Custom 3D-Printed Acetabular Implants for Complex Revisions: Medium-Term Follow-up

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Abstract

Custom 3D-printed acetabular implants are an exciting new technology being used in hip surgery with ever-increasing frequency. They have been used in New Zealand and Australia to reconstruct severe bone deficiency since the mid-2000's. However, there are few cohort studies and very little published regarding cost-effectiveness.

We performed a retrospective cohort study of 20 patients who had a unilateral revision using a custom 3D-printed acetabular implant (Ossis, Christchurch, New Zealand). Clinical evaluation comprised Oxford Hip, Harris Hip and WOMAC scores. Radiographs were evaluated to classify the preoperative acetabular defect and assess postoperative restoration of biomechanical hip centre and osseointegration.

The mean age of the patients at surgery was 66 years (range 53 to 79, standard deviation 7.42) and the mean follow up was 48 months (range 29 to 87, standard deviation 18). Four patients were not included in the results analysis; one patient who had infection present prior to revision had a re-revision due to septic loosening, one patient died due to metastatic cancer despite her custom acetabular implant performing well, one patient was unwilling to participate in the study and one patient received an Ossis custom implant as a successful primary treatment due to a fracture secondary to myeloma. The 16 patients included in the results analysis, had their pre-operative X-Rays assessed independently to classify each defect using the Paprosky and Gross classifications (9 Paprosky 3b, 2 Paprosky 3a, one patient Paprosky 2c, two patients Paprosky 2b and two patients Paprosky 2a). The post-operative hip centre was restored in 12 of the 13 patients assessed for hip migration (92%) and the Moore score for osseointegration showed evidence of osseointegration for all 16 patients. The mean Oxford Hip Score was 47/60 (range 34 to 58, standard deviation 7.13) at the final follow up. The mean Womac Score was 94/120 (range 67 to 120, standard deviation 16.8) at the final follow up. The mean Harris Hip Score was 80/100 (range 36 to 100, standard deviation 15.5). In a heterogeneous group with severe bone loss the Ossis custom acetabular implants performance was encouraging at mid-term.

Introduction

Acetabular revision surgery in the presence of major bone loss is challenging. The New Zealand Joint Registry reports a revision rate for primary total hip replacements of 5.65%, with re-revision rate of 0.75% in a sixteen-year review period. Non custom made implants are available for such cases, but suffer from sizing discrepancies and non-modifiable fixation point design. Therefore, they do not necessarily match the defect and often require excision of significant quantities of bone, with potential loss of structural integrity in attempting to achieve stability. Additively manufactured custom made acetabular implants were designed by surgeons in collaboration with engineers to help overcome the problems of poor fit, loosening, prolonged rehabilitation and surgical complexity engendered by substantial bone loss.

We report a retrospective observational study outcome of 16 patients revised for failed acetabular components with associated severe bone loss between November 2007 and July 2013. All cases utilised an additively manufactured Ossis custom acetabular implant incorporating an integral porous scaffold.

To date, there have now been a total of 100 Ossis custom acetabular implants manufactured and inserted with no re-revisions, but the authors felt that a minimum two-year follow-up was necessary to assess clinical and radiological outcomes.

Patients and Methods

Patients undergoing revision of a hip replacement with a custom acetabular implant, (Ossis, Christchurch, New Zealand) between November 2007 and July 2013, were eligible for inclusion in this retrospective observational study, which was submitted for but not deemed to require ethical approval (Ethical committee approval reference 16/NTA/37)[1]. All patients gave informed consent to allow access to surgical and post-surgical follow-up data from their medical records, and to complete follow-up surveys, clinical examination and x-ray evaluation. Patients were usually re-assessed at 3 months, 6 months, 1 year, and annually thereafter.

The decision to use a custom implant was made by the surgeon for each individual patient based on anatomy that was considered unsuitable for an off-the-shelf product. Eight of the patients presented with severe osteolysis resulting in large defects. Additionally, four patients had pelvic dissociation due to osteolysis. Three patients presented with loosening due to infection and one patient had had multiple surgeries secondary to hip dysplasia. All operating surgeons were experienced in revision arthroplasty. Septic loosening revisions were all carried out in two stages. Postoperative instructions, and clinical follow-up were not standardised but were based on the routine clinical practice at each centre.

