Monoflange custom-made partial pelvis replacements offer a viable solution in extensive Paprosky III defects

functional outcome and risk factor analysis in 79 cases

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Cite this article:
Bone Jt Open 2024;5(8):
688–696.

DOI: 10.1302/2633-1462.
58.BJO-2024-0029.R1

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Aims

Custom-made partial pelvis replacements (PPRs) are increasingly used in the reconstruction of large acetabular defects and have mainly been designed using a triflange approach, requiring extensive soft-tissue dissection. The monoflange design, where primary intramedullary fixation within the ilium combined with a monoflange for rotational stability, was anticipated to overcome this obstacle. The aim of this study was to evaluate the design with regard to functional outcome, complications, and acetabular reconstruction.

Methods

Between 2014 and 2023, 79 patients with a mean follow-up of 33 months (SD 22; 9 to 103) were included. Functional outcome was measured using the Harris Hip Score and EuroQol five-dimension questionnaire (EQ-5D). PPR revisions were defined as an endpoint, and subgroups were analyzed to determine risk factors.

Results

Implantation was possible in all cases with a 2D centre of rotation deviation of 10 mm (SD 5.8; 1 to 29). PPR revision was necessary in eight (10%) patients. HHS increased significantly from 33 to 72 postoperatively, with a mean increase of 39 points ($p < 0.001$). Postoperative EQ-5D score was 0.7 (SD 0.3; -0.3 to 1). Risk factor analysis showed significant revision rates for septic indications ($p \leq 0.001$) as well as femoral defect size ($p = 0.001$).

Conclusion

Since large acetabular defects are being treated surgically more often, custom-made PPR should be integrated as an option in treatment algorithms. Monoflange PPR, with primary iliac fixation, offers a viable treatment option for Paprosky III defects with promising functional results, while requiring less soft-tissue exposure and allowing immediate full weightbearing.

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Take home message

- Monoflange partial pelvis replacements with primary intramedullary fixation offer a viable solution for extensive Paprosky III defects.
- Two-stage approach should be considered in aseptic cases where extensive metal artifacts are present, to ensure optimized implant model planning.
- Postoperative full weightbearing can be achieved with sufficient implant position due to the high primary stability, limited by femoral reconstruction.

Introduction

Custom-made partial pelvis replacements (PPRs) can achieve adequate anatomical reconstruction in severe acetabular defect with adequate functional outcome and,[1,2] with meticulous preoperative planning, can be placed with a high degree of accuracy.[3,4] As this technique is now being incorporated into the normal treatment algorithm for revision total hip arthroplasties (rTHAs), the evidence base is becoming sound, with several studies, including meta-reviews and medium-term results, now having been published.[5,6] However, uniform treatment algorithms, as well as designs, are yet to be established.[7] Historically, triflange systems, first developed for tumour orthopaedics, have been more common. This requires extensive soft-tissue exposure, which is associated with secondary risk factors, and may be unnecessary when a wide resection is not performed in revision arthroplasty. Additive layer manufacturing processes facilitate new designs and ingrowth structures, allowing the authors of the present study to develop a monoflange system with primary intramedullary iliac fixation using 8 mm screws or 9 mm modular stems for Paprosky III defects. Rotational stability was provided by a relatively small iliac monoflange, thus reducing soft-tissue exposure. In exceptional cases, with sparse secondary fixation options and acetabular defects reaching beyond the sciatic notch, tricortical iliosacral (IS) fixation was conducted through this monoflange system. To evaluate the design, functional outcome as well as risk factors were analyzed.

Methods

Implant design and surgical technique

As the detailed planning procedure was published previously,[4] the authors want to point out the key factors (Example Case: Figures 1 to 3). Reconstruction focused on the centre of rotation (COR), acetabular inclination (AC), and anteversion (AV). Main fixation was achieved by cranial fixation using a long 8 mm intramedullary screw and/or highly porous 9 mm stem with orientation to the main load-bearing axis. In cases where insufficient bone-stock was available, iliosacral (IS) fixation was chosen (Figure 4).[8] This allowed for a small iliac monoflange to conterol rotation forces. To reduce risk of dislocation, an acetabular diameter of at least 60 mm was planned to enable implantation of a dual-mobility component with a sufficient cement thickness and a possible combination with a 28 mm head (e.g. 50 mm). If a two-stage exchange was conducted, all implant material was removed in septic cases. In aseptic cases however, stem retention was carried out; if possible, the stem taper was protected with a sleeve or a dual-mobility liner. Acetabular preparation for the planned COR was conducted and reamed, if possible, up to a reamer with a diameter of 60 mm.

