



■ HIP ARTHROPLASTY: MANAGEMENT FACTORIALS

The patient-specific Triflange acetabular implant for revision total hip arthroplasty in patients with severe acetabular defects

PLANNING, IMPLANTATION, AND RESULTS

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Aims

Few reconstructive techniques are available for patients requiring complex acetabular revisions such as those involving Paprosky type 2C, 3A and 3B deficiencies and pelvic discontinuity. Our aim was to describe the development of the patient specific Triflange acetabular component for use in these patients, the surgical technique and mid-term results. We include a description of the pre-operative CT scanning, the construction of a model, operative planning, and surgical technique. All implants were coated with porous plasma spray and hydroxyapatite if desired.

Patients and Methods

A multicentre, retrospective review of 95 complex acetabular reconstructions in 94 patients was performed. A total of 61 (64.2%) were female. The mean age of the patients was 66 (38 to 85). The mean body mass index was 29 kg/m² (18 to 51). Outcome was reported using the Harris Hip Score (HHS), complications, failures and survival.

Results

The mean follow-up was 3.5 years (1 to 11). The mean HHS improved from 46 (15 to 90) pre-operatively to 75 (14 to 100). A total of 21 hips (22%) had at least one complication with some having more than one; including dislocation (6%), infection (6%), and femoral complications (2%). The implant was subsequently removed in five hips (5%), only one for suspected aseptic loosening.

Conclusion

The Triflange patient specific acetabular component provides predictable fixation with complication rates which are similar to those of other techniques.

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Combined deficiencies of the acetabular rim and columns are difficult to manage at revision total hip arthroplasty (THA). Several techniques for addressing this problem have been described including the use of bulk allograft,¹⁻⁵ porous metal augments⁶⁻⁹ an acetabular component-cage reconstruction,¹⁰⁻¹² pelvic distraction,^{4,13} and a patient specific Triflange acetabular component (Biomet, Warsaw, Indiana).^{12,14-18} All are technically difficult and surgically demanding and have met with varied, but encouraging results. This paper includes, to our knowledge, the largest multi-centre series of acetabular revisions using the Triflange acetabular component, which was designed to enhance pre- and peri-operative planning in order to allow improved fixation and positioning. The technique includes the use of multiplanar CT scanning to outline the complex geometry of the deficiencies, the proposed position of the screws used for

fixation and to identify areas which are to be supplemented with bone graft. The outcome is assessed using the Harris Hip Score (HHS),¹⁹ the rate of failure and survival curves.

Patients and Methods

Databases from three regional arthroplasty centres, Indiana (26 cases), Ohio (41 cases) and Tennessee (27 cases), were searched for the use of the Triflange acetabular component in complex revision cases, those involving patients with Paprosky 2A, 3A, 3C deficiencies and pelvic discontinuity.²⁰ Such cases were not felt to be suitable for the use of routine revision techniques. The prospectively gathered demographics of the patients were recorded and the indication for revision with the outcome, rate of failure and survival. The methods for surgical planning, design, manufacture, and implementation are described.

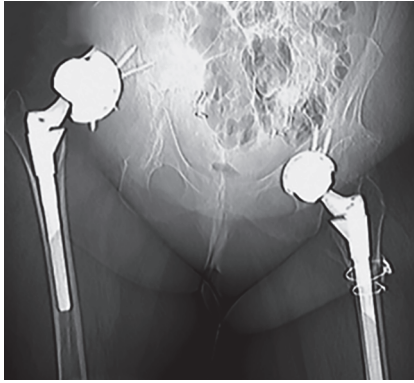


Fig. 1

Anteroposterior radiograph showing the pelvis of discontinuity.

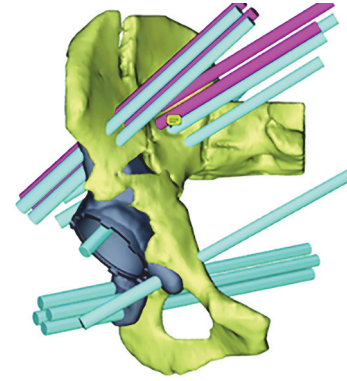


Fig. 3

Map of screw placement.

