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ORIGINAL STUDY

Custom-made triflanged acetabular components in the treatment of major acetabular defects. Short-term results and clinical experience

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We report on the Belgian experience with the aMace® custom-made triflange acetabular component in revision total hip arthroplasty between September 2009 and November 2014. We focused on (1) the complexity of the preoperative planning and reimbursement procedure; (2) the surgical problems and operative experience; and (3) the early outcome. We collected 20 patients' reviews and 22 surgeons' reviews, with a mean follow-up of 25 months. The preoperative planning and reimbursement procedures were rated as time-consuming and cumbersome. In 6/22 cases, the operation was difficult or very difficult. Technical problems occurred in 8/22 cases, including problematic fitting in four. However, all aMace® components could be implanted successfully. The mean postoperative Harris Hip Score (HHS) was 68/100; patients' satisfaction was high and most patients experienced no or mild pain. Complications occurred in 8/22 cases, half of them dislocations. The aMace® implant **can provide a solution for complex acetabular revisions. As dislocations were common, the use of dual-mobility cups should be considered. Because of the high cost and the lack of bone stock restoration, we suggest using custom-made triflange acetabular implants only in cases with large cavitational and segmental defects, which would be difficult to reconstruct with alternative methods.**

Keywords : revision total hip arthroplasty; acetabular defects; custom-made triflanged acetabular components.

INTRODUCTION

Revision total hip arthroplasty (THA) can be challenging. On the acetabular side, major non-contained acetabular defects with a limited bone stock or in the presence of pelvic discontinuity (Paprosky type 3A or 3B (*21*)) are particularly difficult to deal with. In these cases, the major challenges are: (i) restoration of hip biomechanics, particularly the center of rotation, (ii) achieving initial implant stability and durable fixation and (iii) restoration of bone stock to facilitate future revisions. To achieve these goals, various techniques and devices are available (*4,11,16,23*)

Standard implants, double cups and jumbo cups require good initial stability and need large contact areas with host bone for osteointegration. As such, they are not always suitable to treat large structural defects of both columns (Paprosky type 3A or 3B) and do not allow major bone stock restoration.

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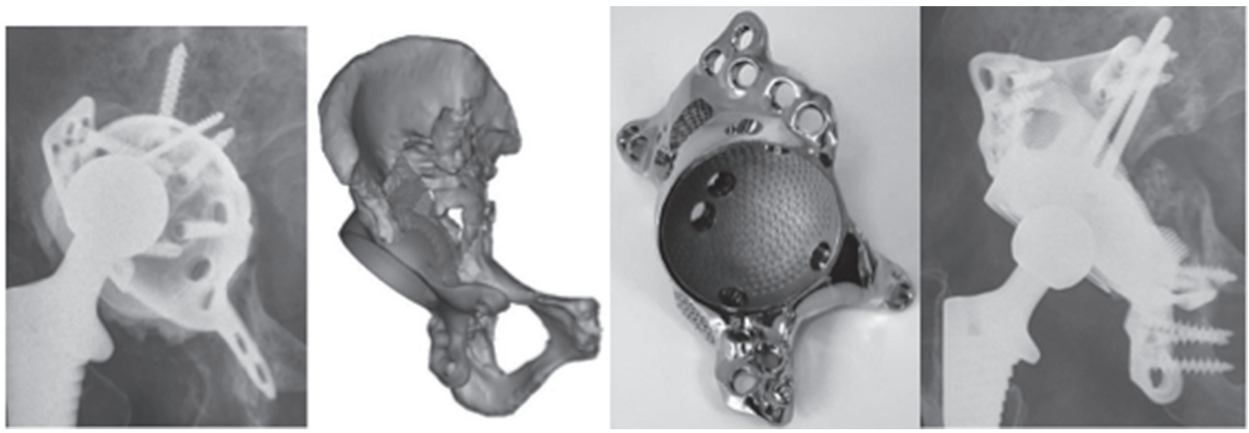
On the other hand, they provide good long-term results once osteointegrated and are easy to use when defects are limited (*4,23*). When bone stock is insufficient, especially in superiorly, a high hip rotation center can be an option. However, abductor muscle tension and leg length should be restored by inserting the stem in a prone position (*6,16,25*).

