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Original Research

Multiacquisition Variable-Resonance Image Combination Magnetic Resonance Imaging Used to Study Detailed Bone Apposition and Fixation of an Additively Manufactured Cementless Acetabular Shell

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ABSTRACT

Background: The ability to utilize magnetic resonance imaging (MRI) to assess bony fixation in 3 dimensions may allow a better understanding of the implant design and bony integration. We hypothesized that a new 3-dimensionally printed cementless highly porous acetabular component (Stryker Trident II Tritanium^{TM}) would show better fixation than an earlier cup from the same manufacturer as assessed by the noninvasive technique of multispectral MRI.
Methods: Multiacquisition variable-resonance image combination selective metal suppression MRI was performed in 19 patients implanted with a new 3-dimensionally printed cup and 20 patients who had received a previous-generation cup from the same manufacturer at 1-year follow-up. Each cup was graded globally as well as by 9 specific zones. Integration grades were performed for each zone: 0, full bone integration; 1, fibrous membrane present; 2, osteolysis; and 3, fluid present. A mixed-effects logistic regression model was used to compare fixation between the 2 groups.
Results: All cups in both cohorts showed greater than 90% estimated global bony integration (3-dimensionally printed cups, 99.4%; regular cups 91.6%) with no osteolysis or fluid observed in any cup. The 3-dimensionally printed cup had 1 of 171 zones (0.6%) graded as fibrous membrane present, while the 2-dimensional group had 15 of 180 zones (8.3%) graded as fibrous. Of note, screw hole regions were omitted but may be read as fibrous membrane areas.
Conclusion: Using multiacquisition variable-resonance image combination selective MRI, our analysis showed greater osteointegration and less fibrous membrane formation in the 3-dimensionally printed cups than the control group at 1-year follow-up.

Introduction

Total hip arthroplasty (THA) is considered one of the most successful surgical procedures in orthopaedic surgery because of its ability to provide pain relief and restore joint function [1]. Cementless acetabular fixation was introduced in the early 1970s as an alternative to cemented fixation to reduce the need for revision associated with periprosthetic osteolysis and fixation failures [2,3].

Different implant design, materials, and fixation methods were introduced over the last 40 years with the goal of long-term survival rates by providing quality fixation of the acetabular component to the surrounding bone [4,5].

Despite the long-term success of several cementless acetabular components with a variety of roughened and 3-dimensional (3D) porous surfaces, highly porous acetabular components were introduced over the past decade to enhance initial fixation and reduce micromotion at the bone-implant interface [5]. The first highly porous acetabular component was introduced in 1997 [6]. Porous tantalum (Trabecular Metal™, Zimmer Biomet TMT, Parsippany, NJ) was used to create a trabecular network with uniform

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structural continuity, low stiffness, high porosity, and high coefficient of friction [7]. Since then, additional materials have been introduced by implant manufacturers, using other materials such as titanium alloy and new techniques for fabrication such as additive manufacturing [8].

Tritanium (Stryker, Mahwah, NJ) is a highly porous material introduced a decade ago [9]. More recently, a 3-dimensionally printed version produced via additive manufacturing process with different surface topography was released [8]. The Trident II® Tritanium™ shell is fabricated using a specific type of additive manufacturing technology (laser rapid manufacturing), which uses a focused laser beam to melt layers of metal powder in a fusion bed [10]. The 3-dimensionally printed Tritanium shells have an average porosity of 60%, a mean pore size of 434 μm, and a coefficient of friction of 1.2 [11].

Using additive manufacturing technology, this acetabular shell was fabricated with a thin wall that in combination with optimal polyethylene thickness enables the use of large femoral head sizes to further increase the range of motion and joint stability [12].

THA loosening is traditionally detected by migration of components from serial radiographs and by areas of radiolucency [8,13,14]. Challenges of these techniques include how implanted radiopaque components obscure implanted markers, if used, and the bone-implant interface [15,16]. Plain film radiography also has a limited detection rate for loosening (~41.5%) [17,18], which may be attributed to the size of the periprosthetic lesions [17]; it also requires a delay in diagnosis because of the need for serial evaluation. Computed tomography (CT) has greater sensitivity than radiographs in detecting THA loosening [17] but is dependent on the local anatomy [19]. CT also exposes patients to ionizing radiation, a concern for longitudinal evaluation, and suffers from beam hardening artifact because of the presence of metallic components.

