Implant Fracture Analysis of the TFNA Proximal Femoral Nail

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Background: Mechanical failure of intramedullary nails is rare. This investigation was prompted by a series of cases of observed breakage of the recently introduced TFNA Proximal Femoral Nailing System (TFN [Trochanteric Fixation Nail]-Advanced; DePuy Synthes) in our region. Laboratory analysis and case data are presented, in contribution to post-market surveillance.

Methods: Medical and imaging records from the 3 public tertiary orthopaedic trauma hospitals in Western Australia were reviewed. Relevant data of patients in whom breakage of the TFNA implant occurred between 2016 and 2018 were collected and analyzed. Laboratory review of retrieved implants was conducted at the Centre for Implant Technology and Retrieval Analysis (CITRA) in Western Australia.

Results: A total of 16 cases of TFNA implant breakage were recorded and analyzed. The predominant OTA/AO fracture classification was 31A3 (12 cases, 75%). The reduction quality was good in 10 cases, acceptable in 4 cases, and poor in 2 cases. The mean time to failure (and standard deviation) was 5.0 ± 2.2 months (range, 2.2 to 9.8 months). The treatment modality for the breakage was revision nailing in 11 cases, arthroplasty in 3, and nonoperative management in 2. All nails broke at the proximal screw aperture, with 1 nail additionally breaking at the distal aperture. Of 8 patients treated with a second TFNA implant for nail breakage, 3 (38%) returned with breakage of the revision implant. Laboratory analysis of the broken nails demonstrated a unique fracture pattern, with a stepped propagation pathway.

Conclusions: This study represents the largest series, to our knowledge, of proximal femoral nail breakages in the published English literature and is the first that we are aware of to involve laboratory analysis of the TFNA implant. Changes to the nail design and/or alloy may have contributed to the observed cases of breakage, and this study will be followed by an evaluation of breakage rates in comparison with those of previous generations of nailing systems. We advise close clinical and radiographic surveillance of patients with unstable hip fracture patterns who undergo osteosynthesis with use of a TFNA implant.

Level of Evidence: Therapeutic Level IV. See Instructions for Authors for a complete description of levels of evidence.

Hip fractures are common and are associated with patient mortality as well as high economic burden. The overall health-care cost per patient is approximately $44,000 (USD) in the first 12 months following fracture, with an annual total burden of nearly $17 billion in the United States[1,2]. The number of fractures and their associated cost are anticipated to rise[2].

Intramedullary nails are frequently employed in the treatment of proximal femoral fractures. Implant-related complications include peri-implant femoral shaft fracture, loss of fixation, osteonecrosis, nonunion, infection, and pain[3,4]. Mechanical failure of the implant in the form of nail breakage is rare but may result in substantial morbidity for the patient. A cohort that is generally frail and elderly is subjected to a second

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operative procedure and further rehabilitation, along with additional financial burden. Risk factors for nail breakage include young age, a low ASA (American Society of Anesthesiologists) grade (I to II), subtrochanteric fracture, and pathological fracture[5]. In the majority of cases, breakage occurs at the proximal aperture for the cervicocephalic screw.

The TFNA Proximal Femoral Nailing System (TFN [Trochanteric Fixation Nail]-Advanced; DePuy Synthes) was introduced to the global market in 2015 and is made from a titanium-molybdenum (TiMo) alloy (Ti-15Mo)[6]. The TFNA was first used in Western Australia on March 1, 2016, and is still in use locally and internationally. TiMo is said to provide improved fatigue resistance and strength compared with TAV (titanium-aluminum-vanadium, Ti-6Al-4V) and TAN (titanium-aluminum-niobium, Ti-6Al-7Nb) alloys, according to biomechanical testing data from DePuy Synthes Trauma[7]. TiMo has also been shown to have a lower elastic modulus compared with TAV (78 versus 112 GPa), meaning that it should behave more like the surrounding cortical bone[8]. The TFNA offers both blade and screw fixation of the femoral head with sliding or static locking.

