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Original Research

Early Radiographic and Clinical Outcomes of an Additive-Manufactured Acetabular Component

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ABSTRACT

Background: Additive manufacturing has recently gained popularity and is widely adopted in the orthopaedic industry. However, there is a paucity of literature on the radiographic and clinical outcomes of these relatively novel components. The aim of this study was to assess the 2-year clinical and radiographic outcomes of a specific additive-manufactured acetabular component in primary total hip arthroplasty.

Methods: We performed a retrospective review of 60 patients who underwent primary total hip arthroplasty with the use of the Stryker's TRIDENT II acetabular component. Evaluation of radiographs was performed at 6 weeks, 1 year, and 2 years postoperatively. Radiographs were evaluated for radiolucencies in Charnley and DeLee zones, signs of biologic fixation, and acetabular inclination and anteversion measurements. Patient-reported outcomes and complications were also obtained.

Results: There were no cases of component loosening or changes in component position during follow-up, with an average follow-up time of 1.7 years. A radiolucent line was identified in one patient in zone 1 at 6 weeks; this was absent at 1 year. Radiographic signs of cup biologic fixation were present in 85% of cases by final follow-up. The average inclination was 45.1 (SD = 4.0), and the average anteversion was 26.9 (SD = 5.2). Patient-Reported Outcomes Measurement Information System scores significantly increased at the final follow-up, and there were no complications in this cohort.

Conclusions: This study demonstrated excellent radiographic and clinical outcomes with this novel additive-manufactured acetabular component at early follow-up. Although longer-term follow-up is warranted, this additively manufactured highly porous titanium acetabular component demonstrated excellent biologic fixation and reliable fixation at mid-term follow-up.

Introduction

Over 1.4 million total hip arthroplasty (THA) procedures are performed worldwide every year. This number is expected to grow significantly with an estimated 500,000 THAs predicted to be performed per year in the United States by 2030 [1,2].

THA outcomes have continued to improve with newer components providing excellent short- and long-term fixation. Most acetabular implants used in the United States are uncemented, or press-fit, which allow for reduced operative time, versatility in positioning, ability to add increased stability with screw fixation, and generally produce excellent clinical outcomes in terms of aseptic loosening compared to cemented cups in nonelderly patients [3-5].

For press-fit acetabular components to obtain long-term fixation, several design principles must remain constant: the implant must maintain initial rigid stability with micromotion <150 micrometers, the implant surface must have a porous surface to allow fixation, and the implant must maintain contact with viable host bone [3,4,6-8]. Despite improvements in surgical training, surgeon

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education on new acetabular implants, and improved manufacturing of components, we continue to see cases of THA failure [2,3,9].

As cementless acetabular fixation has gained momentum over the past decade, advancements in manufacturing technology and optimization of acetabular fixation have led to an array of cementless options entering the market. Additive manufacturing is a three-dimensional printing method that has recently gained popularity in the production of customized uncemented acetabular components. It is theorized to allow for the optimization of initial acetabular stability with subsequent long-term fixation and restoration of native hip biomechanics [1,10,11]. The process of additive manufacturing acetabular components utilizes a layer-over-layer approach via selective laser melting or electron beam melting to effectively yield the final product with appropriate pore size and fixation potential [10,11].

While an abundance of literature exists on conventional manufacturing technologies, additive-manufactured acetabular components lack short- and long-term outcome studies. The purpose of this study is to assess the 2-year clinical and radiograph outcomes of a novel additive-manufactured acetabular component in primary THA. We hypothesized that this acetabular component would demonstrate exceptional clinical and radiographic outcomes without evidence of loosening at early postoperative follow-up.

Material and methods

We performed a retrospective radiographic and chart review of 60 consecutive patients who received a novel additive-manufactured acetabular implant (Stryker's TRIDENT II) as part of their THA at a single academic medical center. Patients were consecutively selected to receive this implant between June 2017 and September 2019 based on age >18 years old and <85 years old, body mass index (BMI) <40, diagnosis of primary osteoarthritis of the operative hip, no history of septic arthritis or previous arthroplasty of the operative hip, and absence of the comorbidities listed in exclusion criteria below. This study was sponsored by Stryker and approved by the University of Utah Institutional Review Board.

Patients were included in the study if they had a primary THA, received the previously mentioned acetabular component, were at least 18 years of age and less than 85 years of age, had at least 1 year of follow-up, and had postoperative standing radiographs.