On receiving a prescription for a custom acetabular implant, radiographs and a CT scan organised by the operating surgeon, were assessed with regard to the patient's anatomy and degree of bone loss. Ossis' biomechanical engineers created a high definition 3D computer model of the anatomy from the CT scan data. Taking into account the surgeon's requirements and the individual patient's anatomical deficiency they then designed a custom triflange acetabular implant to fit the pelvic defect. Individualised screw placement, trajectory and length were designed for each implant to enable locking head screws to be placed with safety and adequate surgical access into the best available bone stock. Porous scaffolds were designed to maximise bony apposition and ingrowth. When the surgeon and engineer were happy with the design, the CAD file was sent for manufacture. A sterilisable plastic anatomical model and an implant trial were 3D printed for pre-operative and intra-operative planning purposes.

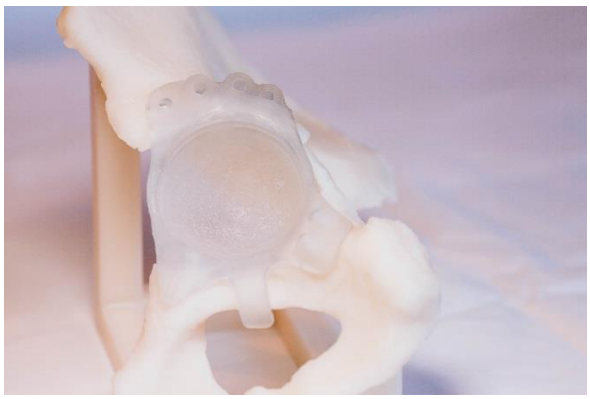

Figure 1 Plastic Anatomical Model and Implant Trial

Ossis utilises advanced imaging, design and manufacturing technologies to produce the custom triflange acetabular implant. This implant is manufactured of titanium alloy metal using additive manufacturing (AM) technology. This additive manufacturing technology produces a single piece, integrated, solid-porous implant by fusing metal particles layer by layer. The AM allows highly osteoconductive bone tissue scaffolds to be manufactured integrally with the solid shell and flanges providing increased osseointegration and reduced mechanisms for failure of the device. The porosity of the scaffold areas is 70%. The custom nature of the imaging and manufacturing processes enables the implant to fit the patient's bony anatomy precisely, leading to minimal bone resection where little bone remains allowing for ease of insertion, facilitating the promotion of osseointegration.

Figure 1 Ossis Custom Triflange Acetabular Implant

The surgical approach in all cases was posterior. Anaesthetic preference (general or spinal/epidural) was at the discretion of the operating surgeon's anaesthetist. Routine thrombotic embolic prophylaxis was employed. Initial dissection was confined to approaching the acetabulum but if femoral surgery was required, the approach was extended to include, if necessary, a trans femoral osteotomy. The acetabulum was cleared of the bone cement and membrane. Complete visualisation of the acetabular circumference was effected. The plastic anatomical bone model and resected bone model shows both the presenting anatomy before the acetabulum is first exposed and after acetabulum preparation is complete. By using these two plastic components as references, a burr is used to shape the bony acetabular margin until it conforms to the shape of the plastic implant trial. The plastic implant trial is used to confirm perfect fit before the definitive prosthesis is inserted. Having achieved excellent apposition of the trial implant with host bone, the definitive prosthesis is introduced and screwed into position using locking screws. The rotational orientation, angle of inclination and screw depth have all been predetermined by the engineers constructing the prosthesis and it merely remains for the surgeon to insert the screws. After establishing rigid fixation, an acetabular component of the surgeon's preference is then cemented in position. Trial reduction with the femoral component is then effected before irrigation and wound closure.

Post operation management varied from fully weight bearing to partial weight bearing for 12 weeks and was at the surgeon's discretion.

Patient demographical data, hip replacement surgery history and clinical characteristics were obtained from patient medical records. Acetabular bone defects were categorised prior to surgery using the Gross classification[2] and the Paprosky classification[3] by an independent radiologist.

