

### 3 Case report: unique failure of a Synthes TFNA fenestrated lag screw in a peritrochanteric nonunion

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**Background:** Intertrochanteric femur fractures are a common orthopaedic injury that are often treated surgically. Cephalomedullary nails (CMN) are frequently the implant of choice for intertrochanteric femur fractures, resulting in low complication rates. Implant failure is a rare but reported complication. Common locations of failure include the proximal nail aperture, distal screw holes, and implant shaft. In this case report, we describe a CMN failure pattern through fenestrated cephalic screw holes.

**Case:** A 70-year-old female sustained an OTA 31A-2.2 peritrochanteric fracture during a motor vehicle collision. She was treated the following day with a Synthes Trochanteric Fixation Nail—Advanced CMN utilizing a fenestrated cephalic screw. There were no intraoperative complications. She was made non-weight bearing for 8 weeks after the procedure due to ipsilateral foot fractures. At 6 months follow-up she was noted to have a delayed union. 11 months postoperatively she suffered a ground level fall and the cephalic lag screw failed through its fenestrations, resulting in varus collapse of her fracture at the femoral neck. The patient then underwent nail extraction and salvage total hip arthroplasty.

**Conclusion:** Cephalomedullary nail implant failure is presented with implant fracture propagation through a fenestrated cephalic screw. Cephalomedullary lag screw failure is rare and can be difficult to manage. It is important to monitor new implants for unique failure mechanisms.

**Keywords:** case report, implant failure, intertrochanteric fracture, non-union, Synthes TFNA

#### 1. Introduction

Intertrochanteric femur fractures are a common injury seen in orthopaedic trauma. By 2050, the annual incidence of hip fractures is estimated to surpass 6.3 million worldwide.<sup>[1]</sup> These injuries are usually treated surgically, with both intramedullary or extramedullary devices. Cephalomedullary nails (CMN) have gained popularity due to their biomechanical superiority and

minimally invasive implantation.<sup>[2–7]</sup> In fact, CMNs have now become the dominant mode of fixation for intertrochanteric hip fractures across the United States.<sup>[5,6,8,9]</sup>

Intramedullary implants used for treatment of intertrochanteric fractures have demonstrated a failure rate between 0% and 22%.<sup>[10–15]</sup> Implant-related complications include intraoperative peri-implant fracture, postoperative peri-implant fracture, implant cut-out, loss of fixation, anterior perforation of the distal femur, and rarely implant failure.<sup>[16–18]</sup> The reported incidence of CMN implant breakage is 0.2% to 5.7%.<sup>[19–22]</sup> The majority of these occur at the proximal nail aperture. There have been reports of rare implant failure at the distal screw aperture, the distal locking screw itself, and the shaft of the CMN. Cephalomedullary lag screw fracture is a rare mode of failure and can be difficult to manage. We report a case of a fenestrated cephalic lag screw implant failure in a peritrochanteric nonunion using the Trochanteric Fixation Nail—Advanced (TFNA) Proximal Femoral Nailing System (DePuy Synthes, Paoli, Pennsylvania).

#### 2. Case report

Submission to our Institutional Review Board (IRB) determined that this case report is exempt from Institutional Review Board approval. Informed consent was obtained from the patient for reproduction. This report has been approved for publication by our institutions committee on research ethics in accordance with the Declaration of the World Medical Association.

A 70-year-old female sustained a right closed displaced peritrochanteric proximal femur fracture from a high-speed motor vehicle collision (Fig. 1). The patient was previously an independent ambulator and had a past medical history of

Source of funding: Nil.

None of the authors received financial compensation for their involvement in this work.

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The authors have no conflicts of interest to disclose.

