



Bone cement augmentation of femoral nail head elements increases their cut-out resistance in poor bone quality– A biomechanical study

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ABSTRACT

The aim of this study was to analyze biomechanically the impact of bone cement augmentation on the fixation strength and cut-out resistance of Proximal Femoral Nail Antirotation (PFNA) and Trochanteric Fixation Nail Advanced (TFNA) head elements within the femoral head in a human cadaveric model with poor bone quality. Methodology: Fifteen pairs of fresh-frozen human cadaveric femoral heads were randomized to three sets of five pairs each for center-center implantation of either TFNA blade, TFNA screw, or PFNA blade. By splitting the specimens of each pair for treatment with or without bone cement augmentation, six study groups were created. All specimens were biomechanically tested under progressively increasing cyclic loading featuring a physiologic loading trajectory in a setup simulating a reduced intertrochanteric fracture with lack of posteromedial support. Number of cycles to 5° varus collapse was evaluated together with the corresponding load at failure. Results: Compared to the non-augmented state, all types of implants demonstrated significantly higher numbers of cycles to failure and load at failure following augmentation, $p \leq 0.03$. Augmented TFNA blades resulted in highest numbers of cycles to failure and loads at failure (30492; 4049 N) followed by augmented PFNA blades (30033; 4003 N) and augmented TFNA screws (19307; 2930 N), $p = 0.11$. Augmented TFNA screws showed similar numbers of cycles to failure and loads at failure compared to both non-augmented TFNA and PFNA blades, $P = 0.98$.

From a biomechanical perspective, bone cement augmentation significantly increases the cut-out resistance of instrumented TFNA and PFNA head elements and is a valid supplementary treatment option to these nailing procedures in poor bone quality.

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1. Introduction

Due to the aging of the human population and the increasing activity status of the elderly, an ongoing growth in osteoporotic hip fractures and corresponding complications is observed (Friedman and Mendelson, 2014). The problems and complications

related to geriatric hip fracture treatment are well known. First, osteoporotic hip fractures mainly occur in a comorbid geriatric population, leading to high perioperative morbidity and complication rates, and consequently to an increase in healthcare costs (Papadimitriou et al., 2017; Svedbom et al., 2013). These costs are mainly due to acute inpatient and postacute institutional care needs (Friedman and Mendelson, 2014) as up to 20% of the hip fracture patients will need to be institutionalized after their fracture as they cannot return to the premorbid place of residence due to functional decline (Vanhaecht et al., 2012). Second, local osteopenic or osteoporotic bone might interfere with implant

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fixation and lead to implant failure and/or secondary fracture displacement (Brunner et al., 2016).

Extra- or intramedullary implants can be used to treat intertrochanteric proximal femoral fractures. A Cochrane review from 2010 supports evidence that sliding hip screw and plate constructs perform superiorly in the treatment of the more common extracapsular hip fracture types (Parker and Handoll, 2010). A more recently conducted update of this review could not prove the superiority of one intramedullary implant design over another (Queally et al., 2014). Nevertheless, the authors recognize the increasing use of intramedullary nails for fixation of intertrochanteric hip fractures in general, as well as the recently introduced numerous developments and modifications to these implants. The problematic anchoring of the cephalic implants (head elements, HE) in osteoporotic femoral heads has been ameliorated by using blade-shaped HEs, however, it could not be solved completely so far (Konstantinidis et al., 2016; Li et al., 2015). The Trochanteric Fixation Nail Advanced system (TFNA, DePuy Synthes, Zuchwil, Switzerland) gives the surgeon the freedom of choice to select intraoperatively either a helical blade or a screw as fixation HE in the femoral head and neck. In patients with poor bone quality, polymethylmethacrylate (PMMA) bone cement can be injected into the femoral head to reduce the risk of cut-out failure. This technique of implant augmentation can be performed through both HE types as the blade and the screw are cannulated and perforated. So far, no biomechanical studies have investigated the effect of cement augmentation on the fixation strength of these two different types of TFNA HEs. The beneficial effect of cement augmentation of the helical blades of another intramedullary nail (Proximal Femoral Nail Antirotation, PFNA, DePuy Synthes, Zuchwil, Switzerland), however, has been demonstrated in numerous biomechanical and clinical studies (Sermon et al., 2012; Sermon et al., 2014; Kammerlander et al., 2014). Augmentation of the PFNA HE increases its purchase in osteoporotic bone by at least 100% depending on its position in the femoral head (Sermon et al., 2014).

Therefore, the aim of this study was to analyze biomechanically the impact of bone cement augmentation on the fixation strength and cut-out resistance of PFNA and TFNA HEs within the femoral head in a human cadaveric model with poor bone quality. We tested the hypothesis that augmented HEs would demonstrate a significant increase in resistance to cut-out failure compared to non-augmented HEs.

