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ORIGINAL PAPER

Customized implants for acetabular Paprosky III defects may be positioned with high accuracy in revision hip arthroplasty

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Abstract

Purpose In revision hip arthroplasty, custom-made implants are one option in patients with acetabular Paprosky III defects.

Methods In a retrospective analysis, we identified 11 patients undergoing cup revision using a custom-made implant. The accuracy of the intended position of the implant was assessed on post-operative 3D CT and compared to the pre-operative 3D planning in terms of inclination, anteversion, and centre of rotation. In addition, the accuracy of post-operative plain radiographs for measuring implant position was evaluated in relation to the 3D CT standard.

Results We found a mean deviation between the planned and the final position of the custom-made acetabular implant on 3D CT of 3.6° ± 2.8° for inclination and of − 1.2° ± 7.0° for anteversion, respectively. Restoration of center of rotation succeeded with an accuracy of 0.3 mm ± 3.9 mm in the mediolateral (*x*) direction, − 1.1 mm ± 3.8 mm in the anteroposterior (*y*) direction, and 0.4 mm ± 3.2 mm in the craniocaudal (*z*) direction. The accuracy of the post-operative plain radiographs in measuring the position of the custom-made implant in relation to 3D CT was 1.1° ± 1.7° for implant inclination, − 2.6° ± 1.3° for anteversion and 1.3 mm ± 3.5 mm in the *x*-direction, and − 0.9 mm ± 3.8 mm in the *z*-direction for centre of rotation.

Conclusion Custom-made acetabular implants can be positioned with good accuracy in Paprosky III defects according to the pre-operative planning. Plain radiographs are adequate for assessing implant position in routine follow-up.

Keywords Total hip arthroplasty · Revision · Custom-made implant · Acetabular Paprosky III defects · 3D CT

Introduction

Total hip arthroplasty (THA) is one of the most frequently performed procedures in orthopaedic surgery and a successful curative treatment option of advanced hip osteoarthritis [1, 2]. Despite continuous improvement in surgical technique and implant design, the number of revision arthroplasty is still expected to grow [3]. By the year 2026, the demand for hip revision procedures is projected to double in the USA [4].

Revision of the acetabular component represents a complex and challenging procedure especially in patients with large osseous defects and compromised bone quality. In clinical practice, the Paprosky classification is frequently used to quantify the extent of acetabular bone loss and consequently choose the right operative treatment strategy [5]. The Paprosky system has been shown in literature to have high validity and reliability [6]. In this classification, type III defects represent the most severe form with extensive bone loss from major destruction of the acetabular rim and supporting structures [5].

Custom-made implants are one option to address these large bony defects [7]. However, the intra-operative situation might vary from the pre-operative templating after hardware removal. Furthermore, due to the applied surgical approach, the positioning of these custom-made pelvic implants might be compromised. In a previous study of 16 patients with acetabular Paprosky type III defects, the accuracy of positioning of custom-made implants has been reported as encouraging

This work was performed at Regensburg University Medical Center, Department of Orthopaedic Surgery, Bad Abbach, Germany.

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using 3D CT [8]. Although a variety of different studies already exist researching into the accuracy of 3D CT compared to plain radiographs in primary joint replacement [9–11], custom-made implants present additional difficulty during radiographic assessment due to the individual geometric configuration of the implant and the presence of large acetabular defects. In a previous study, only 56% of cups in Paprosky III defects were reported to be within the intended safe zone according to Lewinnek as assessed on radiographs [12]. To the best of the authors' knowledge, no study so far has analyzed the accuracy of plain radiographs for post-operative evaluation of implant position compared to 3D CT in Paprosky III defects treated with customized implants.

In the current study, we aimed to (1) assess the accuracy of a novel custom-made acetabular implant between pre-operative planning and post-operative position using 3D CT in acetabular Paprosky type III defects and (2) to assess the accuracy of plain radiographs in assessing the post-operative position of the custom-made implant compared to 3D CT.

Materials and methods

The current study is a retrospective analysis of 11 consecutive performed acetabular revisions with Paprosky type III defects. All operations were performed by two senior surgeons (BC, TR) between December 2013 and March 2017 at our Department of Orthopaedic Surgery, Regensburg University Medical Center, Germany. The investigation was approved by the local medical ethics committee (No.: 17-415-101).