Cages and rings are often used in combination with impaction bone grafting. They can be positioned to maximize implant stability, independently from the cup orientation. In a second stage, a cemented all-poly or dual mobility cup allows optimizing cup positioning. This versatility is a major advantage in the presence of large rim defects. Moreover, cages allow bone stock restoration but require a minimum of host bone contact and are mainly applicable in contained defects without large structural deficiencies (*13,18,22,23*).

Augments and structural allografts can provide good structural support even in the presence of large non-contained defects of both columns. However, augments do not restore bone stock and large structural allografts may fail before osteointegration. Moreover, achieving primary implant stability in the presence of large defects might be challenging (*4,10,19,20,23*).

Although most bone defects can be dealt with by "standard techniques", large non-contained defects extending in both columns and/or pelvic discontinuity remain problematic. Custom-made triflanged acetabular components (CTAC) were developed to restore hip biomechanics and achieve primary implant stability, even in extreme cases. Implant stability is favored by maximizing host bone contact and by three flanges that fit the iliac, ischial and pubic bone. The custom made central hemispherical cup allows optimizing the position of the hip rotation center. A polyethylene liner can either be cemented or locked within the implant (*3,5,7,9,15,17,24,26*).

One of the CTACs available in Belgian is the aMace® Acetabular Revision System (Mobelife, Materialise, Leuven, Belgium). Like other CTACs, the design of aMace® implants is based on 3D models produced from CT scans. First, the patient-specific bony situation is evaluated and an implant proposal is formulated including a biomechanical assessment, i.e. the cup anteversion and inclination angles, the position of the rotation center and an analysis of the bone stresses generated by the implant (*12*). The implant proposal also includes patient-specific screw positions based on bone quality and drill guides to achieve the planned position. Moreover, and in contrast to other CTACs, the medial side of aMace® implants can be provided with a porous defect-filling scaffold to favour osteointegration. In a second stage, surgeons and engineers come together to discuss surgical approach and implant design issues. At this stage, each case is presented to Belgian health insurance companies to request implant reimbursement. Additive manufacturing techniques, i.e. 3D printing, are used to manufacture



A B C D

Fig. 1. — A : Preoperative situation after two revisions. B :Preoperative plan. C : Final implant. D : Postoperative situation..

an epoxy model of the hemipelvis, the triflanged cup and the drill guides (*11*). Selective laser melting, in which a focused laser beam melts Titanium powder layer-by-layer, is used to produce the final implant (Fig. 1). Sterilization of the models, the jigs and the implant is performed at the hospital (*11*).

This study investigates the initial experience with the aMace® system in Belgium. We report on the complexity of the preoperative planning and reimbursement procedure, on the user-friendliness of the system, the intraoperative problems, complications and short-term results.

MATERIALS AND METHODS

After approval by the ethical committee of the UZ Brussel (B.U.N. 143201422977) (blinded), all patients treated in Belgium with the aMace® custom-made triflange acetabular component between September 2009 and November 2014 were retrospectively identified by Mobelife. Only those patients receiving an aMace® implant as part of a revision THA were included. All operating surgeons were invited to participate and were asked to complete a standardized survey and to provide patients' demographic and contact information. Standardized patient reviews were completed either during routine follow-up at the out-patient clinic or by phone.

The standardized surgeons' survey questioned the preoperative planning and reimbursement process. The surgeons were also asked to score the surgical procedure, i.e. the user-friendliness of the drill guides, the fitting of the component, agreement between the trial implant and the final implant, and agreement between the bone model and the actual bone situation. Finally, the surgeons were asked to grade the difficulty of the operation and to report technical problems.

