
Female/male	49/13	79/21
Left/right	36/26	58.1/41.9
AO 31-A1	10	16.1
AO 31-A2	44	71
AO 31-A3	8	12.9
Hospitalization time, mean	12 days	

Table 2 The main functional outcome parameters separated for certain fracture types

	WHO Performance Score preoperatively	WHO Performance Score at follow-up	Parker Score at preoperatively	Parker Score at follow-up
A1	2	2.3	4.2	3.2
A2	1.9	2	5.8	4.6
A3	2.8	2.3	3.2	3.1

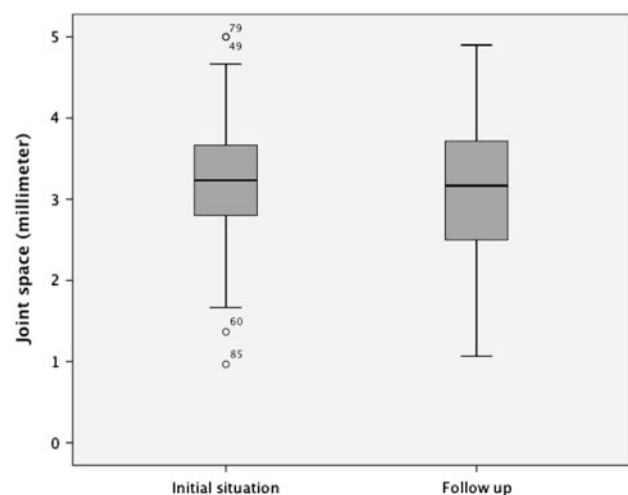


Fig. 3 Mean joint space measured on the initial X-ray and on follow-up shows no significant difference ($p = 0.44$)

augmented version was previously reported to lead to good short-term functional results [16]. Furthermore, the augmentation of the blade gives the fixation construct much more stability due to a larger bone–implant interface [8–11, 37, 40].

59.5 % of our cohort reached their prefracture functional status until the final follow-up. This is an excellent long-term outcome for this age group compared to the literature [17, 20, 26, 35].

Failures requiring reoperation such as a cutting out off the femoral head are still reported to be as high as up to 16 % [2, 25, 29, 36] with screw devices and up to 5.7 % [18] with the PFNA. In this context, it is worth to notice that this affects a high number of people due to the increasing incidence of pertrochanteric fractures. In the elderly, where most of these fractures occur, every complication leads to a high perioperative morbidity and mortality due to their little reserves and comorbidities. Studies of the follow-up X-rays showed no unexpected blade migration such as a cut-out or cutting through and no loosening of the blade in this series. These facts suggest that the additional cement augmentation may have prevented the blade from cutting out off the femoral head in this present study.

The surgical complication rate in the presented study was 3.2 % with no complication related to the cement augmentation. This is an acceptable rate compared to other reports in the literature [20, 35].

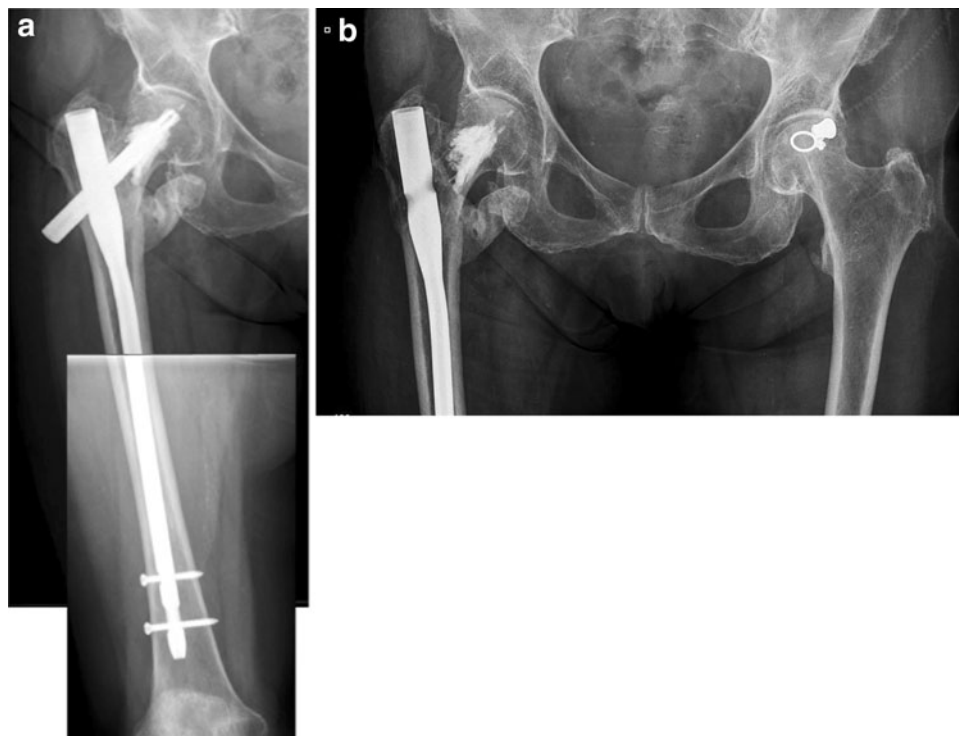
Within the study period in one patient, an additional fall resulted in a subsequent fracture at the tip of the nail.

