

# The Clinical Outcome of Custom-Made Implants in Primary and Revision Hip Arthroplasty

## Klinický výsledek individuálně vyrobených implantátů u primární a revizní artroplastiky kyčle

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### ABSTRACT

#### PURPOSE OF THE STUDY

Facing the increasing number of primary and revision hip arthroplasties, the therapy of complex osseous defects becomes a crucial issue. Large acetabular defects cannot be treated with standard implant. Individual, customized implants based on 3D computed tomography (CT) scans are used for reconstruction. However, high complication and revision rates come along with final favorable outcomes.

#### MATERIAL AND METHODS

Eight patients underwent primary or revision total hip arthroplasty by an anterolateral surgical approach using patient matched implants based on 3D CT scans. Six patients with a Paprosky type IIIB acetabular defect, one patient with a non-union acetabular and femoral neck fracture and one patient with a severe hip dysplasia were included. The clinical data and the Merle d'Aubigné score assessing the clinical outcome pre- and postoperatively were analyzed retrospectively.

#### RESULTS

Patient matched implants were used for eight patients (four male and four female). The mean Merle d'Aubigné score improved from 8.1 (range 2–11) pre-operatively to 13 (range 9–17) at the final follow-up ( $p < 0.01$ ). Postoperative complications were recorded in 3 cases.

#### CONCLUSIONS

Customized implants of severe acetabular defects provide a solution with a favorable outcome. Nevertheless, dislocation presents a significant complication. A reduction of complications in order to achieve the optimal custom-made implant is desirable.

**Key words:** revision arthroplasty, patient-matched implants, Paprosky IIIB defects, clinical outcome.

### INTRODUCTION

The raising number of primary hip arthroplasty procedures lead to an increment of revision surgeries. In consequence osseous defects become more common. (19) The reconstruction of these complex osseous defects remain challenging surgical procedures. The prevalence of Paprosky Type IIIB bone defects is 11% in patients undergoing acetabular revision surgery. (23) The preoperatively classification of the defect is essential for the selection of the correct implant. (8) The Paprosky system classifies defects according to the acetabular walls and the ability of the anterior and posterior columns for rigid support of the acetabular component. Type 3 defects show a severe bone loss resulting in major destruction of the acetabular rim, sub classified into 3A and 3B. The component usually migrates greater than 2 cm in Type 3A and 3B defects. In type 3B defects, from the nine o'clock to the five o'clock position, the acetabular rim is destroyed. Furthermore, there is a complete destruction of the medial wall and severe destruction of the posterior column with a superomedial component

migration. (17) Especially in case of large defects, the major bone loss and poor bone quality leads to further difficulties in primary fixation of the implant. Various techniques and different standard implants are available to reconstruct severely compromised acetabula. (8, 19) As these techniques do not fully fill up the lost bone, individual implants have become an established treatment modality for large acetabular defects. Based on a thin-cut preoperative computed tomography scan of the pelvis, the customized implants are designed. The choice to select the implant is often based on available bone stock, available implants and surgical expertise. However, no single technique of acetabular reconstruction has shown superior results. (16) Though using custom-made implants the complication rate of  $29.0 \pm 1\%$  and revision-rate of  $19.3 \pm 17.3\%$  show the difficulty of compensating large acetabular defects properly. (2) Dislocation remains the major indication for a revision in  $11.5 \pm 10.7\%$  of cases. (2) The reestablishment of the former anatomical center of rotation of the hip is essential for a favorable long-term outcome. (7) In this study, we reviewed the institutional experience with the use of pa-

tient matched implants for hip arthroplasty. The issue of this study is to demonstrate the outcome of custom-made implants in hip arthroplasty and the most frequent complications. Furthermore, we want to demonstrate that the anterolateral approach is suitable.

## MATERIAL AND METHODS

### Study group

Between 2014 and 2020, we identified retrospectively eight patients (four female and four male patients) who underwent primary or revision total hip arthroplasty by using patient matched implants. All patients underwent preoperative plain radiography and high resolution computerized tomography (CT) with a slice thickness of 1 mm of the complete pelvis. Afterwards, the operation procedure and implants were planned by the CT scan. The acquired images were transformed to the manufacturing company. An accurate 3D virtual image was created in consultation with the surgeon. Approximately after three to six weeks, the custom-made implants were available. By the help of engineers, the screw holes, the screw lengths and other fixation-tools were designed, in order to increase the stability of the implant. The personalized prostheses come along provided with individualized cutting guides and the surgeon received preoperatively an exact surgical instruction. In one case the implant from Implantcast Ltd., C-Fit 3D was used. In seven cases the implants from Zimmer Biomet, Triflange acetabular component, were used.

