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Cement augmentation of the Proximal Femoral Nail Antirotation (PFNA) – A multicentre randomized controlled trial

Christian Kammerlander[a,*], Einar S. Hem[c], Tim Klopfer[d], Florian Gebhard[e], An Sermon[f,g], Michael Dietrich[h], Olaf Bach[i], Yoram Weil[j], Reto Babst[k], Michael Blauth[b]

[a] Department for General, Trauma and Reconstructive Surgery, Ludwig Maximilian University Munich, Marchioninistrasse 15, 81377 Munich, Germany
[b] Department for Trauma Surgery, Medical University of Innsbruck, Anichstrasse 35, 6020 Innsbruck, Austria
[c] Sykehuset I Vestfold HF Tønsberg, Halfdan Wilhelmsens allé 17, 3103 Tønsberg, Norway
[d] Clinic for Traumatology and Reconstructive Surgery, BG Trauma Center Tübingen, Schnarrenbergstrasse 95, 72076 Tübingen, Germany
[e] Department of Orthopedic Trauma Surgery, Ulm University, Steinhoevelstrasse 9, 89075 Ulm, Germany
[f] Department of Traumatology, University Hospitals Leuven, Herestraat 49, 3000 Leuven, Belgium
[g] Department of Development and Regeneration, KU Leuven, Herestraat 49, 3000 Leuven, Belgium
[h] Surgical Clinic, Waid City Hospital, Tièchestrasse 99, 8037 Zurich, Switzerland
[i] Department of Orthopedics, Trauma and Hand Surgery, Sophien- und Hufeland-Klinikum Weimar, Henry-van-de-Velde-Straße 2, 99425 Weimar, Germany
[j] Hadassah Medical Organization, p.o.b.12000, 91120 Jerusalem, Israel
[k] Departments of Surgery and Traumatology, Cantonal Hospital Lucerne, Spitalstrasse, 6000 Lucerne 16, Switzerland

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ABSTRACT

Introduction: New implant designs like the Proximal Femoral Nail Antirotation (PFNA) were developed to reduce failure rates in unstable pertrochanteric fractures in the elderly. Standardized implant augmentation with up to 6 mL of polymethylmethacrylate (PMMA) cement has been introduced to enhance implant anchorage by increasing the implant-bone interface in osteoporotic bone conditions. Biomechanically, loads to failure were significantly higher with augmentation. The primary objective of this study was to compare the mobility of patients with closed unstable trochanteric fractures treated by PFNA either with or without cement augmentation.

Patients and methods: A prospective multicentre, randomized, patient-blinded trial was conducted with ambulatory patients aged 75 or older who sustained a closed, unstable trochanteric fracture. Surgical fixation had to be performed within 72 h after admission. Outcomes were evaluated at baseline, during surgery, 3 to 14 days after surgery, 3 months, 6 months, and 12 months after surgery. To evaluate the primary objective, patients' walking speed was assessed by the Timed Up and Go (TUG) test. Secondary objectives included the analysis of implant migration assessed on radiographs, quality of life measured by the Barthel Index, mobility measured by the Parker Mobility Score, and complications.

Results: Of 253 randomized patients, 223 patients were eligible: 105 patients were allocated to the PFNA Augmentation group and 118 to PFNA group. At 3 to 14 days after surgery, there was no statistical significant difference in mean walking speed between the treatment groups. For the secondary objectives, also no statistical significant differences were found. However, no patient in the PFNA Augmentation group had a reoperation due to mechanical failure or symptomatic implant migration compared to 6 patients in the PFNA group.

Conclusions: Augmentation of the PFNA blade did not improve patients' walking ability compared to the use of a non-augmented PFNA but might have the potential to prevent reoperations by strengthening the osteosynthesis construct.

* Corresponding author at: Department for General, Trauma and Reconstructive Surgery, Ludwig Maximilian University Munich, Marchioninistrasse 15, 81377 Munich, Germany.
E-mail addresses: Christian.Kammerlander@med.uni-muenchen.de (C. Kammerlander), einhehe@online.no (E.S. Hem), TKlopfer@bgu-tuebingen.de (T. Klopfer), florian.gebhard@uniklinik-ulm.de (F. Gebhard), an.sermon@uzleuven.be (A. Sermon), michael.dietrich@waid.zuerich.ch (M. Dietrich), O.Bach@Klinikum-Weimar.de (O. Bach), weily@hadassah.org.il (Y. Weil), reto.babst@ksl.ch (R. Babst), michael.blauth@i-med.ac.at (M. Blauth).

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Introduction

Background

Trochanteric hip fractures are very common in the elderly, their already high incidence is still increasing and the treatment leads to significant healthcare expenditure [1]. The main reason for these fractures in this age group is a simple fall in combination with an osteoporotic bone. Multiple comorbidities are complicating the perioperative procedure in these patients [2]. The functional outcome in this age group about activities of daily living and self-capability is mainly determined by the patients' previous health status and the treatment in the acute hospital [3,4]. Intramedullary implants are widely used for treatment of unstable pertrochanteric fractures [5]. Overall rates for mechanical failure in these type of fractures including extramedullary fixation techniques have been reported up to 20.5% [6]. So-called catastrophic failures like cut out (cranial perforation of the head neck element) or cut through (central perforation) require reoperations, prolonged hospital stay, increased non-surgical complication rates, and consequently higher costs. Catastrophic failure rates have been reported at 4.9% and up to 9.8% and 13% and might be even higher [6–9].

