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Original Research

Minimum 2-Year Outcomes of a Novel 3D-printed Fully Porous Titanium Acetabular Shell in Revision Total Hip Arthroplasty

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ABSTRACT

Background: Fully porous acetabular shells are an appealing choice for patients with extensive acetabular defects undergoing revision total hip arthroplasty (rTHA). This study reports on the early outcomes of a novel 3-D printed fully porous titanium acetabular shell in revision acetabular reconstruction.
Methods: A multicenter retrospective study of patients who received a fully porous titanium acetabular shell for rTHA with a minimum of 2 years of follow-up was conducted. The primary outcome was rate of acetabular revision.
Results: The final study cohort comprised 68 patients with a mean age of 67.6 years (standard deviation 10.4) and body mass index of 29.5 kg/m^2 (standard deviation 5.9). Ninety-four percent had a preoperative Paprosky defect grade of 2A or higher. The average follow-up duration was 3.0 years (range 2.0-5.1). Revision-free survivorship at 2 years was 81% for all causes, 88% for acetabular revisions, and 90% for acetabular revision for aseptic acetabular shell failure. Eight shells were explanted within 2 years (12%): 3 for failure of osseointegration/aseptic loosening (4%) after 15, 17, and 20 months; 3 for infection (4%) after 1, 3, and 6 months; and 2 for instability (3%). At the latest postoperative follow-up, all unrevised shells showed radiographic signs of osseointegration, and none had migrated.
Conclusions: This novel 3-D printed fully porous titanium shell in rTHA demonstrated good survivorship and osseointegration when used in complex acetabular reconstruction at a minimum of 2 years.
Level of evidence: IV, case series.

Introduction

Total hip arthroplasty (THA) has proven to be a highly effective and safe procedure in the treatment of osteoarthritis, with excellent long-term results [1]. Nonetheless, THA may fail due to hip instability, aseptic loosening, or infection and require revision [2,3]. Acetabular bone loss is a common occurrence during revision surgery, as 22% of revisions are conducted due to aseptic loosening of the acetabular component, and 8% are conducted for acetabular osteolysis [4]. Various strategies have been developed to address this complication, including the use of reinforcement cages, custom-made acetabular components, and jumbo shells [5–7]. Despite these technological advances, 8%-16% of patients with large preoperative acetabular defects will undergo a revision within 5-10 years [8].

Given the projected 43%-70% increase in revision THA (rTHA) by 2030 [9] and poorer outcomes for patients with significant

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acetabular bone loss, [6] it is important to evaluate new technologies to improve fixation and osseointegration. In particular, the use of porous tantalum components in the context of patients with severe acetabular defects has shown promising results for encouraging improved osseointegration [10]. Porous tantalum implants have shown to have successful results and reduce rates of aseptic loosening in clinical studies [11]. In this study, we report the results of a novel fully porous shell, created with additive manufacturing (ie, 3-D printing) utilizing titanium alloy, which mimics cancellous bone in an effort to improve the ingrowth of host bone into the implant. Titanium alloy has a modulus of elasticity closer to bone, is highly biocompatible, and has a long track record demonstrating superb osseointegration. Titanium alloy is also cheaper to procure and manufacture than tantalum, making it more affordable for mass production as the demand for THA continues to rise [12].

This study reports the early to midterm outcomes of patients who had complex acetabular reconstruction with a novel, 3D-printed, fully porous titanium acetabular shell. We hypothesized that this novel acetabular shell would demonstrate excellent survivorship and osseointegration when used to reconstruct large, complex acetabular defects.

Material and methods

Study population

This retrospective cohort included patients who underwent rTHA with a novel 3-D-printed, nonmodular, fully porous titanium acetabular shell (REDAPT Fully Porous Cup System; Smith & Nephew, Memphis, TN) at 6 large medical centers in the United States, Canada, and United Kingdom between March 25, 2016, and August 2, 2019. rTHA Was defined as a procedure involving exchange of implants from a prior THA. Patient and implant data were extracted from the electronic medical record system (Epic Systems Corporation, Verona, WI). Patients were included if they had an rTHA with confirmed use of a fully porous titanium acetabular shell upon review of the operative note and implant log. Only patients with follow-up at 2 years were included in the study. Ethical approval for the study design was provided by our institutional review board, and the study protocol was followed in accordance with the tenets of the Declaration of Helsinki.

