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Cephalomedullary Nail Breakages in a Multicenter Insertion vs. Retrieval Database Comparison

A Retrospective Cohort Study of 3,882 Patients

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Background: Cephalomedullary nails are used for internal fixation of proximal femur fractures, pathological fractures, and for revision fixation in the case of failures. Nail breakages are rare, with published figures demonstrating a high variability with a previous benchmark set at less than 1.3%. The aim of this study was to use a large and geographically isolated patient cohort to better define and compare the proportion of implant breakages across a range of cephalomedullary nails.

Methods: Implantation data were collected from electronic theater records at all tertiary public orthopaedic hospitals in the state of Western Australia between 1 January, 2001, and 5 July, 2017, to capture a consecutive series of implant insertions across all indications. This was linked to Western Australia's Centre for Implant Technology and Retrieval Analysis (CITRA) nail repository records to identify broken nails received for analysis in the subsequent years until data collection ceased on 5 July, 2024.

Results: Three thousand eight hundred eighty-two cephalomedullary nails were implanted. There were 18 nail breakages in this cohort recovered by CITRA, giving an overall breakage proportion of 0.5%. While breakages were rare, the Trochanteric Fixation Nail-Advanced (TFNA) demonstrated a 7-fold higher proportion of reported breakages (6/393; 1.5%) compared with its predecessor the proximal femoral nail antirotation (PFNA; 6/2,621; 0.2%, p = 0.002). The proportions of reported breakages in the Gamma3 and PFN prostheses were 0.6% (2/320) and 0.7% (4/548), respectively.

Conclusions: In this large consecutive sample of cephalomedullary nail patients, the TFNA appears to have a higher proportion of reported breakages than one of its predecessors, the PFNA, and this sits outside our previously defined benchmark. Breakages need to be considered in conjunction with other causes of failure and the index diagnosis when making decisions about implant choice in the management of proximal femur fractures. Further studies that are better able to deal with the many confounding variables of implant fatigue failure are required.

Level of Evidence: Therapeutic Level III (Retrospective Cohort Study). See Instructions for Authors for a complete description of levels of evidence.

Introduction

The recommended treatment of most subtrochanteric and unstable trochanteric hip fractures is intramedullary nailing[1]. The treatment goals are to stabilize the fracture, allow early weight-bearing and facilitate bony union[2]. Surgeons aim to allow ambulation while the fracture unites. These cycles of ambulation place stress on the device, which if greater than the fatigue limit of the implant may lead to eventual nail breakage. This is particularly true for slow to heal fractures such as pathological fractures, unstable fracture patterns, and revision nailing for nonunion[3].

Disclosure: The **Disclosure of Potential Conflicts of Interest** forms are provided with the online version of the article (http://links.lww.com/JBJSOA/A780).

The features of some commonly used nails are outlined in Table I[4-11]. Over time, manufacturers have decreased the proximal nail diameter to reduce insertion impingement and preserve bone. Changes in design and alloy influence breakage susceptibility. For example, stainless steel is less sensitive to notching than titanium[12-15]. Implants may also become more susceptible to failure if they are damaged in the process of implant insertion[16,17].

The background proportion of breakages across multiple prostheses has been defined by this research group as 0.6% in a recent meta-analysis; however, comparisons between the nail groups were not possible[18]. A benchmark breakage proportion of less than 1.3% was defined as a suggested acceptable maximum in this review.

We previously reported a number of nail breakages of a newer generation implant, the Trochanteric Fixation Nail-Advanced (TFNA, DePuy Synthes)[19]. Database review studies published on the safety of the implant have reported a low proportion of breakages between 0.2% and 0.7%[20-22]. By contrast, a smaller institution-based series of 127 patients assessed by Nayar et al. reported a much higher breakage figure of 4.7%[23]. A more recent poster presentation of a multicenter retrospective review of 2,130 patients reported a TFNA breakage rate of 1.3%, which after accounting for confounders was 4.1 times greater than the control nails being the Gamma3 (Stryker) and InterTAN (Smith & Nephew)[24]. McAleese et al. also recorded TFNA breakages at 2.2%, in a single center retrospective review of 803 cases[25]. Implant breakage is just one form of mechanical failure and conflicting reports exist as to which implant has the lowest overall failure rate[25,26].

