



## Original Research

# Discrepancy of Trial Rasp and Femoral Stem Relative Position Within the Femoral Canal of a Coated Tapered System: An Intraoperative, Inpatient Controlled Study

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## ABSTRACT

**Background:** For a successful total hip arthroplasty, the final position of the trial rasp should be adopted by the femoral stem to achieve correct positioning. This study aimed to characterize the discrepancy of the stem and rasp position *in vivo* of a widely used dual-tapered straight stem with rectangular cross section that is known to have an oversized stem with respect to the rasp.

**Methods:** The distances between the tip of the greater trochanter and the shoulder of the implant and rasp were measured on 39 intraoperatively acquired fluoroscopic image pairs. Leg-length discrepancy was also measured clinically before and after surgery.

**Results:** A paired t-test showed a significant average protrusion of the femoral stem with respect to the final rasp position of 2.63 mm (standard deviation = 2.3 mm,  $P < .001$ ), while 88% of the cases had no leg-length discrepancy after surgery. The quantified stem protrusion was statistically significant but did not reach clinical relevance and was easily mitigated in our study.

**Conclusions:** The quantified stem protrusion appears to be clinically manageable, as only 2 cases required attenuation of stem positioning: in one case by the use of a femoral head with a shorter neck and in the other case by rerasping the femoral bed. Neither case was associated with the most extreme differences in position of the stem with respect to the final rasp. In addition, the used stem shows good overall outcomes in other studies. It appears that factors other than stem and rasp position play a critical role to the surgeon and for total hip arthroplasty success.

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## Introduction

As the incidence of joint disease continues to increase, an ever-growing percentage of the affected population will undergo total hip arthroplasty (THA). With increasing life expectancy, the demands on these devices are also rising [1]. The success of a hip replacement is highly influenced by the correct position and orientation of the implant components [2]. A malposition of the femoral stem may cause leg-length discrepancy, tension problems, as well as risk of luxation, impingement, and wear, all of which may

be followed by early loosening [3]. Digital templating should be performed preoperatively to assess the correct position of the hip stem and acetabular cup. During surgery, the final position of the last rasp should correspond to the preoperatively planned position and the same position should be adopted by the femoral stem.

It is known that the dimensions of hip stems do not always exactly match the dimensions of the final trial rasp. For example, a stem designed to be slightly larger than its final trial rasp will favor additional press-fit for initial fixation in the femoral bed. Furthermore, in some cases of titanium/hydroxyapatite (Ti/HA) coating, the added layer creates an oversize of between 0.3 mm and 0.9 mm compared with the corresponding last trial rasp [4–7]. In theory, this would lead to a protrusion of the stem with respect to the final rasp position. To our knowledge, the extent of such a protrusion has not been directly assessed *in vivo*, and therefore, the clinical implications remain mainly unknown.

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The goal of this study is to evaluate whether there is in fact an *in vivo* difference (D) between the positions of a coated femoral stem with respect to the corresponding last trial rasp. A positive difference would be a relative protrusion.

To evaluate a positional difference between a coated femoral stem and the last trial rasp, intraoperatively acquired fluoroscopic images were compared. We examined a widely used dual-tapered straight stem with a rectangular cross section that has an oversize due to the coating compared with the final trial rasp [4].

In addition, the leg-length discrepancy before and after surgery was measured to investigate a possible influence by the difference in stem and final rasp position. Possible confounding factors such as the implant size, bone structure, and patient demographics were also analyzed.

## Material and methods

### Study design and patient selection

This prospective study was conducted at 3 orthopaedic hospitals between April 2016 and September 2017. The study was performed in accordance with ISO 14155:2011 guidelines and the Declaration of Helsinki.