Between January 2014 and December 2023, treatment with a custom-made PPR was conducted in 97 consecutive patients (98 implants), manufactured by three different companies, in a referral centre (C-Fit 3D; Implantcast, Germany; ProMade; Lima Corporate, Italy; CustomLink; Waldemar Link, Germany). The only inclusion criterion was that the patient underwent revision arthroplasty (n = 93). To evaluate the treatment algorithm, a minimum follow-up of nine months was deemed sufficient, analogous to already published studies;[9] thus, 14 patients were excluded, leaving 79 revision arthroplasties reconstructed with a monoflange PPR which were included in the study. The mean follow-up was 33 months (SD 22; 9 to 103). Five patients were lost to follow-up. Indications for PPR were periprosthetic joint infection (PJI) (n = 38) and aseptic loosening (n = 41). Baseline parameters are shown in Table I. Defect evaluation showed 21 Paprosky IIIA and 58 Paprosky IIIB defects with pelvic discontinuity in 30 cases. In 14 cases, additional iliosacral fixation was performed.

Ethical approval was obtained prior to the investigation from the local ethics committee (reference number 21-10438-KOBO) for patients treated with the C-FIT 3D System, otherwise consent was obtained on an individual basis.

Observed indicators

Functional outcome was measured using the Harris Hip Score (pre- to postoperatively) and the postoperative EQ-5D to measure patient satisfaction. Postoperative scores were collected at the latest follow-up. To evaluate the treatment algorithm, revision-free, infection-free, and implant survival were analyzed. Additionally, subgroup analysis was conducted to identify risk factors for revision, functional outcome, and implant positioning.

Statistical analysis

Data analysis was performed using the Statistical Package for Social Sciences Software (SPSS Statistics Version 24; IBM, USA). Descriptive statistical results were recorded to describe comorbidities, complications, and previous procedures. Shapiro-Wilk test was performed to determine non-normal/normal distribution. Independent-samples *t*-test was used for parametric values, and Mann-Whitney U test for non-parametric values in univariate analysis. To determine risk factors, univariate and multivariate logistic regression analyses were conducted. Multicollinearity was tested through the variance inflation factor (VIF) for the multivariate regression. A VIF smaller than 5 was considered unproblematic. Significance level was set at $p < 0.05$.

Results

Implantation was possible in all planned cases, with a mean operating time of 209 minutes (SD 72; 116 to 322) in iliac PPR. In cases where an IS fixation was performed, the mean operating time was 230 minutes (SD 57; 170 to 387) ($p = 0.201$, Mann-Whitney U test). Isolated acetabular revision was conducted in 33 cases. Two-stage revision in aseptic cases was performed in 29 cases; this was based on the suspected artifacts due to the implant size and materials. As artefacts drastically reduce image quality and therefore planning accuracy, as well as planned implant fitting, this approach was chosen when metal cups with bone contact

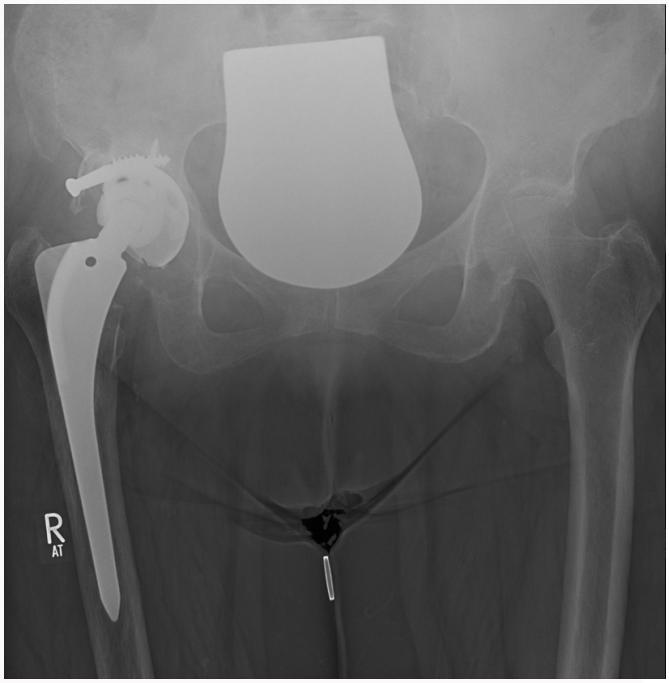

Fig. 1
Example case 1: preoperative anteroposterior radiograph showing a Paprosky IIIA defect in a 69-year-old female patient with aseptic component loosening, treated with a one-stage exchange.

