Implant Breakage in Proximal Femoral Nails: A Data-linked State-wide Assessment of Failures and the Role of Iatrogenic Implant Damage

Anton Philip Lambers

MBBS BMedSc(Hons) DipMgt MS(Dist) FRACS(Orth) FAOrthA



This thesis is presented for the degree of Doctor of Philosophy of The University of Western Australia

Medical School

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Thesis Declaration

I, Dr Anton Lambers, certify that:

This thesis has been substantially accomplished during enrolment in this degree. This thesis is my own work and does not contain any material previously published or written by another person, except where due reference has been made in the text or Authorship Declaration.

This thesis does not contain material which has been submitted for the award of any other degree or diploma in my name, in any university or other tertiary institution. In the future, no part of this thesis will be used in a submission in my name, for any other degree or diploma in any university or other tertiary institution without the prior approval of The University of Western Australia and where applicable, any partner institution responsible for the joint-award of this degree.

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Signature: 

Date: 15th May 2025

Abstract

Background:

Fatigue failure of cephalomedullary nails used to treat proximal femur fractures is a rare but devastating complication. Little is known around the underlying frequency with which it occurs, if there are differences in how frequently or quickly different designs fatigue and the prevalence of and the role played by iatrogenic damage at the time of implant insertion.

Methods:

This six-part thesis begins to address the unknowns in this research field. A systematic review and meta-analysis was conducted to define the rates of breakage published so far and define a benchmark of performance. The proportion of and time to breakage was then compared across a range of implants using a data-linkage study across all tertiary public hospitals in the state of Western Australia linking to the Centre for Implant Technology and Retrieval Analysis (CITRA). A systematic review and meta-analysis was then conducted to examine the reporting of iatrogenic insertional damage inflicted on implants in retrieval studies. A standardised damage assessment system was developed to address deficiencies in prior reporting. This was subsequently applied across a range of broken and intact implants for comparison to gain insights into patterns of damage and if there is a difference in the damage pattern seen in those that eventuated in fatigue failure.

Results:

Systematic review and meta-analysis revealed a median reported rate of fatigue failure of cephalomedullary nails of 0.6%. Of the studies reporting breakages, 95% had a rate of 1.3% or less, which defined a benchmark for future studies. In the data linkage studies, one nail type was identified as an outlier for more frequent and earlier fatigue failures which was a novel finding. This implant is currently in high volume use internationally. Studies reporting on insertional damage to nails were rare and reporting quality was poor. A novel system of reporting – the Nail Damage Assessment System (NDAS) – was developed to address this. In the largest and most detailed assessment of explanted cephalomedullary nails to date, the system was then applied to 55 implants in a laboratory setting and revealed that some form of damage was ubiquitous and often severe. It also highlighted differences in areas of damage between left and right sided implants.

Discussion:

This research is the largest contribution to this field of orthopaedic metallurgical and implant research to date. The papers presented each discuss future avenues for research and the valuable findings of each study. Although an uncommon complication, it appears that some of the currently used implant types may be underperforming in this area and this warrants further investigation.

Recommended Pre-reading

Lambers A, D'Alessandro P, Yates P, Kopp A. "Implant Breakage in Proximal Femoral Nails: Design, Metallurgy and Failures." University of Western Australia, Master of Surgery Thesis, June 2020. Article Link.

Klima M, Lambers A. "Evaluating Implant Fractures with the Premiere Hospital Databank." JBJS. Letter to the Editor, 16th September 2021. DOI: 10.2106/JBJS.20.02002. Article Link.

Lambers A, Kop A, Rieger B, D'Alessandro P, Yates P. "Implant Fracture Analysis of the TFNA Proximal Femoral Nail." The Journal of Bone & Joint Surgery (JBJS Am) Vol. 101, Issue 9, Pages 804-811, May 2019. DOI: 10.2106/JBJS.18.00997. Article Link.

Klima ML. "Trust but Verify: Design Differences in The Prevention of Targeting Errors in Cephalomedullary Nails." J Orthop Trauma. 2023 Oct 1;37(10S):S41-S48. DOI: 10.1097/BOT.0000000000002670. PMID: 37710374. Article Link.

Wallace A, Amis J, Cafri G, Coplan P, Wood J. "Comparative Safety of the TFN-ADVANCED Proximal Femoral Nailing System: Findings from a U.S. Health-Care Database." J Bone Joint Surg Am. 2021 Sep 1;103(17):1637-1645. DOI: 10.2106/JBJS.20.02002. PMID: 34014860. Article Link.

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Abbreviations

*Key terms in **bold***

A	Anterior
AL	Author Name: Anton Lambers
AK	Author Name: Alan Kop
ASA	American Society of Anaesthesiologists
BR	Author Name: Bertram Rieger
CITRA	**Centre for Implant Technology and Retrieval Analysis**
CMN	**Cephalomedullary Nail**
G3	**Gamma3 Nail**
FDA	Food and Drug Administration
FHHS	Fremantle Hospital and Health Service
FSFHG	Fiona Stanley Fremantle Hospitals Group
FSH	Fiona Stanley Hospital
IA	Inferior Anterior
ICD	International Classification of Diseases
IP	Inferior Posterior
JBJS	Journal of Bone and Joint Surgery
JP	Author Name: Jessica Perring
MeSH	Medical Subject Heading
MHA	Microhardness Assessment
MI	Macroscopic Inspection
MP	Author Name: Moreica Pabbruwe
MSA	Microstructural Assessment
NA	Not Applicable
NDAS	**Nail Damage Assessment System**
NS	Not Specified
OM	Optical Microscopy
P	Posterior
PDA	Author Name: Peter D'Alessandro
PFN	**Proximal Femoral Nail**
PFNA	**Proximal Femoral Nail: Antirotation**
PICOS	Population Intervention Comparators Outcomes Study design
PRISMA	Preferred Reporting Items for Systematic Review and Meta-Analysis
PY	Author Name: Piers Yates
RACS	Royal Australasian College of Surgeons

RPH	Royal Perth Hospital
RTP	Research Training Program
SA	Superior Anterior
SCGH	Sir Charles Gairdner Hospital
SP	Superior Posterior
SEM	Scanning Electron Microscopy
TAN	Titanium, Aluminium, Niobium Alloy (Ti-6Al-7Nb)
TAV	Titanium, Aluminium, Vanadium Alloy (Ti-6Al-4V)
TB	Author Name: Tom Briffa
TFN	**Trochanteric Fixation Nail**
TFNA	**Trochanteric Fixation Nail: Advanced**
TiMo	**Titanium Molybdenum Alloy (Ti-15Mo)**
TMS	Theatre Management System
UMRN	Unique Medial Record Number
WA	Western Australia
ZNN	**Zimmer Natural Nail**

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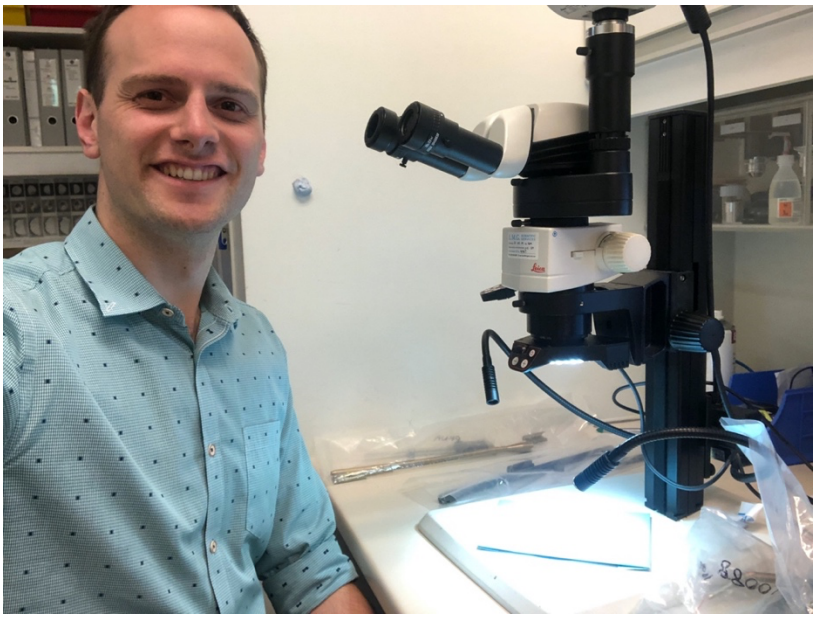
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Hospital and Health Service (Mr Omar Khorshid), Sir Charles Gairdner Hospital (Prof. Richard Carey Smith) and Royal Perth Hospital (Mr. Alan Prosser).

And to my beautiful and supportive wife Amelia: research has been a constant passion of mine since we met in 2010, but every minute spent on research is a minute taken away from either our family or my sleep. Thanks for your unrelenting support and for believing in me in all endeavours. I promise that I will now stop enrolling in university research degrees.

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Authorship Declaration

Presentations

I have presented this project at the following peer-reviewed meeting:

- Australian Orthopaedic Association Western Australian Branch State Meeting, Perth, 2022

Papers

This thesis, presented as a series of papers, includes the following 6 co-authored published and unpublished papers:

Defining Cephalomedullary Nail Breakage Rates: A Systematic Review and Meta-Analysis

- Status: **Published**
- Journal: J Orthop Trauma 2023;37:S33–S40
- Date: 11th July 2023
- DOI: 10.1097/BOT.0000000000002673
- Authors: AL, PDA, PY
- Location in thesis: Chapter 2
- Article Link

Cephalomedullary Nail Breakages in a Multicentre Insertion vs. Retrieval Database Comparison: A Retrospective Cohort Study of 3,882 patients.

- Status: **Published**
- Journal: JBJS Open Access Apr 2025;10(2):e24.00196
- Date: 22nd January 2025
- DOI: 10.2106/JBJS.OA.24.00196
- Authors: AL, BR, AK, MP, TB, JP, PDA, PY
- Location in thesis: Chapter 3
- Article Link

Early Fatigue Failures in TFNA Cephalomedullary Nails: A Retrospective Cohort Study of 41 Implants in a Statewide Retrieval Centre

- Status: **submitted awaiting revision**
- Authors: AL, AK, MP, JP, PDA, PY
- Location in thesis: Chapter 4

Iatrogenic 'Insertional Damage' to Cephalomedullary Nails: A Systematic Review and Meta-Analysis

- Status: **unpublished, yet to submit**
- Authors: AL, AK, MP, PDA, PY
- Location in thesis: Chapter 5

Insertional Damage of Cephalomedullary Nails: Proposal of a Standardized Nail Damage Assessment System (NDAS)

- Status: **unpublished, yet to submit**
- Authors: AL, AK, MP, PDA, PY
- Location in thesis: Chapter 6

Insertional Damage to Cephalomedullary Nails: A Review of 55 Broken and Intact Retrieved Nails Applying the NDAS Reporting Framework

- Status: **unpublished, yet to submit**
- Authors: AL, AK, MP, PDA, PY
- Location in thesis: Chapter 7

Student contribution to work

(Applicable across all papers)

Lead investigator, conceptualisation, data curation, formal analysis, investigation, methodology, project administration, visualisation, writing – original draft, writing – review & editing. The laboratory analysis reports (photographs and implant reports) were performed when relevant by CITRA laboratory scientists (AK, PM) and additional analyses of CITRA data including in person implant reviews were conducted by myself.

Student signature:

Anton Lambers (AL):



Date: 18th February 2025

Coordinating Supervisor Statement:

I, Professor Piers Yates, certify that the student's statements regarding their contribution the work listed above is correct.

Coordinating supervisor signature:



Date: 20th February 2025

Co-author confirmation of student contribution:

Piers Yates (PY):

Date: 20th February 2025



Peter D'Alessandro (PDA):

Date: 18th February 2025



Alan Kop (AK):

Date: 14th February 2025



Moreica Pabbruwe (MP):

Date: 28th February 2025



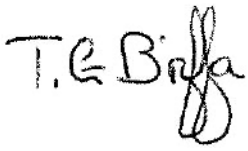
Bertram Rieger (BR):

Date: 14th February 2025



Tom Briffa (TB):

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Jessica Perring (JP):

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Word Count

This thesis comprises 25,030 words (excluding references) and 159 pages

1. Chapter 1: General Introduction

This thesis examines fatigue failures of cephalomedullary nails used for the osteosynthesis of proximal femur fractures. It begins to address the many unanswered questions arising from the previous Master of Surgery dissertation on the same topic.

The impetus for this research arose from the simple observation of a series of novel implant breakages seen at the orthopaedic trauma units in Western Australia in 2016-2017. Had it not been for the astute observation of a small group of local surgeons at this time, with the support of the Centre for Implant Technology and Retrieval Analysis (CITRA), these failures may have gone unnoticed and the opportunity to expand our understanding of these failures would have been missed.

1.1. Study Context

This section educates readers about the geo-medical context of this research which is essential to understanding the study designs as well as to interpret the study findings. What follows is a review the geography, health systems and implant retrieval facility of the state of Western Australia.

1.1.1. Western Australian Healthcare

The state of Western Australia (WA) covers a third of Australia's landmass with a population of 2.7 million in 2021[1]. Perth, its capital city, lies on the

southwest coast (Figure 1.1) and contains three quarters of the state's population (2.1 million) in the greater metropolitan area[1].

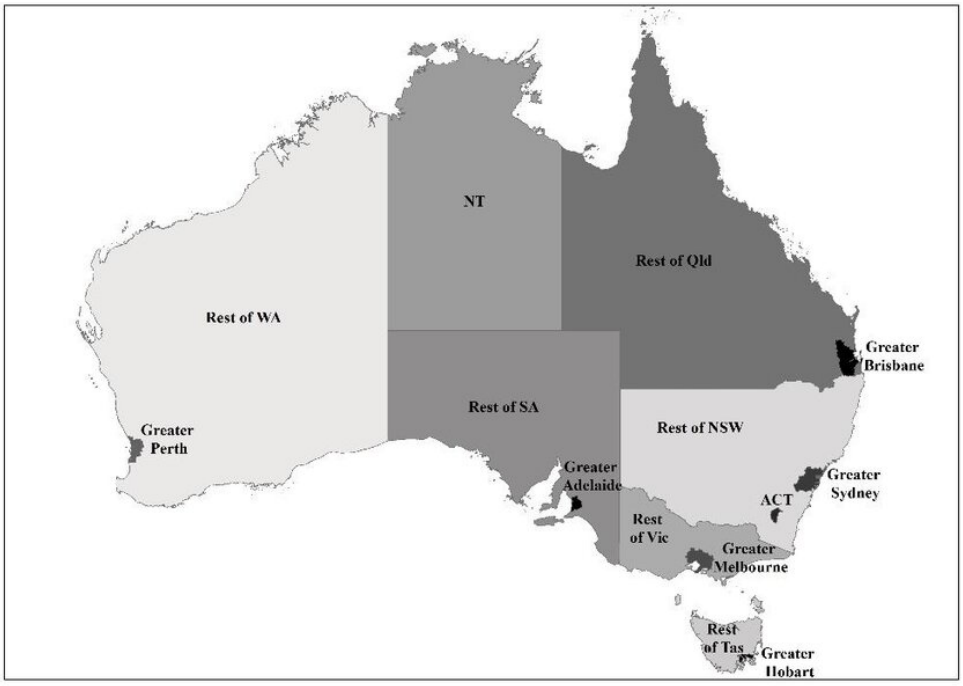


Figure 1.1 Map of Australia

Location of Western Australia and its capital city Perth. Source: Australian Bureau of Statistics.[1]

Most hip fracture treatment in Perth occurs in the public system and the tertiary public hospitals of Perth do most of this work, although there are some small rural and regional centres. The tertiary public hospitals providing orthopaedic trauma care prior to 2015 were Royal Perth Hospital (RPH), Sir Charles Gairdner Hospital (SCGH) and Fremantle Hospital and Health Service (FHHS). In 2015 the newly established Fiona Stanley Hospital (FSH) officially opened and the trauma service from FHHS moved there, and FHHS

became an elective orthopaedic unit. The 2 combined units were thereafter referred to as the Fiona Stanley Fremantle Hospitals Group (FSFHG).

Of importance is the arrangement of ‘on shelf’ prosthesis selection for cephalomedullary nails. At public institutions in Perth, typically there is only one nailing system chosen as the principal system for a particular hospital and it will be used for all indications for that anatomical region. This differs from some other Australian and International centres where each individual surgeon can choose an implant for each patient from a range of suppliers that may be ‘on shelf’ or even ordered in for the case. When a new version of an implant is introduced by an implant manufacturer, the former is typically phased out and replaced as has been the case with the DePuy Synthes implant range. When a hospital changes the provider of nails, the previous design will have the stock returned once the changeover process occurs. This is critically relevant to the study design of the breakage rates and time to failure analyses, as this underpins our ability to compare the different implants – they were not all available at one site and selectively used for certain indications, and rather one was used at a time for all patients.

Western Australia's geographic isolation, combined with its population being heavily concentrated in Perth, distant from other major cities, creates an ideal environment for cohort studies and data collection. From a software and healthcare standpoint, all public institutions use a consistent Unique Medical Record Number (UMRN) system. Medical imaging archives and many

healthcare software platforms are standardized across the state, allowing patient imaging to be easily accessed statewide via the UMRN. Additionally, Perth's strong sense of community and "small town" culture fosters close collaboration among orthopaedic units.

1.1.2. Implant Retrieval Centre (CITRA)

The Centre for Implant Technology and Retrieval Analysis (CITRA) in Perth, Australia, is a government-funded facility based at the Medical Engineering and Physics Department of Royal Perth Hospital. CITRA specialises in the collection, analysis, and reporting of orthopaedic implants that have been removed from patients across Western Australia. With a repository of over 10,000 retrieved prostheses, the centre plays a crucial role in understanding implant performance and failure. Although retrieval submission is voluntary, there is strong statewide participation from all public hospitals, particularly for major implants like trauma nails and hip and knee replacements. CITRA's work supports improvements in implant design, surgical techniques, and patient outcomes.

The two primary biomedical engineers, Alan Kop and Moreica Pabbruwe, are co-authors on several of this thesis' papers and analyse and report on retrieved implants. This provides valuable feedback to the surgeons who return the implant, as well as the opportunity to identify trends across devices and detect patterns of failure.

1.1.3. Implant Design Changes

Over time nail manufacturers aim to develop implants that are more bone-preserving yet stronger and these two priorities are in conflict with one another. As smaller patients demand narrower implants to reduce events such as lateral cortical blow-out, a narrower implant will require metallurgical and/or design changes to maintain strength. As shown in Table 2.1, nail alloy and width has changed over time to meet such market demands.

1.1.4. Clinical Significance

Whilst implant breakage is a rare event, the population who receives the treatment of proximal femoral intramedullary nailing is a particularly vulnerable one. Hip fractures confer significant morbidity and mortality and are often an end of life event and while new designs emerge we need to insure patients do not suffer.

These patients, who often are barely managing to live independently if at all are particularly vulnerable if subjected to a mechanical failure such as implant fatigue. A further hospitalisation event puts these patients at significant risk of further deconditioning, hospital acquired infection and reducing the likelihood of returning to baseline function and independence.

1.2. Unanswered Questions

The Master of Surgery Dissertation focused on implant design and alloy changes over time in the context of a series of unusual fatigue failures of a

novel implant. Laboratory analysis of the failed implants was presented using fractography and other specialised testing. From this many unanswered questions arose about fatigue failure of cephalomedullary nails – how often should they fail? At what time point? Are there differences in fatigue performance between manufacturers? And what is the prevalence and role of iatrogenic insertional damage in fatigue failures?

1.2.1. Breakage Rates

Prior to any attempt at measuring implant fatigue performance the background rate of implant breakage needed to be analysed and defined. The reported rates in the past are highly variable and the rates seemed to be lower with larger study cohorts and with database type study designs. It was decided that a systematic review and meta-analysis would be undertaken to determine the background rate of breakage, define an acceptable benchmark for performance and examine the influence of study design on breakage rates.

1.2.2. Implant Performance

Little research has examined comparative fatigue performance of different nails due to the scarce nature of failures and limited robust detection systems for failures when they do occur. A study was proposed to link insertion and retrieval datasets to examine the rates of failure as well as time to failure between implant generations and manufacturers. It was of particular interest to see if the time to breakage reliably extended beyond the expected time required for bone union in these fractures.

1.2.3. Iatrogenic Implant Damage

A question arising from the failure series was whether iatrogenic implant damage was occurring at the time of implant insertion, resulting in notch sensitivity and premature or more frequent failure. Upon a scoping review of the literature, it was found this had not been previously investigated. A systematic review and meta-analysis was conducted to collate the data published worldwide on iatrogenic ('insertional') implant damage and assess the quality of reporting. From this a novel systematic approach to the reporting of insertional damage was developed called the Nail Damage Assessment System (NDAS). This system was subsequently applied to the entire collection of fatigued and intact cephalomedullary nails at the CITRA laboratory to better understand the prevalence, severity and patterns of damage and see if any damage patterns were unique to those implants that failed.

2. Chapter 2: Defining Breakage Rates

2.1. Preface:

Although previous work had published on the risk factors for breakage of cephalomedullary nails, little had been done to define how frequently it should be expected to occur, and therefore how to define an outlier. This was the aim of the first research paper. A systematic review and meta-analysis was chosen to improve the accuracy of a definition of implant breakage rates, and the goal was to identify a rate which captures 95% of breakage rates previously reported and use this as a benchmark for future performance.

The published article, found in the Journal of Orthopaedic Trauma, can be accessed here and the manuscript is included below.

2.2. Defining Cephalomedullary Nail Breakage Rates: A Systematic Review and Meta-Analysis:

2.2.1. Abstract:

2.2.1.1. Objective:

To establish the background rate of breakage of cephalomedullary nails.

2.2.1.2. Data Sources:

MEDLINE, PubMed, and Web of Science were searched on April 3, 2023.