Prior work compared magnetic resonance imaging (MRI) with CT and radiography for assessment of osteolysis [20,21] and showed that MRI demonstrated 95% sensitivity for detection of periacetabular lesions, while CT detected only 75% and radiographs only 52% with similar specificities. These preliminary results indicate that MRI is the most accurate means by which to detect osteolysis, which clearly displays as intermediate signal intensity at the implant-bone or cement-bone interface [22]. The superior soft-tissue contrast of MRI permits recognition of the fibrous interface, and the lack of ionizing radiation makes MRI best suited for longitudinal evaluation of implant integration.

The primary aim of this study was to compare bone apposition and fixation of a new 3-dimensionally printed additively manufactured acetabular component, Trident II® Tritanium™, to its legacy 2-dimensional (2D) acetabular component, Trident® Tritanium™, using multiacquisition variable-resonance image combination (MAVRIC) MRI to assess bony fixation. We hypothesized that a 3-dimensionally printed cementless acetabular component would show better bony fixation than the traditional 2D cup as assessed by this enhanced imaging platform.

Material and methods

The design and conduct of the clinical trial were approved by the local institutional review board before patients were included in the study. The trial is registered at ClinicalTrials.gov (reg. no. NCT03469817). This study was partly funded by Stryker Corporation to help defray some of the costs associated with obtaining the MRI. A series of 19 patients who underwent primary THA using a 3-dimensionally printed additively manufactured cup (Trident II® Tritanium™) were prospectively enrolled and underwent MAVRIC MRI on the same hip at minimum 1 year postoperatively between February 2018 and May 2018. The comparison group included 20 patients who underwent primary THA using an hydroxyapatite-coated porous titanium cup (Trident peripheral self-locking [PSL] and hemispherical cups) and underwent MAVRIC MRI on the same hip for clinical issues unrelated to component loosening at a minimum of 1 year postoperatively at our institution.

All MRI scans were completed at our institution, and surgery was carried out by an experienced fellowship-trained arthroplasty surgeon. A posterolateral approach in the lateral decubitus position was used in all cases for both groups. The acetabulum was reamed using a line-to-line reaming before cup insertion. The cup was impacted at 35°-45° abduction and 15°-25° anteversion. Cementless femoral components were coupled with this additively manufactured acetabular component. Patients were excluded if they were younger than 18 years or older than 80 years, had a history of claustrophobia with MRI, or had MRI-incompatible aneurysm clips, artificial heart valves, or pacemakers.

Both groups in this study had cluster-hole cups only.

All patients underwent our institution's standard MRI examination of the hip using the clinical THA imaging protocol including metal artifact reduction sequence and MAVRIC-selective (MAVRIC SL) techniques on a 1.5T clinical scanner (General Electric Healthcare, Waukesha, WI).

MRI review was performed by a fellowship-trained musculoskeletal radiologist specializing in MRI with daily clinical experience in interpretation of arthroplasty MRI (H.G.P. who has more than 20 years of experience in assessing bony fixation of acetabular components). The radiologist was blinded to the design of the cup. Coronal MAVRIC inversion recovery, MAVRIC proton density–weighted images, and fast spin echo images were obtained.

Demographics including age, sex, body mass index, laterality, and cup size were captured and compared between the 2 groups. To assess bone apposition and fixation of each acetabular component, an MRI grading system was developed. Each acetabular component was divided into 3 zones (medial, central, and lateral). Each zone was then subdivided into additional 3 zones (anterior, superior, and posterior) (Fig. 1). Thus, a total of 9 zones were examined and scored independently. Each zone was then graded on a scale from 0 to 4 (0 = full bone integration, 1 = fibrous membrane present, 2 = osteolysis, 3 = fluid present).

