

Original research

Variability in Femoral Preparation and Implantation Between Surgeons Using Manual and Powered Impaction in Total Hip Arthroplasty

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ABSTRACT

Background: The influence of the surgical process on implant loosening and periprosthetic fractures (PPF) as major complications in uncemented total hip arthroplasty (THA) has rarely been studied because of the difficulty in quantification. Meanwhile, registry analyses have clearly shown a decrease in complications with increasing experience. The goal of this study was to determine the extent of variability in THA stem implantation between highly experienced surgeons with respect to implant size, position, press-fit, contact area, primary stability, and the effect of using a powered impaction tool.

Methods: Primary hip stems were implanted in 16 cadaveric femur pairs by three experienced surgeons using manual and powered impaction. Quantitative CTs were taken before and after each process step, and stem tilt, canal-fill-ratio, press-fit, and contact determined. Eleven femur pairs were additionally tested for primary stability under cyclic loading conditions.

Results: Manual impactions led to higher variations in press-fit and contact area between the surgeons than powered impactions. Stem tilt and implant sizing varied between surgeons but not between impaction methods. Larger stems exhibited less micromotion than smaller stems.

Conclusions: Larger implants may increase PPF risk, while smaller implants reduce primary stability. The reduced variation for powered impactions indicates that appropriate measures may promote a more standardized process. The variations between these experienced surgeons may represent an acceptable range for this specific stem design. Variability in the implantation process warrants further investigations since certain deviations, for example, a stem tilt toward varus, might increase bone stresses and PPF risk.

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Introduction

Periprosthetic fractures and implant loosening are two of the main reasons for revision of uncemented hip prostheses [1–5]. Both

are serious and demanding complications and may drastically affect the patient's outcome in the long term [6,7]. Especially in an old, fragile patient, collective revision surgeries lead to a significant increase in the mortality rate [8]. Risk factors for loosening and PPFs were identified to be patient-related, such as sex and age [9,10], as well as prosthesis-related, including the type of fixation, size, and the absence of a collar [11–14]. Recently the surgical process was also shown to play an important role in the etiology of PPF, as PPFs tend to occur more frequently intraoperatively or early post-operatively [14]. Registry analyses have shown a decrease in complications with increasing experience and surgical volume [14,15]. Applied impaction force, surgical approach, implant position, and implant size are factors linked to the surgical process. Studies reported large differences in the applied impaction forces between

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surgeons [16–18]. In addition, increasing impaction forces were recorded with greater broach sizes during cavity preparation [17]. High impaction forces during cavity preparation and stem insertion may increase PPF risk while low impaction forces could result in insufficient stem seating [19]. Increasing fracture rates have been associated with the direct anterior and antero-lateral approach, which might be a consequence of the resulting stem positioning [20,21]. The position of the stem also has a corresponding effect on the PPF risk, which increases for varus tilted stems [22]. As surgeons have access to a vast scope of possible implant designs and sizes, preoperative planning and templating is of great importance for correct sizing and positioning [23–25]. Undersizing leads to a lack of primary stability and reduced bone ingrowth [12], while oversizing increases PPF risk [26]. Surgeons performing a high volume of procedures show a more appropriate implant sizing and better survival rate [15,24]. Various surgical approaches, differences in implant positioning and sizing, as well as wide variations in the applied impaction forces illustrate that THA is not a fully standardized process.

Motivated by diverse results for established implant designs, powered impaction approaches were introduced. Powered impaction tools have the advantage over manual impaction techniques of providing close to unlimited energy with a constant input. Consistent energy input may further produce more repeatable results during cavity preparation and stem insertion. Especially inexperienced surgeons would benefit from these devices. An additional benefit of the use of powered impaction tools is a positive effect on the duration of the surgery and fatigue of the surgeon [27].

The specific parameters influenced by variations in the surgical process and their potential relation to less favorable outcomes have not yet been identified. To better understand the complex processes leading to PPFs and the resulting primary stability, it is important to investigate factors being influenced by variations in the surgical process. Once this relation is understood, the process may be improved with the help of surgical training, and the risk of PPF and stem loosening may be reduced.

The purpose of this study was to determine the extent of variability in THA stem implantation between highly experienced surgeons with respect to implant sizing, position, press-fit, contact area and primary stability, and the effect of using a powered impaction tool. Two hypotheses were formulated: First, there are variations even between experienced surgeons. Second, the use of a powered impaction system does reduce the variability between surgeons.

Material and methods

The study was conducted on 16 excised femur pairs stored at -30°C . The supplying donors' age ranged between 56 and 79 years (mean = 68.7 ± 6.9 y, m/f = 9/7 [28]). The Ethics Commission of the Medical Association Hamburg (PV5098) approved this study.

