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HIP

Custom-made acetabular revision arthroplasty for pelvic discontinuity: Can we handle the challenge?

A PROSPECTIVE COHORT STUDY

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Aims

The aim of this study was to assess the clinical and radiological results of patients who were revised using a custom-made triflange acetabular component (CTAC) for component loosening and pelvic discontinuity (PD) after previous total hip arthroplasty (THA).

Methods

Data were extracted from a single centre prospective database of patients with PD who were treated with a CTAC. Patients were included if they had a follow-up of two years. The Hip Disability and Osteoarthritis Outcome Score (HOOS), modified Oxford Hip Score (mOHS), EuroQol EuroQoL five-dimension three-level (EQ-5D-3L) utility, and Numeric Rating Scale (NRS), including visual analogue score (VAS) for pain, were gathered at baseline, and at one- and two-year follow-up. Reasons for revision, and radiological and clinical complications were registered. Trends over time are described and tested for significance and clinical relevance.

Results

A total of 18 females with 22 CTACs who had a mean age of 73.5 years (SD 7.7) were included. A significant improvement was found in HOOS ($p < 0.0001$), mOHS ($p < 0.0001$), EQ-5D-3L utility ($p = 0.003$), EQ-5D-3L NRS ($p = 0.013$), VAS pain rest ($p = 0.008$), and VAS pain activity ($p < 0.0001$) between baseline and final follow-up. Minimal clinically important improvement in mOHS and the HOOS Physical Function Short Form (HOOS-PS) was observed in 16 patients (73%) and 14 patients (64%), respectively. Definite healing of the PD was observed in 19 hips (86%). Complications included six cases with broken screws (27%), four cases (18%) with bony fractures, and one case (4.5%) with sciatic nerve paresthesia. One patient with concurrent bilateral PD had revision surgery due to recurrent dislocations. No revision surgery was performed for screw failure or implant breakage.

Conclusion

CTAC in patients with THA acetabular loosening and PD can result in stable constructs and significant improvement in functioning and health-related quality of life at two years' follow-up. Further follow-up is necessary to determine the mid- to long-term outcome.

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Introduction

Pelvic discontinuity (PD) is a detrimental complication following total hip arthroplasty (THA). PD can occur following primary acetabular component insertion, but more often is a secondary result of gradual excessive bone loss due to osteolysis or implant loosening.[1] The surgical management of PD is challenging. In the past, various techniques, such as reduction and plate fixation,