According to the study protocol, eligible participants were patients after THA undergoing acetabular revision with Paprosky type III defects as estimated on pre-operative 3D CT. Reasons for revision comprised aseptic loosening, recurrent dislocation, and Girdle stone. Anthropometric and intra-operative characteristics of the study group are shown in Table 1. Prior to revision, a 3D-CT analysis of the entire pelvis and femoral implant including femoral condyles was performed to assess the implanted acetabular component and extent of acetabular osseous defect. After obtaining written informed consent from the patient, the 3D-CT data were then transferred to the manufacturer (AQ Implants GmbH, Ahrensburg, Germany).

A 3D CAD model of the pelvis was generated by using a semi-automatic bone segmentation algorithm in order to improve the accuracy of the reconstructed bone geometry. Especially in revision cases with massive metallic components and radiation artifacts within the provided CT data, this procedure facilitates the evaluation of the acetabular bone defect. In dependence of the acetabular defect, quality of the remaining acetabular bone and the position of the reconstructed center of rotation (COR) and the design of the implant combined with the position and orientation of screws and iliac peg as well as areas for porous metal augmentation were templated. The construction of the implant is designated as monobloc component to be fabricated by selective laser melting process. During planning, the surgeon provided feedback and defined the intended position of the implant in terms of anteversion, inclination, and restoration of center of rotation. COR was determined with respect to two main factors: first, physiological restoration of the joint biomechanics concerning symmetry with the contralateral side, offset, and leg length difference [13]; second, sufficient positioning of the acetabular cup with respect to the specific bone geometry of the treat-

Table 1 Patient characteristics of the study group

Patient number	Age (year)	Sex	BMI	ASA	Primary diagnosis	Years since first replacement	Revision number	Reason for revision	Paprosky classification
1	76	F	28	3	OA	22	4th	Aseptic loosening	3A
2	81	F	26	3	OA	2	3rd	Aseptic loosening	3A
3	85	M	24	2	AVN	14	3rd	Recurrent dislocation	3B
4	61	F	24	3	CHD	0	0	NA	3A
5	60	F	28	2	RA	16	3rd	Aseptic loosening	3A
6	85	F	24	3	OA	10	2nd	Recurrent dislocation	3A
7	81	F	24	3	OA	9	4th	Aseptic loosening	3B
8	80	F	31	3	OA	17	2nd	Aseptic loosening	3A
9	76	M	25	2	OA	21	1st	Aseptic loosening	3A
10	79	M	30	3	OA	19	2nd	Girdlestone	3A
11	71	F	40	2	CHD	0	0	NA	3A

BMI, body mass index; *ASA*, American Society of Anesthesiologists Index; *OA*, osteoarthritis; *AVN*, avascular necrosis; *CHD*, congenital hip dysplasia; *RA*, rheumatoid arthritis

ed side, sometimes resulting in small adjustments of the COR for the benefit of sufficient implant fixation to the remaining bone. However, implant position was intended to be within Lewinnek's safe zone. In order to determine the influence by the designer on the COR, inter- and intra-observer tests have been performed for the 2D and 3D matching. For the intraobserver variability, one case was repeatedly planned by one person ($n = 6$ with at least two days or three other cases in between to minimize the training curve). Maximum deviation for repeated COR measurements was below 1 mm for 3D matching and below 2 mm for 2D matching. Similarly, repeated measurements for inclination and anteversion were below 2° for both 3D and 2D matching. For interobserver variability, three different cases were planned by two different designers. The results showed excellent agreement with differences below 1 mm and 1° for 3D matching and 1 mm and 2° for 2D matching. To guarantee sufficient osseous fixation, we aimed for an inclination of 45°. Anteversion was adjusted in relation to the bony defect and ranged from 0° to 20° as a compromise between optimal implant position and sufficient osseous fixation/coverage.

The approved implant design was fabricated by selective laser melting technology (SLM) made of titanium alloy (TiAl6V4) as a monobloc system. Post-processing (grinding, tapping), cleaning, washing, packing, and sterilization were performed according to certified processes at the manufacturer.