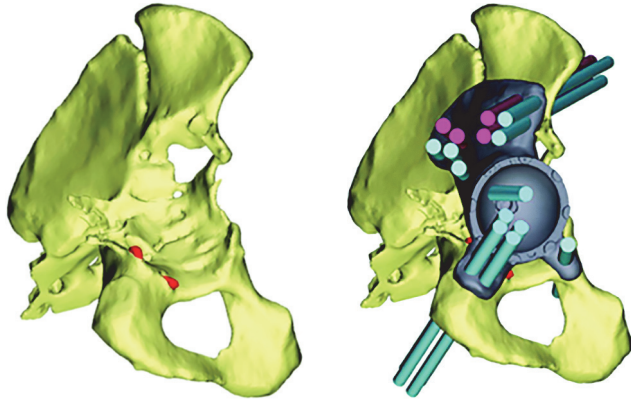


Fig. 2a

Fig. 2b

Image showing a 3D screw placement in the oblique view (a) and the lateral view (b).

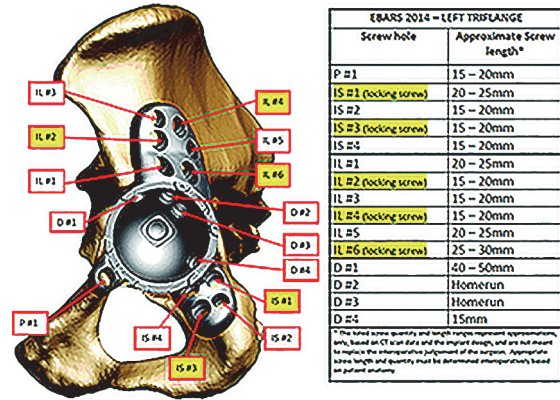


Fig. 4

Screw types and lengths (Homerun, a screw of increased length, ~ 40 mm, that is directed into the best host bone toward the sacroiliac joint; P, pubis; IS, ischium; IL, ilium)

Following routine anteroposterior and lateral radiographs which suggest complex bony deficiencies, a multi-layer CT scan using 2 mm x 2 mm, 2.5 mm x 2.5 mm or 3.3 mm x 3.3 mm sections is performed from the superior aspect of the iliac crest to the mid femur or distal to a femoral component. A standard soft-tissue algorithm without bony enhancement or edge detection is downloaded into Digital Imaging and Communication in Medicine and sent to the manufacturer (Zimmer Biomet, Warsaw, Indiana) through a secure server. These data are assembled into a 3D image in which bony edges and retained metal is outlined.

The segmental outlines are used additively by the engineers to produce a 3D model (Fig. 1), and are imported into a design and sculpting software package (Geomagic: Freeform, 3D Systems, Rock Hill, South Carolina) from which the manufacturing engineer designs a plastic model of the implant and the associated pelvic anatomy. He also asks the surgeon about specific details of the proposed fixation, placement of screws and the use of bone graft.

The preliminary design of the implant is provided to the surgeon as a 'hands on' plastic model, a 3D printed model or PDF document with multiple views (Fig. 2). The preparation

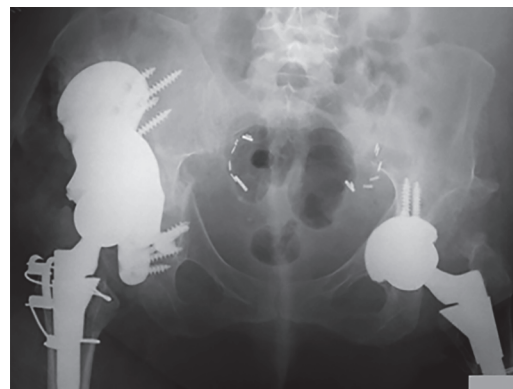


Fig. 5

Post-operative radiograph showing Triflange implant placement.

of the bone, the suggested removal of osteophytes, type of screws to be used and their lengths and placement are presented (Figs 2 to 4). Once the details are approved by the surgeon the component is manufactured (Fig. 5).