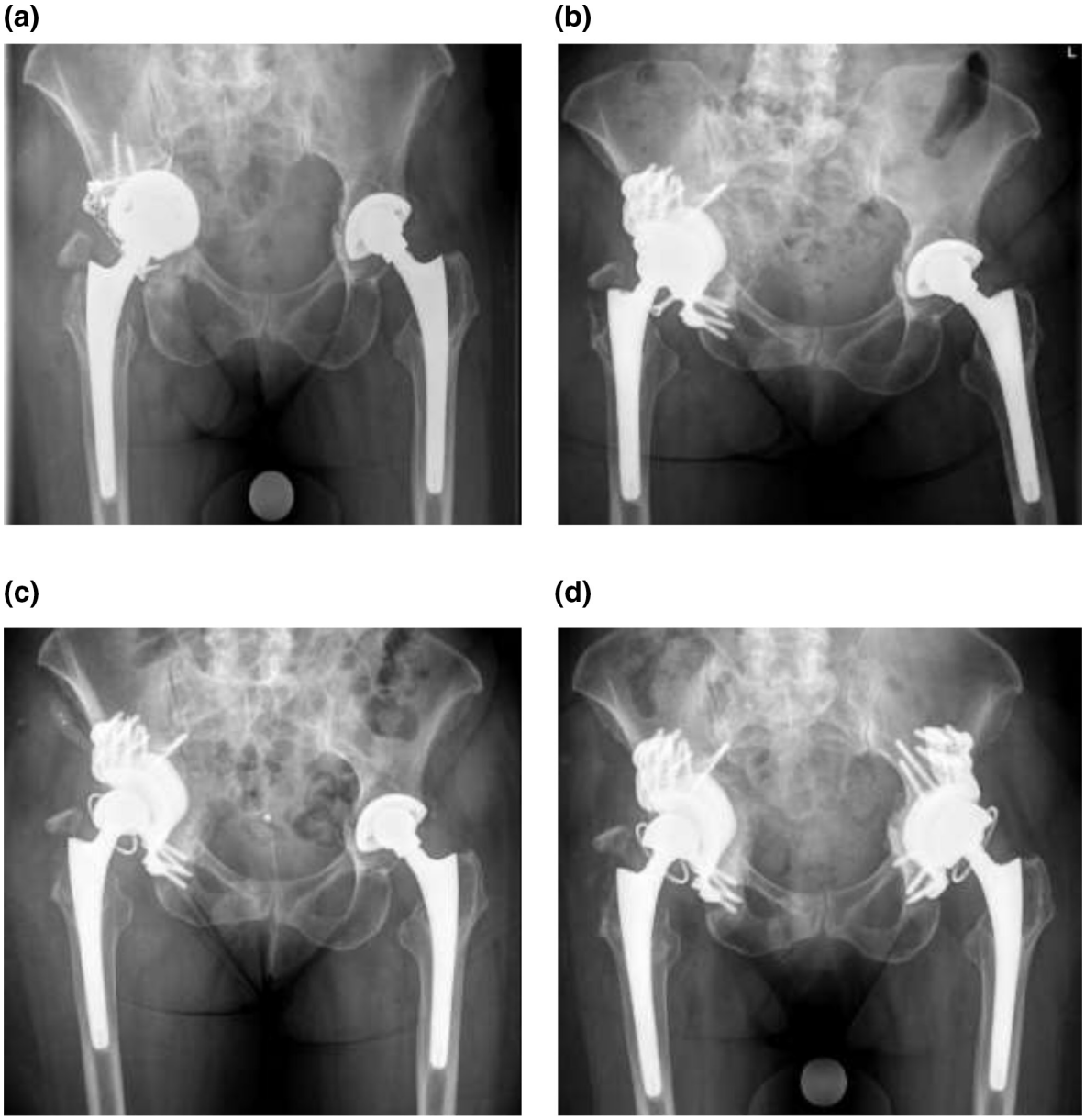

Fig. 1

Case example (case B) of a patient with concurrent (i.e. synchronous) bilateral pelvic discontinuity. A complete discontinuity is shown between the superior and inferior pelvis. b) Non-immediate postoperative anteroposterior pelvic radiograph with a custom-made triflange component of the right hip. Note the concurrent pelvic discontinuity on the left side. c) Revision of the custom-made triflange component on the right hip due to recurrent dislocations six weeks postoperatively, which was managed by open reduction and conversion from a dual-mobility cup to a constrained liner. d) After 11 months: revision of the left hip to a custom-made triflange component with a constrained liner.

cup-cage constructs, and additional bone impaction grafts, have been used; however, high rates of failure and revision were observed.[2,3] More recently, custom-made 3D-printed triflange acetabular components have revolutionized the surgical management of PD by providing a customized and individualized construct to restore and bridge the defect in each individual case.

To date, limited data is available in the literature on the efficacy of such custom-made components for treatment of PD.[3] Previous studies have been limited to retrospective case series with clinician-based outcome measures, which are susceptible to observer bias. Furthermore, they do no capture the patient's perspective on outcome, thereby limiting adequate clinical assessment in present-day patient-centered and value-based healthcare.[4-8]

The aim of this prospective study was to assess the clinical and radiological results of patients with PD who were treated with a custom-made triflange acetabular component. The focus was patient centred; hence, using multiple patient-reported outcome measures (PROMs)