Data collection

Chart review was conducted to record baseline patient demographics and hip-related characteristics. Data recorded included age, sex, body mass index, race, American Society of Anesthesiology score, smoking status, laterality, indication for the present surgery, and number of prior operations. Time-specific variables such as age, body mass index, American Society of Anesthesiology score, and smoking status were recorded based on data at the time of THA. Outcomes recorded included whether the patient required subsequent revision or reoperation within 2 years, for all-causes and aseptic reasons; the reason for any subsequent revision procedures; the time to subsequent revision; the indication for revision; and postoperative complications within 90 days. Patients also responded to the Harris Hip Score (HHS) prior to surgery and at the latest follow-up; 60% of patients completed the questionnaire at both timepoints, as only 4 of the participating sites request completion of HHS as part of the standard of care. Revision was defined as any subsequent procedure that required removal and/or exchange of implants. We report revision for any cause, any acetabular revision (involving explantation of the novel fully porous shell), and acetabular revision for aseptic acetabular shell failure.

Radiographic analysis

Preoperatively and intraoperatively, acetabular defects were evaluated by a fellowship-trained adult reconstruction surgeon using the Paprosky grading system for acetabular bone loss [13]. Postoperatively, osseointegration and migration were evaluated in patients that maintained their implants at 2-year follow-up (Fig. 1). Osseointegration was independently graded by a single study coordinator per site according to the methods of Moore et al [14]. These methods involve assessing an anteroposterior radiograph for the following 5 signs: (1) radiolucent lines, (2) a superolateral buttress, (3) medial stress shielding, (4) radial trabeculae, and (5) inferomedial buttress. When 3 or more signs are present, the positive predictive value for bony ingrowth is 96.9%, the sensitivity is 89.9%, and the specificity is 76.9%. Migration was evaluated via the methods proposed by Nunn et al [15].

Statistical analysis

The primary outcome was rate of revision/re-revision, defined as an additional surgery requiring an arthrotomy within the hip

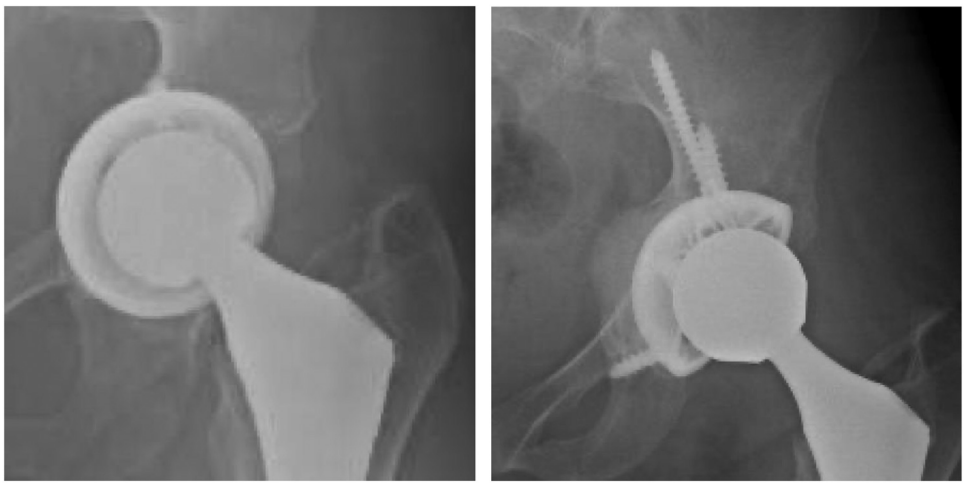

Figure 1. Preoperative (left) and postoperative (right) radiograph for a representative patient undergoing a revision THA with a fully porous titanium shell.

joint. Both aseptic and septic rates of revision were reported, as well as the rate of acetabular shell removal. Secondary outcomes included emergency department (ED) visits, readmissions, and intensive care unit admissions within 90 days after the initial surgery; medical complications; osseointegration; migration; and HHS. Demographics and complications were described using counts and proportions or median and interquartile range. Analyses were performed in R version 4.1.1 (Vienna, Austria).