Postoperatively, patients' outcomes were documen-ted with the Harris hip score (HHS) (*14*), the Oxford hip score (*8*) and the Dutch Womac score (*2*). Patients were also asked to report a general satisfaction score between 0 and 10. Complications occurring during the whole follow-up period were reported by surgeons and patient-specific implant proposals, were analyzed.

Table I. — Patient demographics

Variable	**Patients [n=21]**
Mean age in years (range)	66.6 (50-83)
Sex	
Male (%)	6 (28.6)
Female (%)	15 (71.4)
Side	
Left (%)	13 (61.9)
Right (%)	8 (38.1)
Diagnosis for revision	
Loosening (%)	15 (71.4)
Infection (%)	3 (14.3)
Pelvic discontinuity (%)	3 (14.3)
Mean number of revisions (range)	3.1 (1-12)
Mean number of dislocations (range)	1.9 (0-7)
Mean time since primary THA in years (range)	22 (1-34)
Mean time since last THA in years (range)	5.6 (0.2-16.0)
Primary diagnosis	
Osteoarthritis (%)	12 (57.1)
Trauma (%)	2 (9.5)
Avascular necrosis (%)	1 (4.8)
Developmental dysplasia of the hip (%)	1 (4.8)
Mucopolysaccharidosis type 4 (%)	1 (4.8)
Unknown (%)	4 (19.0)

RESULTS

Patients and demographics

Between September 2009 and November 2014, 20 Belgian surgeons reconstructed 55 hips in 55 patients, with the aMace® custom-made triflange acetabular component (Fig. 1). Four patients presented hip dysplasia and were excluded. Seven surgeons (26 patients) withdrew from participation: four due to lack of time to complete the survey, two conducted their own study and one did not give any reason.

Of the remaining 25 patients, one died of a cause unrelated to surgery before follow-up, and we missed demographic or contact information in four other patients. As such, demographic information was available in 21 patients Table I) and 20 had complete reviews (referred to as 'patients'). In addition we collected 22 surgeon's reviews (referred to as 'cases'), 17 of them concerned patients with a complete patient's review (Fig. 2). The mean time to follow-up was 25 months (SD : 16; range: 350 months).

Most patients were female and young for revision surgery. The majority underwent multiple revisions and the operation site was predominantly on the left. Osteoarthritis was the most common indication for the primary intervention; cup loosening with major bone loss was the most common indication for the revision. The mean time since the primary THA was over 20 years, but the mean time from the last revision was less than 6 years.

Preoperative planning procedure and cost

The preoperative planning procedure started with a high quality CT scan, and a draft proposal by the engineers of Mobelife. The proposal was reviewed by both, the surgeon and the engineer and, on the