The introduced features include a 1.0-m-radius bow and a smaller proximal nail diameter of 15.66 mm. The BUMP CUT design is said to improve fatigue strength and is a protuberance in the middle portion of the proximal aperture on the lateral side on both the anterior and posterior rims (Fig. 1, "A"). Also introduced was the LATERAL RELIEF CUT, whereby the lateral portion of the proximal nail is progressively removed from proximal to distal, leaving a flattened rather than cylindrical shape, to preserve bone (Fig. 1, "B")[6]. With the LATERAL RELIEF CUT, the diameter at the level of the proximal aperture is further reduced to as low as 13.4 mm depending on the distal nail width[6]. The volume of alloy within the wall of the proximal nail is also reduced compared with previous nails by the presence of a cannulated built-in set screw above the aperture and a threaded space below it, to assist with device removal in case of implant breakage.

After a series of cases involving implant breakage were reported at the orthopaedic trauma units in Western Australia, this study was initiated to investigate the patient and surgical characteristics and evaluate the associated laboratory retrieval data.

Materials and Methods

A multicenter investigation was set up across the 3 public tertiary orthopaedic trauma hospitals in Western Australia. A highly concentrated and geographically isolated population facilitated effective data collection. Locally explanted orthopaedic devices from all hospitals are submitted for analysis to a central, government-funded institution known as CITRA (Centre for Implant Technology and Retrieval Analysis). Implants are collected, analyzed, and reported on, with >10,000 retrieved prostheses in storage.

We conducted an analysis of retrieved TFNA Proximal Femoral Nailing System implants that had fractured. Evaluation of the fractured nails included qualitative macroscopic analysis, optical stereomicroscopy (Leica MZ10; Leica), microstructural and microhardness assessment (Orthoplan; Leitz and DuraScan; Struers), and scanning electron microscopy (SEM) of fracture surfaces (NeoScope; JEOL).

Patient files were individually reviewed. Data retrieved from hospital medical records included age, sex, body mass index (BMI), ASA grade, admission diagnosis, mechanism of injury, implant details, procedure details, treatment, and time to failure. Radiographs were independently assessed by 2 of the authors (P.Y. and A.L.) both to classify the original fracture pattern according to the OTA/AO fracture classification system[9] and to qualitatively assess reduction quality, as described by Baumgaertner et al.[10]. All operations were performed by the Orthopaedic Trauma Consultant, Trauma Fellow, or Orthopaedic Registrar under supervision.

Quantitative data were analyzed using Excel for Mac 2016 (Microsoft). Institutional ethics approval was received prior to commencement of the study.

Results

Patient Cohort

At the time of writing, there were 16 reported cases of TFNA implant breakage (13 patients) in our region between 2016 and 2018. Demographic and clinical data are summarized in Table I. There were no pathological fractures. Clinical information by individual case is presented in Appendix I.

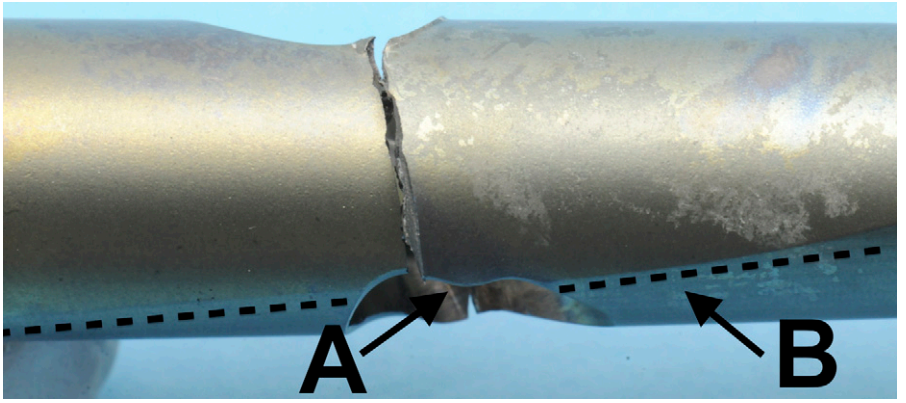

Fig. 1

Photograph of the anterior surface of the proximal portion of a broken nail. "A" indicates the BUMP CUT, and the dashed line ("B") indicates the LATERAL RELIEF CUT.

