ORIGINAL ARTICLE

MEDIUM TERM OUTCOME FOR A CONSTRAINED ACETABULAR COMPONENT AT A SINGLE INSTITUTION: WHAT IS IMPORTANT FOR SUCCESS?

Edward Tayton, Robert Elliott*, Faisal Farooq Butt, William Farrington*, Robert Sharp*

Department of Trauma & Orthopaedics, Royal Berkshire Hospital Reading-United Kingdom, *North Shore Hospital Auckland-New Zealand

Background: The use of constrained Total Hip Replacements (THR) is controversial due to lack of definite indications and potentially high failure rates because of mechanical loosening or component failure. A review was performed to assess a departmental use of a single constrained acetabular component over a ten years period. **Methods:** Patient demographics, operative indications, complications and patient follow-up were recorded. Post-operative Oxford Hip Scores (OHS) were obtained via a combination of New Zealand Joint Registry interrogation and telephonic questioning. Cup version and inclination angles were obtained from standardised anteroposterior radiographs using established techniques. **Results:** Forty-four constrained components (in 39 patients) were implanted between 2005 and 2014. The mean age was 78 years with mean ASA 2.7 and mean follow-up 37.2 months (range 13–116). The mean post-operative OHS was 36 (SD 9.25), and there were 4 failures (3 dislocations and 1 peri-prosthetic fracture). The 3 dislocations had either cup ante version (AV) or inclination angles (IA) outside the data set interquartile range (AV 13–24°, IA 40–50°). The cup inclination was significantly lower ($p<0.01$) in patients with pain on sitting. At post-operative follow-up, 14/39 patients had died from unrelated causes, with only 1 patient surviving beyond 6 years. **Conclusions:** Constrained acetabular components offer a solution to hip instability in a difficult group of patients. This study has shown good medium-term outcomes of a single component type in a predominantly frail group of low demand patients. Despite constraint, correct cup placement (particularly inclination) remains important to prevent dislocation or poor reported outcome.

Keywords: Acetabulum; Constrained; Inclination; Medium term; Outcome

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INTRODUCTION

Dislocation rates post THR have been cited to range between 0.04% for primary procedures, up to 25% in revision surgery and are related to a number of different factors.[1–4] Management is related to underlying cause and includes component reposition or modification (larger head, offset, dual mobility cup etc), bony and soft tissue procedures and excision arthroplasty.[5–9] However, recurrent dislocation post THR remains an on-going dilemma in a certain group of patients and the consequences can often be devastating.

Constrained hip prostheses were first described in 1969 for the management of peri-acetabular tuberculosis, but have subsequently found a use as a potential solution for multidirectional instability, abductor compromise or prevention of dislocation in patient groups that could not tolerate this complication.[10,11] They have met with a mixed response due to concerns over a risk of early prosthetic loosening and mechanical failure secondary to the increased stresses to which the acetabular component is exposed, and reduced range of movement.[12,13]

Early components generally consisted of a linked polyethylene component, locked to an outer acetabular shell via a constraining ring, and have shown variable results. Anderson *et al*, reported that six of twenty-one (29%) patients had repeat dislocation after insertion of an S-ROM constrained acetabular component, whereas Lombardi *et al* reported only 5 out of 50 dislocations at medium term (3 year) follow-up.[14,15] Kaper *et al* reported failure mechanisms of four patients who had the same implant, two were associated with a fracture of the constraining ring and in the other two the femoral head was dislocated but the acetabular shell and liner remained in place.[16]

The design of a 'tripolar' prosthesis has attempted to reduce the incidence of mechanical component failure. Goetz *et al* reported the outcome of average 10.2 year follow-up of a series of 56 tripolar constrained components, with mechanical failure of the device in only 4.[17] Jones *et al* reported the short term outcome (mean 24 months) of the Omnifit constrained prosthesis, citing only 2 failures in 77 patients (1 for acetabular avulsion and 1 dislocation).[18] However, the extra articulation has had

reports of failure, and the extra strains at the bone implant interface remain high.[19,20]

The purpose of this study was to assess the departmental indications and results for a single constrained 'tripolar' implant at a busy district hospital, with analysis of component position in relation to failures and poor outcome.