We sought to assess the proportion of breakages of 4 intramedullary nails in an adult proximal femur fracture population over a 16-year period across all 3 of the tertiary public hospitals in Perth, Western Australia. Based on our anecdotal experience, the primary hypothesis was that the TFNA would have more frequent breakages compared with other nail types.

TABLE I Summary of Cephalomedullary Nails

Nail	Year Introduced	Proximal Nail Width (mm)	Alloy
PFN	1996	17.0	Ti-6Al-7Nb*
TFN	2002	17.0	Ti-6Al-7Nb
Gamma3	2004	15.5	Ti-6Al-4V
PFNA	2004	16.5	Ti-6Al-7Nb
Intertan	2006	16.3 × 15.3†	Ti-6Al-4V
TFNA	2015	15.7 (14.1‡)	Ti-15Mo

*Stainless steel was also available. †Square rather than circle cross-section shape. ‡At level of proximal screw aperture in an 11-mm nail. Sources: surgical techniques and value design briefs[3-10]. PFN = proximal femoral nail, PFNA = proximal femoral nail antirotation, TFN = Trochanteric Fixation Nail, and TFNA = Trochanteric Fixation Nail-Advanced.

The secondary hypothesis was that there would be an inverse relationship with the proportion of breakages for both the proximal nail diameter (thicker implants) and the implant neck-shaft angle (lower stress).

Materials and Methods

A retrospective observational study of consecutive adult patients with cephalomedullary nails inserted at all public tertiary hospitals in the state of Western Australia between the dates of January 1, 2001, to July 5, 2017, was conducted. The study size was defined by these temporal limits. The start date was selected as it was the first year the proximal femoral nail (PFN) was implanted in Western Australia. The end date was selected so that changes in practice after an oral presentation on that date which described a series of local TFNA failures did not bias results[19]. Changes in practice observed after this oral presentation included a change in the cephalomedullary nail used at one hospital and a change in the indications for use of the implant at another hospital. The cutoff also allowed ample time for fatigue failures to occur and be sent for analysis, which were captured until July 5, 2024, so that at least 7 years elapsed from the last implant insertion to study cessation.

The implants assessed were all those used routinely at the centers over that period: Gamma3, PFN (Synthes), proximal femoral nail antirotation (PFNA, Synthes), and TFNA. No other cephalomedullary nails (including the Trochanteric Fixation Nail [TFN], from DePuy Synthes) were routinely used over this period. At public tertiary hospitals in Western Australia, there would usually be only one cephalomedullary nail available in use (“on shelf”) at any one time. This is related to acquisition contracts and familiarity for theater staff, and as a result, all surgeons of the department will use the same implant. Patients in Western Australia are “zoned” based on residential address to a single tertiary hospital. Each institution dealt with all presentations that arrived (acute fractures, pathological fractures, failed fixation) using the “on shelf” prosthesis available at the time. This on shelf prosthesis would only change if implants were superseded with a newer version or if the orthopaedic department decided to change the implant company.

Data for implant insertions were extracted from each hospital's Theater Management System (TMS), an electronic record of operations and prosthesis usage that is collected at the time of surgery typically using barcode scanning of device packaging. Data obtained included patient unique record number, date of insertion and implant used such as its brand, neck-shaft angle, diameter, length, and the side of surgery (for long nails and 235 mm TFNA nails). Nail length was defined as long at 260 mm or greater. The cause of the initial fracture, fracture pattern, reduction quality, and patient factors, such as weight, comorbidities, sex assigned at birth, race, ethnicity, and socioeconomic indicators, were not available. Our population is predominantly White. Insertions were captured across all indications to capture “typical use” of each implant, which included all fracture patterns, pathological fractures, and revision fixation.

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Nail breakage cases were captured through our statewide implant retrieval facility, the Centre for Implant Technology and Retrieval Analysis (CITRA). Photographs of a selection of the broken nails at CITRA are shown (Fig. 1). Data collected from the CITRA laboratory included age at revision for breakage, date of revision surgery, sex, side of surgery, diagnosis at index fracture, diagnosis for cause of failure, implant details, and breakage location within the implant. All broken nails at CITRA were cross-referenced with the TMS implantations database to identify those of the implantation cohort who had subsequently suffered nail breakage. The proportion of breakages overall and for each prosthesis was then able to be calculated. Data were cleaned and checked against medical records and radiographs when required and available.