Rationale

Optimal fracture reduction and good implant placement are important factors to avoid such complications, but catastrophic failures are still observed. Therefore, new implant designs like the Proximal Femoral Nail Antirotation with a helical blade (PFNA; DePuy Synthes, Oberdorf, Switzerland) [10–12] were developed to reduce failure rates as the helical blade compacts the surrounding bone during driving in and therefore leads to a biomechanical higher stability compared to conventional screws. The standardized use of bone cement around the blade in the head-neck-fragment to enlarge the bone-implant interface is an additional option to improve the primary stability and long-term implant anchorage. This biomechanically superior treatment option was studied previously in clinical observational trials, and underlined the need for a comparative trial [13–16]. The aim of this study was to investigate the clinical effects of the additional use of bone cement with the PFNA in mobile elderly patients with closed unstable trochanteric fractures on functional outcome as indicated by the postoperative recovery of walking speed.

Patients and methods

Study design and setting

This was a prospective multicentre, randomized, patient-blinded trial with a follow-up period of 12 months after initial treatment. Patients were enrolled from 9 study centres in Europe and the Middle East, from March 2012 through July 2015. Patients were treated either by PFNA or by PFNA with cement augmentation. Full weight bearing as tolerated was allowed right after surgery. In case of complications, the local investigator took the decision to re-operate. Standard anteroposterior and lateral radiographs were independently analysed by a radiologist and the co-principal investigator. All source data were entered in a central study database. The study design allowed for a re-estimation of the sample size after inclusion of the first 100 patients, due to uncertainty of involved parameters.

Participants/study subjects

Patients 75 years and older who had a closed trochanteric fracture (AO Type 31 A2–A3) due to a low energy trauma and with indication for fixation with a PFNA within 72 h after admission were enrolled. The ability to walk independently (customary walking aids were allowed) as well as basic knowledge of the national language to give informed consent were required. Patients with fractures due to malignancy, additional or open fractures, polytrauma, any implant at the same hip or hemiplegia were excluded. Patients who had a recent history of substance abuse, those who had an active malignancy or were classified according to the American Society of Anesthesiologists (ASA) classification as class V and VI, those who had participated in any other clinical trial of a drug or device possibly affecting the results of the present study within the previous month, and those with legal guardian were also excluded. If patients were to be treated with augmentation, they were not allowed to have a known hypersensitivity or allergy to any of the components of the used polymethylmethacrylate (PMMA) Traumecem V+ cement (DePuy Synthes, Oberdorf, Switzerland). If during surgery, the guide wire used for the PFNA blade perforated the femoral head, though creating a risk for potential cement leakage into the joint, or for any other reason the surgeon decided to use other implants than PFNA, the patients were also excluded. Ethical approval from all local authorities was obtained. This study was conducted in accordance with the ethical principles set forth in the Declaration of Helsinki (DoH) including amendments as well as the International Council for Harmonisation Good Clinical Practice (ICH GCP) guidelines, the European Standard EN ISO14155/2003-2011, and the laws and regulations of the individual countries in which the research was conducted. The ClinicalTrials.gov Identifier is NCT01473082.

Description of experiment, treatment or surgery

The operative techniques used for both PFNA with and without cement augmentation are well known and have been published previously [15]. The cement was applied in a standardized way. A side opening cannula was inserted into the blade after its insertion. At first, a contrast dye was injected to control for any leakage into the hip joint. In case of no leakage, the cement was applied into the blade through the same device under fluoroscopic control.

Description of follow-up routine

All patients were mobilised under physiotherapeutic supervision within the first 2 days after surgery, starting as soon as the patient's condition allowed for it.

Variables, outcome measures, data sources, and bias

Patients were randomly allocated to either the PFNA or the PFNA Augmentation group and relevant baseline data including the comorbidity status (measured by the Charlson Comorbidity Index [17,18]) were collected.

Walking speed has a significant influence on the functional outcome in older hip fracture patients, and early mobilisation is crucial to prevent medical complications in the early postoperative phase [3,19]. Therefore, we primarily decided to compare the mobility of patients with closed unstable trochanteric fractures, 5 to 7 days after treatment with either a PFNA with augmentation or a PFNA (control), using the Timed Up and Go (TUG) test [20,21]. However, after study commencement, a considerable number of patients were unable to perform the TUG test that early, due to pain, frailty and weakness. Therefore, the time window for taking the test was extended to 3 to 14 days after surgery.

The assessment of implant migration including the measurement of the Tip Apex Distance (TAD) and the Parker Ratio (blade

position), and the joint space on anteroposterior and lateral radiographs, complications, quality of life (QoL) measured by the Barthel Index (patient‘s independence), and patients' mobility measured by the Parker Mobility Score were secondary objectives [22–27].

Outcomes were evaluated at baseline (before surgery), during surgery, 3 to 14 days after surgery, 3 months, 6 months, and 12 months after surgery. The treating surgeon and the study nurses completed all follow up controls including the TUG test. The site staff entered all source data into a web-based Electronic Data Capture system (RedCap). The sponsor monitored and made queries on a regular basis to each participating site as needed to ensure the quality and integrity of the data.

Standard anteroposterior and lateral radiographs were taken at baseline, immediately after surgery (before mobilisation of the patient), and 3 months, 6 months, and 12 months after surgery. Data management was performed by the sponsor.

Randomization was done at the day of inclusion and prior to surgery, and was stratified for each participating centre with block sizes of 2 and 4. To maintain allocation concealment, the pattern of the blocks was kept confidential.