2. Materials and methods

2.1. Specimens

Fifteen fresh-frozen (-20°C) matched human cadaveric femoral pairs from nine male and six female donors aged 82.6 years on average (range 63–96 years) were collected for this study from an accredited donation program (Science Care, Inc., Phoenix, AZ, USA). All donors gave their informed consent inherent within the donation of the anatomical gift statement during their lifetime. The femurs were screened and classified as osteoporotic or osteopenic based on Dual-Energy X-ray Absorptiometry (DEXA) measurements with T-scores lower than -2.5 or between -2.5 and -1.5 , respectively (Kwang, 2011). In addition, bone mineral density (BMD) was measured in the femoral head of each specimen by means of high-resolution peripheral quantitative computed tomography (HR pQCT) using an XtremeCT scanner (SCANCO Medical AG, Brüttisellen, Switzerland). Based on the DEXA measurements, eleven pairs were classified as osteoporotic (T-scores between -4.5 and -2.6) and four pairs as osteopenic (T-scores between -2.3 and -2.1). The BMD values of the specimens – measured by HR pQCT – ranged between 109.4 and 288.4

mgHA/cm³ and corresponded to osteoporotic values reported in previous studies on human cadaveric femora from a similar population of donors (Singh et al., 2005: values between 90 and 290 mgHA/cm³, Sermon et al., 2012: values between 98 and 220 mgHA/cm³).

2.2. Study groups

Based on BMD, the fifteen femoral pairs were assigned to three sets of five matched pairs each for implantation of either TFNA blade, TFNA screw, or PFNA blade HEs by stratified randomization, ensuring a balanced BMD distribution among the sets. The bones of each pair were then split and assigned for treatment with or without bone cement augmentation. As a result, a total of six study groups with similar BMD distribution, being paired within each set and implant type and consisting of five specimens each ($n = 5$), were created. The sample size of five specimens per group was considered sufficient for detection of existing significances among the corresponding groups, based on previous published work with similar study design, investigating different fixation methods of intertrochanteric fractures in six study groups, clustered in paired fashion in three sets of five femoral pairs each (Jiang et al., 2014; Konstantinidis et al., 2013).

2.3. Surgical technique

All femora were thawed for 24 h at room temperature prior to preparation. The femoral heads were sawed 50 mm distal to the articular surface orthogonal to the planned implant axis. A guidewire was then placed in the center of the femoral head at a depth of 40 mm to avoid its perforation. Fenestrated TFNA and PFNA HEs of 100 mm length were implanted into the femoral heads using the following protocol. Each HE was inserted over the guidewire without predrilling to a depth of 38 mm allowing for a Tip Apex Distance of 24 mm. Once the HE was inserted according to the surgical guidelines, the guidewire was removed. Those femoral heads assigned for augmentation were warmed up to 37°C prior to cement injection using a water bath (Y6, Grant Instruments Cambridge Ltd, Shepreth, UK). A total of three ml PMMA-based bone cement (Traumacem V+, DePuy Synthes, Zuchwil, Switzerland) was applied to each specimen. The disposition of the augmentation material was verified by means of radiographic images (Fig. 1). The volume of three ml was injected in a standardized manner as follows: after injection of one ml through the perforations of the HE into the cranial side of the femoral head, the cannula was turned 180° , allowing caudally directed injection of another one ml. Subsequently, the cannula was withdrawn over 10 mm, and the same procedure was repeated by injecting 0.5 ml twice.

2.4. Biomechanical testing

Biomechanical testing was performed on an MTS Mini Bionix II 858 hydraulic test system (MTS Systems Corp., Eden Prairie, MN, USA) equipped with a 25 kN load cell at an accuracy of 10 N, representing accuracy class 1 for axial loading.

A modified setup from previous work was used to test each specimen by simulating a reduced unstable intertrochanteric fracture with lack of posteromedial support and load sharing at the fracture gap. The femoral head was mounted on a polycarbonate base plate that rested on two cylindrical rollers. The virtual intertrochanteric fracture line was located in a plane crossing the axis of the cylindrical rollers, around which the construct was allowed to collapse into varus (femoral head rotation around the antero-posterior axis). Two movements were simulated in the model by allowing longitudinal sliding and varus rotation of the implant (Fig. 2, Sermon et al., 2012). The HEs were rigidly mounted to a

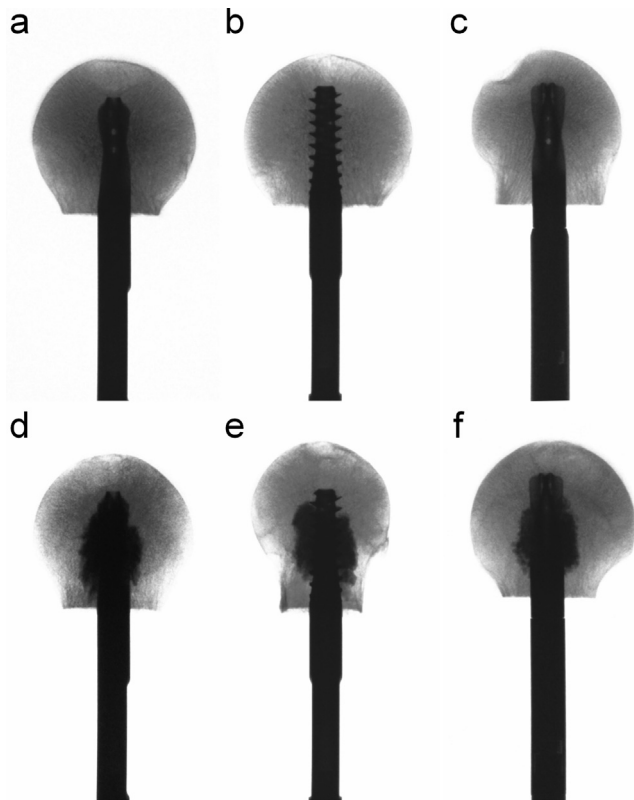


Fig. 1. Radiographs of specimens instrumented with TFNA blade (left, a, d), TFNA screw (middle, b, e) and PFNA blade (right, c, f; TFNA = Trochanteric Fixation Nail Advanced, PFNA = Proximal Femoral Nail Antirotation) without application of bone cement (upper row) and with cement augmentation (lower row).

