Implant Breakage in Proximal Femoral Nails: Design, Metallurgy and Failures

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Thesis Declaration

I, Dr Anton Lambers, certify that:

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Date: 23rd March 2020

Abstract

Background:

Hip fractures are common and cause significant morbidity and mortality and a substantial economic burden. Breakage of intra-medullary nails used in treating these fractures is rare and poorly understood. Little is known about usage and breakage patterns of these implants and implant manufacturers are regularly modifying designs, alloys and indication profiles. After a series of observed breakages with a relatively new implant (TFNA, DePuy Synthes, Oberdorf, Switzerland) in Western Australia, we investigated 3 commonly used proximal femoral nails. Outcomes and key clinical messages are detailed.

Methods:

Implant manufacturers were contacted in conjunction with a literature review to analyse modern proximal femoral nail design features and metallurgical modifications. Through multi-site collaboration, the data for Synthes nails use was collected across all public tertiary hospital trauma sites in our state over an 18 year period (2001 – 2018). This was supplemented by a clinical, radiographic and laboratory analysis of cases of TFNA breakage.

Results:

Proximal femoral nails are implants with significant design and metallurgy complexities that have evolved significantly in recent times. Local usage rates of proximal femoral nails, in particular short nails, have had steady incremental increases over the last 2 decades. In our cohort of TFNA breakages, patients were of normal BMI, aged 70-90 years and overall had a good reduction of what were mostly unstable fracture patterns. Implant analysis after retrieval demonstrated unique fracture characteristics not previously described.

Discussion:

This thesis explores the more recent history of nail development and regional usage patterns. A range of recent failures are assessed from both clinical and laboratory perspectives. This infomation should increase the level of awareness of the international orthopaedic community with regards to the features and mode of breakage of this novel TFNA implant. It highlights how changes to the nail design and/or alloy may have contributed to this series of observed breakages. We advise vigilant clinical and radiological surveillance of patients with unstable hip fracture patterns who undergo osteosynthesis with a TFNA. We recommend against considering revision of a broken TFNA to another TFNA implant, as this appears to have a higher than acceptable rate of re-breakage.

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Abbreviations

AO	Arbeitsgemeinschaft für Osteosynthesefragen
ANZHFR	Australia & New Zealand Hip Fracture Registry
AVN	Avascular Necrosis
BCC	Body-Centred Cubic
CITRA	Centre for Implant Technology and Retrieval Analysis
DHS	Dynamic Hip Screw
FEA	Finite Element Analysis
FHHS	Fremantle Hospital and Health Service
FSFHG	Fiona Stanley and Fremantle Hospitals Group
FSH	Fiona Stanley Hospital
G3N	Gamma 3 Nail
J&J	Johnson & Johnson
LGN	Long Gamma Nail
Nail	Intramedullary Nail Fixation Device
PFN	Proximal Femoral Nail
RPH	Royal Perth Hospital
RTP	Research Training Program
SCGH	Sir Charles Gairdner Hospital
SGN	Standard Gamma Nail

TAN	Ti-6Al-7Nb Titanium Alloy
TAV	Ti-6Al-4V Titanium Alloy
TGN	Trochanteric Gamma Nail
THR	Total Hip Replacement
TiMo	Ti-15Mo Titanium Alloy
UMRN	Unique Medical Record Number
UWA	The University of Western Australia
WA	Western Australia

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Laboratory analysis and technical assistance was provided by our centralized implant retrieval laboratory, the Centre for Implant Technology and Retrieval Analysis (CITRA) Western Australia as discussed in the methods and results chapters. In particular to thank Alan Kop and more recently Moreica Pabbruwe for their time, ideas and scientific contributions. Thanks for taking me into the lab and teaching me the science that underpins our practice.

This project also relied heavily on the co-operation of all public tertiary hospitals in the state of Western Australia – without such co-operation the comprehensive and complex data collection across sites would not have been possible. I would like to thank the heads of departments at each of the participating institutions for approving participation of their sites, namely Fiona Stanley Hospital (Mr. Andrew Mattin/Mr Gareth Prosser), Fremantle 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 passion of mine for a long time, but every minute spent on research is a minute taken away from you. Thanks for your unrelenting support and for believing in me in all endeavours.

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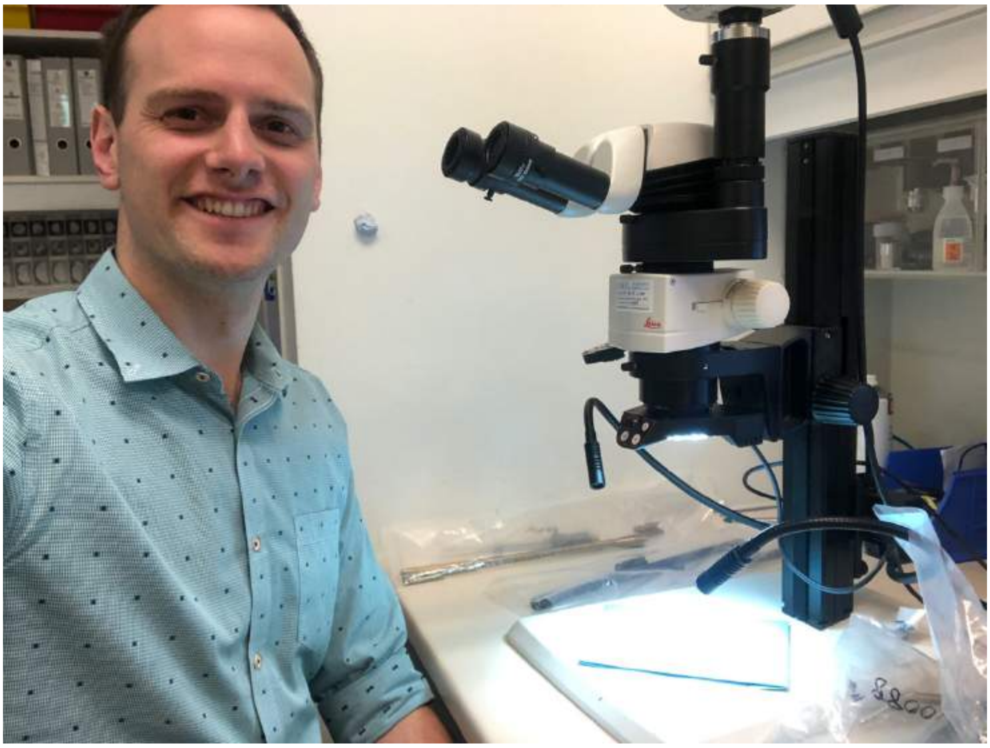

Authorship Declaration

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

- Australian Orthopaedic Association National Annual Scientific Meeting, Perth, 2018

- Australian Orthopaedic Association WA Branch Scientific Meeting, Perth, 2018. ***(Recipient: AOA WA Research Prize for Best Paper)***

- Australian Orthopaedic Association VIC Branch Scientific Meeting, Melbourne, 2019. ***(Runner-Up: AOA Vic Research Prize for Best Paper)***

- Oxford Orthopaedic Unit's Girdlestone Orthopaedic Society (Oxford Alumni) 56th Annual Scientific Meeting, Perth, 2018

This thesis also has been published as a co-authored publication:

Details of the work: *Implant Fracture Analysis of the TFNA Proximal Femoral Nail*. A. Lambers, P. Kop, B. Rieger, P. D'Alessandro, P. Yates J Bone Joint Surg Am. 2019;101:804-11, DOI: 10.2106/JBJS.18.00997, PMID: 31045668.
Location in thesis: Appendix A
Student contribution to work: lead investigator, conceptualisation, data curation, formal analysis, investigation, methodology, project

administration, visualisation, writing – original draft, writing – review & editing. The laboratory analysis was performed by CITRA laboratory scientists including photography (A. Kop).

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Date: 23rd March 2020

1. Introduction

This study examines the breakage of proximal femoral nails used for osteosynthesis of hip fractures, after a series of implant breakages were observed at the orthopaedic trauma units in Western Australia. This study was initiated to better understand the breakages on a scientific basis and investigate the patient and surgical characteristics of these cases to ascertain possible causes for failure.

1.1. Study Context

To understand the strengths, weaknesses and conduct of this state-based study it is important to understand the context of the study location. A summary of the geography, healthcare system and implant retrieval system of the state of Western Australia is described below.

