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ORIGINAL PAPER

Influence of calibration on digital templating of hip arthroplasty

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Abstract

Introduction Digital templating for total joint replacement is the current standard. For image calibration, external calibration markers (ECM) are used. However, there are concerns regarding the precision of the method. This study aimed to identify the direct influence of calibration errors on digital templating.

Patients and methods A retrospective analysis of 100 post-operative radiographs with unilateral total hip arthroplasty was performed. The magnification factor of the ECM and of the internal prosthetic femoral head (ICM) as a reference value was calculated for each radiograph. Two blinded observers performed templating of the contralateral hip using a randomized list for all radiographs and both markers. The component size templated by the ECM magnification was compared to the reference by the ICM magnification.

Results Mean magnification factors of ICM and ECM differed significantly ($p = 0.006$). The absolute difference was 5.2% (range 0.0–23.3%, SD 4.8%). Templating of the acetabular or the femoral component showed no significant differences ($p = 0.120$, $p = 0.599$). Differences of more than one size were found in 26% of the acetabular components and 14% of the femoral components and differences over two sizes in 10% respectively 3%. Correlation coefficients for magnification error and size differences of acetabular components were -0.645 ($p < 0.001$) and for the femoral component -0.607 ($p < 0.001$).

Interpretation The calibration error of external calibration markers in digital templating for hip replacement influences component sizes significantly. Thus, correct positioning of ECM is of utmost importance.

Keywords Total hip arthroplasty · Digital templating · Radiography · Calibration

Abbreviations

a.p.	Anteroposterior
ECM	External calibration marker
ICM	Internal calibration marker (i.e., THA head)
THA	Total hip arthroplasty

Introduction

Templating of total hip arthroplasty is an essential step in elective joint replacement surgery [1]. The application of radio-opaque markers to calibrate the digital radiograph is

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the standard method in templating software [2]. However, there are relevant concerns regarding the precision of these markers due to positional errors [3–6]. It is supposed, that mal-positioned markers result in incorrect calibration and, therefore, negate the positive effects of templating [3, 6]. To evaluate the quality of templating, previous studies focused on the correlation of acetate or digital templating and the implanted prosthesis. A precision of ± 1 component size between pre-operative templating and implanted component has been defined acceptable [7]. Of note, Iorio et al. found only 60% of the acetabular cups and 74% of femoral stems to be within one size of the pre-operative assessment in digital templating in comparison to 78% and 77% in acetate templating [8]. Efe et al. found 34% of digitally templated prosthesis within one size and 79% within two sizes [7]. However, comparing the pre-operatively assessed component size with the intra-operatively implanted component combines multiple steps and is therefore susceptible to a number of confounding factors. For example, the process of digital templating itself is influenced by experience and training. Furthermore, the person performing the templating and the surgical procedure could differ. Subsequently, the surgeon might find intra-operative reasons to adapt component sizes; these might be surgeon- or patient-specific.

The present study aimed to dissect the problem of calibration to the level of digital templating itself. The magnification factors of external calibration markers (ECM) were compared to the magnification factors of implanted total hip replacements (internal calibration marker; ICM). It was hypothesized that there is a linear correlation between the magnification error and the differences in the templated component sizes.

Patients and methods

We identified 100 standing antero-posterior (AP) radiographs of the pelvis in a retrospective digital search in the hospital picture archiving and communication system (PACS). Images with unilateral total hip arthroplasty of known component size and an external calibration sphere of 28 mm diameter positioned medially between the legs at the palpated height of the greater trochanter were included. Radiographs were acquired using a Philips DigitalDiagnost (Philips GmbH, Hamburg, Germany) with the X-ray beam centered on the symphysis. The tube-to-detector distance was 1100 mm. For elimination of the anticipated femoral anteversion, the feet were internally rotated.

The diameter of the internal (i.e., acetabular shell) and external calibration marker was measured and entered into a data sheet.