Inclusion criteria were patients of skeletal maturity of more than 21 years undergoing primary THA. The following exclusion criteria were used: history of infection in the affected joint, systemic infections, and severe muscle, nerve, or vascular diseases. Additional exclusion criteria were lack of bone substance or defective bone quality that jeopardized the stable seating of the prosthesis, concomitant diseases that may jeopardize the implant function, study device allergy, diagnosis of immunosuppressive disorders, or pregnancy.

A total of 41 primary THAs were performed in a cohort of 40 patients (25 women and 15 men). The mean patient age, height, and weight at the time of surgery were 71.8 years (range, 48.5–90.1), 167.7 cm (range, 150–183), and 77.7 kg (range, 50–110), respectively. The predominant diagnosis was primary osteoarthritis in 36 (88%) hips, followed by 3 (7%) hips with dysplasia and 2 (5%) hips with avascular necrosis. Femoral bone types were classified based on preoperative planning radiographs as per the Dorr classification system [6]. Three (7%) hips were categorized as type A, 32 (78%) hips as type B, and 6 (15%) hips as type C. Thirty-four (83%) hips were treated with the standard offset version of a Ti/HA-coated dual-tapered straight stem with a rectangular cross section (SL-PLUS MIA Ti/HA, Smith & Nephew Orthopaedics AG, Baar, Switzerland) for minimal invasive surgery with a neck angle of 131°. Seven (17%) hips were treated using the lateralized offset version with a neck angle of 123°. These were furnished with a ceramic head (BIOLOX, Smith & Nephew, Orthopaedics AG, Baar, Switzerland and Smith & Nephew Inc., Memphis, TN) or cobalt-chromium femoral head (Smith & Nephew, Orthopaedics AG, Baar, Switzerland and Smith & Nephew Inc., Memphis, TN). On the acetabular side, a noncemented acetabular shell combined with either ceramic or polyethylene liners was used (R3 INTL Ceramic or R3 XLPE liner, Smith & Nephew Inc., Memphis, TN).

### Surgical technique

The size of the implant components was preoperatively planned and verified intraoperatively. An anterolateral approach, between the gluteus medius and fasciae latae muscle and in the supine position, was used in all surgeries. The femoral bone was prepared for implantation of the stems using the associated set of rasps with the slap hammer, Woodpecker (IMT Integral Medizintechnik AG, Luzern, Switzerland), or mallet, which was dependent on the normal surgical protocols at each hospital.

### Outcomes

A minimum of 2 intraoperative fluoroscopic anterior-posterior images were acquired during each surgery, except for 2 patients where images were not acquired. This led to a fluoroscopic image sample from 39 hips as opposed to 41 hips treated. All 41 hips were evaluated for leg-length discrepancy clinically before and after surgery.

The first intraoperative fluoroscopic image showed the final trial rasp with the trial head. In all these images, except for one, the trial head was a radiograph-transparent version and was not actually pictured on the images. The second intraoperative fluoroscopic image showed the stem with the final ball head. While the images were acquired, the joint was reduced (Fig. 1). In cases where multiple images were acquired, the image most suitable for analysis was selected based on the appearance of relevant structures and the alignment of the stem or rasp on the image plane.

The difference between the position of the stem and rasp was defined as  $D = x_{\text{rasp}} - x_{\text{stem}}$ , with  $x_{\text{rasp}}$  being the distance between the shoulder of the trial rasp and the tip of the greater trochanter and  $x_{\text{stem}}$  being the distance between the shoulder of the implant and the tip of the greater trochanter. Therefore, a positive value for the difference in position indicates a more proximal position within the medullary canal of the stem in relation to the last trial rasp, that is, a relative protrusion.

The distances  $x_{\text{rasp}}$  and  $x_{\text{stem}}$  were measured in pixels on digital fluoroscopic images and converted to millimeters after each image was calibrated to account for different image magnifications. For this purpose, we scaled a known reference dimension on the implant and also on the rasp with respect to the corresponding lengths measured on the images. The stem and rasp lengths were preferentially used for calibration because of the lower susceptibility to measurement uncertainties. In case the rasp or stem was not completely depicted, the diameter of the cup was used for calibration.