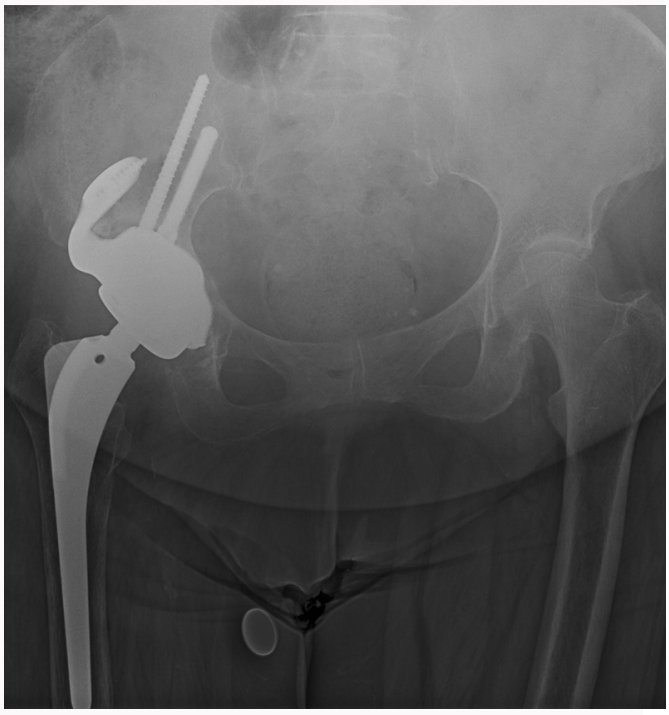

Fig. 3
Example case 1: anteroposterior pelvis radiograph at two-year follow-up post-implantation.

area still intact in the main fixation zones were present. In PJI cases a two-stage exchange was conducted, except for one case where the risk of a complication due to the interval and the second operation was considered too high. In 75 cases a dual-mobility cup was used, otherwise a cemented polyethylene inlay was used. Primary iliac fixation was carried

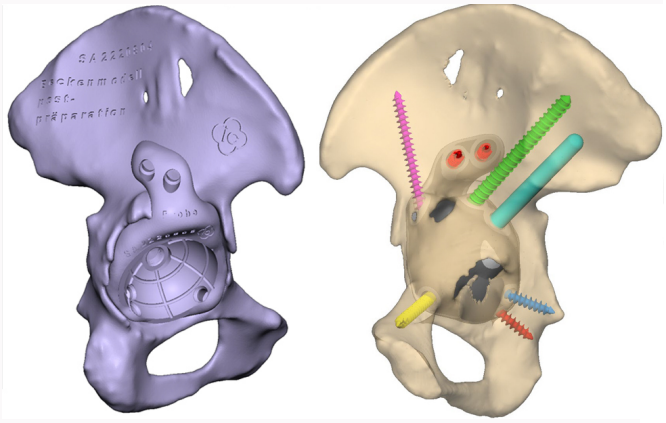

Fig. 2
Example case 1: implant and fixation model planning.

out with either one (n = 45) or two (n = 8) 8 mm screws, one (n = 8) 9 mm stem, or a combination of both fixation methods (n = 18). Anatomical COR reconstruction was planned and performed in 73 cases with a mean 2D deviation vector of 10 mm (SD 5.8; 1 to 29). In 34 cases the stem was retained. Femoral implants (n = retained) consisted of a primary stem in 22 (n = 20), a revision stem in 24 (n = 12), and a megaprosthesis (either proximal femoral replacement (PFR) or total femoral replacement (TFR)) in 33 (n = 1) cases.

HHS increased significantly from 33 (SD 15; 10 to 83) preoperatively to 72 (SD 11; 26 to 95) with a δ of 39 points (SD 15; 1 to 62) ($p < 0.001$, Mann-Whitney U test). The EQ-5D was 0.7 (SD 0.3; -0.3 to 1) with a EQ-5D VAS of 70 (SD 25; 5 to 100). Individual risk factors were assessed but showed no statistical significance for the functional parameters (Table II). Full weightbearing was allowed in 50 (63%) patients postoperatively.

During the follow-up, only one implant had to be removed due to persisting PJI, resulting in an implant survival of 98%. All-cause revision was conducted in 17 cases (21%); revision due to recurrent or persisting PJI was necessary in six cases, resulting in an infection-free survival of 92%. Detailed results are present in the Kaplan-Meier survival analysis (Figure 5). In four cases, a debridement, antibiotics and implant retention procedure was needed due to recurrent or persistent postoperative PJI. Two cases showed a persistent PJI: in one case a Girdlestone procedure was conducted, in the other case a persistent fistula was established.

Aseptic causes for revision were: 1) dislocation in six patients with a PFR (18% of all P/TFR), treated by leg lengthening in five cases (in one case due to recurrent dislocation a constrained liner was implanted); 2) inferior screw loosening in two cases which was treated by isolated screw removal; 3) one postoperative seroma; 4) one periarticular ossification resection; and 5) one traumatic periprosthetic femoral fracture, treated with stem exchange and osteosynthesis.

One patient died due to a postoperative thromboembolism; two patients died during the follow-up period due to non-implant-related causes.

Risk factor analysis for PJI related revisions was not possible as all events occurred in septic patients, treated with a two-stage complete exchange (n = 6).