A pseudonymized list of the radiographs was created with two entries for each radiograph: one for the external and one for the internal marker templating. The diameter was measured by identification of three points on the circumference of each marker. The magnification factors of both markers were calculated by the formula

$$\text{Magnification factor} = \text{Measured diameter}/\text{True diameter} \times 100 \quad (1)$$

Then, the order of the list was randomized. The first observer (SW) performed templating for all entries, blinded to the type of marker (ICM or ECM). The first and the second observer (JB) templated ten radiographs in the same fashion; these were selected using a random generator. Both observers were blinded to the previous results.

Templating of the radiographs was performed with a PACS client (IMPAX EE, AGFA HealthCare GmbH, Bonn, Germany) and a proprietary digital templating software (mediCAD Version 2.5, mediCAD Hectec GmbH, Altdorf bei Landshut, Germany). For reproducible calibration, the previously calculated magnification factors were entered. In all cases, the non-operated hip was planned for a non-cemented total hip arthroplasty. The same components were templated in all cases. Only the fit of the shaft in the femur was templated; restoration of femoral offset and leg length was not considered. The templating followed the instructions of the software producer and the implant manufacturer. A standardized protocol was established. Both observers were trained in the method before the study, templating about 50 hips in the same fashion under supervision of a board certified orthopaedic surgeon specialized in joint replacement surgery (CKB).

Statistics

For descriptive analysis, absolute mean values and ranges of the measured variables are reported. A paired sample two-tailed *t* test was used to compare continuous variables. Spearman correlation coefficients were calculated. Intraclass correlation coefficients (ICC) were calculated for repeated measurements of two independent observers. The level of significance was set at 0.05.

A power calculation was performed using an Altman nomogram [9].

IBM SPSS Statistics 25 for Mac and Microsoft Excel (Office 365) for Mac version 15.33 were used.

Ethics

The study protocol followed the principles of the Declaration of Helsinki and following the local ethics committee, no formal informed consent was required for this retrospective analysis.

Results

Magnification factors

The internal and external calibration markers resulted in a mean magnification factor of 122.6% (range 106.5–135.8%, SD 3.9%) and 124.5% (range 109.6–147.1%, SD 6.3%), respectively. There was a significant difference between the magnification factors ($p = 0.006$). The mean difference was − 1.9% (range − 23.3–16.8%, SD 6.8%); the absolute difference was 5.2% (range 0.0–23.3%, SD 4.8%); Fig. 1 shows the distribution of ICM and ECM magnification in a scatter-plot. Spearman correlation coefficients were 0.204 ($p = 0.042$).

Digital templating

Acetabular component

Digital templating of the acetabular component using the ICM did not differ significantly from ECM templating ($p = 0.120$). Spearman correlation coefficients were 0.876 ($p < 0.001$). Twenty-six percent of the components showed size differences of more than one size and 10% over two sizes (Table 1).

Femoral component

Digital templating of the femoral component using the ICM did not differ significantly from ECM templating ($p = 0.599$). Spearman correlation coefficients were 0.664 ($p < 0.001$).