In this case, the short nail was changed to a long and both the removal of the blade and the reinsertion of a new blade were performed without any complication. Unfortunately, the patient died 4 weeks after the second operation due to myocardial infarction. The mean lateral blade migration was 5.2 mm (± 4.6) and led in two cases to an irritation of the iliotibial tract with consecutive blade removal (Fig. 4). Both procedures were done without a problem.

The mean cortical thickness index as by Sah et al. [31] was measured in the fracture X-ray and at the final follow-up. It indicated that all patients first suffered from osteoporosis and showed no significant change at follow-up.

A mean volume of 3.8 ml of cement was injected and there were no significant associations between the amount of cement and pain at follow-up or functional recovery. Furthermore, the joint space showed no significant change within the study period. Hisatome et al. [15] report a negative influence of PMMA cement to the cartilage if it is placed in a subchondral area where an exothermic reaction while hardening of the cement is proposed to be a possible reason for this finding [14]. Furthermore, a bone necrosis could be imaginable if higher temperatures are reached [14, 19]. Fliri et al. [11] showed that the Traumacem V+[®] leads to maximum temperatures of 41 °C at the cement–bone interface when instilled a volume of 3 ml around the blade. The same study also showed that the reached temperature is dependent on the amount of injected cement. For the present study, a lower amount of cement was used (mean 3.8 ml) and it is assumed that this amount does not lead to

Fig. 4 A well-healed unstable pertrochanteric hip fracture of an 85-year-old female patient stabilized with an augmented PFNA with lateral protrusion of the blade irritating the tractus iliotibialis (a) and b the same patient after removal of the blade without any complication



negative impact on both bone and cartilage as previously described [4, 43]. Our findings that there were no radiological signs of osteonecrosis at follow-up and that there was no significant change of the joint space support this statement. On the other side, this small volume is enough to biomechanically enhance stability significantly [4, 19, 23, 33, 34, 40]. A possible limitation to the statement about bone necrosis is that previous authors reported an onset after 3 years [3, 22, 27].

The main limitation of this study is the lack of a control group. However, an acceptable long-term outcome of the augmented PFNA could be shown. Furthermore, there were no hints of cartilage damage or bone necrosis within the follow-up period of 15 months. Thus, standardized augmentation of the PFNA blade seems to be a safe and feasible method to treat pertrochanteric femoral fractures. From the socio-economic perspective, additional costs have to be taken into account and the number of hip fractures to treat with an augmented PFNA to prevent one failure remains unclear. In this context, it has to be noted that additional cement may not be necessary in stable A1 fractures fixed with a PFNA. To our personal opinion, the standardized augmentation of an unstable pertrochanteric fracture in an osteoporotic bone in the elderly who are known to have several comorbidities and little reserves can provide more safety for the overall treatment. Nevertheless, achieving a good fracture reduction and careful implant placement are essential [21, 26, 35].

A randomized trial comparing geriatric patients with unstable pertrochanteric fractures with a PFNA either with or without augmentation has been initiated and will help identify patients at risk for surgical failures and define the indications for augmentation more precisely.

Conclusion

The standardized augmentation of the PFNA with perforated blade is a safe method to treat pertrochanteric femoral fractures. It prevents migration of the implant within the head-neck fragment and leads to good functional results without causing cartilage damage or bone necrosis.

Conflict of interest No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

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