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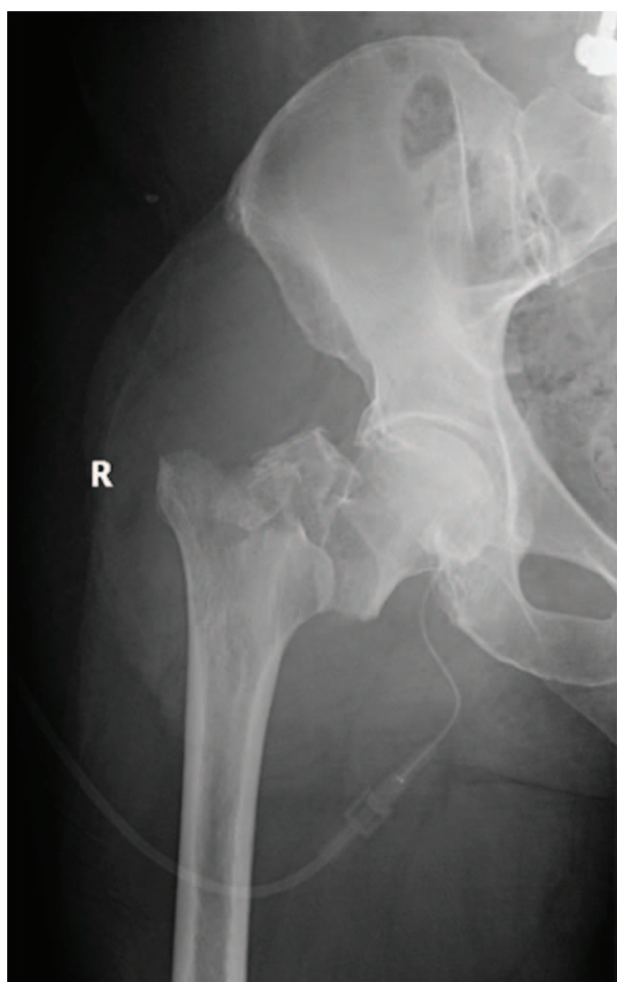
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OTA (2022) e203

Received: 25 August 2021 / Accepted: 5 February 2022

Published online 18 April 2022

<http://dx.doi.org/10.1097/O19.000000000000203>



**Figure 1.** Anteroposterior radiograph of the right peritrochanteric proximal femur fracture described in this case report.

hypertension and lumbar stenosis status post decompression and fusion. She was overweight with a body mass index of 26.52 kg/m<sup>2</sup> and her American Society of Anesthesiologists score was III. The fracture was classified as OTA/AO 31-A2.2, Evans type III fracture. The lateral wall measured 17.6 mm according to the technique described by Hsu et al.<sup>[23]</sup>

The patient was treated operatively on the day following her injury with closed reduction on a fracture table. It was noted intraoperatively that the fracture extended into the region of the superior femoral neck. Her closed reduction was deemed adequate and was held temporarily with 2-mm Kirschner wires during nail insertion to prevent displacement. She underwent uneventful internal fixation using a 130° Synthes TFNA CMN which measured 340 mm in length and 10 mm in diameter with a 90 mm fenestrated cephalic lag screw. The cephalic screw was placed and interfragmentary compression was achieved across the fracture site using the compression nut as described in the manufacturer's technique guide.<sup>[24]</sup> There were no observed complications during drilling or insertion of the cephalic lag screw. The cephalic screw was set in the static position. Two distal static interlocking screws were placed. The remainder of the procedure was uneventful. The patient also presented with multiple ipsilateral foot fractures that were treated during the index procedure and she was made non-weight bearing postoperatively for her ipsilateral foot injury.

The patient was seen regularly for postoperative follow-up visits. At her 6-week follow-up, adequate radiographic healing of her ipsilateral foot fractures was visualized and her weight bearing precautions were lifted (Fig. 2). She was ambulating without pain by her 3-month follow-up visit (Fig. 3). She was asymptomatic and ambulating without assistive devices at her 6-month follow-up visit and had no complaints but her radiographic images demonstrated a delayed union or nonunion of her peritrochanteric fracture (Fig. 4). Given the patient's lack of symptoms, a delayed union/nonunion workup was not initiated at that time. She was scheduled to return for a 1-year postoperative follow-up visit.

