



## Case report

## Early aseptic loosening of the Tritanium primary acetabular component with screw fixation

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## ABSTRACT

Ultraporous acetabular components were developed to improve osseointegration and fit for increased longevity and better outcomes after total hip arthroplasty. There is a paucity of literature detailing this acetabular component's clinical performance, with even less detailing those with screw fixation. We identify 5 patients at our institution who underwent revision total hip arthroplasty for early aseptic acetabular cup loosening of an ultraporous acetabular component known as the Tritanium primary cup with secondary screw fixation. They all presented with groin and hip pain after index surgery and underwent follow-up radiographic examination consistent with component loosening requiring revision surgery. This case series reports on the risk of early acetabular cup loosening and its associated clinical presentation, workup, and surgical management in patients with the Tritanium primary cup augmented with screws.

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## Introduction

Total hip arthroplasty (THA) is a reliable treatment for degenerative hip pathology that decreases pain and improves function. According to the Centers for Disease Control and Prevention National Center for Health Statistics, which released data from the National Hospital Discharge Survey in 2010, the reported number of THAs increased from 138,700 in 2000 to 310,800 in 2010 [1]. Projections suggest that THA incidence in the United States will rise by a further 174% over the next decade, reaching 572,000 by 2030 [2].

THAs are widely considered one of the most successful orthopaedic procedures available [3,4]. Multiple studies and joint registries have reported on outcomes of THA using a wide range of implants. These sources have documented survival rates that exceed 90% at a 10-year follow-up and approach 85% at a 15-year follow-up in patients undergoing THA using a cementless

acetabular component with supplementary screw fixation [5–16]. However, early implant failures necessitating revision surgery continue to occur. These failures most commonly occur as a result of aseptic loosening, infection, or instability. Aseptic loosening of the hemispherical acetabular components is one of the leading causes of early failure of primary THA necessitating revision THA [5,6,17–19]. Mean hospital resource utilization for revision THA is significantly higher than primary THA with an estimated \$7171 in additional hospital costs [20]. As hospitals shift their focus to providing care that meets quality and cost expectations, there is a growing need to identify the cause of these early component failures.

The Tritanium primary cup (Stryker Orthopaedics, Mahwah, NJ) has been on the market in the United States since 2008. Tritanium is a highly porous, 3-dimensional titanium metal interface that serves as a primary acetabular component in THAs [21]. With its ultraporous surface, a modulus of elasticity similar to bone [22], and high friction coefficient [23], its design sought to improve osseointegration, reduce stress shielding, and increase stability respectively [24]. Naziri et al. [21] suggested that this particular component produces excellent results with 100% survivorship in 252 patients at a mean follow-up of 36 months (range: 24–56 months).

Conversely, a recent study by Carli et al. [24] reported poor outcomes and cup loosening at a mean follow-up of 5 years with the solid-backed Tritanium primary cup without screws, raising

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concerns about its initial ingrowth [24]. Here we present 5 cases of these acetabular cups implanted with secondary screw fixation that required revision secondary to early postoperative aseptic loosening. All revision THA cases were done at our institution among 3 fellowship-trained arthroplasty surgeons. Of the 5 revision cases, 3 of the initial primary THAs were performed at our institution among 2 fellowship-trained surgeons. The remaining 2, however, were performed at 2 outside hospitals by 2 separate fellowship-trained surgeons.

### Case histories

This series examines 5 cases of acetabular cup loosening in patients who had the Stryker Tritanium primary cup implanted from 2011 to 2016 at a high-volume institution with approximately 5000 arthroplasty cases per year. At our institution alone, approximately 169 Tritanium primary cups have been implanted within the aforementioned time period, underscoring the importance of this case series. The Institutional Review Board at our institution approved the series and waived consent as the study was retrospective in nature.

Patient demographic data, including age, gender, body mass index (BMI), smoking status, and comorbidities, were collected. We reviewed each patient's prerevision symptoms. All patients who received an anteroposterior pelvis and anteroposterior/lateral hip radiograph were analyzed for component orientation and the presence of radiolucent or radiosclerotic lines, per the system of Charnley and DeLee [25]. Component orientation was evaluated by a single author using Lewinnek's "safe zone" and was deemed appropriate if anteversion angles were within 0°–30° and inclination angles were within 30°–50°, respectively [26].

During the index surgery, all acetabular components were placed to achieve a 1-mm press fit as described by the Stryker protocol for the Tritanium primary cup. In all hips, a highly cross-linked polyethylene liner was placed. All 5 acetabular cups were augmented with screw fixation as per surgeon preference. Immediate postoperative radiographs confirmed proper orientation and cup seating without lucency.

