



Case Report

Failure of Screw/Shell Interface in the Trident II Acetabular System in Total Hip Arthroplasty

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ABSTRACT

We report a case series of 2 patients with screw/shell interface failure in the Stryker Trident II Acetabular System. Both failures consisted of screw penetration through the Trident II acetabular shell. One failure was observed postoperatively after a revision from a cephalomedullary nail to a total hip arthroplasty while the other was observed intraoperatively during a primary total hip arthroplasty. Both component failures were managed conservatively with weight-bearing as tolerated and radiographic monitoring. These are the first reported cup/screw failures of the Stryker Trident II system and should raise awareness of the potential complication and implant design flaw. When placing acetabular screws, we recommend obtaining intraoperative orthogonal screw radiographs that are tangential to the shell surface to assess for screw/shell failure.

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Introduction

The need for primary total hip arthroplasty (THA) continues to increase with projections suggesting a demand of 572,000 per year by 2030 in the United States and over 400,000 in the United Kingdom by 2035 [1,2]. As the number of patients who need THA increases, so does the need for implant design improvement. THA implants have transitioned from cemented acetabular components to cementless acetabular components with lower failure rates and improved long-term results [3–5]. Acetabular implant material has also changed with the implementation of ultraporous metal integration to enhance osteointegration, increase stability, and reduce stress shielding [6]. While THA implants are continuing to be refined, design flaws still occur. This has been demonstrated throughout THA history with the introduction of metal-on-metal articulating THA and, even more recently, with aseptic loosening observed in Tritanium (Stryker, Kalamazoo, MI) acetabular cups [6]. In 2017, Stryker performed a limited market release of the Trident II Tritanium Clusterhole shell, followed shortly after in 2018 with a

market-wide release of the Trident II Acetabular System. This system features recessed solid screw cores that fit low-profile hex screws to limit the possibility of interference with liner seating. These recessed screw cores also allow for up to 37 degrees of angulation in each hole. Here, we present 2 cases where low-profile screws penetrated through the acetabular shell. One failure was observed intraoperatively during a fluoroscopy-assisted primary anterior THA, while the other was observed in a postoperative office visit after a revision THA. Each patient was operated on by a single fellowship-trained joints surgeon who has implanted over 900 Trident II acetabular cups with approximately 10% of those cases involving 1–2 acetabular screws. This case report was written following consensus-based clinical case reporting guidelines [7]. The study protocol (178378-1) was reviewed and approved by our institution's institutional review board. Both patients reviewed this manuscript and provided their consent for publication.

Case histories

Case 1

A 75-year-old female with a history of schizoaffective disorder presented to the emergency department of a level 1 trauma center

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on December 8, 2020, for worsening right hip pain. She previously underwent surgical stabilization of a right intertrochanteric femur fracture on October 17, 2020, with a short intramedullary nail (Fig. 1a and b) after a ground-level fall. Imaging in the emergency department demonstrated 21-mm screw cutout with penetration into the acetabulum (Fig. 1c). The decision was made to take patient for hardware removal and conversion to a right THA. She was taken to the operating room where a direct lateral incision was used. Intraoperatively, the compression bolt was grossly loose within the gamma nail with the only thing preventing the screw from disengaging laterally were the threads on the screw itself. Healing around the greater trochanter was observed, and the nail was removed. A Stryker Dall-Miles beaded stainless steel cable was placed in the subtrochanteric region to prevent fracture during reaming and stem placement. The acetabulum was exposed after the femoral head was removed and demonstrated a large defect approximately 10×20 -mm wide and 25-mm deep. Cancellous bone allograft and femoral head autograft measuring 30 cc were used to fill the defect. The graft material was reverse-reamed into the defect, and then the acetabulum was reamed to accommodate a press fit size 52-mm Stryker Trident II Clusterhole HA acetabular shell. Additional allograft was placed, reverse reaming was again performed, and the acetabular shell was then impacted. The shell had good fit and was stable upon impaction, but given the acetabular bone loss and poor bone quality while reaming, the decision was made to place 2 cancellous low-profile hex screws (6.5×45 mm, 6.5×25 mm) in the acetabular dome for additional stability. Screw implantation was performed by predrilling using a drill guide and a 3.3-mm drill bit. The depth gauge was then used to obtain the screw length. The screw length was recorded and checked by the device representative, scrub nurse, and surgeon prior to opening the screw onto the back table, and the screw was then inserted. This process was repeated for the second screw. The screws were inserted with good purchase and appeared to be well-fixed in the shell on visual examination. On manual palpation of the inner surface of the shell, screw heads were not felt to be proud of the acetabular shell. A Trident X3 36-mm polyethylene insert was then placed in the acetabular cup. A 36-mm outer diameter, +0 neck length Stryker BioloX delta ceramic c-taper femoral head along with a size 9 Stryker Omnifit HFX 127° hip stem were placed. Postoperative anterior-posterior and frog-leg lateral radiographs were obtained demonstrating a well-fixed and well-aligned THA (Fig. 2); however, cross-table lateral views of the right hip were not obtained.