Eleven months after her index surgery, she suffered a ground level fall in her home. She complained of pain and inability to bear weight and was taken to a nearby hospital by local Emergency Medical Services. She was then transferred to our facility for higher level of care where she was found to have sustained implant failure of the cephalic lag screw portion of the TFNA in the setting of nonunion and varus collapse (Fig. 5). Computed Tomography scan revealed nonunion of the peritrochanteric fracture with varus collapse and breakage of the cephalic lag screw through the femoral neck. The cephalic lag screw appeared to have failed through the fenestrations (Fig. 6). She underwent revision surgery with removal of the broken nail and total hip arthroplasty was performed (Figs. 7 and 8). Explanted hardware was inspected and confirmed failure of the cephalic lag screw through the fenestrations.

### 3. Discussion

Cephalomedullary nails are the treatment of choice for unstable peritrochanteric proximal femur fractures and have even become the most utilized mode of internal fixation for stable peritrochanteric fractures across the United States.<sup>[9,25]</sup> There are several reports in the literature describing cephalomedullary nail breakage. The most common site of nail breakage is at the aperture for the cephalic lag screw or blade. At this location the cross-sectional area of the intramedullary nail is narrowed by 73%.<sup>[26–28]</sup> Prior reports also show evidence of eccentric drilling at the proximal nail aperture causing implant notching and decreased fatigue strength.<sup>[28–31]</sup> Other previously reported sites of implant breakage include the distal screw aperture, the distal locking screw itself, and the shaft of the cephalomedullary implant.<sup>[19,20,22,28,32]</sup> We present a unique failure of the TFNA cephalomedullary nail in a peritrochanteric nonunion.

There are several risk factors that have been associated with nail breakage including a low American Society of Anesthesiologists score (I or II), young age, reverse obliquity intertrochanteric fractures, subtrochanteric fractures, and pathological fractures.<sup>[13,16,33]</sup> Early implant failures have been attributed to poor insertion technique with notching of the proximal nail aperture with the Gamma nail (Stryker, Kalamazoo, Michigan).<sup>[34]</sup> Late implant catastrophic failures have been attributed to inadequate reduction, delayed union, or nonunion. As in our patient, any implant will eventually fail in the setting of nonunion based on its fatigue life of the implant and the stresses placed upon it. Being critical of our own work, the closed reduction was imperfect but acceptable. The decision to place a static cephalic screw was made based on the lack of medial cortical contact and concerns of overcompression and loss of femoral neck length. In retrospect, a short femoral neck that collapsed and compressed may have prevented a return to the operating room, but may have also resulted in relative abductor weakness.