Patients were excluded from analysis if they had pyogenic arthritis, were <18 years of age or >85 years of age, had severe hip dysplasia (Crowe III or IV), had a history of congenital dislocation, had undergone prior arthroplasty or prior infection of the affected hip, had morbid obesity (BMI >40), had severe osteoporosis, had known neuromuscular impairment, were immunosuppressed, or were on dialysis.

All surgical procedures were completed by the senior author (J.M.G.) through a standard direct anterior approach on a Hana table (Mizuho OSI, Union City, CA). Acetabular preparation is completed via a consistent technique: after removal of acetabular soft tissues, the acetabulum is reamed to match the patient's anatomy using line-to-line reaming to the stated size of the implant. Acetabular sizing and cup position are adjusted and typically are 2-3 mm larger than the native femoral head size to prevent overhang. The cup itself is inherently oversized by 0.5 mm from the stated size (ie, 52 mm shell = 52.5 mm diameter), so there is always at least 0.5 mm of underreaming. Direct visualization is used to assess cup positioning and correct sizing. The cup is then impacted into place under fluoroscopic guidance, and an artificial intelligence-based fluoroscopic imaging application (OrthoGrid Systems, Inc., Midvale, UT) is used to ensure proper anteversion and abduction. Anteversion is adjusted intraoperatively to prevent overhang and avoid iliopsoas impingement. Supplemental screw fixation is completed at the surgeon's discretion based on an intraoperative assessment of relatively inferior resistance with press-fit cup placement. Our experience with this subjective method of determining fixation has yielded encouraging outcomes, though we recognize a more objective method would be preferred, as illustrated by Fehring et al [12]. Four patients received supplemental screw fixation and were removed from the analysis. After assessing cup position with fluoroscopy, the final acetabular liner is then impacted into place based on templating.

Radiographs were reviewed by a musculoskeletal radiologist and by a senior orthopaedic resident. Radiographic measurements were obtained at 6 weeks, 1 year, and 2 years postoperatively. We noted cup inclination, cup anteversion, presence of a superolateral buttress, presence of medial stress-shielding, presence of radial trabeculae, and presence of an inferomedial buttress. Figures 1 and 2 below provide examples of radial trabeculae and inferomedial buttress on radiographs, respectively. We documented any lucencies in the zones around the acetabular component as described by Charnley and DeLee [13] and performed a chart review of patient-reported outcomes (PROs) and any revisions required for aseptic loosening.

We reviewed PROs including Patient-Reported Outcomes Measurement Information System physical health, mental health, pain, and physical function scores. PROs were analyzed as a secondary outcome to investigate postoperative improvement in patient outcomes. PROs were recorded and compared to their 6-week, 1-year, and 2-year postoperative scores.

All statistical analysis was performed at our institution, using simple statistics to assess averages and the Mann-Whitney U test to evaluate *P*-values of trends in PROs.

Sixty consecutive patients with an average follow-up time of 1.7 years were included in our final analysis. Four were excluded from final analysis due to supplemental screw fixation. Fifty-six completed the 6-week follow-up, 42 completed the 1-year follow-up, and 35 completed the 2-year follow-up (Table 1). Our cohort had an average age of 62.6, a BMI of 28.9, an American Society of Anesthesiology of 2.1, and 53.6% were women. (Table 2)

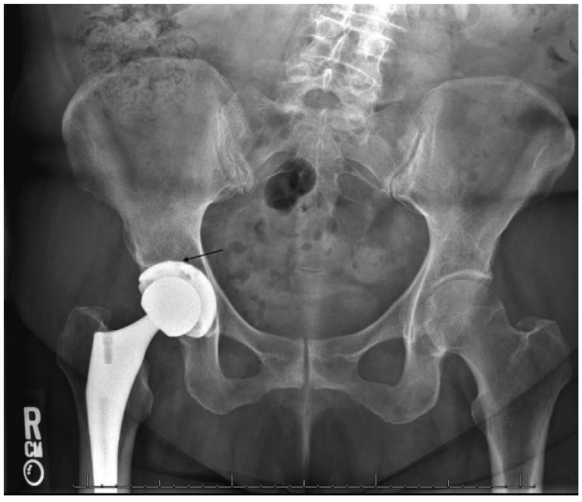

Figure 1. Demonstration of radial trabeculae. The above figure demonstrates a TRIDENT II acetabular cup with a radiographic example of radial trabeculae (black arrow) suggestive of biologic fixation at the cup-acetabulum interface.