MATERIAL AND METHODS

The details of all patients who underwent THR using a constrained tripolar acetabular prosthesis (Trident® Constrained Acetabular Insert, Stryker, Kalamazoo, Michigan, USA) were obtained via a local database. Patient demographics, operative indications, and outcomes were obtained via interrogation of individual patient hospital records. Data points recorded included age, sex, ASA, history of previous surgery to the hip, indication for constrained component, surgical and implant details, pre and post-operative function and residential status, complications, and date and cause of death if appropriate. Primary outcome measures were Oxford Hip Scores (OHS), dislocation, groin pain on sitting and radiological evidence of acetabular loosening.

Patients underwent a standardised post-operative X-ray imaging series consisting of post-operative standing anteroposterior (AP) radiographs of the hips and a separate image focused on the operated hip. Cup inclination and version angles were calculated from these using validated techniques as described by De Haan *et al* and Pradhan.[21,22] In brief, inclination angles were measured from the digital images using Agfa study viewer software (Version 5.01, Agfa Health Care, Mortsel, Belgium) by measuring the angle between two parallel bony landmarks (e.g teardrops) and the long angle of the cups. Measurement of the acetabular anteversion angle was possible due to the presence of a circular metallic ring within the polyethylene component, parallel with the outer surface (Figure-1). On the focused AP hip radiographs, a bisecting line was drawn and the distance (X) measured between the apices of the oval formed from the angle at which the circular ring was imaged. At a point 1/5 of the way along this line a perpendicular line was drawn, and the distance to the intersection of the metallic ring was measured (Y). Using the formula: Anteversion angle = Sin^{-1} (Y / 0.4X), anteversion angles were calculated for each acetabular component. The occurrence of the angle measured actually relating to retroversion was ruled out on standard lateral X-rays. The parameters for each patient were measured independently by two authors, and the mean angles calculated. The data was entered into a statistical software program (GraphPad Prism 6, GraphPad Software Inc., La Jolla, CA, USA). The data was non-parametric, and hence median and interquartile ranges were calculated and displayed graphically as box and whisker plots. The Mann Whitney U test was performed for statistical analysis between data sets when appropriate.

Oxford Hip Scores were obtained from the New Zealand Joint Registry (NZJR), which attempts to record outcome scores for all patients undergoing revision hip procedures for any cause. However, due to the patient comorbidities, often reduced mental status and the fact that some of the procedures were performed as primary procedures, this data set was limited. Further scores were obtained (along with other missing data points) via either clinical or telephonic consultation. Up to date radiographs were also obtained where possible, in order to assess for evidence of component loosening.

RESULTS

Between 2005 and 2014 a total of 39 patients (10 males, 29 female) were identified, who had a total of 44 constrained acetabular components inserted over the 10-year time period. The mean age was 78 years (SD 9.18), and mean ASA 2.72 (SD 0.50). The surgery was performed on the right side in 25 patients and on the left side in 19 patients, with a mean follow-up of 37.2 months (range 13–116). At the time of investigation, 14 out of 39 patients had died, all from unrelated causes, with only one patient surviving more than 6 years from the time of surgery. By combination of OHS available from the NZJR (taken at 6 months post-op), and those obtained at patient follow-up, scores were available for a total of 26 patients. Mean OHS at 6 months was 35.10±10.06 (16 patients) and at a mean follow-up of 4.16 years was 31.60±4.46 (12 patients). Table-1 displays the OHSs for both of these time points categorised into excellent, good, fair and poor as described by Khalairajah *et al*.[23] Pre and post-operative mobility was recorded as independent, single walking aid, frame/walker or dependent, and was shown to have improved in 14%, remained at the same level in 43% and deteriorated in 43%. There had been a mean of 1.60 previous procedures performed on the patients' hips, with indications for constrained liners falling into 4 broad categories (Table-2). Comorbidities ranged from medical issues placing a patient's life at significant risk should further procedures be required, to mental health issues or dementia, such that post-operative compliance