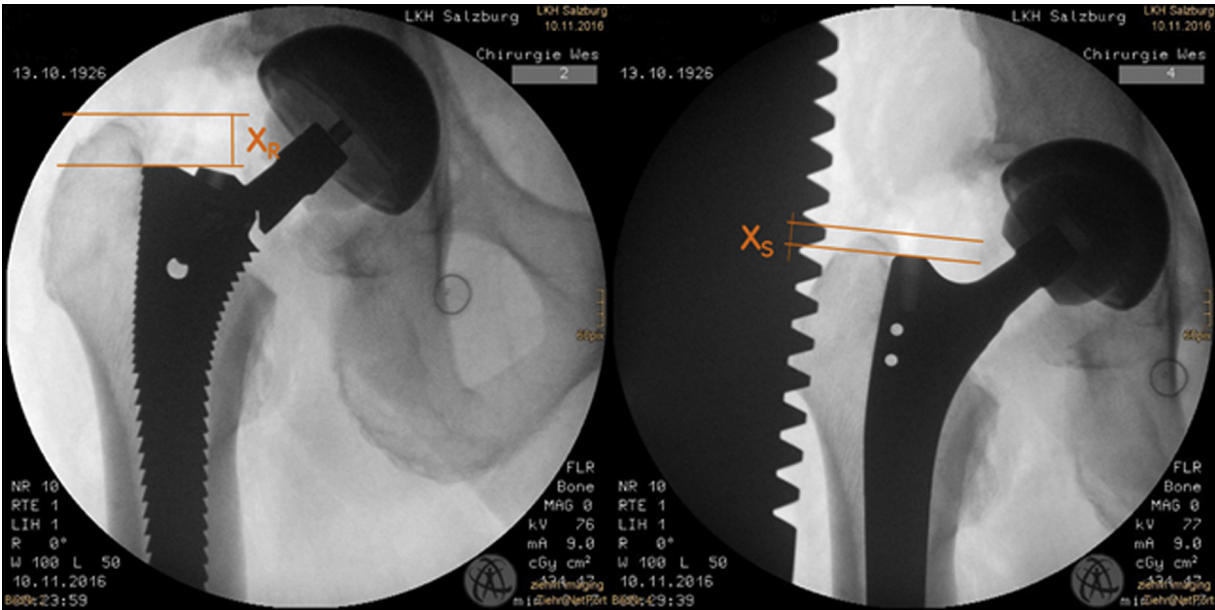
The length of the stem/rasp was measured as a straight line from the tip of the stem to the shoulder. This line was drawn so that it intersected with a line matching the edge of the shoulder as perpendicularly as possible (Figs. 1 and 2). This guaranteed that the measured length corresponded most accurately to the manufacturer's specifications. The line matching the shoulder was then parallel displaced until it matched the tip of the greater trochanter (or another bony landmark at the trochanter apparent on both images). Then, the shortest distance was measured between the 2 lines. Image analysis was performed using ImageJ 1.50i [8].

The clinical leg-length discrepancy was measured before and shortly after surgery with the patient in the supine position. For that purpose, the length of each lower extremity was measured with a measuring tape as the distance between the anterior superior iliac spine and the medial malleolus [9]. The difference between the ipsilateral and contralateral measurement was the leg-length discrepancy. The smallest measurable increment of the measuring tape was 1 mm, and therefore, any differential measurement of 1 mm or greater was considered a leg-length discrepancy.

### Statistical analysis

The sample size required was calculated for a two-sided *t*-test ( $\alpha = 0.05$  and  $\beta = 0.1$ ). An average difference between the position of the rasp and stem of 2 mm was considered relevant with equal-sized standard deviation of 2.5 mm for both groups and no correlation between paired measurements. This yielded a minimal sample size of 35 patients. A sample size of 40 patients was used to account for up to 13% possible missing data.