2.2.1.3. Study Selection:

All English-language studies that examined trochanteric with or without subtrochanteric fractures and identified cephalomedullary nail breakage as an outcome measure and a breakage rate could be derived were included. Implants captured were predominantly the TFNA, TFN and PFN by DePuy Synthes, various versions of the Gamma nail by Stryker, the Zimmer Natural Nail by Zimmer Biomet, and the Intertan by Smith and Nephew.

2.2.1.4. Data Extraction:

The author, year of publication, dates of implant insertion, study design, method of detection of breakages, implant used, number of implant breakages, number of implants inserted, breakage rate, and follow-up were extracted.

2.2.1.5. Data Synthesis:

Meta-analysis of included studies used descriptive non-parametric statistics and a non-comparative proportion for the pooled result. Differences in results between study design types were compared using the mean breakage rate per study design.

2.2.1.6. Conclusions:

Cephalomedullary nail breakage is a rare complication with a median reported rate of 0.6% and a pooled result rate of 0.4%. Ninety-five percent of studies had a breakage rate of 1.3% or less which sets a benchmark from the reported literature for future studies. There is wide variability in rates of breakage reported between different types of study designs with single-centre review studies reporting breakage rates nearly 4-fold greater than large-scale administrative database reviews. The rate of implant breakage should not be used in isolation to judge an implant's performance.

2.2.1.7. Level of Evidence:

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

2.2.2. Introduction

Treatment of proximal femur fractures often employs a cephalomedullary nail to achieve osteosynthesis. As described by Gaebler et al., they are "a temporary implant characterized by a limited life expectancy under continuous dynamic stress[2]." After sufficient cyclical loads any implant will

undergo fatigue failure if the fracture does not heal and the fatigue limit of the implant is surpassed during activity cycles. Risk factors for cephalomedullary nail breakage include low American Society of Anaesthesiologists (ASA) score, unstable fracture types (pathological, reverse oblique, subtrochanteric), younger age, poor reduction quality, loss of posteromedial support, prior radiotherapy, and a large offset from nail to medial blade/screw tip[3-6]. Implant damage at insertion may also play a role, as discussed by Klima et. al.[7]. Thus, the implant at risk of breakage is one that is poorly supported biomechanically (unstable fracture pattern, pathological lesions) for an extended period (non- or delayed union for more than 4 months) and placed in an active (younger, healthier) patient who will put the device through many load cycles. Breakages that occur early (during the expected fracture healing time) are unusual and do not fit this paradigm of delayed healing resulting in fatigue failure of the implant. Although time to implant breakage is deliberately excluded in this paper to focus on rates of breakage instead, previous authors have demonstrated that cephalomedullary nail breakage usually occurs at a mean of 9 months after insertion[8].

The breakage rate of a cephalomedullary nail is the number of implant breakages (numerator) divided by the total number of implants inserted (denominator). This is different to the overall ‘failure rate’ which may include other causes of mechanical failure such as loss of fixation or cut out,

which may be as high as 5 to 6%[9]. A standard reference rate for cephalomedullary nail breakage in the literature is lacking with reported rates varying between 0 and 8%[4, 5, 10-12].

There are several challenges constructing both the numerator and the denominator in a breakage rate. Without registries or mandatory reporting, implant breakage detection in institutional studies generally relies on re-presentation to the same hospital for treatment of implant breakage with appropriate documentation or coding to capture the event. Patients with failures may not present to the same institution as their index procedure and would then be missed. Laboratory repositories are another detection method, and our research group based in Perth, Western Australia is fortunate to work alongside a state-wide biomedical engineering department that collects and analyses broken implants. This involves hospitals returning faulty or broken implants after removal from the patient to a central government-funded and independent repository. Biomedical engineers undertake review of the prostheses, produce a report and store the implants in case later additional review is required. This system is unique and is not seen in other states of Australia. Whilst voluntary, contribution rates are high and this combined with an isolated, urban population provides high quality data. This resource facilitated the reporting of a series of breakages recently, which has led to numerous studies in response looking into the poorly-investigated topic of cephalomedullary nail breakage[13].

To increase participant numbers some authors have interrogated large-scale US healthcare databases[14-17]. These are considered administrative rather than clinical databases, as the information is typically compiled from billing information and is not recorded primarily for clinical research purposes[18]. Administrative databases that utilize the International Classification of Diseases (ICD) codes to capture implantation or breakages rely on accurate translation of records and operation reports by health information managers who may not understand the differences between implant types or revision procedures. Schneble et al. demonstrated that accuracy in ICD coding for proximal femur fracture diagnosis was consistently poor[19]. Breakage detection in these studies also relies on searching for the appropriate queries to include all the various treatments. These include non-operative treatment (which most detection methods will miss altogether), isolated implant removal, revision nailing, arthroplasty (resection, partial or total), proximal femur replacement and extramedullary osteosynthesis[20].

Although administrative databases have the advantage of enrolling a higher number of patients, these studies often lack specific critical clinical information in the data. A quality study on implant breakage should include a subgroup analysis and specify the types of fractures treated in their study population. Studies that look at pathological (8%), subtrochanteric (5%) or reverse obliquity (4%) fractures in isolation demonstrate higher breakage

rates than others[4, 5, 12]. Additionally, time to failure, and the location of the implant breakage are both clinically relevant pieces of information, that should be included in any comprehensive study on implant breakage. To maintain a focus on failure rates in this paper the location of the failures has been omitted, and is well published elsewhere[11].

The primary aim of this study is to identify a reference rate of cephalomedullary nail breakage reported in the literature. A secondary aim was to assess and explore the variability in breakage rates calculated between different study designs. It was hypothesized that there would be significant variability between studies, that large-scale databases searches would under-report breakage rates and that the breakage rates would remain low across studies.

2.2.3. Methods

2.2.3.1. Inclusion and Exclusion

English-language studies were identified through a systematic review conducted on the April 3, 2023, using Ovid MEDLINE® (Wolters Kluwer), PubMed (National Library of Medicine) and Web of Science Core Collection (Clarivate™). The bibliographies of published studies were reviewed, and additional papers included where relevant. The systematic

review was guided by the standards of the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) Statement[21].

The search terms used are listed below. Medical Subject Heading (MeSH) terms were used when available (Ovid MEDLINE and PubMed).

Ovid MEDLINE: Bone Nails/ and Femoral Fractures/ and ("nail breakage" or "nail fracture" or "Nail rupture" or "broken nail" or "Implant Failure" or "Implant Breakage" or "Implant Fracture")

PubMed: (bone nails[MeSH Terms]) AND (femoral fractures[MeSH Terms]) AND ("nail breakage"[Text Word] OR "nail fracture"[Text Word] OR "Nail rupture"[Text Word] OR "broken nail"[Text Word] OR "Implant Failure"[Text Word] OR "Implant Fracture"[Text Word] OR "Implant Breakage"[Text Word])

Web of Science: (TS=(intramedullary nail OR cephalomedullary nail)) AND TS=("nail breakage" OR "nail fracture" OR "Nail rupture" OR "broken nail" OR "Implant Failure" OR "Implant Breakage" OR "Implant Fracture") AND TS=("femur" OR "femoral")

2.2.3.2. Study Eligibility Criteria

Eligibility criteria was based on the PICOS (Population Intervention Comparators Outcomes Study design) framework. Studies were included that met the following criteria:

Population: Studies with human adult participants aged 18 years and over. Studies had to specifically mention implant breakage, failure, or rupture as an outcome in the abstract, methods or results sections. Implantation needed to occur during or after 1989 (chosen as the year of release of the first Gamma nail).

Interventions/Comparators: Treatment with a cephalomedullary nail for a proximal femur fracture. The fracture type had to include trochanteric fractures with or without subtrochanteric fractures if specified. Studies or subgroups containing solely pathological fractures were excluded. Having some pathological fractures in the study cohort was not an exclusion criterion.

Outcome: Number of broken and total number of cephalomedullary nails able to be derived.

Study Design: No restrictions.

2.2.3.3. Outcomes and Prioritization

The primary outcome of interest was the implant breakage rate expressed as a percentage. These were used to collate and compare breakage rates according to study design and calculate a pooled breakage rate.

2.2.3.4. Screening and Data Extraction

Screening was conducted by the lead author (AL) in 3 stages. Stage 1 involved the 3 database searches using the specific search terms listed, combining the results with any additional references, and removing duplicates. Stage 2 involved screening of full abstracts. At stage 3 full-text articles were retrieved and assessed against the eligibility criteria. A risk of bias assessment was not performed as the review involved cohort studies screening for the same outcome, without comparator groups.

Data extraction was performed by the same author (AL) and included the author, year of publication, dates of implant insertion, study design, method of detection of breakages, implant used, number of breakages, number of implants inserted, breakage rate and follow-up. Follow-up was recorded as it was found in the publications as a mean, minimum or range.

2.2.3.5. Approach to Evidence Synthesis

Breakage rate was described individually for each study. Descriptive statistics were undertaken using Microsoft Excel (Microsoft, USA). Non-parametric data was described using median and interquartile range. A pooled result for all studies was calculated by the sum of all breakages divided by all implanted cephalomedullary nails. The pooled analysis excluded the 2 systematic reviews as these had overlap with the other included studies and some studies included in the meta-analyses did not

meet our strict inclusion criteria. Where more than 1 publication was available for a particular study design, the breakage rates were compared by study design as an average rate (the mean of each study design's rates).

2.2.4. Results

2.2.4.1. Systematic Review

Database searches revealed 635 potential records with an additional 36 records identified through reference review. After duplicate removal 407 records remained. After abstract review 363 articles were excluded leaving 47 which were assessed by full-text review. Twenty-three further studies were excluded leaving 24 studies included in the meta-analysis. The PRISMA flow diagram is shown in Figure 2.1.

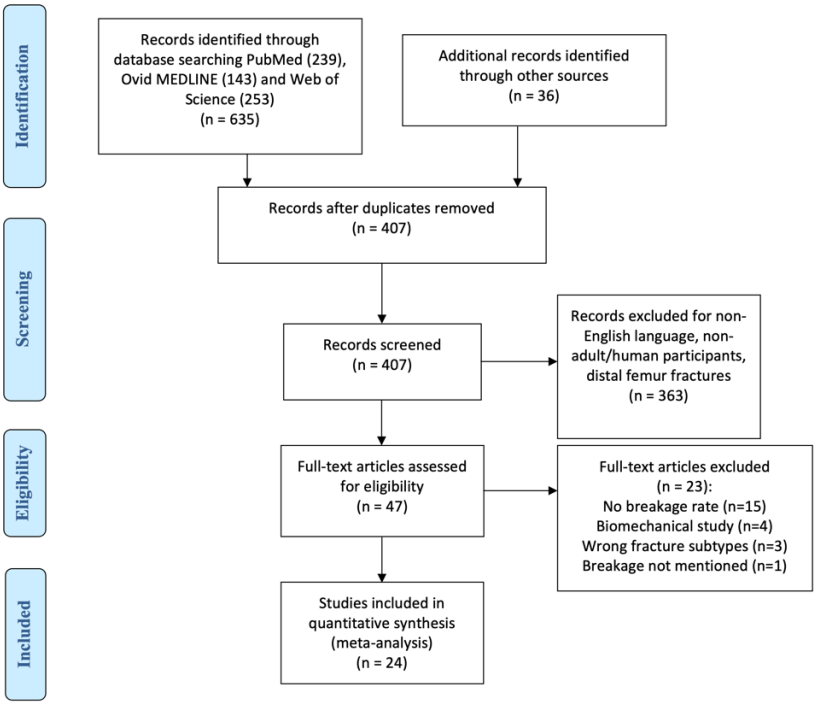


Figure 2.1 PRISMA flowchart

2.2.4.2. Individual Study Analysis

A total of 24 studies demonstrated a positively skewed non-parametric distribution of results as demonstrated in Figure 2.2.

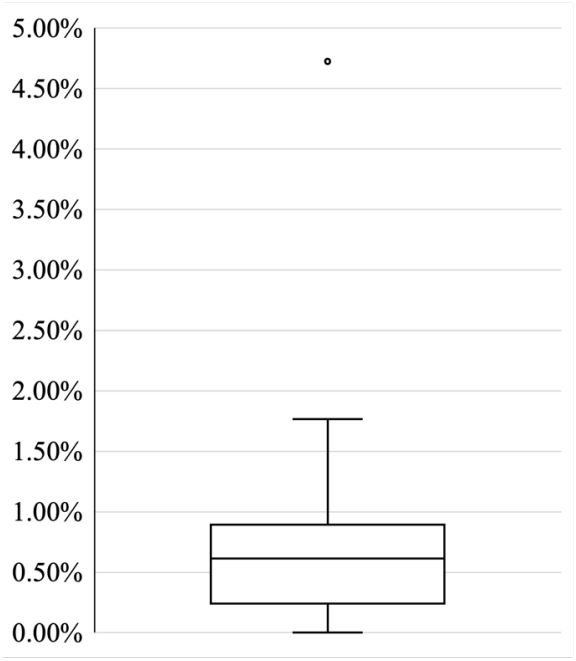


Figure 2.2 Box plot of distribution of breakage rates

The median breakage rate was 0.6% with an interquartile range of 0.6% (0.3 to 0.9%) and a range from 0.0 to 4.7%. The follow up was greater than 6 months in all individual studies though in 1 study it was not specified.[22] Pooling the results, with the 2 meta-analyses excluded, a total of 206 breakages were reported in 51,952 patients. This gives a pooled breakage rate across the cohorts of 0.4%. Table 2.1 summarizes the findings. There was 1 statistical outlier which reported a high implant breakage rate of 4.7%[22]. This study examining the TFNA implant had a mean time to failure

of 10 months and 3 of the 6 implant breakages occurred in patients with a confirmed or suspected pathological fracture. As also noted by the author's own research there was a high prevalence of reverse oblique fracture patterns in this cohort[13].

Table 2.1 Summary of Systematic Review by Author

TABLE 1. Summary of Systematic Review by Author

Author	Year	Study Design	Failure Capture	Dates	Nail	Nail Breakages	Nails	Rate	Follow-up
Alvarez et al[22]	2004	Retrospective Institutional: Single Center	Hospital Records Review	1990–2002	Gamma (Pre-Gamma 3)	5	843	0.6%	6–10 m
Appelt et al[23]	2007	Retrospective Institutional: Single Center	Hospital Records Review	2002–2003	PFN	0	178	0.0%	>6 m
Ballal et al[24]	2008	Retrospective Institutional: Single Center	Hospital Records Review	2000–2006	PFN	1*	160	0.6%	>6 m
Chitnis et al[14]	2020	Retrospective Database: Mercy Health Electronic Health Records	ICD code search	2016–2020	TFNA	0	733	0.0%	10 m
Chitnis et al[15]	2021	Retrospective Database: IBM MarketScan Commercial and Medicare Supplemental Claims	ICD code search	2016–2019	NS	73†	11,128	0.7%	<2 y
Cruz-Sanchez et al[25]	2015	Retrospective Institutional: Single Center	Hospital Records Review	2003–2012	Gamma 3 (7/1117), Affixus (0/52), LNS-GT (0/14) and PFN (1/63)	8‡	1180	0.7%	13 m
Docquier et al[26]	2002	Retrospective Institutional: Single Center	Hospital Records Review	1990–2000	Gamma (Pre-Gamma 3)	1	323	0.3%	10 m
Erez and Dougherty[27]	2012	Retrospective Institutional: Single Center	Hospital Records Review	2006–2008	Intertan	1	127	0.8%	14 m
Gaebler et al[1]	1999	Retrospective Institutional: Single Center	Hospital Records Review	1992–1996	Gamma (Pre-Gamma 3)	2	839	0.2%	NS
Gallagher et al[28]	2019	Retrospective Institutional: Multicenter (3 sites)	Radiographic Review Only	2002–2004	PFN	0	106	0.0%	4–7 y
Goodnough et al[13]	2022	Retrospective Database: Integrated Health-care System Hip Fracture Registry (35 sites)	Detection of revision (method NS) and Hospital Records Review	2014–2019	TFNA (5/3972) and TFN (2/4007)	7	7979	0.1%	3 y
Iwakura et al[10]	2013	Literature Review and Meta-analysis	NA	Various	Gamma (Pre-Gamma 3)	19	3761	0.5%	NA
Kasimatis et al[29]	2007	Retrospective Institutional: Single Center	Hospital Records Review	1991–2002	Gamma (Pre-Gamma 3)	4	412	1.0%	NS
Li et al[7]	2021	Retrospective Institutional: Single Center	Hospital Records Review	2008–2018	NS	6	785	0.8%	>12 m
Liu et al[30]	2013	Retrospective Institutional: Single Center	Hospital Records Review	2003–2009	TFN	2	223	0.9%	24 m
Nayar et al[21]	2021	Retrospective Institutional: Single Center	Hospital Records Review	2017–2020	TFNA	6	127	4.7%	NS
Rollo et al[9]	2018	Literature Review and Meta-analysis	NA	Various	Mixed use	58	5835	1.0%	NA
Schmitz et al[31]	2022	Retrospective Institutional: Single Center	Hospital Records Review	2011–2016	Gamma 3 (5/797) and TFNA (3/542)	8†	1339	0.6%	3 y
Shannon et al[32]	2019	Prospective: Randomized	Patient & radiographic review	2014–2017	TFNA (0/89), Gamma 3 (0/67) and Affixus (0/12)	0	168	0.0%	14 m
Swift et al[33]	2022	Retrospective Institutional: Single Center	Hospital Records Review	2014–2018	ZNN & TFN (breakdown NS)	4	662	0.6%	9 m
Tomás-Hernández et al[19]	2018	Retrospective Institutional: Single Center	Hospital Records Review	2010–2015	Intertan, TFN, IMHS (breakdown NS)	13	1481	0.9%	>12 m
von Ruden et al[34]	2015	Retrospective Institutional: Single Center	Hospital Records Review	2005–2013	Gamma 3	8	453	1.8%	>6 m
Wallace et al[16]	2021	Retrospective Database: Premier Healthcare Database (365 sites)	ICD code search	2014–2019	TFNA (27/14,370) and Gamma 3/ZNN combined (29/8260)	56	22,630	0.2%	18 m
Yee et al[35]	2020	Retrospective Institutional: Multicenter (2 sites)	Hospital Records Review	2015–2019	TFNA	1	76	1.3%	13 m

Follow-up is described as the mean, range or minimum according to the publication terminology. The literature review papers include some articles already listed separately in the table.

*The pathologic fracture series in this publication is excluded.

†Nail breakages indirectly calculated from total nails and breakage rate.

‡Screw only breakages excluded from review.

NA, not applicable; NS, not specified.

Study Designs

There were 2 meta-analyses, 1 prospective randomized trial, 2 multi-centre retrospective reviews, 4 retrospective database reviews, and 15 single centre retrospective reviews. The mean breakage rate of all the studies for each study design is shown in Figure 2.3. The single prospective randomized trial had a cohort of 168 patients with no breakages reported and is not included in this chart.

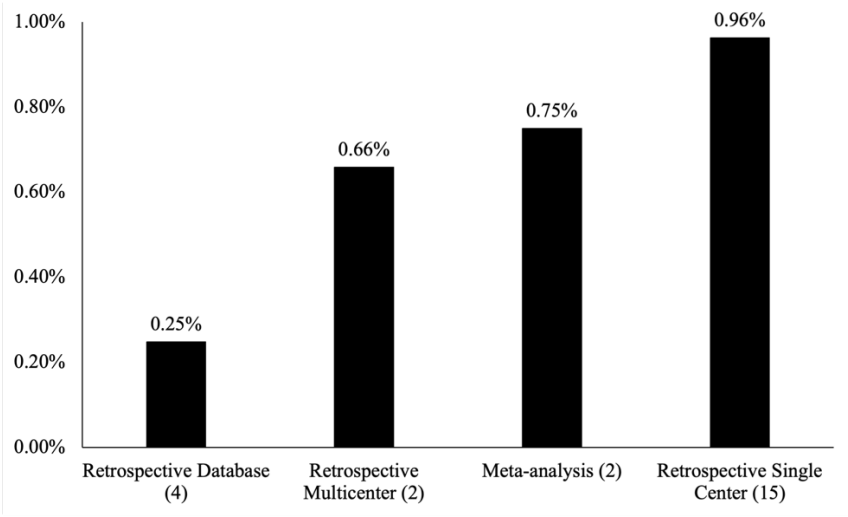


Figure 2.3 Average nail breakage rate by study design

The total number of studies for a particular study design is denoted in brackets.

2.2.4.3. Detection of Breakage

Detection of breakage in the prospective study as well as in the retrospective single- and multi-centre studies occurred through hospital record review (usually a combination of patient notes and imaging). For database papers, 3 of the studies detected breakage by ICD code searches for 'breakdown of internal device' AND (femur fracture repair OR device removal from femur) occurring in 1 hospital admission[15-17]. The fourth study detected

revisions defined as any operation after index procedure in which a component was removed and/or replaced, however it did not specify how the database was queried for that outcome[14]. Those patients then had a hospital record review.

2.2.4.4. Implant Types

A range of manufacturers and designs were assessed. Heterogeneous studies and small subgroup numbers meant that a comparison of breakage rates between implants would be statistically invalid.

2.2.5. Discussion

This study is the first systematic review to summarize and pool results from the literature that specifically examines cephalomedullary nail breakage. The median breakage rate of 0.6% sits within the range outlined in other non-systematic reviews (0.5 & 1.0%)[10, 11]. The narrow spread of results (interquartile range of 0.6%) is an improvement to the wide variation in rates previously reported by other studies suggesting this is a more accurate estimate (Figure 2.2). Ninety-five percent of the studies had a breakage rate of 1.3% or less. This serves as an upper limit for the standard breakage rate reported in studies against which to compare future results. It is important to note that breakage rates alone should not be used to determine implant effectiveness[23]. Revision for all causes, cost, union rates, and patient

reported outcomes are other important tools for determining overall implant safety and performance.