Results

The final study population included 68 rTHA patients who received a fully porous titanium acetabular shell. The mean follow-up duration was 3.0 years (standard deviation 0.6, range 2.0-5.1). Twenty-eight patients were male (41%), and the mean patient age was 67.6 years (standard deviation 10.4). Additional cohort demographics are reported in Table 1.

Hip characteristics and surgical considerations are reported in Table 2. The most common indications for rTHA were aseptic loosening in 33 hips (49%), infection in 15 (22%), and instability in 14 (21%). Most patients had an acetabular defect of 2A or greater (94%). Twenty-three patients (34%) were revised to a dual-mobility construct (REDAPT POLARCUP; Smith & Nephew, Memphis, TN). The remainder of patients had a system-specific, all-polyethylene liner cemented into the shell. All cases employed the use of locking screws, with a median of 4 screws used.

Revisions within 2 years

Revision-free survivorship at 2 years was 81% for all causes, 88% for acetabular revisions, and 90% for aseptic acetabular shell failure (Table 3). A Kaplan-Meier analysis of revision-free survival is shown in Figure 2. Overall, 8 shells were explanted within 2 years (12%). Two patients (3%) were revised after presenting with dislocations of dual-mobility constructs: one who experienced a fracture-dislocation of the ilium 7 days after surgery when completing postoperative rehabilitation exercises, and a second with an interprosthetic dissociation upon sitting, 28 days following surgery. Three (4%) underwent shell removal for periprosthetic joint infection (PJI) at 1 month, 3 months, and 6 months. Another 3 patients (4%) were explanted for failure of osseointegration/aseptic loosening after 15, 17, and 20 months; 2 had a Paprosky 3A defect (17 months, 20 months), and 1 had a Paprosky 2C defect (15 months). At the latest follow-up, all the unrevised shells showed signs of osseointegration, and no shells had migrated. Patients demonstrated a significant improvement in HHS at the latest follow-up ($P < .0001$).

Table 1
Cohort characteristics (N = 68).

Variable	N (%) unless otherwise specified
Male (%)	28 (41%)
Mean age	67.6 (10.4)
Mean BMI	29.5 (5.9)
Race	
White	48 (70%)
Black	6 (9%)
Other	6 (9%)
Declined/unknown	8 (12%)
Smoking status	
Current smoker	3 (4%)
Former smoker	30 (44%)
Never smoker	35 (52%)
ASA	
1	0 (0%)
2	40 (59%)
3	26 (38%)
4	2 (3%)
Mean years of follow-up (SD)	3.0 (0.6)

ASA, American Society of Anesthesiology; BMI, body mass index; SD, standard deviation.

Table 2
Surgical considerations.

Variable	N (%) unless otherwise specified
Right side	36 (53%)
Paprosky	
1	4 (6%)[a]
2A	19 (28%)
2B	14 (23%)
2C	10 (15%)
3A	15 (21%)
3B	6 (9%)
Indication for surgery	
Aseptic loosening	33 (49%)
Infection	15 (22%)
Instability	14 (21%)
Periprosthetic fracture	3 (4%)
Metal-on-metal articulation complications	2 (3%)
Broken acetabular liner	1 (1%)
Median shell size (range)	60 (48-76)
Median head size (range)	32 (22-40)
Inner Diameter If DM	28 (22-28)
Outer Diameter if DM	46 (42-52)
If Standard Modular Components	36 (28-40)
Median number of screws utilized (range)	4 (2-15)
Dual mobility liner	23 (34%)
Concurrent stem revision	29 (43%)
Extended trochanteric osteotomy performed	6 (9%)
Augmentation	
Allograft	19 (28%)
Cage	7 (10%)
Median surgical time in minutes (range)	129.5 (25-398)
Median length of stay in days (range)	4 (1-21)
Disposition	
Home	45 (66%)
Home health care	3 (4%)
Skilled nursing facility	11 (16%)
Subacute rehabilitation	4 (6%)
Other inpatient facility	1 (1%)
Not reported	4 (6%)