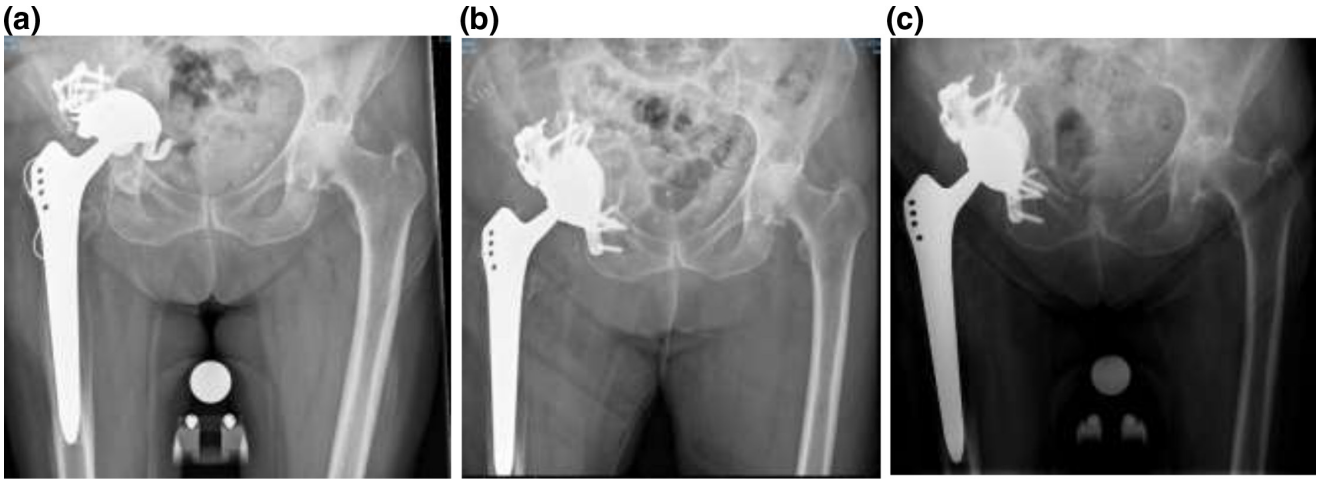

Fig. 2

a) Preoperative anteroposterior pelvic radiograph: failed acetabular component with protrusion and pelvic discontinuity. b) An immediate postoperative radiograph demonstrating a fixed custom-made triflange component. c) A two-year postoperative radiograph demonstrating fixation and healed discontinuity.

to evaluate functioning and health-related quality of life (HRQoL) from the patient's perspective, along with a construct stability and complication assessment.

Methods

Study design and patient population. This is a single centre, prospective cohort of patients with THA acetabular component loosening and pelvic discontinuity who presented after 2013. Patients were included in a prospective database and assessed pre- and postoperatively at one- and two-year follow-up. Inclusion criteria were patients with a failed THA and pelvic discontinuity (diagnosed on CT preoperatively and confirmed at time of surgery) who were subsequently treated with a custom-made triflange acetabular component. Patients were only included if they had a follow-up of two years. Protocol of the present study was approved by the local review board of our institution. Ethical (insitutional review board) approval was not required, as the Dutch Act on Medical Research involving Human Subject does not apply to screening PROMs that are part of routine clinical practice. Fully anonymized and identified data were obtained for analyses and report.

Preoperative assessment and surgical management. From 2013 through 2022, all patients with a (suspected) pelvic discontinuity were treated by a two surgeon team (GvH, MS) with a custom-made triflange acetabular component (CTAC; Amace, Materialise, Belgium). Preoperative CT-scans were acquired to assess the acetabular defect and discontinuity and perform the digital reconstruction planning. Both surgeons were involved in the entire developmental process by providing feedback on the defect analyses and optimal orientation of the implant (e.g. anteversion, inclination, and centre of rotation). A porous metal augment and a triflange cage with flanges on ilium, ischium, and pubis was designed as a monoblock for optimal host fixation. Accordingly, optional screw fixation points in the ilium, ischium, and pubis were planned into good host bone quality areas, which is an essential part of the CT defect analysis. All patients underwent a standard posterolateral approach and a 3D-printed hemipelvis, a trial implant, and patient-specific drill guides were available during surgery. Following fixation of the CTAC implant, either a dual-mobility cup or a constrained liner (in case of abductor deficiency) was cemented in the custom-made implant. Further details of the defect analysis and surgical technique have previously been reported by authors from our institution.[9-11] Perioperative systematic antibiotics were routinely administrated, and continued until results of intraoperative cultures were obtained. Use of allogenic bone chips in cases with poor bone quality or severe bone stock loss was left to the discretion of the treating surgeons. These allografts were obtained from our own institution's bone bank. Furthermore, standardized postoperative protocols were used, including immediate mobilization and six weeks of 50% weightbearing on the operated leg. Finally, low-molecular-weight heparin (LMWH) were prescribed for the first six weeks following the procedure.

Data collection: PROMs, radiological, and clinical complications. Demographic data, including sex, age, and BMI, were gathered. Validated PROMs were used to evaluate functioning and HRQoL as outcome domains: The Hip disability and Osteoarthritis Outcome Score Physical Function Short Form (HOOS-PS), modified Oxford Hip Score (mOHS), EuroQol five-dimension three-level (EQ-5D-3L) utility, EQ-5D-3L Numeric Rating Scale (NRS; 0 to 100), and visual analogue score (VAS; 0 to 100) to indicate the level of pain during rest and activity. The HOOS-PS and mOHS are both questionnaires that evaluate the

Table I. PROMs at baseline, and one- and two-year follow-up.