would be compromised. Reasons for THR instability generally included abductor and soft tissue compromise. The operations were performed by a total of 6 surgeons (all consultants). The outer acetabular polyethylene component was cemented directly to bone on 20 occasions, fixed uncemented into an outer shell on 13 occasions and was cemented into an outer shell on 11 occasions. Prior to 2006 the system did not have a component specifically designed for cement fixation (Trident® All-Poly Constrained Insert), and thus on these occasions the outer side of the polyethylene shell was scored using a reciprocating saw in order to enhance interference fixation. Two patients suffered from post-operative infections, one superficial infection (*Staphylococcus epidermidis*) responded to a short course of antibiotics, and one patient (multiple previous surgeries for deep infection) suffered an ongoing deep infection, which was treated with washout, debridement and lifelong suppressive antibiotics.

Due to patient comorbidities, residential status, limited mobility and death rate, follow-up radiographs performed at least 1 year post-operatively were available for 26 patients. At mean 3.7 years (range 1–9.2 years), new lucency around the acetabular component was seen in 11 zones in 7 hips (4 cemented, 3 uncemented (15.9%) and including the patient with ongoing infection), although there was no cup migration or symptoms requiring further surgery in any.

There were 4 failures requiring revision, which consisted of 3 dislocations (7%) and 1 femoral peri-prosthetic fracture. The 3 dislocations had either cup version or inclination angles outside the data set interquartile range (Figures-2(a) and 2(b)). The radiographs are displayed in Figure-3 (A–C). Due to low numbers statistical comparison was not appropriate, but as can be seen, all patients were complex revisions with poor acetabular bone stock and lack of obvious bony landmarks (one requiring bone grafting and augmentation) making accurate cup positioning difficult.

The cup inclination angle was also found to be significantly lower (mean 36.8º±4.4º versus 46.5º±6.4º, Mann Whitney U Test $p< 0.01$) in patients who had pain on sitting. Figure-4(b). There was however no significant difference between the acetabular anteversion angles between the two groups (mean 17.0º±5.0º versus 18.3º±6.7º, Mann Whitney U Test $p=0.57$.) Figure-4(b). Interestingly, the acetabular inclination angle was also less for the cohort of patients who had new radiographic lucency compared to those with stable radiographic findings (47.8º±8.0º versus 40.7º±8.0º), although this difference only approached significance (Mann Whitney U Test $p=0.07$).

Table-1: The functional outcome of the patients for whom Oxford Hip Scores were available.

Outcome* (OHS)	No. of Patients	
	6 months	4.2 years
Excellent (>41)	5	0
Good (34-41)	8	5
Fair (27-33)	0	5
Poor (<27)	3	2
Total	16/39	12/39

Table-2: The operative indications for constrained acetabular components in the patient cohort.

Surgical Indication	Number
Fracture Neck of Femur	2
Primary + Comorbidity	7
Unstable THR	27
Revision + Comorbidity	8

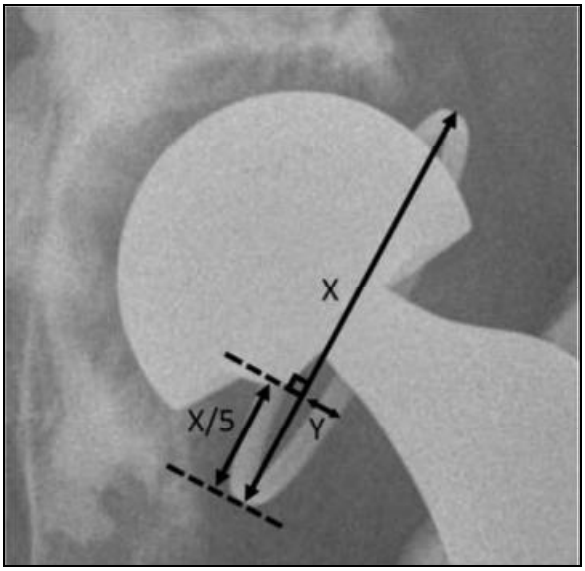

Figure-1: Radiograph with annotation showing measurements required for calculation of outer shell polyethylene acetabular anteversion angle. (Angle = Sin^{-1} (Y/0.4X)).