Two-sided paired *t*-tests were used to compare preoperative and postoperative outcomes. A Shapiro-Wilk test was used to test



**Figure 1.** Intraoperative fluorography showing measurements of the stem and rasp positions, left:  $x_{Rasp}$  equals the distance between the shoulder of the trial rasp and the tip of the greater trochanter; right:  $x_{Stem}$  equals the distance between the shoulder of the implant and the tip of the greater trochanter.

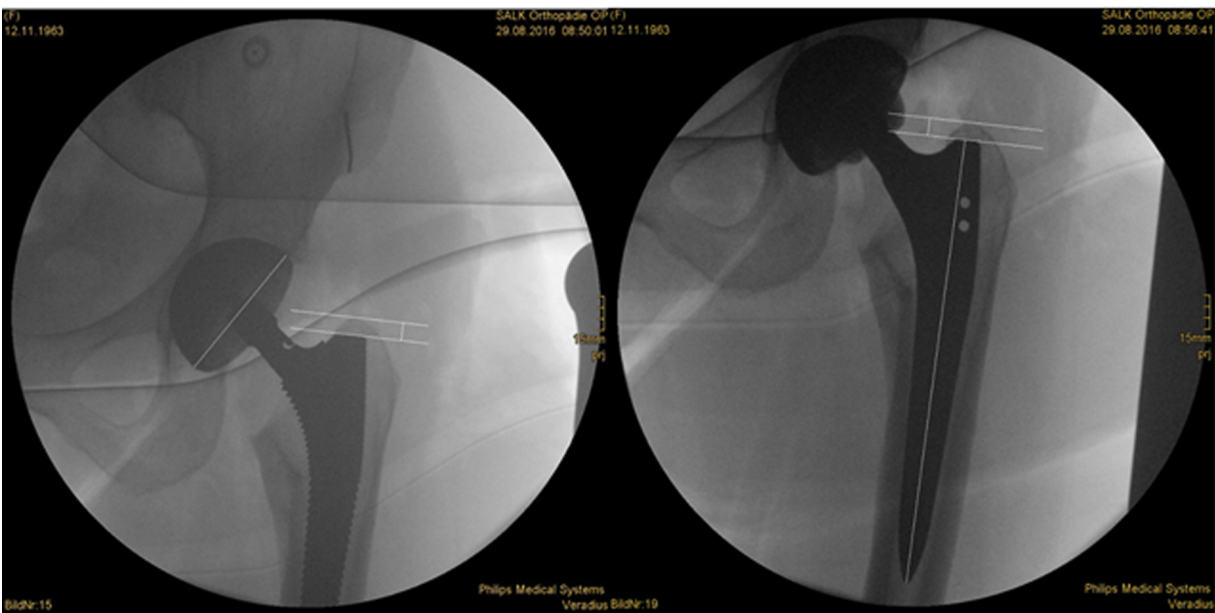
for normal distribution of the data. Unless otherwise noted, the data were normally distributed. For all comparisons between multiple groups, one-way analyses of variance (ANOVAs) with Tukey honest significant difference (HSD) post hoc tests between groups were used. Significance values of less than 5% ( $P < .05$ ) were considered as statistically significant.

**Results**

Fluoroscopic images were available for 39 of the 41 hips (40 patients) included in the study. Images were not acquired for 2 patients as they were forgotten to be collected during surgery.

The mean distance between the tip of the greater trochanter and the shoulder of the last trial rasp ( $x_{Rasp}$ ) was 7.8 mm (standard deviation [SD] = 5.0 mm). The mean distance between the tip of the greater trochanter and the shoulder of the final implant ( $x_{Stem}$ ) was 5.2 mm (SD = 5.0 mm). A paired *t*-test revealed a significant mean difference between the 2 positions ( $P < .001$ ), with a positive mean of 2.6 mm (SD = 2.3 mm, range: -1.5 mm to 7.5 mm) indicating an average protrusion of the stem with respect to the final rasp (Fig. 3).