PROMs	Baseline	1 year	2 year	F-value	p-value*
Mean mOHS (SD)	53.0 (12.0)	35.3 (11.1)	36.9 (12.7)	$F_{(2, 21)} = 35.2$	p < 0.001†
Median HOOS-PS (IQR)	74.8 (64.9 to 93.1)	53.4 (28.7 to 82.4)	48.5 (19.1 to 61.6)	$F_{(2, 21)} = 14.8$	p < 0.001‡
Mean VAS Rest (SD)	39.1 (24.7)	8.2 (10.3)	14.0 (23.9)	$F_{(2, 21)} = 13.7$	p = 0.008†
Median VAS Activity (IQR)	79.0 (44.5 to 97.0)	12.5 (1.8 to 43.4)	14.5 (0.8 to 35.0)	$F_{(2, 21)} = 37.5$	p < 0.001‡
Mean EQ-5D-3L NRS (SD)	52.6 (21.3)	67.2 (12.7)	67.1 (11.9)	$F_{(2, 21)} = 7.3$	p = 0.013†
Mean EQ-5D-3L Utility (SD)	0.25 (0.34)	0.56 (0.28)	0.56 (0.37)	$F_{(2, 21)} = 12.1$	p = 0.003†

*p-values between baseline and two-year follow-up are depicted.
†Analysis of variance (ANOVA) test was used for mOHS, VAS Rest, EQ-5D-3L NRS, and EQ-5D-3L.
‡Friedman test was used for HOOS-PS and VAS Activity.
EQ-5D-3L, EuroQol five-dimension three-level; HOOS-PS, Hip disability and Osteoarthritis Outcome Score Physical Function Short Form; IQR, interquartile range; mOHS, modified Oxford Hip Score; NRS, Numeric Rating Scale; PROMs, patient-reported outcome measures; SD, standard deviation; VAS, visual analogue scale.

Table II. Radiological and clinical complications, including reasons for revision of 22 hips with pelvic discontinuity who were treated with a custom-made triflange component.

Variable	N
Radiological complications	
Screw loosening	**6**
3 x ischium and 1 x pubis*	
1 x ischium	
2 x ischium	
2 x ischium	
1 x ischium (breakage)	
1 x ischium	
Fracture	**4**
Ramus inferior	
Calcar	
Greater trochanter	
Ilium	
Discontinuity non-healing	3
Breakage or loosening of component	0
Clinical complications	
Wound leakage more than ten days	3
Nerve damage	1
Urinary tract infection	1
Reasons for revision	
Debridement, antibiotics and implant retention	2
Recurrent dislocations	1

*Patient with concurrent bilateral pelvic discontinuity that had revision surgery due to recurrent dislocations that was managed by open reduction and conversion from a dual-mobility cup to a constrained liner (Case b).

limitations in functioning caused by hip pain. Both PROMs have been shown to be valid, reliable, and responsive in patients following hip arthroplasty.[12-15] Moreover, floor and ceiling effects are prevented.[14] The total sum score of the HOOS-PS and mOHS ranges from 0 to 100 (the lower the score, the better the functioning). The total sum score of EQ-5D-3L utility ranges from -0.329 to 1 and EQ-5D-3L NRS ranges from 0 to 100 (the higher the scores, the better the perceived health status).

Anteroposterior (AP) radiographs of the pelvis were obtained during follow-up and assessed by independent musculoskeletal radiologists at our institution for failure of the implant, screw breakage, or loosening (defined by radiolucency around the screws), bony fractures, and/or discontinuity non-healing. Also, clinical complications, including wound leakage for more than ten days, nerve damage, and urinary tract infection during admission and final follow-up were registered. Finally, the number and reasons for revision (i.e. infection or dislocation) were reported separately. Mechanical failure was defined as breakage or loosening of the CTAC.

Statistical analysis. To ensure valid statistical analyses, data were subjected to a normality test using the Shapiro-Wilk test. Baseline characteristics were described using mean and standard deviation (SD) for continuous parameters and count (percent) for categorical parameters. A repeated measures analysis of variance (ANOVA) analysis was performed to identify significant differences in PROMs over time, meaning between baseline, and at one- and two-year follow-up. In case of non-normal distribution of data, non-parametric equivalents were used (i.e. median, interquartile range (IQR), and Friedman test). Previous published thresholds for minimal clinically important improvement (MCII) in mOHS (five points) and HOOS-PS (23 points) were used to identify the number (percent) of patients who achieved clinically relevant change.[16,17] It should, however, be noted that follow-up completeness is a prerequisite for reliable outcome assessment.[18] As such, a complete case analysis was performed and patients were only included in the present study if they had complete data points at baseline, and one- and two-year follow-up. All statistical tests were performed with PRISM 9.0 GraphPad software (GraphPad, USA). All p-values < 0.05 were considered statistically significant.