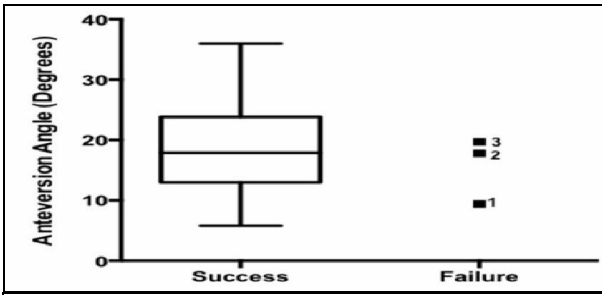

Figure-2A: Box and whisker plot displaying median, interquartile range and range of successful cup inclination angles compared to the 3 patients who underwent dislocations

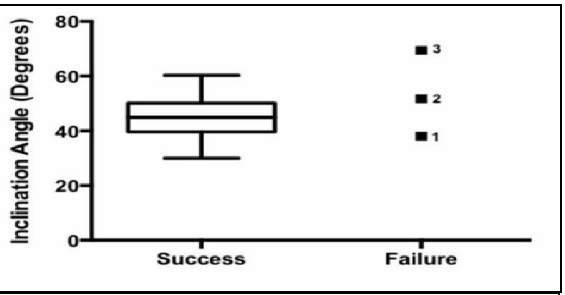

Figure-2B: Box and whisker plot displaying median, interquartile range and range of successful cup anteversion angles compared to the 3 patients who underwent dislocations

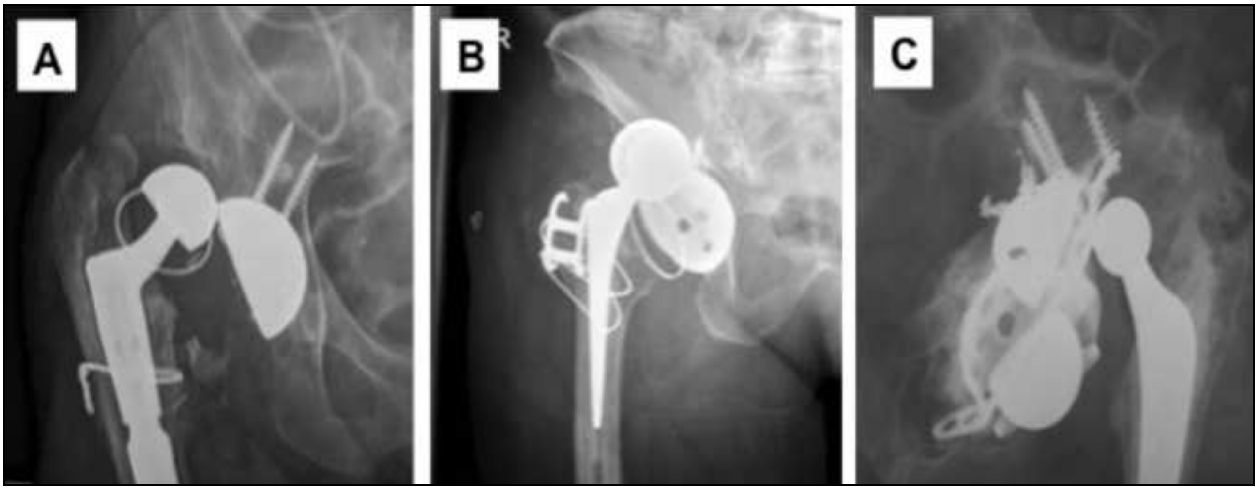

Figure-3: Radiographs (AP hip) of the 3 patients who dislocated post-operatively. (A) Type II failure at the mechanism holding the constrained liner to the outer metal shell, (B) Type III failure of the retaining mechanism of the bipolar component and (C) Type IV dislocation of the prosthetic head at the inner bearing of the bipolar component.