Quantitative data were analyzed using Microsoft Excel (Excel for Mac 2016; Microsoft). Statistical analysis was conducted using SPSS (IBM SPSS Statistics, Version 29.0, Released 2023: IBM). Breakage proportions between nail types were compared for significance using the Fisher exact test given the low event counts (under 5 in 2 nail groups). The Agresti-Caffo method was used to determine the 95% confidence intervals for the difference in breakage proportions between nails in head-to-head analyses. The study was conducted in accordance with the World Medical Association Declaration of Helsinki and was approved by an institutional review board. No external funding was received for conducting this project.

Results

A total of 3,882 consecutive intramedullary nail implant events were captured in TMS over the 16-year period. A summary of the nail characteristics is presented in Table II. Ten breakages occurred in male patients and 8 in female patients. The median patient age at time of breakage was 79 years (range, 45-92 years). The diagnosis at index nail insertion was not specified in 7 patients, hip fracture in 5 patients, prior broken nail in 4 patients, and pathological fracture in 1 patient. The surgeon's diagnosis of cause of breakage was nonunion or delayed union in 12 cases and not specified on the retrieval form in 6 cases. Appendix I contains the patient-level data of all cases. The Gamma3 had the longest usage window (2006-2017). The PFN (2001-2007), PFNA (2004-2017), and TFNA (2016-2017) were design iterations from the same manufacturer and replaced the prior design as it was phased out.

There were 18 nail breakages from this cohort sent to CITRA with a pooled breakage proportion of 0.5%. The proportions of nail breakage events are compared between designs in Table III. The TFNA vs. PFNA was the only comparison that was statistically significant ($p = 0.002$). Low event counts combined with low insertion numbers for the PFN and Gamma3 resulted in wide confidence intervals in any comparison involving either nail, as shown in the head-to-head analysis summary (Fig. 2). There were insufficient breakage events to perform meaningful subgroup analyses by neck-shaft angle or nail diameter. The breakage location was through the single proximal aperture for head fixation in all cases for the PFNA, Gamma3, and TFNA. The PFN breakages all occurred through the larger (more distal) of the 2 proximal screw apertures. One TFNA case had an additional implant breakage through the distal screw aperture of a short nail.

Discussion

This article is the first to assess nail breakage proportions in a large consecutive population across multiple nail types over an extended time frame. It also uses a novel method for obtaining breakage proportions by linking an implantation database to a failed implant retrieval center, unique to this region.