1.1.1. Western Australian Healthcare

Western Australia (WA) is a state covering a third of Australia's landmass with a population of 2.5 million in 2018.[1] The capital city Perth lies on the southwest coast of the state (Figure 1.1), and contains approximately 80% of the state's population (2.1 million) in the greater metropolitan area.

Figure 1.1 Map of Australia

Location of Western Australia and its capital city Perth. Source: WorldAtlas.com.[2]

The 3 major 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 early 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). This is of importance in understanding the numbers – effectively ignoring the transition of work from FHHS to FSH, the data will be considered as three separate units with FSFHG representing an amalgamation of FHHS and FSH data. The vast majority of hip fractures in Western Australia are treated at these 3 sites.

The geographical isolation of WA from other states, in particular the population concentration in the city of Perth, which is far from neighbouring capital cities, results in an ideal population for cohort studies and data collection. The population is relatively immobile, particularly in the age group of hip fracture patients. From a software and healthcare perspective, the patient Unique Medical Record Number (UMRN) is the same at all public institutions. The medical imaging archiving systems and many healthcare software packages are uniform throughout the state and thus searching for a patient by UMRN effectively yields their imaging results from across the state. There is also a palpable culture of collegiality and 'small town feel' in Perth that means the orthopaedic units are closely linked, surgeons frequently communicate between each other on both a personal and professional level and interdepartmental research is practical and encouraged.

1.1.2. Implant Retrieval Centre (CITRA)

Explanted orthopaedic devices from all hospitals in WA are submitted for analysis in a central, government funded institution called the Centre for Implant Technology and Retrieval Analysis (CITRA). Based at the Medical Engineering and Physics Department of Royal Perth Hospital, implants are collected, analysed and reported on. The centre currently has more than 10,000 retrieved prostheses in storage. Although retrieval analysis is not mandatory all public hospitals actively participate and there is a strong local culture of sending broken implants (excluding smaller devices such as screw breakages) to the lab, primarily nails in trauma; and hip and knee replacements in arthroplasty.

1.2. Hip Fractures

1.2.1. Burden of Disease

Hip fractures are common, present significant morbidity for patients and are associated with a high economic burden. The overall healthcare costs per patient are approximately US$44,000 in the first 12 months following fracture, with an annual burden of nearly US$17 billion in the USA.[3] The number of fractures and their associated cost is anticipated to rise.[4]

Across Australia and New Zealand alone more than 25,000 people suffer a broken hip on an annual basis. The average age is 82, and these typically occur in a frail population.[5] The majority of patients are previously independently living with 72% of Australian hip fracture patients in 2019 presenting from home.[5] Not only is this a common problem but it also is a significant cause of morbidity and disability and many patients do not return to independent living. This further increases the associated costs of hip fractures to the greater community.

1.2.2. Fracture Configurations

Fracture configuration is an important consideration when understanding hip fractures and the surgical options for treatment. Fractures that result in a compromise to the blood supply of the femoral head place the femoral head at risk of avascular necrosis (AVN).[6] Many of these patterns of fractures, particularly in the elderly, are treated with some form of joint replacement.

The focus of this paper is intramedullary nails, which are used to treat hip fractures where the femoral head at low risk of AVN. These include trochanteric and subtrochanteric fractures as illustrated in Figure 1.2.

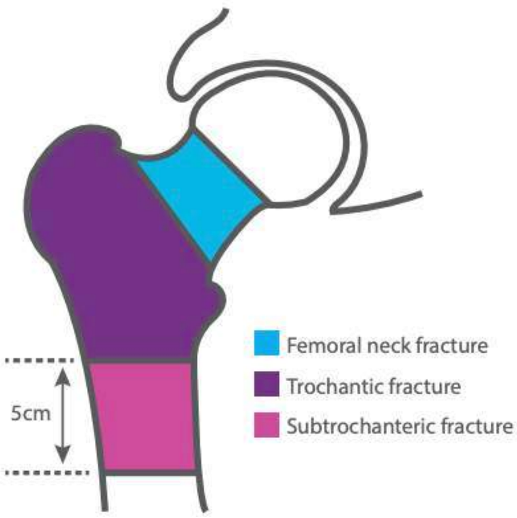

Figure 1.2 Zones of Hip Fracture

Figure outlining the anatomical areas of hip fractures which is relevant for operative decision making. Source: ANZHFR Annual Report 2019.[5]

In Australia over the past 4 years approximately 55% of fractures recorded in the Australian and New Zealand Hip Fracture Registry (ANZHFR) were extra-capsular fractures where fixation is the most common treatment, being either per- or inter-trochanteric ('trochanteric') fractures and subtrochanteric fractures.[5] The implants utilised for osteosynthesis must not only ensure the security of the fixation construct, but be easy to use and cost-effective given the high community prevalence of hip fractures.

1.2.3. Treatment Options

1.2.3.1. Non-operative Management

Less than 5% of Australian patients with a hip fracture are treated without surgery.[5] This is due to the significant pain that is caused by an untreated hip fracture which typically warrants operative intervention on its own, including patients who minimally ambulate. Non-operative management is typically considered either in patients so unwell that their life expectancy is estimated at only a few days and are palliated without surgery, or rarely in those whom a stable form of fracture has occurred, and the patient has already been ambulant without displacement. In the latter case patients may undergo weightbearing restrictions and regular clinical and radiographic surveillance.

1.2.3.2. Internal Fixation

In fracture patterns where the blood supply to the femoral head is preserved, the aim is to stabilise the fracture and allow it to heal.[7] Fixation is usually performed with either a nail (intramedullary rod fixation device) or plate/sliding screw combination (dynamic or sliding hip screw). An illustrated example of the two fixation methods is seen in Figure 1.3.

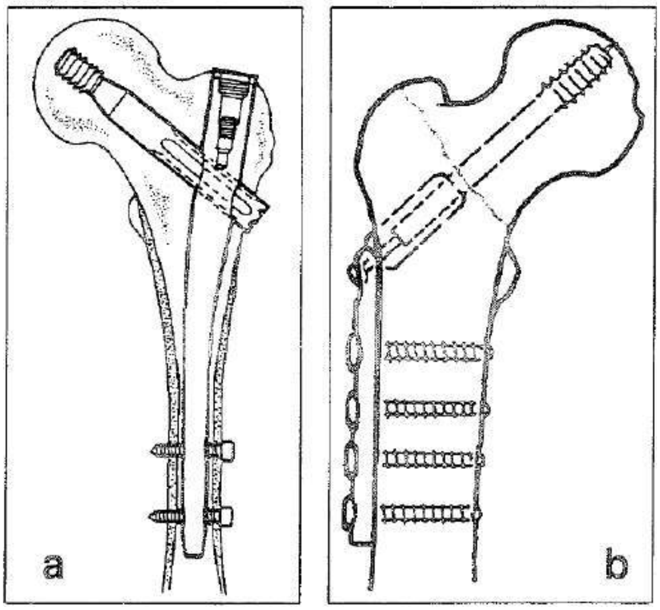

Figure 1.3 Nail and DHS

An intramedullary nail 'a' and a sliding hip screw (Dynamic Hip Screw (DHS)), 'b' is shown. Source: Kukla et. al.[8]

Adams et. al. in a prospective randomised controlled trial of intramedullary nail versus DHS in 400 UK patients did not find a significant difference in terms of re-operation rate.[9] Other studies have demonstrated some improvements with intramedullary nailing compared to open reduction and internal fixation such as reducing the size of the surgical incisions, post-operative wound infection rates and earlier patient mobilisation.[10,11]

1.2.3.3. Arthroplasty

The standard of care for displaced subcapital femoral neck fractures in the elderly is with joint replacement, either a hemiarthroplasty (femoral head replaced only) or total hip replacement (THR; femoral head and acetabulum) .[12,13] These are very occasionally employed in patients with trochanteric fractures either due to severe pre-existing osteoarthritis of the hip or in other cases due to bone loss or severe osteoporosis.[14-16] An example of both forms of treatment is shown below in Figure 1.4.