base fixture for vertical axial loading and inclined at 149° to the vertical axis, accounting for a situation of a femur with 130° femoral neck (caput-collum-diaphyseal, CCD) angle, oriented in 3° adduction and subjected to a load vector transferred to the femoral head in a physiological orientation of 16° to the vertical line (Fig. 3, Bergmann et al., 2001, Sommers et al., 2004). An inclinometer (8.IS40.23321, Kübler Group GmbH, Villingen-Schwenningen, Germany) was attached to the base plate via a metal clamp to monitor and record varus movements of the femoral head. In addition, a Kirschner wire was inserted into the femoral head in the sagittal plane for referencing purposes during imaging. The HE shafts were placed in interchangeable flange sleeves designed according to their different geometries. To allow its insertion into the fixture, the protruding aspect at the endcap was turned down to a diameter of 10.7 mm. All implants were free to slide along their shaft axis during testing, mimicking full implant dynamics.

The specimens were tested under progressively increasing cyclic loading at a rate of 2 Hz. In order to simulate an alternating load during walking, an appropriate loading trajectory was derived from in vivo measurements in the human hip (Bergmann et al., 2001). Starting at 1000 N, the peak load of each cycle was monotonically increased by 0.1 N/cycle until failure of the bone-implant construct occurred. The valley load of the cycles was maintained at 100 N throughout the whole test. Testing was stopped when either 10 mm axial displacement of the machine actuator or 20° varus deformation – as measured with the inclinometer – occurred with respect to test initialization. Previous investigations have shown that these stop criteria are well-chosen end points for biomechanical testing, with considerable

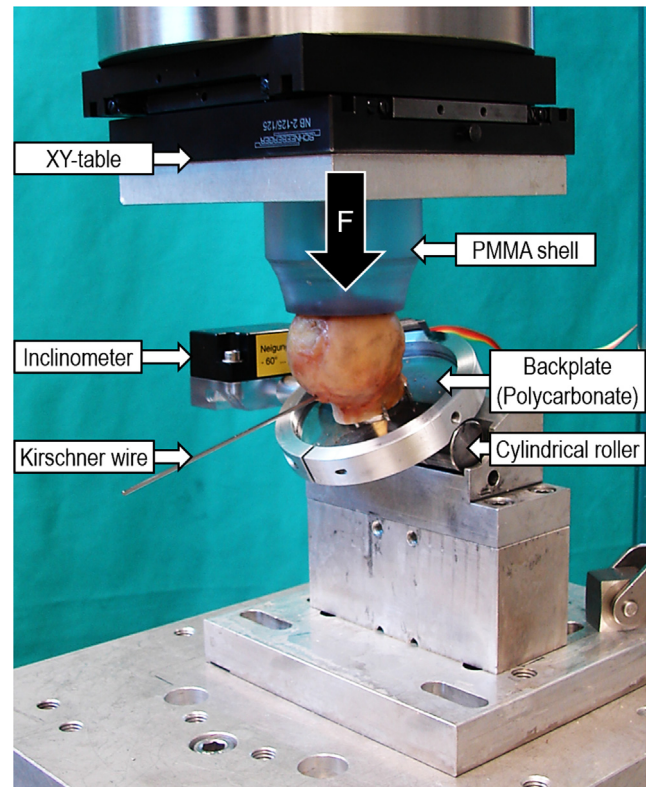


Fig. 2. Setup with a specimen mounted for biomechanical testing. Loading direction is indicated by vertical arrow. Each specimen is free to collapse into varus. An XY-table compensates the resulting displacements.

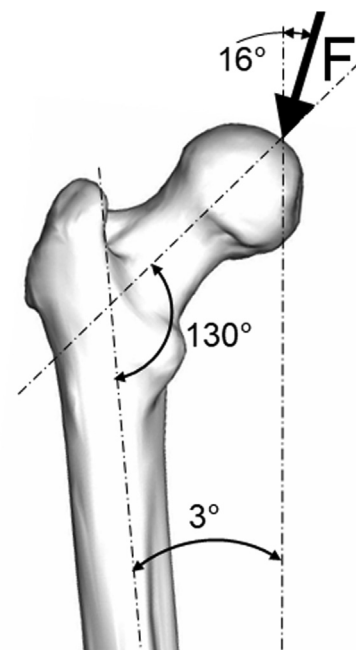


Fig. 3. Illustration of the simulated load transfer at the proximal femur according to Sommers et al., 2004. Assumed 3° adduction of the femoral shaft, 130° caput-collum-diaphyseal angle and 16° orientation of the resultant hip joint contact force (F) to the vertical line result in a 149° angle between implant axis and force direction.

damage to the bone-implant interface and allowing for sound retrospective data analysis (Sermon et al., 2012).

2.5. Data acquisition and evaluation

Both machine data in terms of axial displacement (mm) and axial load (N), and inclinometer output data in terms of varus deformation ($^{\circ}$) were simultaneously recorded at a rate of 128 Hz. Based on the inclinometer data, 5° varus deformation was defined as a criterion for clinical failure, and the number of cycles to failure were calculated together with the corresponding load at failure for all specimens. This failure criterion was derived from a previous work (Sermon et al., 2012).