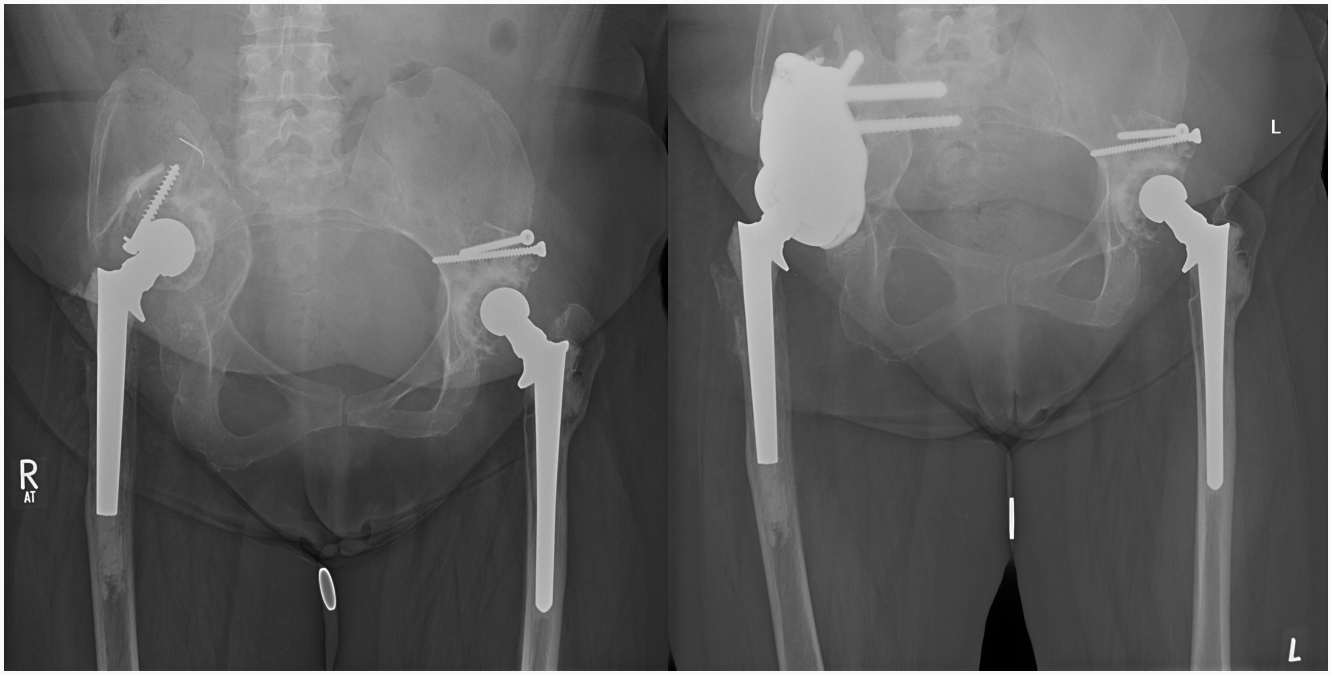

Fig. 4
Example case 2: a 65-year-old female patient with an extensive illiacal bone loss due to polyethylene wear after a primary arthroplasty 27 years earlier. The patient was treated with a custom-made implant with iliosacral fixation in a one-stage exchange. Due to insufficient follow-up, the patient was not included in the study.

Table I. Patient parameters (total n = 79).

Variable	Patient data
Mean age, yrs (SD; range)	70 (11; 30 to 88)
Mean BMI, kg/m^2 (SD; range)	28 (6; 21 to 45)
Mean ASA grade (SD; range)	3 (0.5; 2 to 4)
Mean previous surgeries after primary arthroplasty (SD; range)	3 (1.8; 0 to 9)
Mean additional 6.5 mm screws (SD; range)	4 (2.5; 1 to 8)
Mean operating time, mins (SD; range)	209 (57; 123 to 387)
Mean cup diameter, mm (SD; range)	50 (3; 32 to 56)

ASA, American Society of Anesthesiologists.

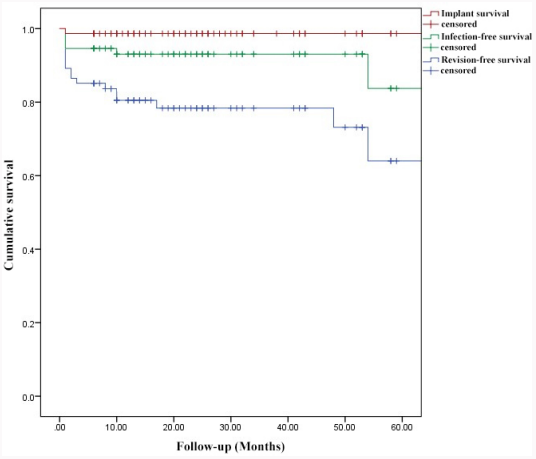

Fig. 5
Kaplan-Meier survival analysis for implant, infection-free, and revision-free survival.