There was a wide variability in rates of breakage reported between different types of study designs with single-centre review studies reporting breakage rates that are nearly 4-fold greater than large-scale administrative database reviews. The rate was lowest among the large-scale administrative databases and progressively increased from retrospective multi-centre trials to meta-analyses, to retrospective single-centre studies (Figure 2.3). Two possible explanations for the higher rates in institution-level reviews include a relatively captive population with better detection rates for the numerator or missing patients in the denominator who have had implants placed but were not captured correctly. Lower rates of breakage captured in large-scale administrative databases may be due to poor sensitivity in detection methods of breakage (such as not capturing certain revision procedure codes), or due to misclassification of the at-risk population to unintentionally increase its size (such as including additional non-intramedullary implants).

There could also be bias introduced from patient selection. The Medicare supplemental claims database as an example excludes patients under 65 years of age, and as young age is a risk factor for implant breakage, this dataset may under-estimate breakage rates. Chitnis et al. derives 74% of its

study population from the Medicare supplemental claims database[16]. It is also worth noting that 3 of the 4 large-scale database searches were conducted by employees of a medical technology company that manufactured the implant it studied which would have the potential to introduce bias from conflict of interest[15-17]. With no gold standard reference the true accuracy of all studies remains unknown.

The study designs also differed in their reported explanation of breakage. The administrative databases tended to explain implant breakages as the result of more general causes such as delayed union and early weightbearing[14, 17]. This was likely because the smaller single centre institutional studies had access to more detailed data that could evaluate variables such as adequacy of reduction.

Despite large volumes of insertions, the implant breakage events were rare which makes the studies under-powered to draw meaningful conclusions in comparing performance between implants. For example, the Goodnough et al. paper had a lower rate of breakage in the TFN compared to the TFNA group (0.06% vs. 0.2%); however, the events were only 2 and 5 breakages captured respectively[14]. None of the studies that specified 2 or more types of broken implants had more than 7 breakages of any 1 prosthesis type. Wallace et al. captured 56 breakages: however, it pooled the Zimmer

Natural Nail and Gamma 3 Nail in their analysis without a breakdown of the numbers of each, preventing meaningful comparison[17].

The major strength of this systematic review is the strict inclusion criteria selecting papers that examined cephalomedullary nail breakage as an outcome. This ensures that breakage cases were at least examined even if they did not occur and improves on 2 previous non-systematic literature reviews[10, 11]. The major limitations of the studies included the accuracy and reliability of event capture in database and hospital record searches. For example, in cities with more than 1 hospital for trauma care, patients may be brought to a different hospital for the treatment of an implant breakage. These patients are typically missed in institutional review study designs. For database searches, the ICD codes used for detection of revisions appeared narrow and relied on a coding diagnosis of device removal or fracture repair at the time of revision. A conversion to arthroplasty that fails to code the implant removal or breakage would then be missed.

The population at risk decreases rapidly in hip fracture cohorts due to high postoperative mortality, and not taking this into account could falsely lower the breakage rate by exaggerating the size of the population at risk. Only 2 studies accounted for censoring of patients due to death[14, 15]. In contrast, the rate could potentially be lower than reported, such as if breakages were diagnosed when they did not occur (coding or documentation errors) or

partial capture of patients at risk (missing patients that had the implants inserted).

So which study design should be trusted to guide surgeons? None are completely accurate, though institution studies may have a closer estimation of true cephalomedullary nail breakage rates given the higher rate of breakage detection. These studies have the downside of smaller population sizes.

Future avenues for research include data linkage across health services for improving detection of breakages when care is transferred to another institution and comparative studies of breakage rates between different implant designs in prospective randomized controlled trials. The ideal study would accurately capture both insertions and breakages with high sensitivity and specificity. Expanding ICD codes for detection of breakages to capture the broad variety of revision procedures could also improve the sensitivity of database searches and specificity could be maintained by careful record and imaging examination of those patients captured. Medical technology companies could consider assisting such research through directly providing access to data on implant insertion volume, which would make the denominator more robust. This typically does not occur as this company-derived information is considered commercial in confidence.

Further studies should consider reporting breakage rate not only as a simple equation of broken implants divided by inserted implants but also account for incidents that remove the implant from the at-risk pool of patients. Incidents such as death or removal of unbroken implants would be censored and a cumulative percent revision reported. Given the great volume of hip fracture care worldwide, and the vulnerability of those who receive it, perhaps proximal femur fracture implants deserve the same scrutiny and performance documentation of their arthroplasty counterparts with large scale national registries.

This systematic review and meta-analysis demonstrates that cephalomedullary nail breakage is rare with a median reported rate of 0.6% and a pooled result rate of 0.4%. Ninety-five percent of studies had a breakage rate of 1.3% or less which sets a benchmark from the reported literature for future studies. However, the rate of implant breakage should not be used in isolation to judge performance. There is wide variability in rates of breakage reported between different types of study designs with single-centre review studies reporting breakage rates that are nearly 4-fold greater than large-scale administrative database reviews. Whilst there is variation between the study designs, none are without shortcomings and there is significant scope for further research in this area. Consideration should be given for improved trauma registries to assist with post-market surveillance.

3. Chapter 3: Statewide Data-Linked Breakage Rates

3.1. Preface:

Once the background rate of breakage was established and an acceptable threshold defined, a database across Western Australia's tertiary hospitals was created to capture all implanted cephalomedullary nails. This could then be linked to a local retrieval database of explanted prostheses, aiming to link the two to determine an individual breakage rate by implant type and allow comparisons of performance between prostheses.

This article, published in the Journal of Bone and Joint Surgery, can be accessed here and is included below as a manuscript.

3.2. Cephalomedullary Nail Breakages in a Multicenter Insertion vs. Retrieval Database Comparison: A Retrospective Cohort Study of 3,882 patients.

3.2.1. Abstract:

3.2.1.1. 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 utilize a large and geographically isolated patient cohort to better define and compare the proportion of implant breakages across a range of cephalomedullary nails.

3.2.1.2. Methods:

Implantation data was collected from electronic theatre 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 5 July 2024.

3.2.1.3. Results:

3,882 cephalomedullary nails were implanted. There were 18 nail breakages in this cohort recovered by CITRA, giving an overall breakage proportion of 0.5%. Whilst breakages were rare, the TFNA demonstrated a seven-fold higher proportion of reported breakages (6/393; 1.5%) compared to its predecessor the PFNA (6/2621; 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.

3.2.1.4. 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.

3.2.1.5. Level of Evidence:

Therapeutic Level III (Retrospective Cohort Study)

3.2.2. Introduction:

The recommended treatment for most subtrochanteric and unstable trochanteric hip fractures is intramedullary nailing[24]. The treatment goals are to stabilize the fracture, allow early weightbearing and facilitate bony union[25]. Most 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 non-union[3].

The features of some commonly used nails are outlined in Table 3.1[26-33]. 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[34-37]. Implants may also become more susceptible to failure if they are damaged in the process of implant insertion[7, 38].

Table 3.1 Summary of Cephalomedullary Nail Features

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	16.3x15.3^	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 11mm nail. Sources: surgical techniques and value design briefs[3-10].

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[39]. 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 TFNA (Trochanteric Fixation Nail-Advanced, DePuy Synthes)[13]. Database review studies published on the safety of the implant have reported a low proportion of breakages between 0.2 and 0.7%[14, 16, 17].

In contrast, a smaller institution-based series of 127 patients assessed by Nayar et al. reported a much higher breakage figure of 4.7%[22]. A more recent poster presentation of a multicentre 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)[40]. McAleese and colleagues also recorded TFNA breakages at 2.2%, in a single centre retrospective review of 803 cases[41]. Implant breakage is just one form of mechanical failure and conflicting reports exist as to which implant has the lowest overall failure rate[41, 42].

We sought to assess the proportion of breakages of four intramedullary nails in an adult proximal femur fracture population over a 16-year period across all three 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 to other nail types. 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).

3.2.3. 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 1st January 2001 to 5th July 2017 was conducted. The study size was defined by these temporal limits. The start date was selected as it was the first year the 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[13]. 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 cut-off also allowed ample time for fatigue failures to occur and be sent for analysis, which were captured until 5th July 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 centres over that period: Gamma3, PFN (Proximal Femoral Nail, Synthes), PFNA (Proximal Femoral Nail Antirotation, 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 theatre 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 implant manufacturer.

Data for implant insertions was extracted from each hospital’s Theatre 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 235mm TFNA nails). Nail length was defined as long at 260mm or greater. The cause of the initial fracture, fracture pattern, reduction quality and patient factors such as weight, co-morbidities, sex assigned at birth, race, ethnicity and socioeconomic indicators were not available. Our population is predominantly Caucasian. Insertions were captured across all indications to capture ‘typical use’ of each implant which included all fracture patterns, pathological fractures and revision fixation.

Nail breakage cases were captured via 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 (Figure 3.1). 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 was cleaned and checked against medical records and radiographs when required and available.

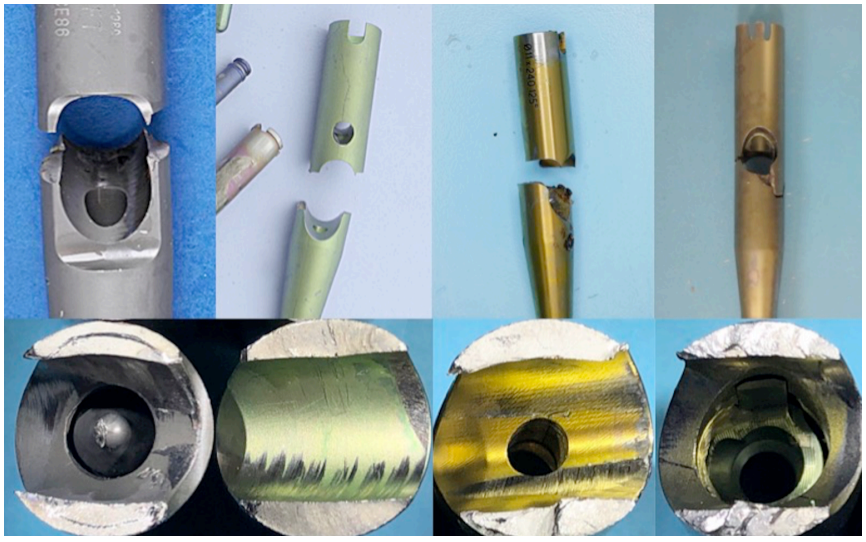


Figure 3.1 Photomicrographs of 4 broken implants

Left to Right, a broken Gamma3, PFN, PFNA and TFNA nails photographed from both the side and from top down onto the fractured surface.

Quantitative data was analysed using Microsoft Excel (Excel for Mac 2016, Microsoft Corporation, Washington, USA). Statistical analysis was conducted using SPSS (IBM SPSS Statistics, Version 29.0, Released 2023. Armonk, NY: IBM Corp.). Breakage proportions between nail types were compared for significance using Fisher's Exact test given the low event counts (under 5 in two 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 carried out in accordance with the World Medical Association Declaration of Helsinki and was approved by an institutional review board. No external funding was received for the conduct of this project.

3.2.4. 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 found in Table 3.2. Ten breakages occurred in males and eight in females. The median patient age at time of breakage was 79 years old (range, 45 to 92 years). The diagnosis at index nail insertion was not specified in 7 patients, hip fracture in 5 patients, a prior broken nail in 4 patients and a pathological fracture in 1 patient. The surgeon's diagnosis of cause of breakage was non-union 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 3.3. The TFNA versus 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 (Figure 3.2).

Table 3.2 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

Table 3.3 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%

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 two proximal screw apertures. One TFNA case had an additional implant breakage through the distal screw aperture of a short nail.

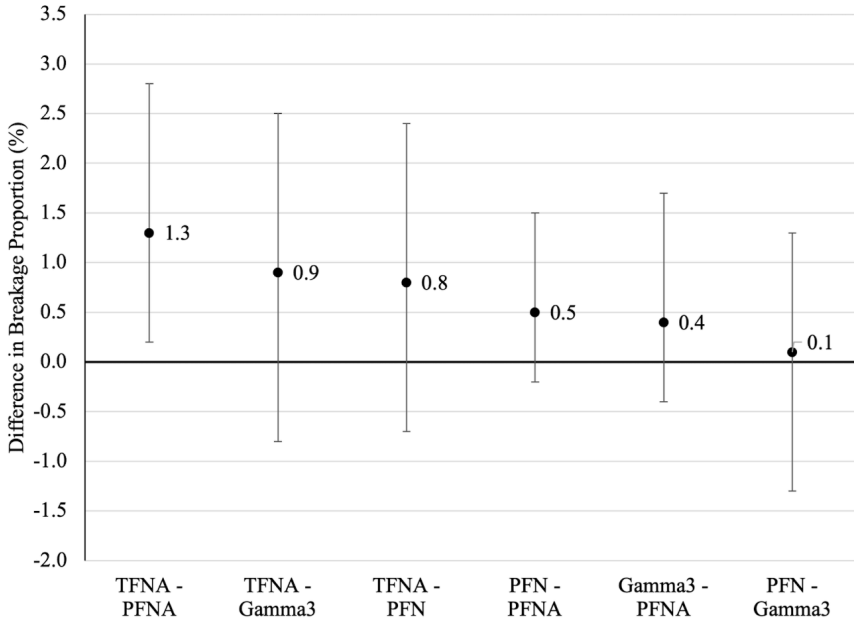


Figure 3.2 Head-to-head analysis of implant breakage rates

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

3.2.5. Discussion:

This paper 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 centre, unique to this region.

The proportion of reported nail breakages was more than seven-fold higher in the TFNA cohort (1.5%) compared to its predecessor the PFNA (0.2%, *P* = 0.002), confirming our primary hypothesis. The proportion of TFNA breakages exceeded the benchmark standard of less than 1.3% defined in our prior systematic review[39]. The Gamma3, PFN and PFNA proportions aligned with the results reported elsewhere[10-12, 20, 43-49]. The TFNA breakage proportion, whilst less than that of the single centre study by Nayar *et al*. (4.7%), was much higher than that described by Chitnis *et al*. (0%) and Wallace *et al.* (0.2%)[16, 17, 22]. We postulate that this is related to study design in that larger non-clinical database studies may be predisposed to under-detecting failures, as discussed previously[39].

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 issues

should be largely 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 analysed due to low event counts.

The clinical significance of these findings is that the TFNA may be of insufficient strength, particularly related to the screw/blade aperture, to maintain a comparable rate of fatigue failures to 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 to other nails (Table 3.1). 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 analyse breakages across a large, isolated population using comprehensive and accessible operating theatre 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 centre. Due to the electronic and built-in tracking of implants, the insertion data is 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. Return 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 centre undertaking proximal femoral fixation being 2,700 kilometres 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 authors[14]. 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 was 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, non-breakage revisions and loss to follow-up was 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 re-operation rate for these devices inclusive of other potentially more common, causes of failure. When implant breakage is considered amongst other causes including cut-out, 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 as well as 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 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.

3.2.6. Appendix I: Individual Patient Data

Case	Nail	Sex	Age	Index Diagnosis	Side	Length	Implant Dimensions	Breakage Location	Revision Diagnosis
1	Gamma3	M	50	NS	L	Long	130°, 420x11mm, 100mm screw	Proximal Aperture	NS
2	Gamma3	F	83	NS	L	Long	130°, 380x11mm, 100mm screw	Proximal Aperture	Non-union
3	PFN	M	80	Pathological	L	Long	130°, 380x10mm, 105 & 80mm screws	Proximal Aperture*	NS
4	PFN	M	88	NS	R	Short	130°, 240x12mm, 105 & 85mm screws	Proximal Aperture*	Non-union
5	PFN	F	89	NS	L	Long	130°, 240x12mm, 110 & 85mm screws	Proximal Aperture*	Non-union
6	PFN	F	80	NS	L	Short	125°, 240x11mm, 105 & 85mm screws	Proximal Aperture*	NS
7	PFNA	M	73	Hip Fracture	R	Long	130°, 340x10mm, 115mm screw	Proximal Aperture	NS
8	PFNA	M	45	NS	L	Short	125°, 240x10mm, 110mm blade	Proximal Aperture	NS
9	PFNA	F	77	NS	R	Short	125°, 240x10mm, 115mm blade	Proximal Aperture	Non-union
10	PFNA	F	73	Hip Fracture	R	Long	130°, 400x10mm, 100mm blade	Proximal Aperture	NS
11	PFNA	F	84	Hip Fracture	L	Short	125°, 240x12mm, 105mm blade	Proximal Aperture	Non-union
12	PFNA	M	87	Hip Fracture	L	Short	125°, 240x11mm, 110mm blade	Proximal Aperture	Non-union
13	TFNA	M	87	Hip Fracture	L	Short	125°, 235x11mm, 105mm blade	Proximal Aperture	Non-union
14	TFNA	M	79	Broken PFNA	L	Short	130°, 235x12mm, 110mm screw	Proximal Aperture	Delayed union
15	TFNA	F	77	Broken TFNA	R	Long	130°, 380x14mm, 110mm blade	Proximal Aperture	Delayed union
16	TFNA	F	59	Hip Fracture	R	Short	125°, 235x10mm, 85mm blade	Proximal + Distal Apertures	Non-union
17	TFNA	M	75	Broken TFNA	L	Long	125°, 380x12mm, 85mm blade	Proximal Aperture	Delayed union
18	TFNA	M	92	Broken PFNA	L	Long	130°, 380x14mm, 100mm blade	Proximal Aperture	Non-union

NS: Not Specified on the Retrieval Form. *The larger (more distal) of the proximal two apertures.

4. Chapter 4: Time to Failure: The Race to Union

4.1. Preface:

A higher breakage rate does not necessarily mean that the implants will not last as long *in vivo*. However, many of the failures of the novel implant were occurring at a time earlier than one would expect the fracture to have healed by. Based on this observation, it was decided to further investigate whether there was a difference in time to failure between the new implant and its current market competitor in our state as well as the implant's predecessors.

4.2. Early Fatigue Failures in TFNA Cephalomedullary Nails: A Retrospective Cohort Study of 41 Failures Using an Implant Retrieval Collection

4.2.1. Abstract:

4.2.1.1. Background:

Early fatigue failures (occurring within 4 months) have been reported in studies relating to the TFNA (Trochanteric Fixation Nail - Advanced, DePuy Synthes) cephalomedullary nail. We sought to compare the time to breakage of cephalomedullary nails that were used over the past 20 years and sent to our statewide prosthesis retrieval centre which captures and stores failed implants.

4.2.1.2. Methods:

Adult patients who suffered a cephalomedullary nail breakage between 2002 and 2023, with the implant sent to our retrieval centre, were analysed for median time to breakage. All index diagnoses for implant insertion were included. The TFNA, PFNA and PFN (DePuy Synthes/Synthes) and the Gamma3 (Stryker) nails were the implants used in our centres over this period. A secondary comparison of nail diameter with time to breakage was conducted for the TFNA implants using a Pearson correlation coefficient, as

it was the only implant to vary the proximal nail width with nail diameter. Institutional ethics approval was obtained for the study.

4.2.1.3. Results:

A total of 41 fractured cephalomedullary nails were sent to the retrieval centre from 2002 to 2023 inclusive (21 TFNA, 8 PFNA, 6 PFN, 6 Gamma3). No early (less than 4 months) breakages occurred in the Gamma3, PFN or PFNA implants. Early failures accounted for 8 of the 21 TFNA breakages. The median time to breakage was 5.6 months for TFNA, 7.4 months for Gamma3, 14.7 months for PFNA and 17.0 months for PFN implants. The shorter time to failure of the TFNA compared with both the PFNA and PFN was statistically significant ($p=0.02$). No strong correlation was shown between TFNA nail diameter and time to breakage.

4.2.1.4. Conclusions:

The TFNA cephalomedullary nail has an earlier median time to breakage than its PFN and PFNA predecessors. TFNA nails were the only group to demonstrate early failures before 4 months in our study. This may be important when selecting an appropriate implant to treat fractures that are slow to heal or unstable such as pathological, reverse oblique or subtrochanteric fractures.

4.2.1.5. Level of Evidence:

Therapeutic Level III (Retrospective Cohort Study)

4.2.2. Introduction:

Cephalomedullary nails need to withstand cyclical loads without undergoing fatigue failure until the fracture unites. The implants need to have a high fatigue limit, being the maximum stress the material will withstand without failure for an infinite number of cycles[2]. Although nail breakage from fatigue is rare (usually less than 1.3%[39]), if a cephalomedullary nail undergoes early fatigue failure (prior to the expected time to union) then fatigue failures would become more common. An 'early' nail breakage has been defined as occurring in less than 4 months from insertion, at which point most fractures have developed bridging callus[7, 45].

Early breakages have been reported with the TFNA, and Klima demonstrated that TFNA (Trochanteric Fixation Nail - Advanced, DePuy Synthes) breakages occurred on average 2 months before Gamma3 nails (Stryker) with a mean of 7 versus 9 months[7] respectively. More than half of the 183 TFNA breakages occurred in the first six months post-surgery. Chitnis *et. al.* demonstrated that half of the TFNA breakages in their analysis had occurred within the first 5 months. Two of the six TFNA breakages reported in a smaller study by Nayar *et. al.* had occurred within the first four months[22]. Conversely, Wallace *et. al.* reported a mean time to

TFNA breakage of 5 months which was longer than the Gamma3 and Zimmer Natural Nail (Zimmer Biomet) pooled result of 4 months[17]. The time to breakage otherwise reported in the literature varies, with a series average of 4-12 months and a range of values as wide as 2 months to 2 years[3, 6, 8, 10, 11, 20, 41, 46, 47, 50]. Most published studies are underpowered to compare nail groups.