Prerevision erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP) levels were measured and confirmed to be negative in all patients. At the time of each revision surgery, the surgeon performed intraoperative assessments to assess implant loosening, component position, implant damage, polyethylene wear, and stability. Each revision THA procedure included in this series demonstrated a grossly loose acetabular component with minimal bony ingrowth.

### Baseline characteristics

Baseline patient characteristics were recorded for each patient (Table 1). Briefly, among the 5 cases examined, 2 patients were male and 3 were female. The mean age at index surgery was 56, with a mean BMI of 30.2 kg/m<sup>2</sup>. Three patients had a left THA and 2 had a right THA. All patients presented with groin and hip pain

with ambulation after index surgery and underwent follow-up radiographic examination consistent with component loosening requiring revision surgery. In the following sections, we discuss the details of the individual cases and their outcomes.

### Case 1

A 54-year-old woman with a past medical history of hypertension underwent a right THA using a direct anterior approach with fluoroscopic assistance in January 2015. A 48-mm Tritanium primary cup along with 2 screws for supplemental fixation was implanted for advanced hip arthritis. The cup was impacted under fluoroscopic imaging guidance, accounting for appropriate version, inclination, and seating. At the 3-month postoperative visit, the patient reported continued groin pain with activity. Follow-up radiographs confirmed that there was no change in implant position with an acceptable orientation as evidenced by an abduction angle of 37° and an anteversion angle of 17° [26]. The patient had a negative infection workup (ESR: 16 mm/h, CRP < 5 mg/L, white blood cell [WBC]: 6). However, as the patient continued to complain of discomfort with ambulation, further follow-up imaging was ordered. A follow-up radiograph in January 2016 and a computed tomography scan in April 2016 revealed lucencies along the margins of the anterior acetabular fixation screw and a complete radiolucent line in zones 1–3 (Fig. 1a–c) [25].

The patient underwent a revision surgery of the right acetabular component using the direct anterior approach with fluoroscopic assistance in May 2016. The stem was stable, but the acetabular cup and screws were loose. The liner was removed, and the screws were backed out before the cup was removed. There was no evidence of bony ingrowth at the cup interface. After removing the loose cup, the acetabulum was reamed, and a size 52-mm porous tantalum cup was impacted into appropriate position. Press fit was obtained with 3 acetabular screws used for additional fixation. At the patient's 1-year follow-up, her groin pain with activity had resolved, and there were no radiographic signs of loosening (Fig. 1d and e).