DM, dual mobility.
[a] (1) Acetabular revision for a failed constrained liner, (2) prior poor cup placement needing substantial revision, (3) acetabular revision for dislocation related to malpositioning with an oversized original cup (×2), (4) revised due to recurrent dislocations and conversion to dual mobility implant.

Complications

Perioperatively, 11 patients had a medical complication (16%, Table 4). *Staphylococcus epidermidis* eventually grew from 1 patient's intraoperative cultures, which was treated with antibiotics. This patient never became septic nor exhibited signs of a localized infection. In total, there were 10 patients (15%) admitted to the ED within 90 days of surgery. Of 3 patients who presented to the ED with a THA dislocation, 1 patient had a dislocation at 15 days treated with a closed reduction, while 2 ultimately required revision surgery (see Revisions within 2 years). All 5 patients with wound drainage were admitted and found to have PJI. The 90-day readmission rate was 16% (11 patients). Eight patients (7%) had a PJI: One had simple wound drainage (12.5%), while all others underwent rTHA as mentioned previously.

Seven reoperations without revision of the acetabular shell occurred (10%). Five patients had an irrigation and debridement for PJI without removal of their acetabular shell, all within 90

Table 3
Two-year outcomes of novel fully porous titanium shell.

Variable	N (%) unless otherwise specified
Revision-free survival at 2 y, N (%)	
All-cause	55 (81%)
Acetabular revisions (shell explanted)	60 (88%)
Acetabular revision for aseptic acetabular shell failure	61 (90%)
Median days survival time if shell removed (range)	460 (1-601)
Osseointegration at latest follow-up, N (%)[a]	61 (100%)
No migration at latest follow-up, N (%)[a]	61 (100%)
Mean HHS score (SD)	
Preoperative	49.94 (12.34)
Postoperative	80.15 (17.67)
Difference [*P* value]	29.62 (17.67) [$P < .0001$]

SD, standard deviation.
[a] Osseointegration and migration only evaluated in hips with retained cups.

Table 4
Complications of a novel fully porous titanium shell.

Variable	N (%) unless otherwise specified
Any perioperative complication	11 (16%)
Atelectasis	1 (1%)
Constipation	1 (1%)
Hyponatremia	1 (1%)
Hypotension	3 (4%)
Neuropraxia	1 (1%)
Positive blood cultures	1 (1%)
Transient anemia not requiring transfusion	4 (6%)
Transient anemia requiring transfusion	5 (7%)
Urinary retention	3 (4%)
ED visits in 90 d	10 (15%)
Ankle sprain	1 (1%)
Hematoma	1 (1%)
THA dislocation	3 (4%)
Wound drainage	5 (7%)
Hip-related readmissions in 90 d	11 (16%)
Periprosthetic joint infection	8 (12%)
THA dislocation	3 (4%)

days of the index surgery. One patient experienced 2 postoperative dislocations within 1 month of her operation and was brought back for a revision to increase femoral neck length and place an anteverted liner. A second patient underwent stem revision for dislocation after 21 days with soft-tissue transfer.

Discussion

The principal findings of this study examining the early experience with the use of a novel, 3-D printed, fully porous acetabular shell in rTHA include (1) 13 (19%) patients required any re-revision within 2 years of the index surgery, only 8 (12%) of which involved explantation of the acetabular component and 7 (10%) of which were acetabular revisions for aseptic reasons; (2) all patients with unrevised shells were found to show signs of osseointegration of the implant, with no evidence of component migration; and (3) complications within 90 days were rare but included 3 prosthesis dislocations and 8 PJIs (12%).