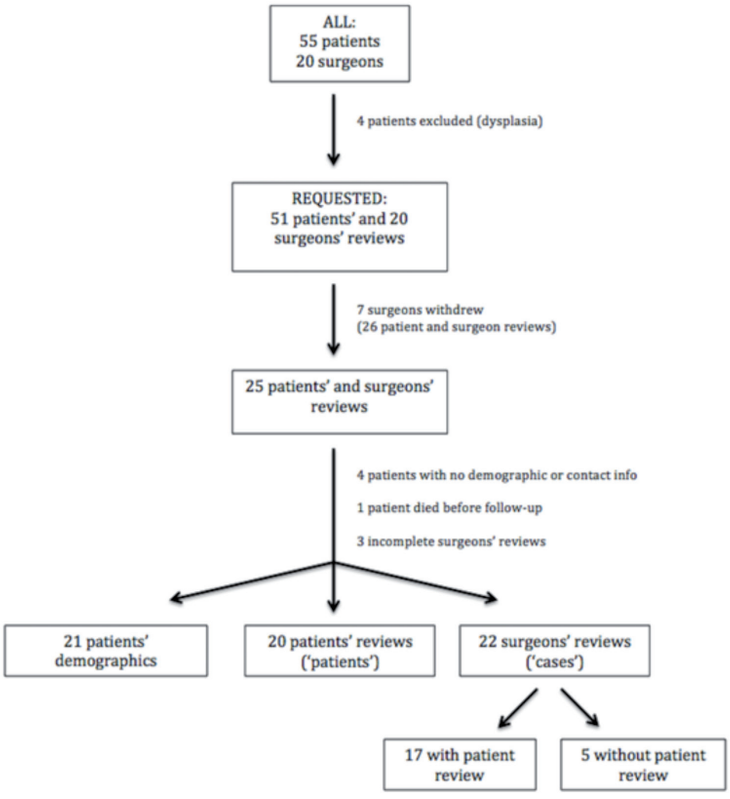


Fig. 2. — Study flow-diagram of surgeon and patient review.

Table II. — Rating by the surgeon of the difficulty and time taken for the reimbursement procedure.

Question	**Number of cases (%) [n=22]**
Difficulty of the reimbursement procedure	
Very easy	0 (0)
Easy	0 (0)
Normal	3 (13.6)
Difficult	18 (81.8)
Very difficult	1 (4.5)
Delay for reimbursement procedure	
No	0 (0)
Little	2 (9.1)
Long	20 (90.9)
Very long	0 (0)

Table III. — Rating by the surgeons of the difficulty of the operation.

	Number of cases (%) [n=22]
Very easy	1 (4.5)
Easy	6 (27.3)
Normal	9 (40.9)
Difficult	3 (13.6)
Very difficult	3 (13.6)

surgeon's request, a 3D printed bone model and triflanged component was produced. If the surgeon agreed on the proposed solution, a finite element analysis model was constructed to evaluate the strength of the triflanged cup and a report was sent to the insurance company for approval. If the surgeon did not agree with the first draft, a modified report and/or model was produced until an agreement was reached. On the surgeon's request, a 3D printed bone model and triflanged component was produced.

In total 13 surgeons reviewed the preoperative planning procedures for 22 cases. The mean time between the decision to use an aMace® implant and the operation was 4.26 months (range: 1-9 months). One reasons for this delay was the reimbursement procedure, which most surgeons rated as time-consuming and difficult (Table II). In 10 patients, CT data did not suitable for pre-operative 3D planning, and a new CT scan was required. In some cases, surgeon-manufacturer interactions were time consuming and the draft was modified in 18/22 cases. Most alterations concerned the acetabular center of rotation, but some cases required a smaller ischial flange or a more posterior position of the iliac flange. All surgeons rated their influence on the final implant as sufficient and appropriate. Four surgeons needed to postpone the operation due to the preoperative planning procedures. But only 6/20 patients (30%) were unhappy with the surgical delay.

The total cost for the aMace© implant was a flat rate of 12 453.30 euro inclusive taxes. Till now, based on an individual analysis of the medical files, Belgian health insurance companies provided full implant reimbursement in all cases.

Operation

The mean surgical time was 241 minutes (SD: 81, range: 150-390 minutes). The difficulty of the operation was rated as normal, easy or very easy in 16/22 cases (73%) (Table III). The 'overall experience' with the aMace® implant was good but with a large variation in the surgeons' scores (mean score 8.1/10, range 2-10). Three different surgeons were dissatisfied with the final implant during surgery (3/22 cases) and answered ≤5/10 on at least three out of the six questions reported in Figure 3.

Technical problems occurred in 9/22 cases (41%), in 4/22 cases multiple technical problems occurred during the same operation. However, the aMace® component could always be implanted and was never abandoned intraoperatively. The most challenging problems occurred during the fitting of the implant in the acetabular defect. Mostly osteophytes and overhanging bone had to be removed as mentioned in the patient-specific documentation. Surgeons were provided with both, a plastic bone model including the amount of bone to be removed as well as a plastic trial implant. However, removing the exact amount of bone was difficult in four cases, and in two of these cases an unforeseen pelvic discontinuity or fracture occurred. This prevented exact fitting of the implant and both parts of the pelvis had to be reduced on the implant itself. As such, the continuity of both, the anterior and posterior column was achieved with the implant as an internal fixation device.