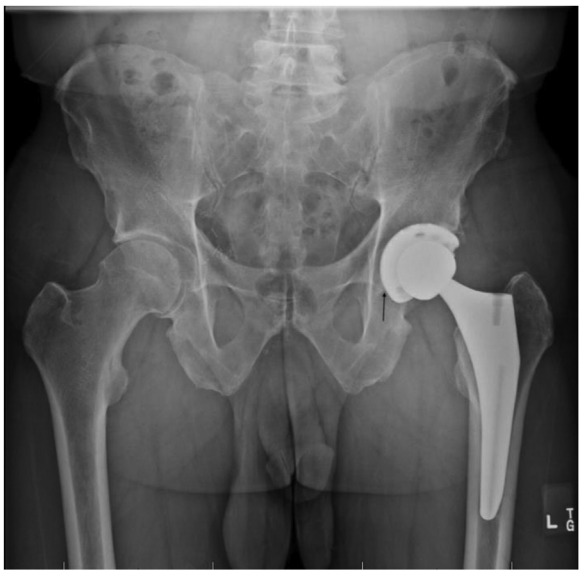

Figure 2. Demonstration of inferomedial buttress. The above figure provides an example of a left TRIDENT II acetabular cup with an inferomedial buttress (black arrow), suggestive of biologic fixation at the cup-acetabulum interface.

Results

Patients consistently improved in PROs preoperatively to 2 years postoperatively: physical function improved from 37.2 to 44.0 ($P < .0001$), physical health improved from 40.3 to 50.9 ($P < .0001$), pain improved from 56.7 to 25.6 ($P < .001$) and mental health improved from 47.7 to 52.6 ($P = .0331$). (Table 3)

On radiographic analysis, the average component inclination was 45.4 degrees and the anteversion was 26.3 degrees. At the 6-week postoperative radiographic evaluation of acetabular components, 21.4% had the presence of a superolateral buttress, 0% had medial stress shielding, 3.6% had radial trabeculae, and 14.3% had an inferomedial buttress.

At the 1-year postoperative radiographic evaluation, 51.2% had the presence of a superolateral buttress, 12.1% had medial stress shielding, 19.5% had radial trabeculae, and 24.3% had an inferomedial buttress.

At 2 years, 57.1% had the presence of a superolateral buttress, 51.4% had medial stress shielding, 37.1% had radial trabeculae, and 31.4% had an inferomedial buttress. (Table 4) No patients had radiolucencies. None of the acetabular components were deemed loose, and no revisions were seen by the final follow-up.

Discussion

This study provides evidence to suggest excellent early- and mid-term radiographic and clinical outcomes for a novel additive-manufactured acetabular implant used in the primary THA setting. Osteolysis and aseptic loosening are considered the most common reasons for revision THA overall [14]. Mechanical failure and adverse local tissue response from metallosis are the most common causes for revisions greater than 2 years out from primary THA (2, 9).

Table 1
Number of patients by data type and time point.

Patient variables	6 wk	1 y	2 y
Completed X-rays	56	41	35
Completed clinic visit	56	42	35
Completed PROs	49	24	34

Table 2
Demographics.

Demographic variables	N = 56
Age, Mean (std)	62.6 (10.1)
BMI, Mean (std)	28.9 (4.4)
ASA, Mean (std)	2.1 (0.7)
Sex, N (%)	
Male	26 (46.4)
Female	30 (53.6)

ASA, American Society of Anesthesiology.

Radiographic evidence of loosening has been evaluated using the Charnley and DeLee zones [13], which we use as the zones of reference in our study. None of our patients had any radiolucent lines in any zone at the final follow-up (average 1.7 years). Moore et al. defined 5 radiographic signs to detect acetabular component biologic fixation: 1) absence of radiolucent lines; 2) presence of a superolateral buttress; 3) medial stress-shielding; 4) radial trabeculae; and 5) presence of an inferomedial buttress [15]. We found evidence of each of these radiographic signs of biologic fixation in several of our patients (Table 4). The radiographic indicators described by Moore et al. demonstrated a high positive predictive value for successful biologic fixation, ranging from 92.2% to 96.3%. The assessment of the presence of superolateral or inferomedial buttress showed excellent reliability when evaluated by the same observer after a 4-month gap, while the other 3 radiographic markers displayed fair to good reliability. Despite this, instances of successful biologic fixation were observed in revision procedures even when these specific radiographic signs were absent preoperatively; the negative predictive value ranged from 18.9-42.9%, suggesting limitations in their predictive power [15].

