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Custom 3D-Printed Triflange Implants for Treatment of Severe Acetabular Defects, with and without Pelvic Discontinuity

Early Results of Our First 19 Consecutive Cases

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Background: Treatment of massive acetabular defects, both with and without pelvic discontinuity, is challenging. The implants utilized in the surgical procedure need to be stable and integrate with poor host bone stock. In the present study, we describe our experience addressing this challenge.

Methods: We identified all patients who underwent surgical implantation of a custom 3D-printed triflange prosthesis with dual-mobility bearings for the treatment of Paprosky 3B acetabular defects between 2014 and 2020. Operative, functional, and radiographic outcomes were assessed.

Results: A total of 19 patients were identified, including 11 women. The mean age was 77 years (range, 53 to 91 years), and 8 patients (42%) had proven or likely pelvic discontinuity. The mean follow-up was 53 months (range, 17 to 88 months; mode, 57 months). The cumulative implant survivorship was 100%. Two patients suffered notable sciatic nerve palsy, with 1 case being recurrent. There were no dislocations or fractures. The mean Oxford Hip Score improved significantly, from a mean of 8.6 (range, 0 to 22) preoperatively to 35 (range, 10 to 48) postoperatively ($p < 0.0001$). Radiographically, there was excellent correlation between implant position and the preoperative plan ($p > 0.05$). There were no cases of implant loosening or migration, which suggests that stabilization was achieved even among cases with pelvic discontinuity.

Conclusions: These early results suggest that the use of a custom 3D-printed triflange implant has potential advantages over traditional constructs in the treatment of massive acetabular defects, with and without pelvic discontinuity. Excellent implant survivorship and functional improvement were demonstrated in this challenging patient cohort.

Level of Evidence: Therapeutic Level IV. See Instructions for Authors for a complete description of levels of evidence.

Component loosening is one of the most common indications for revisions and re-revisions following total hip replacement[1]. The risk of revision-related complications justifies enhanced planning and operative solutions to optimize outcomes[1].

Acetabular component loosening, frequently coupled with adjacent bone loss, was comprehensively classified by Paprosky et al.[2]. Type-3B defects present the greatest technical challenge because of severe overall bone loss, loss of the acetabular rim, ischial lysis, and superomedial component migration. Severe bone loss can result in pelvic discontinuity, increasing the complexity of restoring hip anatomy and achieving stable implant fixation. To address this challenge, a variety of revision techniques have been proposed, including structural allograft, antiprotrusio cages for bone graft containment with plate fixation of the pelvic discontinuity, tantalum augments to infill the defects, oversized tantalum components in distraction mode to improve press-fit, jumbo cups, and cup-cage constructs[2-9]. Subsequent acetabular cup fixation is typically achieved with use of porous cups implanted into the restored acetabular cavity, with or without screw augmentation, or cups cemented into cup-cage constructs or into the restored acetabular cavity[6,7,10]. Although the implant survivorship of these techniques ranges from 50% to 98%, the

Disclosure: The **Disclosure of Potential Conflicts of Interest** forms are provided with the online version of the article (http://links.lww.com/JBJSOA/A331).

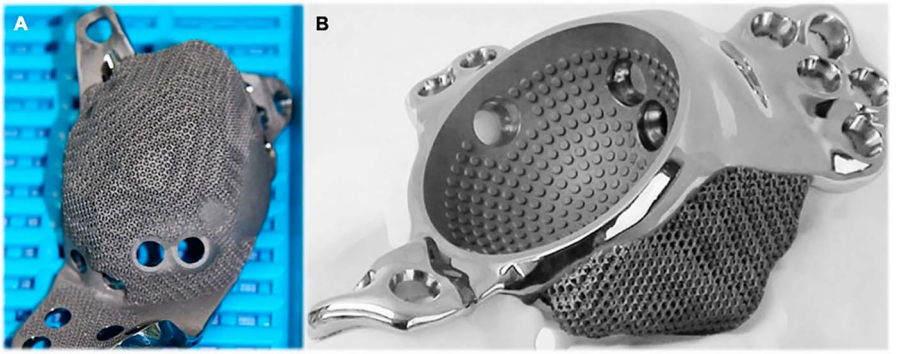

Fig. 1

Fig. 1-A The backside of the lightweight integrated cup and flanges of the aMACE triflange implant. The implant mimics bone properties and is designed to improve secondary fixation through bone ongrowth and ingrowth. The use of a personalized design is meant to maximize bone preservation and optimize the implant fit to patient pathology. **Fig. 1-B** The integrated cup is utilized as a cavity for fixation of bearing surfaces.

surgical procedures can be time consuming, with unpredictable restoration of hip anatomy and attainment of stable implant fixation, and can require extensive hardware. Custom implants have been successfully utilized since the 1990s[11], with recent advances in 3D-printing further enhancing the proficiency and versatility of implant customization[12].

Favorable outcomes have been reported with the use of custom 3D-printed aMACE triflange implants (Materialise)[13,14]. We previously reported promising early results with use of aMACE implants, as well as a rationale for the use of biology-enhancing skeletal stem cell surface augmentation and a demonstration that these cells had the potential for osteogenic activity at the bone-implant interface[15]. The benefits of aMACE implants include preoperative familiarization with pathology, 1-step reconstruction of acetabular bone defects and stabilization of pelvic discontinuity, stable implant fixation with safe augmentation screws, and predictable restoration of the hip center of rotation.