During 3 (7%) hip surgeries, routine adjustments were performed to improve the overall implant position. Each of the methods was used in individual patients: choice of a ball head with a shorter neck (the corresponding difference measured was  $D = 3.9$



**Figure 2.** The image on the left side shows an example measurement showing an intraoperative fluoroscopic image with the measurements of  $x_{Rasp}$  and the cup as reference. The image on the right side shows a measurement of  $x_{Stem}$  of the same patient using the stem as reference. This particular measurement yielded a  $D = 1.2$  mm, a protrusion of the stem with respect to the final rasp position.

mm), a ball head with a longer neck ( $D = 1.5$  mm), and removal of the stem and rrasping the femoral bed with the last trial rasp ( $D = 3.5$  mm, the fluoroscopic images were acquired after the adjustment).

The clinical leg-length discrepancy was measured using a measuring tape in 41 hips (40 patients) before and after surgery as the difference between ipsilateral and contralateral lengths of the lower extremity. This method allowed measurement of leg-length discrepancies of 1 mm or larger. Seventeen (41%) hips had a leg-length discrepancy before surgery, and 24 (59%) did not. Of the 17 hips with a leg-length discrepancy before surgery, 16 hips (39% of 41 hips, mean:  $9.4$  mm  $\pm$   $7.6$  mm) had an ipsilateral shorter leg and one hip (2% of 41 hips, 9 mm) had an ipsilateral longer leg.

After surgery, 36 (88%) hips had no leg-length discrepancy (based on the smallest measurable leg length discrepancy of 1 mm) and 5 (12%) hips had a leg-length discrepancy. Four of these five patients had an ipsilateral shorter leg after surgery (10% of 41 hips, mean:  $8.3$  mm  $\pm$   $2.4$  mm), but the leg-length discrepancy was reduced because of surgery. One of the five hips showed an ipsilateral longer leg of 2 mm after surgery but had an equal leg length before surgery. The corresponding stem protrusion was  $D = 0.9$  mm. The one patient with an ipsilateral longer leg (9 mm) before surgery had no leg-length discrepancy after surgery. The range of all leg-length discrepancies was reduced from a preoperative range of 1 mm to 30 mm to a postoperative range of 2 mm to 10 mm.

The slap hammer was used with the rasping instrument in 11 hips (28% of 39 hips where images were available and  $D$  could be quantified), the Woodpecker in 20 hips (51% of 39 hips), and the mallet in 8 hips (21% of 39 hips). There was no significant overall effect from the type of rasping instrument on the difference in position between the stem and final rasp (one-way ANOVA,  $P = .305$ ). When comparing the trends between groups, the cohort associated with the Woodpecker showed the largest relative protrusion ( $D = 3.18$  mm,  $SD = 1.7$  mm) followed by the mallet ( $D = 2.2$  mm,  $SD = 2.9$  mm) and finally the slap hammer ( $D = 1.9$  mm,  $SD = 2.6$  mm). These nonsignificant differences are further confounded as each instrument was only used at one hospital (Fig. 3).

The structure of the proximal femoral bone, categorized by the Dorr classification, was not a significant factor determining the outcome of  $D$  (one-way ANOVA,  $P = .218$ ). The 3 type A hips (narrow canal with thick cortical walls, 8% of 39 hips where images were available and  $D$  could be quantified) showed an average difference in the stem and rasp position of 2.62 mm ( $SD = 0.6$  mm), compared with 31 type B hips (moderate cortical walls, 79%) with a mean  $D$  of

2.90 mm ( $SD = 2.3$  mm), and 5 type C hips (wide canal with thin cortical walls, 13%) with a mean  $D$  of 0.97 mm ( $SD = 2.2$  mm).