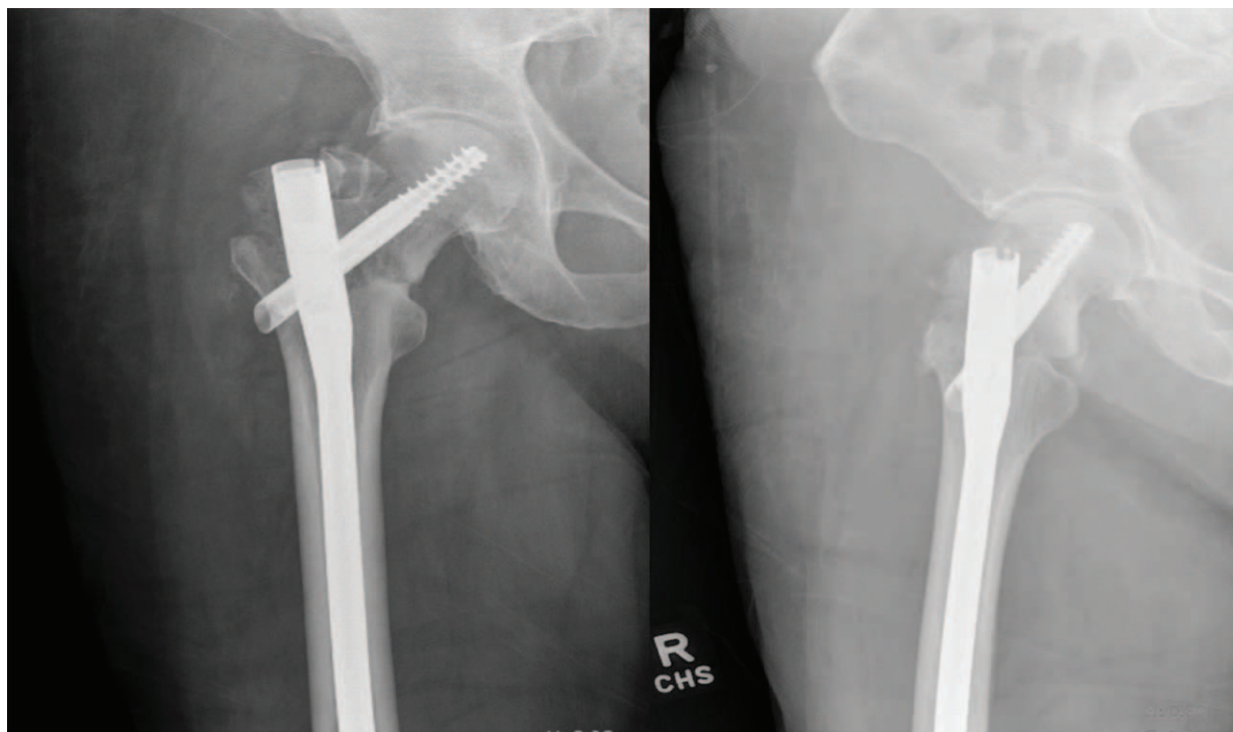


Figure 2. Six-week routine follow-up anteroposterior and lateral radiographs demonstrating right peritrochanteric proximal femur fracture with TFNA fixation.



Figure 3. Three-month routine anteroposterior and lateral radiographs of right peritrochanteric femur fracture with TFNA fixation.