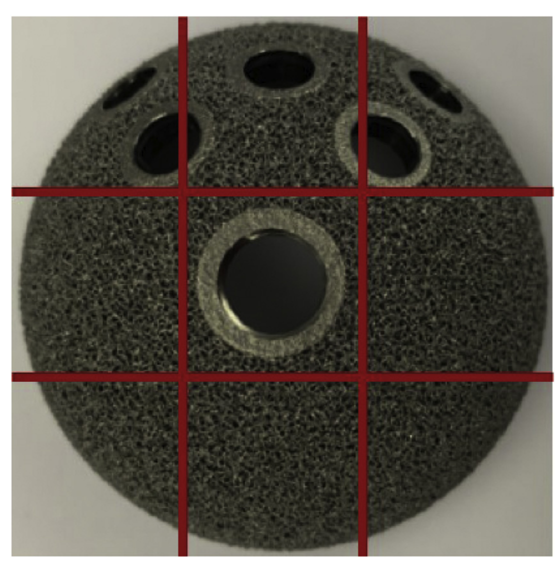

Figure 1. Each acetabular component was divided into 3 zones (medial, central, and lateral). Each zone was then divided into additional 3 zones (anterior, superior, and posterior).

A chi-squared test was performed to detect differences in distribution of sex and laterality by acetabular design. A nonparametric *t*-test was performed to detect the difference in age by acetabular design. A mixed-effect logistic regression model accounting for the 9 zones per patient was used to compare the odds of cup fixation between the 2 different acetabular designs. Significance was set at $P < .05$. Statistical analyses were performed using SAS, version 9.4 (SAS Institute Inc., Cary, NC).

Results

The additively manufactured, 3D Trident II Tritanium group included a total of 19 patients, while the 2D Trident PSL and hemispherical group had a total of 20 patients. Demographic data between the 2 groups are shown in Table 1. No difference in patient age was found between the 2 groups ($P = .22$, Table 1). In addition, no difference in distribution or laterality ($P = .41$) or sex ($P = .43$) was detected. A total of 171 acetabular zones (19 cups with 9 zones each) were evaluated in the test group with the additively printed cups. Only 1 (0.6%) zone was graded as 1 (fibrous membrane present), whereas the other 179 (99.4%) zones were graded as 0 (full bone integration) (Table 2). The global grading for each cup was 4 (>75% integration).

A total of 180 acetabular zones (20 cups with 9 zones each) were evaluated in the 2D Trident PSL/hemispherical group. Fifteen (8.3%) zones were graded as 1 (fibrous membrane present), whereas the other 165 (91.7%) zones were graded as 0 (full bone integration) (Table 3). The global grading for each cup was 4 (>75% integration).

Figure 2 illustrates an example of an imaging sequence of the MAVRIC MRI demonstrating an example of the bony fixation (left) and that of a fibrous membrane (right).

Neither group had osteolysis (grade 2) or fluid (grade 3) present in any zone evaluated. All patients achieved either full bone integration or the presence of fibrous membrane (Fig. 2). The Trident II Tritanium shells showed significantly higher instance of acetabulum osteointegration than the previous generation (odds ratio = 15.55, 95% confidence interval = 1.97-122.68, $P = .009$), indicating that the formation of a fibrous membrane is approximately 8% higher for the 2D Trident PSL/hemispherical group than for the Trident II Tritanium group.

Discussion

THA is an extremely successful operation but may still present with postoperative complications. Aseptic loosening remains a major reason for failure of THA, with almost 52% of revisions performed for this reason [23]. Newer iterations of acetabular cups have been developed to further decrease failure mechanisms and improve fixation with the native bone [4].

Table 1
Demographics between the 2 groups.

	Trident II 3-dimensionally printed cup (n = 19)	Trident 2D cup (control) (n = 20)	*P* value
Age	67.2 ± 10.2	63.6 ± 9.5	$P = .22$
Sex			
Male	10	8	$P = .43$
Female	9	12	
BMI	28.0	28.5	
Laterality			
Right	15	14	$P = .41$
Left	4	6	
Cup size (mean, IQ range)	54 (52-56)	52 (50-56)	$P = .07$

All values expressed as mean ± standard deviation unless noted otherwise.