### Surgical technique

If the acetabular defect could not be treated with standard revision implants, a two staged-procedure was performed. A CT-scan of the pelvis was initiated after the removal of the implant. Preoperatively, a sterile aspiration close to the implanted prosthesis was done. The implantation of the patient matched implant was done after the aspirate was sterile and macroscopic sings of an infection were not visible. In all cases, an anterolateral surgical approach was used. In our study, no bone grafts were used. The acetabular defect was filled with the patient matched implant. The study was approved by the local institutional review board. Postoperatively, full weight bearing in all patients was allowed.

### Data acquisition and statistical analysis

Post-operative assessments: Routine clinical data was collected and analysed retrospectively as anonymized aggregate data. The Merle d'Aubigné score was used for the clinical assessment pre- and postoperatively. The Merle d'Aubigné score is used to assess the functional outcome after hip arthroplasty. (15) The Paprosky system was used to evaluate the degree of bone defect preoper-

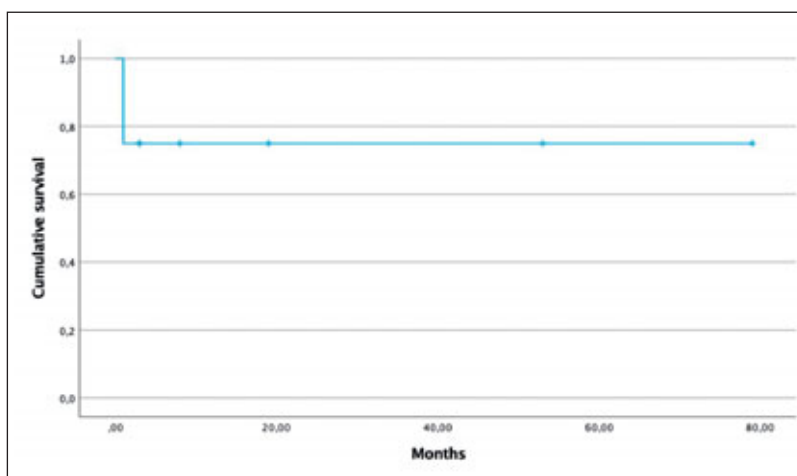


Fig. 1. The cumulative revision-free survival.

atively. A Paprosky IIIB defect was defined as an extensive segmental defect with loss of normal peripheral acetabular boundaries from the eleven to the five o'clock position, with or without an associated cavitory defect and no iliac roof; precluding the use of a conventional hemispherical socket with adjuvant screw fixation. (9) Six patients with a Paprosky type IIIB acetabular defect, one patient with a non-union acetabular and femoral neck fracture and one patient with a severe hip dysplasia, Crowe type 4 were included in this retrospective study. (5, 9)

Statistical methods: Statistical analysis was conducted with SPSS for mac, version 28 (SPSS Inc., Chicago, IL, USA). To evaluate the significance of the findings, the Student t-test was used to compare paired variables. A p value <0.05 was considered to indicate statistical significance. A Kaplan-Meier survival analysis was performed to analyze implant survival with revision, defined as exchange or removal of parts or all of the implant.

## RESULTS

Between January 2014 and April 2020, patient matched implants were used for eight patients. The average age at the time of surgery was 71.8 (range 58 -86) years. The average follow up was  $21.63 \pm 26.9$  months. The mean Merle d'Aubigné score improved from 8.1 (range 2–11) pre-operatively to 13 (range 9–17) at the final follow-up ( $p < 0.01$ ). Postoperative complications were recorded in 3 cases (37,5%). Fig. 1 demonstrates the cumulative revision-free survival.

One patient developed a postoperative nerve palsy with a dorsiflexion weakness and a dislocation of the patient matched implant one month postoperatively. Initially, the patient was treated with a dual head prosthesis due to a complex bone defect, in order to bridge time until a patient matched implant was available. Postoperatively, the patient was noncompliant. The patient put full weight on the dual head prosthesis, so that the patient matched implant did not fit to the changed acetabular



Fig. 2. A 72-year-old man with an acetabular cup loosening on the right side;  
*a* – a preoperative radiograph,  
*b* – a dual-head prosthesis by an intraoperatively complex osseus situation,  
*c* – the custom-made implant loosened at post-operative day 3,  
*d* – the patient underwent re-revision surgery six weeks later using another custom-made implant.

bone structures. One month postoperative a revision was necessary. With the new patient matched implant a stable situation was reestablished (Fig. 2).

A second patient developed a dislocation 17 days postoperatively on the right side. The hip got consequently closed reduced and was treated by a skin traction/New Port Orthesis for 6 weeks. The patient received a patient matched implant by a severe hip dysplasia, Crowe type 4 (5) (Fig. 3).