Operations were performed in the lateral decubitus position using a posterior approach or a Hardinge approach depending on the approach of previous surgery. The femoral component was not revised in eight patients due to appropriate fixation and position. For acetabular revision, first, the original acetabular implant was removed. Then according to the pre-operative 3D-CT planning, additional hardware and osteophytes were cleared if required. Then the custom-made pelvic implant was adjusted according to the planned position and temporarily fixed with Kirschner wires. In one case, there was a difference between the planned anatomy and the intra-operative situation due to additional bone loss during hardware removal. Therefore, the position had to be adjusted accordingly. The position was controlled using intra-operative fluoroscopy. Afterwards, a Kirschner wire was positioned using drill guides for the central iliac peg and the position controlled fluoroscopically. As next step, a larger drill was used for the final preparation of the central peg and the iliac peg impacted. Additional fixation was obtained by cup and flange screws according to the pre-operative planning. For voids and cavitary defects, additional allograft was applied. Finally, after fixation of the custom-made implant, a dual mobility cup (Novae Stick, AQ Implants GmbH, Ahrensburg, Germany) was cemented in the cavity. Mobilization after surgery was allowed with partial weight-bearing of 20 kg on the operated leg for the first six weeks.

Within the first week after surgery, a post-operative 3D CT was obtained in all patients for post-operative control of the custom-made implant as well as plain radiographs of the pelvis. For evaluating the accuracy of the custom-made implant in relation to the pre-operative planning, a 3D approach was utilized comparing the post-op 3D-CT data with the pre-operative 3D-CT template. Therefore, the pre-op CT dataset (including the implant model) was adjusted to match the geometry of the post-op CT dataset. The general workflow is described in Fig. 1. In order to optimize the alignment of the different datasets, the CAD program SolidWorks (Vers. 2015, Dassault Systèms, MA, USA) was used to calculate the 3D deviations of the aligned models. Deviations between both models were overall less than 1 mm. The neutral position of the pelvis was defined by the anterior pelvic plane. After aligning the planned and the post-operative CT dataset (Fig. 2) was performed with sufficient accuracy, the deviation between the post-operative and the planned implant was calculated in the mediolateral (x), anteroposterior (y), and craniocaudal (z) direction as well as for implant anteversion and inclination.

Since 2D plain X-ray images are often used as a golden standard for post-operative control, we then compared the accuracy of the 2D images to 3D CT. Due to the varying posture of the patients and the complex geometry of the custom-made implants, special software at AQ Implants was used for the assessment of the implant position. Besides the generation of the 3D models of the bone geometry from CT data for planning the custom-made implants with respect to the physiological centre of rotation and leg length difference for the patient, the software offers the possibility to deal with 2D X-rays with overlaying 3D-CT data. First, 2D X-rays were imported to the software and scaled according to the distinct implant dimensions. Then, the 3D models of the reconstructed pelvic bone from post-op CT dataset were added including the implant in the position at which it has been positioned in correlation to the pelvic bone (Fig. 3a). In a second step, the orientation of the 3D model of the pelvis together with the bonded implant model was adjusted to fit the pelvis orientation of the X-ray. Care was taken, that all anatomical landmarks fit between the X-ray and the 3D model of the pelvis by using the convenient outline projection of the 3D model (Fig.

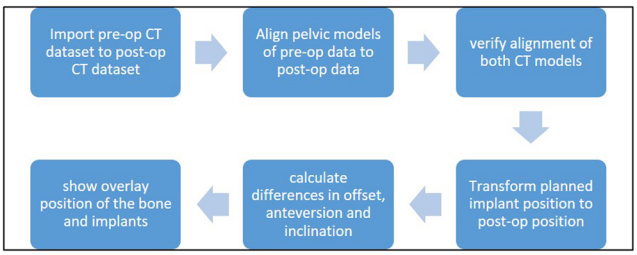

Fig. 1 Workflow for the determination of the differences between planned and current implant position from pre- and post-op CT dataset