After a series of fatigue failures of the TFNA implant were reported in our region of Western Australia, we sought to analyse whether the time to breakage was different to other nail designs[13]. Our primary hypothesis was that the TFNA group would demonstrate a shorter median time to failure than the other nailing systems. A secondary hypothesis was that within the TFNA group there would be a direct relationship between nail diameter and time to breakage due to the increasing proximal nail width with increasing nail diameter, a feature unique to this implant. For example, the width of the TFNA at the proximal aperture ranges from 13.4mm for a 9mm nail through to 15.2mm for a 14mm nail[28]. The Gamma3 (15.7mm), PFN (17.0mm) and PFNA (17.0mm for standard and long nails) have a cylindrical design proximally and the proximal nail diameter is independent of nail diameter[27, 29, 30]. This is relevant as nail breakages tend to occur at the level of the proximal aperture where the nail is weakest[13]. It has been demonstrated in tibial nailing that hardware failure becomes less common with increasing nail diameter[51].

4.2.3. Materials and Methods:

A retrospective cohort study was conducted of adult patients who had suffered an implant breakage of a cephalomedullary nail that was sent to our statewide implant retrieval centre, the Centre for Implant Technology and Retrieval Analysis (CITRA). Nail explant dates covered a 22-year period from the 1st of January 2002 (the first year a cephalomedullary nail was sent to CITRA) until data capture closure on the 31st of December 2023 (to allow for reporting). The hospital setting for insertion and removal surgeries covered both the public and private health sectors, and both metropolitan and regional hospitals across the state of Western Australia, Australia. Nail length was defined as long at 260mm or greater. The CITRA database captures 'routine use' of the implants meaning that all indications for use were included (primary and revision fixation, all fracture patterns, pathological fractures).

Explanted prostheses from all hospitals in the state of Western Australia can be sent for analysis and storage to CITRA when a mechanical failure has occurred or there are other concerns with its performance. Over 10,000 elective and trauma prostheses are held at CITRA and while the process is voluntary the contribution rates are considered high, with all orthopaedic centres participating. CITRA provided data including patient age at

breakage, date of index implant insertion, date of implant removal, sex, side of surgery, diagnosis at index fracture, surgeon's diagnosis for cause of failure, implant details and breakage location within the implant. Data was cleaned and cross-referenced against medical records and radiographs where required, the most common reason being to confirm the date of insertion. Patients were excluded if either the insertion or removal date was unavailable (n=1).

The implants analysed were those used routinely during that period: Gamma3 (Stryker), PFN (Proximal Femoral Nail, Synthes), PFNA (Proximal Femoral Nail Antirotation, Synthes) and TFNA (Trochanteric Fixation Nail - Advanced, DePuy Synthes). The public hospitals, which are the site of most femur fixations, had a single nailing system in use ('on shelf') per site at any one time and it was used for all indications (primary fractures, all fracture patterns, revision nailing, pathological fractures). The breakage date was defined as the date of revision surgery for breakage. The typical time course was a hospital admission at the time of nail breakage and revision occurring within several days, though some patients may have presented later after breakage in less catastrophic presentations.

Quantitative data was analysed using Microsoft Excel (Excel for Mac 2016, Microsoft). Statistical analysis was conducted using SPSS (IBM SPSS Statistics, Version 29.0, IBM). Patient age and time to breakage were both

non-parametrically distributed when assessed for kurtosis using a Shapiro Wilk test and histogram and therefore had descriptive statistics defined as the median and range and a box-and-whisker plot selected for result display. Differences between nail groups for time to breakage were assessed for significance using the Mann-Whitney U test, which was performed as a two samples test (head-to-head) comparing each nail to each of the others. A Pearson correlation coefficient with a one tailed p-value was used to assess the relationship between TFNA nail diameter and time to breakage. The study was carried out in accordance with the World Medical Association Declaration of Helsinki and was approved by a local institutional review board. No external funding was received for the conduct of this project.

4.2.4. Results:

The CITRA laboratory held 42 broken proximal femoral nails at the conclusion of the investigation. One implant was excluded from the study, a PFN retrieved from a 61-year-old male who had their index procedure in another state with no medical records available such that time to breakage could not be calculated. This left 41 nails for time to breakage analysis. There were 23 nails retrieved from female patients and 18 from males. The median age at the time of implant breakage was 79 years old (range, 45 to 92 years). The diagnosis at index nail insertion was documented on the retrieval form in 24 patients (hip fracture, 19; prior nail breakage, 4;

pathological fracture, 1). The surgeon's diagnosis for the cause of breakage at the time of revision was non or delayed union in 25 cases, late infection in 1 case and not specified in 15 cases. The characteristics of the retrieved nails are outlined in Table 4.1 with patient-level details provided in Appendix I.

Table 4.1 Implant Characteristics

Length	
Short	17 (41%)
Long	24 (59%)
Side	
Right	15 (37%)
Left	26 (63%)
Nail Type	
Gamma3	6 (15%)
PFN	6 (15%)
PFNA	8 (20%)
TFNA	21 (51%)
Diameter (mm)	
10	16 (39%)
11	14 (34%)
12	9 (22%)
14	2 (5%)
Nail NSA*	
125	26 (63%)
130	15 (37%)

NSA: neck-shaft angle (degrees).*

The pooled analysis of all 41 nails revealed a median time to breakage of 7.2 months (range, 1.8 months to 4.5 years). In terms of early failures (less than 4 months), there were none recorded in the Gamma3, PFN or PFNA groups. One PFNA failure occurred at 4 months. In the TFNA group more

than one-third of the breakages (8 of 21) were early. The median time to breakage was 5.6 months for TFNA (range, 1.8 to 40.3 months), 7.4 months for Gamma3 (range, 6.8 to 8.4 months), 14.7 months for PFNA (range, 4.0 to 54.5 months) and 17.0 months for PFN (range, 6.3 to 31.1 months), as depicted in Figure 4.1. The comparisons with a statistically significant difference were TFNA vs. PFN and TFNA vs. PFNA (p = 0.02). The remainder of the head-to-head comparisons between all nail groups were not significant, though Gamma3 versus PFN approached significance with a p-value of 0.055. The Pearson's correlation co-efficient between the time to failure and implant diameter within the TFNA group was weak (r = 0.228, one-tailed p-value = 0.160, Figure 4.2).

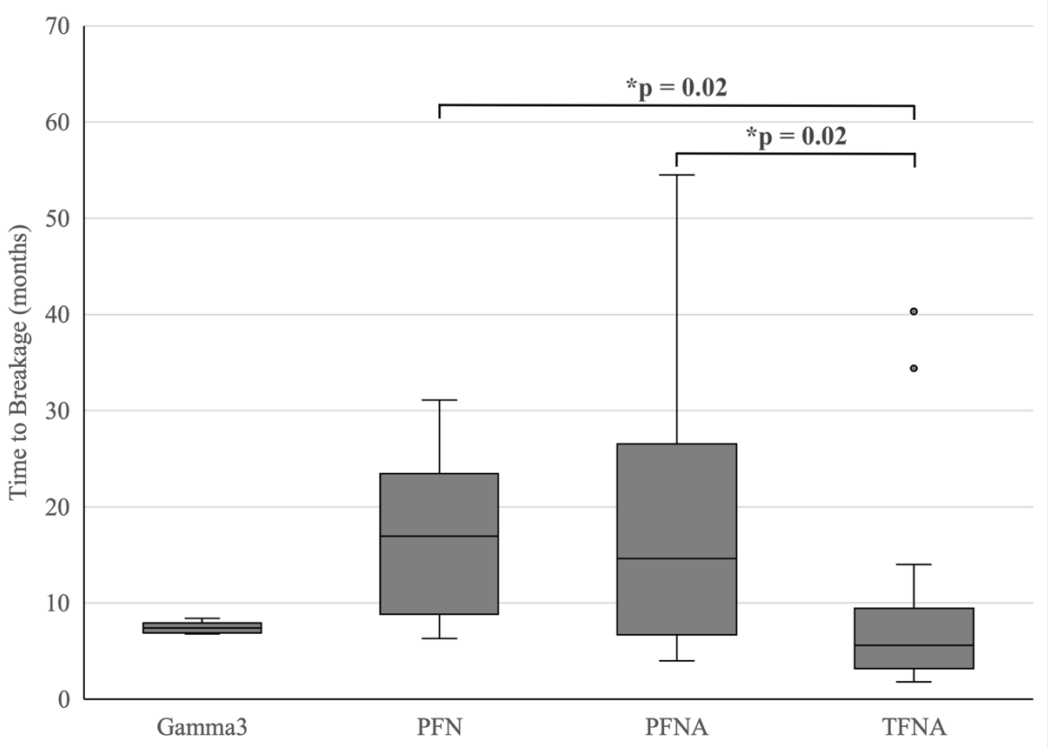


Figure 4.1 Box plot of the time to breakage for each nail

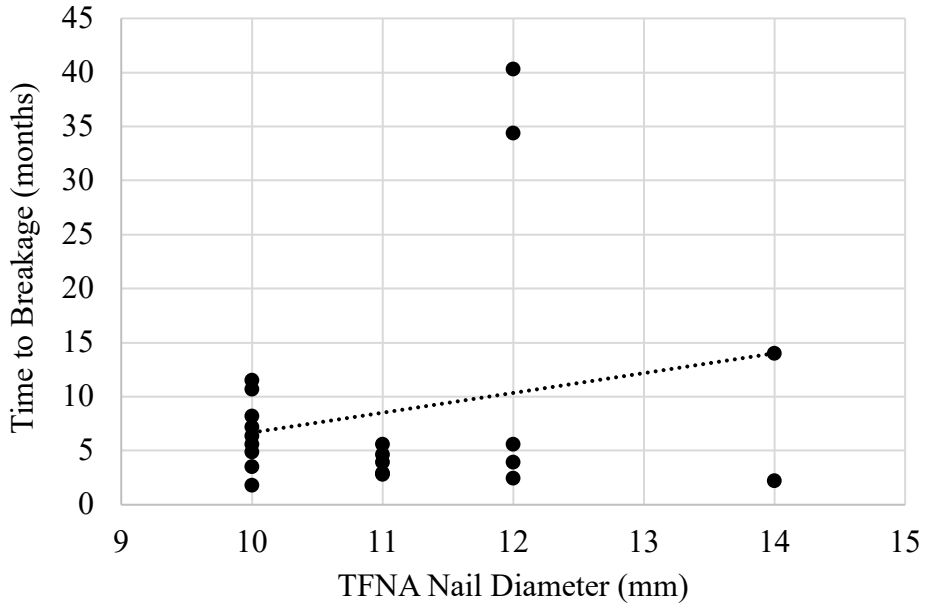


Figure 4.2 Scatter plot of TFNA nail diameter and time to breakage.

Implant breakage was at the level of the proximal aperture for the head screw for the PFNA, Gamma3 and TFNA implants. The PFN cases fractured similarly, at the level of the larger (more distal) of the two proximal screw apertures (the PFN has a two cephalic screw design proximally). One TFNA case had a second implant breakage site through the distal screw aperture of a short nail.

4.2.5. Discussion:

Our study shows an earlier time to breakage of the TFNA implant by more than 9 months when compared to its predecessors the PFNA and PFN,

affirming our primary hypothesis. Interestingly the median time to breakage of the TFNA being two months shorter than the Gamma3 was similar to the data produced by Klima, although this was not a statistically significant finding in our study[7]. The median time to failure of 5.6 months for the TFNA and 7.4 months for the Gamma3 sat within the previously reported ranges from smaller studies[3, 8, 11, 20, 41, 46, 47, 50]. The PFNA and PFN time to breakage was greater than previously reported (PFNA, 8 months; PFN 4 months)[6, 10]. The frequent early breakages in the TFNA group (8 of 21) were concerning as they occurred earlier than when union is expected. There were no early breakages in the Gamma3, PFN or PFNA nails. In the Gamma3 group there were no later failures either, with a maximum time in situ of 8.4 months. The range of times to failure with the Gamma3 would likely have been broader had more breakages occurred.

The secondary hypothesis of proving a longer time to breakage with larger diameter implants in the TFNA subgroup analysis was not supported by the statistical analysis with no significant correlation found. Despite this, inspection of the scatter plot (Figure 4.2) showed that all the 10 or 11mm nails failed within 12 months, and longer times to breakage were only present in the 12 and 14mm nail groups. The small numbers may have precluded defining the real relationship that was shown in tibial nails, or the effect may have been masked by the multifactorial nature of implant breakage[51].

The major strength of this study is the large number of broken nails (n=41). This provides the ability to compare groups of nails for differences as well as perform subgroup analysis. Furthermore, the longitudinal nature of the implant collection at CITRA, having been in existence for more than 50 years, meant that multiple generations of implants were able to be compared.

The main weakness of an implant retrieval study is that some breakages may not have been sent for analysis and is associated with both ascertainment and detection bias. An additional limitation was that the numbers of broken non-TFNA nails were small, which may reflect the fact that the breakage rate is lower in these implants or conversely reflect a more recent interest in cephalomedullary nail breakages. Further research could look at a larger population of TFNA failures to re-assess the relationship of diameter and breakage or examine other modern nail designs such as the InterTAN (Smith & Nephew), Gamma4 (Stryker) or ZNN (Zimmer Biomet).

In conclusion, the TFNA cephalomedullary nail has a significantly shorter median time to breakage than its PFN and PFNA predecessors. It was the only nail group in our study suffering early breakages, defined as occurring in less than 4 months. This is an important consideration for surgeons

treating higher risk pathological, reverse oblique or subtrochanteric proximal femur fractures. These groups of injuries are slow to heal and progress to load sharing, making them less supportive for implants that may have a lower fatigue tolerance.

5. Chapter 5: Prior Reporting of Insertional Damage

5.1. Preface:

A response to the results of the prior two studies from clinicians and from the implant manufacturing industry was to question the role of iatrogenic damage to the implants during their insertion. A systematic review and meta-analysis was conducted to establish and summarise the current evidence for iatrogenic implant damage.

5.2. Iatrogenic ‘Insertional Damage’ to Cephalomedullary Nails: A Systematic Review and Meta-Analysis

5.2.1. Abstract:

5.2.1.1. Objective:

To establish the prevalence of insertional damage on retrieved cephalomedullary nails and perform a quality assessment on damage reporting.

5.2.1.2. Data Sources:

MEDLINE, PubMed, and Web of Science were searched on September 24, 2024.

5.2.1.3. Study Selection:

All English-language studies that examined cephalomedullary nails and reported either an implant breakage or an assessment of nail damage after retrieval.

5.2.1.4. Data Extraction:

The author, year of publication, study design, number of broken implants, total number of implants, implant type, whether damage inspection occurred, number implants inspected for damage, number of implants found to be damaged, methods of implant assessment, damage descriptions used and the authors professions.

5.2.1.5. Data Synthesis:

Meta-analysis of included studies derived a pooled prevalence of insertional damage found on retrieved implants. Qualitative assessment was largely used for the remainder of variables.

5.2.1.6. Conclusions:

Consistency and quality is lacking in the reporting of insertional damage patterns found in retrieved cephalomedullary nails. In the limited studies available for the pooled meta-analysis there was damage present in 163 of 240 nails (68%). Descriptors of nail damage were generally of low quality, poorly defined and hard to compare between studies. Standardization in reporting of damage is needed.

Key Words: intramedullary nail, cephalomedullary nail, proximal femur fracture, breakage rate, mechanical failure, implant failure

Level of Evidence: Diagnostic Level IV.

5.2.2. Introduction

Cephalomedullary nails (CMNs) are commonly used in the treatment of proximal femoral fractures and hardware failure is historically rare[39]. This research group performed a laboratory investigation of a series of failures of a then-novel implant, the TFNA (TFN-Advanced, DePuy Synthes, Raynham, MA), to better understand the root cause of failure[13]. In response to this analysis the manufacturers raised the question of whether inadvertent

damage (‘notching’) to the implants during surgical insertion predisposed the nails to fracture and provided technical advice for surgeons to minimize this risk[52]. In agreement other authors also assert that inappropriate aperture drilling is directly responsible for cases of nail breakage[2, 38, 47, 53]. If inadvertent damage is playing a role in cephalomedullary nail fatigue failures, it is essential we understand its frequency, location, type(s) and severity and determine what has so far been reported in prior research. Currently, little is known about iatrogenic damage to CMNs.

Implant damage occurring at the time of surgery is referred to as insertional damage. Klima defined insertional damage as an “umbrella term applied to any nicks, scratches, abrasions, or ‘notches’ that are inflicted upon the implants during the index procedure[53].” Previous studies report a spectrum of damage from none present in an entire series to ubiquitous damage in another series[13, 53].

The specific area of interest on the implant is the so-called ‘red zone,’ the proximal hole that allows the passage of a head fixation element (screw or blade), named for its red appearance on finite element stress analysis as shown in Figure 5.1[47]. This region has the highest concentration of stress during normal loading as the patient undertakes activities of daily living[25, 54, 55]. Damage in this location is likely to originate from the passage of the main cephalic reamer but can also occur from the guidewire, the initial

reamer (if one is used) or the passage of the definitive screw or blade implant for head fixation[7].

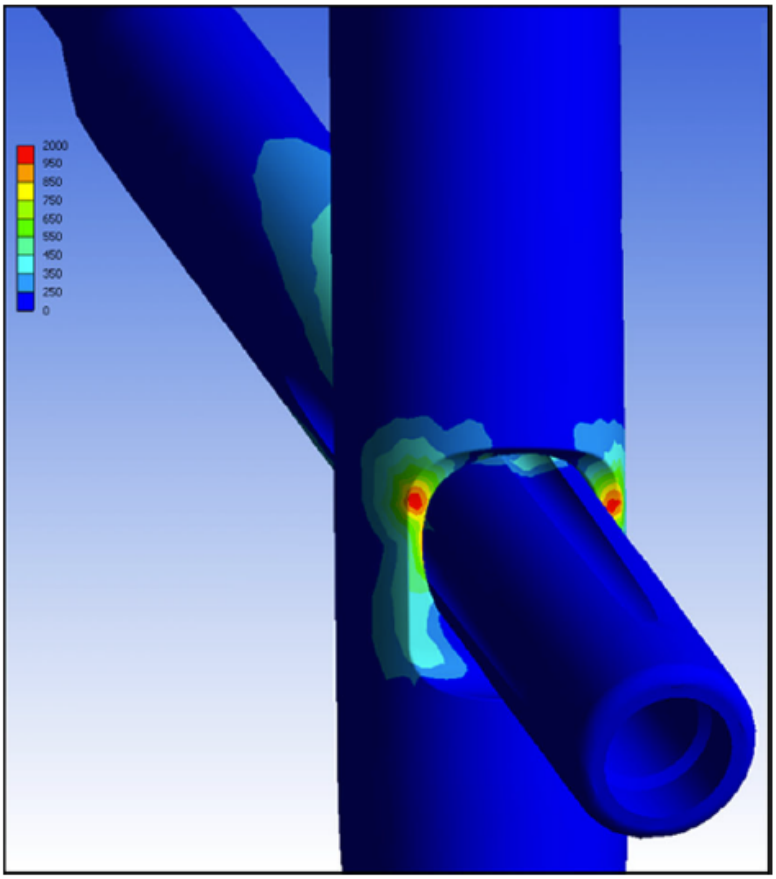


Figure 5.1 Red Zone as demonstrated in study by von Ruden et. al.[47]

The aim of this study was to perform a systematic review to capture all English-language studies reporting nail breakages or nail damage that might provide an assessment of iatrogenic damage occurring to the nail during insertion. These studies could then be assessed to determine how often explanted CMNs are assessed for damage, what techniques are used to assess them and what type of researchers have investigated this in the past.

It was also sought to identify the prevalence of iatrogenic damage to CMNs and which systems and language are being used to report it when present.

The primary hypothesis was that an assessment of explanted implants for insertional damage would rarely occur and if it did then the language used would be heterogeneous and poorly defined. Secondary hypotheses were that some damage would frequently be found on inspection of retrieved implants and that many studies reporting damage would lack an engineering perspective.

5.2.3. Methods

5.2.3.1. Inclusion and Exclusion

English-language studies were identified through a systematic review conducted on September 24, 2024, using Ovid MEDLINE® (Wolters Kluwer), PubMed (National Library of Medicine) and Web of Science Core Collection (Clarivate™). The bibliographies of published studies were reviewed, and additional papers included where relevant. The systematic review was guided by the standards of the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) Statement[21].

The search terms used are listed below and were selected to detect either nail breakage or a report of damage to an implant. Medical Subject Heading (MeSH) terms were used when available (Ovid MEDLINE and PubMed).

Ovid MEDLINE: Bone Nails/ and Femoral Fractures/ and ("nail damage" or "Implant Damage" or "Insertional Damage" or "Notch" or "Drill Defect" or "nail breakage" or "nail fracture" or "Nail rupture" or "broken nail" or "Implant Failure" or "Implant Breakage" or "Implant Fracture")

PubMed: (bone nails[MeSH Terms]) AND (femoral fractures[MeSH Terms]) AND ("nail damage"[Text Word] OR "Implant Damage"[Text Word] OR "Insertional Damage"[Text Word] OR "Notch"[Text Word] OR "Drill Defect"[Text Word] OR “nail breakage"[Text Word] OR "nail fracture"[Text Word] OR "Nail rupture"[Text Word] OR "broken nail"[Text Word] OR "Implant Failure"[Text Word] OR "Implant Fracture"[Text Word] OR "Implant Breakage"[Text Word])

Web of Science: TS=(intramedullary nail OR cephalomedullary nail) AND TS=("femur" OR "femoral") AND TS=("nail damage" OR "Implant Damage" OR "Insertional Damage" OR "Notch" OR "Drill Defect" OR "nail breakage" OR "nail fracture" OR "Nail rupture" OR "broken nail" OR "Implant Failure" OR "Implant Breakage" OR "Implant Fracture")

5.2.3.2. Study Eligibility Criteria

Eligibility criteria was based on the PICOS (Population Intervention Comparators Outcomes Study design) framework. Studies were included that met the following criteria:

Population: English-language studies with human adult participants aged 18 years and over. CMN implantation needed to occur during or after 1989, the year of release of the first true cephalomedullary nail, the Gamma nail (Stryker Orthopaedics, Mahwah, NJ). Pathological fractures were included.