The patient presented in office on January 7, 2021, for her 4-week postoperative visit with no complaints and appropriate progression with physical therapy. In-office imaging was obtained demonstrating no interval change in cup or screw position on anterior-posterior hip views; however, on cross-table lateral views

only, there was evidence of the longer, 45-mm, acetabular screw penetrating through the acetabular shell (Fig. 3). As the patient had otherwise stable acetabular and femoral components, the decision was made to maintain weight-bearing as tolerated, and standard follow-up in office was scheduled. The patient was again seen in the office for her 4-month follow-up appointment on April 15, 2021, with similar-appearing radiographs (Fig. 4) and no complaints.

Case 2

A 70-year-old female with a past medical history of sleep apnea and severe left hip osteoarthritis presented to an outpatient surgical center on June 14, 2021, for elective left THA. Preoperative imaging demonstrated bone-on-bone osteoarthritis with subchondral sclerosis and diffuse osteopenia (Fig. 5a). On the day of surgery, the patient was taken to the operating room where she was positioned on a Hana Orthopedic Surgery Table (Mizuho OSI, Tokyo, Japan), and an anterior approach to the left hip was utilized. Once the femoral neck osteotomy was performed and femoral head removed, the acetabulum was reamed to accommodate a press fit size 52-mm Stryker Trident II Clusterhole HA Acetabular Shell. The acetabular shell had good fit after impaction, but due to the poor quality of bone during reaming, the decision was made to add additional fixation with a cancellous screw. Screw implantation was performed by predrilling using a drill guide and a 3.3-mm drill bit. The depth gauge was then used to obtain the screw length. One cancellous 6.5×30 -mm low-profile hex screw was placed in the acetabular dome for additional stability. Seating of the screw was confirmed visually and manually. However, intraoperative fluoroscopy demonstrated the initial screw completely penetrated the acetabular shell (Fig. 5b), so a second cancellous 6.5×35 mm acetabular screw was placed. Screw length and diameter were confirmed by the device representative, the scrub nurse, and the surgeon prior to implanting. Screw specifications were also recorded in the electronic medical record and verified against the device package labeling. A Trident X3 36-mm polyethylene insert was then placed in the acetabular cup. A 36-mm outer diameter, -2.5 neck length Stryker BioloX delta ceramic V40 femoral head and press fit size 5 Stryker Accolade II 132° neck angle hip stem were placed. The patient presented in office on July 13, 2021, for her 4-week postoperative visit with no complaints and appropriate progression with physical therapy. In-office imaging was obtained demonstrating no interval change in cup or screw position on anterior-posterior hip or cross-table lateral views. The failed acetabular screw was again seen in the anterior-posterior view (Fig. 6). As the patient had otherwise stable acetabular and femoral components, the decision was made to maintain weight-bearing as tolerated, and standard follow-up in office was scheduled. The patient was again seen in office for her 4-month