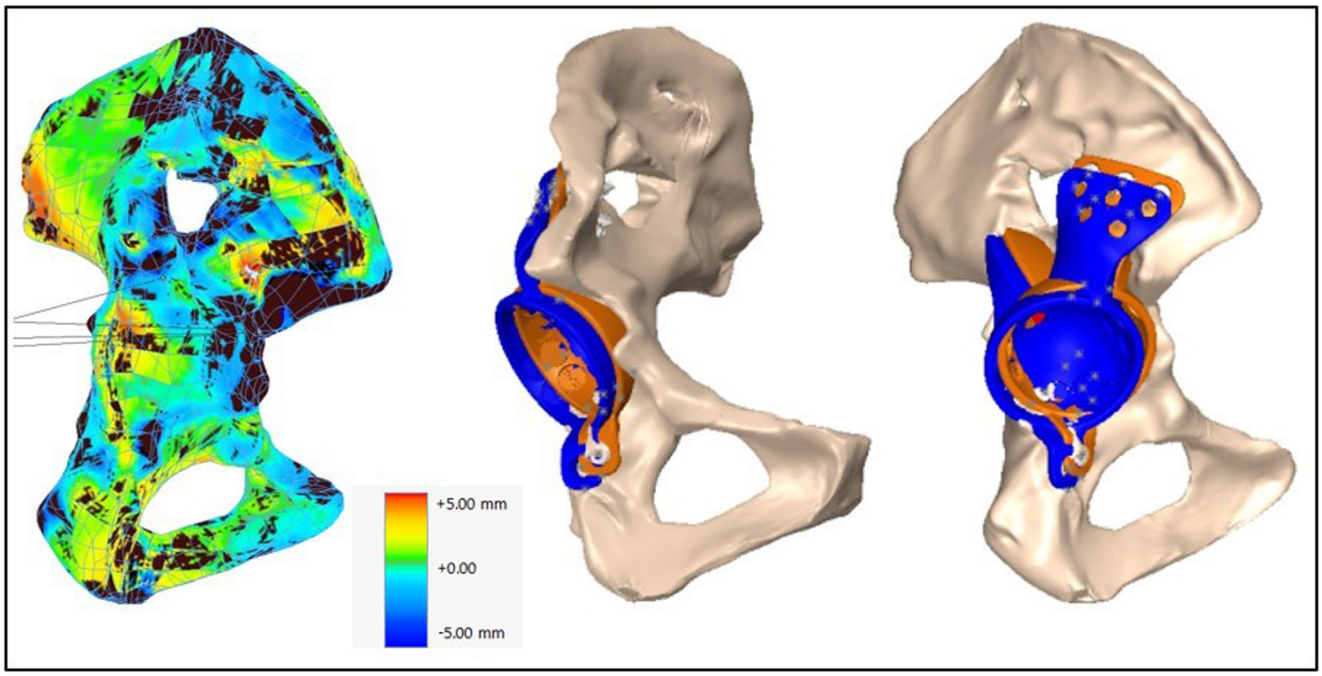

Fig. 2 Geometrical deviations after the alignment mostly occurred due to the slightly different reconstruction of both CT models (pre- and post-op) of the pelvis; in the area of the COR, deviations were less than 1 mm (**a**). Anterior-posterior view of the planned implant position (orange) and the current implant position aligned according to the post-op CT dataset (blue) (**b**). Medial-lateral view of the planned implant position (orange) and the aligned implant position (blue) (**c**)

3b), whereat the 3D model of the implant was still in the planned position (Fig. 3c). In the final step, the pelvis orientation was fixed and only the implant orientation was adjusted to fit to the current implant position from X-ray (Fig. 3d). An anteroposterior translation of radiographs cannot be ruled out when matching 2D images. However, due to the specific geometry of the implant, the metallic augmentation, and the screw fixation, an isolated shift of the implant toward the AP direction is not possible without effecting the other parameters. The final transformation (translation and rotation) was recorded and recalculated for the differences in the position of the centre of rotation as well as for the differences in anteversion and inclination of the cup with respect to the final implant parameters. All calculated parameters were related to the originally adjusted CT dataset, i.e., arbitrary tilting of the pelvis within the X-rays was neglected by using the transformed CT reference system.