Interventions/Comparators: Studies had to specifically mention implant damage or breakage in any manner as an outcome in the abstract, methods or results sections.

Outcome: Study design type, description of damage assessments, frequency of damage presence, techniques for assessment and author's professions.

Study Design: No restrictions.

5.2.3.3. Outcomes and Prioritization

The primary outcome was the presence or absence of a report on implant insertional damage in the study, and where present the terminology used to report the damage.

Screening and Data Extraction

Screening was conducted by the lead author (AL) in 3 stages. Stage 1 involved the 3 database searches using the specific search terms listed,

combining the results with any additional references found such as through paper references, and removing duplicates. Stage 2 involved screening of titles and full abstracts. At this point all papers that mentioned nail breakage, nail removal/revision or nail damage were included with the intention of finding a description of implant damage. At stage 3 full-text articles were retrieved and assessed against the eligibility criteria, primarily being to ensure the implants assessed were indeed CMNs for proximal femur fractures rather than reconstruction and retrograde nails or extramedullary implants. A risk of bias assessment was not performed as there was no comparator group.

Data extraction was performed by the same author (AL) and included the study's first author, year of publication, study design, number of breakages, number of implants inserted and implant name. Study design was assigned 'retrieval study' if it was a dedicated implant retrieval study rather than a clinical study such as a case series. If an inspection for damage occurred, this was recorded as was the number of nails that were inspected, and the number found to have damage present. The method of nail damage assessment was recorded, along with any descriptors used which were grouped into location, type and severity. The employment role of each author was noted. If the part of the implant assessed for damage was not the area of interest (proximal hole) this was recorded.

5.2.3.4. Approach to Evidence Synthesis

A meta-analysis was performed for the pooled prevalence of insertional damage amongst the studies that included damage assessments. Quantitative analysis was conducted for the study design types and frequency of reporting on the location, type and severity of damage. A qualitative analysis was utilized to describe the implants used, the authors' professions and whether a damage assessment occurred and if so, using what techniques. Quotes were extracted from studies to collate the language used to describe the damage that was found. Study authors were classified as Clinicians (surgeons, physicians, rehabilitation staff) or Engineers (encompassing biomedical engineers, metallurgists, material scientists).

Statistical analysis was conducted using Microsoft Excel (Microsoft, Redmond, WA). The study was carried out in accordance with the World Medical Association Declaration of Helsinki. No external funding was received for the conduct of this project.

5.2.4. Results

5.2.4.1. Systematic review

Database searches revealed 870 potential records with an additional 16 records identified through reference review. After duplicate removal 571 records remained. After abstract review, 492 articles were excluded leaving 79 which were assessed by full-text review. Twenty further studies were

excluded leaving 59 studies included in the review. These 59 studies all described implant failures or damage of CMNs and were the papers analysed to look for descriptors of implant damage. The PRISMA flow diagram is shown in Figure 5.2.

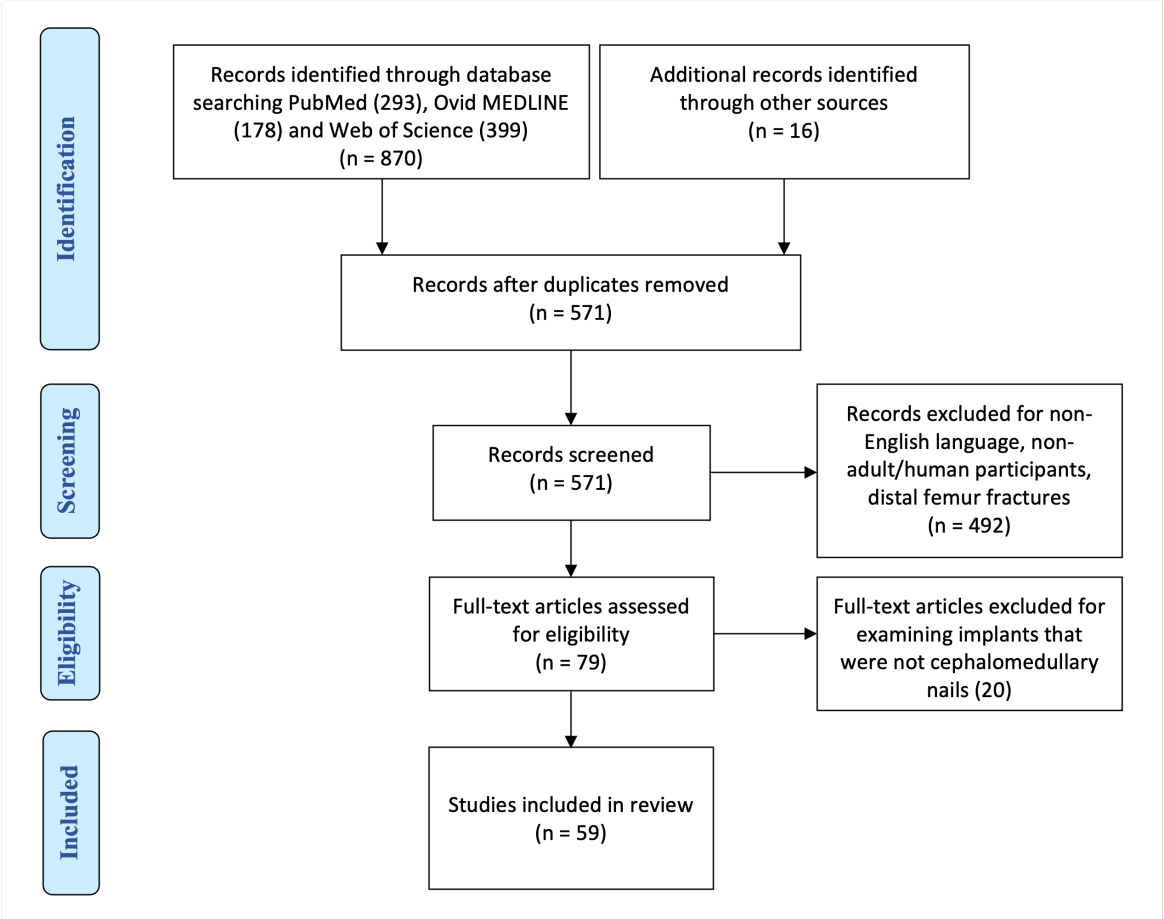


Figure 5.2 PRISMA flow chart for the systematic review

5.2.4.2. Study designs and Reporting of Damage

The different study designs included in the final analysis are listed in Table 5.1. Of the 59 studies that described CMN revision or hardware failure, 12 studies provided an assessment of implant damage. These were five

dedicated retrieval studies and seven case reports or case series studies that also provided an implant damage assessment. No clinical database studies provided an assessment of implant damage. The full report on each of the 59 papers is available in Appendix I.

Table 5.1 Tally of Study Designs Included

Retrospective Case Series	39
Case Report	11
Retrieval Study	5
Retrospective Database Series	3
Prospective Case Series	1
Total	59

5.2.4.3. Damage Prevalence

Not all damage reports related to the CMN body and apertures. Of the 12 studies that reported on damage, one study reported on damage to internal set screws in the TFNA implant and two studies analysed a broken cephalic screw[56-58]. This left 9 studies reporting on the presence or absence of nail damage to be analysed in meta-analysis, providing an overall damage presence proportion of 68% (163 of 240 nails). The individual study results are summarized in Table 5.2. Only one study included assessments of nails that had not undergone fatigue failure[53].

Table 5.2 Summary of the Findings

Findings of Studies Providing an Assessment of CMN Damage

Author	Year	Study Design	Broken Nails	Total Cases	Implant	Nails Damaged	Nails Inspected	% Damaged
Gaebler	1999	Retrospective Case Series	2	839	Gamma	1	2	50%
Giannoudis	2013	Retrospective Case Series	14	14	Gamma 3	0	14	0%
Klima	2021	Retrieval Study	342	342	TFNA, Gamma 3	53	93	57%
Klima	2023	Retrieval Study	12	109	Various	104	109	95%
Lambers	2019	Retrieval Study	16	16	TFNA	0	16	0%
Maes	2012	Retrospective Case Series	2	2	Gamma	2	2	100%
Mierzejewska	2016	Retrieval Study	1	1	Gamma 3	1	1	100%
Rappold	2001	Retrospective Case Series	2	61	PFN	2	2	100%
Yoshino	2006	Case Report	1	1	Gamma 3	0	1	0%
Total			392	1385		163	240	68%

5.2.4.4. Damage Descriptions

The descriptors used for nail damage are summarized in Table 5.3.

Table 5.3 Language Used in Damage Descriptions

Author	Location	Type	Severity
Gaebler, 1999	"In the upper part"	"Marks," "impression mark," "longitudinal marks" and "a flattened area"	NS
Klima, 2021	"Along the lateral margin of the proximal screw aperture" and "along the anterior or posterior proximal screw aperture"	"Radial scuff marks," "burrs," and "drill marks"	NS
Klima, 2023	"Proximal and distal apertures," and "The lateral aspect of the proximal aperture was divided into 6 regions"	Classed as either "Abrasion" or "Chamfer"	"Notch" defined as "chamfering the aperture to such a degree that it altered the external contour whereby it was no longer spherical"
Maes, 2012	"Lateral edge of the anterior bridge in the proximal and distal fragments of the nail [proximal hole]," "on the lateral rim of the lag screw hole of the proximal part of the nail" and "on the lag screw"	"Chamfer-like," "Sharp-edged damage" and "traces of drill contact"	"Significant material abrasion"
Mierzejewska, 2016	"On the interior surface of the nail"	"Abrasive wear," "scratches" and "development of corrosion processes"	"A slight loss of material is also visible"
Rappold, 2001	"In the region of the screw hole at the site of nail breakage"	"Metal abrasion"	"Significant"

NS: Not Specified

Damage Location:

Only one study, by Klima et. al., employed a systematic approach to describing the location of damage to the proximal hole[53]. The lateral aspect was subdivided into 6 regions described as superior anterior (SA), superior posterior (SP), anterior middle (A), posterior middle (P), inferior anterior (IA), or inferior posterior (IP). A diagram was not provided to visualize the exact boundaries of each section. The remaining studies used text descriptions of their observations.

Damage Type:

One author defined a system of damage types, which were classified in a binary manner as either abrasion or chamfer[53]. The definitions of these terms were not provided, however the discussion alluded to abrasions resulting from contact of the proximal reamer against the implant wall and a chamfer being a more severe form of this. Mierzejewska et. al. used metallurgical terminology for their observations[59]. The remaining studies used non-systematic descriptive terminology without definitions.

Damage Severity:

None of the studies provided a system for reporting severity. Klima described "atypical" damage whereby a 'notch' occurs, which he defined as aperture damage to "such a degree that it altered the external contour

whereby it was no longer spherical[53].” This likely refers to interruption in the smooth ovoid shape of the outer rim of the aperture.

5.2.4.5. Assessment Method and Author Professions:

There was an assortment of methods to identify the damage, summarized in Table 5.4. These ranged from brief macroscopic (naked eye) inspections in the operating room to detailed laboratory testing using advanced equipment. One study utilized reports written by manufacturers and stored in the United States Food and Drug Administration (FDA) databases and as such the assessment techniques were not available[7]. The three studies that involved authors with an engineering or science background were more likely to use advanced instruments in assessment.

Table 5.4 Damage Assessment Methods

Author	Insp	MI	OM	SEM	MHA	MSA	Authors
Gaebler, 1999	2	Y		Y			Clin/E
Giannoudis, 2013	14	Y		Y			Clin
Klima, 2023	109	Y	Y				Clin
Lambers, 2019	16	Y	Y	Y	Y	Y	Clin/E
Maes, 2012	2	Y	Y				Clin
Mierzejewska, 2016	1	Y		Y			E
Rappold, 2001	2	Y	Y	Y	Y	Y	Clin
Yoshino, 2006	1	Y		Y	Y		Clin/E

MI: Macroscopic Inspection; OM: Optical Microscopy; SEM: Scanning Electron Microscopy; MHA: Microhardness Assessment; MSA: Microstructural Assessment; Clin: Clinicians; E: Engineers; Insp: Number of implants inspected

5.2.5. Discussion

This is the first review of any kind of the published literature examining iatrogenic insertional damage in retrieved CMNs. Despite 59 studies being identified through systematic review as containing reports on explanted CMNs, only 9 of these performed or had access to a damage assessment on the explanted nails, demonstrating the limited data available in this field of research.

Study design plays a role in the ability to report on damage and it is unlikely that large scale clinical databases capture data such as damage reports as confirmed here. This study highlights the importance of retrieval studies as well as the publication of case reports and case series, particularly when access to metallurgical analysis and qualified scientists exists. In our region a centralized, government-funded facility called the Centre of Implant and Technology Retrieval Analysis (CITRA, Royal Perth Hospital, WA, Australia) provides this service for the entire state[13].

The wide range of damage prevalence reported in Table 5.2 was an unusual finding, with damage found on no implants in some studies and on all implants in others. This could be explained by differences in surgical technique or instrumentation between centres, surgeons and implants, an under-detection (insufficient inspection) in the studies that found no damage, or acceptance that some damage is common and does not warrant

comment. Ironically, this includes one of the author's own studies, which prompted a scheduled repeat closer inspection and documentation of our own retrieved devices.

Most explanted CMNs had evidence of proximal hole damage. This finding also applied to the series made up of predominantly unbroken implants[53]. The high proportion of damaged unbroken nails suggests that proximal hole damage is a common occurrence during nail insertion, is unlikely to be the sole causative factor in breakage, and if it plays any role then factors such as location, type and severity are going to be key considerations.

Unfortunately, data on these descriptors were scarce and of generally poor quality, proving our primary hypothesis true. This information was haphazard, heterogenous and often unaccompanied by definitions of the terms used. One issue identified was the creation of binary definitions of a damage process that is in itself a spectrum of implant injury, such as differentiating damage type into abrasion or chamfer[53].

The approaches to location description were difficult to comprehend and no organized approach to severity description could be found. Location was described as present or not, or as which part of the outer rim was affected (Appendix I). No quantitative descriptions of damage within the length of the proximal hole were provided. Few authors mentioned whether the

fracture plane passed through an area of implant damage, which would have been important information to share[12, 53].

Comparisons between the nine studies were not at all possible due to the different and ambiguous terms used in each author's description. This will also limit comparisons with any datasets published in the future.

The instruments of implant assessment were notable, with almost all studies using Scanning Electron Microscope (SEM) or other advanced inspection tools to elucidate the mechanism and origin of failure. The terminology used was clearer and more advanced assessments were performed when the authorship group included material scientists or engineers, suggesting these staff play an important part in retrieval reporting.

The major strength of this systematic review is the rigorous and first-time interrogation of the literature using a broad database search query and extensive full text review to capture as many relevant papers as possible. Despite this, the review is limited by the paucity of papers focusing on this research area.

A huge potential has been identified to improve the consistency of reporting damage patterns in cephalomedullary nails, and the authors call for standardization in assessing damage in the future. Further comparative

studies between damage patterns in fractured versus intact implants may assist in understanding the role of implant damage in fatigue failure. Given a relationship between damage and failure is likely at least at some level, the remaining conundrum is how to minimize, or ideally eliminate, insertional damage to the proximal hole of CMNs. In this regard one research group has already found a reduction in breakages when a larger diameter guidewire was introduced that was less prone to eccentric placement within the bore[60].

Insertional damage to cephalomedullary nails will be an important focus of future research. Standardizing reporting is a vital next step that the authorship group seeks to address in subsequent publications.

6. Chapter 6: The Nail Damage Assessment System (NDAS)

6.1. Preface:

After establishing a paucity of papers reporting on insertional damage and low quality, haphazard reporting when it was done, it was established that a systematic method of analysing and reporting insertional damage was needed. This was both to facilitate reporting of future studies by our research group as well as to allow valid comparisons with future external publications.

6.2. Insertional Damage of Cephalomedullary Nails: Proposal of a Standardized Nail Damage Assessment System (NDAS)

6.2.1. Abstract:

6.2.1.1. Background:

Reporting on iatrogenic damage observed in retrieved cephalomedullary nails is a novel focus of research and one with a dearth of information. The aims of this study were to define key terms in this field of research and create a standardized reporting system for retrieval analysis of insertional damage.

6.2.1.2. Methods:

An expert advisory group was formed consisting of two biomedical engineers who specialize in implant retrieval reporting and three orthopaedic surgeons with an interest in metallurgy, research and prosthesis design. The group collaborated to define the important aspects of cephalomedullary nail damage and how to report it. A trial series of six cases were tested for inter-observer reliability both between the two engineers and a comparison with a lay staff member.

6.2.1.3. Results:

The Nail Damage Assessment System (NDAS) is defined and presented. It is a systematic approach to reporting on retrieved cephalomedullary nails complete with a checklist, example cases and explanatory notes. Inter-observer reliability using the NDAS was perfect (100%) between the two blinded biomedical engineers working in retrieval analysis. Reporting by a third lay staff member with no experience in retrieval reporting showed moderate to perfect agreement with biomedical engineers in most components of assessment, demonstrating the general applicability of the system.

6.2.1.4. Conclusion:

Reporting on insertional damage to cephalomedullary nails is potentially a key to better understanding fatigue failures. Standardizing how it is reported is vital if progress is to be made in this area of research. The NDAS is proposed as a tool to standardize reporting and facilitate a universal understanding of damage to allow international comparison and collaboration.

6.2.2. Introduction

Fatigue failure in cephalomedullary nails (CMNs) used to treat proximal femur fractures is a rare mechanical complication of surgery[39]. Researchers

have investigated retrieved implants to examine them scientifically for evidence of iatrogenic damage at the time of insertion, a phenomenon known as insertional damage[53]. A systematic review was performed of such studies by this research group to assess the availability and quality of reporting, which was found to be rare, haphazard and heterogenous. As a result of these ambiguities, it is difficult to compare findings between studies. To develop a deeper understanding of insertional damage and its role in fatigue failures of CMNs, a standardized method of reporting the damage is needed.

While some clinicians describe insertional nail damage as 'notching,' in metallurgical terms notching is an intentional process and the authors avoid its use in describing insertional damage. A notch in materials science is a deliberately created defect with the aim of elucidating the mechanical properties of a material to determine if it is notch sensitive or positively responds to a situation of high stress concentration, which may improve material properties[61]. Notch sensitivity describes how a material's strength decreases as a function of the presence of stress concentration, which can lead to fatigue cracks forming and propagating. A relevant example in CMNs is that titanium alloys are more sensitive to notching than stainless steel, with titanium being used in almost all modern nails[34-37].

Any iatrogenic defect created in a CMN during insertion is important, however defects are most significant if they occur at the weakest point in the nail, the proximal hole for head fixation. Damage is likely to occur here from passage of instruments or implants during index surgery[7]. This 'red zone' has the highest concentration of stress during loading[25, 47, 54, 55]. Accordingly, this is the main area of a nail that researchers focus on when discussing nail damage and the potential for catastrophic failure.

The aim of this project was to establish an expert multi-disciplinary team to collaboratively achieve two tasks:

1) To define the language used to describe insertional damage to nails using standard metallurgical scientific terminology with definitions provided
2) To create a standardized system of reporting insertional damage to CMNs

This work is important as it provides a means for clarity in reporting, and in doing so would allow for comparisons and collaboration between international research groups in the future. The overarching goal is to gain a deeper understanding of insertional damage to CMNs and its role, if any, in contributing to fatigue failures in these implants.

6.2.3. Methods

An Australian expert advisory group consisting of two biomedical engineers and three orthopaedic surgeons collaborated to define the important aspects of CMN damage and how to report it. The scientific authorship team comprised of two post-doctoral biomedical engineers (AK, MP) with a combined experience of 40 years reporting on retrieved orthopaedic prostheses. The clinical members were three orthopaedic surgeons each with a strong academic history, an interest in biomaterials science and previous experience in industry consulting work for implant design (PY, PDA, AL).

Definitions were discussed and agreed upon of key terms. The Nail Damage Assessment System (NDAS) was developed by discussion and consensus agreement. Two demonstration cases of explanted nails were reported using the novel system and are presented for educational purposes. To calculate inter-observer agreement, six cases of nail explants were analysed independently by the two biomedical engineers involved in reporting. A third 'lay' staff member external to the retrieval laboratory who was unaware of the study and had no experience with cephalomedullary nails also completed the same six assessments being provided only with the NDAS blank form. All assessments were made independently with assessors blinded to each other's results.

Statistical analysis was conducted using SPSS (IBM SPSS Statistics, Version 29.0, Released 2023. Armonk, NY: IBM). Agreement between user assessments of individual sections was calculated using Cohen's kappa value and percentage agreement with corresponding p-values. The study was carried out in accordance with the World Medical Association Declaration of Helsinki. No external funding was received for the conduct of this project.

6.2.4. Results

6.2.4.1. Defining Insertional Nail Damage

The working group defined the term 'insertional damage' to comprise any form of damage to any part of a cephalomedullary nail that occurs at the time of implantation (index surgery). It was thought such a definition would be easily understood by readers and avoid confusion. Damage to areas other than the holes for fixation element passage is rare given these are not accessed during surgery, and reports of insertional damage to the screw or blade fixing the head have not been reported in the past. These were therefore not included in the reporting system.

6.2.4.2. Defining in vivo Nail damage

The working group also describes damage that may occur during typical loading of the construct *in vivo*. Defining this damage separately to that

occurring during insertion is important when understanding patterns of the marks seen. This *in vivo* loading causes fretting, however in severe cases of insertional damage it can be difficult to notice. Fretting is further defined below. Whilst it may seem difficult to separate insertional, in vivo and extraction-related damage from a single retrieval inspection, in vivo damage is primarily limited to fretting which is self-evident in its wear pattern and extraction damage tends to be a the threaded receiver proximally where the backslap is attached.