Fracture and Treatment

Assessment of fracture reduction, breakage information, and subsequent management are summarized in Table II. Classification of the original fracture pattern according the OTA/AO system showed that fractures were predominantly intertrochanteric (reverse oblique), followed in prevalence by multifragmentary pertrochanteric fractures and subtrochanteric fractures. No breakage in cases of a simple pertrochanteric fracture pattern were seen.

Following the index procedure, all patients had been allowed to weight-bear as tolerated with the use of a gait aid, if required. Postoperative physiotherapy focused on functional rehabilitation including transfers, mobility, sitting out of bed, balance, and reducing the risk of falling. Specific high-load exercises, such as straight-leg raises or squats, were not prescribed.

Two patients with minimal displacement of the fracture despite nail breakage declined further surgery. In 11 cases, breakage was treated with a revision nail: the TFNA implant was used in 8 of these revision cases; the AFN (Antegrade Femoral Nail; DePuy Synthes), in 2 cases; and the PFNA (Proximal Femoral Nail Antirotation; DePuy Synthes), in 1 case. Of the 8 patients treated with a TFNA nail on revision, 3 patients (38%) returned with breakage of the revision implant. These are Cases 2, 4, and 11 in the Appendix, returning as Cases 9, 10, and 14, respectively. Radiographs from Case 3 are shown (Figs. 2 through 5).

TABLE I Summary of Demographic and Clinical Information (N = 16 Cases)

Parameter	Value
Sex *(no.)*	
Female	11
Male	5
Age* *(yr)*	79.4 ± 9.3 (59-94)
BMI* *(kg/m²)*	26.4 ± 3.3 (22-33)
ASA grade *(no.)*	
2	9
3	7
Diagnosis *(no. [%])*	
Hip fracture	11 (69%)
Broken implant	5 (31%)
Mechanism *(no. [%])*	
Fall	12 (75%)
Atraumatic	4 (25%)
OTA/AO classification *(no. [%])*	
31A3	12 (75%)
31A2	2 (13%)
32A2	1 (6%)
32C3	1 (6%)

*The values are given as the mean and standard deviation, with the range in parentheses. Age is at the time of implant breakage.

TABLE II Assessment of Fracture Reduction, Breakage Information, and Subsequent Management

Parameter	Value
Reduction quality* *(no. [%])*	
Good	10 (63%)
Acceptable	4 (25%)
Poor	2 (13%)
Reduction method *(no. [%])*	
Open	9 (56%)
Closed	7 (44%)
Nail length *(no. [%])*	
Long	9 (56%)
Short	7 (44%)
Time to breakage† *(mo)*	5.0 ± 2.2 (2.2-9.8)
Mechanism of breakage *(no. [%])*	
Atraumatic	14 (88%)
Fall	2 (13%)
Breakage site *(no. [%])*	
Proximal aperture	15 (94%)
Proximal + distal apertures	1 (6%)
Diagnosis *(no. [%])*	
Delayed union	11 (69%)
Nonunion	5 (31%)
Management *(no. [%])*	
Revision nail	11 (69%)
Arthroplasty	3 (19%)
Nonoperative	2 (13%)

*Assessed according to the criteria of Baumgaertner et al.[10]. †The values are given as the mean and standard deviation, with the range in parentheses.

