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

[Map \(epsMap.cfm?id=547\)](#)



Adult Reconstruction Hip Poster Session 2

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### INTRODUCTION:

Utilizing novel technology to develop an acetabular implant surface is revolutionizing total hip arthroplasty. Specifically, additive manufacturing allows optimization of specific design characteristics such as shell wall thickness to allow thicker polyethylene bearings, surface roughness for initial stability, and porosity for biologic fixation. The purpose of this study was to evaluate outcomes of patients who underwent primary 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 intervals.

**METHODS:** In a prospective, non-randomized trial across 9 centers, 352 surgical cases (11 bilateral) received an acetabular shell created with additive manufacturing during primary THA. An independent surgeon, who was not a study Investigator, reviewed anteroposterior (AP) pelvis and Lauenstein lateral x-rays preoperatively and postoperatively at 6-weeks, 3-6 months, 1-year, and 2-years. 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 were assessed preoperatively at 6-weeks, 1-year, and 2-years postoperatively and included: all-cause survivorship, Harris Hip Score (HHS), Lower Extremity Activity Scale (LEAS), Veterans Rand 12 (VR-12), and EuroQol 5D Score (EQ-5D). The latest follow-up scores were compared to preoperative scores.

**RESULTS:** The all-cause survival rate of the acetabular shell was 99.44% at 2-year follow up. 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 void of acetabular erosion, stress shielding, or lack of fixation. Of note, there were no reported radiolucencies greater than 2mm for any zone and no findings in any zone for 97.8% of cases at 1-year follow up, and no reported radiolucencies greater than 2mm for any zone at 2-year follow up, respectively (Table 1). Statistically and clinically significant improvement in outcomes were observed as the HHS increased considerably from a mean of 54.2 preoperatively to 86.5 at the latest follow up. The same observation was noted for the latest mean in the HHS, LEAS, VR-12 Physical Component Score, and EQ-5D (Table 2).

**DISCUSSION AND CONCLUSION:** Designs achieved with additive manufacturing support the early encouraging clinical findings that we observed in this study. Additionally, the absence of radiolucencies in 97.83% of hips, along with total cup stability at 1-year, is also consistent with early implant fixation. The patient-reported outcomes that correlate with the radiographic findings give further evidence of early bone-to-implant fixation. Additive manufacturing has the potential to transform the way all orthopaedic implants are manufactured exhibiting a correlation with positive patient results, which supports the future of this technology.

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

| Radiolucency                    | 6-Week | 3-6 Month | 1-Year | 2-Year  |
|---------------------------------|--------|-----------|--------|---------|
| <b>Zone1</b>                    |        |           |        |         |
| >=1 and <2mm                    | 2.94%  | 2.79%     | 2.17%  | 0.00%   |
| >=2mm                           | 0.33%  | 0.93%     | 0.00%  | 0.00%   |
| <b>Zone2</b>                    |        |           |        |         |
| >=1 and <2mm                    | 6.86%  | 1.86%     | 0.72%  | 0.00%   |
| >=2mm                           | 0.65%  | 0.00%     | 0.00%  | 0.00%   |
| <b>Zone3</b>                    |        |           |        |         |
| >=1 and <2mm                    | 0.00%  | 0.93%     | 0.72%  | 0.00%   |
| >=2mm                           | 0.00%  | 0.00%     | 0.00%  | 0.00%   |
| <b>Findings in All Zones</b>    |        |           |        |         |
|                                 | 0.00%  | 0.00%     | 0.72%  | 0.00%   |
| <b>No Findings in any Zones</b> |        |           |        |         |
|                                 | 90.52% | 95.35%    | 97.83% | 100.00% |
| <b>X-rays Reviewed</b>          |        |           |        |         |
|                                 | 306    | 215       | 138    | 61      |

**Table 2. Summary of Latest Mean Patient-Reported Outcome (PROM) Scores**

| Patient Reported Outcome       | Preop         | Latest        | P values (paired T test) |
|--------------------------------|---------------|---------------|--------------------------|
| HHS                            | 54.18 (13.81) | 86.53 (15.75) | p<0.0001                 |
| LEAS                           | 9.48 (3.11)   | 10.21 (3.10)  | p<0.0001                 |
| VR-12 Physical Component Score | 30.96 (9.38)  | 42.54 (10.57) | p<0.0001                 |
| VR-12 Mental Component Score   | 54.27 (10.60) | 55.43 (8.03)  | p=0.0666                 |
| EQ-5D TTO                      | 0.63 (0.19)   | 0.85 (0.16)   | p<0.0001                 |

**Disclosure:** **G. Westrich:** Submitted on: 06/03/2020|Eastern Orthopedic Association: Board or committee member|Exactech, Inc: IP royalties; Paid consultant; Paid presenter or speaker; Research support|Knee Society: Board or committee member|Mallinckrodt Pharmaceuticals: Paid presenter or speaker|Stryker: IP royalties; Paid consultant; Paid presenter or speaker; Research support|; **B. Domb:** Submitted on: 06/22/2020|AANA Learning Center Committee: Board or committee member|Adventist Hinsdale Hospital: Paid consultant|American Hip Foundation: Board or committee member|American Hip Institute: Stock or stock Options|American Orthopedic Foundation: Board or committee member|Amplitude: Paid consultant|Arthrex, Inc: IP royalties; Other financial or material support; Paid consultant; Paid presenter or speaker; Research support|Arthroscopy Journal: Editorial or governing board|ATI Physical Therapy: Research support|Breg: Other financial or material support|DJO Global: IP royalties|Journal of Hip Preservation Surgery: Editorial or governing board|Kaufman Foundation: Research support|MAKO Surgical Corporation: IP royalties; Paid consultant; Research support|Medacta: Paid consultant; Research support|Medwest: Other financial or material support|Munster Specialty Surgical Center: Stock or stock Options|North Shore Surgical Suites: Stock or stock Options|Orthomerica: IP royalties|Pacira Pharmaceuticals: Paid consultant; Paid presenter or speaker; Research support|SCD#3: Stock or stock Options|St. Alexius Medical Center: Board or committee member; Other financial or material support|Stryker: IP royalties; Paid consultant; Research support|University of Illinois College of Medicine: Board or committee member|; **J. Mohn:** Submitted on: 06/24/2020|Stryker: Employee|; **A. Cruz:** Submitted on: 06/30/2020|Stryker: Employee|;