Post-operative patient self-assessments using the Oxford Hip Score (OHS - Range 0 – 60)[4], and the Western Ontario & McMaster Universities Arthritis Index (WOMAC - Range 0 – 120)[5] were mailed to the patients to complete and return to the investigator. Post-operative clinical assessment using the Harris Hip Score[6] was completed by an independent surgeon where possible, or the prescribing surgeon if not. In addition, the classification of Moore et al[7] was used to assess osseointegration of the custom implant. Features assessed for the Moore classification included absence of radiolucent lines, medial stress shielding, a superolateral buttress, radial trabeculae and an inferomedial buttress. According to the Moore's criteria, the presence of three or more signs has 97% accuracy in predicting osseointegration, and fewer than two signs predicts lack of osseointegration in 83%. The hip centre of rotation was measured relative to the inter teardrop line on the pre-operative and post-operative x-rays.

The definition of failure was either re-revision due to aseptic loosening or a post-operative Oxford Hip Score of less than 30. Radiographic failure was defined as >3mm vertical or horizontal hip centre migration and <2 Moore criteria.

Table 1. Patient Demographics

Measure	Mean	Range
Number of patients	16	
Sex	7 Female 9 Males	
Age (years)	66	53 - 79
Follow Up (months)	48	29 - 87
Indication	Osteolysis – 8 Pelvic Dissociation - 4 Infection - 3 Dysplasia – 1	
Paprosky Classification	Paprosky 2a - 2 Paprosky 2b - 2 Paprosky 2c - 1 Paprosky 3a - 2 Paprosky 3b - 5 Paprosky 3b + Discontinuity – 4	
Gross Classification	I - 1 II - 1 III - 6 IV - 7 V - 1	
Operations Prior to Ossis Surgery	1.69	0 - 3

Statistical analysis

Formal statistical analysis was not performed as the number of patients in the study was considered to be too small to produce statistically significant information.

Results

In all, 16 patients were included in the results below, across 9 surgeons in both New Zealand and Australia. Of the 20 patients included in the study, there was one revision of the custom acetabular implant due to septic loosening. One patient died due to metastatic cancer. One patient was not willing to participate in the study. One patient received an Ossis custom implant as a primary treatment due to a fracture secondary to myeloma. These 4 patients were not included in Table 1 or the results below.

Data was available for a total of 16 patients treated by 9 different surgeons at 7 centres in New Zealand and Australia. Patient demographic and clinical characteristics at baseline are shown in Table 1. The major indication for a custom acetabular implant was gross osteolysis in the majority of patients. The posterior approach was used for all patients; duration of surgery was known for 9 patients and was 3.17 to 5.17 (mean 4.3) hours. Surgical times were influenced by the necessity to deal with femoral pathology at the time of the procedure.

There were three reported complications; one pulmonary embolism, one case of heterotopic ossification and one case of deep infection.

16 patients were reported to be doing well at >2 years follow up according to clinical and radiographic review.

None of the 16 patients had evidence of aseptic loosening and all had a post-operative Oxford Hip Score greater than 30. According to the Moore's criteria, the hip centre of rotation was restored in 12 of the 13 patients assessed for hip migration (92.3%) and 16 of the 16 patients (100%) had greater than 2 Moore criteria for osseointegration prediction.

Table 2. Clinical Results

Measure	Mean	Range
Oxford Hip Score	47/60	34 - 58
Womac	94/120	67 – 120
Harris Hip Score	80/100	36 - 100
Survivorship	16/16	

Table 3. Radiological Results

No Radiolucent Lines	8/16 (50%)
No Medial Stress Shielding	10/16 (62.5%)
Superolateral buttress present	14/16 (88%)
Radial trabeculae present	13/16 (81%)
Inferomedial buttress present	11/16 (69%)
>2 Moore Criteria	16/16 (100%)
Migration of Hip Centre	12/13 (92%)

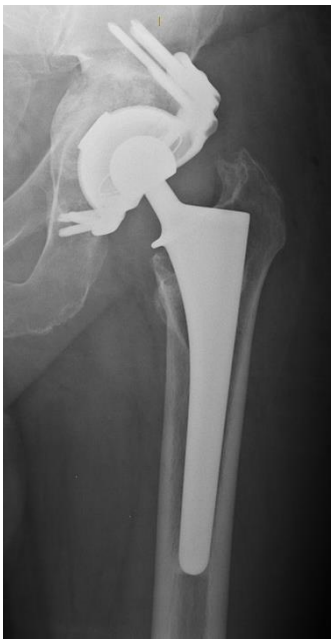

Figure 3 Post-Operative Radiograph with Ossis Custom Triflange Acetabular Implant In Situ