Implant Analysis

Macroscopic Analysis

In all cases, nail breakage occurred at the proximal aperture, with 1 nail additionally breaking at the distal aperture. Breakage occurred with both the blade and screw options for head fixation, with blade fixation having been used in the majority of cases at the time of data collection. Macroscopic analysis of the nails primarily revealed a tortuous crack failure path, with all nails showing multiple secondary cracks stemming from the fracture surface. In this regard, for several nails, small pieces of alloy were missing from the fracture surface, indicative of multiple crack pathways. Of note, in all cases, part of the failure path included a fracture that ran parallel to the long axis of the nail (Fig. 6). In all implants, the fracture origin was at the point of, or adjacent to, the thinnest cross-section of the nail, generally on the lateral aspect of the device associated with the LATERAL RELIEF CUT and BUMP CUT design features of the proximal hole. None of the nails showed intraoperative or insertional damage in that the edges of the

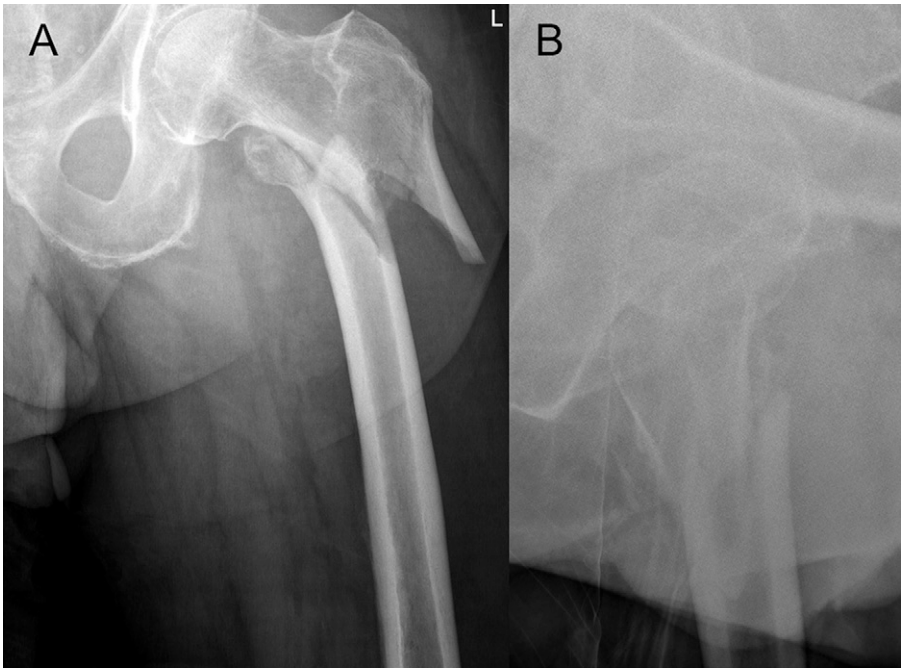

Fig. 2
Anteroposterior (**Fig. 2-A**) and lateral (**Fig. 2-B**) radiographs demonstrating a proximal femoral fracture.