Results

Study population. There were 18 females with 22 CTACs that met our inclusion criteria Patients had a mean age of

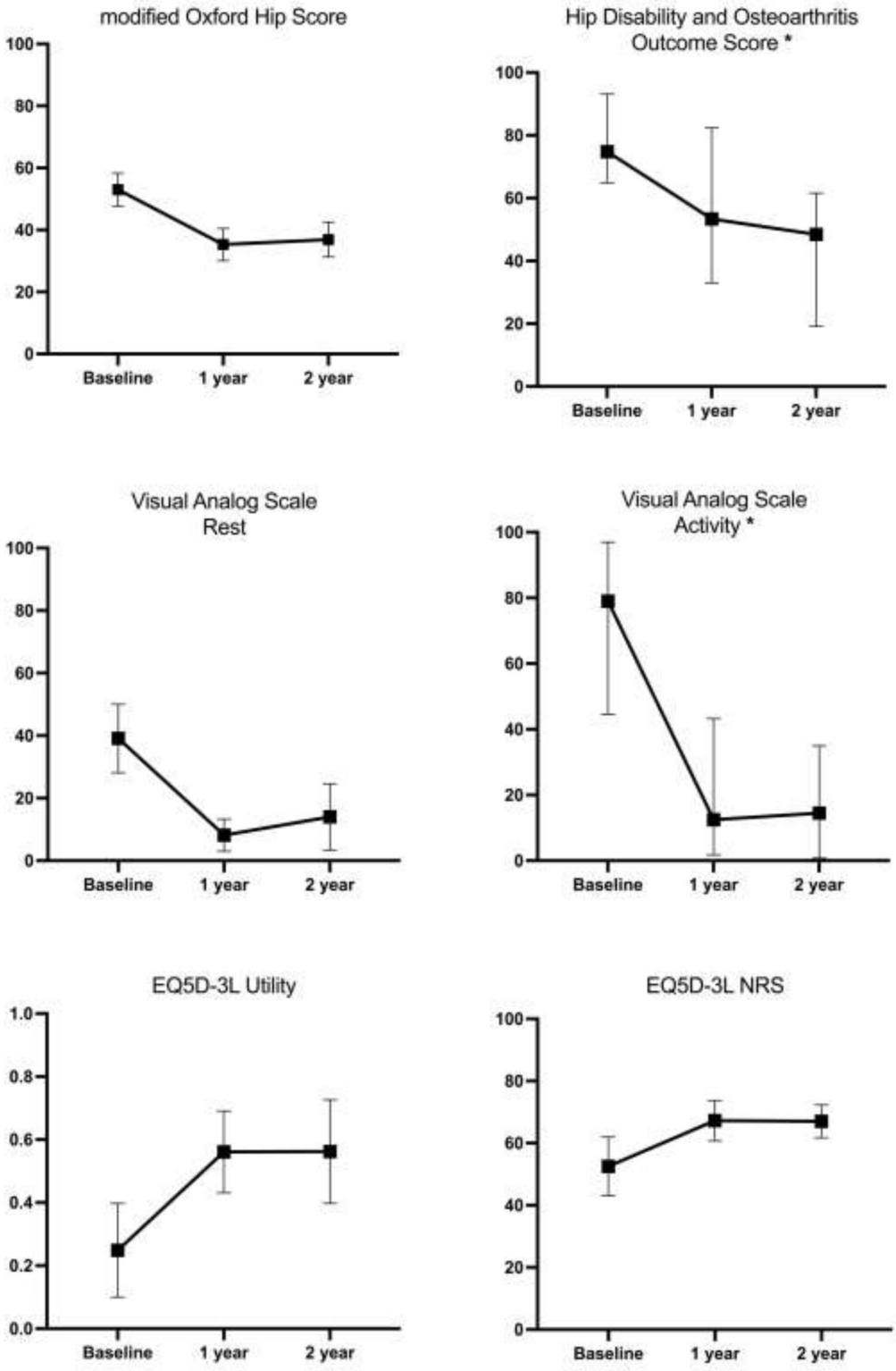

Fig. 3

Patient-reported outcome measures at baseline, and one- and two-year follow-up. Values are depicted as mean and 95% confidence interval for modified Oxford Hip Score, visual analogue scale (VAS) Rest, EuroQol five-dimension three-level (EQ-5D-3L) utility, and NRS (normal distribution of data) or as the median and interquartile range for Hip disability and Osteoarthritis Outcome Score Physical Function Short Form and VAS Activity (non-normal distribution of data).