We additionally verified potential relationships between the relative stem protrusion and weight, age, patient size, gender, and implant size using t-tests and multiple regression. None of these factors showed a significant effect on the outcome.

## Discussion

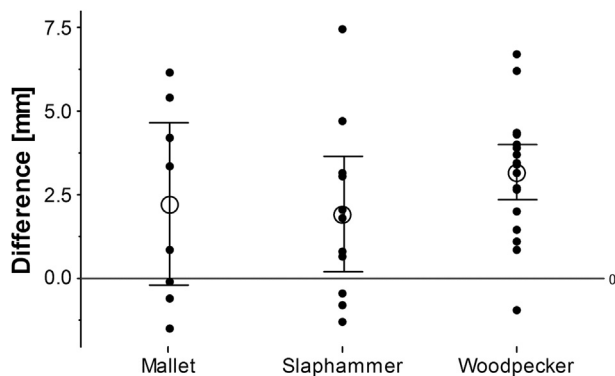
This study assessed the difference between the position of a coated dual-tapered straight stem with rectangular cross section and the position of the last trial rasp. Intraoperatively acquired fluoroscopic images were analyzed to gain a better understanding of the clinical relevance of an oversize of the stem with respect to the corresponding last trial rasp, as well as to investigate the role of a possible stem protrusion with respect to the final rasp. The chosen stem is a widely used type and shows an oversize of up to 0.7 mm because of Ti/HA coating [4]. To our knowledge, there have not been any previous attempts to assess the stem and rasp position in patients.

The present study showed a significant difference of 2.6 mm between the position of the stem and the position of the last trial rasp. This indicates that on average the stem was located more proximal than the rasp along the direction of the medullary canal (ie, a relative protrusion). This could be of clinical relevance as a ball head with a shorter neck may be necessary.

Although this difference may be clinically relevant, it is necessary to emphasize that an adjustment related to a stem position was required in only 2 of the 41 surgeries. The first case required a removal of the stem, and the medullary canal was rasped again, which resulted in a relative stem protrusion of 3.5 mm with respect to the final rasp. The second case required a ball head with a shorter neck to adjust to a relative protrusion of the stem with respect to the rasp of 3.9 mm. There was one further routine adjustment; a ball head with a longer neck was used to increase the tissue tension. Such an adjustment would rather be expected for a too distally placed stem with respect to the rasp. Nevertheless, in this case, the stem protruded by 1.5 mm with respect to the rasp. These cases show that the observed average relative protrusion of 2.6 mm is clinically manageable by, for example, using the modularity of the ball-head-stem system. Such modularity has become routine in modern THA because leg length, hip biomechanics, and hip stability can be improved in almost every case [10]. In fact, in our study, 88% of all patients had an equal leg length after surgery (considering that the leg-length discrepancy that could be measured with the used method was 1 mm or larger).

In addition, it is relevant to note that the aforementioned adjustments were not made in the patients with the most extreme differences between the final rasp and stem positions, which were -1.5 mm and 7.5 mm, respectively. This may imply that other factors play an important role (eg, varus/valgus position) and that a certain protrusion of the stem with respect to the final rasp position may actually be beneficial in certain cases. On the other hand, it must be remembered that the intraoperative fluoroscopic measurement has an intrinsic uncertainty (addressed later in this section of the article).

With respect to the implant survival, the difference between the final rasp and stem positions might be of lower clinical relevance as outcomes and survival rates are reported to be good in the literature and registries. After a follow-up of up to 5 years of a cohort with 1000 implants, 11 (1.1%) revisions were observed (this includes 4 revisions due to infection and revisions of the uncoated version of the stem) [11,12]. The Australian Orthopaedic Association National Joint Replacement Registry on the stem used in this study observed 10 (0.6%) stem revisions after a follow-up of up to 8 years



**Figure 3.** Results plotted of the difference between the stem and final trial rasp positions. A positive value indicates a relative protrusion of the stem with respect to the rasp; the stem was placed less deep into the medullary canal as the rasp. There is no significant effect between the different rasping instruments/sites (ANOVA,  $P = .305$ ). Dots: individual measurements, circles: group mean, and bars: 95% confidence intervals.

of a cohort of 1617 implants [13]. No stem revisions were observed after a follow-up of 5 years in a prospective multicenter observational trial [14].