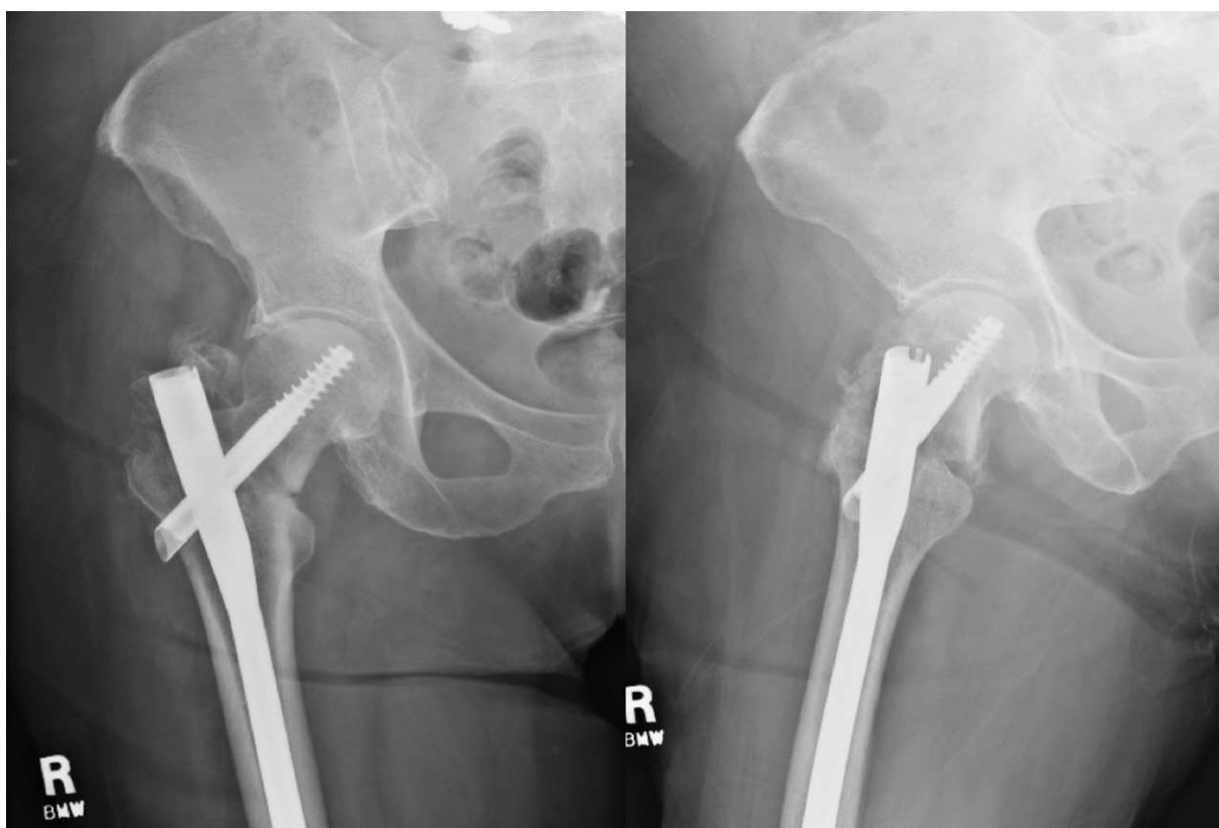


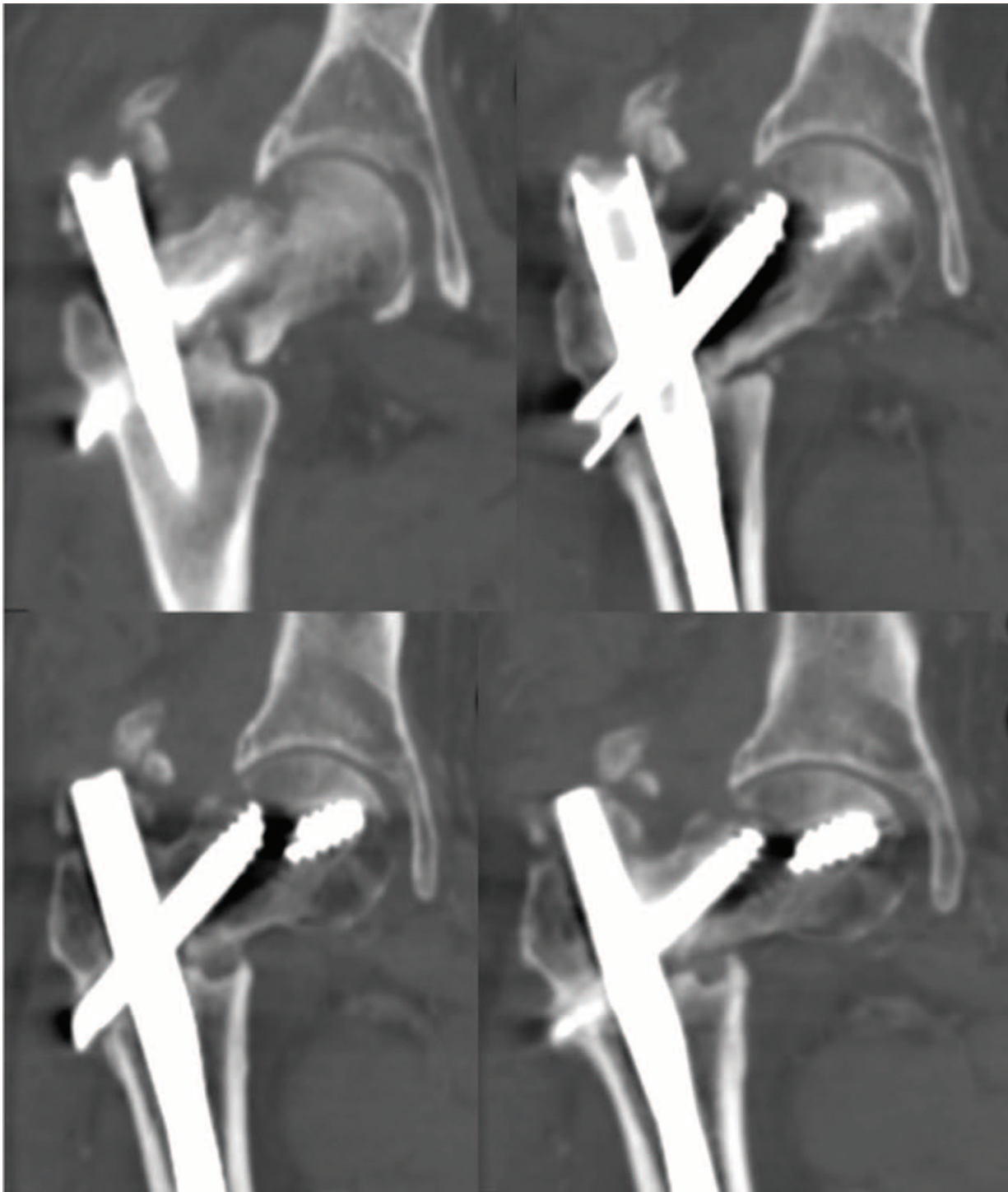
Figure 4. Six-month routine anteroposterior and lateral radiographs of right peritrochanteric femur fracture with TFNA fixation.