Statistical analysis, study size

An original sample size of 144 patients was calculated, based on an expectation that the minimal clinically relevant difference in mean completion times for the TUG test between the PFNA and the PFNA Augmented group would be 15 s with a standard deviation for the completion times of 30 s, a significance level of 5%, a power of 80%, an expected loss of patients due to inability to walk of 10%, and with equal treatment groups. After the planned re-estimation, the sample size was adjusted to 234 patients. All analyses were restricted to eligible patients. An “intention to treat” (ITT) analysis was performed for the primary outcome parameter; PP analyses were performed for both, the primary and the secondary outcome parameters. Complications were assessed in the safety population. The time to complete the TUG test 3 to 14 days after surgery was assessed with the use of a simple summary statistics *t*-test, and subsequently with mixed effects linear regression models to estimate the changes in the time taken after adjusting for age, gender, Charlson Comorbidity Index, Barthel Index, and Parker Mobility Score. Multiple imputation, based on the concepts of Rubin [28], was used to impute missing values, especially due to the Post-Op assessment where 31% of patients were not able to walk. The amount of missing values in the 2 treatment groups was similar. To avoid misspecification of the imputation model and produce biased results, it was considered important that the imputation model should include the outcome (time to complete the TUG test), the adjustment parameters (age, gender, Charlson Comorbidity Index, Barthel Index, and Parker Mobility Score) and pain as an auxiliary variable. Multivariate normal model, which uses a joint normal distribution, was applied. A relatively large number of imputations (50) was implemented to avoid producing a significant Monte Carlo error. Subsequently, as soon as the imputed data set had been generated, mixed effects regression analysis was carried out. Significance was tested with the use of the *t*-test or the Wald test. The changes in radiograph and QoL parameters (including the Parker Mobility Score) were also assessed with the use of mixed effects linear regression models. For surgery technical details that were measured once (Parker ratio, and TAD), a simple summary statistics *t*-test was used to assess the differences between the 2 treatment groups. The analysis was conducted with use of Stata statistical software (release 13.0; StataCorp).

Results

Accounting for all patients/study subjects

Initially, 253 patients had given informed consent and were randomized into this study. After randomization, 223 patients were considered eligible. Eighty-five of 105 patients allocated to the PFNA Augmentation group received their intended treatment and 20 patients crossed over to the PFNA group. In the PFNA group, 3 of 118 patients did not receive their intended treatment: Of those, 2 patients crossed over to the PFNA Augmented group (Fig. 1). For the primary outcome analysis, 125 patients were available. The per-protocol (PP) population comprised 113 patients. Reasons for missings were “dropout” and “inability to complete the TUG test”. During the study, 85 patients were lost to follow-up, due to withdrawal of consent (39 patients), death (20 patients), protocol violation (3 patients), surgeon‘s discretion (1 patient), or other reasons (12 patients). For 10 patients, the reason for dropout remained unknown.

Demographics, description of study population

Sex, age distribution and body mass index were similar in both groups (Table 1). All patients except one sustained their injury due to a simple fall. Based on the on-site radiological assessment, most of the fractures were classified as AO 31-A2 fractures. Fracture types were almost equally distributed between the treatment groups, except AO 31-A2.3 fractures, accounting for 25% of fractures in the PFNA Augmentation group and for 14% in the PFNA group. The mean Charlson Comorbidity score was 2.01 (SD 2.15) for the PFNA Augmentation group and 2.04 (SD 2.00) for the PFNA group. ASA physical status classifications of all patients are provided in Table 1.

Primary outcome

For the ITT population, the mean time to complete the TUG test was similar for patients in both study groups throughout the follow-up period (Tables 2 and 3). Overall, patients required 88.7 s (SD 53.7) after surgery, 30.1 s (SD 21.8) after 3 months, 24.1 s (SD 18.3) after 6 months, and 21.9 s (SD 15.9) after 12 months. Accordingly, patients' walking ability in both groups was classified similar throughout the follow-up period: Around 70% of patients (PFNA Augmentation group: 59/86; PFNA group: 71/102) could walk 3 to 14 days after surgery. Of patients being able to walk, almost all were dependent on walking aids and needed help for transfers to a chair or the toilet (PFNA Augmentation group: 55/57; PFNA group: 65/68). At 12 months, more than 90% of patients in both study groups could walk. However, around 10% (PFNA Augmentation group: 4/49; PFNA group: 7/65) were freely mobile and approximately half of the patients were classified as being independent for basic transfers, i.e. they had been able to complete the TUG test between 10 and 19 s (PFNA Augmentation group: 31/49; PFNA group: 28/65). For the PP population, similar findings as for the ITT population were made (Tables 2 and 3). Furthermore, the results of the multiple imputation were similar to the results of the mixed model analysis (data not shown).

Secondary outcomes

Radiographic outcomes

There were no statistical significant differences between the study groups regarding the joint space width over the follow-up period (Table 4) or the blade position according to the Parker Ratio (Table 5). The TAD and the calcar referenced TAD (measured at