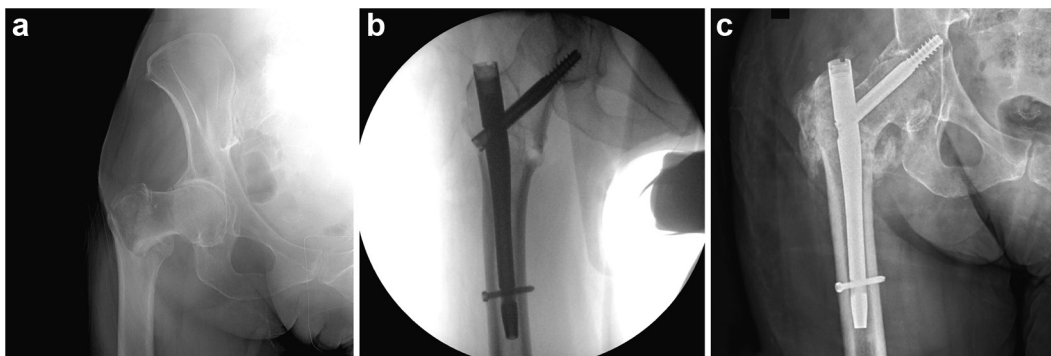


Figure 1. Initial anterior-posterior radiograph of the right hip (a) upon patient arrival in the emergency department demonstrating an intertrochanteric fracture of the right hip. An intraoperative c-arm radiograph (b) demonstrates fixation of the right intertrochanteric fracture with a short cephalomedullary nail. Follow-up anterior-posterior radiograph of the right hip (c) 2 months after the initial surgery demonstrates failure of the cephalomedullary nail with screw cutout and penetration into the acetabulum.

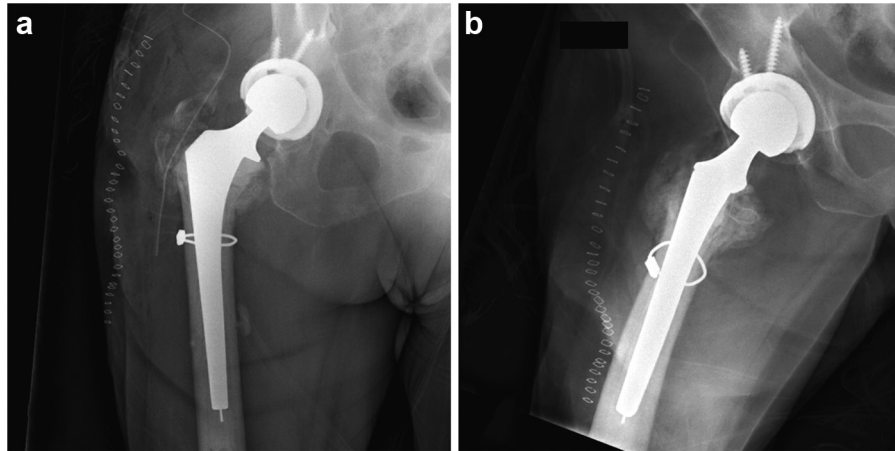


Figure 2. Postoperative anterior-posterior (a) and frog-leg (b) radiographs of the right hip after revision from a failed cephalomedullary nail to total hip arthroplasty. Of note, the failed acetabular screw could not be visualized on these views because orthogonal views of the acetabular cup were not obtained.

follow-up appointment on October 14, 2021, with similar-appearing radiographs (Fig. 7) and no complaints.

Discussion

There have been no previous reports of screw/shell interface failure in the Stryker Trident II Acetabular System. Difficulty in imaging the failure and the relatively recent introduction of the

device may contribute to underreporting and missed failures. To view the screw head penetrating the acetabular shell, intraoperative orthogonal views of the screws tangential to the shell surface must be obtained (Fig. 8). Intraoperative screw/shell failure was seen in patient #2's case, but not observed in patient #1's case. Alternatively, the screw head could be examined with the use of a calibrated instrument to confirm adequate screw seating. As surgical volume and adoption of the implant by surgeons increase,