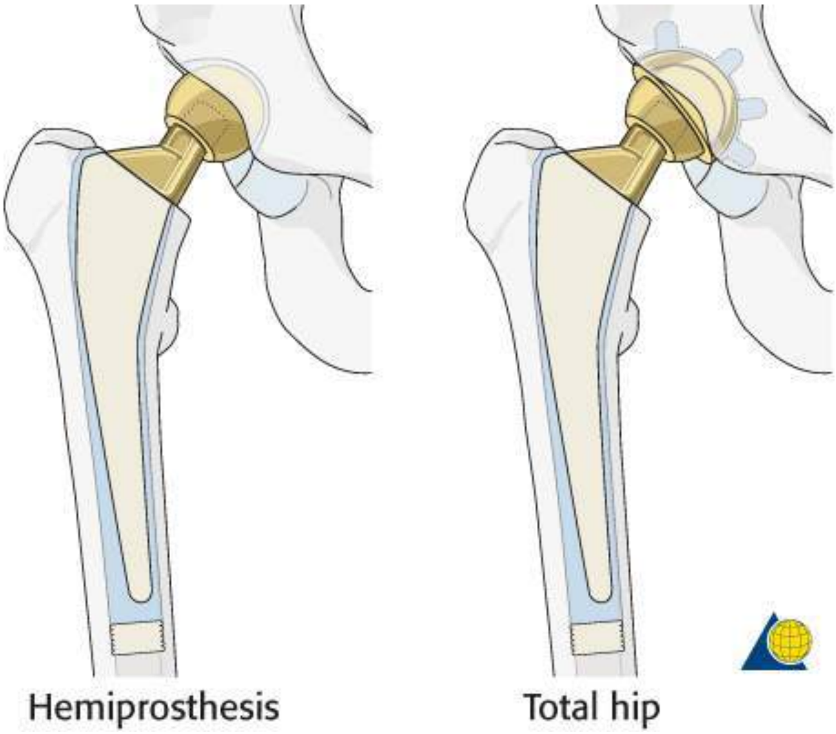

Figure 1.4 THR and Hemiarthroplasty

A half hip replacement (hemi arthroplasty) and total hip replacement is depicted. Source: AO Foundation Surgical Reference.[17]

1.3. Intramedullary Nails

Intramedullary nails, or simply nails as they are commonly referred to, have been used in orthopaedics for decades. This section will cover the history of nails, the relevant biomechanics of their design, usage patterns and conclude with some basic science regarding the metallurgy and material properties of nails.

1.3.1. A History of Nails

1.3.1.1. Küntscher and Pohl

Although attempts at intramedullary nailing have been documented as far back as the 16th century, it wasn't until relatively recently that pioneering of the field became successful.[18] Two names quintessential in any discussion on the topic of nails are Gerhard Küntscher and Ernst Pohl (Figure 1.5).[19,20] The first nail was developed by Küntscher and manufactured in Kiel, Germany by Pohl who was a metallurgic engineer and inventor who collaborated with Küntscher. The first implantation was said to be in a shipyard worker who suffered a femoral shaft fracture falling off a dock, making history when the first 'K-nail' was used in November 1939.[19]

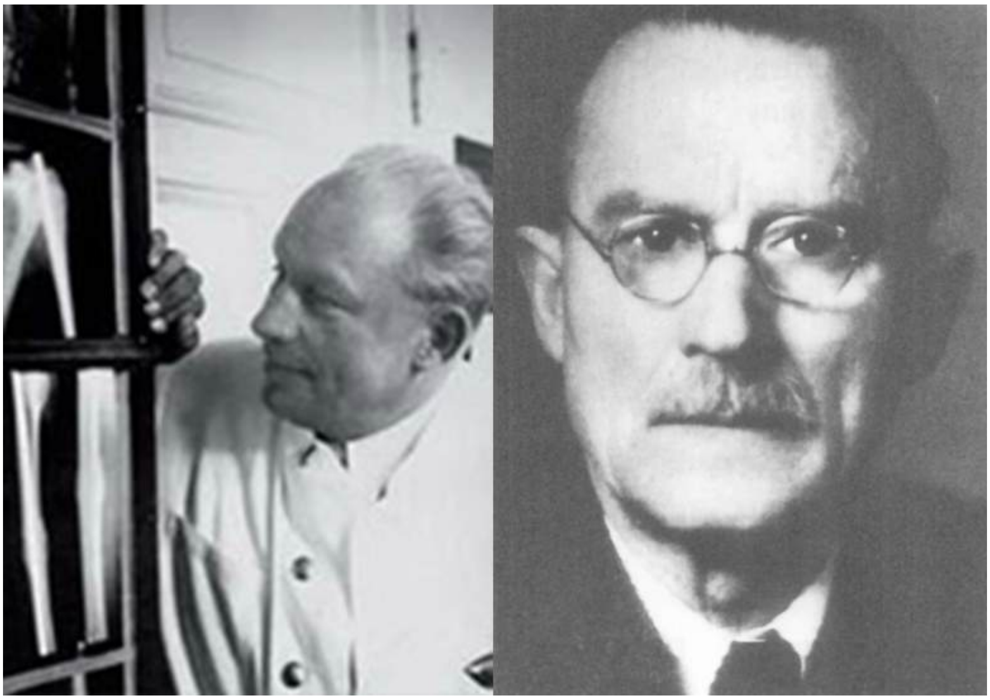

Figure 1.5 Gerhard Küntschner & Ernst Pohl

Pictures of Gerhard Küntschner (left) and Ernst Pohl (right). Sources: Bartoníček and www.kuentschersociety.org.[20,21]

Küntscher, in his original 1940 paper, detailed how intramedullary fixation boasted the significant advantages of lower infection rates (as the incision was remote to the fracture site and associated haematoma), improved healing, less cardiovascular compromise, fewer decubitus ulcers from immobility, traction or plaster and improved functional recovery.[22] Küntscher's seminal paper was later translated from German into English in 1968.[23] Prior to this innovation suffering a femoral shaft fracture meant an average of 2 months of in-hospital bed rest in a combination of plaster and traction.[24] In the early 20th century complications such as infection were so feared and often lethal that the renowned English surgeon and author Ernest William Hey Groves earnt the nickname "Septic Ernie" due to his early attempts with intramedullary nails.[24] Küntscher responded to initial concerns regarding damage to endosteal blood supply stating that its role is minimal compared to the large periosteal callus that is primarily responsible for bone healing.[23]

The intramedullary nailing method for stabilising femoral fractures became more popular subsequent to the ensuing World War II where Gerhard and other Finnish surgeons with whom he worked implanted nails, and surgeons in other countries cared for returned veterans discovering such 'daring' devices had been implanted when injured in duty.[18] Interest in nailing progressed further after the publication in Time magazine on March 12, 1945 called "The Amazing Thighbone" depicting radiographs of a returned soldier

(Figure 1.6) that still questioned the validity of nailing – *"Ingenious. Satisfactory?"*

Figure 1.6 The Amazing Thighbone

Radiographs included in the post-war article that spread word of intramedullary nailing. Source: Time Magazine.[24]

The story of Ernst Pohl is interesting in itself, in that he and Küntscher subsequently had a falling out after his former secretary started a separate company (Ortopedia) who produced similar nails and gave royalties only to Küntscher rather than Pohl.[25] Pohl's company, known as *Ernst Pohl, Kiel*, was bought by Austenal after his death in the 1960s. Austenal became Howmedica in the 1970s, and was acquired by Stryker in 1998.[25,26]

There were 2 designs between the Küntscher nail and modern nails over the following 40 years that came and went without significant uptake internationally. Küntscher used Ernst Pohl's Y-nail in the 1940s in Europe and in the United States Robert E. Zickel introduced a similar design in 1967 (Figure 1.7).[20,27]