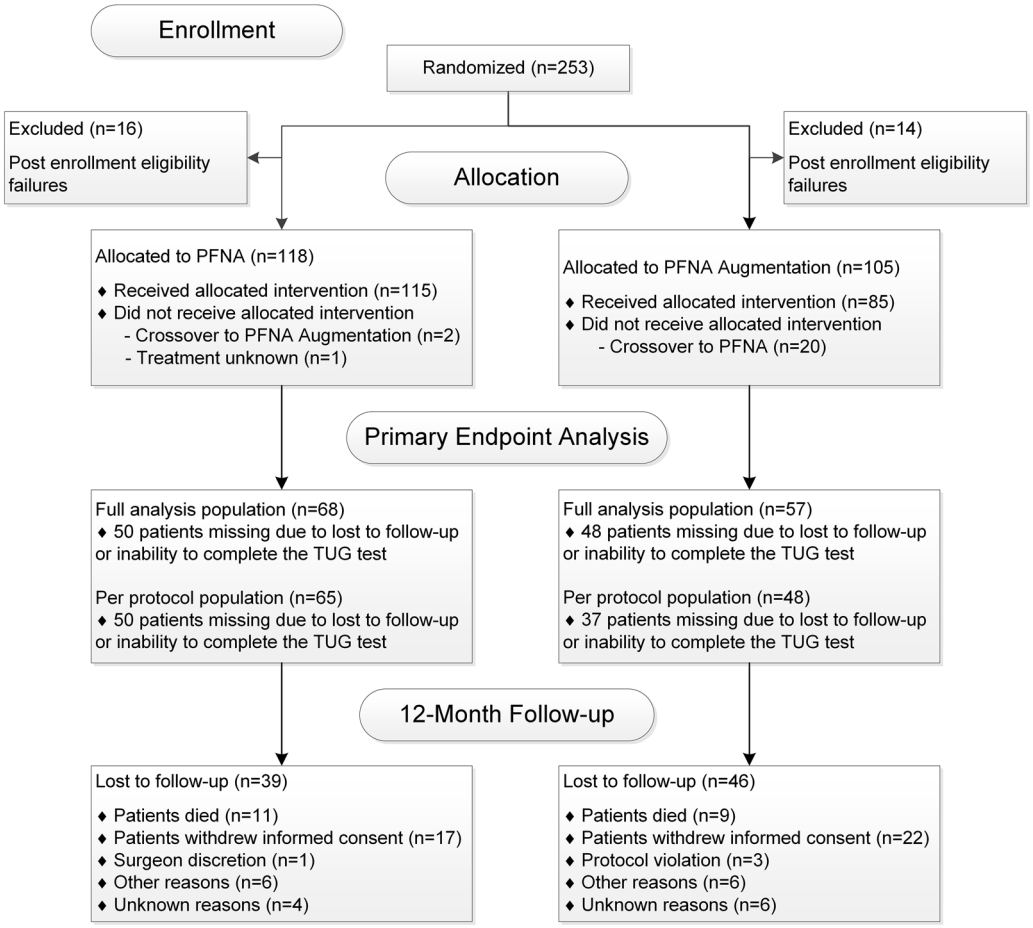

Fig. 1. A CONSORT (Consolidated Standards of Reporting Trials) diagram showing the flow of patients from recruitment through follow-up.

Post-Op) were significantly higher in the PFNA Augmented group (TAD: $p = 0.008$; calcar referenced TAD: $p = 0.036$). Changes in blade migration were similar between the treatment groups (Table 4).

Safety outcomes

For the safety population ($n = 222$), 41 patients (47%) in the PFNA Augmentation group and 68 patients (50%) in the PFNA group had at least 1 reported complication ($p = 0.681$) during the study (Table 6). No reoperation related to the implant was required in the PFNA Augmentation group compared to 6 reoperations (4.4%) in the PFNA group (1 patient had an implant breakage, 1 a cut-out, 1 loosening of the blade and 3 patients had irritations of the tractus illotibialis due to lateral blade migration). The rate of patients experiencing "systemic/rest of body complications" was similar in both groups. Twenty patients died during the follow-up period (9.0%): 8/87 PFNA Augmentation patients (9.2%), 12/135 PFNA patients (8.9%).

Quality of life

There were no statistical differences in the Barthel Index and the Parker Mobility Score between the 2 study groups ($p > 0.05$ for all timepoints and both tests) (Table 7).

Discussion

Hip fractures in the elderly are associated with significant morbidity and healthcare costs. Operative strategies which could provide earlier recovery and lower mechanical complication rates would have the potential to improve patient outcomes and save consequential costs. Standardized implant augmentation could be one tool that potentially supports these strategies. The TUG test is a quick and simple tool to assess the walking ability and physical mobility of a patient after hip fracture and is known to provide valuable prognostic information about the functional recovery [29]. In this study, we found no statistical differences in the walking ability of patients either treated by a PFNA or by a PFNA with cement augmentation. These findings suggest that other factors than blade anchorage might be important for mobilisation. Mechanical complications only occurred in the non-augmentation group, but there was no statistically significant difference between the study groups ($p > 0.05$). However, the overall catastrophic failure rate in this study was low compared to previous reports, which may have influenced our study results [6].

There was no significant difference in the TUG test between PFNA Augmentation and PFNA, measured 3 to 14 days after surgery. According to the simple *t*-test, the PFNA Augmentation group was slightly faster than the PFNA group at 6 months, but this finding was attenuated in the subsequent analyses. Neither the mixed effect modelling nor the multiple imputation showed evidence for an association between the TUG test and any of the treatment groups. Reindl et al. investigated a similar population treated with either a Dynamic Hip Screw (DHS) or an intramedullary nail and found no significant differences between the treatment groups in gait speed over the follow-up time [19]. In 56 patients with femoral neck fractures treated with hemiarthroplasty, patients required a mean of 17 s for the TUG test at 3 months compared to 82 s at 4 days postoperatively ($p = 0.01$) [29]. In this

Table 1
Baseline patient demographics and clinical characteristics according to treatment allocation (eligible randomized patients).