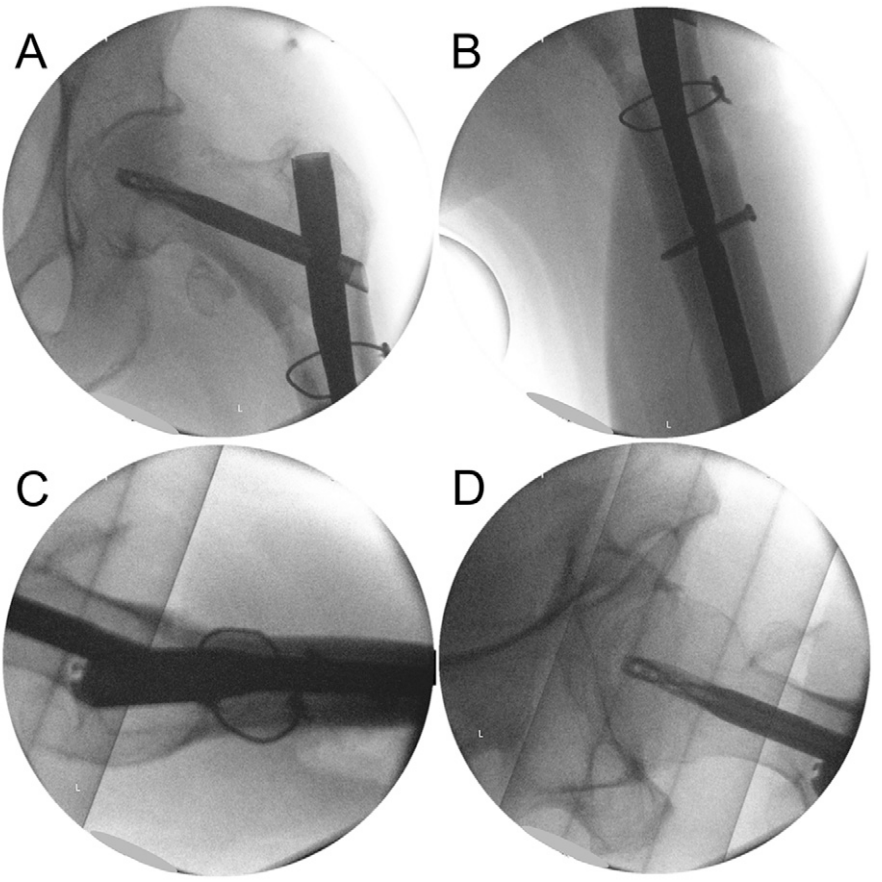

Fig. 3
Intraoperative fluoroscopic radiographs at the time of nail insertion.

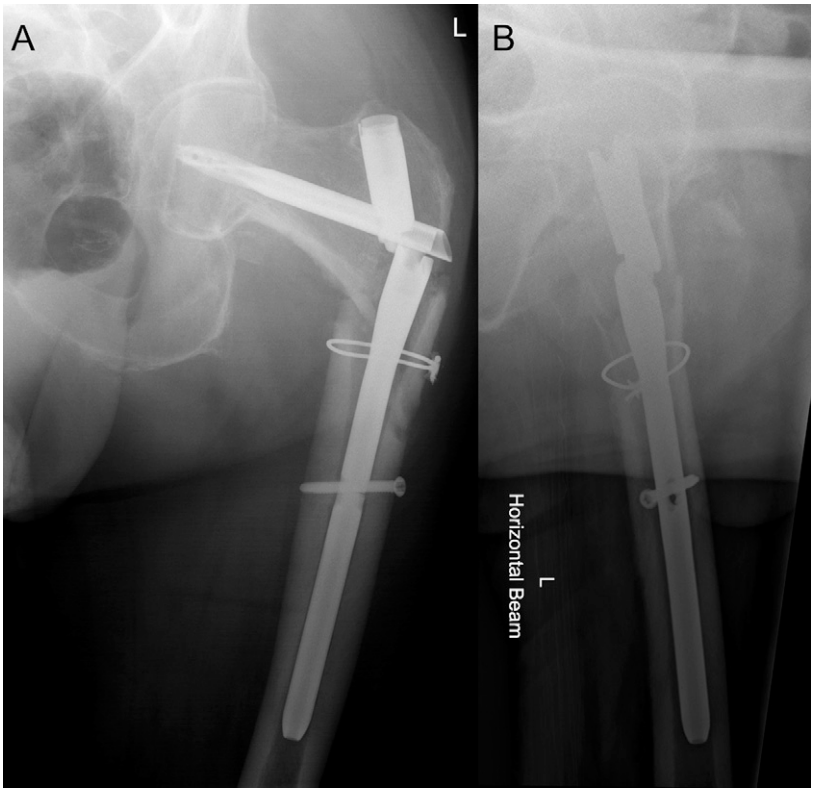

Fig. 4
Anteroposterior (**Fig. 4-A**) and lateral (**Fig. 4-B**) radiographs demonstrating implant breakage.