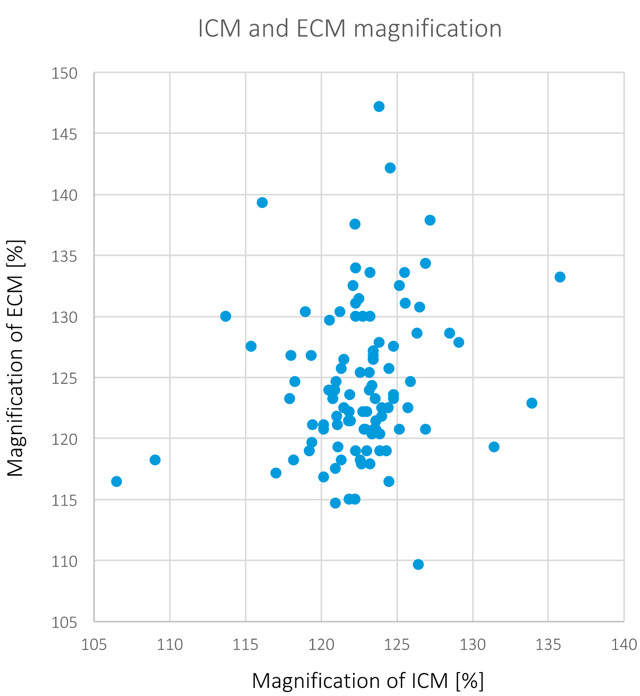

Fig. 1 Scatterplot of ICM and ECM-based magnification of radiographs in percent

Table 1 Distribution of differences in the component sizes between ICM and ECM templating

Difference in component size	Acetabular component (n)	Femoral component (n)
0	37	46
1	37	40
2	16	11
3	5	2
4	2	1
5	2	0
6	1	0
Sum	100	100

Fourteen percent of the components showed size differences of more than one size and 3% over two sizes (Table 1). Table 1 shows the distribution of differences in component size between ICM and ECM templating.

Co-linearity/correlation

Spearman correlation coefficients for magnification error and size difference of acetabular components were − 0.645 ($p < 0.001$; Fig. 2a). Those for the femoral component were − 0.607 ($p < 0.001$ Fig. 2b).

Reliability

Intraclass correlation coefficients for intra- and inter-rater reliabilities are shown in Table 2.

Power analysis

A standardized difference of 0.5 was assumed and 100 radiographs (equivalent to sample size of 200) were included. The power of the relative difference was > 0.5; the power for of absolute differences was > 0.99.

Discussion

The importance of pre-operative templating for total hip replacements is generally accepted [3, 10–13]. It can help optimize logistics in the operating theatre and reduce risks and complications as leg length differences [13]. The introduction of digital radiographs and templating has led to the necessity to use calibration markers [8]. Alternatively, fixed magnification factors similar to acetate templating can be applied. [4, 5] However, all methods of calibration have immanent risks of misinterpretation of the true magnification of the hip plane in conventional radiographs [4]. Spherical external calibration markers are the standard in THA templating [4]. As shown