Another patient also developed a dislocation on the left side after the first custom-made implant. After the closed reduction, there were further dislocations, whereupon a revision of the implanted cup followed. Intraoperatively, a dislocation and fracture of the polyethylene inlay was seen. After the revision of the cup and the

inlay, a superficial infection occurred, treated by a wound debridement and a vacuum assisted closure-therapy (Fig. 4).

The patient presented in our emergency department in January 2020 after a seizure and persistent left hip pain. Anterior posterior (AP) radiograph showed a periprosthetic acetabular fracture. The acetabular defect was classified as a Paprosky III B defect. A custom-made acetabular implant was used. After 2 years and 3 months postoperatively, no aseptic loosening or periprosthetic fracture was seen (Fig. 5).

To conclude, one dislocation of the implant and nerve palsy, one superficial infection and two dislocations occurred. The postoperative dislocation was observed at 17 day and 37 day postoperatively.



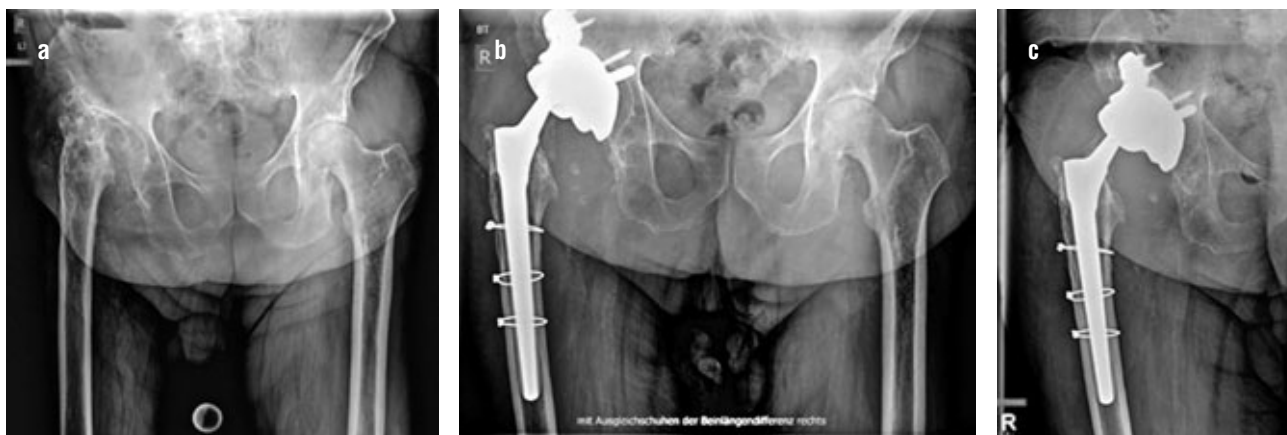


Fig. 3. A 65-year-old man with a severe hip dysplasia on the right side;  
a – a pre-operative radiograph,  
b – a postoperative radiograph,  
c – a radiograph 17 days after the closed reduction.



Fig. 4. A 76-year-old man with a acetabular cup loosening on the left side;  
a – a pre-operative radiograph,  
b – a fracture and a dislocation of the polyethylene inlay,  
c – the patient underwent a revision surgery seven weeks later.



Fig. 5. The patient, who was followed at least two years and 3 months.

## DISCUSSION

Due to the increasing demands of the aging population, the number of primary arthroplasties is rising globally. Subsequently, the incidence of total hip arthroplasty revision procedures is projected to be nearly the double until 2026. (11) The management of acetabular defects involves the use of different implants and reconstruction techniques, depending on the classification of the defect situation. The Paprosky classification is reliable and valid for acetabular defects. It considers acetabular supporting structures, assesses specific osseous structures concerning deficiency and it is anatomically oriented. (19) Paprosky Type IIIB defects with a defect of the dorsal pillar and with a pelvic discontinuity (non-contained) are treated by a fixation of the revision implant at the Os ileum, intramedullary. The primary stability of the implant at the host bone is one of the aims in the treatment of acetabular defects. (1) We preferred an in-

dividual implant due to the inadequate contact surface of the autochthone bone of standard implants. (18) The use of a custom-made implant using planned screws increases the intraoperative safety and is also taking into account the bone quality. (12) Furthermore, the pedestal cup or ice cream cone prosthesis, which is used in cases of huge superomedial and cranio-lateral acetabular defects, can lead to a secondary "high" rotation center of the hip. In order to achieve a favorable long-term outcome, an adequate center of rotation is one of the most crucial factors. (1) Various solutions such as impaction grafts, structural bone graft, cages, augments or patient specific implants for the treatment of severe acetabular defects can be found in the literature. Every solution has its own pros and cons. (18) Patient-specified implants offer the possibility of precise matching to the patient's altered anatomy and an immediate rigid fixation at the host bone. Nevertheless, impaction bone grafting or bone grafts are attractive treatment options for restoring severe acetabular defects. However, these procedures are complex and the results are variable. (10,18) Kawalkar et al. demonstrated excellent results by using custom triflange patient matched implants for complex and extensive acetabular defects without using bone grafts. The acetabular defect was addressed by the perfect fit of the patient matched implant. (10)