In the present study, we report our experience with revision total hip replacement involving massive type-3B acetabular defects, including a large proportion of cases with pelvic discontinuity, with use of aMACE triflange implants. The primary

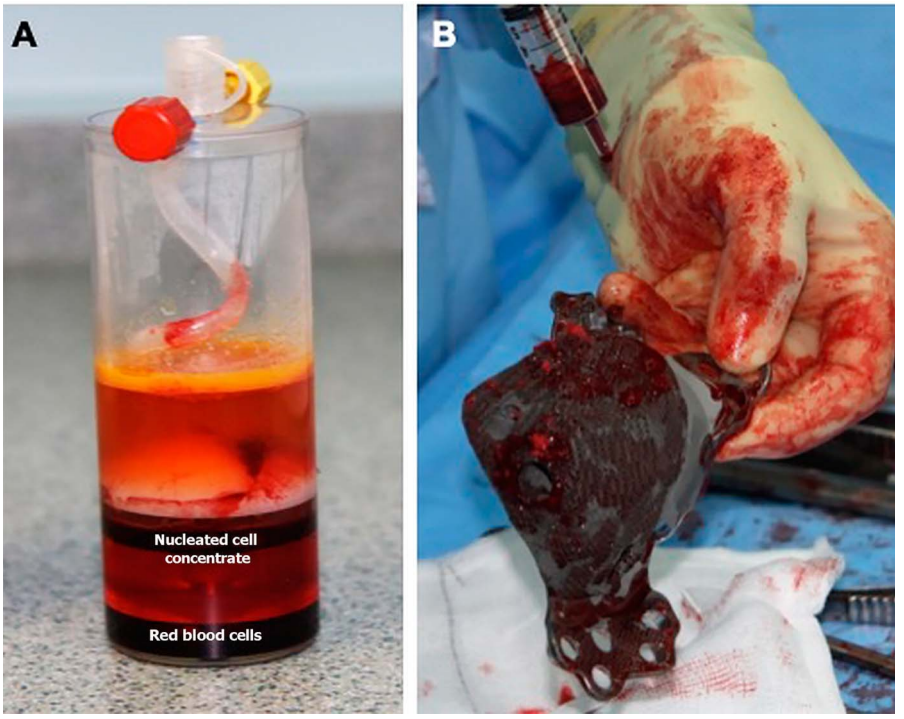

Fig. 2

Fig. 2-A Marrowstim tube (Zimmer Biomet) showing distinct layers of separation of nucleated cells from red blood cells following centrifugation. **Fig. 2-B** Application of the nucleated cell fraction to the backside surface of the definitive implant.

objective of this study was to review implant survivorship and clinical outcomes. Secondary objectives included the review of complications and radiographic outcomes.

Materials and Methods

We performed a retrospective review of all patients who underwent surgical implantation of a custom 3D-printed triflange prosthesis with dual-mobility bearings for the treatment of Paprosky 3B acetabular defects between 2014 and 2020. Patients eligible for treatment with the custom rather than "off-the-shelf" implants were those with complex massive bone loss, previous failure of acetabular revision with conventional techniques, and presence of pelvic discontinuity. Ineligible patients included those with known hip infection and those who were unfit for a major surgical procedure. All patients had previously been declined for re-revision at another institution, and therefore treatment with custom implants at our institution was considered a final, definitive attempt at restoring hip function.

Consent was obtained from each patient in accordance with local ethical guidelines. Operative treatment and follow-up visits were performed by the senior author (D.G.D.) in the university hospital setting.

Implant Construct and Implantation

Acetabular revisions were performed with use of an aMACE triflange component in all cases. All acetabular defects were massive and complex, and there was a high proportion of cases with pelvic discontinuity.

The aMACE implant, which comprises an integrated cup, flanges, and a defect-filling porous augment (Fig. 1), was designed to restore hip-joint anatomy while avoiding the cup center lateralization and ensuring appropriate flange sizing—potential