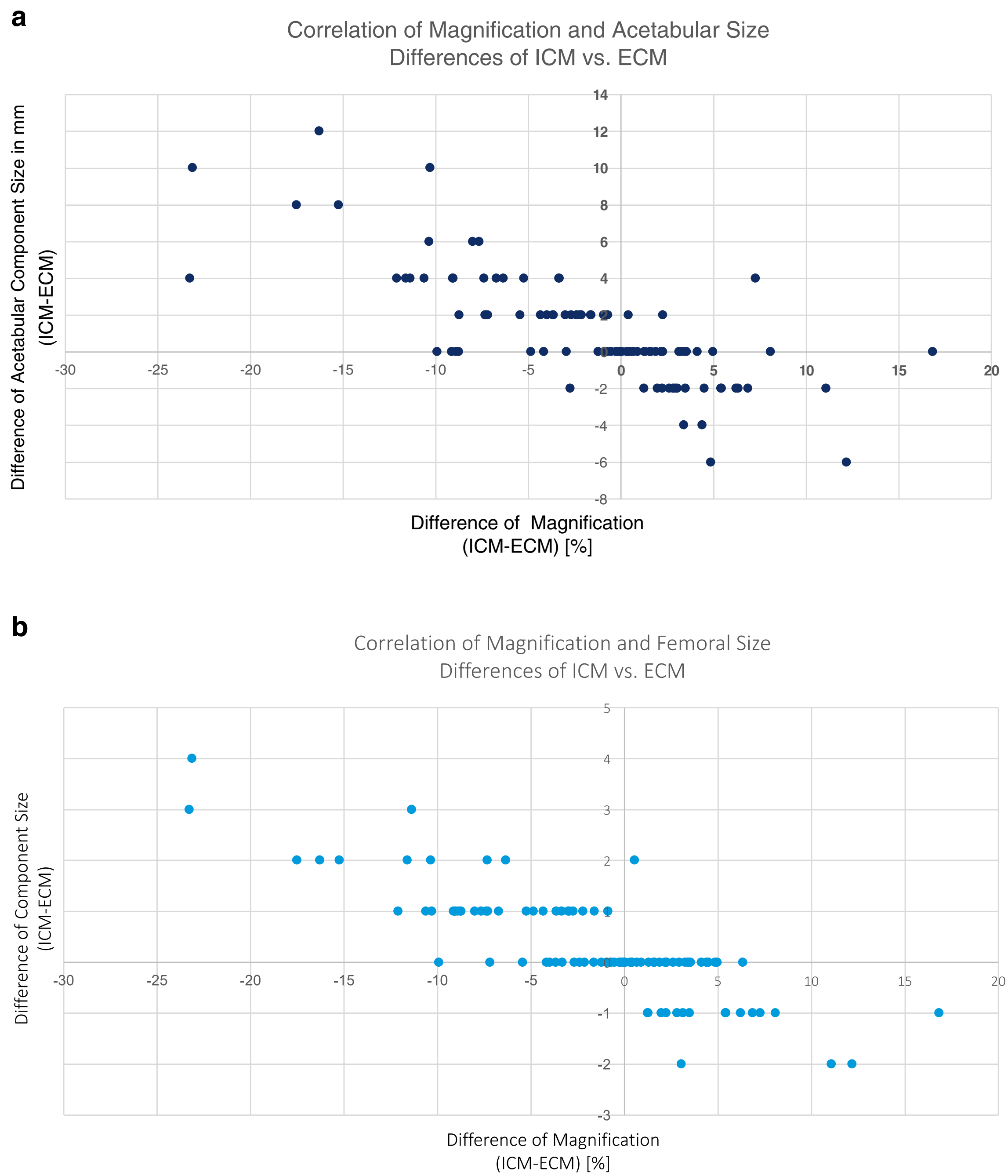

Fig. 2 **a** Correlation of magnification differences between ICM and ECM and differences in templated acetabular component sizes as component diameter in mm. **b** Correlation of magnification differences between ICM and differences in templated femoral component sizes

by Kniesel et al., the correlation of pre-operative templating and implanted component size in THA improved with the application of a marker ball but was weak overall [12]. While various authors showed the imprecision of this method and detected underlying reasons for the mal-positioning of the ECM, its direct effect on digital templating itself has not been addressed so far. Previous studies determined the precision of acetate or digital templating by comparing templated and definitively implanted components [7, 11, 12]. However, this approach ignores the effect of experience on templating as well as individual intra-operative decisions regarding component size.

To eliminate these confounding factors, we performed a study comparing templating of unilateral THAs based on internal calibration markers (gold-standard) and external markers. Overall, the study showed good correlations between magnification errors and differences in templated component sizes. The reliability analysis showed excellent correlations for repeated measurements of one and two observers.

Table 2 Intraclass correlation coefficients for intra- and inter-rater reliabilities

	ICM	ECM
Acetabular component		
Inter-rater	0.934 ($p < 0.001$)	0.968 ($p < 0.001$)
Intra-rater	0.953 ($p < 0.001$)	0.883 ($p < 0.001$)
Femoral component		
Inter-rater	0.981 ($p < 0.001$)	0.897 ($p < 0.001$)
Intra-rater	0.944 ($p < 0.001$)	0.845 ($p < 0.001$)

While the means of the ICM and ECM magnification were close (122% and 124%), the correlation was weak. Differences of up to 23.3% with a mean of 5.2% confirmed previous studies. Bayne et al. found a mean error of 8.9% with a standard deviation of 8.0% [11], while Franken et al. found the mean error of a medially placed marker ball to be 2.0% (maximum 6.5%) [4]. Finally, Sinclair et al. identified an error of 6.8% (range 0–26%), comparable to our current results [5].