The manufacturing of the implant involves programming for machining which is done from a solid bar of Ti6, A14,

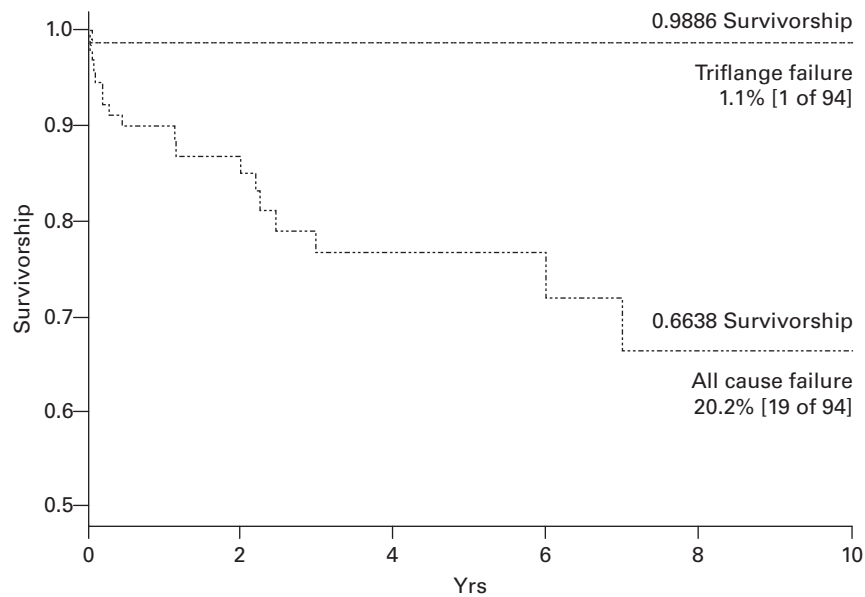


Fig. 6

Patient demographics.

V alloy. Surfaces where bony contact will occur are porous coated with Porous Plasma Spray. Hydroxyapatite is applied if requested by the surgeon. After polishing and sterilisation, the implant is dispatched. The time between the initial contact between the surgeon and the engineer and completion of the implant is about six weeks, and its approximate cost, including design work, is \$11 000.

Surgical technique. An extensile exposure is necessary and combinations of posterior, anterolateral, and transtrochanteric approaches are used, based on the evaluation of the deficiencies and the experience of the surgeon. A standard, extended, or slide type of transtrochanteric osteotomy may be used. The nature of the osteotomy which is required is often dictated by the complexity of the femoral revision. Protection of the sciatic nerve and the superior gluteal neurovascular pedicle is mandatory. The lateral wall of the ilium is exposed subperiosteally. The ischium and pubis are dissected as necessary for exposure and positioning of the implant. Initially, the superior aspect of the implant is slid beneath the abductor musculature. This is followed by seating the inferior flanges on the exposed surfaces of the ischium and pubis. One non-locking 65 mm compression screw is placed in the ilium and one in the ischium. These are tightened to pull the implant into position. The subsequent screws are placed using standard measuring and tapping techniques as directed by the pre-operative model. The screws in the dome are the last ones to be introduced.

Trial polyethylene liners (Zimmer Biomet) are used with the femoral component to determine the appropriate position of the liner to maximise the range of movement, stability, and offset. Either standard liners or dual mobility components (Zimmer Biomet) are used with the largest femoral head possible to reduce the incidence of instability.

Since these patients are usually not highly active, wear should not be a problem (Fig. 6).

Statistical analysis. This was performed at the Joint Replacement Surgeons Research Foundation, Mooresville, Indiana. Means and ranges were calculated for the data points. Complications were calculated as a percentage of hips in the study. Kaplan-Meier survivorship analysis was then performed.