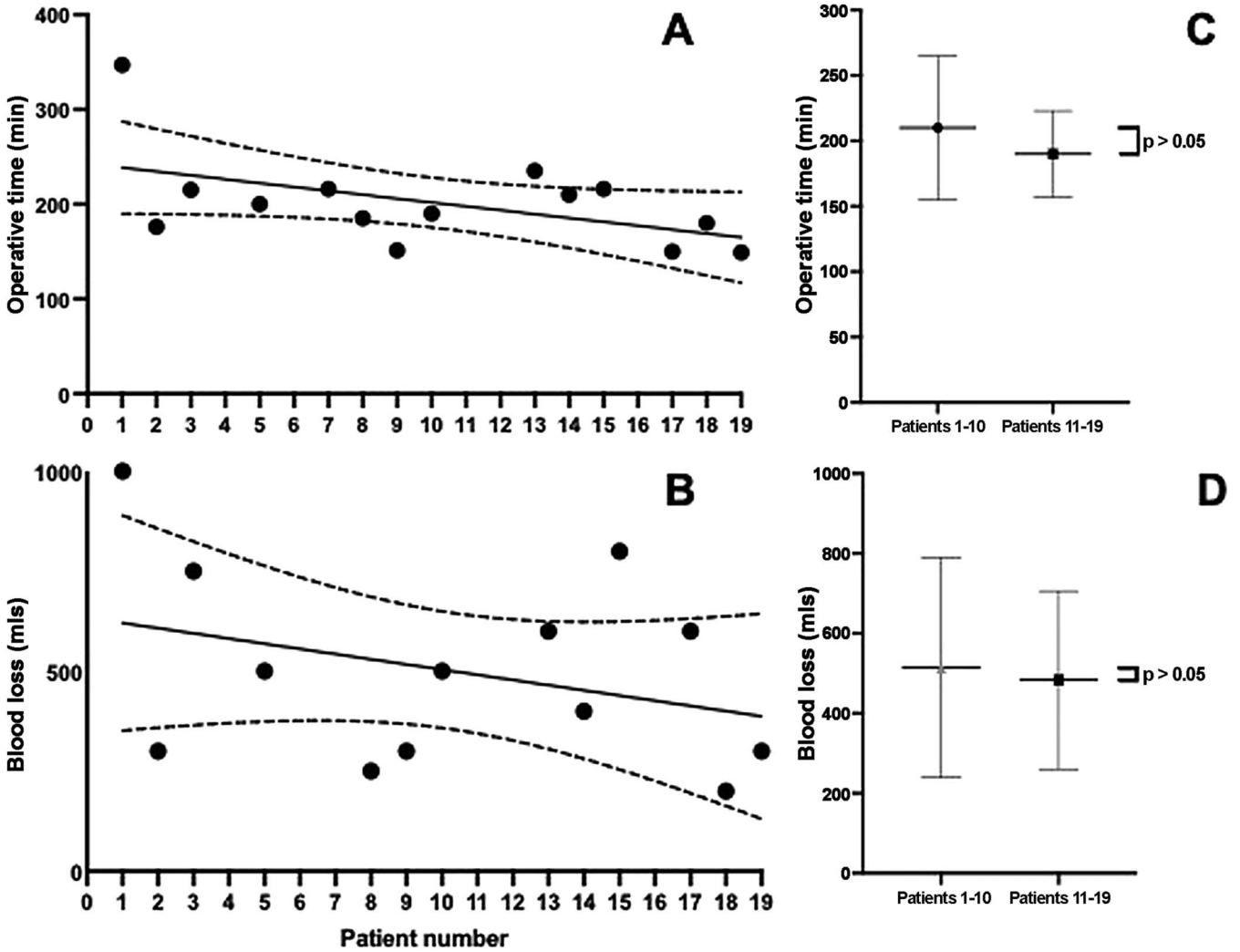

Fig. 3

Figs. 3-A and 3-B Operative time (**Fig. 3-A**) and blood loss (**Fig. 3-B**) plotted against sequential patient order, showing linear regression results with 95% confidence intervals. **Figs. 3-C and 3-D** Comparison of the mean operative time (**Fig. 3-C**) and blood loss (**Fig. 3-D**) between the first 10 and subsequent 9 patients to illustrate the learning curve. Whiskers indicate the standard deviation.

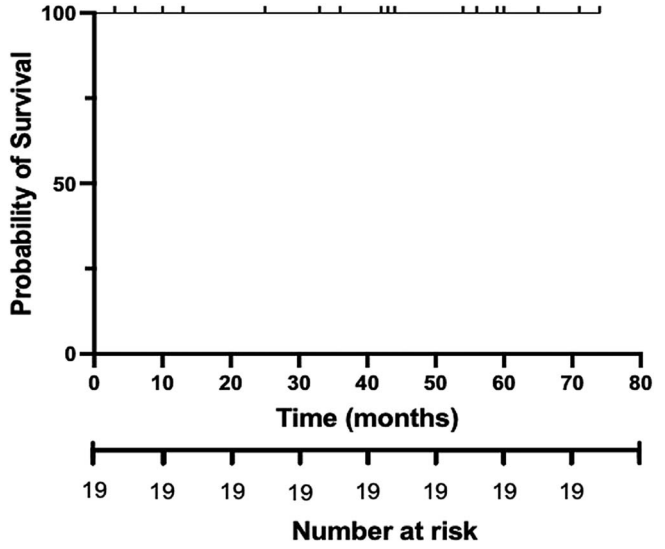

Fig. 4

Kaplan-Meier curve of overall implant survival. Time zero is the time of the total hip replacement revision. The x axis shows time (in months) since the surgical procedure, with the number of patients at risk for re-revision (i.e., those with implants still in situ) listed underneath.

problems when utilizing this implant in smaller patients. The issues may arise as a result of spatial constraints restricting the volume of the implant balanced against the implant structural strength and the size of the socket, as well as the flange sizes balanced against the optimal fixation and screw orientation. Each implant was designed with use of the Mimics Innovation Suite (Materialise) in order to create accurate 3D models based on segmented computed tomography (CT) analysis of acetabular defects, followed by virtual implantation. Provisional plans were reviewed by the lead surgeon, including guidance regarding the spatial relation of the implant to the local soft tissues, particularly screw trajectory. The surgeon tended to reduce leg-length correction (accepting a higher center of rotation) in cases with substantial, longstanding shortening because of technical issues associated with lengthening and to avoid substantial neurovascular stretching. Once validated, the models were exported to a 3D printer and fabricated from titanium with use of laser-melting additive manufacturing. The personalized fit enabled maximal host bone contact, enhancing bone preservation and primary stability. There were a number of cases of unexpected minimal bone defects following explantation of the previous implant; the first of these cases was treated with bone grafting, which was found to complicate the implant fit, and so all subsequent cases were left unfilled. Multiple screws with a predetermined trajectory targeting the best remaining bone stock were utilized to augment implant fixation in these often-osteoporotic patients, among whom there was a high proportion of pelvic discontinuity. Although uniquely pathology-specific, implant stability was generally achieved with a minimum of 3 ischial, 2 pubic, and 2 long iliac screws toward the sacrum and 3 iliac blade screws, with an average of 14 to 16 screws per construct.