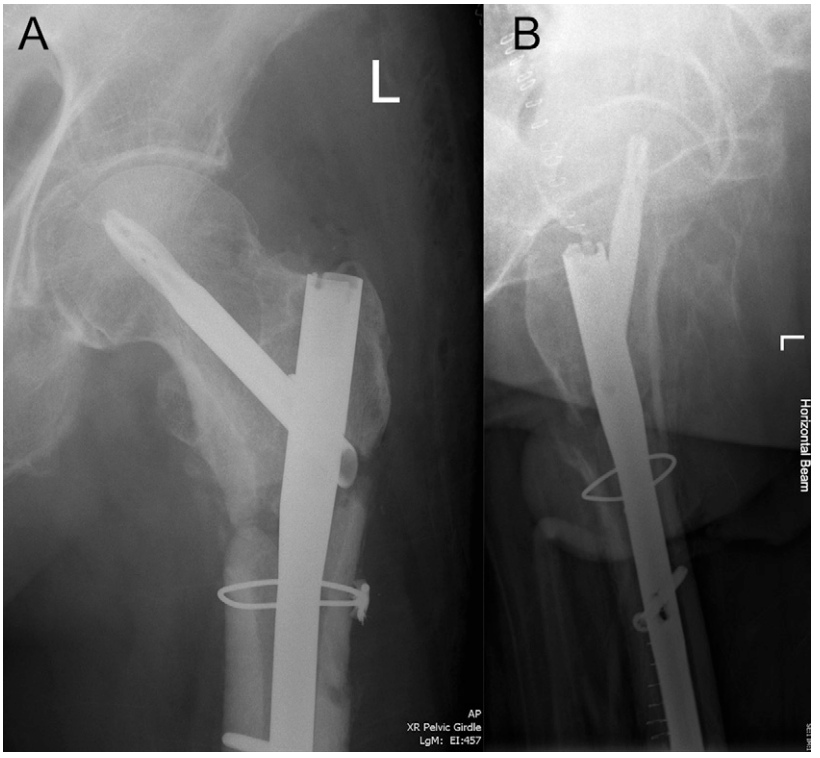

Fig. 5
Anteroposterior (**Fig. 5-A**) and lateral (**Fig. 5-B**) radiographs following revision nailing.