The radiographic signs identified by Moore et al. are believed to be a consequence of Wolff's Law, which hypothesizes that bone adjusts and adopts patterns in response to applied forces. These adaptive patterns may involve increased bone density (as seen in buttresses) or decreased bone density (as seen in shielding). These responsive structures are suggested to be absent if the force is transmitted beyond the implant-bone interface, a scenario observable in a loose cup. The presence of a buttress is hypothesized to arise from the transmission of load toward the periphery of the bone-implant interface, a phenomenon occurring with biologic fixation of the implant, enabling the forces for remodeling to be transferred through these regions [15]. The radiographic signs established by Moore et al. should be used in conjunction with previously described methods of determining cup loosening (ie, presence of radiolucent lines or cup migration) to increase their predictive value [15].

It is unknown if the presence of these radiographic signs coincides with improved PROs, and this was not directly analyzed in this study. This study analyzed multiple PROs including Patient-Reported Outcomes Measurement Information System physical health, mental health, physical function, and pain scores. Physical health, physical function, mental health, and pain scores all saw significant improvement postoperatively. This study does not investigate the correlation between specific radiographic signs of biologic fixation and PROs, but rather investigates these 2 factors independently.

As the volume of THA procedures continues to increase, it is paramount that new methods of fixation and new implants are vetted for efficacy, reliability, and noninferiority to previously used

Table 3
Patient-reported outcomes.

PROMIS score domains	Preoperative	6-wk	1-y	2-y	*P*-value for trend[a]
	Mean (std)	Mean (std)	Mean (std)	Mean (std)	
Physical function	37.2 (5.1)	40.7 (6.9)	44.0 (6.7)	44.0 (7.5)	<.0001
Physical health	40.3 (7.4)	47.2 (9.2)	49.5 (13.4)	50.9 (13.9)	<.0001
Mental health	47.7 (9.4)	52.8 (9.7)	51.7 (10.3)	52.6 (9.5)	.0331
Pain	56.7 (24.7)	28.3 (21.4)	28.8 (24.2)	25.6 (28.6)	<.0001

[a] Mann Whitney U test.

implants. Cemented acetabular fixation remains the gold standard method of fixation throughout many areas of the world, but evidence suggesting poor long-term outcomes in nonelderly patients has caused many providers in the United States and Western Europe to transition to uncemented (biologic) fixation [3,4,7]. Cemented vs uncemented implantation of acetabular components remains a highly debated topic. Cemented fixation was originally proposed in 1962 by Professor John Charnley, revolutionizing the arthroplasty industry at that time [3,16]. Longer follow-up provided evidence that there was increased osteolysis in this method of fixation and subsequently led to the ideology of "cement disease," which was further identified to be a "particle disease" more so related to polyethylene wear and debris [3,9,17-19]. Nonetheless, this concern has led to increased research into cementless acetabular components that rely on biologic fixation at the bone-implant interface.

The preference for acetabular component fixation is largely surgeon-dependent, and the results of cemented or uncemented fixation may be largely skewed by the heterogeneity of surgical approaches, cohort analysis, study designs, materials and bearing surfaces used, and level of comfort with either method [2,3,8,20]. As cementless fixation has become increasingly popular, so too has the research behind optimizing this practice [4,7]. Current acetabular implant designs use a porous textured rough surface for initial rigid stability and are typically resurfaced with materials that further lead to long-term stability via biologic fixation [4,7,20-23].

Threaded acetabular components without porous coating were initially trialed, which relied on mechanical interlock between the component and the acetabular bone for initial stability and long-term fixation [7]. Multiple studies [7,24-27] demonstrated unacceptably high revision rates for these implants with one study reporting only a 49% survival rate at 17 years of follow-up [27].

Threaded cups have since been modified to include fixation surfaces for uncemented use, ranging from grit-blasted, hydroxyapatite (HA)-coated, or titanium-beaded surfaces [7]. Literature has supported better outcomes regarding radiographic loosening and revision rates when comparing these variable surfaces to their smooth surface threaded acetabular implant counterparts [7,28]. A matched-pair analysis between otherwise identical porous coated vs nonporous coated threaded implants demonstrated improved outcomes for porous coated, reporting evidence of radiographic loosening of 0% compared to 29% and revision rates of 0% vs 10.7%, respectively, across a 2.5-year follow-up [7,28].