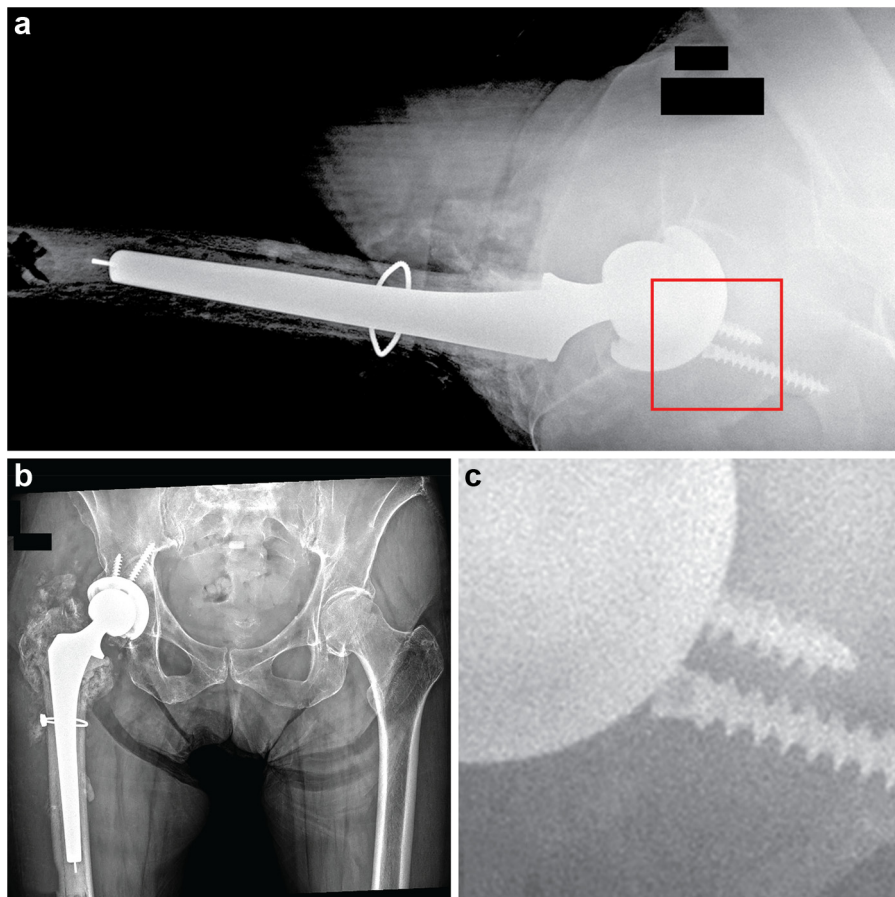


Figure 3. Two-week postoperative anterior-posterior (a) and cross-table lateral (b) radiographs of the right hip after revision from a failed cephalomedullary nail to total hip arthroplasty. On the cross-table lateral view, there is evidence of failure in 1 of the acetabular screws (red box); (c) magnified image.