Risk factor analysis for all cause revisions was performed through univariate logistic regression analyses and showed significant results for indication (septic – aseptic) (OR 12.7 (95% CI 2.7 to 60.7), p = 0.001) and complete exchange in comparison to isolated acetabular revision (OR 17.1 (95% CI 2.1 to 136.7), p = 0.007). To test for interaction between the two parameters, they were included in a multivariate logistic regression model. Multicollinearity between the factors was not given (VIF = 1.78). If both parameters were included simultaneously, there was no statistical significance (OR 5.3 (95% CI 0.9 to 30.9), p = 0.066 for indication, OR 5.9 (95% CI 0.6 to 61.8), p = 0.142) for exchange). As all events occurred in patients treated with a two-stage exchange, the treatment method could not be considered in the risk factor analysis. Additionally, proximal femoral arthroplasty was associated with a significant risk for revision (OR 7.2 (95% CI 2.1 to 24.5), p = 0.001), as dislocations only occurred in proximal femoral arthroplasty group (p = 0.001). Functional outcome analysis is shown in Table II.

Lessons learnt and design adaptions over the study period

Partial pelvis arthroplasties are complex, and require meticulous preoperative planning and careful intraoperative execution. Due to the use of a monoflange as the standard design in our series, constant re-evaluation was conducted to optimize the treatment and to ensure design continuity the planning was conducted by three senior surgeons (CG, MW, YH). Therefore, we want to emphasize several factors which

Table II. Risk factor analysis.

All-cause revision	OR (95% CI)	p-value*
Indication (septic vs aseptic)	12.7 (2.7 to 60.7)	0.001
One-stage vs two-stage	N/A†	N/A†
Complete exchange vs isolated acetabular exchange	17.1 (2.1 to 136.72)	0.007
Paprosky defect 3A vs 3B	1.2 (0.4 to 4.3)	0.752
Proximal femur replacement vs standard stem	7.2 (2.1 to 24.5)	0.001
PJI revision		
Indication (septic vs aseptic)	N/A	N/A
One-stage vs two-stage	N/A	N/A
Complete exchange vs isolated acetabular exchange	N/A	N/A
Paprosky defect 3A vs 3B	1.9 (0.2 to 17.1)	0.576
Proximal femur replacement vs standard stem	3.1 (0.5 to 18.31)	0.193
COR deviation < 10 mm		
Indication (septic vs aseptic)	1.3 (0.5 to 3.3)	0.577
One-stage vs two-stage	0.6 (0.2 to 2.2)	0.964
Complete exchange vs isolated acetabular exchange	1.8 (0.5 to 3)	0.682
Paprosky defect 3A vs 3B	4.5 (1.4 to 14.4)	0.081
Proximal femur replacement vs standard stem	0.8 (0.3 to 2)	0.248
Mean postoperative EQ-5D < 0.7		
Indication (septic vs aseptic)	1.6 (0.5 to 4.8)	0.393
One-stage vs two-stage	0.8 (0.2 to 3.3)	0.325
Complete exchange vs isolated acetabular exchange	0.4 (0.1 to 1.2)	0.326
Paprosky defect 3A vs 3B	0.6 (0.2 to 2.2)	0.175
Proximal femur replacement vs standard stem	1.8 (0.6 to 5.4)	0.691
Mean postoperative EQ-5D VAS < 64		
Indication (septic vs aseptic)	0.9 (0.3 to 2.5)	0.783
One-stage vs two-stage	1.5 (0.3 to 6.7)	0.792
Complete exchange vs isolated acetabular exchange	1.8 (0.6 to 5.1)	0.747
Paprosky defect 3A vs 3B	3.2 (0.8 to 12.9)	0.543
Proximal femur replacement vs standard stem	0.4 (0.1 to 1.3)	0.151
Mean postoperative HHS < 72		
Indication (septic vs aseptic)	1 (0.3 to 2.6)	0.854
One-stage vs two-stage	0.7 (0.2 to 2.7)	0.438
Complete exchange vs isolated acetabular exchange	1 (0.3 to 2.8)	0.512
Paprosky defect 3A vs 3B	0.8 (0.2 to 2.8)	0.524
Proximal femur replacement vs standard stem	1.8 (0.6 to 5.1)	0.342

The p-value stated for mean parameters refers to the absolute numbers instead of greater/smaller than the mean value.
*Mann-Whitney U test.
†No event in one of the cohorts, therefore not calculated.
COR, centre of rotation; EQ-5D, EuroQol five-dimension questionnaire; HHS, Harris Hip Score; N/A, not available; OR, odds ratio; PJI, periprosthetic joint infection; VAS, visual analogue scale.

were discussed during the development of our algorithm, as follows. First, two-stage exchanges should be considered in aseptic conditions if metal artefacts are present as these greatly reduce the planning and segmentation quality, leading to sequential errors. While secondary risk factors (immobilization, risk of thromboembolism) should be considered, we report no differences for the functional outcome or the EQ-5D between one- or two-stage exchange groups (0.51, 0.32). Second, opposing the often-chosen triflange construct,[5] inferior fixation in a monoflange PPR is not always needed, and should only be considered if rotational stability is inadequate after monoflange and intramedullary fixation. We have now almost completely abandoned this (2014 to 2012: n = 47/60; 2022 to 2023 n = 5/19). Third, inferior fixation in cases with pelvic discontinuity might lead to screw loosening, as seen in two cases in our cohort (Supplementary Figures a to d) (Figure 7 to 9).