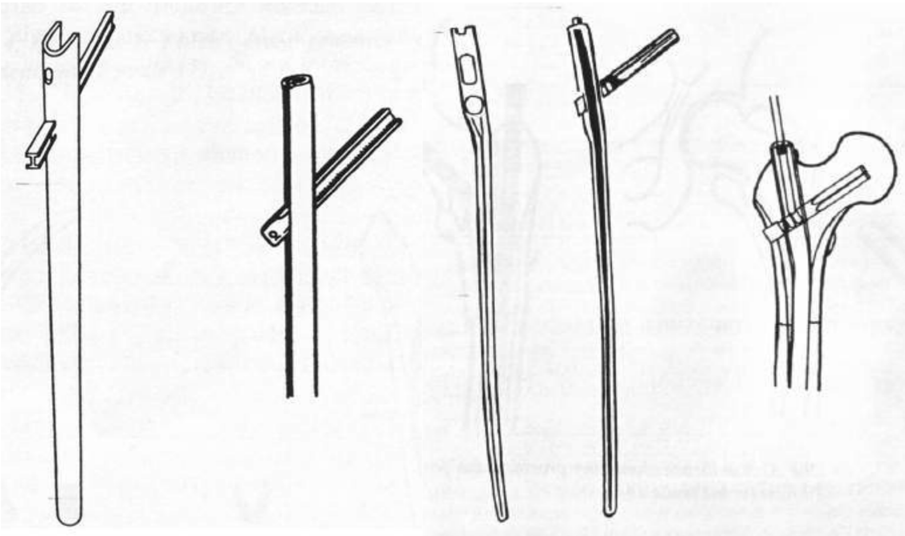

Figure 1.7 Y-Nail and Zickel Nail

Y-Nail developed by Pohl (left) and the Zickel Nail by Robert Zickel (right). Sources: Bartoníček and Pierach.[20,24]

It was in fact the Y-nail that saw the introduction of dedicated external jigs that facilitated cross locking of implants internally through percutaneous incisions (Figure 1.8).[20] Interestingly Pohl's other designs from the 1950s bear a remarkable resemblance even to newly developed implants such as the DePuy Synthes FNS (Femoral Neck System) (Figure 1.9).

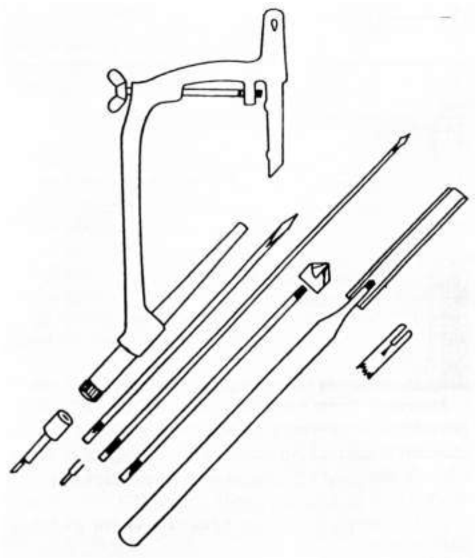

Figure 1.8 Y-Nail Insertion Instrumentation

Jigs designed for the Y-Nail by Ernst Pohl to allow percutaneous cross locking of implants. Source: Bartoníček.[20]

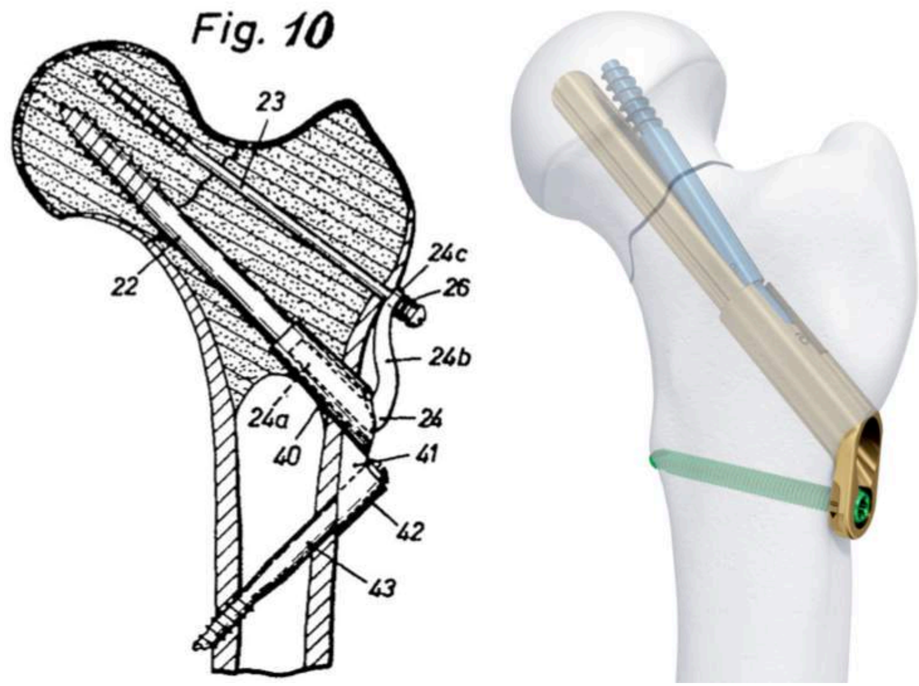

Figure 1.9 Pohl's Conjoined Double Screws

Resemblance of the DePuy Synthes FNS™ with Pohl's earlier designs of the 'Conjoined Double Screws' device. Sources: Bartoníček and Johnson & Johnson.[20,28]

1.3.1.2. Modern Nails

It wasn't until the 1980's that a nail designed for proximal femur fractures started to gain traction and widespread use. Simultaneously in 2 separate clinics Drs. Grosse, Kempf and Taglang at the Strasbourg Centre de Traumatologie et de l'Orthopedie (CTO) in France and Drs. Halder and Gill at Halifax in the United Kingdom developed the Standard Gamma Nail (SGN), launched in 1988 by Howmedica.[19] The long nail version, the Long Gamma Nail (LGN) was released in 1993. In 1997, nine years after the SGN was released, saw the second iteration released known as the Trochanteric Gamma Nail (TGN). This was followed by a titanium alloy version in 2001 called Gamma Ti and the Gamma nail that is currently in use, the Stryker Gamma 3 (G3N), in 2004.[29] Currently the G3N is manufactured and sold by Stryker Trauma, following the aforementioned acquisition of Howmedica-Osteonics in 1998, who produced the original Standard Gamma Nail.

From the 1990s, the peak body for the study of internal fracture fixation 'Arbeitsgemeinschaft für Osteosynthesefragen' (AO, translated from German as Association for the Study of Internal Fixation) began developing proximal femoral nails. The AO is a not-for-profit organisation and surgeon network that aims to improve knowledge through education and practice through innovation.[30] Synthes was created in 1960 as the trademark and financial body affiliated with the non-profit AO to manufacture and sell orthopaedic implants and formally purchased all remaining branding and intellectual property from AO in 2006. In 2012 the Johnson & Johnson (J&J) Medical

Devices umbrella acquired Synthes for US$19.7 billion merging it with DePuy which J&J had acquired in 1998. From then on the orthopaedic arm of J&J has been known as DePuy Synthes.

Synthes came into the proximal femoral nail market with the aptly named Proximal Femoral Nail (PFN) in the mid 1990s. Since then there have been multiple changes including to both design and alloy. It released the Trochanteric Fixation Nail (TFN) in 2002, Proximal Femoral Nail Anti-rotation (PFNA) in 2004 and more recently the Trochanteric Fixation Nail Advanced (TFN-A) in 2015.[31-34] The specific details of the changes will be discussed in the results as part of the project's investigation into design and metallurgy developments in modern proximal femoral nails.

The Synthes and Stryker nails are by far the most common nails used in Australia and will be the focus of this dissertation, though it is prudent to acknowledge the presence of other nail manufacturers that are currently in use locally, in particular the Smith and Nephew Trigen and Zimmer Affixus nail varieties.

1.3.2. Biomechanics and Design

Biomechanics and design are critical considerations in the evaluation and comparison of different variations of intramedullary nails. Nails were in fact developed with the intent of improving biomechanics of fracture fixation. As pointed out by Küntscher, "from the mechanical-biological point of view this method represents the most favourable of all fracture therapy. Pressure stress affects the entire fracture line while the nail absorbs all injurious pushing, shearing and bending stresses."[23] Küntscher recognised the mechanical advantages of nailing, in particular the shortened lever arm when compared to a side-plate construct, as depicted in Figure 1.10.