### Case 2

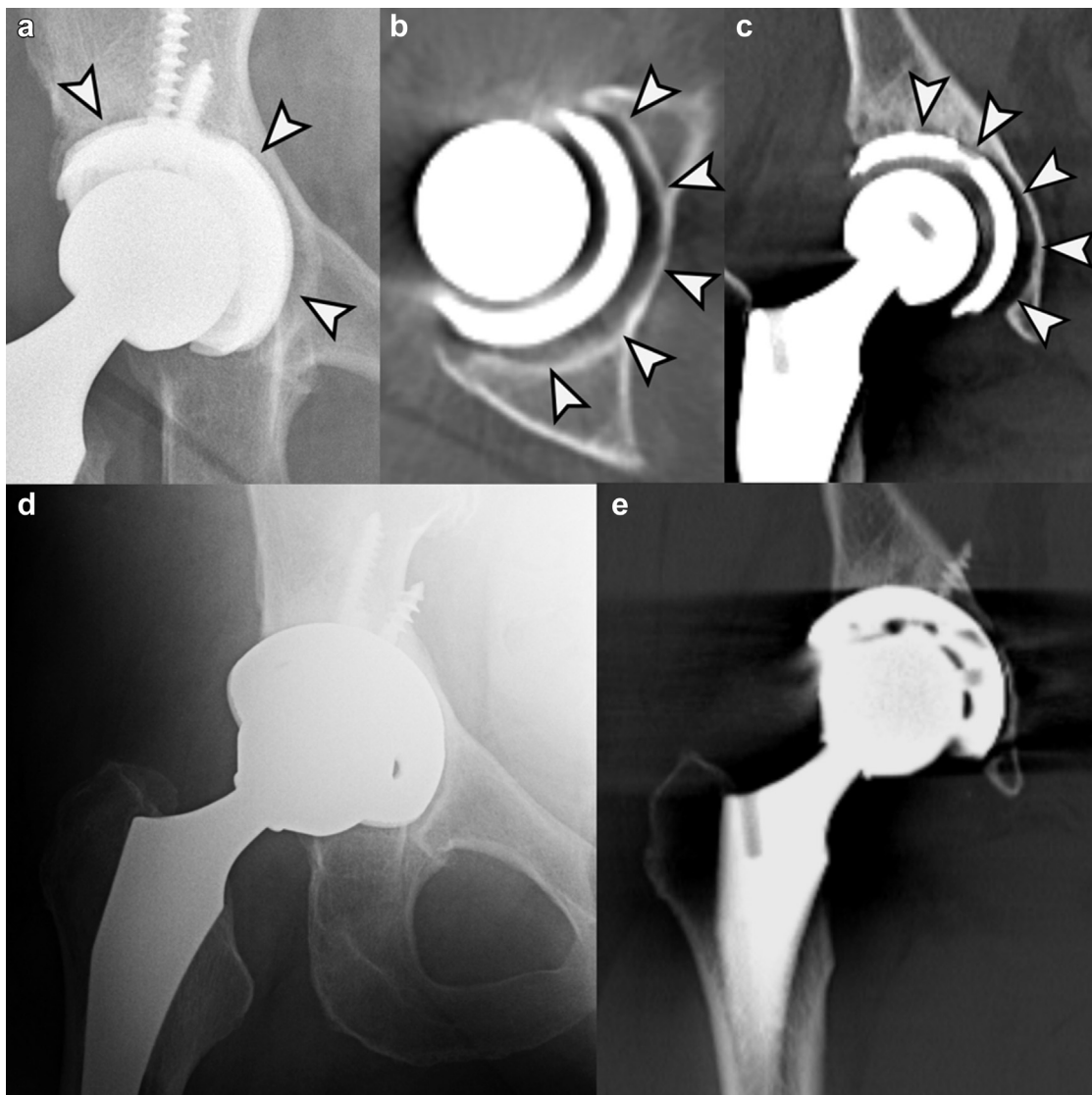
A 49-year-old man with a past medical history of asthma, hypertension, and morbid obesity (BMI of 44.6 kg/m<sup>2</sup>) underwent an uncomplicated left THA using the posterolateral approach in December 2011 with a 52-mm shell Tritanium primary cup with 2 screws. Attention was paid to make sure that the orientation and seating of the cup was appropriate. At the patient's 1-year follow-up, he complained of left hip and groin pain with activity over the preceding 3 months. Radiographs demonstrated radiolucencies in zones 1, 2, and 3 [25]. The patient's infection workup (ESR: 4 mm/h, CRP: 0.5 mg/L) was negative. Joint aspiration showed no growth on fungal or bacterial cultures.

The patient underwent a revision THA using the posterolateral approach in June 2013. The acetabular cup and screws were grossly loose. After removal with a Kocher, the acetabular component was

**Table 1**  
Baseline characteristics at time of index surgery.

Case	Age	Gender	BMI (kg/m <sup>2</sup> )	Laterality	Surgical approach	Cup size (mm)	Time interval from primary to revision (mo)
1	54	F	26.2	R	Direct anterior	48	15
2	49	M	44.6	L	Posterolateral	52	18
3	61	F	21.7	L	Direct anterior	50	9
4	48	M	25.6	L	Posterolateral	52	56
5	68	F	32.8	R	Posterolateral	48	15

F, female; M, male; L, left; R, right.



**Figure 1.** (a) Anteroposterior (AP) radiograph of case 1 demonstrating complete radiolucency in zones 1-3 at 1 year after primary THA. (b) Axial view of a computed tomography scan of case 1 demonstrating a complete radiolucent line in all zones (white arrowheads) 14 months after primary THA. (c) Coronal view of a computed tomography scan of case 1 demonstrating a complete radiolucent line in all zones (white arrowheads) 14 months after primary THA. (d) AP radiograph of case 1 demonstrating no evidence of radiolucency 13 months after revision THA. (e) Coronal view of a computed tomography scan of case 1 demonstrating no evidence of radiolucency 13 months after revision THA.

examined and fibrous ingrowth around the cup was noted. The acetabulum was then reamed, and a 58-mm revision Tritanium shell was implanted with 3 screws. At the patient's 3-year follow-up, his hip and groin pain was improved, and there was no evidence of implant loosening on radiograph.