Statistical analysis was performed using SPSS software package (v.23, IBM SPSS, IBM, Armonk, NY, USA). Descriptive evaluation was conducted to report outcomes in terms of mean values and ranges. Normality of data distribution in each study group was screened and proved by means of Shapiro-Wilk test. Significant differences between the paired and non-paired study groups were checked with Paired-Samples T-test and One-Way Analysis of Variance (ANOVA) test, respectively. Level of significance was set to 0.05 for all statistical tests.

3. Results

Morphometric characteristics of the separate specimens and the total volume of injected bone cement used for each augmentation are presented in Table 1. According to the T-scores, 11 pairs were osteoporotic and 4 osteopenic. Concerning the injected cement volume, the targeted 3 ml could be injected in 6 specimens, whereas in 9 specimens there was backflow of the cement at the osteotomy site. Detailed outcomes of each pair and specimen in terms of number of cycles to failure, load at failure, and percentage increase of cycles to failure and load at failure in augmented versus non-augmented sides within each pair are presented in Table 2. Compared to the non-augmented state, all types of implants demonstrated higher numbers of cycles to failure and load at failure following the augmentation within each pair. Descriptive data from the biomechanically tested specimens is summarized in Table 3. Data distribution was normal within each study group ($P \geq 0.126$). Differences between donors in terms of age, CCD angle, BMD and T-Score were non-significant between the groups ($P \geq 0.162$). The number of cycles to failure and load at failure were significantly higher for all augmented versus the corresponding non-augmented paired groups, $P \leq 0.03$ (Fig. 4). Augmented TFNA blades resulted in highest numbers of cycles to failure and load at failure (30492; 4049 N), followed by augmented PFNA blades (30033; 4003 N) and augmented TFNA screws (19307; 2930 N), $P = 0.11$. Augmented TFNA screws showed similar numbers of

cycles to failure and load at failure compared to both non-augmented TFNA and PFNA blades, $P = 0.98$.

Most of the tested specimens failed by 5° varus collapse of the femoral heads. Two specimens in the augmented group instrumented with TFNA blade failed by crushing at the superior femoral neck site and did not reach this failure criterion. In addition, two specimens of the same pair instrumented with PFNA blade fulfilled the failure criterion of 5° varus collapse by implant breakage at the entry point into the sleeve.

4. Discussion

Our hypothesis that augmentation of TFNA and PFNA HEs would demonstrate a significant increase in resistance to cut-out failure compared with non-augmentation was confirmed in the present study. Each augmented HE – blade or screw – revealed both a higher number of cycles to failure and a higher load at failure, compared with its corresponding non-augmented implant at the contralateral side of the pair, as a result of enhanced anchorage in the femoral head provided by the bone cement. Hence, the decision to use a blade or a screw would likely have no influence on construct stability in the context of augmentation. However, our study also demonstrated the most inferior biomechanical performance of non-augmented TFNA screws, together with no detected significant difference between augmented TFNA screws and non-augmented TFNA and PFNA blades in terms of numbers of cycles to failure and load at failure. These findings support the preferred use of blades as head element instead of screws to decrease cut-out rates and are in agreement with previous reports (Li et al., 2015).

The study results clearly demonstrate that augmentation of PFNA blades, and TFNA blades and screws is a feasible procedure in human cadaveric femoral heads. No technical difficulties were encountered with either type of head element used. As experienced in previous cadaveric and clinical studies (Sermon et al., 2012; Kammerlander et al., 2018), implant augmentation through blade-shaped head elements can be safely performed in osteoporotic bones. The exact injected cement amount and its distribution in the bone, however, is strongly related to both the local quality of bone surrounding the implant, and the possible cancellous bone impaction around the implant (Sermon et al., 2012). As all specimens used in the current experiments were either osteoporotic or osteopenic, the augmentation procedure could be easily performed. These findings are in line with a previously conducted study on helical blade augmentation of the hip, demonstrating a similar distribution of PMMA around the cephalic implant being

Table 1

Specimen's characteristics: set assignment (TFNA = Trochanteric Fixation Nail Advanced, PFNA = Proximal Femoral Nail Antirotation), pair number, augmented side (R = right, L = left), bone mineral density (BMD, aug = augmented; non-aug = non-augmented, HA = hydroxyapatite), T-score of left sided specimens, age, gender and injected cement volume.

Set	Pair number	Side augmented	BMD aug [mg HA/cm ³]	BMD non-aug [mg HA/cm ³]	T-score	Age [years]	Gender	Cement volume [ml]
TFNA blade	1	R	125.5	120.6	-2.9	96	m	3.0
	2	R	163.7	170.0	-3.1	78	f	3.0
	3	L	211.8	175.5	-2.2	78	f	1.0, backflow after
	4	R	204.9	213.7	-3.5	89	m	1.0, backflow after
	5	L	268.3	254.1	-2.7	63	m	2.5, backflow after
TFNA screw	1	R	126.1	119.6	-4.5	89	f	0.5, backflow after
	2	L	188.8	193.5	-2.8	81	f	0.5, backflow after
	3	L	188.7	205.4	-2.3	87	f	3.0
	4	R	204.3	219.8	-2.6	84	m	3.0
	5	R	269.0	237.2	-3.5	68	m	3.0
PFNA blade	1	R	109.4	137.1	-3.2	88	m	3.0
	2	L	194.6	112.0	-2.2	79	f	0.5, backflow after
	3	L	185.6	187.1	-2.8	88	m	2.0, backflow after
	4	R	217.2	224.7	-3.8	91	m	2.5, backflow after
	5	L	288.4	261.4	-2.1	80	m	1.5, backflow after

Table 2

Cycles to failure and load at failure of the specimens in each set (TFNA = Trochanteric Fixation Nail Advanced, PFNA = Proximal Femoral Nail Antirotation), together with the percentage increase in the augmented (aug) versus non-augmented (non-aug) side of each pair, and the corresponding mean value in each study group.