Femur preparations and implantations were performed by experienced senior orthopedic surgeons (surgeon A: 300 procedures/year, surgeon B and surgeon C: 150 procedures/year with the implant design investigated) using the standard collarless Corail hip stems with compaction broaches and corresponding instruments (Depuy Synthes, Leeds, UK). Surgeon A and surgeon B completed the procedure for six femur pairs simulating the direct posterior approach. Surgeon C implanted prostheses in four femur pairs using the anterolateral approach. The preliminary stem size was determined from scout views of CT images of the unprepared femurs (TraumaCad; Brainlab, Inc, Westchester, IL). The final size of the stem was left to the surgeon's discretion during broaching to ensure adequate stability as it is routine in the clinical setting.

Each femur pair was prepared by a single surgeon with two different implantation methods. One bone of each pair was manually prepared, and the contralateral side was prepared with a powered impactor with a constant impact energy of 3.5 J (Kincise; Depuy Synthes, Warsaw, IN [29]). None of the surgeons had prior experience with powered impaction tools. Surgeon A and surgeon C chose a large mallet (1.4 kg) while surgeon B favored a smaller mallet (0.6 kg). Surgeon A was the only one using a calcar mill after broaching. A left-right randomization of the specimens was performed for the two impaction methods. Surgeon A and surgeon B used the single hit mode of the powered impaction tool while surgeon C applied the continuous mode operating at a frequency of 6 Hz. Stem impaction was performed using the same implantation method as for broaching. Only in the case of PPF, stem implantations were subsequently performed manually regardless of the previous implantation method. After the implantation of the stems, specimens of surgeon A and B were refrozen.

Specimens were CT-scanned (120 kV, Brilliance 16; Philips, Hamburg, Germany) with a calibration phantom (QSA; QRM, Möhrendorf, Germany) at four distinct time points of the testing procedure: native, with final broach, with broached cavity and with implanted stem. The scans were taken with a voxel size of $0.5 \times 0.5 \times 0.5 \text{ mm}^3$. Hounsfield units were converted to bone mineral density (BMD) in terms of mgHA/cm^3 using Structural Insight (Structural Insight 3; University Medical Center Schleswig-Holstein, Kiel, Germany [30]). The BMD of the proximal trochanteric, neck, and head trabecular structure was determined using a wave propagation segmentation approach [31]. The specimens were assigned to the respective surgeon groups to achieve similar mean group BMDs.

Data analysis

Axial implant seating, stem tilt (valgus-varus and ventral-dorsal), canal-fill-ratio ratio (CFR), press-fit, and contact area were selected as output variables. Specimens implanted by surgeons A and B were additionally tested for primary implant stability.

The final axial implant seating was determined as the offset between the final position of the broach and the final position of the implant in the axial direction. qCTs With final broach and implanted stem were aligned using the gray values of the cortical shell (250 to 1500 mgHA/cm^3 , Avizo Lite 2019; Thermo Fischer Scientific, Waltham, MA). The broach and the implanted stem were segmented (threshold: 1800 to 2500 mgHA/cm^3) and aligned with surface models of the stems obtained from laser scans (Handyscan 3D; Creaform, Ametek, Berwyn, PA). The junction between the polished stem part and the coating was used as the discrete region of interest to compare the final broach position with the final implant position in the anatomical coordinate system of the femurs (Matlab 2018b; Mathworks, Natick, MA).

The selected stem size and stem position with respect to the femur were described by the CFR and the stem tilt. Segmented surface models of the cortical bone (native qCT) and of the stem (qCT with implanted stem, Avizo Lite 2019) were used for the analysis. As the excised femora were sectioned above the condyles, the anatomic femoral axis was defined using a best-fit approach through the diaphysis between 2% times the donor-specific body height (BH) [32] and 8% times the BH below the lesser trochanter. The frontal plane was specified for each specimen by the anatomical femur axis and the femur head center. The valgus-varus alignment of the implant was determined by the angular inclination between the main stem axis and the anatomical femoral axis in the frontal plane (Fig. 1a). The ventral-dorsal stem tilt was analyzed in the sagittal plane. The CFR was introduced to determine variations in implant sizing. Sagittal cross-sections were taken every 0.5