Intraoperatively, the aspiration of autologous bone marrow from the posterior iliac spine and isolation of the nucleated cell population containing skeletal stem cells were performed as previously described[15]. This cell concentrate was applied to the porous backside surface of the prosthesis prior to the surgical procedure (Fig. 2).

Following implantation, dual-mobility cups (SERF), ranging from 47 to 51 mm, were cemented into the cup component, allowing for further adjustments of the acetabular cup alignment. Femoral components always underwent head exchange, but the stems were retained if no loosening was demonstrated.

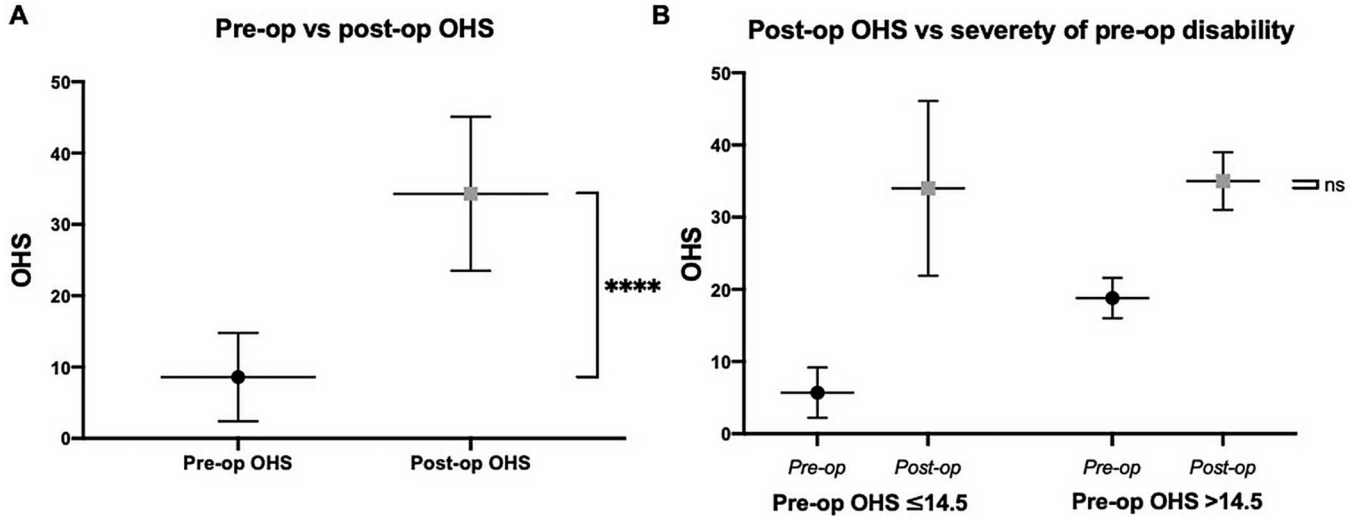

Fig. 5

Fig. 5-A Graph showing the preoperative and postoperative mean OHS. Whiskers indicate the standard deviation. ****P < 0.0001. **Fig. 5-B** Graph showing the preoperative and postoperative mean OHS among patients with a preoperative OHS ≤14.5 and >14.5. Whiskers indicate the standard deviation. ns = not significant (p > 0.05).