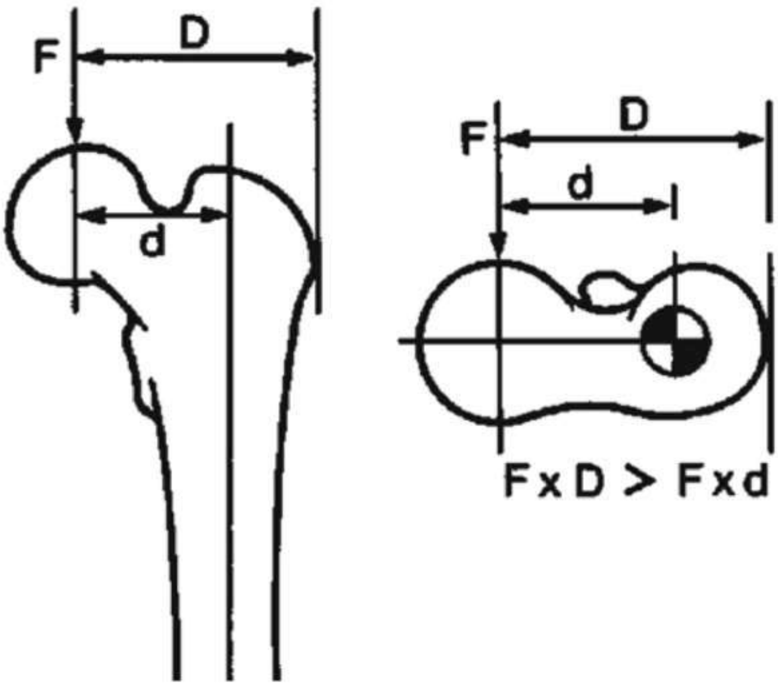

Figure 1.10 Shortened Lever Arm of Intramedullary Nails

Depiction of the advantageous reduced lever arm 'd' in intramedullary nails compared to side plating, 'D'. Source: Muller-Daniels, H.[19]

Structural properties including rigidity and strength are influenced not only by variables such as nail diameter or implant thickness, but also by geometry (shape). The cross-sectional appearance of the original Küntscher nail was V-shaped, but later developed into a cloverleaf pattern.[24] Studies have examined the torsional rigidity and strength of nails of various patterns demonstrating the differences between not only the various cross-sectional shapes of the nail (diamond, cloverleaf, round) but also the changes with the orientation of the nail.[35] In particular those with an open section ('slotted' nails) were shown to have a polar moment of inertia 50 times less than those without (so-called 'non-slotted' nails) leading to the conclusion from Allen at. al. in 1968 that open section structures should from thereafter be avoided.[35] The differences between some of the different early design patterns are illustrated in Figure 1.11.

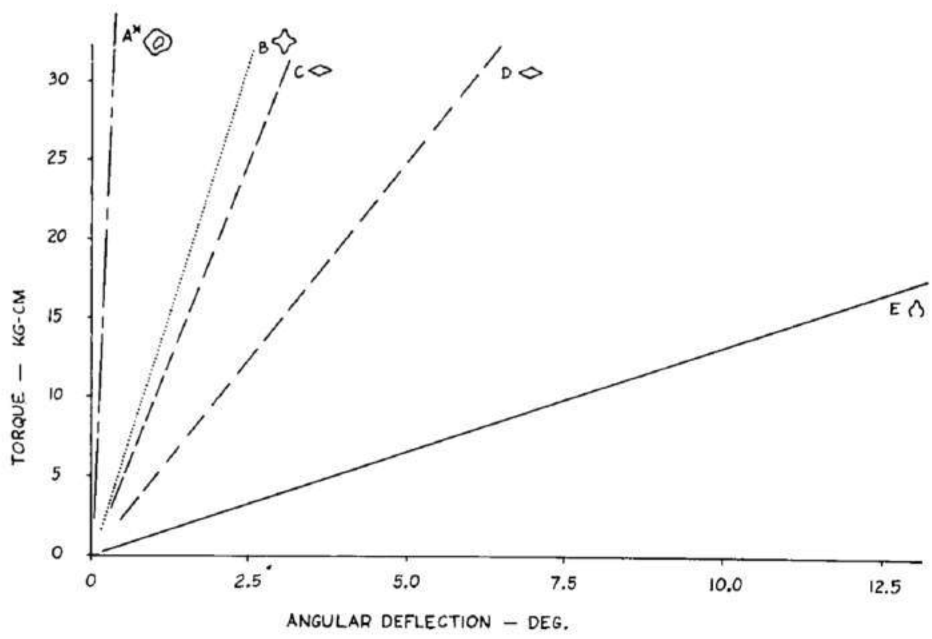

Figure 1.11 Angular Deflection of Nail Designs

Relative angular deflection of bone (the femur; A*), the Schneider nail (B), a short (C) and long (D) diamond nail and a cloverleaf nail (E). Source: Allen et. al.[35]

Over the subsequent 50 years not only did open section nails disappear but so too did the diamond, V-shaped and cloverleaf cross-sectional geometries, replaced primarily by closed section round nails with or without shallow longitudinal grooves running along their surface.

As will be discussed in the methods chapter, one aim of the project was to undertake a detailed analysis of modern design and alloy developments which is reported on in the results.

1.3.3. Usage Patterns

Intra-medullary nails are being used with increasing frequency in the management of proximal femoral fractures compared to sliding hip screws. This is reported anecdotally to be due to smaller incisions, less soft tissue dissection, shorter operating time and simplified instrumentation. The 2015 Annual Report from the National Hip Database in the UK showed that 10% of all hip fractures are treated with intra-medullary nailing, which had increased by 47% over the preceding 5 years.[36] At Fiona Stanley Hospital in Western Australia, intra-medullary nails were used in 38% of all hip fractures in 2018.[37]

On a population level the ANZHFR again provides insights, with reference to the anatomic fracture patterns depicted in Figure 1.2. Sliding hip screws from 2015 through to 2018 have consistently reduced in prevalence in the treatment of trochanteric hip fractures down from 42% to 28%, with intramedullary nailing increasing to be the most popular from 53% to 62%.[5] In subtrochanteric fractures nailing has long been preferred and remains the procedure chosen in more than 80% of cases.[5]

Cost is an additional factor to consider when deciding between sliding hip screws and intramedullary nails for trochanteric fractures where either would be appropriate. The 2020 Australian National Prosthesis List serves as a surrogate to approximate prosthesis cost to Australian hospitals.[38] A standard (235mm) DePuy Synthes TFNA nail will cost A$1,370 for the nail, up to A$472 for the lag screw if a blade is used, and A$143 for a distal locking screw for a total of A$1,985. A short (180mm) Stryker Gamma nail is priced at A$1,010 for the nail, A$199 for the lag screw and A$143 for a distal locking screw for a total of A$1,352. Use of an endcap is an additional A$96. Conversely, a DePuy Synthes Dynamic Hip Screw costs A$502 for the plate/barrel, A$215 for the lag screw and $80 for each of at least 2 cortical screws for a total of A$877, less than half the cost of a nail.

Little is known about the patterns of use of different brands of proximal femoral nails in terms of the different implants used and the changes in practice over time. After a literature search yielded no further information, a formal assessment of implant usage patterns on a state level became a secondary aim of this project.

1.3.4. Metallurgy and Mechanical Properties

Performance of implants in the human body depend on 2 key factors. These are biofunctionality (ability to achieve their function *in vivo* in the human body) and biocompatibility (ability to avoid stimulation of a foreign body response from the host).[39] An implant's biocompatibility then depends on the host response to the material and the materials response to the host (degradation in body fluid).[40] Whilst increased implant stiffness is generally considered an advantage, this is relative, as an implant far stiffer than the healing bone it protects will bear *too much* of the load through that bone, shielding the bone from a 'healthy' amount of stress required to encourage new bone formation in a phenomenon known as stress shielding.[41] Strength is important as implants may need to act supporting some bones for several months while healing occurs. Corrosion resistance is also critical due to the surrounding electrolyte dense fluid that human tissue contains.

The commonly used alloys in orthopaedic implants are stainless steel, cobalt-chromium and titanium-based alloys. Cobalt-chromium is not typically used for intramedullary nails. A brief summary of some of their mechanical properties is summarised in Table 1.1 below.

Table 1.1 Overview of Implant Alloys

Source: Bălţatu et. al.[41]

	Titanium	**Cobalt**	**Stainless Steel**
Stiffness	Low	Medium	High
Strength	High	Medium	Medium
Corrosion Resistance	High	Medium	Low
Biocompatibility	High	Medium	Low

1.3.4.1. Stainless Steel

Stainless steel was one of the earliest alloys used in orthopaedic implants and has been in use for over 100 years. The original Küntscher nails in the 1940s were manufactured in V2A steel.[23] V2A is named after 'Test Smelt 2 Austenite' (Versuchsschmelze 2 Austenit) and is known in the construction industry for its resistance to rust.[42] It is typically comprised of 18% chromium and 8% nickel, and is rarely used in modern implants nor even in construction. Modern stainless steel medical implants are made of 316L stainless steel.