Set	Pair number	Cycles to failure			Load at failure [N]		
		Non-aug	Aug	Increase [%]	Non-aug	Aug	Increase [%]
TFNA blade	1	9408	21,926	133.1	1940.8	3192.6	64.5
	2	9020	21,019	133.0	1902.0	3101.9	63.1
	3	18,878	34,650	83.5	2887.8	4465.0	54.6
	4	22,115	33,756	52.6	3211.5	4375.6	36.2
	5	36,233	41,109	13.5	4623.3	5110.9	10.5
	Mean	19,131	30,492	59.4	2913.1	4049.2	39.0
TFNA screw	1	1021	7546	639.1	1102.1	1754.6	59.2
	2	9010	17,056	89.3	1901.0	2705.6	42.3
	3	17,886	19,145	7.0	2788.6	2914.5	4.5
	4	24,976	28,989	16.1	3497.6	3898.9	11.5
	5	10,168	23,799	134.1	2016.8	3379.9	67.6
	Mean	12,612	19,307	53.1	2261.2	2930.7	29.6
PFNA blade	1	11,835	16,026	35.4	2183.5	2602.6	19.2
	2	15,249	28,892	89.5	2524.9	3889.2	54.0
	3	21,776	32,953	51.3	3177.6	4295.3	35.2
	4	19,708	30,217	53.3	2970.8	4021.7	35.4
	5	32,748	42,077	28.5	4274.8	5207.7	21.8
	Mean	20,263	30,033	48.2	3026.3	4003.3	32.3

Table 3

Descriptive data of the biomechanically tested non-augmented (non-aug) and augmented (aug) specimens of each set TFNA blade, TFNA screw and PFNA blade (TFNA = Trochanteric Fixation Nail Advanced, PFNA = Proximal Femoral Nail Antirotation) in terms of mean value and range for each parameter of interest (CCD angle = caput-collum-diaphyseal angle, BMD = bone mineral density, HA = hydroxyapatite) and study group separately.

Parameter	TFNA blade		TFNA screw		PFNA blade	
	Non-aug	Aug	Non-aug	Aug	Non-aug	Aug
Age [years]	80.8 (63 to 96)		81.8 (68 to 89)		85.2 (79 to 91)	
CCD angle [°]	123.6 (118 to 130)	125.8 (121 to 130)	129.6 (126 to 134)	129.6 (123 to 135)	125.6 (122 to 130)	126.0 (122 to 133)
BMD [mg HA/cm ³]	194.6 (120.6 to 254.1)	202.5 (125.5 to 268.3)	198.3 (119.6 to 237.2)	198.2 (126.1 to 269)	197.0 (112 to 261.4)	207.3 (109.4 to 288.4)
T-Score	−3.2 (−3.5 to −2.9)	−2.7 (−3.1 to −2.2)	−2.7 (−4.5 to 0.0)	−3.1 (−4.3 to −2.3)	−2.3 (−3.8 to 0.0)	−2.6 (−3.5 to −2.1)
Cycles to failure	19,131 (9020 to 36234)	30,492 (21019 to 41109)	12,612 (1021 to 24976)	19,307 (7546 to 28989)	20,263 (11835 to 32748)	30,033 (16026 to 42077)
Load at failure [N]	2913.1 (1902 to 4623.3)	4049.2 (3101.9 to 5110.9)	2261.2 (1102.1 to 3497.6)	2930.7 (1754.6 to 3898.9)	3026.3 (2183.5 to 4274.8)	4003.3 (2602.6 to 5207.7)

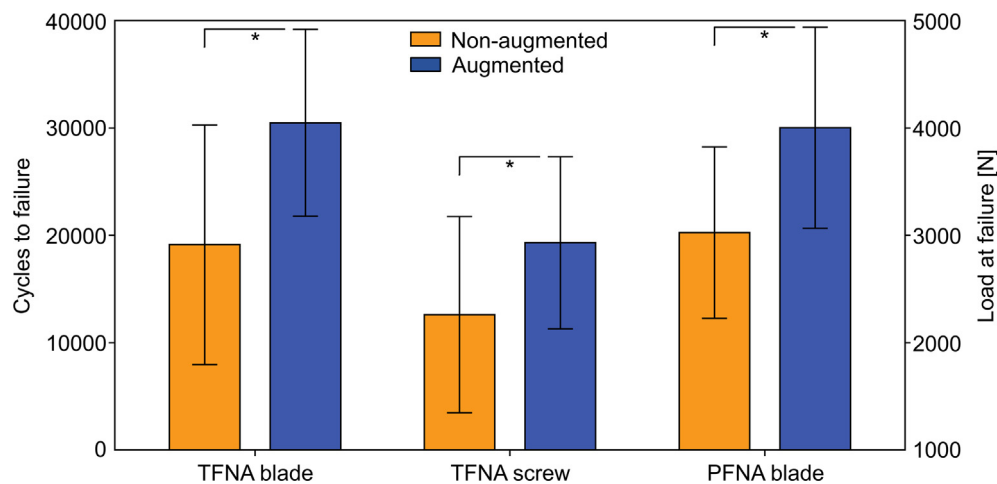


Fig. 4. Cycles to failure and corresponding load at failure in the study groups in terms of mean value and standard deviation, with stars indicating significant differences ($P \leq 0.03$) between the non-augmented and augmented paired groups within each of the three sets TFNA blade, TFNA screw and PFNA blade (TFNA = Trochanteric Fixation Nail Advanced, PFNA = Proximal Femoral Nail Antirotation).

related to the local bone density, as well as difficulties to augment more dense cadaveric bones (Sermon et al., 2012).