Fourth, primary iliac fixation with secondary osseointegration is necessary for long-term implant survival. Therefore, highly porous fixation should be considered, e.g. with a 9 mm bolt if inadequate press-fit is present in the main weightbearing area. This was used in 25 cases for iliac fixation; all cases with IS fixation were performed with at least one 9 mm bolt. Fifth, transferring the force vector to intramedullary fixation allows for minimal flange design, resulting in a monoflange of about 20 mm for iliac fixation with only two screws, as this is sufficient to preserve rotational stability. Sixth, to compensate for small intraoperative positioning differences, we opted to design the 6.5 mm screws with 10° of freedom. Finally, design alterations are shown in Figures 6 and 7, with a 3D model of each variant shown in Figure 8. Various patient outcomes are shown in Supplementary Figure e.

Discussion

Anatomical reconstruction of large acetabular defects represents a demanding challenge in modern revision arthroplasty, as defects 'beyond' Paprosky III are more frequently encountered. While best practice treatment algorithms are yet to be developed in these cases, custom-made implants have been shown to be a viable treatment alternative.[7] While the first published PPR for rTHA adapted implant design features that are well established for tumour endoprosthesis designs, several key factors might be addressed with a different approach. Although there are no uniform design basics for PPR, triflange designs are common,

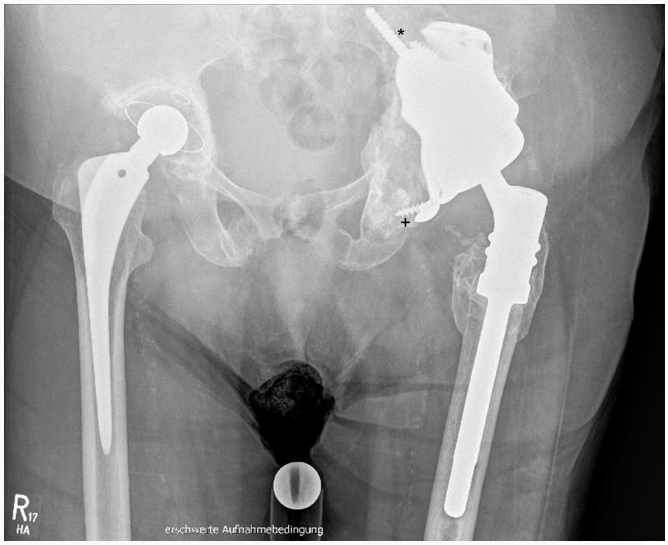

Fig. 6
A 79-year-old female patient at seven-year follow-up, treated with a two-stage exchange due to periprosthetic joint infection. * designates the 8 mm screw for primary stability. + designates the small inferior flanges which were used in the first designs as, well as the inferior fixation which is no longer conducted regularly but remains an option.

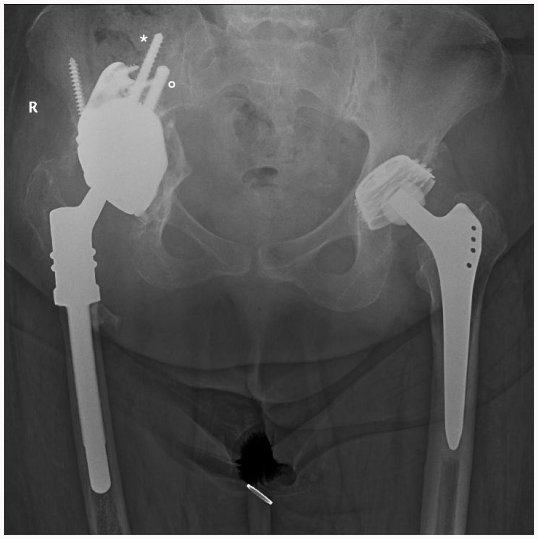

Fig. 7
A 68-year-old female patient at one-year follow-up, who presented with a girdlestone due to a polybacterial periprosthetic joint infection, treated with a two-stage exchange. * designates the 8 mm screw which is still used in all cases. ° designates the 9 mm highly porous stem which was added later on.