#### Case 3

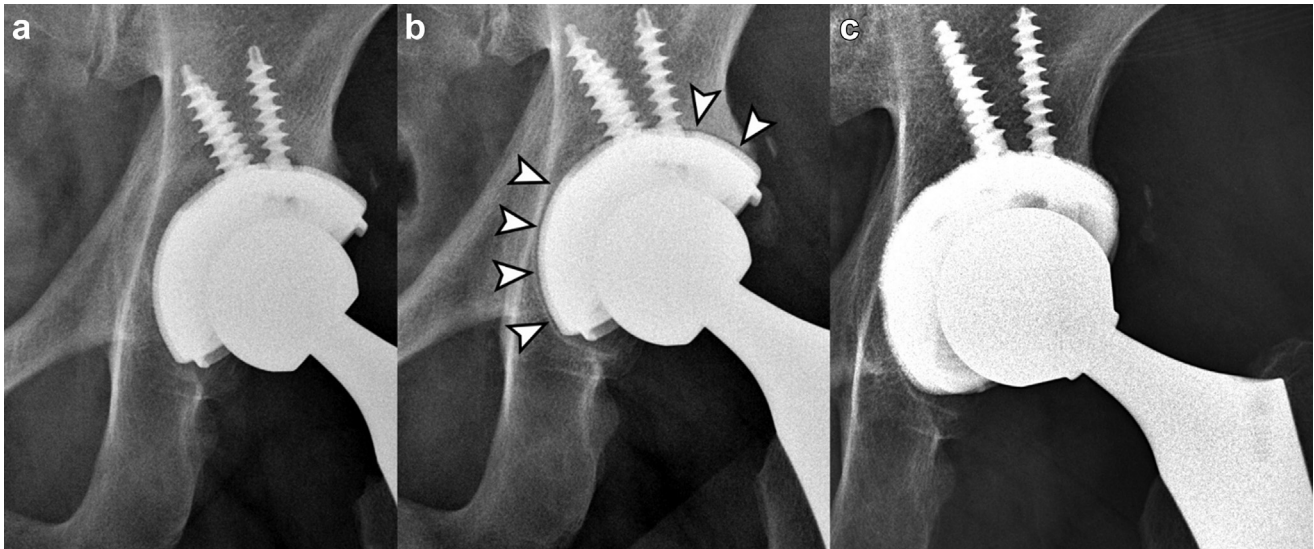
A 61-year-old woman with a past medical history of hypertension and right hip dysplasia underwent a left direct anterior THA using a size 50-mm Tritanium primary cup with 2 screws in January 2016. Intraoperatively, the cup version, inclination, and seating were deemed appropriate. She was symptom free at her 3-month follow-up visit but began to complain of constant moderate left hip pain at her 6-month postoperative follow-up visit. Blood work, including an ESR and CRP, was normal (ESR: 9 mm/h, CRP: < 5.0 mg/L, WBC 6.9), but radiographs demonstrated a circumferential radiolucent line from zones 1-3 [25].

At the time of revision surgery (September 2016), the acetabular component was grossly loose with fibrous growth around the periphery and no bony ingrowth. A 56-mm porous tantalum acetabular cup was impacted and augmented with 3 screws. At her most recent postoperative visit, the patient reported a complete resolution of start-up pain in her hip and groin, and her radiographs showed no evidence of implant loosening.

#### Case 4

A 48-year-old man with a past medical history of hypertension and hyperlipidemia underwent a left THA using the posterolateral approach in June 2012 with a 52-mm shell Tritanium primary cup with 3 screws. Good fixation was noted intraoperatively. His BMI was 25.6 kg/m<sup>2</sup> at the time of surgery.

At his 3-month follow-up visit, the patient complained of some intermittent pain in his left groin. Radiographs were negative for any evidence of loosening (Fig. 2a). The patient did not return to clinic until April 2016. At this visit, the patient noted continued



**Figure 2.** (a) AP radiograph of case 4 demonstrating no radiolucency 3 months after primary THA. (b) AP radiograph of case 4 demonstrating circumferential radiolucency in all 3 Charnley zones 3.5 years after primary THA. (c) AP radiograph of case 4 demonstrating no sign of loosening 2 months after revision THA.

start-up pain localized to his left groin. Radiographs demonstrated radiolucency around the entire acetabular component and screws (Fig. 2b) [25]. ESR, CRP, and hip aspirations were all negative for infection.