Weber et al. demonstrated that custom-made implants are positioned accurately and lead to an optimal reconstruction of the rotation center. (22) A systematic review confirmed a satisfactory clinical and radiological outcome at a mid-term follow up and a survival rate of more than 90% by using customized implants by severe acetabular bone defects. (2) The results revealed a complication rate of 37,5%, reflecting the complex osseous pathology. Nevertheless, all patients showed a favorable outcome at an average follow-up of  $21.63 \pm 26.9$  months.

The common complications of custom-made triflange implants are dislocations, deep infections, nerve palsy and component failures. The dislocation rate ranges from 15.5% to 25%. (2, 6, 20) In line with the reports by De-Boer et al. and Taunton et al., the present dislocation rate was 25%. (6, 20)

In a serie, Colen et al. reported about six patients without dislocations at a minimum of 10-month follow-up by using an anterolateral approach as also used in this study. (4) However, the most common approach for the implant is the posterior or posterolateral approach. (6, 20) The optimal surgical approach for revision hip arthroplasty has not yet been defined and depends on the experience of the surgeon. Nevertheless, the anterolateral approach is suitable for primary and revision hip arthroplasty and could lead to a lower dislocation rate. In the present study, the custom-made implant failure rate was 12.5%. Holt et al. reported a component failure rate of 11%. (9) There was no deep infection in this present study.

Gibon et al. showed in a five year follow up, by using Kerboul acetabular reinforcement devices, an increase of the mean Merle d'Aubigné score from 12.5 preoperatively to 16.5 postoperatively. (8) Philippe et

al. demonstrated in a retrospective survival analysis of 95 hips with Paprosky type II and III defects, during an average follow-up of 8 years an improvement of the Merle d'Aubigné Score from 8 preoperatively to 14.8 after the follow-up period. (18) These results are comparable to our results at the final follow-up. However, we included in our study only patients with Paprosky type IIIB defects or other primary complex osseous situations, which required the use of patient-matched implants. In regard to the improvement of the Merle d'Aubigné Score, the use of patient-matched implants lead to a favorable clinical outcome in our study.

In the systematic review of Chiarlone et al. the estimated mean complication rate was  $29.0 \pm 16.0\%$  and a global rate of periprosthetic infections was  $4.0 \pm 3.9\%$ . (2) The major indication for revision surgery was a dislocation of the hip, an implant instability or a nerve palsy. In our small study, hip dislocation and implant instability were also the major indications for revision of the acetabular component. We recorded 37.5% of post-operative complications in our study. In conclusion, a higher complication rate was observed. However, in the literature contradictory complication rates are reported. Respective studies of Colen S et al. and Citak M. et al. showed missing complications v.s. 55.6% of complications. (3, 4) The number of publications and systematic reviews examining the clinical follow-up after the treatment of severe acetabular bone defects increased in the recent years. Malahias et al. showed in a systematic review, discussing the custom triflange techniques, a failure rate less than 5% at the mean mid-term follow up. (13) However, there are some reviews showing high failure rates of the custom-made triflanges cups. (21) Therefore, a consensus regarding the impact of different types of acetabular reconstruction methods is missing. A potential advantage of the custom-made implant is the stable and rigid fixation on the remaining autologous bone. (9, 14) Besides, the already known disadvantages of custom-made implants are increased costs and the delay of surgery. Furthermore, there is a limited space to address changed bony situations by using customized implants.

It is undisputed that our study has some limitations. First of all, this is a small cohort with a retrospective nature. A control group is missing. The study impairs observational and selectional bias. Secondly, a long-time follow-up is necessary to assess survivorship. Thirdly, the operative approach and the choice of the implant depends on the surgeon and his experience. In literature, a large prospective randomized trial in order to compare different modern treatment techniques with a control group, suffering from similar severe defects and treated with common implants is missing.

## CONCLUSIONS

Customized implants provide a viable solution for severe acetabular defects, like Paprosky Type III B or and other complex osseous acetabular situations, which cannot be addressed by standard implants, including

a favorable outcome. This complex osseous situations are caused by multifactorial reasons varying individually. Until now an ideal solution and bone substitute material is not available. In the future, a systematical reduction of complications in order to achieve the optimal custom-made implant is desirable.

*The study was approved by the local institutional review board (Ethik Committee des Saarlandes, No. 222/20).*

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