	PFNA (N = 118)	PFNA Augmentation (N = 105)	Total (N = 223)
Gender – n (%)	118	105	223
Female	99 (84)	87 (83)	186 (83)
Male	19 (16)	18 (17)	37 (17)
Age at surgery (years)			
n	118	105	223
Mean (SD)	85.6 (4.9)	86.1 (4.6)	85.8 (4.8)
Median (Min; Max)	86.2 (75.2; 95.6)	86.3 (75.4; 94.4)	86.3 (75.2; 95.6)
BMI (kg/m^2)			
n	117	105	222
Mean (SD)	24.8 (4.6)	24.1 (4.0)	24.5 (4.3)
Median (Min; Max)	24.0 (15.0; 41.6)	24.0 (15.6; 36.5)	24.0 (15.0; 41.6)
Smoker – n (%)	117	104	221
No	103 (88)	97 (93)	200 (90)
Yes	14 (12)	7 (7)	21 (10)
Mechanism of injury – n (%)	118	105	223
Fall	117 (99)	105 (100)	222 (100)
Other[a]	1 (1)	0 (0)	1 (0)
AO classification – n (%)	118	105	223
AO 31-A2.1	43 (36)	34 (32)	77 (35)
AO 31-A2.2	37 (31)	36 (34)	73 (33)
AO 31-A2.3	16 (14)	26 (25)	42 (19)
AO 31-A3.1	5 (4)	3 (3)	8 (4)
AO 31-A3.2	8 (7)	3 (3)	11 (5)
AO 31-A3.3	9 (8)	3 (3)	12 (5)
Charlson Comorbidity Index[b]			
n	108	95	203
Mean (SD)	2.04 (2.00)	2.01 (2.15)	2.02 (2.07)
Median (Min; Max)	1.50 (0.00; 10.00)	1.00 (0.00; 10.00)	1.00 (0.00; 10.00)
ASA physical status classification – n (%)	117	104	221
I A normal healthy patient	13 (11)	10 (10)	23 (10)
II A patient with mild systemic disease	44 (38)	31 (30)	75 (34)
III A patient with severe systemic disease	55 (47)	59 (57)	114 (52)
IV A patient with severe systemic disease that is a constant threat to life	5 (4)	4 (4)	9 (4)

ASA = American Society of Anesthesiologists, BMI = Body mass index, PFNA = Proximal Femoral Nail Antirotation.
[a] The patient went skiing, and after having stopped in front of her house, she fell on the side at slow speed.
[b] The Charlson Comorbidity Index was calculated for each patient as the sum of their comorbid conditions using weights as follows: 1 for myocardial infarction, congestive heart failure, peripheral vascular disease, cerebrovascular disease, dementia, chronic pulmonary disease, connective tissue disease, ulcer disease, mild liver disease, diabetes; 2 for hemiplegia, moderate or severe renal disease, diabetes with end organ damage, tumour (including leukaemia and lymphoma); 3 for moderate or severe liver disease; 6 for metastatic solid tumour, AIDS. The following comorbid conditions were treated as mutually exclusive: diabetes and diabetes with end organ damage, mild liver disease and moderate or severe liver disease, and tumour (including leukaemia and lymphoma) and metastatic solid tumour. The minimum possible score is 0 and maximum 29. The response "not assessed" was treated as a missing response when calculating the total score and the total score was left missing if there was a missing response for any of the component questions.

Table 2
Time to complete the Timed Up and Go test over the course of follow-up for both treatment groups.

Characteristic	PFNA		PFNA Augmentation		P value[4]
	n	Mean (95%CI)	n	Mean (95%CI)	
Time to walk 3 m and back (sec)					
Treatment allocation (ITT[a])	*118*		*105*		
Post-Op[b]	68	91.3 (77.9; 104.7)	57	85.5 (71.8; 99.3)	0.552
3 months	79	31.2 (26.2; 36.3)	57	28.6 (23.1; 34.1)	0.486
6 months	76	27.2 (22.1; 32.3)	54	19.7 (17.3; 22.1)	0.009
12 months	65	22.6 (18.6; 26.7)	49	20.9 (16.4; 25.3)	0.562
Treatment received (PP[c])	*115*		*85*		
Post-Op[b]	65	92.8 (79.0; 106.6)	48	89.3 (73.5; 105.1)	0.741
3 months	69	31.8 (26.3; 37.3)	40	29.0 (22.4; 35.7)	0.538
6 months	64	27.0 (21.1; 32.9)	35	20.0 (16.7; 23.3)	0.039
12 months	60	21.8 (17.5; 26.0)	34	22.4 (16.4; 28.3)	0.870

ITT = Intention to treat, PP = Per-protocol, PFNA = Proximal Femoral Nail Antirotation, TUG = Timed Up and Go.
[a] All eligible, enrolled and randomized patients, even if they had not received surgery.
[b] Due to pain or inability to walk, a considerable number of patients were likely not to be able to perform the TUG test within the originally pre-specified window of 5 to 7 days after surgery. Therefore, the visit window was extended to 3 to 14 days following surgery.
[c] All patients who were treatment compliant and who were assessed according to the defined treatment windows.
[4] P values were calculated using the *t*-test.

Table 3
Mixed effect models derived estimates of the changes in time to complete the Timed Up and Go test after adjustment for potential confounders for both treatment groups.

Characteristic	PFNA		PFNA Augmentation		Mean difference (95%CI)[d]	P value[5]
	n	Mean (95%CI)	n	Mean (95%CI)		
Time to walk 3 m and back (sec)						
Treatment allocation (ITT[a])	*118*		*105*			
Post-Op[b]	62	92.4 (83.2;101.7)	53	85.4 (75.6;95.2)	−7.0 (-18.1;4.1)	0.216
3 months	72	30.8 (21.9;39.7)	52	30.6 (20.7;40.5)	−0.2 (-11.0;10.7)	0.976
6 months	68	26.3 (17.3;35.4)	50	20.7 (10.6;30.7)	−5.7 (-16.7;5.4)	0.317
12 months	58	22.6 (13.1;32.2)	43	22.0 (11.4;32.6)	−0.6 (-12.6;11.3)	0.917
Treatment received (PP[c])	*115*		*85*			
Post-Op[b]	60	94.4 (84.2; 104.6)	45	87.3 (76.0; 98.7)	−7.1 (-19.7; 5.5)	0.272
3 months	63	31.5 (21.4; 41.6)	36	30.6 (18.3; 42.9)	−0.9 (-14.2; 12.4)	0.892
6 months	56	27.4 (16.9; 38.0)	33	20.3 (7.6; 32.9)	−7.2 (-21.1; 6.7)	0.312
12 months	55	23.6 (13.0; 34.2)	31	24.2 (11.2; 37.1)	0.6 (−13.6; 14.7)	0.938

ITT = Intention to treat, PP = Per-protocol, PFNA = Proximal Femoral Nail Antirotation, TUG = Timed Up and Go.
Results from a mixed-effects linear regression model with a random constant at the patient level and a random constant at the study centre level. The model was adjusted for age, gender, Charlson Comorbidity Index, functional independence (Barthel Index), and the Parker Mobility Score.
[a] All eligible, enrolled and randomized patients, even if they had not received surgery.
[b] Due to pain or inability to walk, a considerable number of patients were likely not to be able to perform the TUG test within the pre-specified window of 5 to 7 days after surgery. Therefore, the visit window was extended to 3 to 14 days following surgery.
[c] All patients who were treatment compliant and who were assessed according to the defined treatment windows.
[d] Contrasts in the direction PFNA Augmentation versus PFNA.
[5] P values were calculated using the Wald test.