An error of magnification can result in differences of the templated prosthetic components. A pictorial case is presented in Fig. 3 to show the influence of misplaced ECMs on digital templating.

The comparison of digital templates and surgical results has been used to analyze the quality of the templating procedure [12]. Accuracy was defined as the agreement between size of templated and implanted prosthetic component. While this is

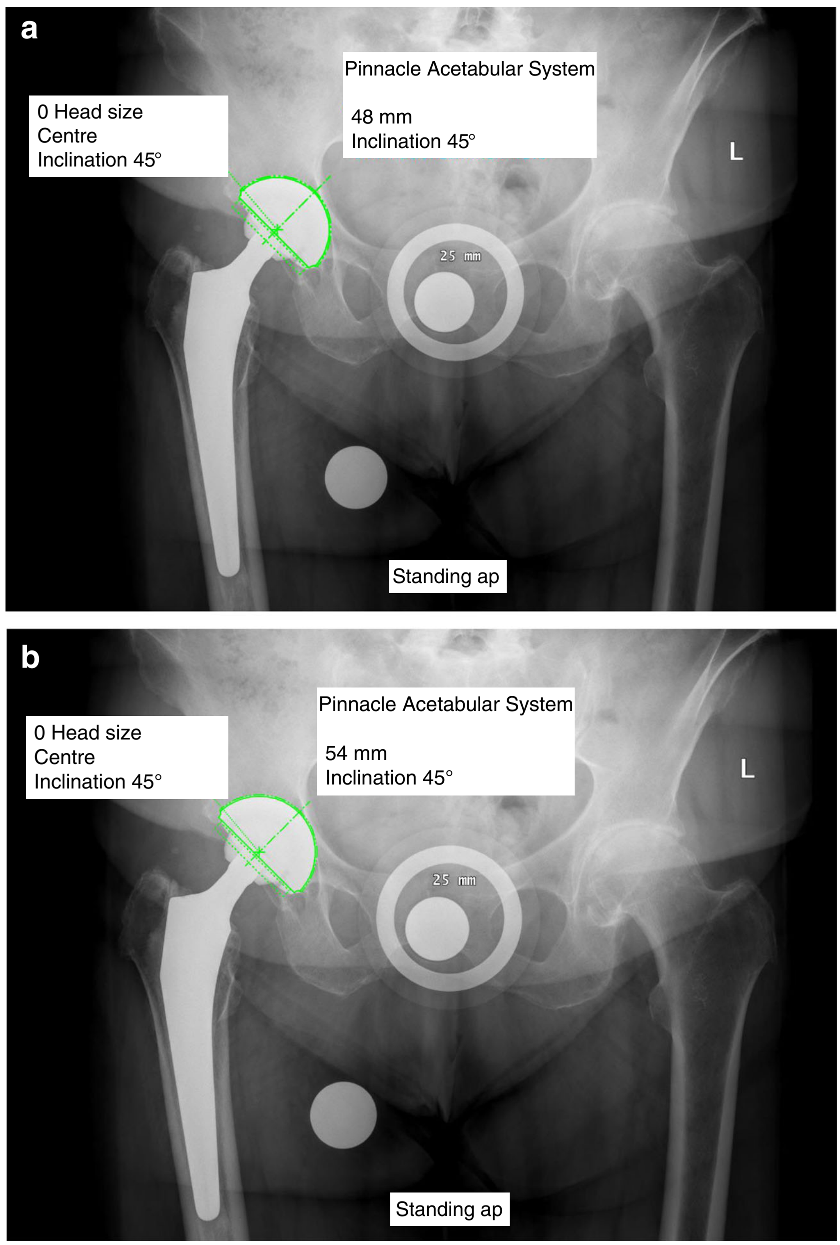

Fig. 3 Case of a 73-year-old female. Antero-posterior pelvic radiograph in standing position. A 32-mm femoral head component and a 28-mm external calibration marker were used. Additionally, a dual calibration marker at the pubic symphysis is visible, which was not part of this study. **a** Digital re-template of the implanted acetabular component using the ECM (139% magnification). **b** Digital re-template of the implanted acetabular component using the ICM (124% magnification). The difference of 15% of the magnification factor resulted in a difference of three component sizes (6 mm diameter)

