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Radiographic and Clinical Outcomes in Total Hip Arthroplasty Utilizing a Porous Acetabular Shell Developed with Additive Manufacturing

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Abstract

This is a prospective data collection across seven centers in a non-randomized, post-market study where an additive manufactured cementless acetabular shell was used in primary total hip arthroplasty. There was a total of 254 hips/246 patients across seven centers. Clinical outcomes including all-cause survivorship, the Harris Hip Score (HHS), Lower Extremity Activity Scale (LEAS), Veterans Rand 12 (VR-12), EuroQol 5D (EQ-5D) and radiographs were collected pre- and postoperatively. Radiographs were analyzed for presence of radiolucencies, migration and overall cup stability. All-cause survival rate was 99.61% and there were no reported radiolucencies greater than 2mm for any zone. There was a reduction in radiolucencies from the 6-week to 1-year postoperative timeframe. All cups reviewed at 1-year were stable with no radiolucencies in 96% of hips. These early results demonstrate the favorable properties of this shell and the use of additive manufacturing in orthopaedic surgery.

1 Introduction

Cementless acetabular components for total hip arthroplasty became popular in the United States in the early 1980s, primarily due to poor long-term results with cemented cups. Superior radiographic performance has been reported for cementless cups as compared with cemented fixation.[6]

Primary THA utilizing cementless acetabular components requires initial implant stability to allow for biologic fixation, which provides long-term durability of the prosthesis when properly achieved.[6] To this end, there are several surface options available for cementless acetabular fixation; titanium fibermesh, sintered bead surfaces, plasma spray and trabecular metal are some widely used examples, all with good clinical history.[8,9] Della Valle[10] et al. published Kaplan-Meier survivorship results on a titanium fibermesh cup, reporting 96% survivorship at 20 years. Similarly, positive results have been reported at slightly shorter time points for both sintered bead surfaces[10] (0.7% revision for aseptic loosening at 9.5 years) and plasma sprayed surfaces[11] (0% revision for aseptic loosening at 8.5 years).

Utilizing technology to develop an acetabular implant surface is revolutionizing total hip arthroplasty[1]. Specifically, innovative additive manufacturing has the ability to construct layers of titanium alloy powder for a slim acetabular shell wall, allowing for optimal polyethylene thickness to potentially aid in greater range of joint motion[2]. The outcome yields a shell with a roughened surface and high coefficient of friction[3,4]. The purpose of this study was to evaluate outcomes of patients who underwent total hip arthroplasty (THA) using a highly-porous titanium shell produced via additive manufacturing. We assessed radiographic outcomes and patient-reported outcomes at various time points.

2 Methods

Data was prospectively collected from 254 hips/246 patients (113 male, 133 female, 8 bilateral) across seven centers in a non-randomized, post-market study where a cementless acetabular shell created with additive manufacturing (Trident II Tritanium, Stryker, Mahwah, NJ) was used in primary total hip arthroplasty.

An independent surgeon, who was not a study Investigator, reviewed the patients' low anteroposterior (AP) pelvis and Lauenstein lateral x-rays preoperatively and postoperatively at 6-weeks, 3-6 months, and 1-year. Radiographic analysis of the acetabular component employed three zones (Zone 1 – Zone 3) in the AP views. Parameters reviewed included radiolucency and migration, in addition to overall cup stability. Radiolucency in at least 50% of a zone and measuring at least 1 mm in width was defined as radiolucency present.

Clinical outcomes such as all-cause survivorship, the HHS, LEAS, VR-12, and EQ-5D were also collected preoperatively and postoperatively.

3 Results

The all-cause survival rate of the acetabular shell was 99.61%. One patient suffered a perioperative acetabular fracture resulting in the lone failure of an implant which was successfully revised eight months postoperatively. Of the reviewed radiographs, all cups were reported stable at all time points. Furthermore, no cases of acetabular erosion, stress shielding, or lack of fixation were reported.

Table 1 summarizes radiolucency specific to acetabular zones. Of note, there were no reported radiolucencies greater than 2mm for any zone and no findings in any zone for 96.0%of cases at 1-year follow-up, respectively. These trends translated into enhanced clinical outcomes with 89.9% of cases scoring an excellent HHS at 1-year postoperatively. Additionally, from preoperatively to 1-year postoperatively, the VR-12 Physical Component and VR-12 Mental Component increased 16.71 points and 2.12 points, respectively. Table 2 summarizes an increase of all patient-reported outcomes over time.

4 Discussion

It has been shown via metallographic images that key morphological characteristics of the implant's porosity are within the range of values seen for cancellous bone[5]. There was a reduction of radiolucencies from the 6-week to the 1-year time intervals postoperatively. Additionally, all cups reviewed at 1-year postoperative were stable with an absence of radiolucencies in 96.00% of hips. The patient reported outcomes that correlate with the radiographic findings give further evidence of early bone-to-implant fixation.

As recently as 2018, additive manufacturing was discussed in an AAHKS symposium as potentially too expensive for larger orthopaedic implants[6]. These very early (1 year) results but show great promise for the use of additive manufacturing in orthopaedic surgery. We believe additive manufacturing coupled with improved understanding of the anatomy of the host bone will allow more predictable surfaces that optimize fixation of orthopedic implants in the future. We look forward to continuing to report on this cohort of patients over the duration of the 10-year study.