Table 4
Mixed effect models derived estimates of the changes in radiograph parameters for both treatment groups (per protocol patients).

Characteristic	Treatment received (N = 200)				Mean difference (95%CI)[a]	P value[2]
	PFNA (N = 115)		PFNA Augmentation (N = 85)			
	n	Mean (95%CI)	n	Mean (95%CI)		
Change of blade migration lateral from Post-Op (mm)						
3 months	65	5.1 (4.2; 5.9)	39	5.1 (4.1; 6.2)	0.1 (−1.3; 1.4)	0.913
6 months	57	5.6 (4.7; 6.4)	36	4.9 (3.8; 6.0)	−0.6 (-2.0; 0.8)	0.370
12 months	60	5.9 (5.0; 6.7)	31	5.2 (4.0; 6.4)	−0.7 (-2.1; 0.8)	0.354
Change of blade migration medial from Post-Op (mm)						
3 months	65	−0.1 (-0.4; 0.2)	39	−0.1 (-0.6; 0.3)	0.0 (−0.6; 0.6)	0.996
6 months	57	−0.1 (-0.4; 0.3)	36	0.2 (−0.3; 0.7)	0.2 (−0.3; 0.8)	0.402
12 months	60	0.0 (0.0; 0.0)	31	0.0 (0.0; 0.0)	0.0 (0.0; 0.0)	0.999
Joint space width (AP view) (mm)						
Post-Op	107	4.23 (4.01; 4.46)	84	4.06 (3.82; 4.30)	−0.18 (-0.42;0.07)	0.157
3 months	65	4.21 (3.97; 4.46)	39	4.14 (3.86; 4.42)	−0.07 (-0.37;0.23)	0.635
6 months	57	4.15 (3.91; 4.40)	36	4.08 (3.80; 4.36)	−0.07 (-0.38;0.23)	0.633
12 months	60	4.34 (4.09; 4.58)	31	4.05 (3.76; 4.34)	−0.29 (-0.60;0.03)	0.073

AP = anteroposterior, PFNA = Proximal Femoral Nail Antirotation.
Results from a mixed-effects linear regression model with a random constant at the patient level and a random constant at the study centre level.
[a] Contrasts in the direction PFNA Augmentation versus PFNA.
[2] P values were calculated using the Wald test.

study, patients required 30 s at 3 months compared to 89 s at Post-Op. This may be because patients with comorbidities affecting mobility, including cardiovascular and pulmonary disease, were excluded from the other study.

The injection of cement into a metaphyseal area is frequently discussed within peers. In a recent study in sheep, PMMA cement was injected subchondral and the trabecular structure and cartilage were reviewed after 2 and 4 months [30]. No significant difference between the PMMA specimens and the untreated control was found, leading to the conclusion that injecting PMMA in a metaphyseal region does not harm the subchondral cortex nor adjacent joint cartilage. In a prospective, multicentre study in 62 patients with osteoporotic pertrochanteric fractures managed with PFNA Augmentation, also no complications related to PMMA cement were shown [13]. These findings were confirmed by this study. Changes in radiological joint space could indicate potential cartilage damage by the PMMA augmentation but no differences in joint space were observed over the follow-up period between the treatment groups. No complications like hypersensitivity or local soft tissue reactions related to cement application were reported. There was a single patient with a suspicion of intraoperative cement leakage into the joint, for whom the injection was immediately stopped after detection. Over the course of follow-up, no further damage to the hip joint was detected. Cement leakage can be avoided by using a contrast dye test before instillation of the cement to exclude any connection to the hip joint [14]. Regarding radiological outcome parameters, a TAD above 25 millimetres is associated with significant higher cut-out rates [8,22]. In this study, both the mean TAD and the calcar referenced TAD were significantly higher in the PFNA Augmented group than in the PFNA group ($p < 0.05$), and are at high risk for cut-out. The significant differences may be due to surgeons' attempt of not perforating the femoral head with the initial K-wire to ensure augmentation. As the rate of local implant/surgery complications

Table 5
Summary of indicators of post-op blade position (continuous variables) by treatment received, simple summary statistics *t*-test (per protocol patients).

Characteristic[a]	Treatment received (N = 200)				P value[2]
	PFNA (N = 115)		PFNA Augmentation (N = 85)		
	n	Mean (95%CI)	n	Mean (95%CI)	
Blade position (ap) (Parker ratio)	108	50.6 (49.4; 51.9)	84	50.6 (48.9; 52.3)	0.976
Blade position (lateral) (Parker ratio)	106	49.6 (48.2; 51.1)	80	48.2 (46.2; 50.2)	0.245
Tip Apex Distance (mm)	105	24.2 (23.0; 25.5)	80	26.9 (25.4; 28.4)	0.008
Calcar referenced Tip Apex Distance (mm)	105	29.8 (28.7; 30.8)	80	31.4 (30.2; 32.6)	0.036

AP = anteroposterior, PFNA = Proximal Femoral Nail Antirotation.
[a] Data available only at post-op measurement.
[2] P values were calculated using the *t*-test.

in the PFNA Augmented group was not higher than in the PFNA group, this could be an indirect hint that augmentation prevents catastrophic failures due to higher biomechanical stability. One patient requiring reoperation due to a loosening of the blade in the PFNA group had a TAD above 25 mm. In this patient the blade was exchanged to an augmented blade.