73.5 years (SD 7.7) and a median BMI of 26.1 kg/m^2 (IQR 23.5 to 33.4). Notably, three patients developed bilateral

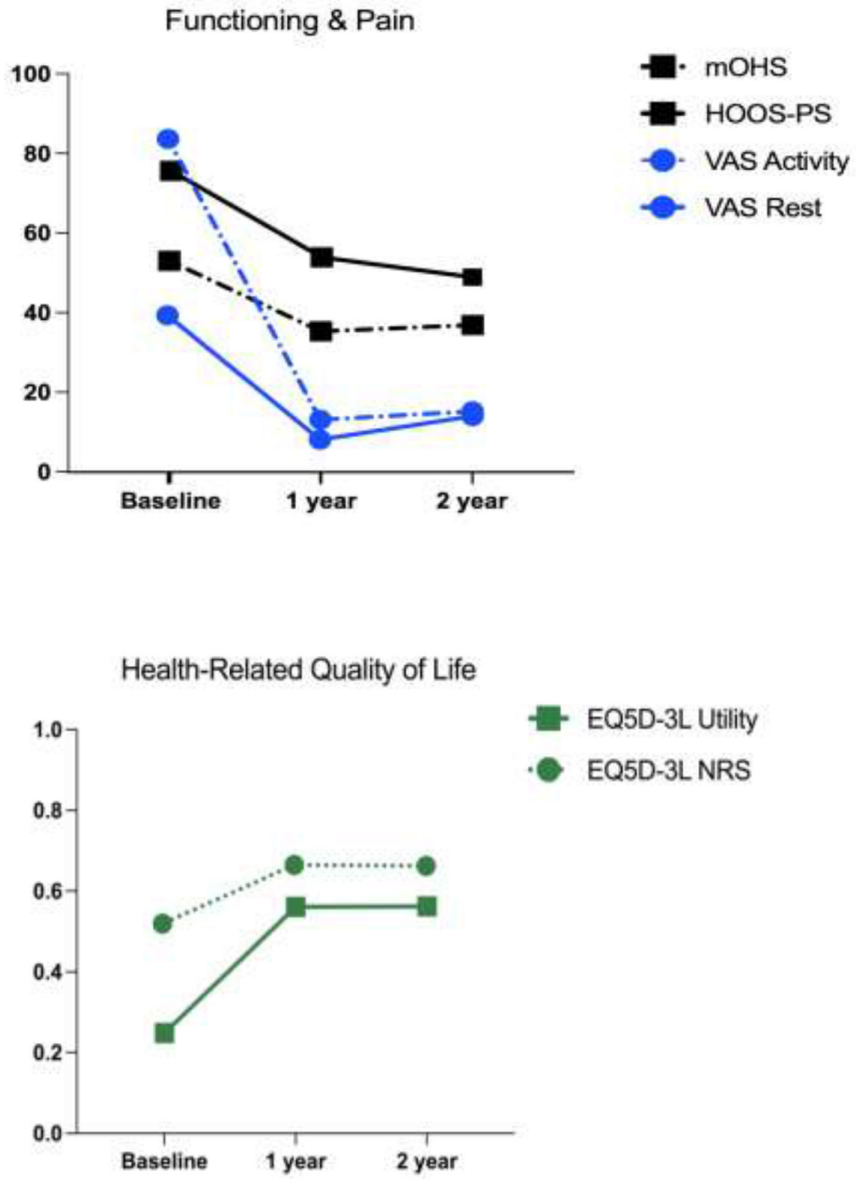

Fig. 4

Illustration of patient-reported outcome measures at baseline, and one- and two-year follow-up. Stratification according to functioning, pain, and health-related quality of life.

PD over time, and there was one patient with concurrent bilateral PD (case B (Figure 1)). No patients passed away during the two year follow-up. All patients had a Paprosky type 3B defect with pelvic discontinuity. A dual-mobility cup was placed in 20 hips and a constrained liner in two hips. Allogenic medial bone graft was used in ten hips (45%). Figure 2 is a case example of a patient with PD treated with a custom-made triflange component.

Patient-reported outcome measures (PROMs). Table I and Figures 3 and 4 present the results of all PROMs at baseline, and the one- and two-year follow-up assessments. At one-year follow-up, data points were missing for mOHS (n = 2), HOOS-PS (n = 1), VAS rest (n = 4), VAS activity (n = 4), EQ-5D-3L utility (n = 2), and EQ-5D-3L NRS (n = 5). No data points were missing at baseline and two-year follow-up. A non-normal distribution of values at the different time points was seen for HOOS-PS and VAS Activity. In terms of total scores of mOHS and HOOS-PS, a significant improvement between baseline and the two-year follow-up was shown. More specifically, previous established MCII of mOHS of five points[16] and HOOS-PS of 23 points[17] was observed in 16 patients (73%) and 14 patients (64%), respectively. Furthermore, all patients reported significant improvement in their level of pain during rest and activity between baseline and at two-year follow-up, including EQ5-D-3L utility and NRS scores. No

significance differences were found between one- and two-year follow-up assessments.