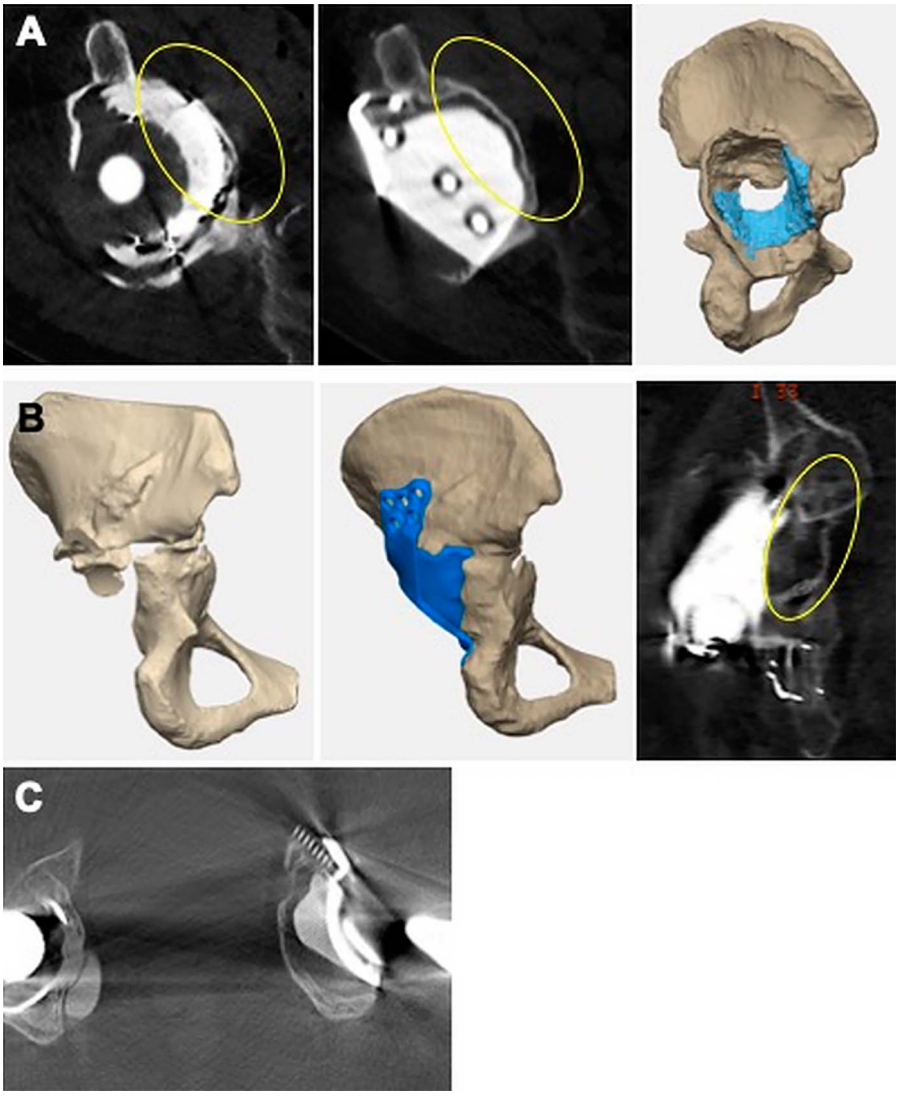

Fig. 6

Fig. 6-A CT scans and 3D reconstructions showing medial acetabular defect restoration by newly formed bone. **Fig. 6-B** Comparison of a 3D reconstruction showing healed pelvic discontinuity versus a CT scan showing only patchy bone islands within the defect. **Fig. 6-C** CT scan showing overlapping beam-hardening artifact, resulting in an overestimation of bone formation. Note the straight artifact edges.

Clinical Outcome Assessment

The operative database was queried for operative time, blood loss, complications, and implant failure. Implant survivorship was calculated utilizing all-cause re-revision as an end point and was presented as a Kaplan-Meier graph.

Functional outcomes were assessed with use of the modified Oxford Hip Score (OHS), which is scored from 0 to 48, with 48 representing the best possible outcome[16]. Change in function was calculated by comparing preoperative and postoperative OHS.

Imaging Evaluation

Radiographic evaluation was performed preoperatively, immediately postoperatively, and annually thereafter. Pelvic discontinuity was identified as either a visible fracture line through the anterior and posterior columns, a break in the Kohler line with medial translation of the inferior aspect of the hemipelvis relative to the superior aspect, or asymmetry of the obturator rings with rotation of the inferior aspect of the hemipelvis relative to the superior aspect[3].

Postoperatively, radiographic evaluation focused on host integrity, implant position and stability, bone defect infill at the interface, and pelvic discontinuity healing. Implant stability was assessed according to the acetabular cage-loosening criteria, including horizontal and/or vertical migration of >5 mm, a complete or progressive radiolucent line medial and superior to the implant or around the screws, hardware breakage, and progressive radiolucency medially or superiorly[4].

Restoration of the hip center of rotation was assessed in relation to the preserved teardrop and native contralateral hip.

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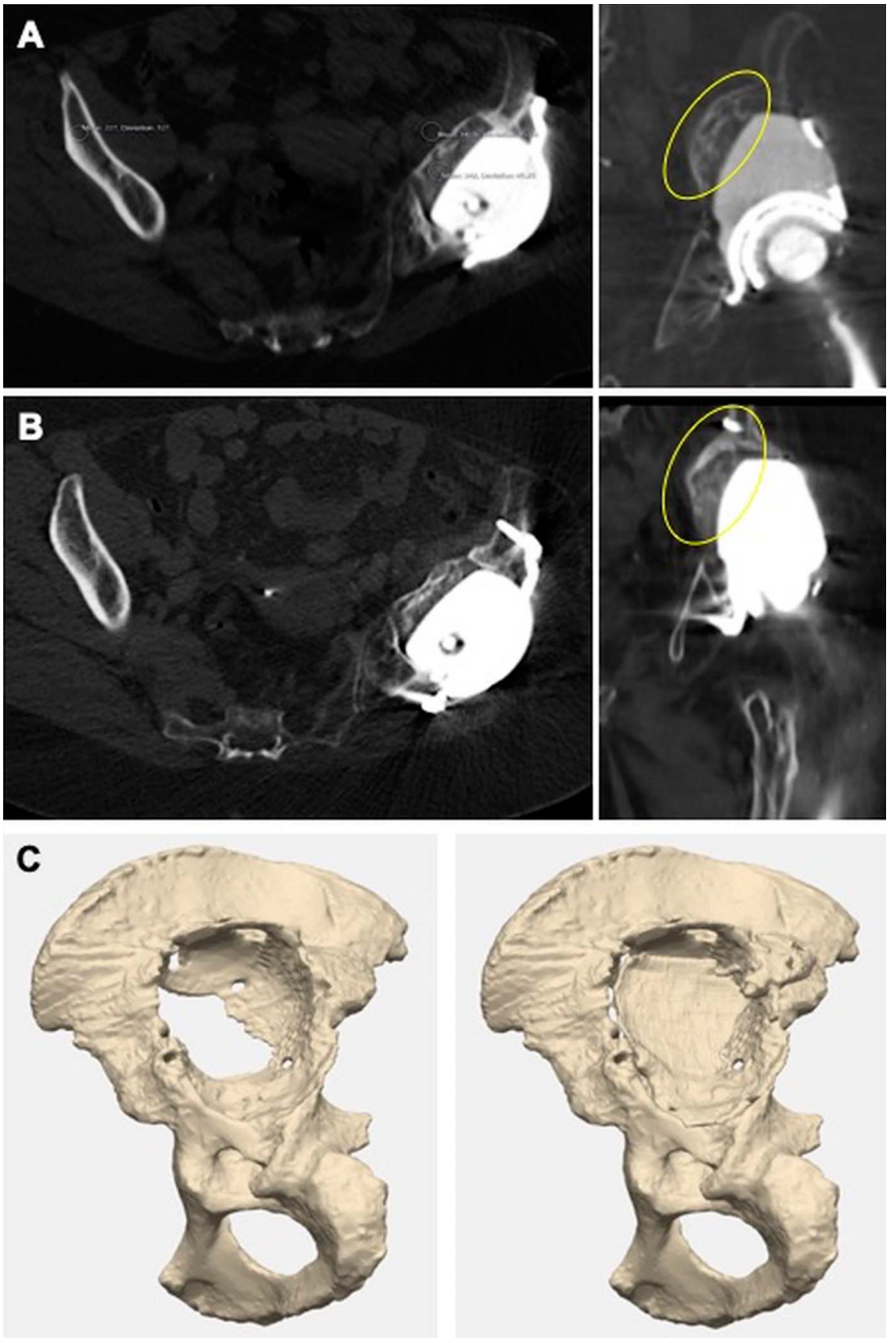