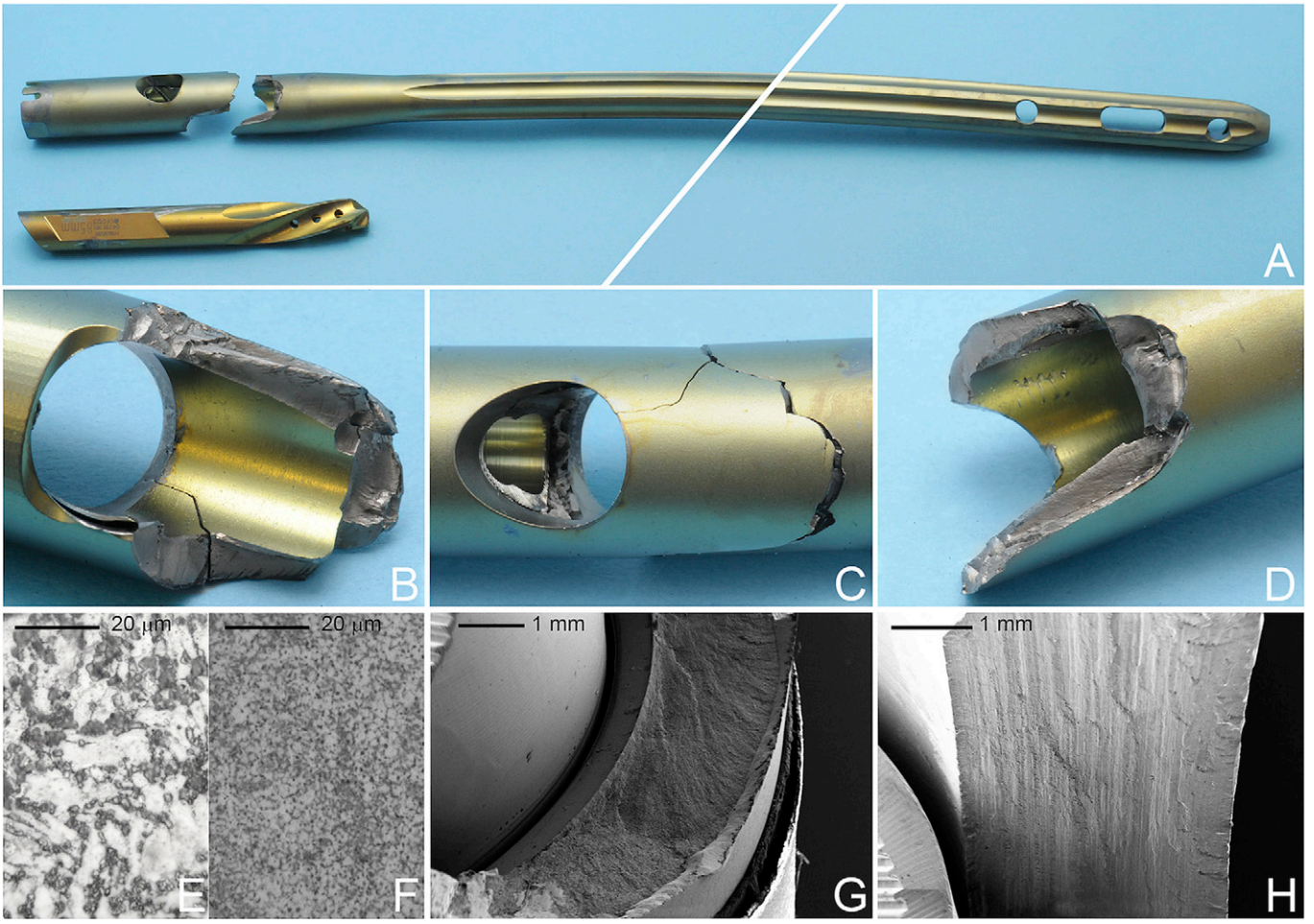

Fig. 6

Figs. 6-A through 6-D Typical appearance of a fractured TFNA implant. **Figs. 6-E and 6-F** Microstructures of the DePuy Synthes TFNA (**Fig. 6-E**) and PFN (**Fig. 6-F**) nails. **Figs. 6-G and 6-H** SEM images of the horizontal (**Fig. 6-G**) and vertical (**Fig. 6-H**) fracture surfaces, highlighting fatigue striations and a surface ridge.

aperture both medially and laterally appeared unaltered outside of the crack pathway.

Microscopic Analysis

The phases (microstructure) of titanium alloys in the solid state can be *alpha, beta,* or *alpha-beta.* Alpha phase refers to a crystalline structure that is closely packed and hexagonal in shape. Beta phase is a cubic structure that is body-centered. The TiMo alloy of the nail conforms to ASTM 2066 (ASTM International) and can be manipulated by processing conditions to produce these various structures[11]. In the present analysis, the microstructure consisted of a fine equiaxed alpha structure in a beta structure (alpha-beta), which is indicative that the alloy had been worked in some way, as expected in the production of an intramedullary nail[12,13].

Microhardness

Microhardness was evaluated by sequential testing traversing from the outer to the inner diameter. Of note was a decrease in hardness from the outer surface to the middle of the cross-section and then a slight increase in hardness at the inner surface.

SEM Analysis

SEM of the fracture surfaces was confounded by the tortuous fracture path with "vertical/axial" fracture faces, which is in contrast to the more commonly observed planar fracture surface of other failed intramedullary proximal femoral nails. Fatigue striations were observed on all nails as expected, while a noticeable surface ridge was also present, which corresponded to the microhardness results.