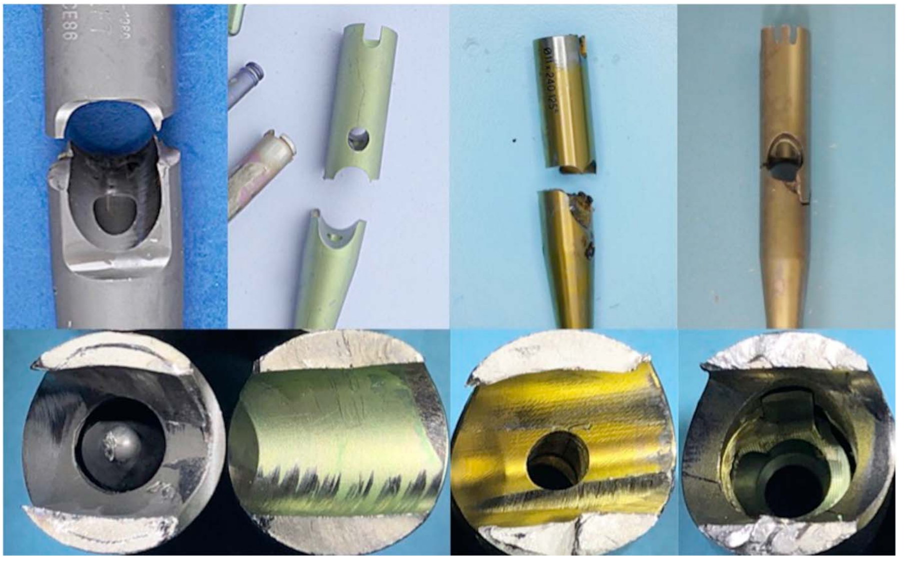

Fig. 1

Left to Right, a broken Gamma3, PFN, PFNA, and TFNA nails photographed from both the side and from top down onto the fractured surface. PFN = proximal femoral nail, PFNA = proximal femoral nail antirotation, and TFNA = Trochanteric Fixation Nail-Advanced.

TABLE II Implant Characteristics*

Length	
Short	3,163 (81%)
Long	719 (19%)
Side	
Right	516 (51%)
Left	498 (49%)
Nail type	
Gamma3	320 (8%)
PFN	548 (14%)
PFNA	2,621 (68%)
TFNA	393 (10%)
Diameter (mm)	
10	1,887 (49%)
11	1,334 (34%)
12	647 (17%)
14	14 (<1%)
Nail NSA	
120	16 (<1%)
125	1,958 (50%)
130	1,836 (47%)
135	72 (2%)

*NSA = neck shaft angle, PFN = proximal femoral nail, PFNA = proximal femoral nail antirotation, and TFNA = Trochanteric Fixation Nail-Advanced.

The proportion of reported nail breakages was more than 7-fold higher in the TFNA cohort (1.5%) compared with its predecessor the PFNA (0.2%), confirming our primary hypothesis. The proportion of TFNA breakages exceeded the benchmark standard of less than 1.3% defined in our prior systematic review[18]. The Gamma3, PFN, and PFNA proportions aligned with the results reported elsewhere[27-37]. The TFNA breakage proportion, while less than that of the single center study by Nayar et al. (4.7%), was much higher than that described by Chitnis et al. (0%) and Wallace et al. (0.2%)[20,21,23]. We postulate that this is related to study design in that larger nonclinical database studies may be predisposed to under-detecting failures, as discussed previously[18].

Hypotheses for the observed higher breakage proportion in the TFNA group are several. Loss to follow-up, transfer to an external healthcare provider for subsequent care or errors in reporting, and identification of nail breakages can reduce breakage detection in other studies. However, these should be mostly overcome in the relatively unique isolated urban population of Western Australia with its established retrieval laboratory receiving failed implants. It could also be that the TFNA group has captured the learning curve of that implant in our state, however, that is also true of the Gamma3, which had a similar volume and included the first series of insertions but did not display a higher breakage proportion. Our secondary hypothesis of a relationship between nail diameter or neck-shaft angle and breakage proportion could not be analyzed due to low event counts.

The clinical significance of these findings is that the TFNA may be of insufficient strength to maintain a comparable rate of fatigue failures with other cephalomedullary nails. It is not yet established as to why this is the case and may be related to alloy selection, nail design, instrumentation, surgical technique, and/or implant damage, resulting in notch sensitivity. A significant contributing factor may be that the overall implant diameter of the TFNA is reduced compared with other nails (Table I). The failures occurred through the proximal aperture which is the area of the smallest cross-sectional area of implant and its weakest point, which was expected.

The ability to analyze breakages across a large, isolated population using comprehensive and accessible operating theater software data in conjunction with the availability of an established pathway of implant retrieval underpins the strength of this study. This provides accurate data collection of implant insertions, and we have benefited from the return of failed prostheses to the implant retrieval center. Owing to the electronic and built-in tracking of implants, the insertion data are considered reliable although errors in coding of implants when scanned would be theoretically possible.

As returning failed implants to CITRA is voluntary, one limitation is the implant breakages described are a minimum only and the true breakage proportion for any group may in fact be higher. Contribution rates for both trauma and arthroplasty for prosthesis failures are considered high across the region's public hospitals, and it is believed that most prosthesis failures are returned for analysis. The proportion of failed prostheses not submitted to CITRA has not been studied. The city of Perth is also geographically isolated with the next major population center undertaking proximal femoral fixation being 2,700 kilometers miles away, which limits the likelihood of missed explant events occurring outside the local healthcare network. Another possibility for missed capture of breakages is if a revision does not occur, which is rare in the authors' experience.