Fig. 7

Fig. 7-A CT scans made 3 months postoperatively showing the bone graft filling the remaining acetabular defect underlying the implant. **Fig. 7-B** CT scans made 5 years postoperatively showing bone graft incorporation. **Fig. 7-C** 3D reconstructions showing the original cavitary osseous defects (contained by fibrous tissue) and the layer of bone graft incorporated into the acetabular floor defects.

CT analysis was performed with use of a Discovery-CT750HD multidetector scanner (GE Healthcare) at 140 kV with 1.0-mm slice thickness and a bone reconstruction algorithm. Preoperative CT scans were obtained according to the specified standardized protocol (Materialise). Postoperative CT scans were performed in order to evaluate the progress of implant osseointegration in cases with minor static radiolucencies at the bone-implant interface.

Postoperative multiplanar CT reformats were assessed by a musculoskeletal radiologist for component-host integrity, evidence of new bone formation at the bone-implant interface, and healing of pelvic discontinuity. Implants were assessed for

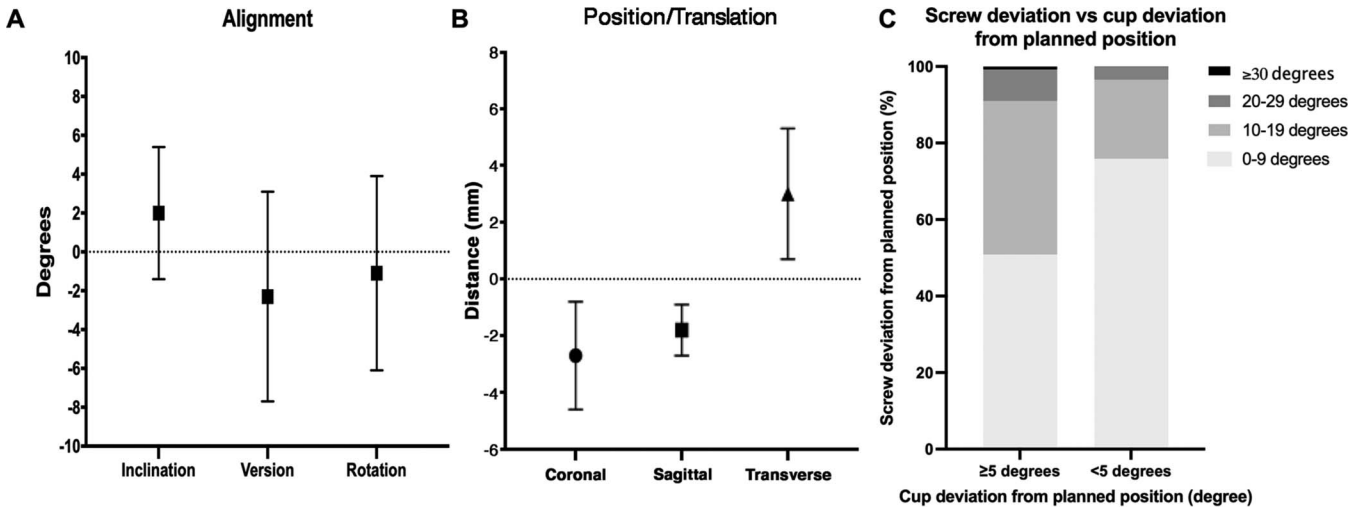

Fig. 8

Figs. 8-A, 8-B, and 8-C Graphs showing the mean deviation of the implant alignment, position, and screw position from the preoperative plan. **Fig. 8-A** Deviation of implant alignment in terms of inclination (positive values = open, negative values = closed), version (positive values = anteversion, negative values = retroversion), and rotation (positive values = clockwise, negative values = counterclockwise). Whiskers indicate the standard deviation. **Fig. 8-B** Deviation of implant position as measured in the coronal (positive values = anterior, negative values = posterior), sagittal (positive values = medial, negative values = lateral), and transverse (positive values = superior, negative values = inferior) planes. **Fig. 8-C** Deviation of screw position, shown as the percentage of screws that deviated by various amounts in implants with cup deviation of ≥5° and <5° from the preoperative plan.

alignment (i.e., inclination, version, and rotation) and translation. Based on the CT data sets, Materialise software was utilized to produce color-coded 3D reconstructions.