Discussion

Techniques available to deal with severe acetabular bone loss include:

- Allografts
- Off-the-shelf components including cup cages and augments
- Impaction Grafting
- Custom Implants

Gross et al[8] reported the results in 32 patients (33 hips) that were treated using a combination of structural allograft and cages with a mean follow up of five years. Six patients required revision for acetabular prosthetic loosening with a stable osseointegrated graft. A further eight patients required revision for acetabular loosening and graft failure including one patient secondary to sepsis. One patient required reoperation for a sciatic nerve palsy. The overall success rate was considered to be 55%.

Off the shelf components such as Birch Sneider Cup Cages and Zimmer Trabecular Metal Acetabular Revision System (TMARS) have been used to treat Paprosky Type 3a and 3b defects. Gross et al[9] reported on the survivorship of 26 pelvic discontinuities at a mean follow up of 82 months. This technique involves placement of a Trabecular Metal shell in contact with a mixture of bleeding host bone and morsellised allograft. The seven-year survivorship was 87.2% for the cup cage group.

Gross et al[10] presented the mid-term review for 34 patients receiving a Trabecular Metal acetabular shell and one or two augments, with a mean follow up of 64.5 months. Hip centre of rotation was restored in 27 patients and the Oxford Hip Score was 37.7 at follow up. There were three aseptic loosening's and the author concluded that the trabecular metal shell and augments might not be a reliable option for treating pelvic discontinuities. Additionally, bone has to be removed to allow for defined augment shapes to fit the defect, thus further compromising the already limited bone.

Impaction grafting of morsellised bone combined with cemented fixation of primary implants is commonly used in revision hip surgery because it offers the opportunity for regeneration of bone stock. Although initial studies have shown good results, E H van Haaren et al[11] reviewed the results of 71 revisions of the acetabular components in total hip replacements, using impaction of bone allograft. At a mean follow up of 7.2 years, a total of 20/71 acetabular components required re-revision for aseptic loosening giving an overall survival of 72%.

Custom implants are a recent option used for treating severe bone defects.

CC Berasi et al[12] reported on 26 patients (28 hips) that had undergone acetabular reconstruction with custom triflange components. The minimum follow up was 2 years with a mean follow up of 57 months. 23 patients (24 hips) were assessed. Four hips required revision surgery: two failures secondary to sepsis, one stem revision and one open reduction internal fixation for periprosthetic femoral fracture. The remaining 19 components were noted to be well-fixed with no obvious migration or loosening. Harris hip scores were 65 at the latest follow up.

M J Taunton et al[13] reported on the retrospective review of 57 patients with pelvic discontinuities treated using a Pinnacle Triflange Acetabular System from Depuy. Minimum followup was 24 months with a mean follow up of 65 months. Twenty-eight patients (49%) required no further surgery at the time of follow

up. Forty-six (81%) had a stable triflange component. The average Harris score post-operatively was 75.

G E Holt et al[14] reported on the retrospective review of 26 hips with massive periacetabular bone loss reconstructed with a custom triflanged acetabular component. Mean follow up was 54 months. Twenty-three of 26 patients (88.5%) were considered clinically successful, with stable fixation. Three failures occurred. Two patients failed with pelvic discontinuity and one patient failed secondary to severe osteopenia.

M J Christie et al[15] reported the retrospective review of 78 hips in 76 patients in whom a large acetabular defect was bridged using a custom-designed, flanged component. 67 hips in 65 patients with an average follow up of 53 months were assessed. There was no further surgery to remove the triflange cups. Six patients received further surgery for recurrent dislocation. The average Harris hip score at follow up was 82 points.

While there are many studies with follow-up data on medium-term and long-term outcomes for patients treated with off-the-shelf products there is a paucity of such data for custom implants, particularly over the longer term. This is largely due to their relatively recent introduction and the comparatively small number of patients treated with custom acetabular implants to date.