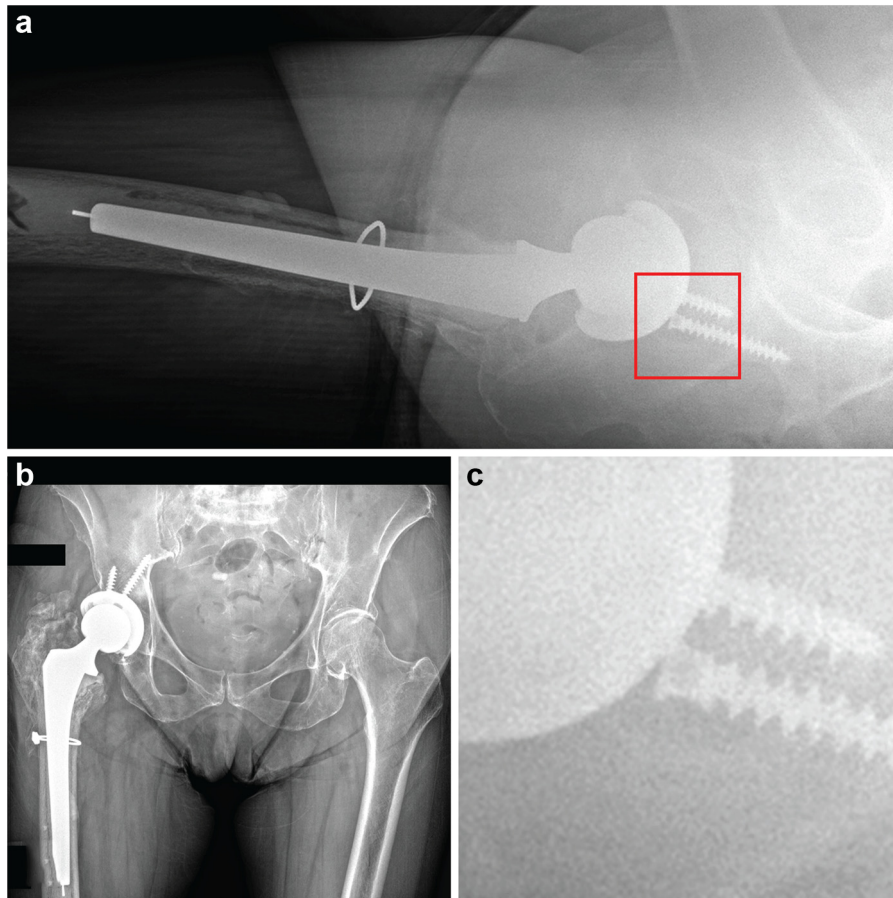


Figure 4. Four-month postoperative anterior-posterior (a) and cross-table lateral (b) radiographs of the right hip. There has been no interval change in the position of the failed acetabular screw (c) seen previously at postoperative week 2 (Fig. 3).

more screw failure occurrences are likely to be reported. In the author’s practice, 926 Trident II cups have been placed since 2018. With these 2 reported failures, this represents a failure rate of 0.22%. While this is a small incidence, when compared to the first-generation Trident—which is over 2 decades old and there have been no reported screw/shell failures—these failures may represent a Trident II design flaw.

The Stryker Trident II Acetabular System differs from the first generation Trident shell in multiple ways. The Trident II is 3-dimensionally printed in titanium using the additive manufacturing technology. Additive manufacturing uses a laser beam to melt layers of titanium powder in a fusion bed, whereas the Trident first-generation cup utilized a 2-dimensional fabrication process [8]. These differences in fabrication allow the Trident II to have a thinner

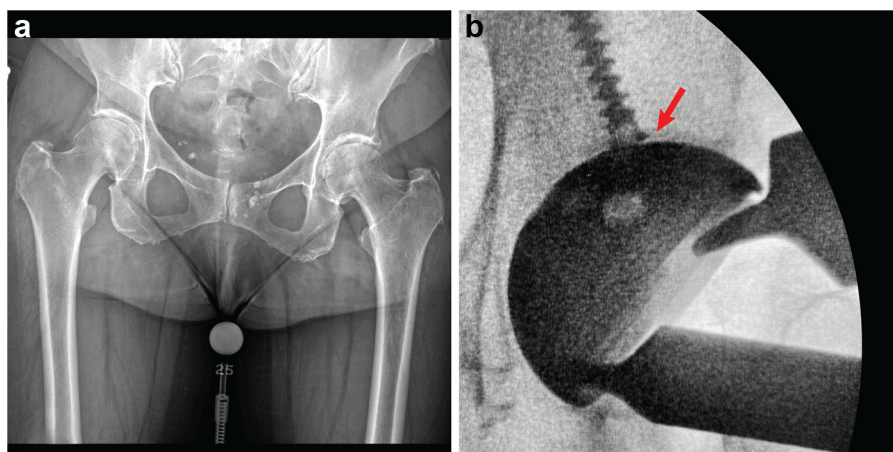


Figure 5. Preoperative anterior-posterior radiograph (a) demonstrating bilateral hip osteoarthritis, with the right hip showing more severe cartilage loss and subchondral sclerosis than the right hip. Intraoperative anterior-posterior radiograph (b) of the left hip with acetabular cup and retractors in place with failure of the acetabular screw (red arrow).