Osseointegration was defined as a region of direct contact between the implant and the adjacent bone without interposed radiolucent lines or in the localized area between the implant and bone with radiating trabecular lines.

Data Analysis

Statistical analysis, calculating means and standard deviations, was performed with use of Microsoft Excel for MacOS (version 16.16.21). Univariate analysis was performed with use of the Mann-Whitney test. Graphs were generated with use of Prism for MacOS (version 8.4.3; GraphPad).

Source of Funding

No external funding was received for this study.

Results

Clinical Outcome Assessment

Unilateral acetabular component revision with an aMACE implant was performed in 19 patients, including 11 women and 8 men, with a mean age of 77 years (range, 53 to 91 years). All patients had previously undergone ≥3 hip replacements and/or revisions. The mean follow-up was 53 months (range, 17 to 88 months; mode, 57 months).

All 19 patients had Paprosky 3B defects. Pelvic discontinuity was identified in 6 patients and suspected in an additional 2 patients (42% total). Pelvic discontinuity was suspected in cases with an intraoperative finding of disproportionate movement of the inferior part of the hemipelvis in relation to the superior aspect as well as the presence of substantial bone loss, usually extending across the anterior and posterior columns. Intraoperatively, the femoral stem was retained in 10 patients (53%). All 19 revisions were performed for aseptic cup loosening with no evidence of infection.

The overall mean operative time was 201 minutes, with operative time trending shorter over the duration of the study (i.e., 347 minutes for the first patient, which was a significant outlier, 176 minutes for the second patient, and 149 minutes for the final patient) (Fig. 3). The mean blood loss was 500 mL, and blood loss trended lower over the duration of the study (i.e., 1,000 mL for the first patient, a significant outlier, 300 mL for the second patient, and 200 mL for the second-to-last patient). Although the overall trend was for shorter operative time and lower blood loss, there was no significant difference in the mean values of either operative time or blood loss between the first 10 patients and the last 9 patients ($p > 0.05$).

All patients had standard annual follow-up visits. The cumulative implant survival was 100%, with 19 hips remaining at risk (Fig. 4). Two patients suffered a notable sciatic nerve palsy that was related to leg lengthening, both with stem retention; 1 of these cases was recurring. There were no dislocations or fractures.

Functional Outcomes

Postoperative OHS scores were available for all patients. The average OHS improved significantly, from 8.6 (range, 0 to 22; mode, 6) preoperatively to 35 (range, 10 to 48; mode, 42) postoperatively ($p < 0.0001$) (Fig. 5).

Imaging Evaluation

Implant Integration

Postoperative radiographs revealed no acute periprosthetic fractures and no evidence of implant loosening, migration, or failure of metalwork.

All 15 patients who required postoperative CT scans demonstrated evidence of periprosthetic new bone formation at a mean of 30 months (range, 1 to 69 months) postoperatively. The CT scans performed at 1 month postoperatively were in a patient who experienced a fall and were performed in order to ensure maintenance of construct integrity, not as a part of routine follow-up. In most cases, new bone formation was observed in areas of acetabular roof stress-loading and/or located adjacent to the flanges or fixation screws, with 8 patients showing partial restoration of defects at the medial wall (Fig. 6). Cortical breaches in pelvic discontinuity showed partial healing (Fig. 6). All CT scans were partially degraded by metal-induced beam-hardening artifact; however, no evidence of loosening, migration, or failure of metalwork was observed.

Although 3D-reconstruction images revealed evidence of new bone formation at the bone-implant interface, the new bone was found to be less extensive on axial and multiplanar CT reformats, calling into question the reliability of the 3D reconstructions.

Additional bone grafting at the time of implant insertion was utilized in the first patient of the series only. Progressive bone graft consolidation was demonstrated on 2 postoperative CT scans (at 14 and 55 months) (Fig. 7).

Implant Alignment and Position

Postoperative implant position and alignment showed excellent correlation with the preoperative plan ($p > 0.05$) (Fig. 8). Although the means of all measured parameters revealed minimal deviation, the cups tended to have minimally more deviation from the preoperative plan. Screw position discrepancy was more pronounced, with deviation of ≥20° identified in 8% of all screws (i.e., 60% of patients had ≥1 screw deviating by ≥20°). Screw deviation was found to be linked to the amount of cup-cage deviation from the planned position. No clinical consequences were noted for these deviations.

The mean center of rotation of the revised hip was displaced by 2 mm (range, 1 to 4 mm) on the horizontal axis and 2 mm (range, 0 to 3 mm) on the vertical axis compared with the nonoperative contralateral limb, as measured in the 5 patients for whom these data were available.

Discussion

The findings of the present study were encouraging, particularly the excellent early to mid-term implant survivorship and patient functional improvement.