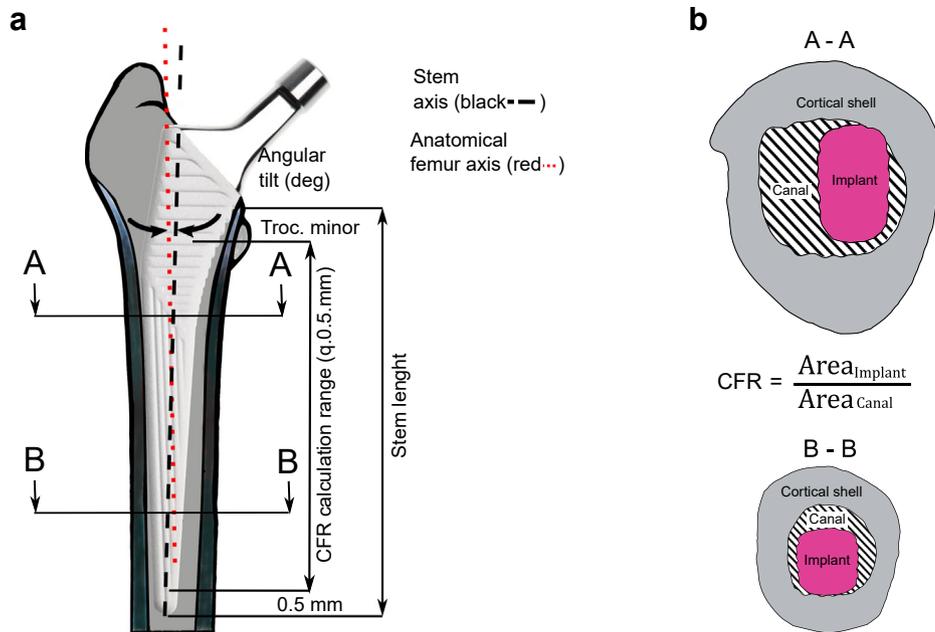


Figure 1. (a) Valgus-varus orientation of the stem in the frontal plane with the cutting plane range used to determine multiple CFRs. (b) Two cross-sectional views (proximally, distally) showing the CFR defined by the quotient of the implant cross-section and the canal cross-section.

mm, starting 5 mm proximal to the tip of the stem and extending to the trochanter minor (Fig. 1a). For all sagittal cross-sections, the ratio between the area of the implant and the area of the empty femoral canal was taken. This ratio was defined as CFR (Fig. 1b), and the mean value of all computed CFRs was reported as the total stem CFR.

Press-fit and contact area were analyzed using qCTs with broached cavity and implanted stem. Scans were registered by superimposing the cortices using gray values (250 to 1500 mgHA/cm³). Cavities were segmented (threshold: -250 mgHA/cm³), and surface models generated, likewise for the implanted stems (threshold: 1800 to 2500 mgHA/cm³, Avizo Lite 2019). To reduce metal artifacts, previously obtained laser-scanned surface models of the stems were aligned with the segmented stems. A surface-to-surface comparison between the cavity and the stem was performed (PolyWorks 2019; InnovMetric Software Inc., Quebec, Canada). The region of interest for the surface-to-surface comparison started 10 mm below the trochanter minor and expanded

proximally up to 17 mm below the shoulder of the implant. The spanned surface was further subdivided into an anterior, a posterior, a medial, and a lateral region. As the press-fit occurred predominantly on the lateral side, the analysis focused on the mean lateral press-fit. The total contact area in percentage was also computed.

Specimens implanted by surgeon A (n = 10; re-use of two stems without any surface damage to the HA coating due to limited availability of sizes) and surgeon B (n = 12) were tested for primary stability measuring the micromotion at the bone-implant interface. Specimens were aligned according to ISO 7206-4 [33] with a 10° and 9° tilt relative to the implant axis and embedded (Technovit 4004; Kulzer GmbH, Wehrheim, Germany) for mechanical testing (Fig. 2a). The stem taper was cleaned and assembled with a metal ball head (M-SPEC; Depuy Synthes, CoCr29Mo, Ø 36 mm). Force-controlled cyclic loading was applied via a polyethylene piston to the head using a servo-hydraulic testing machine (1 Hz; MiniBionix II, MTS, Eden Prairie, MN, Fig. 2b). Two activity levels were