The use of fenestrated implants allows to perform the augmentation procedure through the implant, providing the ability to first make a clinical judgement of the local bone quality when inserting the head element. Although BMD measurements are recom-

mended for patients at risk of fractures, they are rarely performed and patients come in with their fractures without objective measurement of the underlying osteoporosis (Boonen et al., 2011; Emohare et al., 2015). As reported in a previous study on cement augmentation of cadaveric bones, the feasibility of augmentation depends on the local quality of the bone surrounding the head ele-

ment and augmentation is most effective in osteoporotic bone (Sermon et al., 2012). Therefore, augmentation should be limited to these cases where low bone quality is experienced by the operating surgeon. As stated in previous work on femoral head augmentation, cement leakage into the joint needs to be avoided by following the standard surgical technique including a leakage test prior to cement injection (Kammerlander et al., 2011; Kammerlander et al., 2016).

Due to the fracture model used, cement flow in the surrounding bone, followed by backflow at the osteotomy site, was observed in 9 of the 15 augmented cases, thus indicating that existing fracture lines in 50 mm proximity to the femoral head apex could result in PMMA backflow, especially in osteoporotic bone. In such cases, the desired total cement volume of 3 ml would not always be possible to inject in the cancellous bone surrounding the head element. In intertrochanteric fractures, however, the fracture line is usually located more distantly to the apex of the femoral head so the problem with cement leakage at the fracture site is not expected to occur (Rai et al., 2018). In addition, with the fracture line situated at a remote distance to the injected cement, no interference with fracture healing will occur due to thermal or chemical reactions related to PMMA hardening (Fliri et al., 2012).

A more objective, intra-operative determination of the local bone quality would probably be a better predictor of both the need and efficacy of implant augmentation in the femoral head. Until now, we must rely on the subjective clinical judgement of the local bone quality by the surgeon when inserting the head element. For spinal surgery, a clinical study using a device measuring the breakaway torque within the vertebral body, reported a good correlation between this torque, the surgeon's quantified impression of resistance and the local BMD (Popp et al., 2013). A similar intra-operative measurement of the local bone quality in the femoral head would be helpful in determining indications that would benefit from bone cement augmentation. So far, ex-vivo tests as well as a clinical case series demonstrated promising results with mechanical torque measurements in the proximal femur (Grote et al., 2013; Suhm et al., 2008; Bastian et al., 2015; Klotz et al., 2014).

A previous clinical study focusing on the application of implant augmentation of PFNA head elements is in agreement with our results. Patients with augmented implants demonstrated less catastrophic failures due to cut-out as augmentation strengthened the osteosynthesis construct (Kammerlander et al., 2018). Therefore, the use of implant augmentation as an adjunct for mechanical hip fracture stabilization might convince surgeons to let their patients immediately mobilize and weight bear as tolerated. As there is increasing evidence supporting the importance of immediate mobilization and weight-bearing following hip fracture surgery (Pfeuffer et al., 2019), this may lead to a decrease in complications and could have a positive effect on the functional recovery of the patients (Oldmeadow et al., 2006). Moreover, a recent study reported that the geriatric population is not able to comply to weight-bearing restrictions so augmentation will add safety to the surgical procedure (Kammerlander et al., 2018).

This study has some limitations similar to those inherent to all cadaveric investigations, incapable to completely simulate the in vivo environment. A limited number of specimens at a sample size of five per study group were tested, resulting in restriction of the translation to generalized clinical applications. Despite this, we were able to demonstrate significant biomechanical advantages of augmented over non-augmented specimens. Varus collapse was the only failure criterion considered as it is the most common source of fixation failure following operative treatment of intertrochanteric hip fractures necessitating operative reintervention (Li et al., 2015; Yu et al., 2018). Other clinically relevant failure modes, such as posterior tilting of the femoral head and its rotation around

the neck axis of the femur were neglected to prevent any redundant artifactual interferences.

Further, not all specimens failed by classical varus collapse, which was related to the quality of fixation and bone strength as follows: two specimens sustaining bone crushing in the superior neck region were augmented with bone cement, while those associated with implant breakage were the ones with the highest BMD values. This corresponds to findings in the literature supporting the correlation between low BMD and cut-out as failure mode following intertrochanteric fracture fixation (Konstantinidis L., 2016). Correspondingly, by the successful resistance of these specimens against varus collapse during testing due to their higher BMD values, the stress was shifted to other aspects of the construct. Such failure modes are rarely observed in the clinical practice, and we therefore assume that augmentation should not pose a risk factor for such adverse side effects (Brunner et al., 2016). Finally, in contrast to other biomechanical studies, only axial loading was applied for the matter of simplicity, neglecting a physiologically more suggestive multi-planar loading (Born et al., 2011; Ehmke et al., 2005; Santoni et al., 2016).