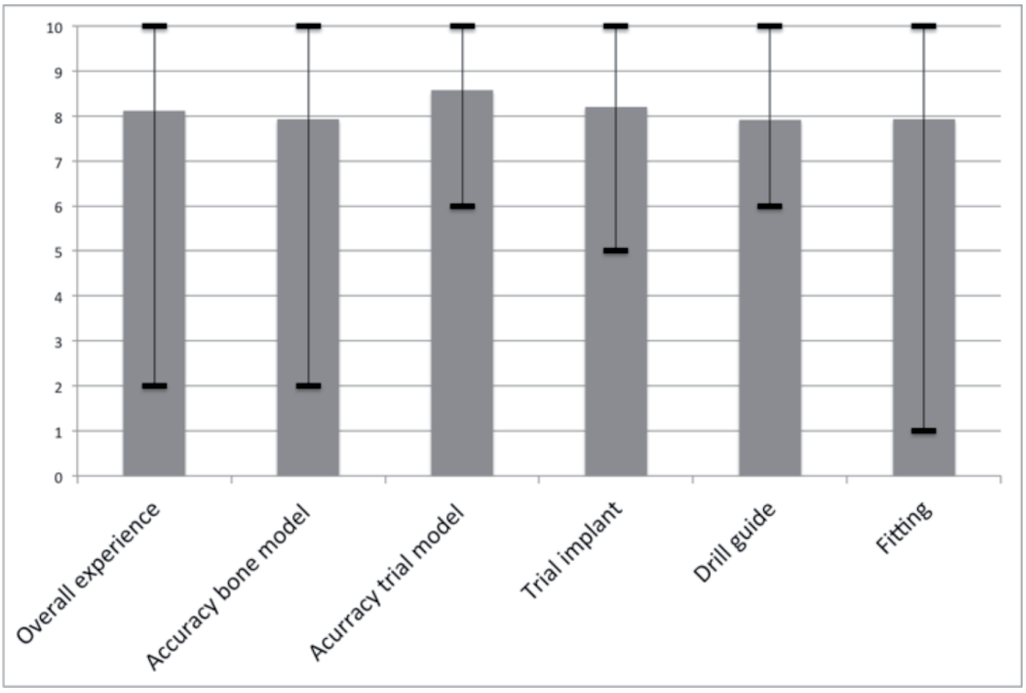


Fig. 3. — Mean operation scores with minimum and maximum

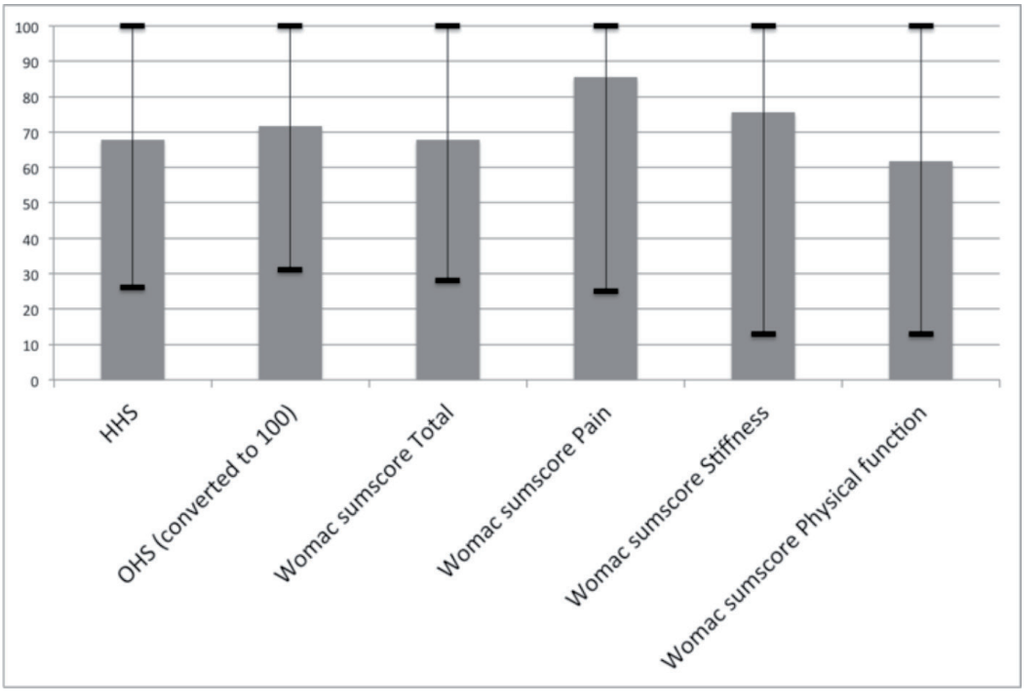


Fig. 4. — Mean postoperative patient scores with minimum and maximum (HHS: Haris Hip Score; OHS: Oxford Hip Score)

Minor problems occurred with the drill guide in 5/22 cases (23%). One of these cases was due to the poor fitting of the implant. In two cases, a combination of smaller drill guides, instead of a single, large guide, would have facilitated the procedure. Subsequently Mobelife provided these separated guides routinely. In the other two cases, soft tissue prevented the use of some of the drill guides and the surgeon drilled free-handed or had to mobilize more soft tissues to fit the guides. Also, during one operation, retained broken screws could not be removed and prevented the insertion of some of the new screws.

Despite some difficulties, all surgeons would consider using the aMace® implant again in a similar case. However, in 4/22 cases the surgeon was not convinced that the aMace® implant was superior to other solutions. In one case the need for a custom-made implant was questioned as the defect was less severe than expected. In another case, the surgeon thought another cup could have been implanted trough a smaller approach. In a third case, the implant lacked primary stability due to suboptimal fitting. In the last case, no specific reason was given.

Functional outcome

Functional postoperative scores were obtained in 20 patients. According to the Womac score, 8/20 patients showed no pain, 7/20 reported no stiffness and one patient had a completely normal physical function (Figure 4). The patients' satisfaction score improved from 2.44/10 (range 0-8) to 8.53/10 (range 5-10). All but one patient would go for the same operation again if needed.

Complications