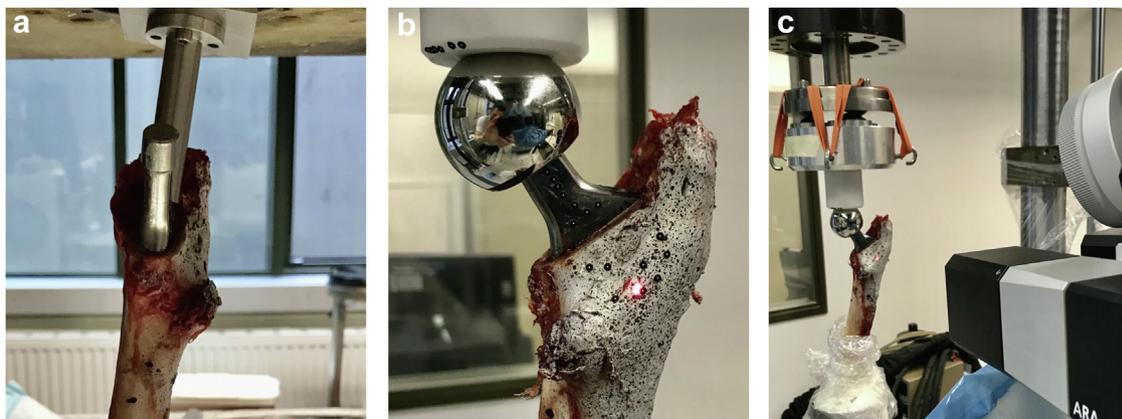


Figure 2. (a) Stem orientation according to ISO 7206-4. (b) GOM markers and sprinkle pattern on the femur cortex to track the micromotion at the bone-implant interface. (c) Hydraulic testing machine and DIC system for micromotion tracking.

simulated (100 N - 800 N; 100 N - 1600 N), each tested for 1200 cycles. Micromotion at the bone-implant interface was measured contactless, using digital image correlation (DIC, ARAMIS 3D Camera, GOM, Braunschweig, NS, Germany). Recordings of 5 s were taken at six definite time points (every 200 cycles) using a frequency of 25 frames per second with a measuring volume of $100 \times 80 \times 50 \text{ mm}^3$ (round markers, $\varnothing 0.4 \text{ mm}$, Fig. 2c). The translational and rotational micromotion was computed between the implant and the bone. The effect of the implant size on the resulting micromotion was analyzed based on the four femur pairs in which different implant sizes were used in the left and right femurs.

A statistical analysis was performed using SPSS 24.0 (SPSS Inc., Chicago, IL). A Type I error level of 0.05 was used for all tests. Data were checked for normality and homogeneity of variance. ANOVA including Bonferroni post hoc tests were performed to determine effects between the surgeons. Multiple Pearson correlations were used to identify relations between the parameters. A Wilcoxon sign-rank analysis was performed to determine effects within femur pairs. For non-normal distributed data, Kruskal-Wallis tests were used to determine effects between the surgeons.

Results

The BMD of the left and right femurs were similar ($P = .795$). Slight differences in the BMD of the femurs prepared by the three surgeons were present: Surgeon A had the lowest BMD ($130 \pm 34 \text{ mgHA/cm}^3$) followed by surgeon B ($157 \pm 35 \text{ mgHA/cm}^3$, $P = .159$) and surgeon C ($164 \pm 23 \text{ mgHA/cm}^3$, $P = .091$; both compared to surgeon A). Spontaneous calcar PPFs occurred in 4 of the 32 tested femurs (all for powered implantation technique). One small femoral fracture of approximately 10 mm (surgeon A) occurred during an implantation into a small female femur with a narrow AP dimension as described by Bonnin et al. (Fig. 3a) [34]. The three fractures of surgeon B were markedly longer (approx. 20 to 50 mm length) and were treated with cerclage before they were tested for primary stability (Fig. 3b-d).

Implant seating varied between the surgeons for the powered implantations ($P = .006$, Fig. 4a) but did not reach statistical significance for manual implantations, due to the small sample sizes ($P = .063$, Fig. 4a). Surgeon A reached similar seating with the manual and powered method ($P > .999$), while surgeon B reached better seating of the stems manually ($P = .010$). The opposite was found for surgeon C achieving better seating with the powered method than the manual ($P = .183$, Fig. 4a). Varus-valgus alignment

between the surgeons was quite similar and not significantly influenced by the implantation method (powered: $P = .604$, manual: $P = .292$). Surgeon B implanted stems close to the neutral configuration while surgeons A and C implanted the stems in a slight varus position (Fig. 4b). In the four specimen pairs with a fracture on one side, a varus tilt of the stem was observed in the fractured femurs + 1.41° toward varus ($\pm 1.36^\circ$) although the difference was statistically not significant because of the small sample size ($P = .144$). Variations between surgeons were also found in the ventral-dorsal stem tilt ($P = .012$) regardless of the used impaction type ($P = .623$). Surgeon A implanted the stems in a neutral configuration compared to surgeon C producing a ventral tilt of the stem (surgeon A = $-0.1^\circ \pm 1.5^\circ$, surgeon C = $+1.9^\circ \pm 0.8^\circ$; $p_{A-C} = 0.010$). A large variation in implant sizing as represented by the CFR was observed ($P = .001$), independent of the impaction type ($P = .751$). Surgeon A implanted smaller stem sizes than surgeon B ($p_{A-B} = 0.024$) and surgeon C ($p_{A-C} < 0.001$, Fig. 4c).