Clinical notes and data of the institutional joint registry were analyzed for intra-operative complications. Furthermore, post-operative complications were recorded by clinical follow-up of at least six months up to three years after surgery. Similarly, clinical outcome was assessed using Harris Hip Score (HHS).

For statistical analysis, continuous data are presented as mean ± standard deviation. Group comparisons for dependent variables were performed using Wilcoxon signed-rank test. Absolute and relative frequencies were given for categorical data. According to literature, malpositioning was defined as a deviation of more than 10° for inclination/anteversion and of more than 5 mm for COR [8]. Furthermore, the final position of the custom-made implant was evaluated according to Lewinnek's safe zone with an intended inclination of 30°–50° and anteversion of 5°–25° [14]. IBM SPSS Statistics 22 (SPSS Inc., Chicago, IL, USA) was used for analysis.

Results

The mean deviation between the pre-operatively 3D-planned inclination of the custom-made acetabular component and the final position post-operatively measured by 3D CT was 3.6° ± 2.8° ($p = 0.01$). Correspondingly, the deviation between the planned pre-operative and the final post-operative anteversion was − 1.2° ± 7.0° ($p = 0.03$, Fig. 4). Using a 10° benchmark for defining malposition, none of the custom-made acetabular components was malpositioned for inclination (0/11) and one for anteversion (1/11). In relation to Lewinnek's safe zone, three custom-made implants (3/11) had an inclination above 50° or anteversion below 5°. However, the difference was below 5° in each case and in one patient, even the planned pre-operative anteversion was below 5° due to the extended bone defect (Table 2).

Regarding the COR, we found a mean deviation of the final implant calculated by 3D CT in relation to the pre-operative planned position of − 0.3 mm ± 3.9 mm in the mediolateral (x) direction ($p = 0.95$), − 1.1 mm ± 3.8 mm in the anteroposterior