In summary, this biomechanical cadaveric study demonstrates that bone cement augmentation of TFNA and PFNA head elements is feasible, significantly increases their cut-out resistance and is a valid supplementary treatment option to these nailing procedures in poor bone quality.

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References

- Bastian, J., Bergmann, M., Schwyn, R., Keel, M., Benneker, L., 2015. Assessment of breakaway torque at the posterior pelvic ring in human Cadavers. *J. Invest. Surg.* 28 (6), 328–333.
- Bergmann, G., Deuretzbacher, G., Heller, M., Graichen, F., Rohlmann, A., Strauss, J., et al., 2001. Hip contact forces and gait patterns from routine activities. *J. Biomech.* 34 (7), 859–871.
- Boonen et al., 2011. Once-yearly Zoledronic Acid in older men compared with women in recent hip fracture. *JAGS* 59, 2084–2090.
- Born, C.T., Karich, B., Bauer, C., von Oldenburg, G., Augat, P., 2011. Hip screw migration testing: first results for hip screws and helical blades utilizing a new oscillating test method. *J. Orthop. Res.* 29 (5), 760–766.
- Brunner, A., Büttler, M., Lehmann, U., Frei, H.C., Kratter, R., Di Lazzaro, M., et al., 2016. What is the optimal salvage procedure for cut-out after surgical fixation of trochanteric fractures with the PFNA or TFN?: a multicentre study. *Injury*. 47 (2), 432–438.
- Ehmke, L.W., Fitzpatrick, D.C., Krieg, J.C., Madey, S.M., Bottlang, M., 2005. Lag screws for hip fracture fixation: Evaluation of migration resistance under simulated walking. *J. Orthop. Res.* 23 (6), 1329–1335.
- Emohare, O., Wiggin, M., Hemmati, P., Switzer, J., 2015. Assessing bone mineral density following acute hip fractures. *Geriatric Orthop Surg Rehabil.* 6 (1), 16–21.
- Fliri, L., Lenz, M., Boger, A., Windolf, M., 2012. Ex vivo evaluation of the polymerization temperatures during cement augmentation of proximal femoral nail antirotation blades. *J. Trauma Acute Care Surg.* 72 (4), 1098–1101.
- Friedman, S.M., Mendelson, D.A., 2014. Epidemiology of fragility fractures. *Clin. Geriatr. Med.* 30 (2), 175–181.
- Grote, S., Noeldke, T., Blauth, M., Mutschler, W., Burklein, D., 2013. Mechanical torque measurement in the proximal femur correlates to failure load and bone mineral density ex vivo. *Orthop Rev (Pavia)*. 5 (2), 77–81.
- Jiang, W., Liu, Y., Yang, L., Xu, W., Liu, S., Zhang, D., Chen, X., Wang, H., 2014. Biomechanical comparative study on proximal femoral locking plate and Gamma3 for treatment of stable intertrochanteric fracture. *Zhongguo Xiu Fu Chong Jian Wai Ke Za Zhi*. 28 (9), 1096–1099.
- Kammerlander, C., Gebhard, F., Meier, C., Lenich, A., Linhart, W., Clasbrummel, B., et al., 2011. Standardised cement augmentation of the PFNA using a perforated blade: A new technique and preliminary clinical results. A prospective multicentre trial. *Injury*. 42 (12), 1484–1490.
- Kammerlander, C., Doshi, H., Gebhard, F., Scola, A., Meier, C., Linhart, W., et al., 2014. Long-term results of the augmented PFNA: a prospective multicenter trial. *Arch. Orthop. Trauma Surg.* 134 (3), 343–349.
- Kammerlander, C., Neuerburg, C., Verlaan, J.J., Schmoelz, W., Miclau, T., Larsson, S., 2016. The use of augmentation techniques in osteoporotic fracture fixation. *Injury*. 47 (Suppl 2), S36–S43.