6.2.4.3. Holes, Bores and Apertures

All three terms have been used previously to describe the openings in the nail which allow for cross fixation into bone. The oblique hole(s) in the proximal part of the nail that accommodates the cephalic fixation device (screw or blade) is the focus of this paper. It extends from the lateral to the medial proximal aspect of the nail. Some nail designs have two proximal holes. The smaller holes for locking screws distally can also be damaged. Hole is synonymous with aperture (meaning opening), a term used in some studies. A bore is a cylindrical hole created within a material and is a term used to describe the internal aspect of the proximal hole. This system refers to these openings as holes for ease of understanding.

6.2.4.4. Proposed Nail Damage Assessment System (NDAS):

See Appendix I for the blank NDAS form with explanatory notes, and Appendix II to view two example cases with photographs and completed NDAS forms.

Background Information

A laboratory identifier number is included to facilitate linking of patient clinical details to the laboratory's dataset. The assessor's name is also included. The date of assessment is important as it gives context to the standard of equipment at the time of reporting. Insertion and removal date then allows time in situ to be calculated, which should be recorded in months to one decimal place.

Patient Details

The routine data collected includes patient identifiers, demographics (sex, age, height and weight) and the patient's activity level. Age is recorded as their age in years (whole number) on the day the implant was surgically retrieved (removal date). Weight and activity level are recorded to give a broad indication as to load cycles and magnitude as both play a biomechanical role in stress. Healthier patients and a younger age are risk factors for nail breakage[3]. Encouraging submitting surgeons to collect this information when retrieving implants is important.

Nail Descriptors

The implant details are collected so that they may be identified as potential risk factors in risk regressions in future studies. The manufacturer, nail name, length in mm, if it is a short or long nail, the neck-shaft angle and body diameter are included. Nail length was defined as long at 260mm or greater, and so-called 'intermediate' nails are labelled short. Missing nail information can usually be found online in cases where it is unclear, using the product code which can be seen printed on the nail proximal to the proximal hole, or placed as a sticker or digital entry in the patient's medical record.

Damage Report

Due to the percutaneous nature of nail insertion, insertional damage is typically confined to the areas accessible by instruments during surgery: the fixation holes and the locking mechanism for jig attachment. As implant damage is both most common and most relevant at the proximal nail aperture this was the focus of the reporting system development, though it could similarly be used to report on damage to distal locking hole(s) or applied to nails used in other anatomical regions.

The initial assessment is broad and focuses on the presence or absence of any markings on the sides of the nail or in the proximal hole. An inspection of the screw preventing sliding of the lag screw or blade (set screw) is

included based on the findings of the Klima paper[56]. Some nail designs such as the PFNA do not have a set screw or it may also not have been retrieved where it was present. In either case, not applicable is selected. Outer (lateral) rim damage is specifically mentioned as it is believed to carry importance in relation to crack initiation on the tensile side of the nail. This covers any damage to the shape of the outer rim. The explanatory notes and photographs in Appendix I demonstrate what is defined as the outer rim in two different nail designs. Whether the nail had broken is noted, along with whether the fracture plane passes through an area of damage (hole or outer rim). In broken nails the site of breakage is recorded as the proximal hole, nail body (shaft), distal hole or other, noting that more than one may apply.

Fracture and Damage Location:

The proximal hole damage location is split into four quadrants of superior, inferior, anterior and posterior. Four was decided as a simpler yet informative option compared to the six regions described by Klima[53]. Damage location is not specified as being related to internal (along the inside of the hole) or external (outer rim) markings, as when both are present the damage is in the same quadrant in the author's experience. Where the damage covers more than one quadrant, the quadrant with the more severe damage type or greater area of damage is listed, with secondary quadrants able to be described in the comments section.

Length of Proximal Hole Damage:

Length was numerically defined as not present (0), the outer rim only - meaning the lateral 5% or less (1), up to half of the length of the internal hole (2) or half or more of the hole length (3). This format was chosen so that the data is ordinal, meaning a higher number describes more damage length. A diagram is provided in the Appendix I explanatory notes for a visual representation of this measurement. This refers to all damage types considered together and represents the total length of visible damage of any kind.

Type and Severity of Damage:

Type of damage and damage severity are intrinsically linked and so it was decided that types of damage would be listed with definitions that outline the increasing severity between the types. The terms used are defined below with accompanying photomicrographs. Scratching, machining and gouging are believed in the author's view to be three increasing levels of contact between instrumentation and nail with increasing degrees of material removal from the implant. In the author's experience this is a spectrum of damage with more than one usually seen when damage is present. Fretting is considered a separate, *in vivo* entity as per below. Each of the four outcomes is binary, and one or more may be present.

Scratching

Superficial markings seen within the hole (Figure 6.1). These are thought to be caused by screw or blade insertion or incidental light drill contact and do not cause gross removal of material (see machining and gouging) but rather linear streaks in the anodized (coloured) surface. There is still anodized surface between the scratches (as opposed to machining).

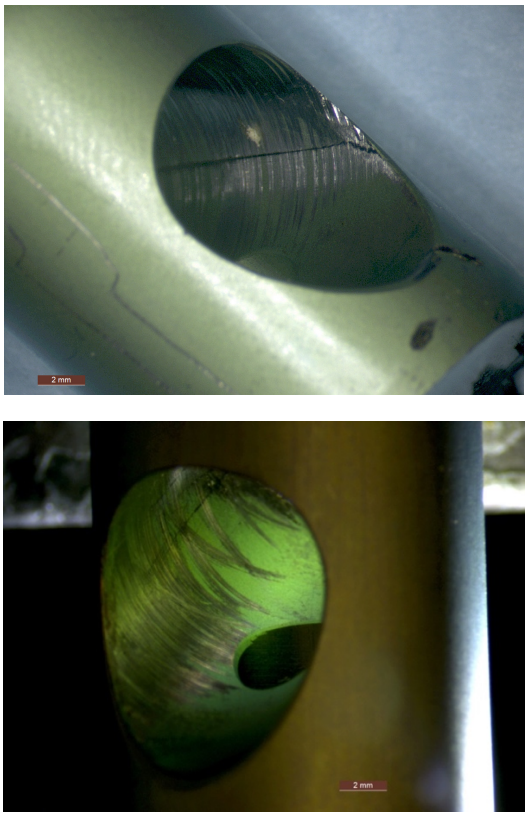


Figure 6.1 Examples of scratching

Machining

The creation of a smooth, machined surface (such as by reamer or drill) without leaving a step or visible trough (Figure 6.2). Being from a rotating tool it has a more uniform finish than scratching but doesn't have the volumetric loss of a gouge which would show a step at the edges. This is a

damage severity between scratching and gouging. It is not ‘boring’ of the hole to increase its diameter as only part of the hole is machined, not the entire inner diameter. Insertion of the head fixation element (screw or blade) is not thought to be able to cause machining.

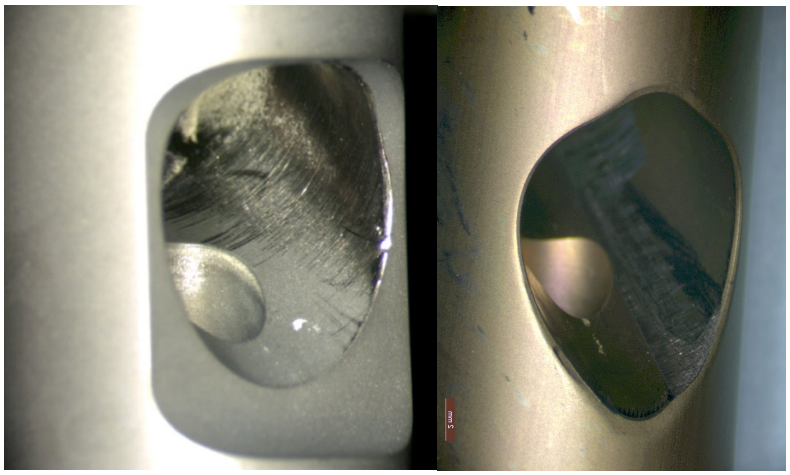


Figure 6.2 Examples of machining

A Gamma 3 (left) and PFNA (right). Note that in the Gamma 3 scratching is also seen in adjacent areas.

Gouge

A deep groove created that visibly removes an amount of material. It is a more severe form of damage than machining and shows a visible step when the length of damage is less than the full bore length (see arrows in Figure 6.3). Once more screw or blade insertion will not have the force required to cause this level of damage and it is believed to arise exclusively from reamer or drill use.

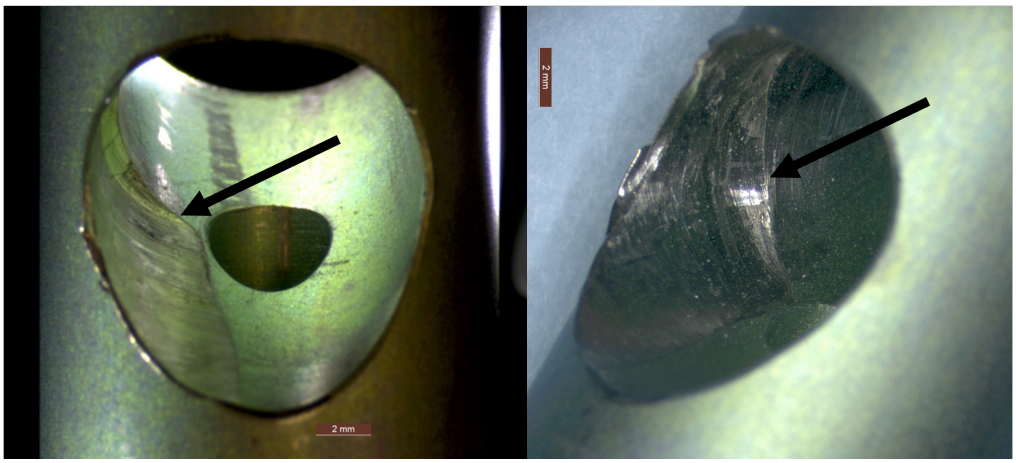


Figure 6.3 Examples of Gouging

A PFN aperture is shown. The black arrow points to the step where gouging ends halfway along the bore. Machining and scratching are seen beyond this.

Fretting

A pattern of *in vivo* abrasive and adhesive wear due to an oscillating motion of the screw or blade when under the physiological loads of gait. This is seen inside the proximal hole medially inferior and laterally superior as a result from the patient loading the construct during gait (Figure 6.4). The marks are more easily seen on the retrieved screw/blade if available. The asperities of the contacting surfaces may adhere or abrade, resulting in damage when movement occurs, both on the material and in the formation of wear debris[62]. Note that fretting is therefore a post-insertion phenomenon, and is not a type of insertional damage per se.



Figure 6.4 Example of Fretting

Fretting visible on a PFNA blade where it sat within the proximal hole.

Other Comments:

Free text notes can be used to describe non-aperture damage if it occurs, though this would be unusual as it is not contacted by hardware during routine insertion. This section can also be used for any other non-categorized information worth noting, such as a description of the fracture plane appearance (fractography results), metal fragmentation at the nail fracture and whether it relates or how it compares to any prior examined

cases evaluated prior. The authors also use this area to list which implants of the assembly were returned as not all may be available. The reports are accompanied by macroscopic and microscopic photography of the implants.

6.2.4.5. Implant Examination Method:

The authors recommend light stereomicroscopy in a laboratory setting for the evaluation of insertional nail damage. Macroscopic inspection by the naked eye, particularly during an operation, is unlikely to provide the detail required to use the NDAS. If a microscope was not accessible, then after the nail is washed and sterilized a macroscopic inspection ideally with some form of magnification such as loupes or a magnifying glass would be the next best approach.

6.2.4.6. Routine vs. Severe Damage:

Any damage, including mild forms of fretting and scratching, could theoretically reduce the fatigue strength of a nail. The authors postulate that superficial fretting from patient movement, or scratching (mild abrasions) from the passage of reamers or fixation elements could be considered somewhat routine and less hazardous. Indeed this was almost ubiquitous in the study by Klima with 95% of implants damaged in some way[53]. Biomechanically, gouging and outer rim damage would be considered more consequential but this has not been assessed *in vivo*.

6.2.4.7. Agreement:

There was no variability between the two biomedical engineers as outlined in Table 6.1. Agreement between the biomedical engineers and the lay person assessment is shown in Table 6.2.

Table 6.1 Agreement in Assessment Between Two Biomedical Engineers

Assessed Item	% Agreement	Kappa	Agreement	p-value
Any Nail Damage	100%	1.00	Perfect	0.01
Nail Fractured	100%	1.00	Perfect	0.01
Set Screw Damage	100%	1.00	Perfect	0.01
Outer Rim Damage	100%	1.00	Perfect	0.01
Fracture Plane passes through damaged area	100%	1.00	Perfect	0.01
Location of bore damage	100%	1.00	Perfect	0.01
Fracture location	100%	1.00	Perfect	0.01
Length of bore damage	100%	1.00	Perfect	0.01
Scratching	100%	1.00	Perfect	0.01
Machining	100%	1.00	Perfect	0.01
Gouging	100%	1.00	Perfect	0.01
Fretting in bore	100%	1.00	Perfect	0.01
Fretting on screw/blade	100%	1.00	Perfect	0.01

Table 6.2 Agreement in Between Engineers and Lay Staff Member

Assessed Item	% Agreement	Kappa	Agreement	p-value
Any Nail Damage	100%	1.00	Perfect	0.01
Nail Fractured	100%	1.00	Perfect	0.01
Set Screw Damage	83%	0.46	Weak	0.01
Outer Rim Damage	100%	1.00	Perfect	0.01
Fracture Plane passes through damaged area	100%	1.00	Perfect	0.01
Location of bore damage	83%	0.71	Moderate	0.02
Fracture location	100%	1.00	Perfect	0.01
Length of bore damage	83%	0.71	Moderate	0.02
Scratching	100%	1.00	Perfect	0.01
Machining	50%	0.00	None	1.00
Gouging	83%	0.71	Moderate	0.02
Fretting in bore	83%	0.71	Moderate	0.02
Fretting on screw/blade	100%	1.00	Perfect	0.01

6.2.5. Discussion

For the first time an intentionally designed and standardized method of analysing damage in retrieved cephalomedullary nails is presented. The Nail Damage Assessment System (NDAS) provides definitions of all terms, photographs to represent terminology used, a checklist for consistent reporting and example cases to aid future use by other investigators.

Whilst reporting of damage was more accurate by those with experience, interobserver variability with the lay person was still moderate to perfect in most areas, demonstrating that the system can be applied by a non-expert in the field. This is important for clinicians interested in assessing insertional damage who do not have the support of a retrieval laboratory or material scientists.

The importance of a standardized reporting system is the novel ability to compare datasets produced with its use in the future and the opportunity to immensely improve the current poor quality and consistency of reporting. A key strength of the study is the inclusion of two biomedical engineers with decades of experience in orthopaedic implant retrieval reporting. A study limitation is the small number of members of the chosen multi-disciplinary team, though this facilitated ease of dialogue between members when discussing and deciding upon terms to be used and NDAS structure.

Reporting on insertional damage to cephalomedullary nails is potentially a key to better understanding fatigue failures. Standardizing how it is reported is vital if progress is to be made in this area of research. It is hoped the NDAS facilitates comparative research between implant collections internationally with the aim of answering the unknowns in implant performance and notch sensitivity *in vivo*.

6.2.6. Appendix I

Nail Damage Assessment System (NDAS)

Standardizing Assessment of Insertional Damage to Cephalomedullary Nails

Lab Number:	**Assessor:**

Date of Inspection:	**Date of Insertion:**	**Date of Removal:**	**Time in Situ:** months

Patient Details

First Name:		**Surname:**			
Hospital URN:		**DOB:**			
Sex:	Male	Female	**Age (years, at removal):**		
Weight (kg):		**Height (m):**		**BMI (kg/m²):**	

Activity Level:	Bed Bound (Sedentary)	Lightly Active (Low Demand)	Moderately Active (Average)	Highly Active (Sports, Exercise)

Implant Details

Manufacturer: _____ **Nail name:** _____ **Length type:** Short / Long

Neck-Shaft Angle (CCD): _____ Degrees **Nail body diameter:** _____ mm **Nail Length:** _____ mm

Damage Report

Any nail damage:	YES	NO	**Set screw damage:**	N/A	YES	NO
Nail broken:	YES	NO	**Outer rim damage:** (see diagram)		YES	NO
Nail fracture plane passes through damaged area:				N/A (NOT BROKEN)	YES	NO

Location of proximal hole damage: (see diagram)	Superior	Anterior	Inferior	Posterior
Nail Breakage location: (circle all that apply)	Proximal Hole	Nail Body (Shaft)	Distal Hole	Other:

Length of proximal hole damage: (select one, see explanatory notes)

- 0 = no damage seen along the proximal hole
- 1 = Confined mainly to outer (lateral) rim, i.e. <5%
- 2 = Damage along the hole of <50% of hole length
- 3 = Damage along the hole of 50% or greater hole length

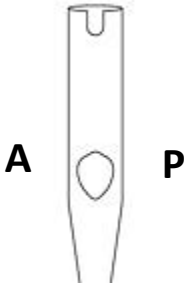
Type of hole damage: (select all that apply, see accompanying definitions in explanatory notes)

Scratching:	YES	NO	Machining:		YES	NO
Fretting in the bore:	YES	NO	Gouging:		YES	NO
Fretting on the screw/blade:				N/A (NOT AVAILABLE)	YES	NO

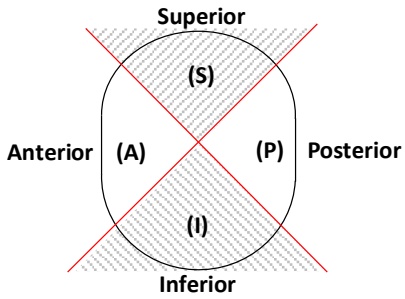
Other Comments:

Explanatory Notes

Location of Damage:



View from lateral aspect of the nail to define "A" (anterior) and "P" (posterior) aspects.
Note: this is for a LEFT nail and is reversed for a RIGHT. If unsure, the lateral hole opening is more distal in the nail than the medial opening.

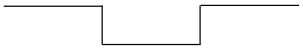


Quadrants of damage location demonstrated, viewed from lateral aspect of nail. Choose one or more.

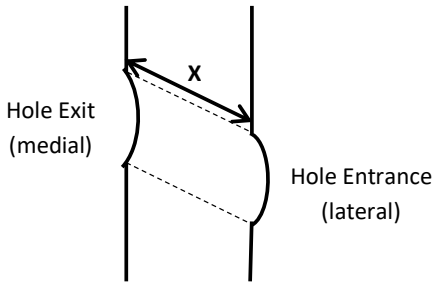
Damage Type: (select all that apply)

See publication for imagery.

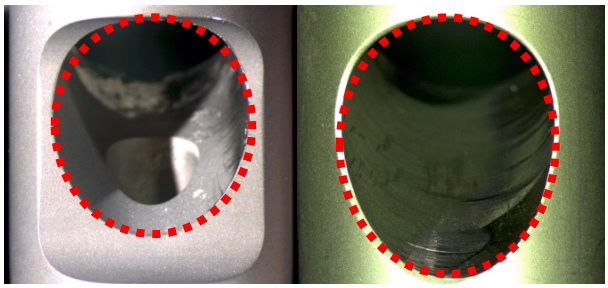
- **Scratching:** superficial linear marks (such as those caused by screw/blade insertion or superficial drill damage).
- **Fretting:** pattern of damage from in vivo loading of the proximal hole by the screw/blade (typically medially inferior and laterally superior). This may be easier to see on the corresponding changes on the retrieved screw/blade
- **Machining:** creation of new smooth surface (such as by drill), that has not left a groove, visible defect or step
- **Gouging**: deeper groove or trench created that removes material (such as deep drill damage):



Length of Damage (of any damage type, expressed as a percentage of hole length 'X' in diagram below):
0 = No damage seen along the proximal hole
1 = Confined mainly to outer (lateral) rim, i.e. <5%
2 = Damage inside hole of <50% of hole length
3 = Damage inside hole of 50% or greater of hole length



The outer rim in a Stryker Gamma3 (left) and DePuy Synthes PFN (right) nail

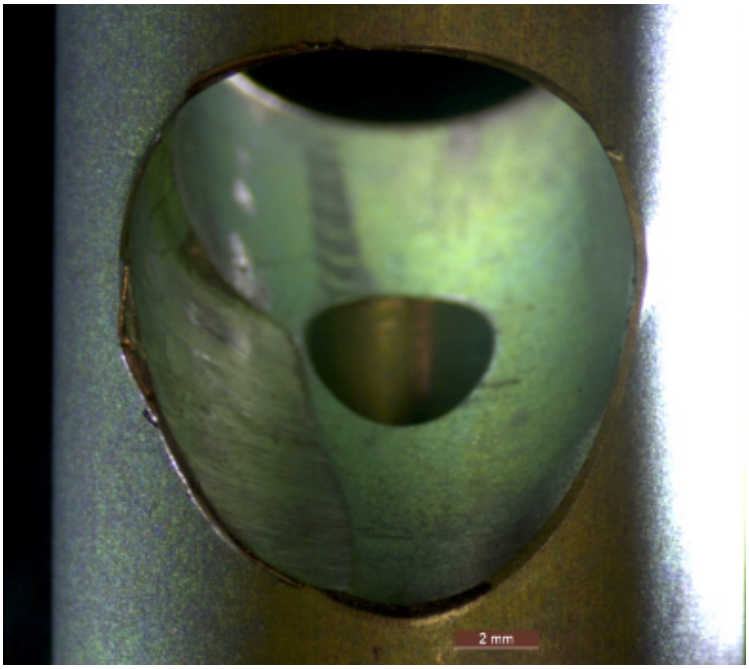


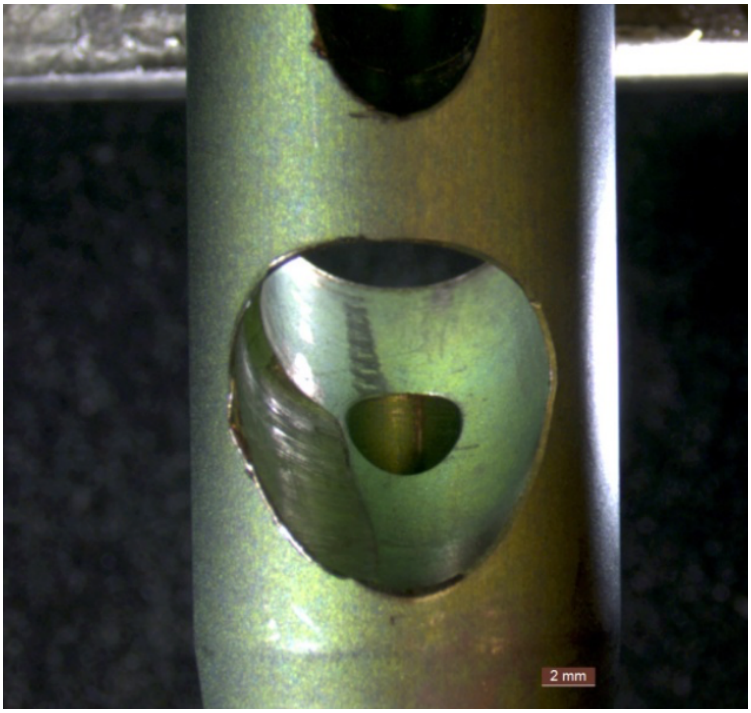
2

6.2.7. Appendix II

EXAMPLE CASE 1: Posterior Gouging in a Non-broken PFN

Mrs Jane Doe's PFN was retrieved during revision for symptomatic aseptic non union of a subtrochanteric fracture. The implant was in situ for 1 year. Imagery below.