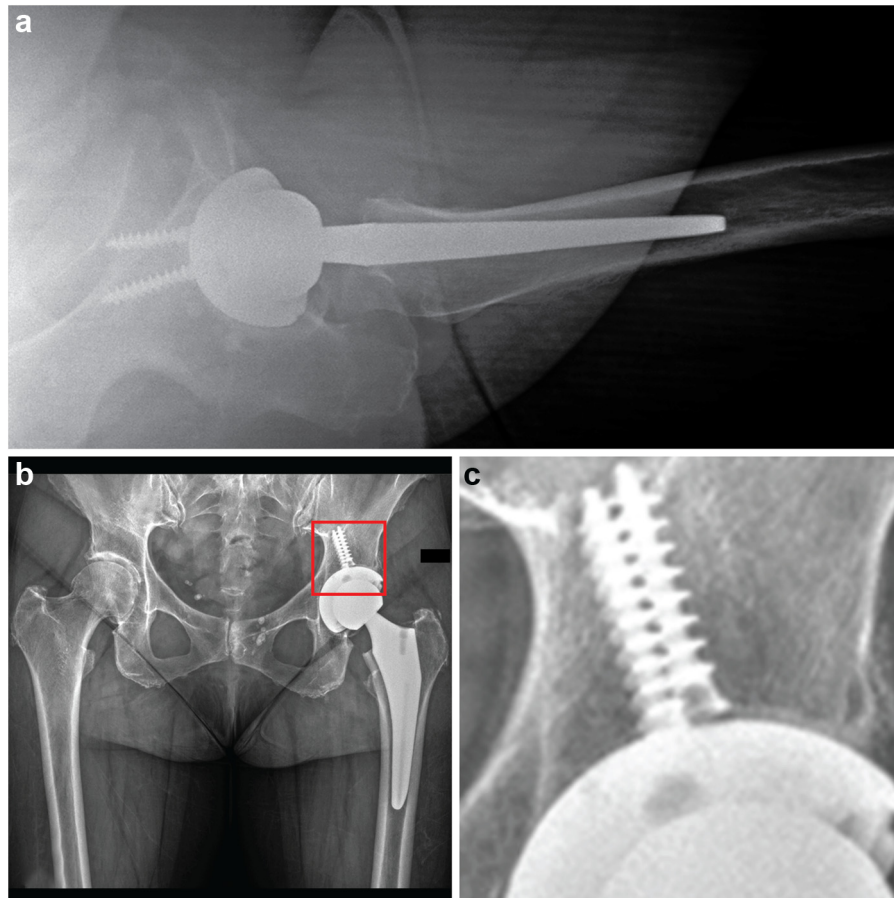


Figure 6. Four-week postoperative anterior-posterior (a) and cross-table lateral (b) radiographs of the right hip after left total hip arthroplasty. On the anterior-posterior view, there is evidence of failure in one of the acetabular screws (red box); (c) magnified image.

shell and a deeper recessed screw position (Fig. 9) [9]. This thinner shell with more recessed screw holes may explain why a new event of screw failure at the screw/shell interface can occur. The maximal diameter of the screw head is 7.25 mm with neck diameter of 5.25 mm tapering up to 5.6 mm, and the acetabular cup holes have an inner diameter of 6.50 mm. It is possible that the screw head or, alternatively, the acetabular cup hole could deform 0.75 mm to allow pull-through. In the author's opinion, it is this new design that incorporates a thinner rim of titanium between the acetabular shell and screw head that puts the Trident II shell at a risk of screw penetration through the shell.

The decision to add an acetabular screw during implantation of press-fit acetabular components is usually determined either preoperatively or intraoperatively when assessing the patient's bone quality. The author typically inserts an acetabular screw when the bone quality may compromise the press-fit nature of the shell or during revision cases when bone loss has occurred. The added acetabular screw is thought to create compression force between the shell and the host bone optimizing overall bone ingrowth [10]. During failure of the screw/shell interface, the additional compressive force is lost, thus eliminating a fixation strength that the surgeon was anticipating they had. This failure ultimately puts the patient at risk of acetabular component loosening or catastrophic failure.

The technique guide for the Trident II cup discusses the 6.5-mm low-profile hex screw insertion [9]. A 3.3- or 4.0-mm drill bit can be used for pilot hole creation. According to the technique guide, if the user is utilizing the guide, then proper alignment of the hole trajectory will be achieved, which facilitates full seating of the screw

head in the shell. It does caution to insert the screw by hand as power screwdriver may damage the screw or driver with excessive torque, but no mention of screw penetration through the shell with or without hand insertion is made. In both cases presented, the drill guide was used, and the screws were inserted by hand. There were no issues fitting the polyethylene liner due to inadequate seating of the screw with the head proud to the inner surface of the shell. While one failure was observed intraoperatively, the other patient's screw failure was observed at a 2-week follow-up office visit. Postoperative anteroposterior imaging failed to identify screw/shell failure in one patient and was only seen on a cross-table lateral radiograph obtained in office. The other patient was only identified to have screw/shell failure using intraoperative fluoroscopy. This suggests that intraoperative acetabular screw assessment for failure is inadequate without additional imaging modalities.