Discussion

This investigation included an analysis of demographic information, radiographic findings, and retrieval data from the largest series, to our knowledge, of proximal femoral nail breakages in the published English literature and was the first study that we are aware of to involve laboratory analysis of the TFNA implant. The regular collection and analysis of cases of implant breakage across a large yet geographically

isolated population through the availability of a centralized, independent implant retrieval center underpins the strength of this study. As a result, our findings may represent the early detection of an implant issue that has not yet been recognized elsewhere.

Similar to other published cohorts of nail breakage, the fractures were mostly of unstable patterns, producing more substantial stresses for the nail. At the time of writing, no simple pertrochanteric type fractures (OTA/AO 31A1) had demonstrated implant breakage in our service area, with unstable reverse oblique fractures representing the majority of nail failures. While a comparison was not performed between cohorts with and without breakage, on the basis of our findings, we postulate that reverse oblique intertrochanteric (AO 31A3) fractures should be added to the list of nail-breakage risk factors identified by Johnson et al.[5].

The mean time to failure of 5 months appears to be briefer than previously observed in our implant retrieval database and will be analyzed in a future study. Although reduction quality is an important predictor of mechanical failure, it was noted that the majority of the patients, in fact, had well-reduced fractures at the time of the index surgery. The patient cohort also had a near-normal mean BMI.

In our relatively small sample of 8 patients treated for intramedullary nail breakage with a revision TFNA implant, a greater than 1-in-3 rate of repeat implant breakage was observed. Other implant choices may be advisable in a revision setting, including other nails or conversion to arthroplasty. In patients presenting with persistent pain despite normal radiographs, computed tomographic (CT) scans are recommended, as 2 cases of implant breakage were radiographically subtle on plain radiographs.

Regarding the mechanics of fracture with this device, it became apparent from the laboratory evaluations that the implant fracture pathway was considerably different from that of retrieved intramedullary nails that have been evaluated in our laboratory for >40 years. While all of the fractures initiated at the thinnest cross-sectional location and generally on the lateral aspect of the nail, which is similar to that seen with other devices, there were multiple crack pathways, some of which led to loss of small "pieces" of metal from the fracture surface. In addition, we are aware of no retrieved device other than the TFNA with a fracture pattern involving a stepped propagation pathway, whereby a planar crack arrested, changed planes by 90°, progressed, arrested, and then changed planes again by 90° until final failure. We hypothesize that a superimposed substructure of alpha and beta phases in the microstructure led to arresting of the crack pathway and the change in direction.

An earlier theory was that malalignment of the aiming device for the stepped reamer for the proximal screw or blade may have caused intraoperative damage to the proximal aperture in the nail, thereby predisposing the nail to failure; however, such damage was not seen on the retrieved implants. The microhardness and SEM results confirmed surface hardening and the presence of a surface ridge, which demonstrate that the alloy has been anodized, an expected finding.

There were multiple changes in prosthetic design that occurred simultaneously with a change in alloy choice for the TFNA, confounding any definitive analysis of failure. We hypothesize that the reduced cross-sectional area of the TFNA at the level of the proximal screw aperture compared with its predecessors may be of importance in the observed cases of breakage. This results from a combination of both the reduced nail width from the LATERAL RELIEF CUT and the reduction in proximal nail wall thickness.

This article should increase the level of awareness of the international orthopaedic community with regard to the appropriate use and follow-up of patients treated with the TFNA implant. Changes to the nail design and/or alloy may have contributed to this series of cases with observed breakage. Given the relatively small sample of cases, this study will be followed by an analysis of breakage rates and overall revision rates compared with those of previous generations of nailing devices. Nevertheless, we advise vigilant clinical and radiographic surveillance of patients with unstable hip fracture patterns who undergo osteosynthesis with use of a TFNA implant.

Appendix

eA Supporting material provided by the author is posted with the online version of this article as a data supplement at jbjs.org (http://links.lww.com/JBJS/F173). ■

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