1

EXAMPLE CASE 1: Posterior Gouging in a Non-broken PFN

Nail Damage Assessment System (NDAS)

Standardizing Assessment of Insertional Damage to Cephalomedullary Nails

Lab Number: 00001	**Assessor:** Dr Alan Kop

Date of Inspection:	**Date of Insertion:**	**Date of Removal:**	**Time in Situ:**
24 May 2002	14 Jan 2001	14 Jan 2002	12 months

Patient Details

First Name:	Jane		**Surname:**	Doe	
Hospital URN:	123456		**DOB:**	07 Feb 1922	
Sex:		Male	(Female)	**Age (years, at removal):**	80
Weight (kg):	60	**Height (m):**		1.54	**BMI (kg/m2):** 25.3

Activity Level:	Bed Bound (Sedentary)	(Lightly Active (Low Demand))	Moderately Active (Average)	Highly Active (Sports, Exercise)

Implant Details

Manufacturer: Synthes **Nail name:** PFN **Length type:** Short / (Long)

Neck-Shaft Angle (CCD): 125 Degrees **Nail body diameter:** 11 mm **Nail Length:** 365 mm

Damage Report

Any nail damage:	(YES)	NO	**Set screw damage:**	(N/A)	YES NO
Nail broken:	YES	(NO)	**Outer rim damage:** (see diagram)		(YES) NO
Nail fracture plane passes through damaged area:				(N/A) (NOT BROKEN)	YES NO

Location of proximal hole damage: (see diagram)	Superior	Anterior	Inferior	(Posterior)
Nail Breakage location: (circle all that apply)	Proximal Hole	Nail Body (Shaft)	Distal Hole	Other:

Length of proximal hole damage: (select one)

	0 = no damage seen along the proximal hole
	1 = Confined mainly to outer (lateral) rim, i.e. <5%
	2 = Damage along the hole of <50% of hole length
X	3 = Damage along the hole of 50% or greater hole length

Type of hole damage: (select all that apply, see accompanying definitions in explanatory notes)

Scratching:	(YES)	NO	Machining:	(YES)	NO
Fretting in the bore:	(YES)	NO	Gouging:	(YES)	NO
Fretting on the screw/blade:			(N/A) (NOT AVAILABLE)	YES	NO

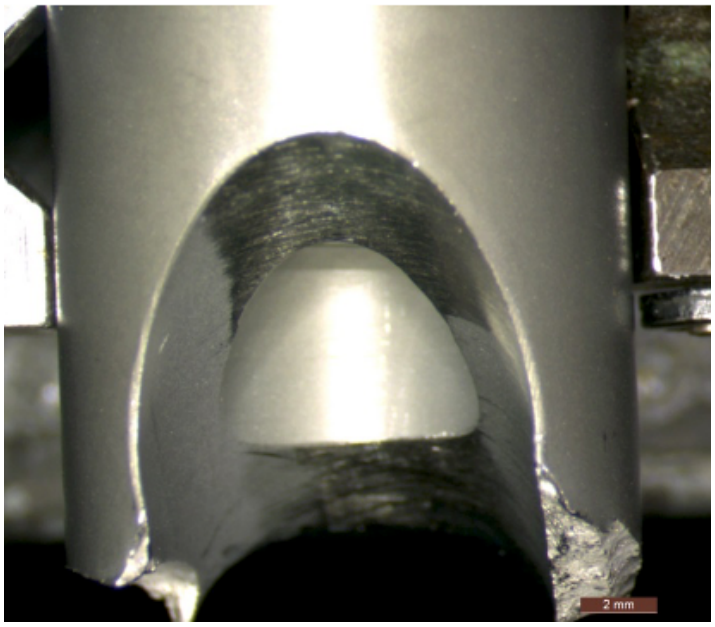
Other Comments:

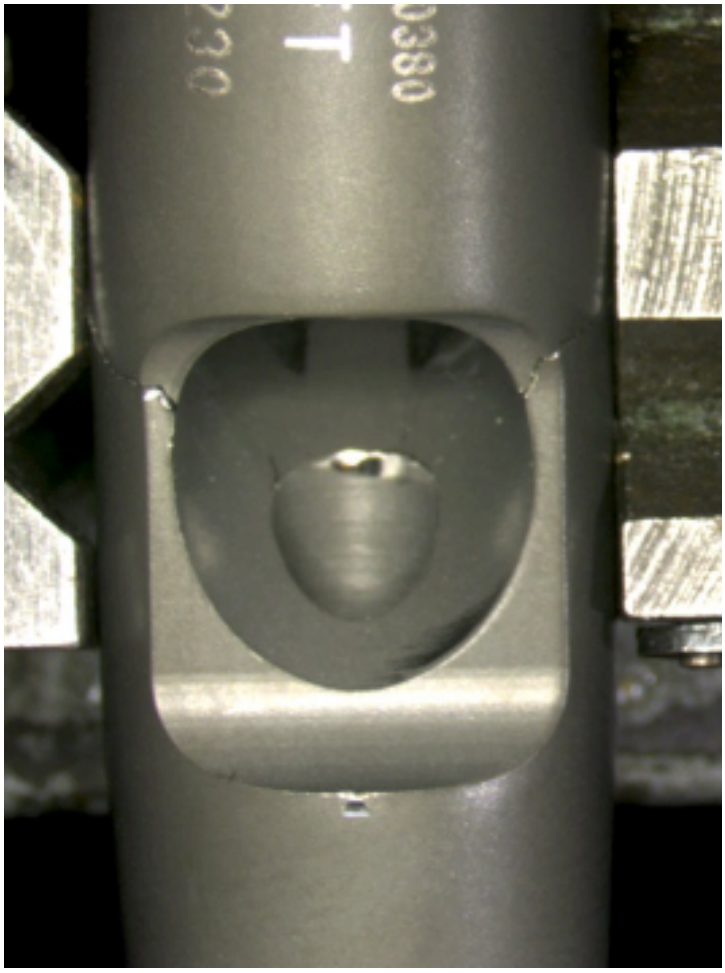
Significant material removal to posterior aspect of outer rim and along the proximal hole. Some inferior damage as well. Larger of the two proximal holes affected. Lag screws not retrieved so not available for analysis of corresponding fretting.

Some scratching along the medial part of the proximal hole internally, quite narrow and possibly resulting from contact by the guidewire.

EXAMPLE CASE 2: Superior Machining in a Broken Gamma 3

Mr Robert Smith's Gamma 3 was retrieved during revision for implant fatigue failure and aseptic non union of a reverse oblique proximal femur fracture 5 months after insertion. Imagery below.





3

EXAMPLE CASE 2: Superior Machining in a Broken Gamma 3

Nail Damage Assessment System (NDAS)

Standardizing Assessment of Insertional Damage to Cephalomedullary Nails

Lab Number: 00002		**Assessor:** Dr Moreica Pabbruwe	
Date of Inspection: 15 July 2024	**Date of Insertion:** 01 Jan 2024	**Date of Removal:** 01 Jun 2024	**Time in Situ:** 5 months

Patient Details

First Name:	Robert	**Surname:**	Smith		
Hospital URN:	123456	**DOB:**	02 Mar 1954		
Sex:	(Male)	Female	**Age (years, at removal):**	70	
Weight (kg):	85	**Height (m):**	1.75	**BMI (kg/m²):**	27.8
Activity Level:	Bed Bound (Sedentary)	Lightly Active (Low Demand)	(Moderately Active (Average))	Highly Active (Sports, Exercise)	

Implant Details

Manufacturer: Stryker **Nail name:** Gamma 3 **Length type:** Short / (Long)

Neck-Shaft Angle (CCD): 125 Degrees **Nail body diameter:** 12 mm **Nail Length:** 380 mm

Damage Report

Any nail damage:	(YES) NO	**Set screw damage:**	N/A	YES	(NO)
Nail broken:	(YES) NO	**Outer rim damage:** (see diagram)		YES	(NO)
Nail fracture plane passes through damaged area:			N/A (NOT BROKEN)	YES	(NO)

Location of proximal hole damage: (see diagram)	(Superior)	Anterior	Inferior	Posterior
Nail Breakage location: (circle all that apply)	(Proximal Hole)	Nail Body (Shaft)	Distal Hole	Other:

Length of proximal hole damage: (select one)

	0 = no damage seen along the proximal hole
	1 = Confined mainly to outer (lateral) rim, i.e. <5%
	2 = Damage along the hole of <50% of hole length
X	3 = Damage along the hole of 50% or greater hole length

Type of hole damage: (select all that apply, see accompanying definitions in explanatory notes)

Scratching:	(YES) NO	Machining:		(YES)	NO
Fretting in the bore:	YES (NO)	Gouging:		YES	(NO)
Fretting on the screw/blade:			N/A (NOT AVAILABLE)	YES	(NO)

Other Comments:
Both parts of fractured nail returned along with set screw, distal locking screws x2 and cephalic screw. Superior part of proximal hole entire length internally) contacted by instrumentation with corresponding machining (predominantly) and some scratching.
Nail fracture across mid hole laterally, which was remote to the location of the damage.

7. Chapter 7: The Presence of Damage in Retrieved Nails

7.1. Preface:

Having established a standardised reporting system, it was applied to one of the world's largest implant retrieval laboratories at CITRA. At CITRA there is a collection of both broken and intact nails available for reporting along with high quality assessment equipment and experienced medical scientists. The aim was to identify locations, patterns and severity of damage consistent across nails and explore any differences between those that had been returned for fatigue failure and those returned intact for other reasons.

7.2. Insertional Damage to Cephalomedullary Nails: A Review of 55 Broken and Intact Retrieved Nails

7.2.1. Abstract

7.2.1.1. Background:

Cephalomedullary nails may be damaged during passage of the guidewire, reamer and screw or blade at the time of index surgery. This has the potential to decrease the fatigue profile of the implant. This aim of this study was to apply a novel reporting framework, the Nail Damage Assessment System (NDAS), to a collection of retrieved nails to examine for damage patterns and their relationship to breakage.

7.2.1.2. Methods:

The NDAS was applied to a series of retrieved implants stored at the Centre for Implant and Technology Retrieval Analysis (CITRA) in Perth, Western Australia. Nails were inspected by two biomedical engineers using optical stereomicroscopy and reporting was done as per the NDAS framework.

7.2.1.3. Results:

Analysis of 32 broken and 23 intact cephalomedullary nails demonstrated that damage to the proximal hole during insertion was ubiquitous and often severe. All implants displayed some form of damage with more than 80% demonstrating more severe forms such as machining and gouging. Of the

broken nails, 44% had a fracture plane that passed through the damaged region of the nail. There were more left than right nails returned for analysis and more of the left nails were broken compared to right sided implants. Left nails were more likely to display damage in the anterior quadrant of the proximal hole, which was most obvious in the broken nail group.

7.2.1.4. Conclusion:

This retrieval study is the first of its kind to apply the NDAS to insertional damage analysis in CMNs, providing a level of data detail and volume that was not previously available. Surgeons should be aware that severe forms of insertional damage occur frequently, and insertion techniques should focus on avoiding undue tension or weight on targeting jigs and drill sleeves to avoid eccentric instrumentation of the proximal aperture.

7.2.2. Introduction

The role of insertional damage of cephalomedullary nails (CMNs) in fatigue failure has been suggested by several researchers and manufacturers alike[2, 38, 47, 52, 53]. Insertional damage refers to changes to the nail, in particular the proximal hole, as a result of contact with guidewires, drills and implants during index surgery[53]. Available data on the extent and frequency of insertional damage is limited to a handful of studies as outlined in a prior systematic review and meta-analysis by this authorship group. In the pooled meta-analysis, 68% of retrieved implants were found to have evidence of

insertional damage to some degree. A prior laboratory review of a case series by this authorship reported no damage to implants and the findings of the systematic review encouraged a further review of our own collection to more closely inspect for subtle areas of damage[13].

In response to low quality damage assessment reports published previously our research group proposed a standardized framework to guide future research, termed the Nail Damage Assessment System (NDAS). So far, this framework is yet to be applied to retrieved CMNs. Data that is of particular interest is a comparison between broken and intact nails retrieved to explore any relationships between patterns of damage that are specific to nail breakage that may be a clue to contributing factors. Klima inspected 109 CMNs under optical microscopy, of which only 12 had broken[53]. A comparison between broken and intact nails was not performed, however insertional damage was noted in over 95% of the implants overall suggesting the phenomenon may be more prevalent than previously thought.

The aim of this study was to apply the NDAS to a large collection of broken and intact nails in our implant retrieval laboratory, the Centre for Implant and Technology Retrieval Analysis (CITRA) in Perth, Western Australia to gain a deeper understanding of nail damage.

Our primary hypothesis was that most implants would have some form of damage present. The secondary hypotheses were that different implant designs, implant sides (right and left) and nail integrity (broken or intact) would influence the damage patterns seen. Implant design may influence damage patterns due to the strength of the different alloys used, the nail design and the design-specific instrumentation that allows passage of guidewires and drills with differing levels of tolerance. For example, Kim et. al. demonstrated a greater tolerance (lower precision) in targeting devices with a longer lever arm[63].

Sidedness was investigated as we hypothesized that the handedness (laterality) of the operative surgeon and the side of the patient together may play a role in the way the targeting arm and driver are held, in turn altering the passage of instrumentation through the proximal hole. Nail integrity status (broken or intact) was selected for subgroup analysis under the hypothesis that certain areas that are damaged would increase notch sensitivity more than others, contributing to failures. It was suspected that the anterior and posterior 'bridges' of the proximal hole would be most susceptible to notch sensitivity given they are narrow compared to damage in the superior or inferior portions of the nail which have thick sections of alloy adjacent to them. Inferior damage was hypothesized to be rare due to the obliquity of the guide sleeve placed on the tough lateral cortical bone,

resulting in the “drill walking” phenomenon where it would tend to be misdirected superiorly[53].

7.2.3. Methods

Locally explanted orthopaedic devices from all hospitals in the state of Western Australia are submitted for analysis in a central, government-funded and independent institution known as The Centre for Implant Technology and Retrieval Analysis (CITRA). Implants are collected, analysed and reported on, with over 10,000 retrieved prostheses in storage. CMNs are typically sent to CITRA in cases of implant breakage, premature failure, loss of fixation or infection.

The nails held by CITRA include the DePuy Synthes’ Proximal Femoral Nail (PFN), Proximal Femoral Nail Antirotation (PFNA) and TFN-Advanced (TFNA) nails (DePuy Synthes, Oberdorf, Switzerland) and Stryker’s Gamma 3 (G3) nail (Stryker, Mahwah, NJ, USA). The first CMN received by CITRA and therefore included in this analysis was a PFN explanted on the 14$^{th\ of}$ February 2003. The nails stored prior to this date were not CMNs and included Kuntscher nails and McLaughlin Hip Nail-Plates. All nails stored were inspected using macroscopic inspection and optical stereomicroscopy (Leitz MZ10; Leitz, Wetzlar, Germany) to identify damage to the proximal hole as seen in Figure 7.1.

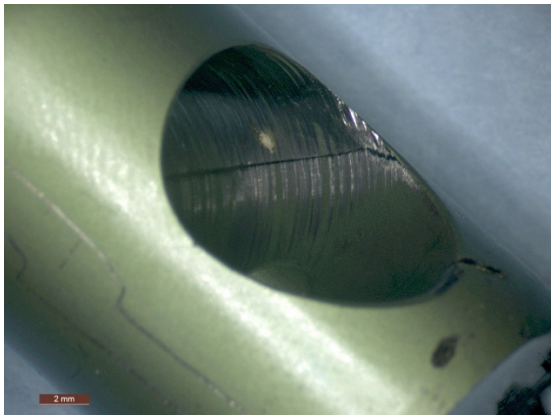


Figure 7.1 Damage inspected inside the proximal hole of a PFN

Data captured included nail model, integrity status (broken or intact), laterality (left or right), whether damage was present in any form and then subcategorized according to the NDAS framework of assessment. Within the NDAS framework nails were assessed for length of hole damage, rim damage, scratching, machining, gouging and fretting (both within proximal hole on the nail and on the screw or blade when available).

Statistical analysis was quantitative and was conducted using Microsoft Excel (Microsoft, Redmond, WA). The study was carried out in accordance with the World Medical Association Declaration of Helsinki. No external funding was received for the conduct of this project.

7.2.4. Results

A total of 55 nails were analysed for damage, with the distribution of broken and intact implants by nail design summarized in Table 7.1. Figure 7.2 summarizes the implants separated by laterality and breakage status.

Table 7.1 Distribution of Broken and Intact Nails

Integrity	G3	PFN	PFNA	TFNA	Total
Broken	6	7	8	11	32
Intact	2	10	6	5	23
Total	8	17	14	16	55

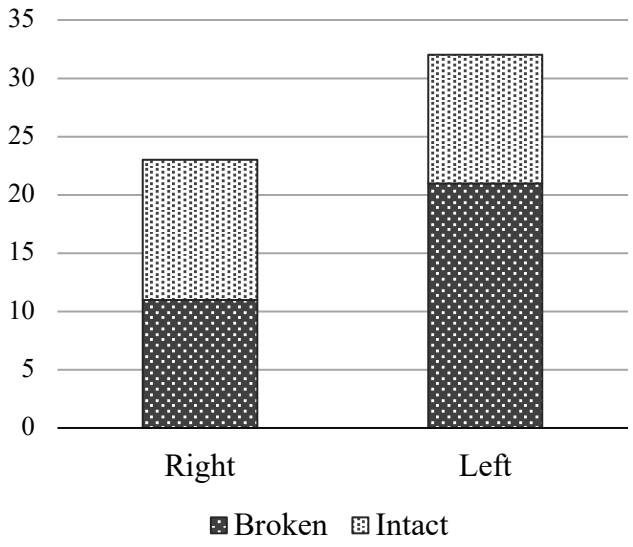


Figure 7.2 The number of right and left implants compared by nail integrity

All 55 nails displayed evidence of damage, with scratching and fretting seen in all cases. The remaining descriptors of nail damage are summarized in in Table 7.2 (compared by nail integrity) and Table 7.3 (compared by nail design).

Table 7.2 Damage Type Presence by Nail Integrity

	Broken			Intact			Overall		
Damage Type	**Yes**	**Total**	**%**	**Yes**	**Total**	**%**	**Yes**	**Total**	**%**
Rim Damage	31	32	97%	23	23	100%	54	55	98%
Scratching	32	32	100%	23	23	100%	55	55	100%
Machining	26	32	81%	22	23	96%	48	55	87%
Gouging	24	32	75%	23	23	100%	47	55	85%
Fretting (Hole)	32	32	100%	23	23	100%	55	55	100%
Fretting (Screw/Blade)*	30	30	100%	20	20	100%	50	50	100%

*3 intact and 2 broken implants did not have screws or blades submitted for analysis

Table 7.3 Damage Type Presence by Nail Type

	Gamma 3			PFN			PFNA			TFNA		
Damage Type	**Y**	**T**	**%**	**Y**	**T**	**%**	**Y**	**T**	**%**	**Y**	**T**	**%**
Rim Damage	8	8	100%	17	17	100%	13	14	93%	16	16	100%
Scratching	8	8	100%	17	17	100%	14	14	100%	16	16	100%
Machining	6	8	75%	15	17	88%	12	14	86%	15	16	94%
Gouging	6	8	75%	16	17	94%	12	14	86%	13	16	81%
Fretting (Hole)	8	8	100%	17	17	100%	14	14	100%	16	16	100%
Fretting (Screw/Blade)*	7	7	100%	14	14	100%	14	14	100%	15	15	100%
Any Damage Type	8	8	100%	17	17	100%	14	14	100%	16	16	100%

*1 Gamma 3, 1 TFNA and 3 PFN implants did not have screws or blades submitted for analysis.