In the present analysis, 90% of the novel fully porous titanium shells remained in situ after 2 years with radiographic evidence of osseointegration and no migration. Only 3 patients (4%) had their

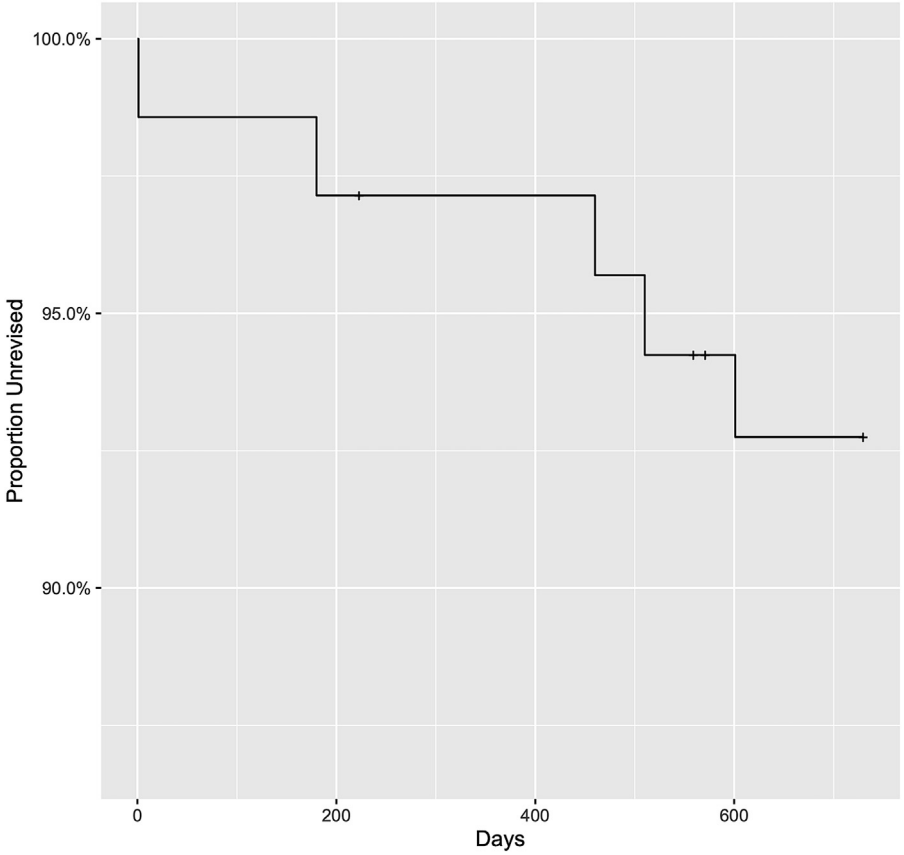

Figure 2. Kaplan-Meier plot of fully porous titanium shell survival, censoring at 2 years.

acetabular shell removed due to failure of osseointegration, suggesting that these shells demonstrated stable fixation despite being used in complex defects. These findings are a positive prognostic factor for the long-term survival of this acetabular shell, as early migration is a useful parameter in gauging long-term fixation and success of implanted hip components [16]. The findings of our study are similar to others assessing the performance of highly porous metal acetabular shells: Both porous titanium and tantalum have shown excellent survivorship with rates between 98% and 100% at 7 years, and virtually no patients show evidence of component migration or loosening [17–19].