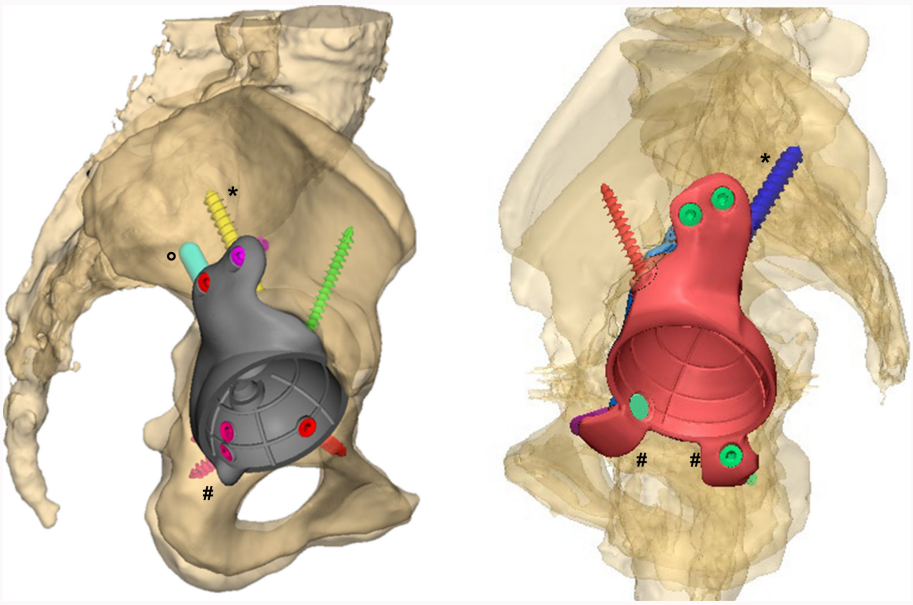

Fig. 8
Implant models for the cases present in Figures 6 and 7. * designates the 8 mm screw. ° designates the 9 mm stem. The small flanges used in the first designs are seen on the left side; later on, only small bulges were used, as seen on the right side (all designated by #).

as seen in a systematic review by Chiarlone et al.[5] These PPRs often require substantial soft-tissue release, which is not necessarily needed for rTHA. On the contrary, it might be postulated that this release is likely to result in poorer function, increased risk of dislocation and infection, and subsequent revision. Therefore, transferring the main force vector to intramedullary, solid primary iliac fixation in the main weightbearing area using screws and/or stems while simultaneously requiring minimal soft-tissue release due to the small flange design is a main advantage for monoflange systems. This adapts a technique firstly published by Schoellner et al[10] for tumour patients which, due to available highly porous materials, can achieve sufficient osseointegration even with short stem length (≥ 5 cm), allowing full weightbearing postoperatively.[10,11]

Furthermore, due to the flange positioning and non-highly porous structure, older multiflange designs were dependent on a "defect follows the implant design" philosophy with the need for callous bone in the interface, often resulting in an artificially achieved large longitudinal defect structure which often requires free-hand preparation. In addition, voluminous implants with extensive surface area

are needed. The combination of a solid primary fixation and highly porous structure – the design in this series – is based on a "implant design follows the defect" and functional reconstruction philosophy. This results in minimal bone loss as, additionally, even in deficient callous bone, sufficient stabilization for osseointegration is not only based on the primary press-fit but also secondary solid intramedullary fixation.

Cases with pelvic discontinuity should be analyzed with special consideration of the forces occurring during weightbearing and walking. Due to the vector changes this might lead to insufficient inferior fixation, leading to aseptic loosening of screws or flanges, also seen in two cases in our study. This was analyzed in a detailed finite element analysis by Dóczi et al,[12] showing an increased load in cages which is comparable to early PPR fixation before osseointegration.

In addition, a near anatomical COR reconstruction is possible due to the minimal required extra acetabular bone contact area, resulting in a mean deviation of 10 mm. To ensure best placement we strongly recommend using life-sized models and patient-specific instrument guides, as it has been published that accurate implantation can be achieved with these additional tools.[3,4]

To our knowledge, our series represents the largest monoflange PPR reported, and ranks among the highest single-centre series when compared to triflange constructs allowing subgroup analysis.[9,13] Although this should be interpreted with caution, we can at least extrapolate factors which are relevant from the clinical point of view.

Similar to other series, the main indication for PPR revision is previous infection. In our collective all PJI related revisions occurred in this subgroup. Similar results have been reported by Fröschen et al[14] with a significantly increased PJI incidence opposed to aseptic loosening in a cohort of 70 patients, resulting in an implant survival of 76% after a mean follow-up of 42 months. As shown in a recent meta-analysis, infection remains the main lifelong risk factor for implant failure and re-revision, even with reduced implant volume and new, well-osseointegrated highly porous materials.[9] Therefore, we strongly advocate for two-stage exchange if a PPR implantation is planned.