- Kammerlander, C., Hem, E.S., Klopfer, T., Gebhard, F., Sermon, A., Dietrich, M., et al., 2018a. Cement augmentation of the Proximal Femoral Nail Antirotation (PFNA) – A multicentre randomized controlled trial. *Injury*. 49 (8), 1436–1444.
- Kammerlander, C., Pfeuffer, D., Lisitano, L.A., Mehaffey, S., Bocker, W., Neuerburg, C., 2018b. Inability of Older Adult Patients with Hip Fracture to Maintain Postoperative Weight-Bearing Restrictions. *J. Bone Joint Surg. Am.* 100 (11), 936–941.
- Klotz, M. et al., 2014. Bone quality assessment for total hip arthroplasty with intraoperative trabecular torque measurements. *J Orthop Surg Res.* 9, 109.
- Konstantinidis, L., Helwig, P., Hirschmuller, A., Langenmair, E., Sudkamp, N.P., Augat, P., 2016. When is the stability of a fracture fixation limited by osteoporotic bone? *Injury*. 47 (Suppl 2), S27–S32.
- Konstantinidis, L., Papaioannou, C., Hirschmüller, A., Pavlidis, T., Schroeter, S., Südkamp, N.P., Helwig, P., 2013. Intramedullary nailing of trochanteric fractures: central or caudal positioning of the load carrier? A biomechanical comparative study on cadaver bones. *Injury*. 44 (6), 784–790.
- Kwang, J.C., 2011. Bone densitometry. *Semin. Nucl. Med.* 41 (3), 220–228.
- Li, S., Chang, S., Niu, W., Ma, H., 2015. Comparison of tip apex distance and cut-out complications between helical blades and lag screws in intertrochanteric fractures among the elderly: a meta-analysis. *J Orthop Sci.* 20 (6), 1062–1069.
- Oldmeadow, L.B., Edwards, E.R., Kimmel, L.A., Kipen, E., Robertson, V.J., Bailey, M.J., 2006. No rest for the wounded: early ambulation after hip surgery accelerates recovery. *ANZ J Surg.* 76 (7), 607–611.
- Papadimitriou, N., Tsilidis, K.K., Orfanos, P., Benetou, V., Ntzani, E.E., Soerjomataram, I., et al., 2017. Burden of hip fracture using disability-adjusted life-years: a pooled analysis of prospective cohorts in the CHANCES consortium. *Lancet Public Health.* 2 (5), e239–e246.
- Parker, M.J., Handoll, H.H., 2010. Gamma and other cephalocondylic intramedullary nails versus extramedullary implants for extracapsular hip fractures in adults. *Cochrane Database Syst. Rev.*
- Pfeuffer, D., Grabmann, C., Mehaffey, S., Keppler, A., Bocker, W., Kammerlander, C., et al., 2019a. Weight bearing in patients with femoral neck fractures compared to pertrochanteric fractures: A postoperative gait analysis. *Injury*. 50 (7), 1324–1328.
- Pfeuffer, D., Zeller, A., Mehaffey, S., Bocker, W., Kammerlander, C., Neuerburg, C., 2019b. Weight-bearing restrictions reduce postoperative mobility in elderly hip fracture patients. *Arch. Orthop. Trauma Surg.* 139 (9), 1253–1259.
- Popp, A.W., Schwyn, R., Schiuma, D., Keel, M.J., Lippuner, K., Benneker, L.M., 2013. DensiProbe Spine: an intraoperative measurement of bone quality in spinal instrumentation. A clinical feasibility study. *Spine J.* 13 (10), 1223–1229.
- Queally, J.M., Harris, E., Handoll, H.H., Parker, M.J., 2014. Intramedullary nails for extracapsular hip fractures in adults. *Cochrane Database Syst. Rev.*
- Rai, A.K., Goel, R., Bhatia, C., Singh, S., Thalanki, S., Gondane, A., 2018. Cement Augmentation of Dynamic Hip Screw to Prevent Screw Cut Out in Osteoporotic Patients with Intertrochanteric Fractures: A Case Series. *Hip & pelvis.* 30 (4), 269–275.
- Santoni, B.G., Nayak, A.N., Cooper, S.A., Smithson, I.R., Cox, J.L., Marberry, S.T., et al., 2016. Comparison of Femoral Head Rotation and Varus Collapse Between a Single Lag Screw and Integrated Dual Screw Intertrochanteric Hip Fracture Fixation Device Using a Cadaveric Hemi-Pelvis Biomechanical Model. *J. Orthop. Trauma* 30 (4), 164–169.
- Sermon, A., Boner, V., Schwieger, K., Boger, A., Boonen, S., Broos, P., et al., 2012a. Biomechanical evaluation of bone-cement augmented Proximal Femoral Nail Antirotation blades in a polyurethane foam model with low density. *Clin Biomech (Bristol, Avon).* 27 (1), 71–76.
- Sermon, A., Boner, V., Boger, A., Schwieger, K., Boonen, S., Broos, P.L., et al., 2012b. Potential of polymethylmethacrylate cement-augmented helical proximal femoral nail antirotation blades to improve implant stability—a biomechanical investigation in human cadaveric femoral heads. *J Trauma Acute Care Surg.* 72 (2), E54–E59.
- Sermon, A., Hofmann-Fliri, L., Richards, R.G., Flamaing, J., Windolf, M., 2014. Cement augmentation of hip implants in osteoporotic bone: how much cement is needed and where should it go? *J. Orthop. Res.* 32 (3), 362–368.
- Singh G, Høiseth A, Eckhardt C, Strømsoe K, Linke B. The utilization of clinical CT scanning as a qualitative tool in preoperative planning of fracture treatment in the future. *An Autopsy Study. Høstmøtet Norsk Kirurgisk Forening Oslo.* 2005;81.
- Sommers, M.B., Roth, C., Hall, H., Kam, B.C., Ehmke, L.W., Krieg, J.C., et al., 2004. A laboratory model to evaluate cutout resistance of implants for pertrochanteric fracture fixation. *J. Orthop. Trauma* 18, 361–368.
- Suhm, N., Lamy, O., Lippuner, K., 2008. Management of fragility fractures in Switzerland: results of a nationwide survey. *Swiss Med Wkly.* 138 (45–46), 674–683.
- Svedbom, A., Hernlund, E., Ivergard, M., Compston, J., Cooper, C., Stenmark, J., et al., 2013. Osteoporosis in the European Union: a compendium of country-specific reports. *Arch Osteoporos.* 8, 137.
- Vanhaecht, K., Sermeus, W., Peers, J., Lodewijckx, C., Deneckere, S., et al., 2012. The impact of care pathways for patients with proximal femur fracture: rationale and design of a cluster-randomized controlled trial. *BMC Health Serv Res.* 12, 124.
- Yu, X., Wang, H., Duan, X., Liu, M., Xiang, Z., 2018. Intramedullary versus extramedullary internal fixation for unstable intertrochanteric fracture: a meta-analysis. *Acta Orthop Traumatol Turc.* 52 (4), 299–307.