The Synthes TFNA system offers both solid and fenestrated helical blade and lag screw options. The fenestrated head elements allow for cement augmentation. There is some evidence that augmented fixation may have a lower rate of failure in

osteoporotic individuals, however evidence demonstrating superiority of cement augmentation in individuals with normal bone density is lacking.<sup>[35-37]</sup> Despite the rare usage of cement augmentation for peritrochanteric fracture fixation, most



Figure 5. Anteroposterior and lateral radiographs demonstrating implant failure of TFNA through the cephalic lag screw at 11 months postoperatively.



**Figure 6.** Coronal reconstructions of sequential CT images demonstrating peritrochanteric fracture nonunion with varus collapse and failure of the cephalic lag screw of the TFNA through the fenestrations. CT, computed tomography.

hospitals, including our institution, only stock the fenestrated implants.<sup>[24]</sup> There is no difference in cost between the fenestrated and nonfenestrated implants. In this case, a fenestrated lag screw was utilized without cement augmentation. The lag screw appears to have failed through the fenestrated holes. Accepting that the nail would have failed in the setting of nonunion, we question if the nail would have failed at the same location if a solid lag screw were utilized. In response to this case, our institution now stocks nonfenestrated cephalic lag screws

and helical blades which are used if cement augmentation is not utilized. Perhaps fenestrated head elements should only be used if cement augmentation is planned.

The cephalic lag screw failure was reported to DePuy Synthes. Engineers at Depuy Synthes were available to discuss the case, the universal adoption of fenestrated head elements, and biomechanical data and testing which supported this decision. DePuy Synthes was willing to share their biomechanical testing methods and the results of early market surveillance after signing



Figure 7. Intraoperative and postoperative clinical images showing explanted failed implant with breakage through the cephalic lag screw fenestrations.