Due to the multitude of studies, including recent systematic reviews, sound evaluation of PPR will be possible in the near future.[5,9] While the implant complications for triflange PPR range between 18% and 29%, as evaluated by Broekhuis et al,[9] our results seem comparable, showing slightly lower revision rates with 21% all-cause and 8% PJI-related revisions. Their functional outcome, with a mean published postoperative HHS of 76 and a δ of 40 points, is comparable to our series (mean 72; δ: 39).

While other monoflange PPR studies have shown higher implant revision rates of up to 30%, functional outcome seems comparable (HHS: 52/Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC): 29.45).[15,16] We attribute our lower revision rates to the use of long intermedullary fixation, whereas some monoflange systems used primarily extracortical fixation.

Choice of implant for acetabular reconstruction in these severe defects depends not only on cost but also on personal preference. Therefore, comparison to modular, highly porous systems needs to be discussed. While these implants provide longer follow-up results, the outcome seems to be comparable.[7] However, as most PPRs are chosen for defects where modular systems might be insufficient, detailed comparison as well as updated defect classifications are needed to evaluate the right indication for each case.

While acetabular bone loss can be addressed with precise anatomical reconstruction,[4] addressing simultaneous femoral bone loss (present in most cases) is one of the key factors, as postoperative dislocation is a major complication, as well as recurrent or persistent PJI, with an incidence ranging between 5% and 11%, comparable to our series (n = 6, 7.5%).[5,17] This is mainly a concern in megaprosthesis, as published by Mancino et al.[18] While simultaneous bone loss on both sides can only be managed insufficiently with soft-tissue balancing, secondary support mechanisms like sock mesh in aseptic situations might support the functional outcome and prohibit dislocation. Additionally, in all cases where a dislocation was presented in PFR, secondary instability was present, as anatomical leg length reconstruction was not possible in the reimplantation due to soft-tissue shortening in the interval period. In cases with recurrent dislocation, constrained liner implantation might be feasible, as seen in the publication by Winther et al[19] in five cases in a triflange (n = 5/39, 13%) system, or in our cohort in one case.

Several study limitations have to be mentioned. As the implant design is relatively new, the follow-up time is limited, however a mean of two years seems comparable to another recent study.[5] As we wanted to emphasize the importance of osseointegration, a minimum follow-up of nine months was chosen to report exclude cases with only mechanical stabilization. As a single-centre study, the implant design as well as the surgical technique are based on the experience of a single institution. Multicentre studies, especially comparing tri- to monoflange implants, are essential, as certain parameters such as aseptic loosening or PJI may become clearer in long-term follow-up in a larger cohort, given the differences in fixation philosophy and required soft-tissue exposure.

Due to manufacturing improvements and availability, custom-made PPRs can be integrated into the treatment of extensive Paprosky III defects. Using monoflange constructs with intramedullary primary stabilization, we were able to report comparable results to the established triflange design while minimizing the amount of soft-tissue exposure required. Presenting one of the largest cohort studies, we were able to successfully demonstrate the implementation of a monoflange PPR in a standardized treatment algorithm of large defects, preventing the patient from having to undergo a Girdlestone procedure and immobilization. Furthermore, we were able to achieve early postoperative full weightbearing and good functional results with acceptable complication rates.

Supplementary material

Figures present another example case, along with pre- and postoperative images for five more example cases that were treated with a partial pelvis replacement. Additionally, a video is provided for the functional outcome at three-year follow-up.

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Funding statement

The authors received no financial or material support for the research, authorship, and/or publication of this article.

ICMJE COI statement

C. Gebert, M. Wessling, and L. M. Jeys act as academic consultants for Implantcast, unrelated to this study. C. Gebert and M. Wessling act as academic consultants for Heraeus Medical, unrelated to this study. C. Gebert has received royalties, payment for expert testimony, and support for attending meetings and/or travel from Implantcast, all unrelated to this study. M. Wessling has received royalties, speaker honoraria, payment for expert testimony, and support for attending meetings and/or travel from Implantcast,

all unrelated to this study. J. Hardes has received financial support from Implantcast for scientific projects unrelated to this study. Y. Hanusrichter has received speaker honoraria from Curasan and Implantcast, unrelated to this study. L. M. Jeys has received speaker honoraria from Zimmer Biomet, Stryker, and Implantcast, as well as payment for expert testimony from Implantcast, all of which are unrelated to this study.

Data sharing

The data that support the findings for this study are available to other researchers from the corresponding author upon reasonable request.

Ethical review statement

This study was performed in line with the principles of the Declaration of Helsinki. Approval was granted by the Ethics Committee of University Essen-Duisburg, Essen, Germany (Date: 29.03.2022; reference number: 21-10438-KOBO). Informed consent and consent to publish was obtained from all individual participants included in the study.

Open access funding

The open access fee for this article was self-funded.