Previous research has demonstrated promising clinical and radiographic outcomes with HA-coated acetabular implants [29-32]. Hydroxyapatite shares a similar structure to the organic apatite crystals of native bone and is osteoconductive, providing for long-term fixation of implants [4,7,30,31,33]. High porosity and a modulus of elasticity similar to bone lead to improved fixation on acetabular surfaces [4,30,34,35]. Limited literature exists on the combination of high-porosity cups with HA coating, but it has been hypothesized that the high porosity may contribute to initial press-fit stability while the HA coating leads to increased long-term fixation that can be capitalized with additional screw fixation [7,30,31,34]. As knowledge continues to advance in the orthopaedic industry, long-term outcomes for additively manufactured acetabular implants and cost-benefit analyses are necessary while considering the context of the increased economic burden of revision THA.

This is a retrospective review and imaging analysis and, as such, has certain limitations. We only reviewed the first 60 novel additive-manufactured acetabular implants that were placed at our institution; analyzing higher numbers of implants in future studies will strengthen the results. Furthermore, no formal analysis of intraobserver reliability was completed; however, all images were reviewed by the senior orthopaedic resident and radiologist with coinciding interpretations. There was heterogeneity among the exact timelines in which patients presented for follow-up, with only 35/59 patients being seen for a final 2-year visit. Future studies would also benefit from including a comparison group. Lastly, it's important to note that a sole fellowship-trained and high-volume arthroplasty surgeon performed all surgeries, potentially limiting the generalizability of the findings.

Table 4
Radiographic evaluations.

Radiographic measures	6 wk (n = 56)	1 y (n = 41)	2 y (n = 35)
	Mean (std)	Mean (std)	Mean (std)
Cup inclination	45.4° (3.6)	45.6° (3.7)	45.1 (4.1)
Cup anteversion	26.3° (4.0)	26.1° (4.9)	26.5 (4.9)
Presence of superolateral buttress, n (%)	12 (21.4)	21 (51.2)	20 (57.1)
Presence of medial stress-shielding, n (%)	0 (0.0)	5 (12.1)	18 (51.4)
Presence of radial trabeculae, n (%)	2 (3.6)	8 (19.5)	13 (37.1)
Presence of inferomedial buttress, n (%)	8 (14.3)	10 (24.3)	11 (31.4)

Conclusions

This study demonstrated excellent radiographic and clinical outcomes with the use of the Stryker's TRIDENT II acetabular component at early follow-up. Although longer-term follow-up is warranted, this novel additively manufactured highly porous titanium acetabular component demonstrated excellent initial biologic fixation and reliable fixation at midterm follow-up.

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Conflicts of interest

M. Soltanolkotabi is a Specialty Content Editor for Foot & Ankle International and Foot & Ankle Orthopedics and a Council Member for the State of Utah, the American College of Radiology, and the Resident/Fellow Education Committee for the Society of Musculoskeletal Imaging and Social Media Ad Hoc Committee for the Society of Musculoskeletal Imaging. B. Blackburn is a board/committee member of AAHKS. J. Gililland receives royalties from OrthoGrid; is a paid consultant for Stryker, OrthoGrid, and Enovis; has stock options in OrthoGrid, CoNextions, and MiCare Path; receives research support from Zimmer Biomet, Stryker, and Medacta; is an editorial board member of Journal of Arthroplasty; and is a board/committee member of AAHKS. L. Anderson is a speaker bureau and paid consultant for Medacta; has stock options in OrthoGrid; and receives research support from Stryker and Zimmer. All other authors declare no potential conflicts of interest.

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CRediT authorship contribution statement

Logan Radtke: Writing – review & editing, Writing – original draft. **Jeffrey J. Frandsen:** Writing – review & editing, Data curation. **Alex J. Lancaster:** Writing – review & editing, Data curation. **Shanna Loughmiller:** Writing – review & editing, Data curation. **Brenna E. Blackburn:** Writing – review & editing, Writing – original draft, Methodology, Formal analysis, Data curation, Conceptualization. **Maryam Soltanolkotabi:** Writing – review & editing, Data curation. **Lucas A. Anderson:** Writing – review & editing, Supervision, Methodology, Investigation, Funding acquisition, Conceptualization. **Jeremy M. Gililland:** Writing – review & editing, Supervision, Methodology, Investigation, Funding acquisition, Data curation, Conceptualization.

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