Surgeons reported an overall complication rate of 36% (8/22 cases) (Table IV). Dislocation was the most frequent complication, but all cases were successfully treated by closed reduction. One infection was diagnosed 3.5 years after the revision operation, when a fistula appeared. The germ was the same as the one found during implantation. Apart from the fistula, the patient had no particular complaints and was treated by lifelong antibiotic suppression. Other complications included one large hematoma, one sciatic nerve palsy with little recovery after three years, and one case of ischial screw loosening after six months in a patient with pelvic instability. At the latest follow-up, no patients had clear radiographic signs of implant loosening.

Table IV. — Postoperative complications.

Complication	Number of cases (%) [n=22]
Dislocation	4 (18.2)
Infection	1 (4.5)
Loosening	0 (0.0)
Re-revision	0 (0)
Other	3 (13.6)

DISCUSSION

Reconstruction of massive periacetabular bone defects requires implant stability, restoration of hip biomechanics and if possible improvement of bone stock for future revisions. Custom-made triflanged acetabular components (CTAC) offer implant stability through structural support and through screw fixation in the ileum, ischium and pubis. This combined with the possibility to plan accurately the cup orientation and the hip rotation center (*1*), opens up new perspectives in difficult cases. This study describes the early Belgian experience with aMace© implants by Mobelife, inserted between September 2009 and November 2014.

Overall, the planning and reimbursement procedure was experienced as cumbersome and time consuming. The overall surgical experience was positive despite some issues of implant fitting in cases of pelvic discontinuity or when significant amounts of bone needed to be removed. As expected, the complication rate was relatively high and involved mainly dislocations. Nevertheless, taking into account the severity of the cases, short-term clinical outcome was satisfactory in most cases.