Multiple aspects of implant design may contribute to these positive findings. First, fully porous components provide scaffolding for bony ingrowth and present with stiffness more similar to that of natural bone to prevent stress shielding or bone resorption following implant placement [20,21]. The choice of material may further enhance osseointegration and construct stability. Both porous tantalum and titanium have been found to show superior osseointegration among common acetabular implant materials in animal studies [22–25]. The biocompatibility of titanium has also shown to be more optimal than that of other conventional implant materials such as tantalum or chrome-cobalt alloys, further lending to the acetabular shell's ability to osseointegrate and remain well-fixed [26]. Finally, this construct utilizes a high-friction surface with angle locking screws to aid in initial implant stability and placement. Biomechanical studies have consistently demonstrated that the use of screws improves construct stiffness against cyclic loading and increases load to failure [27–29]. However, they report conflicting results about whether locking screws are superior to nonlocked or cancellous screws [27,29]. It remains unclear whether the excellent results of this novel implant may be in part attributed to the use of locking screws, and further investigation into this subject may be warranted.

This report demonstrated low complication rates despite the baseline complexity of included procedures. As with any evaluation of a new orthopedic device, it is essential to establish its safety. Most complications were systemic and non-prosthetic-related, nor directly attributable to acetabular implant failure. Overall, the complication and readmission rates reported are similar to those reported in the literature for complex and rTHA [30–34]. Importantly, the 10% rate of PJIs is higher than the 3%-5% rates reported in prior studies of rTHA with porous titanium implants, porous tantalum implants, and porous tantalum augments [34–36] but similar to the rates of infection for rTHA in large population-based studies [37,38]. It is also pertinent that 22% of our cohort underwent placement of the novel implant in the setting of previous PJI, and half of these patients had a history of chronic infection, including prior PJI.

Although this study provides promising results and survivorship for the use of this novel, 3-D printed fully porous titanium shells in rTHA, it is important to note some key limitations. Primarily, this was a retrospective study and did not include a control group for direct comparisons. Future studies may consider a prospective, randomized design to better assess the relationship among the implant, survivorship, and osseointegration. Typically, an acetabular shell shows evidence of osseointegration within the first 2 years [39]. However, it is possible that ongoing osteolytic changes may occur after 2 years, and longer follow-up may be required to further evaluate and validate long-term performance. The study was limited in size and reported on a heterogeneous population of patients with rTHA for multiple indications with both septic and aseptic revisions. Therefore, we had limited power to identify specific predictors of failures in this analysis. Finally, we reported on multiple surgeons and practices, which increases heterogeneity. However, inclusion of data from multiple surgeons and practice settings with variable resources and workflows improves the generalizability of our outcomes.

Conclusions

This study is the first report on the use of a novel, 3-D printed, fully porous titanium acetabular shell in rTHA. It demonstrated positive short-term survivorship and osseointegration despite its use in the reconstruction of complex acetabular defects. Future studies are necessary to determine its long-term performance.

Conflicts of interest

B. Frykberg, W. B. Lutes, E. A. Schnaser, S. A. Jones, R. W. McCalden, and R. Schwarzkopf are paid consultants for Smith & Nephew. W. B. Lutes, E. A. Schnaser, and R. Schwarzkopf have research funding from Smith & Nephew. W. B. Lutes, E. A. Schnaser, and S. A. Jones report speaking fees for Smith & Nephew. S. A. Jones, R. W. McCalden, and R. Schwarzkopf report royalties/licenses from Smith & Nephew. E. J. Berlinberg reports <1% stock options in Amgen and Pfizer, Inc. W. B. Lutes reports stock options and consulting fees for OrthAlign. E. A. Schnaser reports research funding from Lima, consulting fees from Stryker and Zimmer, and speaking fees for OrthAlign and Stryker. S. A. Jones reports consulting fees for OrthoFix and Zimmer, as well as speaking fees for Zimmer. R. W. McCalden reports research funding from J&J DePuy and Stryker. R. Schwarzkopf reports speaking fees from Intellijoint; stock or stock options in Intellijoint, Gauss Surgical, and PSI; is a board or committee member for American Academy of Orthopaedic Surgerons and American Association of Hip and Knee Surgeons; and is on the editorial board for *Arthroplasty Today* and *Journal of Arthroplasty*. All other authors declare no potential conflicts of interest.

For full disclosure statements refer to https://doi.org/10.1016/j.artd.2022.08.007.

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