Table 2
Cross-tabulation table for the presence of fibrous membrane formation.

Number of zones: Acetabulum			
Group	Fibrous membrane formation		
	Absent	Present	Total
Trident (2D)	165 91.6%	15 8.3%	180
Trident II (3D)	170 99.4%	1 0.6%	171
Total	335 95.4%	16 4.6%	351

As part of the evolution in material design, Tritanium was initially developed to serve as a highly porous material [9]. The more recent additively manufactured 3-dimensionally printed version features a slim wall that allows for large femoral head size options and optimal polyethylene thickness to potentially aid in a greater range of motion and joint stability [11].

To assess the bone-implant interface of these cups, the MAVRIC MRI was used. The MAVRIC SL sequence has been shown to significantly reduce metal artifact on MRI compared with the 2D fast spin echo sequence and traditional metal artifact reduction sequence techniques and can increase diagnostic confidence of MRI in patients who underwent THA [24]. The use of MAVRIC SL sequence has been shown to allow for providers to obtain a repeatable assessment of implant integration and was shown to demonstrate greater sensitivity than radiographs to assess implant loosening [25]. Additional studies have also confirmed reduced metal artifact with MAVRIC SL compared with conventionally used sequences [26].

Using the MAVRIC SL MRI sequence allows us to assess areas of fixation with both the newest iteration and the previous generation of the Tritanium cup. In all the zones analyzed with the Trident II cup, we found 99.4% of the zones to have bone integration compared with 91.7% with the previous-generation cups. The 3D

Table 3
Presence of fibrous membrane in 9 acetabular regions evaluated.

Acetabular zones	Group			
	Trident (2D) THA		Trident II (3D) THA	
	n = 20		n = 19	
Medial/anterior				
Full bone integration	19	95.0%	19	100.0%
Fibrous membrane present	1	5.0%	0	0.0%
Medial/superior				
Full bone integration	20	100.0%	19	100.0%
Medial/posterior				
Full bone integration	19	95.0%	19	100.0%
Fibrous membrane present	1	5.0%	0	0.0%
Central/anterior				
Full bone integration	17	85.0%	19	100.0%
Fibrous membrane present	3	15.0%	0	0.0%
Central/superior				
Full bone integration	17	85.0%	19	100.0%
Fibrous membrane present	3	15.0%	0	0.0%
Central/posterior				
Full bone integration	18	90.0%	18	94.7%
Fibrous membrane present	2	10.0%	1	5.3%
Lateral/anterior				
Full bone integration	16	80.0%	19	100.0%
Fibrous membrane present	4	20.0%	0	0.0%
Lateral/superior				
Full bone integration	19	95.0%	19	100.0%
Fibrous membrane present	1	5.0%	0	0.0%
Lateral/posterior				
Full bone integration	20	100.0%	19	100.0%