The bone-implant contact area after implantation showed differences between the surgeons for the manual method ($P = .011$) but not for the powered impaction ($P = .437$). Surgeon C produced smaller contact areas using the manual method than surgeon A and surgeon B ($p_{A-C} = 0.015$, $p_{B-C} = 0.030$; Fig. 5a). No differences between the surgeons were found for the powered method (all $P > .650$). The three surgeons produced different lateral press fits with manual preparation ($P = .014$), but not with the powered method ($P = .135$), although differences were observed (Fig. 5b). Surgeon B achieved a median lateral press fit of 1 mm during manual broaching, which was lower for surgeons A and C with a median of 0.7 mm ($p_{A-B} = 0.027$, $p_{B-C} = 0.042$; Fig. 5b). The powered method resulted in a similar lateral press-fit for all three surgeons ($P > .999$).

Five of the 22 implanted femurs had to be excluded from the micromotion analysis because of fracture during cyclic loading. The three bones with an intraoperative PPF treated with a cerclage were also excluded. This left 14 specimens remaining for analysis (8 surgeon A, 6 surgeon B; 9 manual, 5 powered). Slightly higher translational micromotion was observed for the stems implanted by surgeon A compared to surgeon B for both load levels (Fig. 6a), but not reaching statistical significance ($p_{11} = 0.210$, $p_{12} = 0.285$, small sample size, weak power). However, the specimens of both surgeons showed a similar amount of rotational micromotion ($p_{11} = 0.445$, $p_{12} = 0.383$; Fig. 6b). No overall correlation between the micromotion and BMD was observed (translational: $R^2 = 0.090$, $P = .289$; rotational micromotion $R^2 = 0.060$, $P = .405$). The stems implanted by surgeon A tended to subside more during testing than

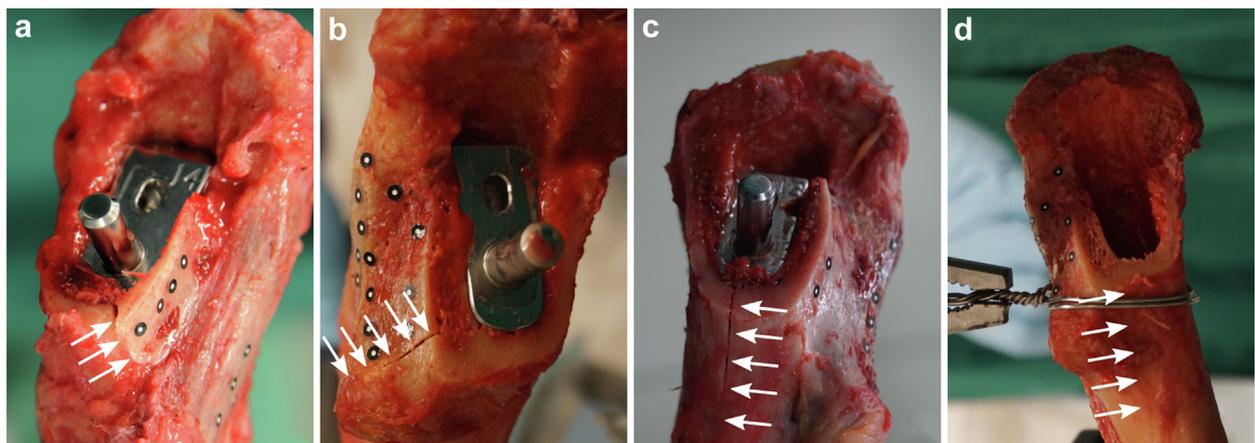


Figure 3. (a) The small calcar fracture produced by surgeon A (indicated by arrows). (b-d) Periprosthetic fractures produced by surgeon B were longer and were treated with cerclages (indicated by arrows).