16 patients have been studied, all of whom received an Ossis custom acetabular implant inserted between November 2007 and July 2013. All patients were assessed by the operating surgeon and were not considered suitable for an off the shelf device. At a mean of 4 years post operatively, none of the 16 patients had undergone a further revision procedure, nor had any radiological evidence of aseptic loosening.

We have compared the success of massive structural allograft with the Ossis custom made prosthesis, and Gross results demonstrate a success rate of only 55% compared to Ossis at 100%.

The results of the Ossis custom acetabular implant differ from Gross' reported results for off the shelf implants with augments, where three cases of aseptic loosenings occurred within comparable time frames. Further, the Oxford hip score reported by Gross was 37.7 at follow up, while the Ossis custom acetabular implant had a mean Oxford score of 47.

When we compare the success of impaction grafting with morseclised bone, with the Ossis prosthesis, the results suggest an improved outcome using an Ossis implant. Hareen's study, at a mean follow up of 7.2 years reported 28% incidence of acetabular loosening requiring a further revision. By comparison, no Ossis custom implants have been revised, with an overall survival rate of 100% to this point. It is appreciated that the Ossis custom implants have been studied over a shorter time period to those studied in Hareen's paper.

Comparing the results of the Ossis custom triflange implant at a mean follow up of 48 months with those reported by Berasi, Taunton, Holt and Christie, with an average mean follow up of 60 months, Ossis reported a post-operative Harris score of 80, compared to an average mean post-operative Harris score from the four papers reviewed of 75. Ossis report no dislocations post-operatively, however, the four papers reviewed report an average dislocation rate of 14.5%. There were no revisions of the Ossis custom acetabular implant, as compared to an average rate of triflange removal across four papers reviewed of 7%. Additionally, the rate of aseptic loosening of the Ossis custom acetabular implant of 0%, compares favourably against the average rate of aseptic loosening across the four papers reviewed of 6.65%. The Ossis custom acetabular implant compares favourably in overall survivorship against the other custom triflange implants reviewed.

Additionally, we recognise that as the population continues to age and healthcare costs rise, it may no longer be sufficient for prostheses to simply deliver superior clinical outcomes. The economic cost of those outcomes and their relativity will assume greater importance. An economic analysis carried out demonstrated the early stage assessment of cost savings resulting from the use of Ossis' custom acetabular implant in comparison to the use of tantalum shell and augment systems. Through discussions with industry and analysis of data provided by both public and private sector healthcare funders and providers, the authors have determined that on average the treatment of severe acetabular defects, in the public healthcare system, using an Ossis custom acetabular implant results in a total cost saving of approximately $5,309 in comparison to the use of tantalum systems. This cost saving stems mainly from improved bed and theatre utilisation and reduced risk of prosthesis failure and complications. The total cost saving represents a 14.3% saving on the estimated current total cost of treating severe acetabular defects using tantalum systems.

The authors feel the strengths of the study show that multiple surgeons all of whom are experienced in hip revision surgery, but none are sub-specialists in hip arthroplasty surgery alone, can obtain successful

results in treating severe defects due to osteolysis by using an Ossis custom acetabular implant. However, it is acknowledged that the study is limited by the fact that it is a retrospective study of a small sample size with a minimum follow up period of 2 years.

One of the weaknesses of this study has been the geographic separation of patients (Australia and New Zealand). Radiographic classification was dependent on the format of radiographs available and different radiology programmes are used in the two countries. Some X-Rays were presented as hard copy and therefore, hip centre migration was not able to be accurately assessed. In four patients, the ability to measure the hip centre migration was compromised because access to digitised data was not available. Further, there was an absence of standardisation of patient position in the radiographs used in the assessment of hip centre migration. Due to the geographic separation, clinical assessment using the Harris hip score was not standardised between the prescribing surgeon and an independent surgeon. As the Harris hip score was not clinically assessed by an independent observer in all cases (10 cases were assessed by the operating surgeon), there is a potential for bias in this assessment.

Conclusion

Although these results are very preliminary, the use of an Ossis custom acetabular implant is very encouraging. While, only 16 cases in excess of two years post operatively have been studied, a total of 100 implants have been inserted to date. 50 of these prostheses, will be in excess of two years post insertion by October 2016 and we intend to report on the results at this time

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Conflicts of interest

None of the authors have any financial conflicts of interest regarding the Ossis company.

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