Results

Between 25 May 2004 and 07 March 2016 the patient specific Triflange implant was used in 94 patients (95 hips), which constituted 3.7% of the number of revision THAs performed at these institutions during this time. The mean number of previous procedures was 1.6 (1 to 3). A total of 20 hips (21%) had a concomitant femoral revision. The demographics of the patients are shown in Figure 6. The mean time from most recent previous surgery 4.7 years (0.1 to 10). The mean follow-up was 3.6 years (0.3 to 10.7).

Many patients had more than one indication for revision. Acetabular loosening was present in 60 hips (63.8%), infection in 15 (15.9%), severe osteolysis in 13 (13.8%), previous acetabular fracture in three (3.1%), pelvic discontinuity in eight (8.5%) and failure of a cage reconstruction in six (6.4%). Paprosky classification was 2B in five, 2C in six, 3A in six, 3B in six, 3C in five, and there were four pelvic discontinuities in eight hips. Three hips were not classified pre-operatively.

The fixation of the implant involved a mean of 12 screws (4 to 18), a mean of three were locking (0 to 7). The mean size of the femoral head which was used was 36 mm (28 to 44). The mean HHS improved from 46 (15 to 90) pre-operatively to 75 (14 to 100). The patterns of gait and use of

Table I. Reasons for failure

Reasons	Hips, n (%)
Femoral cortical perforation	1 (1.1)
Open reduction and internal fixation of a femoral fracture	1 (1.1)
Dislocation	6 (6.4)
Infection	6 (6.4)
Liner and head for recurrent dislocation	1 (1.1)
Liner exchange for recurrent dislocation	1 (1.1)
Loose	1 (1.1)
Metastatic fracture requiring acetabular component revision	1 (1.1)
Poly failure	1 (1.1)
Total	19 of 94 (20.2)

walking aids post-operatively was not recorded. Many patients, however, used walking aids in view of the complexity and extent of these procedures, as reflected in the low post-operative HHS. A representative sample of 23 HHSs were reviewed to determine which portions of the score were most responsible for the lowering of the overall score. The scores, however, were evenly distributed with no particular portions being responsible for the downward trend.

Formal radiographic evaluation was not performed. Loosening was defined as progressive radiolucency, broken screws and/or migration. There were two hips with one radiolucency of 1 mm each, one in zone 1 and one in zone 3.²¹ No progressive radiolucency, broken screws or migration was identified in the surviving implants.

At least one complication occurred in 21 hips (22%) and included dislocation and infection in six each (6%) and femoral complications (including femoral perforation and fracture) in two (2%). A portion of the composite implant was removed at a further revision in 11 hips (11.6%); however, only one uninfected implant was grossly loose at this time and this was two weeks post-operatively, when revision for recurrent dislocation was performed. This was the only failure due to loosening of the implant. Other complications which required further surgery occurred in 14 hips (14.7%). These included infection in six, dislocation in six, one pathological fracture due to metastases, and one traumatic femoral fracture. Nine hips underwent more than one subsequent surgery. The implant was removed in seven hips (7.37%); a further Triflange implant was used in four and an excision arthroplasty was performed in three after failure of re-implantation due to infection.

Two hips had five further procedures, two had four further procedures, five had two further procedures and ten had one further procedure.

Five of the infections were treated with incision and drainage (three had more than one). A total of 11 hips had more than one portion of the acetabular reconstruction revised. Only one of the patients with a pre-operative infection developed an infection post-operatively. No patient had a nerve palsy. There was one trochanteric non-union. Failures, considered as any reason for a further procedure, are shown in Table I. Survival at ten years with failure for any reason as the endpoint was 66%. Survival at ten years for failure due to aseptic loosening alone was 99%.

Kaplan-Meier survival curves are shown in Figure 6 reflecting failure for any reason and failure for loosening alone.