Radiological complications. Table II provides a detailed overview of radiological and clinical complications, including number and reasons for revision. There were six hips (27%) with one or multiple screw breakage or loosening (defined by radiolucency around the screws), four (18%) with bony fractures, and three (14%) with non-healing PD. Screw loosening was mostly observed in the inferior part of the discontinuity (ischium and pubis). No revision surgery was performed for screw failure or implant loosening.

Clinical complications. One patient (4.5%) had a sciatic nerve paresthesia on the operated side without significant improvement at the time of final follow-up. Three patients (14%) had persistent wound leakage more than ten days postoperatively, of whom two patients underwent debridement, antibiotics and implant retention (DAIR), and one did not require any additional intervention (wound healed 11 days postoperatively). Finally, one patient (4.5%) appeared to have a urinary tract infection during admission who was treated with antibiotics.

Reasons for revision. There was one patient (4.5%) with concurrent bilateral PD that had revision surgery due to recurrent dislocations, with no breakage or loosening of the components. This patient was managed by open reduction and conversion from a dual-mobility cup to a constrained liner (Figure 2). No revision surgery was performed for screw failure or implant breakage (mechanical failure rate of 0%). The overall revision rate (including recurrent dislocations and DAIR procedures) for any reason was 14% (three of 22 hips) at final follow-up.

Discussion

The incidence of total hip revision procedures is projected to double in Western societies by 2030, and the management of detrimental complications, such as PD, will become a growing burden to overcome.[19] Although a large number of techniques to deal with PD have been described, little data exist on the efficacy of custom-made components. To the best of our knowledge, this study provides the first prospective clinical outcome report of patients with PD who were treated with a CTAC. Condition-specific PROMs were used to evaluate functioning and HRQoL from the patient's perspective. Although limited radiological and clinical complications do exist, we have demonstrated that such custom-made components in PD can result in stable constructs with significant improvement in clinical outcome over a follow-up period of two years.

The current literature contains a limited number of retrospective case-series that report on the treatment of PD with a custom-made triflange acetabular component.[3] DeBoer et al[5] and Taunton et al[4] both demonstrated that such custom-made implants can provide a good solution with satisfactory clinical results for patients with PD. However, both studies were retrospective case-series that did not include PROMs. Although not originally designed for hip arthroplasty (but for post-traumatic arthritis), both studies included the Harris Hip Score (HHS), which is a clinician-based outcome measure rather than a PROM.[20] Moreover, ceiling effects are commonly observed when using the HHS, limiting its validity and usefulness in adequate outcome assessment.[21] In the present study, multiple condition-specific and validated PROMs were used to evaluate functioning as an outcome domain, including the mOHS and HOOS-PS. Both outcome measures have been shown to be valid, reliable, and responsive in patients following hip arthroplasty, without floor and ceiling effects.[12-15] We found significant and clinically relevant improvement between baseline and final follow-up in mOHS, HOOS-PS, EQ-5D-3L utility, EQ-5D-3L NRS, and VAS pain scores during rest and activity (Table I and Figure 3). More specifically, a clinically relevant mean change in mOHS of 16.2 points and HOOS-PS of 28.4 points were observed between baseline and final follow-up, exceeding previous established MCII.[16,17] Consequently, our study results support that a CTAC is a viable option for patients with PD.

The mechanical success of a construct is determined by its primary stability, but ultimately by the healing of the discontinuity. The studies by DeBoer et al[5] and Taunton et al[4] reported a discontinuity healing rate of 90% and 81%, respectively. In the present study, a similar rate of discontinuity healing of 86% (19 of 22 hips) was observed (Table II). Although mechanical failure seems to be the leading cause of failure in the present study,[1] no revision surgery was performed for screw failure, implant breakage or loosening. Notable, there was only one patient that had revision surgery due to recurrent dislocations. These results are different from those reported by Taunton et al,[4] in which 21% of patients developed mechanical failure and instability. It should be mentioned however, that in the group of patients reported by Taunton et al,[4] 51% (29 of 57 hips) had a preoperative trochanter escape, predisposing to instability. DeBoer et al[5] reported a dislocation rate of 30% (six of 20 hips). Dual-mobility cups and constrained acetabular liners were, however, not placed routinely by DeBoer et al.[5] As a matter of fact, the first custom-made implants in the 1990s did not have the possibility to implant a dual-mobility cup or a constrained liner. This may have contributed to their relatively high rate in dislocations. Indeed, in the present study, a dual-mobility cup or a constrained liner was cemented in all patients. Still, the contradicting findings in mechanical failure and dislocation rates may also be explained in part by the difference in follow-up time. Taunton et al[4] and DeBoer et al[5] had a mean follow-up time of five years and ten years, respectively, whereas the present study had a relatively

short follow-up time of two years. Indeed, maintaining follow-up of patients who participated in the present study is mandatory to demonstrate clinical outcome and survivorship at the mid- to long-term.