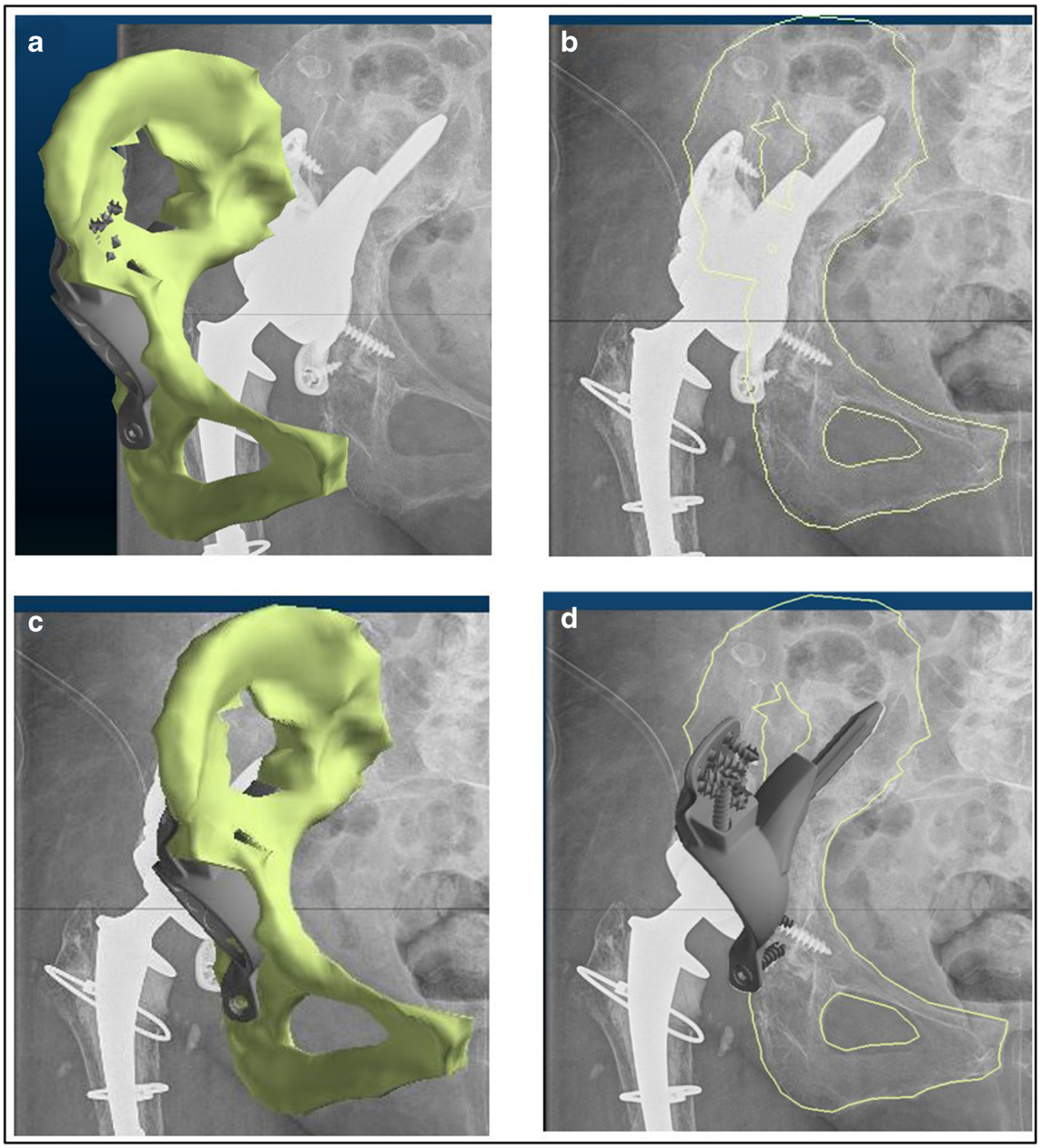

Fig. 3 **a** Non-positioned 3D CT model of the pelvis and custom-made implant. **b** Adjusting the model of the pelvis as against the X-ray by using the outline illustration of the pelvic model. **c** Adjusted pelvis with respect to the X-ray with implant in pre-op planned position. **d** Adjusting the implant according to the current implant position from post-op X-ray

(y) direction ($p = 0.29$), and 0.4 mm ± 3.2 mm in the craniocaudal (z) direction ($p = 0.64$). Outliers for COR deviation above 5 mm compared to the pre-operative planning were observed for two patients in the x-direction, for two patients in the y-direction, and for one patient in the z-direction (Table 3).

Researching into the accuracy of post-operative 2D analysis using post-operative plain radiographs compared to 3D CT, we found a difference of 1.1° ± 1.7° between 2D and 3D for implant inclination ($p = 0.05$) and of − 2.6° ± 1.3° for anteversion ($p = 0.01$). The deviation of COR between post-operative 2D and 3D measurements was 1.3 mm ± 3.5 mm in the x-direction ($p = 0.28$) and − 0.9 mm ± 3.8 mm in the z-direction ($p = 0.96$, Table 4).

Analyzing clinical outcome, mean HHS improved from 27.8 ± 5.3 pre-operatively to 69.1 ± 16.8 at the latest follow-up ($p = 0.03$). In terms of complications, one patient showed a partial sciatic nerve palsy, which partially recovered within the following six months. One patient had a dislocation one week after surgery which was treated successfully by closed reduction. Another patient presented two months after surgery with a periprosthetic stem fracture after a fall event. One further patient had post-operative limping most likely due to the