The difference between the positions of 2 other hip stems with respect to the position of their corresponding final rasp has been previously measured in human cadaver femora. Both stems (CLS, Centerpulse and CBC-T, Mathys) have an oversized rasp dimension with respect to the stem. Nevertheless, the proximal-distal mismatch was opposite for the 2 systems, which was explained by a subtle difference in the geometry (undersized corners) of the CLS [3]. This finding indicates that our results might not be directly generalizable to other similar implant systems. The authors of the cadaver study further concluded that a slightly more proximal position of the stem might be beneficial in terms of stability, as the muscles and capsule are stretched accordingly, and that a deviation of less than 2 mm was of very low clinical relevance.

The head-neck modularity was also previously used to indirectly assess the position of the stem with respect to the last trial rasp (Taperloc, Biomet) [7]. In this study, the stem was also oversized due to the coating of up to 0.89 mm. Nevertheless, only 11% of the cases required a shorter neck, which corresponds to a relative protrusion of the stem with respect to the final rasp position and 8% required a longer modular neck to achieve stability or equal leg lengths as the position of the stem did not exactly match the position of the rasp.

The secondary outcome of this study was the leg-length discrepancy, which was assessed before and after surgery. The measured rasp-stem mismatch, and therefore the achieved position of the femoral stem, did not show an apparent negative impact on adjustments of leg lengths, as 88% of the hips had no leg-length discrepancy after surgery (considering that the leg-length discrepancy that could be measured with the used method was 1 mm or larger). The range of leg-length discrepancy could also be reduced, with results showing a preoperative range from 1 mm to 30 mm, compared with a postoperative range of 2 mm to 10 mm. Only one patient had a postoperative ipsilateral longer leg of 2 mm ( $D = 0.9$  mm), but no leg-length discrepancy was recorded before surgery. No patient had leg-length discrepancy after surgery of more than 10 mm, which has been referenced as a critical factor for symptoms such as back pain, limp, stiffness, hip dislocation and early failure [15], lower patient satisfaction, more frequent use of walking aids [16,17], and gait disorders [18]. Furthermore, previous research has indicated that leg-length discrepancy is strongly related to the femoral component position [18,19]. Our results indicate that the discrepancy between the stem and final rasp positions could have a small effect on the leg length, but this could be mitigated intraoperatively, as we described before.

The present study has several limitations. The clinical measurement of leg-length discrepancy was performed using a measurement tape, which has presumably a larger uncertainty than more comprehensive assessments, such as standing full-leg radiographs [9]. In our study, the chosen method allowed measurement of a leg-length discrepancy of 1 mm or larger. This smallest discrepancy is relatively large compared with the average difference between the position of the stem and final rasp of 2.6 mm. Nevertheless, we used the leg-length discrepancy to control, whether the largest differences in stem and rasp positions would be associated with the largest leg-length discrepancies.

One further limitation was the relatively small sample size. Despite being sufficiently large to detect a difference between the stem and rasp positions of 2 mm, the sample size calculation did not include the additional uncertainty introduced by the fluoroscopic measurements.

In addition, the different hospitals used different rasping techniques (slap hammer, Woodpecker, or mallet). Although the

rasping technique might affect the final rasp position, we believe that the difference between the final rasp and stem positions is mainly governed by the difference in their respective sizes. Nevertheless, we made an attempt to investigate a potential bias by the various rasping techniques and by patient-related factors such as weight, age, patient size, gender, implant size, and proximal femur anatomy. Although we did not observe any influence, it is clear that the study was not designed to detect smaller confounding effects.