Discussion

Revision THA in patients with complex acetabular bony deficiencies including pelvic discontinuity remains a very difficult procedure. Previous studies using structural allografts provided promising short-term results and added the potential benefit of restoring bone.^{1,2,5} Lee et al^{1,2} described further revision in 15 of 74 hips due to failure of the graft with a 8% survival of grafts 15 to 20 years post-operatively. However, resorption of graft in some form occurred in most of their patients. Berry et al²² suggested using a cage as protection for allografts involving the anterior or posterior columns of the acetabulum. Many types of reconstruction using metal implants with or without bone grafts including cages, porous acetabular components, and porous tantalum augments have had promising results.^{1,2,7,10,11,13} Often various combinations of these techniques have been used.^{1,2,7,10,11,13}

Using tantalum augments, Whitehouse et al¹⁸ reported three failures for aseptic loosening in 56 patients, but no revisions were for pelvic discontinuity. Batuyong et al²³ had two aseptic loosening in 24 hips. Weeden and Schmidt²⁴ had no aseptic loosening in 43 hips at short-term follow-up. Secondary support using modular components, cages and plates were needed for those with pelvic discontinuity. Acetabular component-cage reconstruction may be used to deal with pelvic discontinuity. A series initially reported by Amenabar et al¹⁰, of 24 patients who were re-evaluated by Abolghasemian et al¹¹, described four failures due to migration. However, three of these stabilised and were not revised. The pelvic discontinuity healed in all cases at a mean follow-up of nine years. Re-operations were for dislocations and infections.

Most of these constructs require several components to be assembled and fitted into the patient at the time of surgery. Many decisions about bone loss and the proper orientation and offset of the implants is required of the surgeon. With the benefit of CT scanning and 3D reconstruction, bony geometry and retained hardware can be outlined. A single implant can be designed to maximise bony contact for ingrowth, localise areas of bone loss for grafting, restore offset, calculate the exact placement and length of screws for fixation, and span areas of discontinuity.

This multicentre study combined cohorts from three revision practices. The results are promising, particularly relating to fixation. Only one revision was for aseptic loosening which was noted when exploration undertaken two weeks post-operatively for recurrent dislocation. The rate of failure for the other major complications, such as infection and dislocation, is comparable with those reported in studies previously cited^{1,2,7,10,11,13} and still remain troubling. These promising results for fixation and healing of complex acetabular reconstructions are similar to those previously reported by Berasi et al¹⁵ Taunton et al¹⁷ and Christie et al¹⁴ but with a larger cohort. These studies describe the use of custom made Triflange implants for severe acetabular deficiencies including pelvic discontinuity. These implants were designed using contemporary imaging technology and thus are comparable with this design. Taunton et al¹⁷ reported a 98% survival based on the stability of the implant at a mean follow-up of 65 months, but with only 65% free of revision for any reason. All revisions were undertaken for pelvic discontinuity. They felt that healing of the discontinuity was difficult to assess due to the amount of metal which was present. Berasi et al¹⁵ described only four of 28 failures of reconstructions of the hip in patients with Paprosky type 3B defects. None were for loosening.

Drawbacks to the technique include the radiation exposure from the use of CT scans, expense and the time required for planning. Although the cost is high (about \$12 500), it is similar to the cost of an acetabular component cage trabecular metal construct (\$11 250) and the use of two trabecular metal augments, screws and a polyethylene liner (\$14 500).¹⁷ These drawbacks may be offset by the ability to plan pre-operatively for anatomical variations, deficiencies of bone, the use of a single implant and the choice of the type and length of screws.

Limitations of this study include its retrospective nature, the short- to mid-term follow-up, the inclusion of several types of acetabular defects and the fact that the operations were undertaken by many different surgeons.



Take home message:

- The Triflange custom implant provides a reliable option in the treatment of complex acetabular revision surgery.
- Through the use of CT mapping and pre-operative plastic model reconstruction, the placement of the implant and screw fixation can be predicted.
- The results of fixation are predictable and complication rates are similar to other methods of revision of these complex reconstructions.

Author contributions:

M. E. Berend: Contributing author, Surgeon, Case review.
 K. R. Berend: Contributing author, Surgeon, Case review.
 A. V. Lombardi: Contributing author, Surgeon, Case review.
 H. Cates: Contributing author, Surgeon, Case review.
 P. Farris: Contributing author, Surgeon, Case review.

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