In a patient necessitating the additional fixation and stability provided by acetabular cup screws, failure of the screw/shell interface could lead to catastrophic failure of the acetabular cup [11–14]. Not only does a screw that penetrates through the acetabular shell compromise the stability of the implanted THA, but if the screw penetrates too deeply, neurovascular structures can be compromised. Anatomic studies have demonstrated that too long of a screw even in the “safe zone” of the posterior superior quadrant of the acetabulum can injure the superior gluteal artery or nerve [15]. There is a risk of uncontrolled screw advancement when the screw penetrates through the acetabular shell unnoticed during insertion, which could lead to catastrophic neurovascular injury. While the 2 patients in our study had no adverse clinical outcomes,

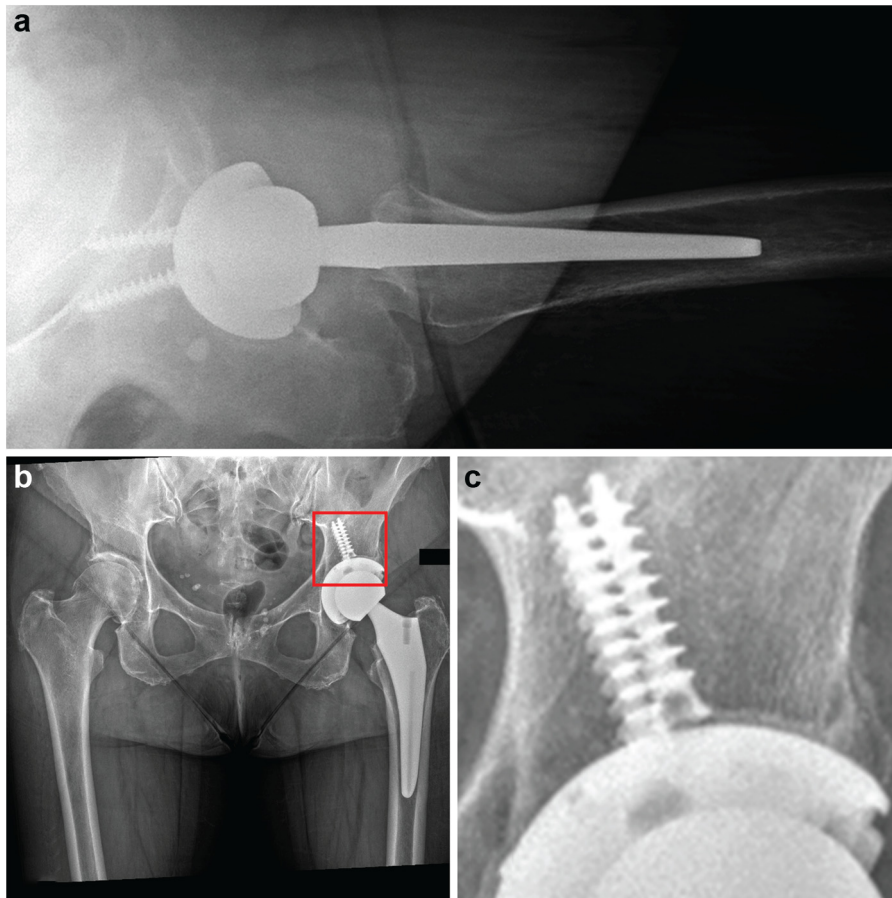


Figure 7. Four-month postoperative anterior-posterior (a) and cross-table lateral (b) radiographs of the right hip. There has been no interval change in position of the failed acetabular screw (c) seen previously at postoperative week 4 (Fig. 6).