One other relevant limitation of this study is the uncertainty associated with the use of the basic fluoroscopic image analysis. A basic uncertainty analysis was performed focusing on intrinsic factors attributed to the fluoroscopic image formation leading to image unsharpness and extrinsic factors attributed to the positioning and orientation of the relevant landmarks (for further details, refer to the study by Burckhardt et al [20]). We approximated the individual uncertainties as standard deviations from rectangular distributions based on our experience from the image analysis and geometric projection of the used stem that was rotated with respect to the image plane. The uncertainties were scaled with the averaged results and then combined using standard methods [21]. This resulted in a combined uncertainty of the measurement method of  $\pm 1.0$  mm (1 standard deviation).

As our uncertainty is clearly an approximation (and probably an underestimation), we compared our results with measurements of stem subsidence performed with radiograph imaging. These are in principle the same measurements. The reported accuracy for a widely used software tool (EBRA-FCA, Ein Bild Roentgen Analyse - Femoral Component Analysis) was  $\pm 1.5$  mm [22], whereas others report values in a similar range for software-aided measurements, ranging from  $\pm 0.5$  [23] to  $\pm 2.5$  mm [24]. We could not use EBRA-FCA in our study as the ball head is required to be visible on the images. Basic methods, such as the one used in the present study, are associated with accuracies ranging from  $\pm 0.5$  mm [25] to  $\pm 5$  mm [26]. Unfortunately, these values are not directly comparable to a standard uncertainty because of differences in methodology.

A maximal error of 0.37 mm was estimated by a theoretical analysis and by applying  $5^\circ$  rotations to the stem [27]. One main factor affecting the uncertainty in the present study was the (flat) shape of the rasp/stem shoulder, whereas in the theoretical model, an elliptical shape was used. This might explain the differences in the reported values. We limited our uncertainty assessment to the same amount of rotation on the parasagittal plane.

## Conclusions

This was the first attempt to quantify a clinically relevant mismatch of the stem position with respect to the last trial rasp *in vivo*, using intraoperatively acquired fluoroscopic images. Our results show that an oversize of up to 0.7 mm leads to an average stem protrusion with respect to the last trial rasp of 2.6 mm. The quantified relative protrusion appears to be clinically manageable, as in only 5% of the cases did the position of the stem need to be compensated for by rasping the femoral bed again and using a ball head with a shorter neck length. In view of the good midterm results (currently up to 8 years of follow-up) of this widely used stem, and that the aforementioned adjustments to balance the limb length, biomechanics, and soft-tissue tension were not related to the cases with the most extreme differences in the position of the stem and rasp, other additional factors appear to be critical to the surgeon and the clinical outcome. Potentially, a protrusion of the stem with respect to the last trial rasp in certain cases might even be beneficial for hip stability and the long-term outcome of the surgery if properly managed through the choice of an optimal ball-head length. Nevertheless, surgeons should know about this

difference as it could be clinically relevant. This difference in the stem and final rasp positions should therefore be noted in the surgical technique.

### Conflict of interests

T. Hofstädter is a paid consultant for Smith and Nephew, Zimmer Biomet, and Lima Ltd and has received research support as a principle investigator from Smith and Nephew; G. Fessel is a paid employee of Smith and Nephew and owns company shares from Smith and Nephew; L.C. Orlandini is a part-time paid employee of Smith and Nephew and owns company shares from Smith and Nephew; R. Hube receives royalties from Zimmer Biomet, is a speaker/a part of paid presentations for Zimmer Biomet and Smith and Nephew, holds stock options from Parvizi Surgical Solutions, receives research support as a principle investigator from Smith and Nephew and Zimmer Biomet, is on the editorial/governing board of the AOTS, and is the president of the German Knee Society; M. Najfeld declares that he has no conflict of interest.

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