We found no difference in blade position between the study groups. Although not statistically significant, 6 patients in the PFNA group required revision surgery due to mechanical failure, but none in the PFNA Augmentation group. The single patient with cut out in the PFNA group had a TAD of 24 mm, and was reoperated with an arthroplasty.

Despite the overall low occurrence of mechanical failure in this study, a higher stability with augmented osteosynthesis constructs may be suggested. Of note, 3 patients with mechanical failure had a documented irritation of the tractus ilotibialis following lateral blade

Table 6
Summary of complications (patient level) according to treatment received (safety population[a]).

	Treatment received						P value[4]
	PFNA (N = 135)		PFNA Augmentation (N = 87)		Total (N = 222)		
AE Occurred[b]	n	% (95%CI[c])	n	% (95%CI[c])	n	% (95%CI[c])	
Any complication	68	50 (41.6; 59.1)	41	47 (36.3; 58.1)	109	49 (42.3; 55.9)	0.681
Intraoperative complication	8	6 (2.6; 11.3)	1	1 (0.0; 6.2)	9	4 (1.9; 7.6)	0.093
Cement leakage	0	0 (0.0; 2.7)	1	1 (0.0; 6.2)	1	0 (0.0; 2.5)	0.392
Hypersensitivity or allergy	1	1 (0.0; 4.1)	0	0 (0.0; 4.2)	1	0 (0.0; 2.5)	1.000
Event leading to change of surgical procedure	1	1 (0.0; 4.1)	0	0 (0.0; 4.2)	1	0 (0.0; 2.5)	1.000
Poor intraoperative fracture reduction	1	1 (0.0; 4.1)	0	0 (0.0; 4.2)	1	0 (0.0; 2.5)	1.000
Loss of reduction with nail insertion	0	0 (0.0; 2.7)	0	0 (0.0; 4.2)	0	0 (0.0; 1.6)	–
Iatrogenic fracture at nail insertion site	0	0 (0.0; 2.7)	0	0 (0.0; 4.2)	0	0 (0.0; 1.6)	–
Other intraoperative adverse event	5	4 (1.2; 8.4)	0	0 (0.0; 4.2)	5	2 (0.7; 5.2)	0.159
Postoperative complication	65	48 (39.5; 56.9)	41	47 (36.3; 58.1)	106	48 (41.0; 54.5)	0.891
Local implant/surgery	3	2 (0.5; 6.4)	0	0 (0.0; 4.2)	3	1 (0.3; 3.9)	0.282
Bending/Breakage of implant	1	1 (0.0; 4.1)	0	0 (0.0; 4.2)	1	0 (0.0; 2.5)	1.000
Cut out of blade	1	1 (0.0; 4.1)	0	0 (0.0; 4.2)	1	0 (0.0; 2.5)	1.000
Cut-through of blade	0	0 (0.0; 2.7)	0	0 (0.0; 4.2)	0	0 (0.0; 1.6)	–
Loosening of blade	1	1 (0.0; 4.1)	0	0 (0.0; 4.2)	1	0 (0.0; 2.5)	1.000
Local bone/fracture	8	6 (2.6; 11.3)	6	7 (2.6; 14.4)	14	6 (3.5; 10.4)	0.783
Delayed union	0	0 (0.0; 2.7)	0	0 (0.0; 4.2)	0	0 (0.0; 1.6)	–
Nonunion	0	0 (0.0; 2.7)	0	0 (0.0; 4.2)	0	0 (0.0; 1.6)	–
Malunion/Loss of reduction	1	1 (0.0; 4.1)	2	2 (0.3; 8.1)	3	1 (0.3; 3.9)	0.563
Refracture secondary fracture	4	3 (0.8; 7.4)	3	3 (0.7; 9.7)	7	3 (1.3; 6.4)	1.000
Avascular head necrosis	0	0 (0.0; 2.7)	0	0 (0.0; 4.2)	0	0 (0.0; 1.6)	–
Peri-implant fracture	3	2 (0.5; 6.4)	1	1 (0.0; 6.2)	4	2 (0.5; 4.5)	1.000
Local soft tissue/wound	7	5 (2.1; 10.4)	4	5 (1.3; 11.4)	11	5 (2.5; 8.7)	1.000
Irritation of the tractus iliotibialis	3	2 (0.5; 6.4)	0	0 (0.0; 4.2)	3	1 (0.3; 3.9)	0.282
Deep wound infection	0	0 (0.0; 2.7)	0	0 (0.0; 4.2)	0	0 (0.0; 1.6)	–
Neurological symptoms (dys-paraesthesia)	1	1 (0.0; 4.1)	0	0 (0.0; 4.2)	1	0 (0.0; 2.5)	1.000
Superficial wound infection	1	1 (0.0; 4.1)	3	3 (0.7; 9.7)	4	2 (0.5; 4.5)	0.302
Hematoma (requiring revision)	3	2 (0.5; 6.4)	1	1 (0.0; 6.2)	4	2 (0.5; 4.5)	1.000
Systemic/rest of the body	57	42 (33.8; 51.0)	37	43 (32.0; 53.6)	94	42 (35.8; 49.1)	1.000
Thromboembolic complications	1	1 (0.0; 4.1)	4	5 (1.3; 11.4)	5	2 (0.7; 5.2)	0.079
Sepsis	1	1 (0.0; 4.1)	0	0 (0.0; 4.2)	1	0 (0.0; 2.5)	1.000
Delirium	6	4 (1.6; 9.4)	2	2 (0.3; 8.1)	8	4 (1.6; 7.0)	0.486
Pneumonia	8	6 (2.6; 11.3)	2	2 (0.3; 8.1)	10	5 (2.2; 8.1)	0.322
Renal insufficiency	2	1 (0.2; 5.2)	2	2 (0.3; 8.1)	4	2 (0.5; 4.5)	0.646
Bleeding (gastrointestinal cerebral)	1	1 (0.0; 4.1)	1	1 (0.0; 6.2)	2	1 (0.1; 3.2)	1.000
Cardiac (myocardial infarction new arrhythmia)	5	4 (1.2; 8.4)	5	6 (1.9; 12.9)	10	5 (2.2; 8.1)	0.519
Stroke	6	4 (1.6; 9.4)	2	2 (0.3; 8.1)	8	4 (1.6; 7.0)	0.486
Other postoperative event	41	30 (22.8; 38.9)	30	34 (24.6; 45.4)	71	32 (25.9; 38.6)	0.557