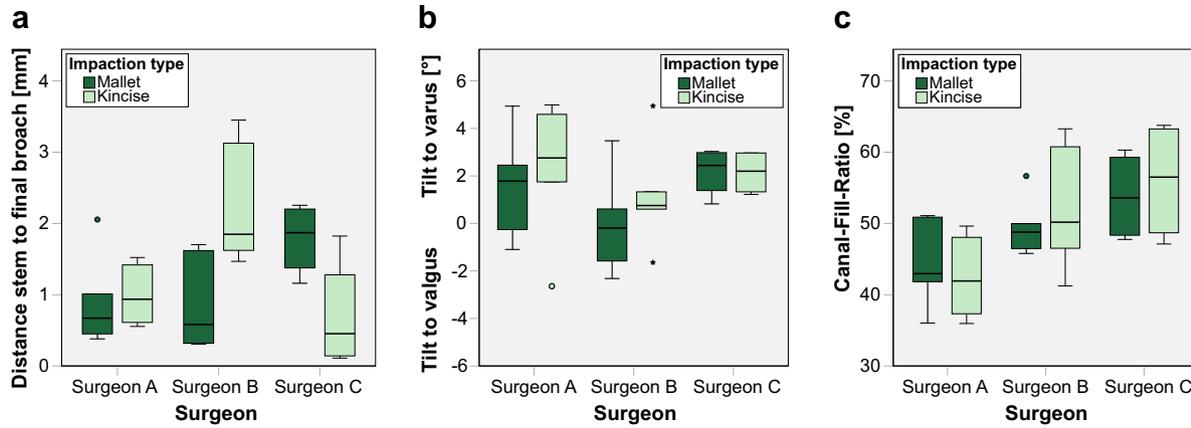


Figure 4. (a) Implant seating dependent on impactation method and surgeon. (b) Angular stem orientation dependent on impactation type and surgeon. (c) CFR dependent on impactation type and surgeon.

the stems implanted by surgeon B ($P = .073$, Fig. 6c). A strong correlation was found for increasing stem migration with decreasing BMD ($R^2 = 0.480$, $P = .006$; Fig. 6c). Analyzing the difference between both surgeons using BMD as a covariate indicated a significant influence of the BMD on the difference in migration observed between the two surgeons ($P = .021$). Including BMD in the analysis removed the significance for the comparison between surgeons ($P = .291$).

Specimens with a smaller implant size exhibited significantly higher translational micromotion than the contralateral specimen of the same pair with larger implant size ($p_{11} = 0.009$, $p_{12} = 0.016$; Fig. 7a). Rotational micromotion also tended to be higher for smaller stems in this comparison ($p_{11} = 0.111$, $p_{12} = 0.112$; Fig. 7b). The same trend was observed for stem migration with higher final subsidence of the smaller stems ($P = .192$; Fig. 7c).

Discussion

With all surgeons being highly experienced in THA, the observed variations in the parameters investigated were surprising. Including less experienced surgeons in the analysis may even increase the observed variability [15]. The use of the powered impactation tool reduced variations in the contact area and lateral press-fit. A more balanced press-fit is desirable, as an exaggerated press-fit of the

stem can result in PPFs, while an insufficient press-fit provokes loosening of the prosthesis [35]. Powered impactations have a decisive advantage over the conventional manual approaches as a unidirectional dynamic force is applied. Unintentional shear forces as they may occur with manual techniques can lead to an inhomogeneous cavity and thus incongruent contact between the bone and the implant and reduced contact area. Besides the impactation approach variations in the contact area, the press-fit also depends on the bone quality [36]. However, this relation could not be confirmed in this study. Variations in the final implant seating and position can be attributed either to the broaching process or the implantation itself or to a combination of both factors. The large differences in the final implant seating observed for the powered impactations could be due to the lack of experience with the powered impactation device or the different haptic feedback compared to the mallet. This study was carried out using exclusively compaction broaches, and the results may be different using cutting extraction broaches especially for specimens with low BMD [36].

Implant size and position differed between surgeons but not between the impactation methods. Size selection and stem positioning are both related to the surgeon's specific technique and depend on training and experience [15,24]. The surgeons performed the procedure with different philosophies regarding the surgical approach after their clinical practice. Surgeon C produced

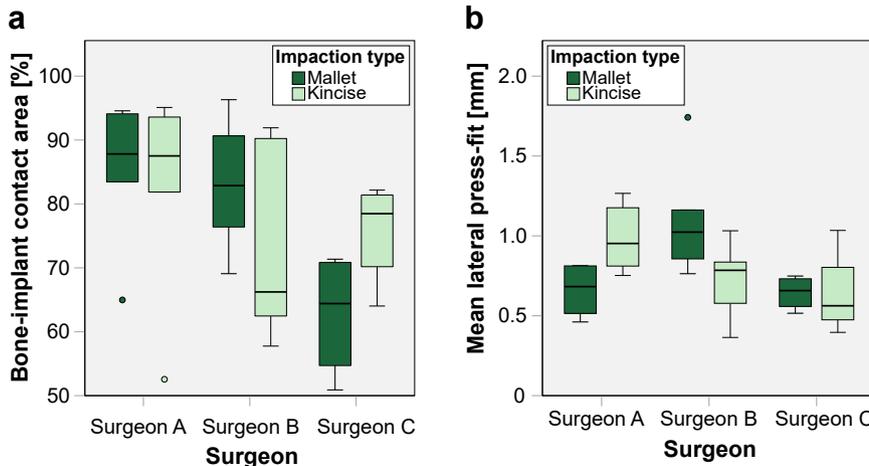


Figure 5. (a) Observed variations of the bone-implant contact area dependent on the impactation type and surgeon. (b) Variations in mean lateral press-fit dependent on the impactation type and surgeon.