The 300 series of stainless steel implants are nickel-based austenitic steels, with a minimum of 8% nickel required to an 18% chromium stainless steel to convert all the ferrite to austenite.[43] The 'L' of 316L stands for 'low,' distinguishing it from 316 stainless steel which has a higher carbon content – almost double from 0.03% to up to 0.08%. The lower carbon content of 316L makes it favourable for implantation due to its lower corrosion susceptibility when in contact with biological fluids.[40] The approximate alloy constituents, from high to low concentration, include:

- Iron (65%)
- Chromium (17%)
- Nickel (12%)
- Molybdenum (3%)
- Manganese (2%)
- Carbon, phosphorus, sulphur, silicon and nitrogen (<1%)

1.3.4.2. Titanium Alloys

Titanium is a relatively new alloy in the context of orthopaedic implants, yet it has undergone widespread uptake through a gamut of applications worldwide. Of particular interest in orthopaedics is the material property of having an elastic modulus closer to bone than many other metal alloys.[41] Up until recently orthopaedic applications of titanium alloys were typically either 'TAN' or 'TAV'. TAN (Ti-6Al-7Nb) contains 6% aluminium and 7% niobium and TAV (Ti-6Al-4V) contains 6% aluminium and 4% vanadium. TiMo (Ti-15Mo) has only recently been introduced into the intramedullary nailing alloy range and contains 15% molybdenum.[44] A summary of TAV, TAN and TiMo mechanical properties is seen in Table 1.2 alongside the same characteristics for 316L stainless steel and cortical bone.

Table 1.2 Mechanical Properties of Alloys

Sources: Adapted from Bălţatu et. al. & AZO Materials[40,41]

	Tensile Strength (MPa)	Yield Strength (MPa)	Elongation (%)	Elastic Modulus (GPa)
Ti-6Al-4V	900	850	8	112
Ti-6Al-7Nb	1000	900	8	105
Ti-15Mo	874	544	21	78
316L SS	1000	400	25	200
Bone (Cortical)	200	-	2	30

Also, it is important to note that titanium alloys exist in one or both of 2 distinct material phases, alpha and beta. The 2 crystalline states of titanium have different structures and as a result demonstrate different material properties.[45] The alpha crystalline phase is a low-temperature, close-packed hexagonal crystal structure. The beta phase is conversely a high-temperature bcc (body-centred cubic) crystalline lattice. The two patterns are depicted in Figure 1.12. The beta transus temperature (when alpha phase undergoes allotropic transformation to beta) is 880°C. The outcome of alloying titanium therefore relies significantly on the temperature and can produce alpha, beta or alpha-beta microstructures. This relatively unpredictable process is further influenced by the alloying of additional metals (substituting).[45] Most medical applications of titanium alloys exist in an alpha-beta phase (mixed).

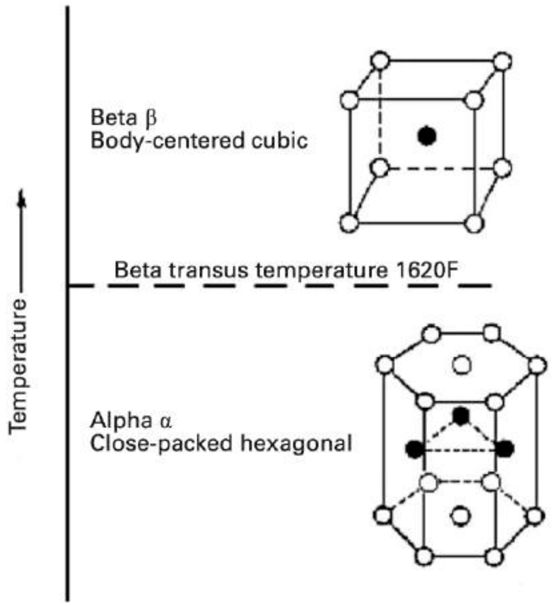

Figure 1.12 Alpha and Beta Titanium Phases

The 2 crystalline phases of titanium alloys. Source: Froes et. al. [45]

1.4. Failure of Intramedullary Nails

1.4.1. Common Complications

Implant-related complications include peri-implant femoral shaft fracture, loss of fixation, cut-out, avascular necrosis, non-union, infection and pain.

1.4.2. Implant Breakage

Nail breakage is a rare complication.[46] Risk factors for nail breakage determined by Johnson et. al. include younger age at time of initial injury, fracture instability, inadequate reduction at index surgery, subtrochanteric or pathological fractures, poor rehabilitation programs and delayed bony union.[47]

Reduction at time of index surgery is important for implant breakage as anatomical reduction improves construct stability and reduces fracture healing time, thereby reducing load borne by the implant. Baumgaertner et. al. created a reporting system for the reduction of proximal femoral fractures which is used in this paper, summarised in Table 1.3.

Table 1.3 Baumgaertner's Reduction Quality Assessment Tool

View	Good	Acceptable	Poor
Alignment: AP	Normal or slight valgus	Alignment or displacement criteria met but not both	Neither the alignment nor displacement criteria met
Alignment: Lateral	<20° angulation		
Displacement	<4mm		

The majority of implant fractures occur at the proximal aperture for the cervicocephalic screw or blade.[11] This is likely simply due to the fact that this is the region of greatest stress concentration, followed usually by the distal aperture for the distal locking screw.[48]

Implant breakages typically occur when the implant is cycled beyond its yield stress, usually occurring in slow to heal fractures where more cycles of loading occur before bony healing is eventually completed. If this does not occur in sufficient time, the excess load on the implant leads to eventual breakage thus creating the so called 'race' to union. It is known through FEA studies that for both stainless steel and titanium alloys stresses during single leg stance do reach levels where implant failure would be expected to occur if enough cycles occur before it heals.[48]

1.4.2.1. Segmental Breakage

Segmental breakage of any nail, meaning a nail that breaks into 3 distinct parts (2 separate breakage points), is also rare. There are no previously published cases of segmental nail breakage in proximal femur fractures, however there are three following femoral shaft fractures.[49-51] None of these three patients reported secondary trauma or infection, and all of the breakages occurred through the shaft of the prosthesis rather than at the screw aperture interface.

Mazzini et al described a case of a 31-year-old male who sustained an open fracture of the femoral shaft which was treated with a Küntscher femoral nail.[49] The patient had distal screw breakage four months post-operatively and re-presented seven months after surgery with a segmental nail breakage in the distal third. This was treated with exchange nailing and bone graft. Kouvidis et al reported a case of a Grosse Kempf femoral nail (Howmedica, Rutherford, NJ, U.S.A.) in a 35-year-old male who suffered a segmental nail breakage at 11 months post-operatively and was treated with exchange nailing.[50] Sivananthan et al reported a case of a segmental femoral intramedullary nail breakage in a Targon nail (Braun, Aesculap, Tuttlingen, Germany).[51]

2. Study hypothesis and aims

This investigation was in response to a sudden increase in observed nail breakage frequency in our region. It sought to comprehensively examine nail design changes, patterns of use, patient factors and importantly perform a laboratory analysis on the broken nails to investigate possible causes of failure.

2.1. Hypothesis

This study was based on the following hypotheses:

- Significant changes to both implant metallurgy and design may explain the increased reported number of breakages
- There would be a large shift in use from the DePuy Synthes PFNA to the novel TNFA
- Patients would be young, slim and active as per the findings of Johnson et al.[47]
- Laboratory investigation may provide insight into the patterns of damage

2.2. Aims

The aim developed from our hypotheses was therefore to answer the following questions:

1. What are the changes to implant design and metallurgy in proximal femoral nails that have occurred over time that may contribute to nail breakage?
2. What are the patterns of DePuy Synthes proximal femoral nail usage in Western Australian tertiary public hospitals?
3. What are the patient and fracture characteristics in whom proximal femoral nail breakage occurs?
4. What are the findings when subjecting broken proximal femoral nails to laboratory analysis, including macroscopic and microscopic observations?

2.3. Thesis Outline

This thesis explores the key questions above relating to proximal femoral nails. It explores the history of nail design and processing and the usage patterns of specific nail types locally. This information is important to help understand the patient factors that may have contributed to breakage. Finally, an in-depth analysis is performed on the retrieved implants. We examined not only location and patterns of breakage but also conducted laboratory assays on the implants and to provide insights into theories for breakage.