PFNA = Proximal Femoral Nail Antirotation.
[a] All eligible, enrolled and randomized patients who had received either PFNA Augmentation or PFNA treatment.
[b] Note: the same patient can contribute to more than one category.
[c] Confidence intervals for percentages were calculated using the Exact method.
[4] P values were calculated using the Fisher's exact test.

Table 7
Mixed effect models derived estimates of the changes in total Parker Mobility Score, and Barthel Index (per protocol patients).

Characteristic	Treatment group (N = 200)				Mean difference (95%CI)[c]	P Value[5]
	PFNA (N = 115)		PFNA Augmentation (N = 85)			
	n	Mean (95%CI)	n	Mean (95%CI)		
Parker Mobility Score[a]						
Pre-Op	106	6.91 (6.32;7.49)	73	6.77 (6.11;7.43)	−0.14 (-0.79;0.51)	0.678
3 months	80	4.65 (4.04;5.27)	55	4.70 (4.00;5.40)	0.05 (−0.67;0.76)	0.902
6 months	74	5.57 (4.94;6.19)	44	5.60 (4.87;6.33)	0.04 (−0.73;0.80)	0.925
12 months	74	5.72 (5.09;6.34)	42	5.91 (5.17;6.65)	0.19 (−0.58;0.96)	0.629
Barthel Index[b]						
Pre-Op	107	90.5 (85.8;95.3)	75	90.6 (85.3;95.9)	0.1 (−5.3;5.4)	0.983
3 months	92	80.4 (75.6;85.3)	61	78.6 (73.1;84.1)	−1.8 (-7.5;3.8)	0.524
6 months	85	81.9 (77.0;86.9)	53	81.4 (75.7;87.0)	−0.6 (-6.4;5.2)	0.842
12 months	77	82.4 (77.5;87.4)	47	81.3 (75.5;87.0)	−1.2 (-7.1;4.8)	0.703

PFNA = Proximal Femoral Nail Antirotation.
Results from a mixed-effects linear regression model with a random constant at the patient level and a random constant at the study centre level.
[a] The Parker Mobility Score ranges from 0 to 9 points, with higher scores indicating higher function. The score is the sum of the responses to 3 mobility questions, each with a range 0 to 3 points, addressing the patients' ability to i. walk inside house, ii. walk outside house, and iii. go shopping or to a restaurant. All 3 responses must be complete for a total to be calculated.
[b] The Barthel Index ranges from 0 to 100 points, with higher scores indicating greater functional independence. The score is the sum of the responses to 10 disability questions, with scores of 0, 5, 10 or 15 possible for 2 questions (transfer and mobility), scores of 0, 5, or 10 possible for 6 questions (bowels, bladder, toilet use, feeding, dressing, and stairs), and scores of 0 or 5 possible for 2 questions (grooming and bathing). The total score is only calculated if there are non-missing responses for all component questions.
[c] Contrasts in the direction PFNA Augmentation versus PFNA.
[5] P values were calculated using the Wald test.

migration, accounting for an overall rate of 2.2%. In these patients the blade was changed to a shorter one, and additionally augmented in one case. In the literature, rates between 4.4% and 9.4% are reported for this event, however, only clinical relevant lateral blade migration which required a reoperation was reported [6,31].

As expected, the mean values of the Parker Mobility Score and the Barthel Index were comparable for both study groups, i.e. there was no association between augmentation and any of these QoL parameters detectable. Most patients were not able to recover fully. However, the overall loss of independence during the study was comparable to the results of Prestmo et al [32].

This study has a number of limitations: First, the fact that 85 patients were not available for the final follow-up due to withdrawal of consent or death. High dropout rates are well known problems in studies with geriatric patients [33,34] and could be compensated with a higher number of patients and a more stringent study organization. Second, the need to extend the initial time frame for the primary outcome parameter from 5 to 7 days to 3 to 14 days after surgery. Third, the fact that a walking aid was allowed for the TUG test, which might have resulted in faster walking speeds [35,36]. However, if no walking aid would have been allowed, probably more patients would have been excluded from the study. Fourth, there may have been a selection bias as only patients who were mobile before their index fracture were included. For example, patients with higher degrees of osteoporosis due to immobility could be more likely to be excluded from this study, although they might have a high benefit from PFNA Augmentation. Positive patient selection may have led to better functional results.

Conclusions

In the presented study, PFNA Augmentation did not result in a significant improvement in patients' walking ability measured by the TUG test 3 to 14 days after surgery compared to patients with a non-augmented PFNA. The additional use of cement in a standardized way in pertrochanteric fracture treatment seems to be safe as it did not lead to additional related complications. PFNA Augmentation furthermore might have the potential to prevent reoperations related to catastrophic failures by strengthening the osteosynthesis construct.

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