We found a dislocation rate of 4.5% (one of 22 hips). Notably, this patient was suffering from concurrent bilateral PD, which is an additional risk for dislocation (Figure 2 and Table II).[22] Martin et al[22] reported a dislocation rate of 83% (five of six) in patients with concurrent bilateral PD who were treated with a cup cage construction and/or a posterior column plate. It may well be that continued motion of the contralateral side predisposes to instability. These findings indicate that a high dislocation rate can be expected in patients with concurrent bilateral PD, regardless of the techniques used for acetabular reconstruction. Further research in novel reconstruction approaches specifically aimed at concurrent bilateral PD would add to the understanding of this difficult (and fortunately rare) problem.

In recent years, multiple techniques have been described in the management of PD, including reduction and plate fixation, distraction methods, cup-cage constructs, and bone impaction grafts.[1] Regardless of the technique that is used, the main goal of PD reconstruction is achieving a stable construction by providing a bridge between the superior and inferior part of the pelvis that stimulates bony healing. Berry et al[23] described three general guiding principles for the treatment of PD: 1) identification of the problem; 2) stabilization or re-establishment of the continuity between the superior and inferior hemipelvis; and 3) placement of a stable acetabular implant, preferably with bone-grafting at the site of the discontinuity. Currently, the cup-cage construct is the most popular technique to address PD. Multiple short- to medium-term results have been published. At a mean follow-up of 32 months, Rogers et al[24] reported a mechanical failure rate of 8.5% in a total of 42 patients with PD who were treated with a cup-cage construct. Amenabar et al[25] also reported a similar mechanical failure rate of 9% at a mean follow-up of 77 months in 45 cup-cage constructs used to address PD. Whereas at a mean follow-up of 72 months, Konan et al[26] reported a substantial higher mechanical failure rate of 17% in 24 patients with PD. Interestingly, in all aforementioned studies, the most commonly reported reason for revision was dislocation, followed by mechanical failure. As mentioned above, in the present study, no revision surgery was performed for loosening or breakage of the component. A reasonable explanation for this might be that the customized anatomical design of the flanges help to maintain the reconstructed anatomical centre of rotation and acetabular version with adequate fixation, and therefore the optimal pre-planned implant position that stimulates osseous consolidation of the discontinuity. Moreover, secondary fixation might also take place due to ingrowth of the titanium scaffold of the construct and into the host bone. Finally, screw fixation points in the ilium, ischium, and pubis were preplanned into good bone quality areas (which is an essential part of the CT defect analysis), thereby optimizing the initial stability of the construct.

Limitations of the current study include the relatively short follow-up time of two years and the small sample size. Nonetheless, data were tested for normality and concomitant statistical tests were used. We will continue to monitor and follow-up on our patients to demonstrate clinical outcome and survivorship at the mid- to long-term. Moreover, previous studies have demonstrated that early (i.e. within one year postoperatively) migration in THA will increase the probability of revision for aseptic loosening.[27,28] In the present study, component migration was not assessed on CT scans, as these were not routinely acquired during follow-up assessments. However, using the similar custom-made implant, Zampelis et al[29] demonstrated good agreement of < 1° and 1 mm in implant positioning between direct postoperative and one year follow-up regarding both rotational and translational migration values, respectively. Whether, and to what extent, this will affect the secondary stability of the implant, especially in PD, will need to be evaluated in future CT-based migration studies.

In conclusion, we provide the first prospective assessment in clinical outcome of patients with PD who were treated with a CTAC. We have demonstrated that CTAC in patients with THA acetabular loosening and PD can result in stable constructs with no mechanical failures. Moreover, significant and clinically relevant improvement in functioning and HRQoL at two years' follow-up was observed. Further follow-up is needed to determine mid- to long-term clinical outcome and implant survivorship.

Take home message

- Custom-made triflange acetabular component in patients with total hip arthroplasty acetabular loosening and pelvic discontinuity can result in stable constructs, and significant improvement in functioning and health-related quality of life at two years' follow-up.

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