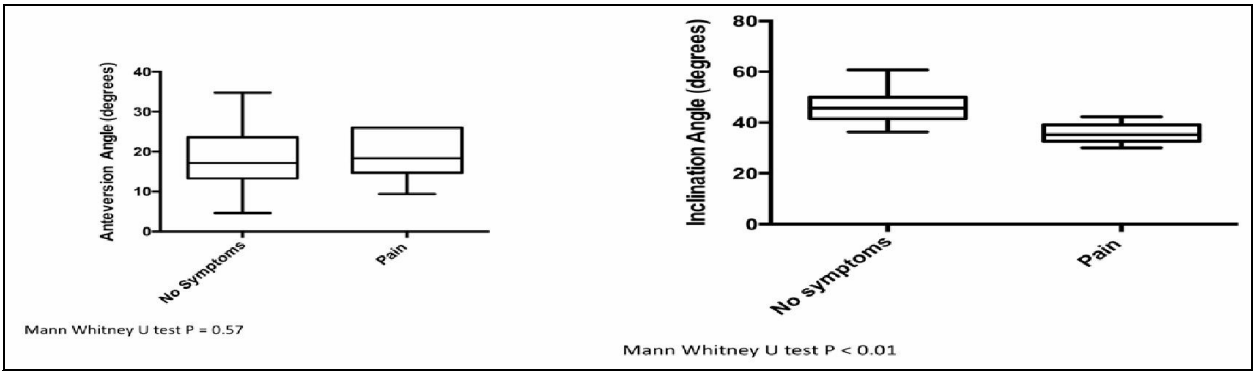

Figure-4 A: Box and whisker plot displaying median, interquartile range and range of anteversion angle of patients with no pain compared to patients with pain on sitting. (* Mann Whitney U test: $p = 0.57$).

Figure-4B: Box and whisker plot displaying median, interquartile range and range of cup inclination angle of patients with no pain compared to patients with pain on sitting. (* Mann Whitney U test: $p = 0.01$

DISCUSSION

This paper serves to highlight the medium-term outcome of a single centre, multiple surgeons, use of a particular constrained 'tripolar' acetabular implant. The survival, failure rate and complications are in keeping with other published studies using similar implants.[17,18] The patient cohort was generally found to be low demand, frail and elderly, and the prostheses were used as a last resort. This finding was born out by the fact that at mean follow-up of 36.2 months, 14 of the 39 patients had died from unrelated

causes, and a further 10 of 39 were in either residential or nursing home care. Most studies would advocate the use of the implant in these situations. Bigsby *et al* analysed the outcome of over 100 patients who had the Omnifit constrained acetabular component implanted. The median age of the patients was 82, and over 45% had died at a median time of 33 months from surgery.[24]

There still however remains concern with constrained implants regarding early failure due to increased stress experienced at the implant bone interface and at the articulations between the femoral and acetabular components.[12,13] This study noted new lucency around the acetabulae in 7 of 26 patients who had radiographs performed >1 year post surgery, although none had symptomatic loosening or had required revision. A study of 34 patients, using the same prosthesis for recurrent dislocation used Roentgen Stereophotogrammetric Analysis (RSA) to assess component migration post-operatively, noted higher failure rates for loosening.[25] At mean 3 years they had reported an overall rate of aseptic loosening of 11.8% (4 of 34 patients who had or were awaiting revision). In addition, RSA of the other 30 components confirmed migration of up to 1.06 mm of translation and 2.32º of rotation at 24 months, indicating potential further failures. Conversely, in a series of 110 constrained arthroplasties, Shrader *et al* reported that only two (1.8%) acetabular components were revised for aseptic loosening but radiolucent lines were present around the cup in fifteen hips (14%) with six (5.5%) having radiolucent lines in all zones.[26]