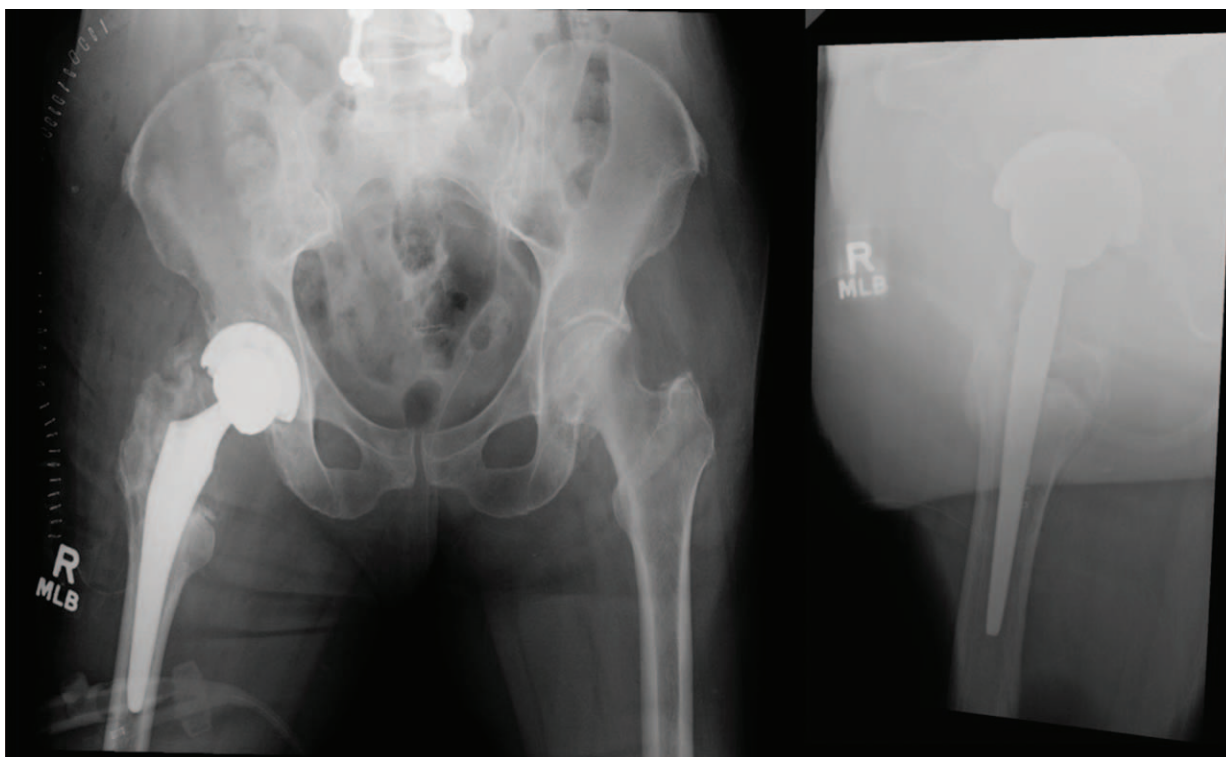


Figure 8. Anteroposterior pelvis and lateral hip radiographs following revision surgery and total hip arthroplasty.

## Device Enhancement

A device enhancement in the form of a design modification has been made to the TFN-ADVANCED™ Proximal Femoral Nailing System (TFNA) Fenestrated Lag Screw [Figure 1]. The design of the Lag Screw contains fenestrations that enable the use of augmentation (TRAUMACEM™ V+ Augmentation System), allowing the cement to flow through the head element into the bone within the femoral head. This design modification repositioned all fenestrations on the Lag Screw to within the root of the threads (i.e., moved laterally from original position), and reduced each fenestration diameter from Ø2.25 mm to Ø1.80 mm [Figure 2]. This reduced diameter of Ø1.80 mm is the same as the Proximal Femoral Nail Antirotation System (PFNA™ System).\*

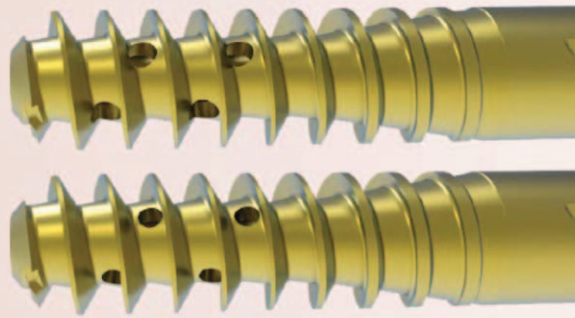


Fig. 1: Original Fenestrated Lag Screw (top) compared to modified Fenestrated Lag Screw (bottom). Design modification included moving fenestrations by approximately 1mm laterally and reducing the diameter from Ø2.25 mm to Ø1.80 mm.