obviously a surrogate for the accuracy of the calibration process, it is so far the only quality control published. Besides others, Gamble et al. found good agreement between templating and implants. Eighty-five percent of the femoral and 80% of the acetabular components were within one size. On the other hand, Efe et al. found the agreement to be 82% and 76%, respectively [7]. Kniesel et al. found identical sizes in templating and surgery of the acetabular in only 27% with marker balls and 15% without [12]. Within one size difference were 67% and 29%, respectively. This shows differences between templated and implanted component sizes of 15–24% and more. The et al. reported an even lower agreement for different types of prosthesis of 52–72% and 66–79%, respectively [14]. Overall, there remain relevant concerns regarding the reliability of digital templating. To account for the role of the calibration process, a more basic approach was followed in the present study.

In concordance with these previous publications, this study found the templating error based on the ECM to result in size differences of up to six sizes for the acetabular and four sizes for the femoral component. Seventy-four percent of the acetabular components and 84% of the femoral components were templated within one size. This seems comparable to the results of Efe et al., Kniesel et al., and Gamble and colleagues [7, 12, 15]. It strengthens the assumption of a significant role of calibration in templating-errors for THA. Notably, some cases with significant magnification errors were identified that resulted in no or only slight differences of the templated components (Fig. 2a, b). Possible reasons are issues to identify landmarks during the templating process and the experience of the planner. Though following a strict protocol, not all aspects of the templating process can be standardized, and the decision may be based to some degree on experience and intuition. However, spearman correlation coefficients of − 0.645 and − 0.607 clearly showed the co-linearity of the magnification error and size difference in the templated components.

Additionally, the reliability analysis showed high correlations between repeated templating by one and two observers. This indicates a reliable protocol and reproducible results.

Notably, the development of dual marker calibration might present a feasible solution to templating errors. Most recently, Boese et al. presented theoretical results of such a method and found better prediction in comparison to calibration with a fixed value and a single marker [16]. However, this method needs to be proven in real life first. The application of CT based three dimensional templating might be an alternative to radiograph based planning [17]. It allows for more complex analysis and can take multiple factors into account. Here, the combined anteversion plays an important role. However, recently Ohmori et al. criticized this concept and indicated another approach to find optimal component placement based on simulated motion and impingement in 3D templating [12]. Overall, these studies show the need to enhance our understanding of pre-operative templating and its implications.

The major limitation of this study is the experience of the observers. While templates are often performed by younger colleagues (e.g., Efe et al.), in our study, a repeated analysis by highly trained endoprosthetic specialists has been performed. Thus, outliers in the correlation analysis might be reduced.

The major strength of this study is the direct approach to identify the influence of the calibration error on templating. To our knowledge, this has not been done before. Based on these results, there seems to be a necessity to further improve digital templating for THA.

Interpretation

The calibration error of external calibration markers in digital templating for hip replacement influences component sizes significantly. Thus, correct positioning of ECM is of utmost importance. There is a need to establish instruments to identify mal-placed markers or improve the calibration quality in general.

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Author contributions All authors have participated in the research.

Data analysis: CKB, PL, and JB. Interpretation of data: CKB, JB, SW, and PL. Drafting of manuscript: CKB, JB, and PL. Critical review and writing of the manuscript: CKB, JB, SH, and PL. Approval of final version of the manuscript: all authors.

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Compliance with ethical standards

Conflict of interest CKB is an employee of Smith & Nephew GmbH. The other authors declare no relevant conflict of interest.

Ethical approval and informed consent The study protocol followed the principles of the Declaration of Helsinki and following the local ethics committee, no formal informed consent was required for this retrospective analysis.

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