The planning process and availability of patient-specific plastic practice models permitted a superior understanding of pathology and enhanced orientation, facilitating technical operative steps and diminishing the supplementary inventory required for successful acetabular reconstruction. The relative ease of implantation led to reduced operative times and blood loss, in turn reducing the risk of infection and other operative complications[17] and improving theater efficiency compared with other techniques. Surgical proficiency improved throughout the 19 cases, with mean operative times of 210 and 190 minutes and mean blood loss of 514 and 483 mL for the first 10 and subsequent 9 patients of the series, respectively. Typical operative times for the last few cases, once the previous implants had been removed and the acetabulum had been prepared, were <1 hour. A previous study reported a mean operative time of 173 minutes among 8 patients with Paprosky 3B defects who underwent implantation of a Pro-Made custom implant (Lima)[18]. In our experience, aMACE implants were better suited for more complex configurations of acetabular defects, with preoperative investigations guiding the implant choice. In turn, the complexity of the underlying pathology likely affected operative times.

There were no cases of postoperative implant loosening, migration, or failure, whereas new bone formation was observed, particularly in the weight-bearing aspect of the bone-implant interface. These findings suggest a mechanically improved environment, leading to stabilization of the preoperative pelvic discontinuity and attainment of implant osseointegration. Satisfactory bone-implant contact was demonstrated, which suggests adequate contact attained at initial implantation and/or postoperative infill of residual defects through de-novo bone formation (Fig. 8). The process of osteogenesis at the interface was triggered by an osteoconductive/osteoinductive implant topography and was potentially further enabled by skeletal stem cells on the implant surface[15]. The definitive nature of each revision in this cohort was deemed critical, and we previously demonstrated the osteogenic potential of aspirated skeletal stem cells[15]. Therefore, we postulated that the use of skeletal stem cells was justifiable because of the potential regenerative benefits and the negligible associated cost (~£400) and risk. Skeletal stem cell concentrates were purposely seeded onto the backside surface, and the effectiveness of this treatment was further augmented by skeletal stem cells routinely dislodged during bone preparation and hardware implantation. This method of enhancing osteogenic capacity, previously advocated in complex hip reconstructions[19], may also improve healing following treatment of pelvic discontinuity, although no firm conclusions on its efficacy can be drawn from the present study.

Despite the complexity of intraoperative implantation, we demonstrated excellent conformity between the preoperative plan and the postoperative implant alignment and position. These results were similar to previously published data[14]. Strengths of the preoperative planning and implant design included the targeting of good bone stock and safe anatomical zones for the augmentation screws. We identified ≥20° deviations from the preoperative plan in 8% of all screws, likely caused by minor deviation from the planned implant position (24% and 49% of screws deviated by >9° in constructs that deviated by <5° and ≥5°, respectively). Although alarming, as screw deviation could both jeopardize the implant fixation and

damage the adjacent anatomical structures, major screw deviation was relatively rare. Nevertheless, the surgeon should remain vigilant during the implant positioning and fixation, and further implantation refinements are required. Of note, these deviations were not sufficient to raise concerns on the postoperative radiographs.

We demonstrated a stark functional improvement in this complex patient cohort. The improvement was similar to that with other techniques reported for acetabular defect reconstructions[4-9]. It should be emphasized, however, that custom implants in the present study were utilized among patients in whom other means of acetabular reconstructions were deemed inadequate or had previously failed.

The functional outcomes in the present study were similar to those reported for aMACE implants by Hipfl et al., although 27 of 35 patients were lost to follow-up in that study[13]. The superior survivorship observed in the present study (100%) may be a result of our patients presenting with aseptic loosening only. This cohort was uniformly more complex, comprising only Paprosky 3B defects with a high prevalence of pelvic discontinuity. We utilized dual-mobility bearings in all cases, which may explain the 0% rate of postoperative instability. We did not use additional hardware to stabilize the pelvic discontinuity or to reconstruct the acetabular defects, relying entirely on the physical morphology of the custom implant.

In a systematic review of custom acetabular implants in revision cases with severe bone defects, the rate of reoperation was 19.3% ± 17.3% and the rate of re-revision was 5.2% ± 4.7%[20]. Reconstruction of severe acetabular defects with antiprotrusio cages has a reported failure rate of 25% at 5 years, which increases to 50% when there is associated pelvic discontinuity[21]. Kosashvili et al. reported a rate of implant migration of 11.5% with use of antiprotrusio cages and Trabecular Metal (Zimmer Biomet) acetabular components for the treatment of severe bone loss and pelvic discontinuity[4]. The use of cup-cage constructs resulted in rates of re-revision of 8% and 9% in cases with and without pelvic discontinuity, respectively, at 5 to 6 years of follow-up[9].

The present study had limitations. Specifically, this study was retrospective, had a relatively short follow-up, and had a small patient cohort. However, only the most complex acetabular revisions were selected for inclusion. The use of custom 3D-printed implants introduced a number of variables, as each patient-specific unit was unique and defied capture into sizeable cohorts for accurate evaluation over time. We acknowledge the presence of implant heterogeneity, which may affect long-term results. However, the heterogeneity of the patient cohort is representative of the clinical reality and contributes to the pragmatism of this study. There was also a selection bias, as only the most severe cases were selected for revision with a custom implant. An introduction of a comparison group would have compromised the ethical consideration of giving these often elderly and frail patients the optimal definitive treatment.

Conclusions

Despite heterogeneity in baseline patient pathology and physiology, the use of an aMACE triflange implant to restore Paprosky 3B defects, even in cases with pelvic discontinuity, resulted in excellent implant survivorship and functional improvement. The benefit of these custom implants lies in their suitability for more complex clinical scenarios, speed of implantation, and predictable hip anatomy restoration, as well as the favorable functional and survival outcomes. ■

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