Figure 1: Highly Porous Titanium Surface Created with Additive Manufacturing

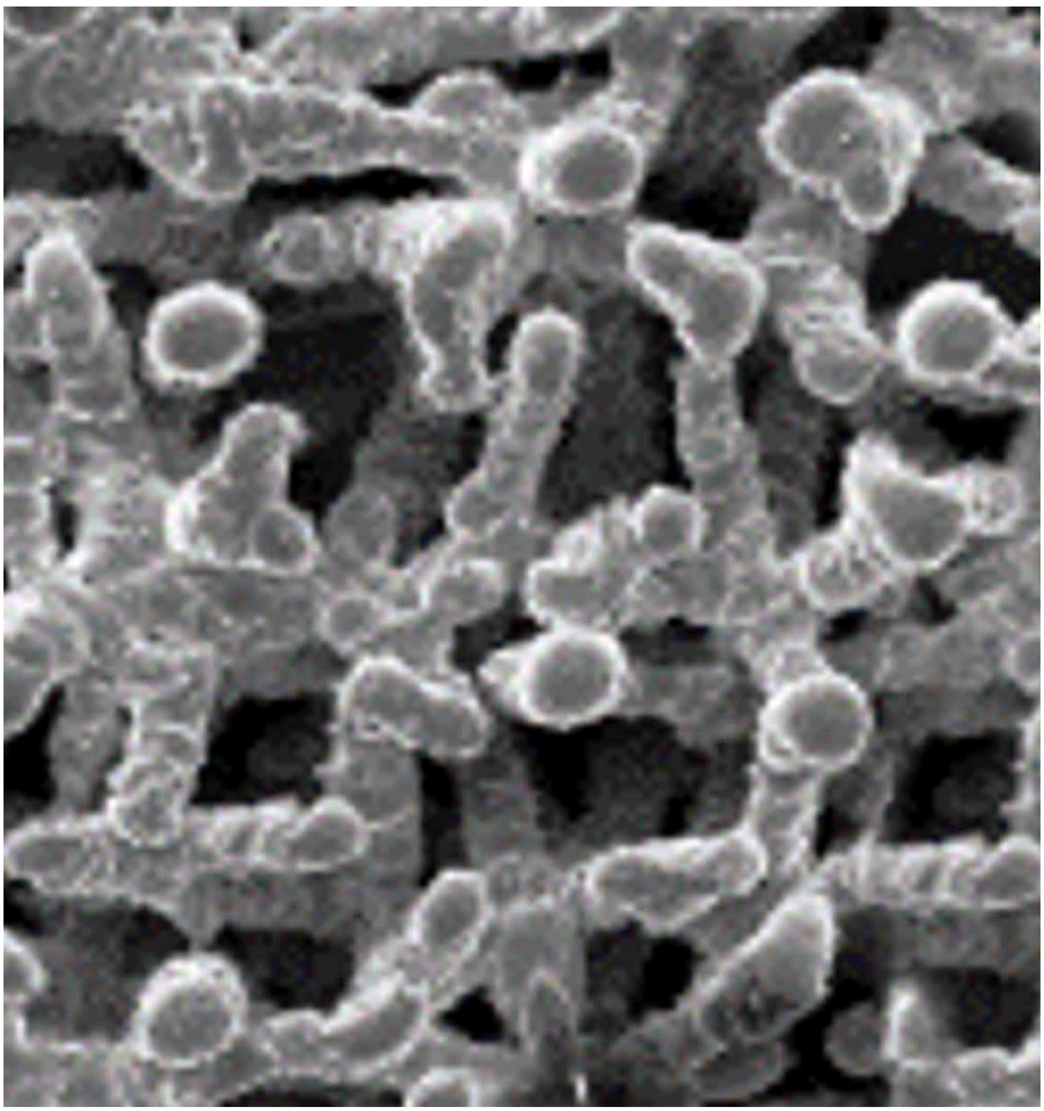

Table 1. Percentage of Patients with Radiolucent Findings Across Acetabular Zones 1-3.

Radiolucency	6 weeks	3-6 month	1 year
Zone1			
>=1 and <2mm	2.72%	2.70%	4.00%
>=2mm	0.54%	1.80%	0.00%
Zone2			
>=1 and <2mm	7.07%	3.60%	0.00%
>=2mm	0.54%	0.00%	0.00%
Zone3			
>=1 and <2mm	0.00%	0.90%	0.00%
>=2mm	0.00%	0.00%	0.00%
Findings in All Zones	0.00%	0.00%	0.00%
No Findings in any Zones	89.67%	93.69%	96.00%
X-rays Reviewed	184	111	50

Table 2. Summary of Mean Patient-Reported Outcome (PROM) Scores at Different Time Intervals

Mean (SD) PROM Score	Preoperative	6 Week	1 Year
HHS	55.08 (13.85)	79.73 (16.94)	94.99 (8.12)
EQ-5D TTO	0.65 (0.19)	0.81 (0.14)	0.89 (0.12)
LEAS	9.13 (2.89)	8.58 (2.26)	10.99 (2.95)
VR-12 Physical	31.26 (9.55)	37.81 (10.13)	47.97 (8.38)
VR-12 Mental	54.67 (9.98)	55.98 (8.88)	56.79 (7.11)

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