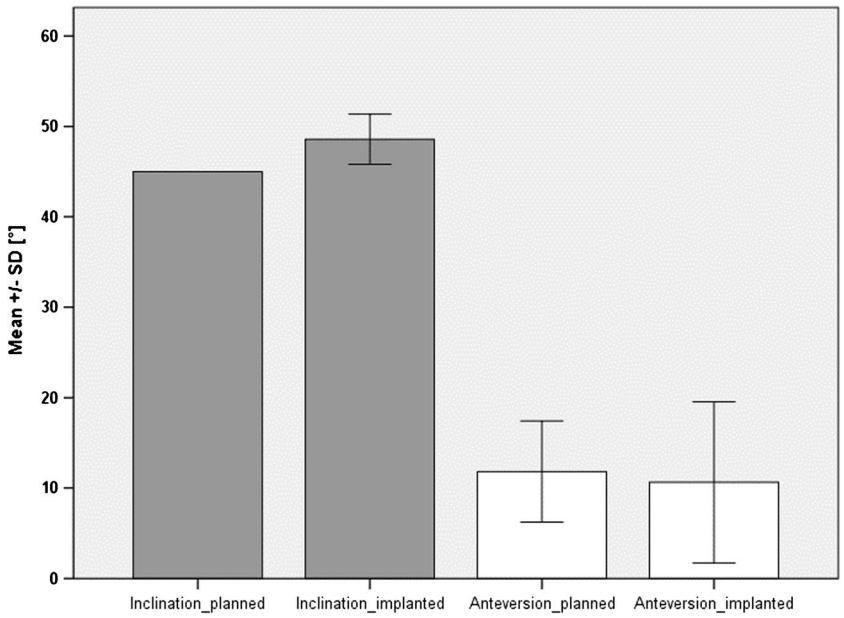

Fig. 4 Mean planned and final inclination and anteversion of the custom-made implant

applied surgical approach. In one patient, debridement of the wound due to persistent wound leakage was required. Intraoperative cultures were negative without signs of infection. No intra-operative fractures or signs of early loosening within the first six months were observed.

Discussion

In revision surgery with large acetabular defects, the positioning of a revision implant is challenging. In the current retrospective analysis of patients undergoing acetabular revision surgery after THA with Paprosky type III defects, the accuracy of positioning a custom-made implant compared to the pre-operative 3D-CT planning was observed. We found deviations of the custom-made implant compared to the 3D-CT planning within 10° regarding inclination and anteversion and within 5 mm regarding COR restoration in the majority of patients. Furthermore, plain radiographs were less accurate in estimating implant position than 3D CT but still with acceptable accuracy.

There are several limitations of the current study. First, a retrospective study design was used. To reduce potential bias, a consecutive series of patients was included. Second, the study is limited by numbers. This is due to the applied inclusion criteria since patients with Paprosky type III defects are rare even in a university medical centre with over 300 revision arthroplasties per year. However, according to Audigé et al., a sample size of at least ten subjects is required for analyzing a new method [15]. Third, all operations were performed in the lateral decubitus position using either a posterior or a Hardinge approach depending on the approach used for previous surgeries. Therefore, the choice of approach might be a risk factor of potential bias.

Table 2 Absolute planned and post-operative inclination and anteversion of the customized acetabular implant

Patient number	Incl planned (°)	Antev planned (°)	Incl final (°)	Antev final (°)
1	45	10	46	6.5
2	45	0	52.5	− 5.5
3	45	10	47.5	14.5
4	45	10	51.5	9
5	45	10	48	2.5
6	45	20	49.5	21.5
7	45	15	47.5	5.5
8	45	20	52	18.5
9	45	15	49	8
10	45	10	43	11
11	45	10	48	25.5

Incl, inclination; *Antev*, anteversion; planned, pre-operatively planned implant position; final, post-operative implanted position of the customized component

Table 3 Difference between planned and post-operative position of the custom-made acetabular implant regarding center of rotation

Patient number	*x*-axis (mm)	*y*-axis (mm)	*z*-axis (mm)
1	− 7.5	3.5	− 2.5
2	− 6.2	6	5.2
3	− 2	6.5	4
4	3.5	− 5	0
5	5	1	1
6	2	0	− 5
7	2.5	4.5	0.5
8	− 2	0	2
9	0	0	0
10	1	0.5	3
11	0	− 4.5	− 4

Difference, post-operative planned position; *x*, mediolateral direction; *y*, anteroposterior direction; *z*, craniocaudal direction