In March 2017, the patient's acetabular component was revised. The acetabular component and screws were grossly loose without any evidence of bony ingrowth. The acetabulum was then reamed, and a 56-mm revision Tritanium shell was implanted with 2 screws (Fig. 2c). At his latest follow-up visit, the patient reported significant relief of his start-up groin pain, and radiographs did not show any sign of implant loosening.

#### Case 5

A 68-year-old woman with a history of chronic kidney disease, hypertension, hyperlipidemia, and hypothyroidism, underwent a right THA using the posterolateral approach in January 2016. The cup was impacted into appropriate version and inclination, and good fixation was obtained. Her BMI was 32.8 kg/m<sup>2</sup> at the time of

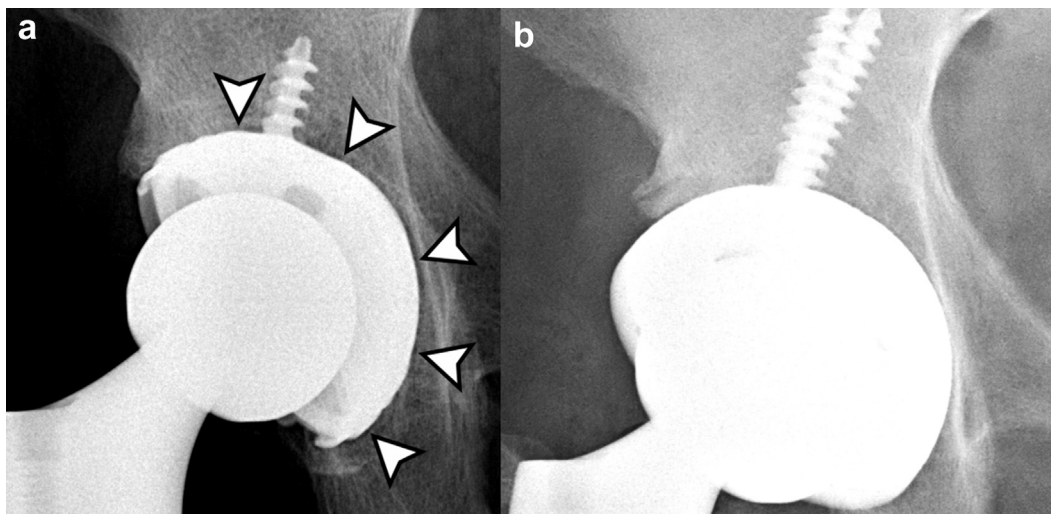
surgery. A Tritanium 48-mm primary cup was impacted into the acetabulum with 1 screw for supplemental fixation (Fig. 3a).

At her 6-month follow-up, she noted increased hip pain with ambulation. Workup for infection was negative (ESR: < 10 mm/h, CRP: < 9.0 mg/L and WBC: 5.5). Radiographs demonstrated radiolucencies in zones 1, 2, and 3 (Fig. 3a) [25].

The right hip was revised in March 2017. At the time of the surgery, the primary cup was grossly loose after removal of the screw (Fig. 4). After removal of the cup, the acetabulum was reamed, and a size 52-mm porous tantalum acetabular cup was impacted and placed with 3 additional screws for supplemental fixation (Fig. 3b). At her most recent follow-up, she was ambulating without any hip pain, and her radiographs showed no signs of loosening (Fig. 3b).

#### Discussion

The use of the Tritanium primary cup represents the growing trend toward ultraporous 3-dimensional acetabular cups. The



**Figure 3.** (a) AP radiograph of case 5 demonstrating circumferential radiolucency (white arrowheads) 6 months after primary THA. (b) AP radiograph of case 5 demonstrating no evidence of loosening or radiolucency after revision THA.



**Figure 4.** Removed Tritanium acetabular shell from case 5 that was grossly loose intraoperatively.

increased porosity of the cup is believed to be beneficial for osseointegration of the implant [27]. However, few studies have examined the clinical and radiographic implications of this implant thoroughly.