Planning and cost

Till now, eight other studies (*3,5,7,9,15,17,24,26*) describes results of CTAC (Table V). As in our study, most papers (*5,9,15,24*) report the preoperative planning to be complex and time consuming.

Table V. — Comparison of the results of the studies involving CTAC..

Study	No. of patients (no. of hips)	Mean follow-up months (range)	Mean age in years at revision (range)	Classification of acetabular bone loss	Preop clinical score	Postop clinical score	Increase in clinical score	Complication rate (%)	Dislocation rate (%)	Revision rate for any reason (%)	Revision rate (%) of component	Component failure rate (%)
Christie et al. [35]	76 (78)	53 (24-107)	59 (29-87)	AAOS III and IV	33 HHS	82 HHS	49 HHS	17 (22)	12 (15)	10 (13)	6 (8)	0
Holt and Dennis [36]	26 (26)	54 (24-85)	69 (44-82)	Paprosky IIIB	39 HHS	78 HHS	39 HHS	7 (27)	2 (8)	1 (4)	1 (4)	3 (12)
De Boer et al. [37]	18 (20)	123 (89-157)	56 (30-77)	AAOS IV	41 HHS	80 HHS	39 HHS	7 (35)	6 (30)	6 (30)	6 (30)	0
Joshi et al. [38]	27(27)	58 (48-72)	68 (55-77)	AAOS III	2.3 M d'A	5.3 M d'A	3 M d'A	6 (22)	1 (4)	3 (11)	2 (7)	0
Taunton et al. [39]	57 (57)	65 (24-215)	61 (35-81)	AAOS IV	-	75 HHS	-	20 (35)	12 (21)	20 (35)	15 (26)	9 (16)
Wind et al. [40]	19 (19)	31 (16-59)	58 (42-79)	Paprosky IIIA and B	38 HHS	63 HHS	25 HHS	3 (16)	5 (26)	6 (32)	4 (11)	2 (11)
Colen et al. [41]	6 (6)	29 (10-58)	69 (63-78)	AAOS III and IV	-	61 HHS	-	0	0	0	0	0
Berasi et al. [42]	23 (24)	57 (28-108)	67 (47-85)	Paprosky IIIB	42 HHS	65 HHS	23 HHS	6 (25)	0	4 (17)	2 (8)	0
Current study	25 (25)	25 (3-50)	67 (50-83)	Paprosky	-	68 HHS	-	8 (36)	1 (5)	0	0	0
Total	**282**	/	/	/	/	/	/	**74 (26)**	**39 (14)**	**50 (18)**	**36 (13)**	**14 (5)**

Moreover, surgeons see the need for a standardized preoperative CT scanner, the lack of bone stock restoration, the high cost of the implant as well as the working time for surgeons/staff, as major disadvantages (*5,9,15,24*).

The cost of the aMace® implant in Belgium is at the higher end compared to other implants (€12 453.30 versus $5200 to $12 500) (*5,9,15,24*). Till now, all aMace® implants have been reimbursed by the publicly funded Belgian health care system based on case-by-case scrutiny. However, without evidence that this approach is superior to cheaper alternatives, full reimbursement could be jeopardized in the future. On the other hand, if good clinical outcomes and/or lower needs for re-revision can be demonstrated, the balance on the long-term could be favorable. As such, we believe that expensive CTAC implants should only be considered in those extreme cases where no other solution is adequate on the short- or medium-term. In all other cases, less expensive solutions with more possibilities for bone stock restoration should be favored.

Surgery

Overall, the operation either went smoothly and surgeons were happy with the implant and the instrumentation or, technical problems occurred and the procedure became troublesome and, took much more time and effort to be completed. Specific surgical problems were not reported in most other series. However, we and others (*5,9,15,17,24,26)* perceived the fact that the implant could not be modified during surgery as a general drawback. In our study, lack of fitting during surgery due to of pelvic discontinuity or inadequate bone removal was the major problem. In case of pelvic discontinuity, the implant could be used to reduce and fix both parts of the pelvis but that strategy led to ischial screw migration in one case. To avoid this, cement augmentation of the ischial screws has been suggested (*9,15*). Previous studies also advocated fixing the ischial screws first and reducing the discontinuity by bringing the component into close contact with the host bone (*5,9,24*). An alternative is additional column plating but if performed prior to inserting the CTAC, this could compromise an adequate fit.