A major limitation as a retrieval database study is there is no radiographic or patient clinical data on the insertion population, where confounding factors such as comorbidities, pathological fractures, fracture pattern, and reduction quality will influence breakage frequency, and this issue is similarly noted by other

TABLE III Proportions of Broken Implants*

	Gamma3	PFN	PFNA	TFNA	Total
Implanted	320	548	2,621	393	3,882
Breakages	2	4	6	6	18
Proportion	0.6%	0.7%	0.2%	1.5%	0.5%

*PFN = proximal femoral nail, PFNA = proximal femoral nail antirotation, and TFNA = Trochanteric Fixation Nail-Advanced.

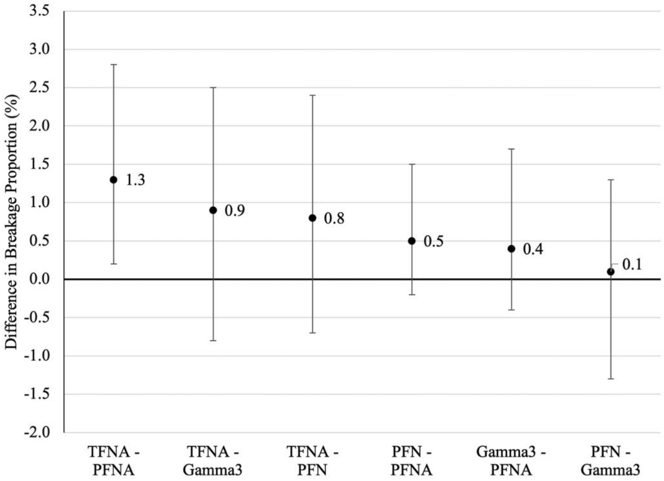

Fig. 2

Difference in breakage proportions (Nail A minus Nail B) between nail types expressed as a percentage with 95% confidence intervals.

authors[22]. In this study, the radiographs of most patients were no longer available to assess index diagnosis, fracture pattern, and reduction quality. Paper-based medical records would need to have been individually accessed for all 3,882 patients to record data, such as comorbidities, which were not feasible. While index diagnosis was occasionally filled out on the retrieval form by the revising surgeon, it was often missing which precluded subgroup analysis of breakage rates by index diagnosis. Furthermore, censoring and survival charts were not possible as data on deaths of patients, nonbreakage revisions, and loss to follow-up were not available. These confounders are somewhat mitigated by capturing the routine use of these implants in a large, consecutive series across a 16-year longitudinal period. Having institutions use a single device for all indications of cephalomedullary nailing and each institution treating all patients zoned to it further limits the extent of bias from confounders. However, the lack of control for specific confounding factors limits the internal validity of this study.

It is important to acknowledge that this study does not address the overall reoperation rate for these devices inclusive of other potentially more common causes of failure. When implant breakage is considered among other causes including cutout, periprosthetic fracture, and loss of fixation, the overall rate of failure for each nail group will better guide implant choice.

These results should be generalizable due to the large population captured combined with the fact that most hip fracture cases in Australia are dealt with in the public sector, which is the study setting. However, the absence of sex, race, or ethnicity data on individuals may affect the study's generalizability to other populations. Further avenues of research could focus on a more comprehensive failure assessment that incorporates all modes of failures and the ability to censor patients and perform survival analysis. Examining the damage on the explanted nails could also be helpful.

The TFNA implant in this series was an outlier with a higher proportion of implant breakages compared with the PFNA. This would be particularly important in cases where union is anticipated to be slow or the implant stresses are high, such as revision fixation, unstable fracture configurations, or pathological fractures. No difference in breakage proportion was found in the head-to-head comparisons involving the PFN or Gamma3. The inability to account for important confounders is a significant limitation to this type of study design, and ideally prospective studies should re-examine this area of research with this in mind. Implant breakage needs to be considered in conjunction with other causes of failure and the index diagnosis when determining appropriate implant choice, particularly in higher risk fractures.

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/JBJSOA/A781). This content has not been copyedited or verified. ■

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