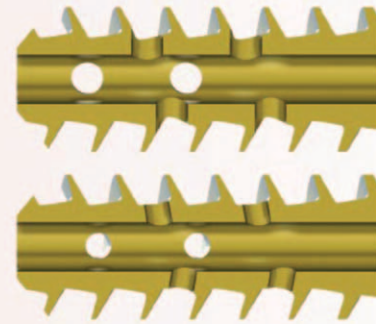


Fig. 2: Cross-section of original Fenestrated Lag Screw (top) compared to modified Fenestrated Lag Screw (bottom).

## Finite Element Analysis Evaluation

A Finite Element Analysis (FEA) was conducted to evaluate the impact this modification had on the stresses seen on the Lag Screw. The original Lag Screw design positioned the fenestrations in locations causing stress concentrations (i.e., at a position where the thread flank intersected the core diameter of the Lag Screw), whereas the modified design has repositioned the fenestrations away from these locations [Figure 3]. This resulted in a reduction of stress by approximately 32% compared to the original design.<sup>1</sup>

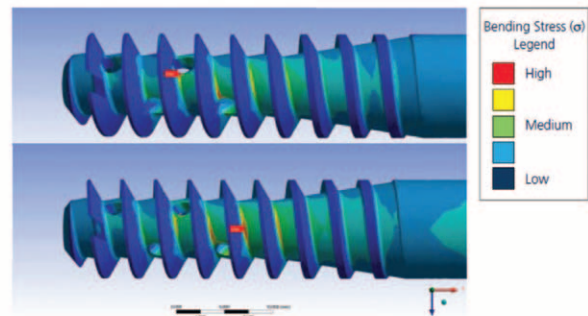


Fig. 3: FEA analysis comparing original Fenestrated Lag Screw (top) to the modified Fenestrated Lag Screw (bottom). Stress is indicated in red, and modified locations of fenestrations are shown to reduce stress.

**Figure 9.** Figure provided by Johnson & Johnson DePuy Synthes (Paoli, Pennsylvania) and approved for reprinting, describing new design changes to the fenestrated screw head element in response to biomechanical testing and device surveillance.

a nondisclosure agreement. In response to early surveillance data and finite element analysis, the fenestrated lag screw has recently been redesigned and optimized to improve fatigue strength (Fig. 9).

This particular patient was salvaged with total hip arthroplasty; however, this failure mode would be difficult to treat if revision open reduction internal fixation were attempted. The broken head element can be removed with a reverse threaded extraction cone from the broken screw removal set. Careful attention would be required not to spin the femoral head during this extraction preventing damage to its blood supply. In a series of patients treated for TFNA failures at the proximal nail aperture, 38% revised to a second TFNA experienced a second implant failure.<sup>[16]</sup> It is unclear if this trend would be similar for nail failure at the cephalic lag screw.

Close follow-up is recommended for unstable peritrochanteric proximal femur fractures as displacement of a delayed union or nonunion can have catastrophic consequences. CMN case, closer monitoring after the 6 month visit and more timely workup of nonunion may have prevented catastrophic implant failure.

## 4. Conclusion

Cephalomedullary nails have become the most common treatment for peritrochanteric fracture fixation in the United States. We report a unique failure of the TFNA implant at the fenestrated cephalic lag screw. It is important to recognize and monitor new implants for unique failure modes.

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