Complications

As expected for this type of surgery, the number of complications reported in literature is high (overall, including this study: 74/282 cases, 26%). In our study, the complication rate (36%) was comparable *(9,15,24)* or higher (3,7,*17,*26) than in other series (Table V). Despite the possibility to restore hip biomechanics accurately (*1*), dislocations (overall, including this study: 39/242 cases, 14%) remain the major problem *(3,7,5,9,15,17,24,26)*. This could to be due to the extensive approach and the poor quality of the soft tissues in multioperated patients. Although some authors advocate the use of constrained liners (*5,17,24*), we would suggest using

cemented dual mobility cups whenever possible to limit the strains on the bone-implant interface.

On the short-term we report screw migration in one case and one infection, but none of the implants was grossly loose. Till now, none of these cases was revised, but they both are at risk. These findings are in line with other studies, the overall published revision rate including this study being 18% (50/282 cases) *(3,7,5,9,15,17,24,26)*. However, these figures need to be seen in the light of the difficulties to revise large acetabular components, making these interventions particularly risky and unpopular.

Patient function

Patient satisfaction after revision with CTAC implants has not been reported before in literature. In our study, patient satisfaction was high, mainly because of pain reduction and improved walking ability. However, multiple revisions leading to extensive soft tissue damage and massive bone destruction prevented excellent results in most cases.

Limitations of the study

As this was a retrospective study we miss preoperative data. Nevertheless, most surgeons kept good records of these rare cases and patients were reviewed personally by one of the authors. Additionally, despite efforts to collect data from all revision patients operated on with an aMace® implant in Belgium, only 13/20 surgeons (65%) were willing to participate and 21/51patients (43%) were reviewed. This seems inevitable when multiple centers are allowed to try out new techniques outside a global prospective study protocol. On the other hand, this is the largest series reporting on a country's initial experience with CTAC implants.

As aMace® implants have been available only recently, follow-up is limited to less than five years. Finally, due to the large heterogeneity of published series it is difficult to compare our results with those of other CTAC studies or other techniques.

Future perspectives

Providing an easier standardized reimbursement procedure for selected indications (e.g. Paprosky type IIIA, IIIB and pelvic discontinuity) could shorten the surgical delay and avoid cumbersome case-by-case approvals. From the insurance perspective it could also limit the use of an expensive technique when other cheaper alternatives are adequate.

Despite plastic models, removing selected parts of periacetabular bone was problematic in some cases. As such, the amount of bone to be removed should be limited to the strict minimum to facilitate proper implant fitting.

To restore bone stock for future revisions, bone grafting between the implant and host bone should be considered. For this, the implant should not aim to achieve full contact with the host bone, but only sufficient contact for structural support and implant stability. In those areas without direct host bone contact, room could be left for impaction bone grafting of cavitational defects.

As screw fixation could be problematic in poor quality bone and because full bone-implant contact could not always be achieved, locking screws in the flanges should be considered. This could prevent screw migration and improve fixation especially in cases of pelvic discontinuity.

CONCLUSION

This study showed that, at least on the short-term, custom-made triflanged acetabular components as the aMace® implant, provided adequate fixation and acceptable clinical results with a high degree of patient satisfaction in complex revisions. Despite a high complication rate, the use of such implant seems justified in carefully selected patients with massive uncontained acetabular bone defects. Due to the high cost we would advise there use only in those cases where no good clinical results can be expected with other treatment options, i.e. Paprosky type IIIA, IIIB and pelvic discontinuity. Further improvement of the system with the use of locking screws and the combination with graft impaction techniques should be investigated.

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