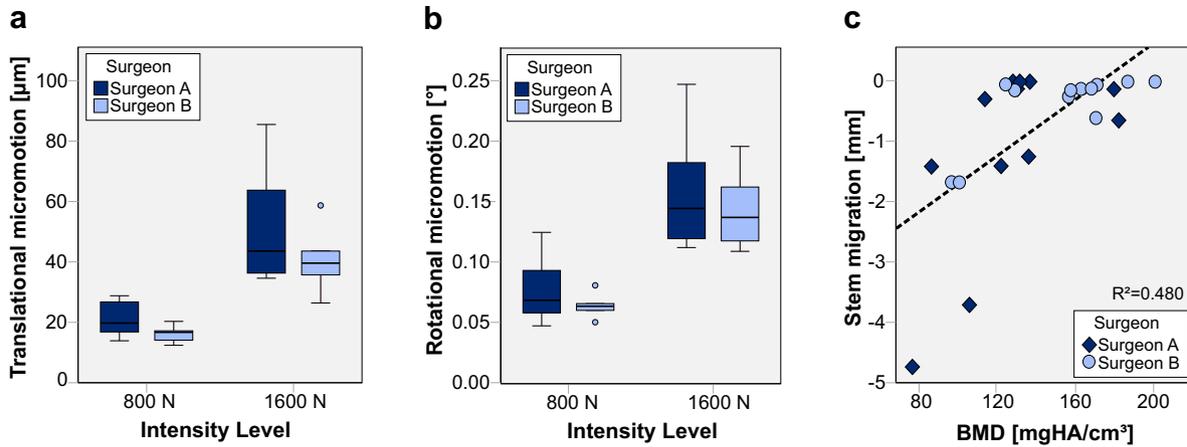


Figure 6. (a) Translational micromotion for both intensity levels separated by the surgeon. (b) Rotational micromotion for both intensity levels separated by the surgeon. (c) Final stem migration after testing for both surgeons in correlation with the BMD of the specimen.

no PPF although his preferred anterolateral approach is associated with an increased PPF risk [20,21].

Surgeon A actually “predicted” the occurrence of his single PPF due to the narrow ap-dimension of the respective female specimen before implantation [34]. A plausible explanation why the increased PPF risk for surgeon A and surgeon B was only observed using the powered impaction tool could not be found in this study. One explanation may be the lack of training with the device including the different haptic feedback, which could cause slight differences in stem positioning or wrong size selection. Another one may be the mode of the powered impaction device used (surgeon A and B: single hit; surgeon C: continuous mode). This should be further investigated before drawing a definite conclusion.

A pronounced varus tilt of the stem observed for all fractured femurs compared to the unscathed contralateral side corresponds with the literature. The varus position of the stem does not only change the patient’s morphology but also increases the PPF risk as it may act as a stress riser on the medial cortex [37]. Pronounced lateral opening of the femur canal during cavity preparation may avoid the varus tilt and the interference with the medial cortex. Observed variations in the sagittal stem tilt are rather related to dislocation or impingement rather than PPFs and primary stability [38].

Surgeon A selected smaller stem sizes than surgeon B and surgeon C. This is consistent with the micromotion measurements that were performed on the specimens of surgeon A and B. The majority of the difference in micromotion can be explained by the different BMD of the femurs prepared by the surgeons. Still, trends of higher micromotion were found for the stems implanted by surgeon A compared to surgeon B. The increased translational and rotational micromotion for smaller stem sizes suggests undersizing of the implant and emphasizes the results of previous work that showed increased stem subsidence for smaller stem sizes [12,39]. In addition, early axial stem migration has been associated with markedly lower implant survival and promotes early loosening of the stem [11,40]. The claim that stem migration further increases with valgus-tilted stems, as suggested by Kutzner et al., could not be confirmed by the results of this study [39]. Proper templating and sizing can be important not only to achieve appropriate and optimal primary stability but also in preventing PPFs. Spina and Scalvi found an increased PPF risk for oversized stems [26]. This could be one explanation why PPFs occurred more frequent for the specimens by surgeon B than for specimens by surgeon A. However, it is not entirely clear why surgeon C produced no PPF even though he proportionately used the largest stem sizes.