3. Materials and methods

3.1. Ethics and Approvals

This project was reviewed by the UWA Master of Surgery selection panel and deemed suitable for a Masters level thesis. Ethics approval was obtained from Fiona Stanley Hospital as the principle investigation site in collaboration with their Quality Improvement Department.

Site specific approval at each individual public orthopaedic centre in Western Australia was obtained via written collaboration agreements with the Head of Department at each site. These were Fiona Stanley Hospital (Mr Andrew Mattin/Mr Gareth Prosser), Fremantle Hospital (Mr Omar Khorshid), Sir Charles Gardener Hospital (Prof Richard Carey Smith) and Royal Perth Hospital (Mr Alan Prosser).

A waiver of consent was obtained for review of files in accordance with Section 3.2.10 of the NHMRC National Statement on Ethical Conduct in Human Research.

3.2. Materials

3.2.1. Data Collection

In order to capture a comprehensive database of information, data was collected across multiple sources as outlined in Table 3.1.

Table 3.1 Data Sources

A summary of data sources for collection of patient and laboratory data

Source	Data Collected
Department of Health - Private Health Insurance Prosthesis List	Implant costs
Implant company websites and surgical technique guides	Implant design features, metallurgy, surgical technique
Literature review	Implant design features & metallurgy
CITRA (Centre for Implant Technology and Retrieval Analysis)	Retrieval analysis and breakage features
Hospital Theatre Database	Implant numbers, types, dates of insertion and patient URN
Hospital Records	Patient age, ASA, BMI, imaging, presenting history, operative records

3.3. Methods

Methods of addressing the 4 key research questions are outlined. Broadly, a multicentre investigation was set up across the only 3 public tertiary orthopaedic trauma hospitals in Western Australia in conjunction with our implant retrieval centre (CITRA). A highly concentrated and geographically isolated population facilitated effective data collection.

3.3.1. Changes to Design and Metallurgy of Proximal Femoral Nails

By accessing manufacturer implant technical information documents and websites, and conducting a comprehensive literature review, the designs and metallurgy of modern proximal femoral nails were assessed. This focussed on type of alloy, nail geometry and any unique design features or design changes across the iterations/generations of nails.

3.3.2. Patterns of Local Proximal Femoral Nail Usage

A review was conducted at all 3 current and one former public tertiary trauma hospitals in Western Australia between the dates of 1st January 2001 to 5th July 2017. The start date was selected as this was the first year the Synthes PFN was used in Western Australia (the oldest nail examined in the study). The end date was selected so that at the time of the study in early 2019 the nails implanted had appropriate clinical follow up time, along with sufficient time (18 months) for implant failure/breakage to occur.

After departmental agreement, the key hospital staff responsible for theatre record keeping were approached at each site. At the time of the study all sites utilised the identical Theatre Management System (TMS) software package owned by the Western Australian Department of Health. A key component of this software is the scanning of implants scanned prior to opening/insertion in theatre. Utilised implants are recorded electronically in the database, along with the following information

- Operation site
- Operation date
- ICD10 code
- Procedure title
- Item removal or insertion

- Implant manufacturer
- Item description (including nail code, diameter, length, neck-shaft angle)
- Patient Unique Medical Record Number (UMRN)

The search criteria were for Synthes (and more recently DePuy Synthes) intramedullary nails implanted during the investigation period. Synthes nails were selected as they were by far the most commonly used in our region and examining changes to Synthes nails over time was a primary aim of the study. Using the above information, it was possible to tabulate the Synthes nails used in public institutions for the 16-year period across the state.

3.3.3. Patient and Fracture Characteristics with Broken Nails

Patients assessed through clinical record and radiological examination were those who had suffered a breakage of the proximal femoral nail during the observed period 1st January 2001 to 5th January 2019. Patients were identified predominantly via the retrieval lab receipt of an implant (CITRA). A minority of patients presented during the time of the study with broken implants in situ and still able to bear weight who were treated non-operatively and thus patient characteristics were available, but not retrieval data.

Patient files were individually reviewed. Data retrieved from hospital medical records included age, gender, Body Mass Index (BMI), American Society of Anaesthesiolgy (ASA) grade, admission diagnosis, mechanism of injury, implant details, procedure details, treatment and time to failure. Plain radiographs were independently assessed by two authors (PY, AL) to both classify the original fracture pattern according to the AO/OTA Fracture Classification System and to qualitatively assess reduction according to Baumgaertner.[52] All operations were performed by qualified members of the respective Orthopaedic Departments; either the Orthopaedic Trauma Consultant, Trauma Fellow or Orthopaedic Registrar under supervision. The type of revision procedure, if performed, was also recorded along with implants used.

3.3.4. Laboratory Investigation of Retrieved Nails

Locally explanted orthopaedic devices from all hospitals are submitted for analysis in an independent government funded institution, the Centre for Implant Technology and Retrieval Analysis (CITRA). Implants are collected, analysed and reported on, with over 10,000 retrieved prostheses currently in storage. Though retrieval analysis is not mandatory, all public hospitals actively participate and there is a strong local culture of sending all broken implants (excluding smaller devices such as screw breakages) to the laboratory. The majority of retrieved implants are intramedullary nails and hip and knee replacements.

Analysis is performed on nails in the laboratory. Evaluation of the fractured nails included qualitative macroscopic analysis, optical stereomicroscopy (Leitz MZ10; Leitz, Wetzlar, Germany), microstructural and microhardness assessment (Leitz Orthoplan, Wurthemburg, Germany & Struers Durascan, Zweigniederlassung, Osterreich) and Scanning Electron Microscopy (SEM) of fracture surfaces (JEOL Neoscope, Japan). Retrieved nails of interest were examined in this thesis, being the Synthes PFN, PFNA and the DePuy Synthes TFNA. Reporting was available for the nails along with macroscopic and microscopic photography.

3.3.5. Statistical Analysis

Quantitative data was analysed using Microsoft Excel (Excel for Mac 2016, Microsoft Corporation, Washington, USA).

4. Results Chapter 1: Changes to Design and Metallurgy of Femoral Nails

A comprehensive review of both manufacturer and publicly available information was conducted spanning operative techniques, book chapters, basic science and historical narratives. Through this the implant design and materials used in current and previous generations of proximal femoral nails were examined in-depth as part of a root cause analysis for breakages of a new implant.

4.1. Stryker Nails

The sequence of evolution of the nails described in the introduction is depicted in Figure 4.1. The change from SGN to TGN in 1997 reduced nail length by 2cm to 180mm and the medial-lateral bend from 10° to 4°.[19,53] After 2001 the TGN was also available as a titanium alloy after being released as a stainless steel implant initially. From TGN to Gamma3 a significant change was the reduction of the proximal nail diameter from 17mm in the TGN to 15.5mm in the Gamma3. Reducing bone removal and minimising the invasiveness of approach were the key design targets of the development team in the Gamma3 inception and was said to remove up to 20% less trochanteric bone in its preparation as a result of the reduced diameter. The lag screw diameter was reduced to 10.5mm but changes to the design of the screw were added with the aim of overall reducing cut out despite the smaller diameter.[19]

The current generation Gamma3 nail is made of a TAV titanium alloy.