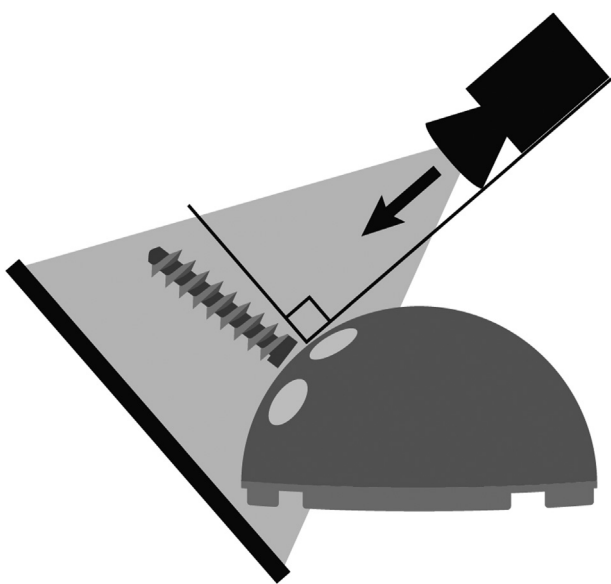


Figure 8. Schematic of the ideal angle to image acetabular screws and detect potential failure. The x-ray tube (black camera) and detector should be aligned tangential to the acetabular cup surface at the site of the screw. An additional orthogonal view should be acquired.

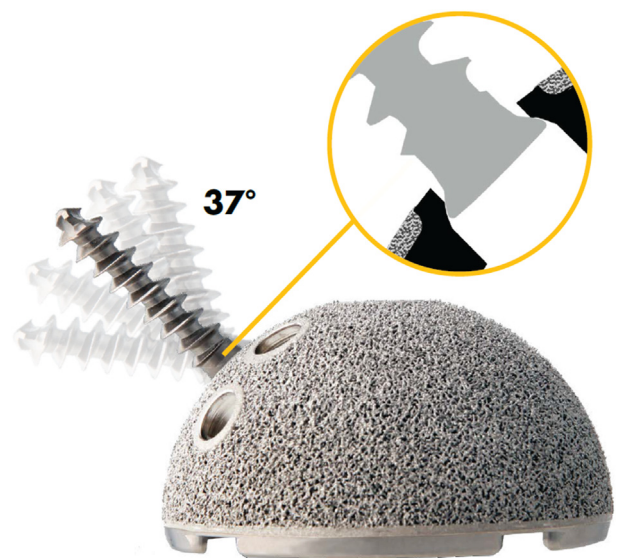


Figure 9. Rendering of the Stryker Trident II Acetabular System demonstrating the solid core screw hole profile. The recessed screw holes and low-profile hex screws enable up to 37 degrees of screw angulation and minimize the risk of interference with the liner bearing. However, the lower profile design may also contribute to the acetabular screw failure [9].

this potential risk further amplifies the significance of identifying a possible manufacturing error in the acetabular screw/shell interface. The failure of the acetabular screw/shell interface in 2 of our patients has prompted a change in the implant company our surgeon uses when a patient may need further stability with acetabular screws during THA. This study should prompt biomechanical testing of the Trident II cup/screw interface along with further case studies to examine the screw failure rate and overall prognosis of this new event.

Summary

This is the first case report of in vivo cup/screw interface failure in the recently released (2018) Stryker Trident II Acetabular System. Due to the high frequency of cup/screw interface failure, the author utilizes a non-Trident II Acetabular System in patients requiring increased fixation with acetabular cup screws during THA. Future biomechanical studies should examine the screw/shell interface of the Trident II Acetabular System to elucidate the mode of screw or shell failure that has been observed clinically. If surgeons continue to use the Stryker Trident II Acetabular System with acetabular screws, we recommend obtaining intraoperative orthogonal views of the screws tangential to the shell surface to confirm screw placement and function.

Conflicts of interest

The authors declare there are no conflicts of interest.

For full disclosure statements refer to <https://doi.org/10.1016/j.artd.2022.07.010>.

Informed patient consent

The authors confirm that informed consent has been obtained from the involved patients or if appropriate from the parent, guardian, power of attorney of the involved patients, and they have given approval for this information to be published in this article.

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