Y: Yes; T: Total

The length of the damage along the inside of the proximal hole in all nails was greater than 50% of the proximal hole length (NDAS Grade 3/3). The results for damage location are presented in Figure 7.3. Of the 32 broken nails, 14 (44%) had a breakage plane that traversed an area of nail damage. This was further analysed by location in Figure 7.4. All breakages occurred at the level of the proximal aperture, with one implant simultaneously also demonstrating a distal screw hole breakage as well.

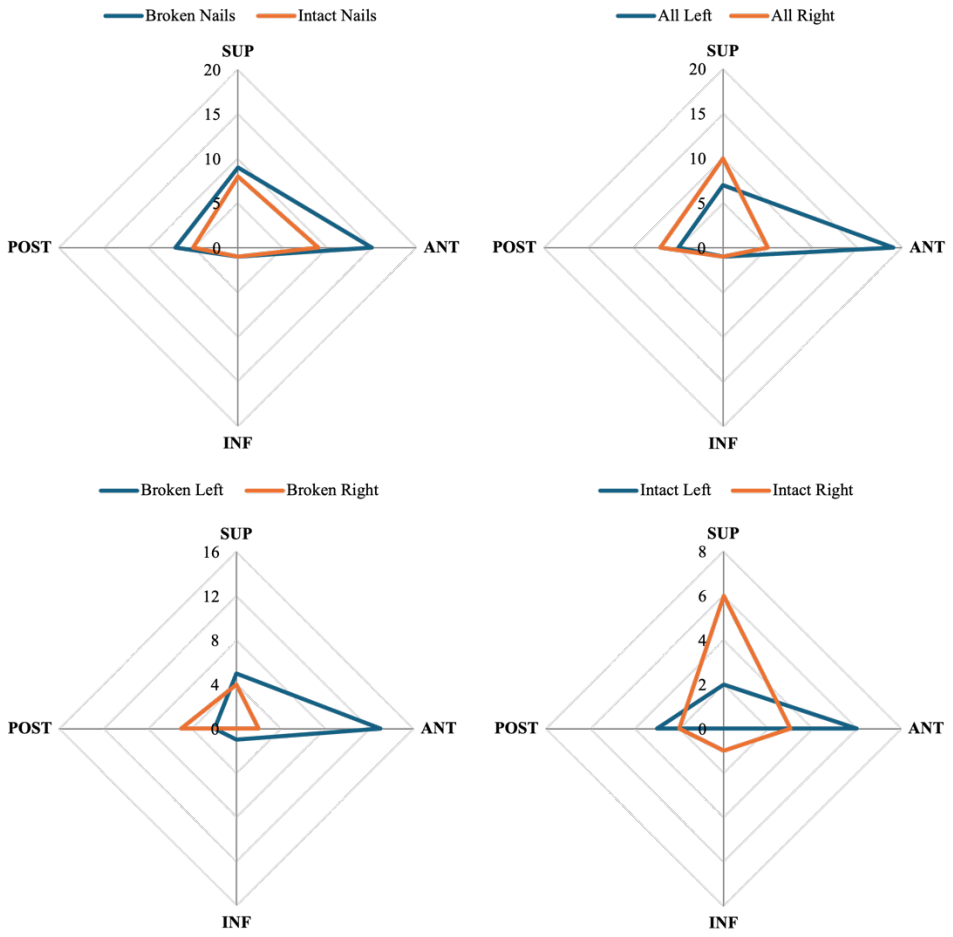


Figure 7.3 Comparison of damage location between different subgroups

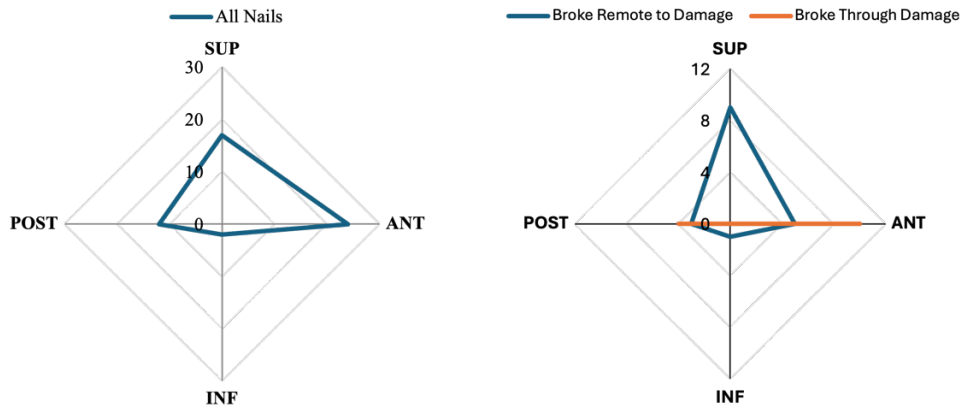


Figure 7.4 Damage location by breakage location.

7.2.5. Discussion

This study presents the most detailed body of evidence in the field of insertional damage found on retrieved CMNs to date. This research builds on the early efforts of the series published by Klima by providing more clarity in reporting, analysing greater numbers of broken nails and performing a deeper analysis of damage location and type[53].

In the 55 CMNs analysed there was a good spread between implant designs and of broken and intact devices (Table 7.1). When laterality was examined, there were 40% more left than right nails in the laboratory (32 vs. 23). When these were broken down by nail integrity status, left sided nails also demonstrated a greater proportion of broken nails (Figure 7.2). The reasons for this remain unclear, but as stated in the introduction may relate to handedness of surgeon and technique of handling the targeting arm and drill.

As hypothesized, damage in some form was found to be universal across all implants, with scratching and fretting found in each sample. This was comparable to the earlier study by Klima that found 95% of the nails in the collection were damaged[53]. More severe forms of damage such as machining and gouging were less frequently found (87% and 85% respectively). Contrary to our secondary hypothesis, these severe forms of damage were not more prevalent in the broken nails collection, with intact

nails demonstrating more frequent severe forms of damage such as gouging and rim damage (Table 7.2). The nail damage was similar across implant designs, although the Gamma 3 had slightly lower rates of machining and gouging than other designs (75% vs. 81-94%). This may be related to instrumentation or prosthesis design. Fretting was found in all proximal holes and all screws and blades, consistent with the patients ambulating.

Damage location radar maps provided a visual depiction of the propensity for damage to the four quadrants of the proximal hole in the NDAS framework (Figure 7.3). Across all the nails damage was most likely to be anterior followed by superior. There was a clear difference between left and right nails with left sided nails reporting 4-fold more anterior damage (19 vs. 5). Whilst we hypothesise an effect from surgeon handedness unfortunately this data was not captured by the retrieval database. Broken and intact nails displayed similar areas of damage. When divided by nail integrity, broken nails were less likely to have superior damage. Across all charts, left sided nails appeared to have more anterior damage, again possibly related to handling of the targeting arm and drill however this requires further exploration.

Our hypothesis of a lack of inferior quadrant damage was confirmed, with only 2 of the 55 nails demonstrating damage in that location. We believe this relates to the obliquity (aiming proximal-medial) of the drill sleeve,

encouraging an error of the guidewire to displace proximally rather than inferiorly as the drill can ‘walk’ along the bone before gaining purchase and entering the lateral cortex.

Only a minority (44%) of the broken nails had a fracture line that passed through the damaged area, suggesting there are perhaps more important predictors of nail breakage than insertional damage. When damage location was compared between nails that broke through the damaged area versus remote to it (Figure 7.4), the distribution of anterior and posterior damage did not differ from that in the general series. Of note CMNs break in the transverse plane (through the anterior and posterior parts of the hole), and coronal plane fractures (with fracture lines passing through the superior or inferior proximal hole surfaces) would be almost impossible. Breakages that occurred through a region of damage by default could then only be anterior or posterior.

Strengths of this study include the spread of broken and intact nails, assessment by highly qualified materials engineers and the use of the standardized NDAS reporting framework. The clear language used and outcomes reported will hopefully facilitate future dataset comparisons. A weakness of the study, due to the rare nature of implant breakages, is the relatively low overall number of implants able to be analysed. Future research could involve international collaboration to develop a larger

database of damage reports. Prospective clinical studies are not feasible to explore causality between damage and failure due to surgeons being blind to insertional damage which occurs inside the femur during surgery. Outside of retrieval studies, laboratory experiments with CMNs deliberately scored to replicate insertional damage could also examine the load to failure consequences of different types, severities and locations of damage.

This retrieval study is the first of its kind to apply a standardized approach to insertional damage analysis in CMNs, providing a level of data detail and volume that was not previously available. Surgeons should be aware that severe forms of insertional damage occur frequently, and insertion techniques should focus on avoiding undue tension or weight on targeting jigs and drill sleeves to avoid eccentric guidewire placement and subsequent reaming of the proximal aperture.

7.2.6. APPENDIX I.

Full List of Individual Nail Inspections

Part A: Intact Retrieved Nails Findings

Nail	Side	Rim Damage	Damage Location	Damage Length	Scratch	Machine	Gouge	Fretting (Hole)	Fretting (Screw or Blade)
G3	L	Y	POST	3	Y	Y	Y	Y	Y
G3	R	Y	SUP	3	Y	Y	Y	Y	Y
PFN	L	Y	ANT	3	Y	Y	Y	Y	Y
PFN	L	Y	ANT	3	Y	Y	Y	Y	NA
PFN	R	Y	ANT	3	Y	Y	Y	Y	NA
PFN	R	Y	ANT	3	Y	Y	Y	Y	Y
PFN	R	Y	INF	3	Y	Y	Y	Y	Y
PFN	R	Y	POST	3	Y	Y	Y	Y	NA
PFN	L	Y	POST	3	Y	Y	Y	Y	Y
PFN	R	Y	SUP	3	Y	Y	Y	Y	Y
PFN	R	Y	SUP	3	Y	Y	Y	Y	Y
PFN	L	Y	SUP	3	Y	Y	Y	Y	Y
PFNA	L	Y	ANT	3	Y	Y	Y	Y	Y
PFNA	L	Y	ANT	3	Y	Y	Y	Y	Y
PFNA	L	Y	SUP	3	Y	Y	Y	Y	Y
PFNA	R	Y	SUP	3	Y	Y	Y	Y	Y
PFNA	R	Y	SUP	3	Y	Y	Y	Y	Y
PFNA	R	Y	SUP	3	Y	Y	Y	Y	Y
TFNA	L	Y	ANT	3	Y	Y	Y	Y	Y
TFNA	L	Y	ANT	3	Y	Y	Y	Y	Y
TFNA	R	Y	ANT	3	Y	N	Y	Y	Y
TFNA	L	Y	POST	3	Y	Y	Y	Y	Y
TFNA	R	Y	POST	3	Y	Y	Y	Y	Y

NA: Screw or Blade Not Available for Analysis; G3: Gamma 3 (Stryker, Mahwah, NJ); PFN: Proximal Femoral Nail (DePuy Synthes, Raynham, MA, USA); PFNA: Proximal Femoral Nail Antirotation (DePuy Synthes, Raynham, MA, USA); TFNA: TFN-Advanced (DePuy Synthes, Raynham, MA, USA)

Part B: Broken Nails Findings:

Nail	Side	Break at Damage	Rim Damage	Damage Location	Damage Length	Scratch	Machine	Gouge	Fretting (Hole)	Fretting (Screw or Blade)
G3	L	Y	Y	ANT	3	Y	Y	N	Y	Y
G3	L	Y	Y	ANT	3	Y	Y	Y	Y	Y
G3	L	N	Y	ANT	3	Y	N	N	Y	Y
G3	R	N	Y	POST	3	Y	Y	Y	Y	NA
G3	L	N	Y	SUP	3	Y	N	Y	Y	Y
G3	L	N	Y	SUP	3	Y	Y	Y	Y	Y
PFN	L	Y	Y	ANT	3	Y	Y	Y	Y	Y
PFN	L	Y	Y	ANT	3	Y	Y	Y	Y	Y
PFN	L	Y	Y	ANT	3	Y	Y	Y	Y	Y
PFN	L	N	Y	INF	3	Y	Y	N	Y	Y
PFN	L	N	Y	POST	3	Y	N	Y	Y	Y
PFN	R	N	Y	SUP	3	Y	Y	Y	Y	Y
PFN	L	N	Y	SUP	3	Y	N	Y	Y	Y
PFNA	R	N	Y	ANT	3	Y	Y	Y	Y	Y
PFNA	L	N	Y	ANT	3	Y	N	Y	Y	Y
PFNA	L	N	Y	ANT	3	Y	Y	Y	Y	Y
PFNA	R	N	N	SUP	0	Y	Y	N	Y	Y
PFNA	L	N	Y	SUP	3	Y	y	Y	Y	Y
PFNA	R	N	Y	SUP	3	Y	Y	Y	Y	Y
PFNA	R	N	Y	SUP	3	Y	Y	Y	Y	Y
PFNA	L	N	Y	SUP	3	Y	N	N	Y	Y
TFNA	L	Y	Y	ANT	3	Y	Y	Y	Y	Y
TFNA	L	Y	Y	ANT	3	Y	Y	Y	Y	Y
TFNA	L	Y	Y	ANT	3	Y	Y	Y	Y	Y
TFNA	R	Y	Y	ANT	3	Y	Y	Y	Y	Y
TFNA	L	Y	Y	ANT	3	Y	Y	N	Y	Y
TFNA	L	N	Y	ANT	3	Y	Y	Y	Y	Y
TFNA	R	Y	Y	POST	3	Y	Y	N	Y	Y
TFNA	R	Y	Y	POST	3	Y	Y	Y	Y	Y
TFNA	L	Y	Y	POST	3	Y	Y	N	Y	NA
TFNA	R	Y	Y	POST	3	Y	Y	Y	Y	Y
TFNA	R	N	Y	POST	3	Y	Y	Y	Y	Y

Break at Damage: Nail fractured through an area of visible damage; NA: Screw or Blade Not Available for Analysis; G3: Gamma 3 (Stryker, Mahwah, NJ); PFN: Proximal Femoral Nail (DePuy Synthes, Raynham, MA, USA); PFNA: Proximal Femoral Nail Antirotation (DePuy Synthes, Raynham, MA, USA); TFNA: TFN-Advanced (DePuy Synthes, Raynham, MA, USA)

8. Chapter 8: General Discussion

8.1. Key Findings

8.1.1. Chapter 2: Defining Breakage Rates

For the first time the background rate and acceptable rates of breakage in cephalomedullary nails have been defined through formal meta analysis. Nail breakage was found to be rare overall with a median reported breakage rate of 0.6% across the studies included in the systematic review and meta-analysis. Pooling the results of all studies gave a breakage rate of 0.4% and 95% of studies had a breakage rate of 1.3% or less.

This 1.3% breakage rate was decided upon as the benchmark for fatigue performance of nails. The reported breakage rate consistently decreased as study design grew from small single centre retrospective reviews (0.96% mean breakage rate) to large scale retrospective database reviews (0.25%). This is important and in contrary to contemporary research strategy where generally larger studies are trusted to provide better data quality and accuracy of findings. It may be that the level of scrutiny and close follow-up applicable to small single-centre studies improves their ability to recognise and report failures.

8.1.2. Chapter 3: State-wide Data-Linked Breakage Rates

The overall rate of breakage across all the insertions captured (3,882 implants) was 0.5%, confirming that fatigue failures are rare events and this was in line with the previously published figures in Chapter 2.

In comparative analysis the TFNA appeared to have a higher rate of breakage (1.5%) compared to its predecessors the PFNA (0.2%) and PFN (0.7%) as well as its competitor the Gamma3 (0.6%). This difference was statistically significant in the TFNA versus PFNA comparison. Whilst hard to draw conclusions regarding the reasons for this, a change in metal alloy (Ti-Mo), change in prosthesis size (narrowing of the proximal nail) and change in implant design (additional features such as lateral relief cut and bump cut) may have played a role.

Before conclusions can be made about overall implant performance it is important to note that fatigue failure is one of several implant failure mechanisms and these findings in isolation do not confer overall superiority of one implant over another.

8.1.3. Chapter 4: Time to Failure: The Race to Union

The TFNA implant with a higher rate of breakage also demonstrated a shorter time to failure. The median time to breakage was 5.6 months for TFNA, 7.4 months for Gamma3, 14.7 months for PFNA and 17.0 months for PFN

implants. Early failures, defined as occurring before 4 months, were only seen in the TFNA group and accounted for 8 of the 21 TFNA failures.

The clinical relevance of this is that bony union is not expected to occur prior to this point in time, and implants need to be designed to at least withstand this period of loading prior to development of new bony support when fracture healing occurs.

8.1.4. Chapter 5: Prior Reporting of Insertional Damage

The systematic review and meta-analysis revealed few studies reporting on breakages that also reported on the presence or absence of damage on retrieved implants. Insertional damage is postulated as a risk factor for fatigue failures and was observed in 68% of implants in the pooled analysis. Several studies revealed close to 100% prevalence of iatrogenic damage on retrieved implants.

Further to this the quality of reporting on variables such as damage location, severity and type was lacking in all studies with no standardised reporting of findings. This was the impetus to subsequently develop a systematic approach to reporting of retrieval findings.

8.1.5. Chapter 6: The Nail Damage Assessment System (NDAS)

The NDAS was developed and defined as an assessment system by the authorship group. Inter-observer reliability was perfect (100%) between the two blinded biomedical engineers and moderate when compared with the results obtained by lay-person use of the NDAS.

A checklist, explanatory notes and example cases were also provided to assist other researchers in adopting the methodology. The goal is to encourage future researchers to adopt the same tool so that results from different publications are better able to be compared and combined in the future.

8.1.6. Chapter 7: The Presence of Damage in Retrieved Nails

Application of the NDAS to the CITRA repository of intact and broken cephalomedullary nails revealed novel insights into the patterns of iatrogenic damage inflicted during implant insertion.

Damage was ubiquitous with all implants demonstrating some form of marking. Over 80% of nails demonstrated more severe forms of damage. In the broken nail cohort, 44% had a fracture plane that passed through a damaged part of the nail. Location differences were observed for left and right nails with left nails more likely to display damage in the anterior quadrant of the proximal hole, which was most obvious in the broken nail group.

No significant differences were found between the broken and intact nails, contrary to the hypothesis of damage predisposing to failure and in fact there was more frequent damage observed in the intact group. The take home message from this is that iatrogenic damage is a regular phenomenon during standard nail insertion and is less likely to be the single major influence on fatigue failure and any contribution is in concert with other implant, patient, fracture and surgery-related risk factors.

8.2. Recommendations for Practice

Defining a benchmark of performance for breakage rates and then subsequently identifying a prosthesis that sits beyond that may suggest that the TFNA implant should be used cautiously. In scenarios where bony union is expected to be slow or delayed or if bone support is low in terms of fracture stability, alternative implants may provide both a lower rate of breakage and a longer time to breakage when it occurs. This gives the biological response of fracture healing more time to succeed prior to increasing its load sharing. Such cases include revision fixation, unstable fracture patterns and pathological lesions.

The finding of a high prevalence of iatrogenic implant damage during insertion also provides an opportunity for improvement. It is known that eccentric wire placement within the proximal locking hole can lead to wire, reamer or implant damage to the nail. It is possible that a more careful

insertion technique or a change to the workflow and instrumentation of insertion tools could reduce the damage that occurs. Perhaps if surgeons notice significant contact between the guidewire and/or reamer and the proximal hole of the nail, such as by failure to advance under pressured reaming and contact noise, they should consider removing and inspecting the nail for damage and replacing it with a new one if visibly damaged.

Though a link to failure can't be proven with the study design undertaken here, notch sensitivity from iatrogenic defects is well established in metallurgical studies. In this regard one research group has already found a reduction in breakages when a larger diameter guidewire was introduced that was less prone to eccentric placement within the bore[60].

Design changes such as narrowing the proximal implant at the area of highest stress concentration may have contributed to the more frequent and earlier failures identified for the TFNA implant and as such future designs should focus on ensuring that proximal aperture fatigue properties are not diminished.

From a laboratory research perspective, the use of the NDAS created here is recommended in any future research work on the topic of insertional nail damage so that consistency in reporting can allow greater collaboration and comparison between datasets globally. This field is still in its infancy.

8.3. Future work

Ideally, comparative studies looking at implant performance in the future should be prospectively performed and look at all causes of mechanical failures, not just fatigue in isolation. The same can be said of further work to define breakage rates, where a prospective study with participant recruitment and active follow-up of patients would give a more detailed and accurate estimate of true rates of breakage and time to failure. If this could incorporate censoring for death or non-failure removal of the implant this would further increase result validity.

Or perhaps what is needed is a national (or global) post-market surveillance program or registry that actively obtains data on the outcome of these implants in real world use. Robust systems have been created to monitor elective arthroplasty implants and perhaps could be similarly considered for the vulnerable population of trauma patients.

Low counts of failure precluded analysis of the relationship between nail diameter and time to failure in the TFNA group however this could be further examined in a larger cohort. The reason this is of interest specifically for that implant is the variable proximal nail width through nail diameter sizes. Inclusion of implants not used routinely in our region at the time of data collection would also be valuable, such as the InterTAN (Smith & Nephew), Gamma4 (Stryker) or Zimmer Natural Nail (Zimmer Biomet).

To further explore the relationship between iatrogenic damage and notch sensitivity, benchtop mechanical testing could be conducted with the aim of introducing reproducible proximal hole damage patterns across different implants and cyclically load them to failure in a laboratory. This could compare the susceptibility to failure between nails and determine which damage patterns, locations and severities are most influential (if any) in predisposing to failure. This could then guide implant and instrument design to reduce failure risk proactively.

Finally, in the field of retrieval science there have been novel technologies emerging that may add to our understanding of insertional damage. These include computed tomography of implants and more advanced microscopic techniques for three dimensional volumetric loss measurements.

8.4. Overall Conclusions

This thesis provides an in-depth exploration of the key issues in fatigue failures in cephalomedullary nailing. It is hoped that it can provide the foundations for many further meaningful research contributions that together can protect patients at risk of fatigue failure from avoidable harm in the future.

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