Although the specimens were assigned to the surgeons according to their BMD, a more homogeneous distribution was not

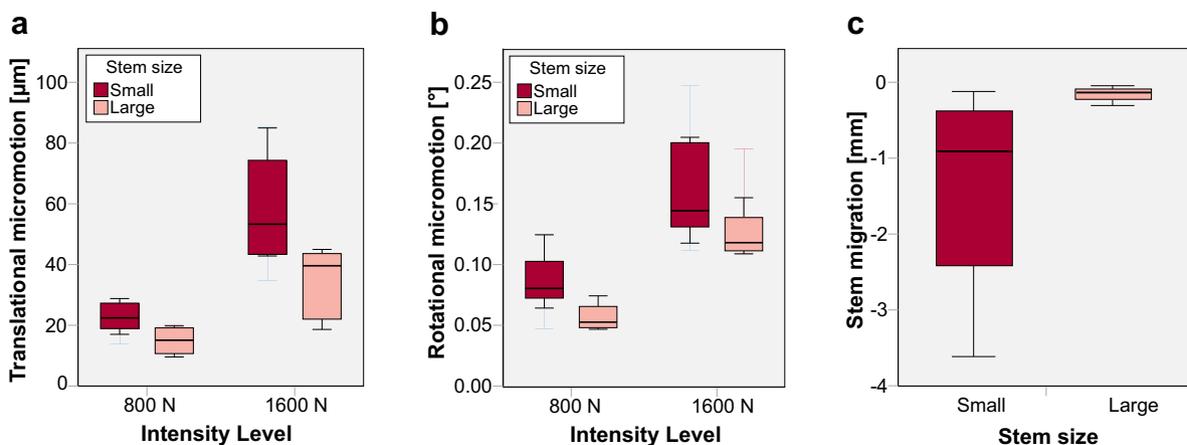


Figure 7. (a) Translational micromotion dependent on intensity level and implant size. (b) Rotational micromotion dependent on intensity level and implant size. (c) Stem migration depends on the implant size.

possible because of limited availability. Variations between the surgeons may partly be biased by the BMD as seen in the press-fit, contact area, and the analysis for primary stability. The majority of the analyses are based on QCT scans. Exact values related to implant size and position, interference fit, and contact area should be treated with caution because of the isotropic voxel resolution of 0.5 mm³. The excised femora were separated above the condyles, which required adjustments for the determination of the anatomical femur axis. The possible inaccuracy of this method applied to all femurs is not expected to undermine the robustness of the overall trends observed. Another limitation was the storage of the specimens before primary stability testing. Specimens with implanted stems were refrozen and stored for 12 months at -30°C. Different thermal expansions of the bone and the implant may have resulted in perturbation of the bone-implant interface, possibly resulting in early failures of the tested specimens in some cases. These femurs were excluded from the analyses reducing the sample size. As the bones implanted by surgeon C were used for another internal follow-up study focusing on the bone-implant interface, it was not possible to determine for primary stability of the implants as the stems had to be removed without possible interface damage. This weakens the statements with respect to the primary stability compared to the other parameters but should not have influenced the general findings.

Variations between the surgeons in THA will remain as long as no fully automatic hip surgeries exist [41]. Various surgical approaches, techniques, and the availability of many different implant designs and sizes will always lead to variations even between experienced and successful surgeons. The observed variations between the three surgeons with the implant system investigated might be in a tolerance range in which a safe application is ensured as those surgeons all have high surgical experience and few clinical complications. Variations may be higher for surgeons with little experience in THA, potentially affecting the success rate of the procedure. The introduction of a powered impaction tool controls to some extent the level of variability. With a more consistent and nearly unlimited energy input [29], the powered impaction tool reduces variations in the impaction forces and may reduce the risk for complications linked to the impaction process. However, powered impaction tools will not compensate for the influence of stem sizing and positioning. Therefore, variations in sizing and positioning can only be reduced by improved preoperative planning and templating in combination with sufficient surgical experience [24].

Conclusion

The use of a powered impaction tool seems to lead to more consistent results between surgeons in terms of press-fit and contact area, potentially benefiting surgeons with less experience in THA. Whether this benefit results in clinically better results need to be shown in clinical studies. A smaller stem may reduce the PPF risk but is also more prone to fail due to a lack of primary stability. Especially for an older patient, collective with poor bone quality, this tradeoff becomes more important as larger stems may be used to achieve good stability but come with a higher PPF risk. The use of collared uncemented or cemented stems should be considered for these patients. Sizing and positioning of the stem are essential for the long-term success of THA emphasizing the importance of sufficient training and experience. Attempts should be made to further standardize the process to achieve an even better outcome in THA as presently is the case.

Conflicts of interest

All experimental studies were performed at the University Medical Center Hamburg-Eppendorf (UKE) and the TUHH Hamburg University of Technology. The Institute of Biomechanics has received financial support by Depuy Synthes to carry out this study.

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