In answer to the first question of the study, the mean difference between the pre-operative 3D-CT planning and the intra-operative position of the custom-made implant was measured with 3.6° for inclination and − 1.2° for anteversion. Similarly, regarding COR restoration, we found a mean difference between pre-operative planning and the intra-operative position of − 0.3 mm in the mediolateral, 1.1 mm in the anteroposterior, and 0.4 mm in the craniocaudal direction. Consequently, the results of this study are comparable to literature. In a previous study using a custom-made trabecular titanium implant, a difference of 2° for inclination and 5° for anteversion was reported between planning and final position using a posterior approach. The deviation of the COR was described with 1.4 mm in the anteroposterior plane, 1.3 mm in the lateromedial plane, and 2.4 mm in the superoinferior plane [8]. Therefore, the results show good accuracy when positioning a custom-made implant even in revision cases with severe acetabular bone loss. Correspondingly, 72.7% (8/11) of the implanted customized acetabular components were within the safe zone according to Lewinnek. In a previous study, 56% of cups were reported to be within the intended Lewinnek safe zone in patients with Paprosky III defects assessed on radiographs using a digital analysis program. But this cohort included different implant designs and surgical reconstruction methods restricting the comparability [12]. However, the presence of outliers in our study reveals the risk of potential implant malpositioning in these operations despite high surgical experience. The difficulty of intra-operative correct assessment of cup position in THA has been reported in a variety of different studies [16, 17], whereas satisfactory results in cup position have been described in another study [18]. Besides the general inaccuracy of component placement in THA, the use of customized implants harbours a further risk of malpositioning. Due to its individual design, the accuracy of component position depends on an exact fitting of the implant in relation to the anatomic situation. However, during the removal of the loose components, additional bone loss might occur leading to a different anatomic situation, which happened once in our study. Furthermore, the fixation might be compromised due to soft tissue restrictions. In addition, intra-operative orientation can also be compromised due to the large osseous defects and thus the lack of anatomical landmarks. All this might contribute to an increased risk of cup malpositioning in large acetabular defects.

Regarding our second question, the use of post-operative plain radiographs for routine post-operative control seems to have acceptable accuracy in evaluating the position of the custom-made implant compared to gold standard 3D CT with differences of 1.1° for inclination and of − 2.6 for cup anteversion. For exact measurements of cup position and COR, 3D CT is still required. This is in accordance with literature that radiographic software is helpful in assessing cup position [11]. Since plain radiographs resemble a 2D projection of a 3D geometry, plain radiographs still might be susceptible to error. Especially detailed measurement of screw length requires CT.

Table 4 Difference of post-operative plain radiographs and post-operative 3D CT for measuring implant position

Patient number	Inclination (°)	Anteversion (°)	*x*-axis (mm)	*z*-axis (mm)
1	8	− 4.5	3	10.5
2	10	− 6	2.4	6.4
3	6	3	− 3.4	1.3
4	5	− 5	5	− 1.5
5	4.5	− 10	5	− 1.5
6	6	− 2	1.5	− 2.5
7	2.5	− 11	6	1.5
8	6.5	− 5.5	− 4.5	− 6.5
9	6	− 10.5	1	3.5
10	4	− 7	1.5	2
11	1.5	18	− 1	− 5

Difference, radiographic - 3D CT measurement; *x*, mediolateral direction; *z*, craniocaudal direction

Until the latest follow-up, patients showed substantial clinical improvement as measured by HHS. Although the absolute score values were lower than those in primary THA [19–21], the results of the current study are in line with those of previous reports of revision hip replacement with large acetabular defects [22–24]. Similarly, we experienced a higher complication rate compared to primary THA [21, 25]. However, in relation to other studies dealing with revision of acetabular components with large bone defects of the acetabulum, our results show comparable complication rates [22–24].

In conclusion, a custom-made acetabular implant can be positioned with good accuracy in revision hip arthroplasty. Postoperative 3D CT remains the gold standard for post-operative control although plain radiographs show acceptable accuracy in evaluation component position for further follow-ups.

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Compliance with ethical standards

The investigation was approved by the local medical ethics committee (No.: 17-415-101).

Conflict of interest TR has received research support by DePuy International, Otto Bock Foundation, Deutsche Arthose Hilfe. TR's research group "patientindividual joint replacement" is supported by the German Ministry of Education and Research (BMBF, grant number 01EZ0915). JG got research support by MSD, Novartis, De Puy, Otto Bock Foundation. Further financial support is from De Puy, Orthotech, Ozo-zours, Fischer Fussfit, Urban & Kemmler. JW is an employee for AQ implants. All other authors declare no potential conflict of interest.

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