Prior investigations have demonstrated conflicting survivorship success rates following procedures that used primary Tritanium acetabular implants [21,24]. Naziri et al. [21] examined 288 hips and reported a 100% survival rate at 2 years with no signs of aseptic loosening. In their study, components showed no changes in position, and zonal radiographic analyses revealed no signs of progressive radiolucency or cup migration [21]. This contrasts sharply with Carli et al.'s [24] recent study, which demonstrated greater acetabular component loosening with the Tritanium cup than with the Trident peripheral self-locking hydroxyapatite acetabular cup (Stryker Orthopaedics, Mahwah, NJ). Acetabular screw fixation was not applied in any of the primary THA procedures using Tritanium primary cups and was only used in 3 of the Trident peripheral self-locking cases. In their study, Carli et al. [24] demonstrated that 40% of their Tritanium primary cups had radiolucencies in at least 2 zones, and 17% involved all 3 zones at a minimum 5-year follow-up. In the Trident comparison group, 2 cups had radiolucent lines in 1 acetabular zone and none had radiolucent lines in greater than 1 zone at a minimum 2-year follow-up. No radiolucent lines were present in any of the Trident cups at a minimum of 5-year follow-up [24]. Our series of patients with failure of bone ingrowth for the Tritanium component despite additional screw fixation, demonstrates more concerning cases of early aseptic failure.

The manufacturing of the Tritanium primary cup requires many steps as described by Muth et al. [28]. The process begins with the combination of a polymeric binding agent, a proprietary sacrificial pore former, and an angular titanium powder, all of which are blended and molded together. The mold is then placed under high pressure and low temperature forming a “green state structure”, which is then machined to the manufacturer’s preferred design. It is at this point that the component is combined with a solid titanium alloy substrate and is then separated from the pore former and binder before bonding the titanium particles together through a sintering process. Finally, machining is employed to create the final desired implant configuration [28].

In contrast to the Tritanium primary cups, we have not noticed similar loosening in the revision Tritanium acetabular cups. The revision cup—manufacturing process starts with the machining of a scaffold from an open cell, polyurethane foam that is coated

with commercially pure titanium. This is also applied using low-temperature arc vapor deposition. After this is complete, the titanium-coated polyurethane structure undergoes a sintering cycle after being placed on a solid titanium alloy substrate. This allows the polyurethane to be volatilized and removed, leaving a scaffold that can be expanded through repeated applications of titanium coating and a polymeric binder. Sintering cycles are again used, this time to remove the binder and to sinter the titanium layers until the preferred porous structure is formed and ready to be machined into the desired form [28].

It is likely that the Tritanium primary cup loosening is at least in part due to these differences in manufacturing processes. Specifically, the pore structure and polymeric binding agent used in the Tritanium primary cup may be directly related to its increased tendency to fail in comparison with the revision cup. In a prospective study of 43 patients, Ramappa et al. [29] examined early postoperative outcomes of the Stryker Tritanium revision shell. They reported 98% integration of cups within 3 months. However, as noted previously, the multi-hole revision shell undergoes a different manufacturing process than the primary shell giving it a markedly distinct surface topography. This difference is an important limitation of the excellent cup survivorship reported by Naziri et al. because the authors did not delineate between the implantation of the primary or revision shell. Thus, further studies investigating the true survivorship of the primary Tritanium cup are warranted.

These past studies have shed light on the varied survival rates among patients with the Stryker Tritanium primary acetabular cup. Unique to our study was the fact that all 5 cases presented had supplemental screw fixation of the primary Tritanium primary cup. Importantly, the decision to augment fixation with screws was based on surgeon preference and not because there was concern for poor fixation intraoperatively. Screw fixation has been linked with enhanced early implant stability and is often used for the theoretical improvement in primary fixation, bony ingrowth (especially directly surrounding the screws), and secondary stability [30–33]. These factors are of particular importance in cases with deficient bone stock [33]. Recent literature, however, suggests that this initial increased stability provided by screw fixation affords no significant difference in rates of revision and osteolysis and may not provide any long-term benefit [34,35]. In our study, not only did these components augmented with screw fixation show radiographic signs of loosening, but also their failure of ingrowth indicated a clinical need for revision surgery. Owing to these early osseointegration failures, we have halted the use of the primary Tritanium acetabular component at our institution. Fortunately in all cases, there was no significant bone loss, and all acetabular components were successfully revised to an ultraporous cup 4–6 mm larger with satisfactory short-term outcomes and no complications.

The limitations of this study included its retrospective nature and population size. Because this was a case series, we were limited to analyze our patients without control comparators. We have thus subsequently proceeded with a more comprehensive multicenter review of the outcomes associated with this cup.

## Summary

This study presents a series of early aseptic failures associated with the use of the Tritanium primary cup with screw fixation in primary THA. It supports the findings from Carli et al.'s study [24], which indicated that these components appear to have a higher rate of early aseptic loosening. More importantly, our data has shown that additional screw fixation may not decrease the risk for implant failure. These results suggest a need to examine the safety of the Tritanium primary cup in THA.

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