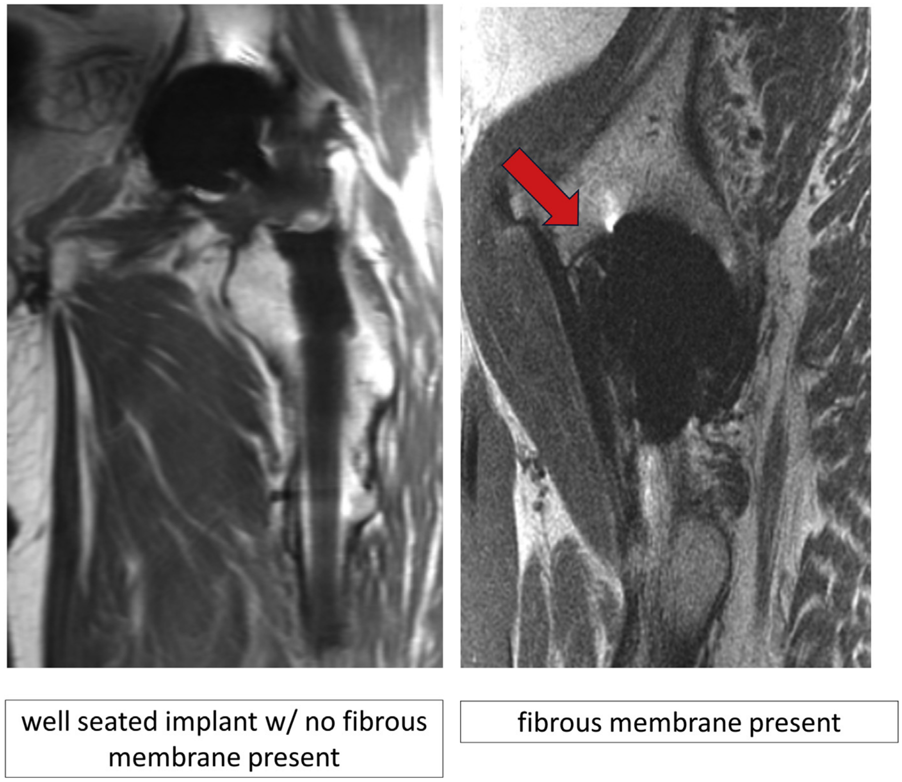

Figure 2. MAVRIC MRI demonstrating bony fixation (left) and fibrous membrane (right). Assessment of bony fixation and fibrous membrane % for 3D additively manufactured (Trident II) and 2D (Trident) cups.

Trident II Tritanium cup had 1 (0.6%) zone graded as fibrous membrane present, while the 2D Trident PSL/hemispherical group had 15 (8.3%) zones graded as fibrous. Because fixation cannot be achieved on screw holes in the cups, these regions when identified were excluded but may be read as fibrous membrane areas. One of the most prominent improvements with the most recent iteration of the Trident II Tritanium cup is the use of additive manufacturing [27]. Additive manufacturing is a type of manufacturing process that allows for manufacturing a complex 3D structure with design freedom and high sustainability, while reducing material wastage [28]. In addition, the use of additive manufacturing can also improve material performance that could previously not be achieved with conventional manufacturing techniques [28]. Owing to the nature of production, additive manufacturing also enables the creation of complex geometries and have been used in the past to develop custom patient-specific instrumentation and implants in total joint arthroplasty [29]. These improvements in design and manufacturing have translated into increased osseous fixation as assessed by advanced imaging modalities.

Although this study offers a unique way of assessing bone fixation through the use of a high-resolution MAVRIC SL MRI of a newly developed acetabular cup manufactured using additive technology, it is not without certain limitations. Although retrieval studies have previously demonstrated much less osseointegration with modern designs through histological studies [30], this study does not necessarily imply that there is greater osseointegration because these are interpreted through radiographic means vs histological analysis as usually done in retrieval studies. Nonetheless, future retrieval studies conducted over an extended period of time are important to further better assess osseointegration from a histological perspective. Regardless, the initial findings show improvements in osteointegration with the new advanced manufacturing process.

Conflict of interest

H.G. Potter is a paid consultant for Ortho RTI and Major League Baseball; is a cofounder and stockholder of Imagen Technologies, is a principal investigator and receives institutional research support from GEHC and NIH R01 (AR064840-05), NIH NIAMS (1R01AR065023-01A1) (site PI), and NBA/GE Healthcare Orthopedics and Sports Medicine Collaboration (site PI), and is an associate Editor for imaging in sports health (American Orthopaedic Society for Sports Medicine [AOSSM]); I.D. Martino is a paid consultant for LIMA Corporate and is a member of the editorial or governing board of the journal *World Journal of Orthopedics*; G. Westrich receives royalties from Exactech and Stryker Orthopaedics, is a member of the speakers' bureau/is a part of paid presentations for Stryker Orthopaedics, Exactech, and Mallinckrodt Pharmaceuticals, is a paid consultant for Stryker Orthopaedics and Exactech, and is a board member for the Eastern Orthopaedic Association; M. Koff is a principal investigator and receives research support from NIH R01 (AR064840-05) and reports that HSS has an institutional research agreement in place with GE Healthcare and is on the editorial board of the *Journal of Orthopaedic Research*; all other authors declare no potential conflicts of interest.

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