In addition to failure at the bone implant interface (Type I), failure of 'tripolar' constrained components can occur at three further locations: failure at the mechanism holding the constrained liner to the outer metal shell (Type II), failure of the retaining mechanism of the bipolar component (Type III) and dislocation of the prosthetic head at the inner bearing of the bipolar component (Type IV).[27] Interestingly, in this cohort there was one failure of each type indicating no single implant design flaw. In keeping, Cooke *et al* described 8 early failures in a series of 58 patients, whereas Guyen *et al* retrospectively analysed a larger series of 43 failed implants, both noting a roughly equal distribution of failure type.[27,28] Moreover, this study adds an analysis of acetabular component position (inclination and anteversion) in relation to failure. Two of the three implant failures had cup inclination angles and the other one of the three had cup anteversion angle outside of the data set interquartile range. This would indicate that despite constraint, component position is still important and likely conforms, at least in part, to the traditionally described 'safe zones'.[29] Anderson *et al* also noted a correlation between increased cup inclination angle and dislocation in a series of constrained THRs.[14]

As stated, the patient cohort was found to be low demand, thus likely to spend the majority of their time seated. In addition to the OHS, questioning was therefore specifically directed towards this aspect of the patients' lives. This study has found a significant correlation between a low acetabular inclination angle and patient reported hip pain on sitting. Nuzik *et al* studied the degree of hip flexion required when rising from sitting and found it averaged 110 degrees.[30] In addition, D'Lima *et al* performed a computer simulation which demonstrated increasing hip flexion at 35, 45 and 55 degrees of cup inclination.[31] From this simulation it can be seen that patients only start to achieve 110 degrees flexion at 45 degrees inclination, and thus potentially explains the finding of increased groin pain on sitting (and trend towards development of periacetabular lucency) with decreased cup inclination, due to mechanical impingement of the components in this position. However, femoral anteversion clearly also plays a significant role in hip stability and range of motion, but this cannot be accurately measured from plain radiographs, and hence was a potential uncontrolled confounding factor in these findings.[31]

Few published studies discuss functional outcome scores following this type of surgery. Follow-up and measurement is difficult due to patient comorbidity, mobility, and often reduced cognitive function, thus resulting in OHS data being only available for around 50% of the patient cohort.[24,32] Despite this shortcoming, a mean OHS at 6 months of 35.1 according to Khalairajah *et al,* shows in general a good functional outcome, which appeared to be largely maintained at mean follow-up of over 4 years, with nearly 60% patients having the same or improved mobilization status.[23] This is in keeping with Bigsby *et al* who describe an 87% patient satisfaction rate at median follow up 7 years and Rady *et al* who using the old (60–12) OHS describe a reduction in preoperative mean OHS from 48.6 to 20.5 (which equates to new OHS 39.5) at the final post-operative examination.[24,32]

CONCLUSIONS

This study shows the medium-term outcome of the Stryker Trident® Constrained Acetabular System to be comparable with other published studies in terms of implant survival, component failure, and post-operative functional status. The use is advocated in the low demand frail / elderly population and acetabular component position (predominantly inclination) appears to remain important to avoid functional pain, and prevent dislocation.

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AUTHORS' CONTRIBUTION

ET: Lead researcher, data collection, analysis, wrote paper. RE: Data collection, analysis, wrote paper. FFB: Data analysis, wrote paper, final draft, submission + alterations. WJF: Performed surgery, senior author. RJS: Performed surgery, senior author.

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Address for Correspondence:

Edward Tayton, Consultant Trauma & Orthopaedic Surgeon, Royal Berkshire Hospital Reading-United Kingdom
Email: edwardtayton@hotmail.com