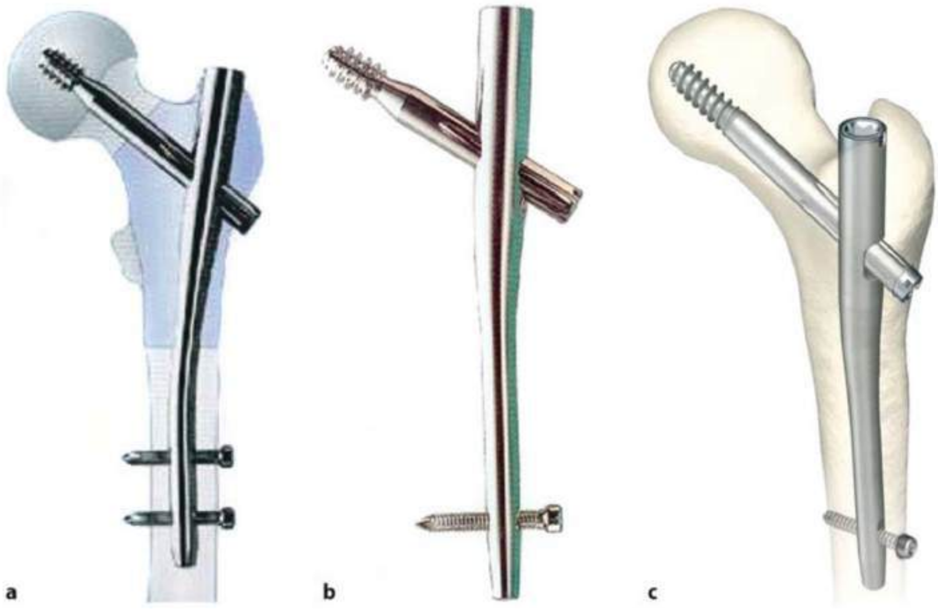

Figure 4.1 Generations of Gamma Nails

The progression of Gamma nails from the SGN ('a'), TGN ('b') to Gamma3 ('c'). Source: Müller-Daniels.[19]

The Gamma3 also introduced a Strength Improvement Groove (SIG) on the lateral aspect of the proximal aperture (Figure 4.2), shown in Finite Element Analysis (FEA) models to share the stress over a greater area, thereby reducing the maximal stress at any point (Figure 4.3).

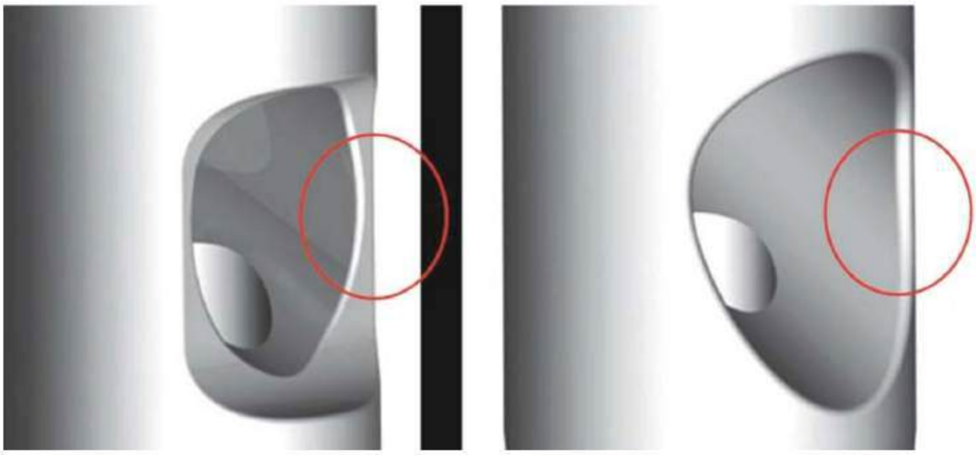

Figure 4.2 Gamma3 Strength Improvement Groove

The cut out on the lateral part of the aperture known as the SIG is shown here (left) compared to the appearance without a SIG (right), which blunts the edges. Source: Müller-Daniels.[19]

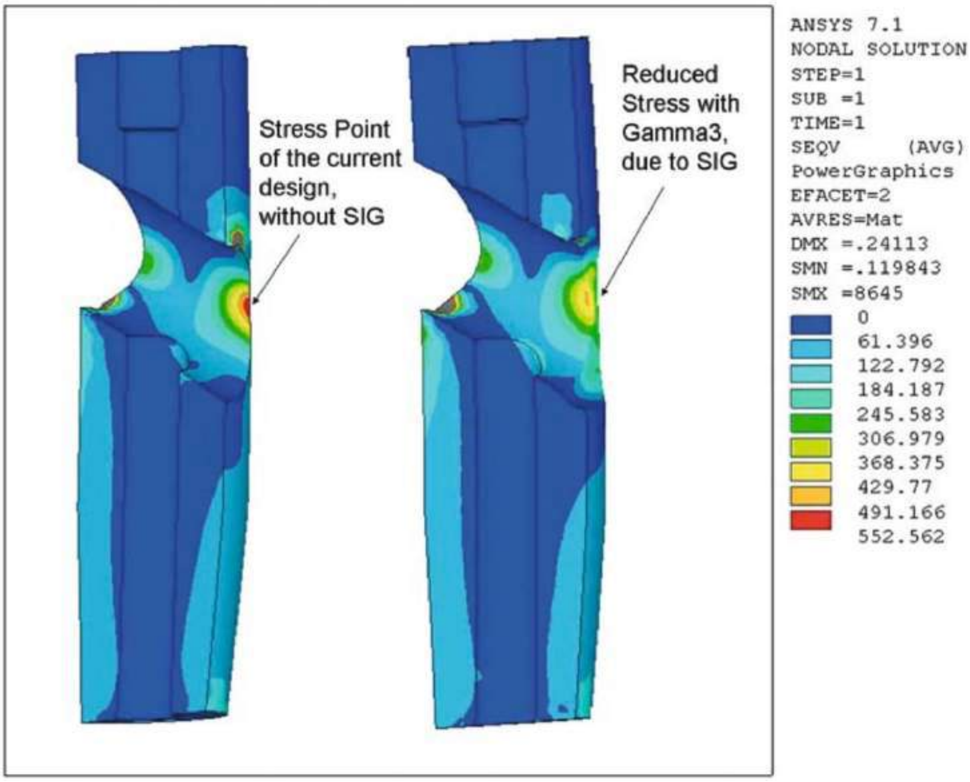

Figure 4.3 Finite Element Analysis of the Gamma SIG

FEA for the proximal aperture in the Stryker Gamma nail without the SIG (left) and with (right). Source: Müller-Daniels.[19]

4.2. Synthes Nails

Nails manufactured by Synthes (now DePuy Synthes as part of Johnson & Johnson Medical Devices) have evolved over time, with changes to the brand name, alloy and design across a 25-year period. These are the Proximal Femoral Nail (PFN), Trochanteric Fixation Nail (TFN), Proximal Femoral Nail Anti-rotation (PFNA) and more recently the Trochanteric Fixation Nail Advanced (TFN-A). The nails are graphically depicted in Figure 4.4.

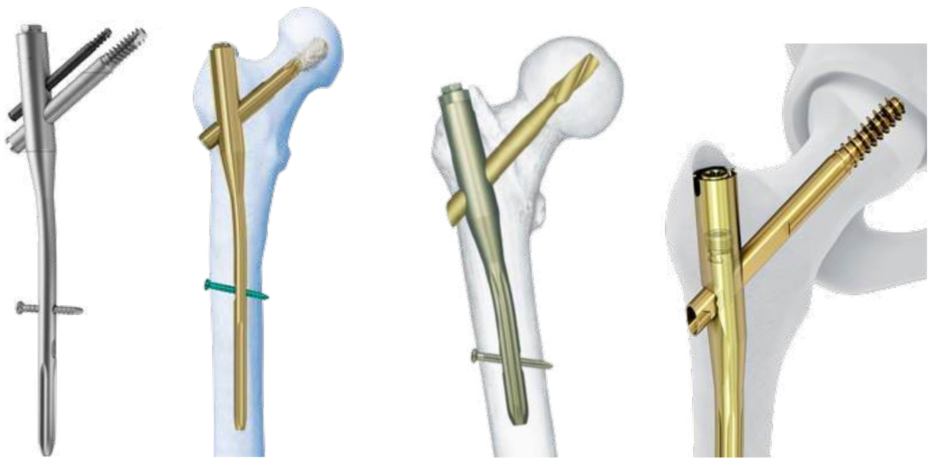

Figure 4.4 Evolution of Synthes Proximal Femoral Nails

Left to right, the PFN, PFNA, TFN and TFNA nails. Source: surgical technique guides.[31-34]

The PFN was released in 1996 and was available as both a titanium alloy (TAN) and in stainless steel, and featured a 17mm proximal nail diameter.[34] The nail body was lime green with an 11mm hot pink neck screw, a 6.5mm navy blue hip pin and a 4.9mm lime green distal locking bolt. Nails were 10, 11 or 12mm in diameter and the short nail was 240mm in length. Neck shaft angle could be 125, 130 or 135 degrees and the medial-lateral angle was 6 degrees.

The TFN was released in 2002 but was never available for use in Australia. The nail was only available as a TAN alloy (Synthes had ceased production of stainless steel nails, presumably due to the excessive stiffness). It also saw the introduction of a helical blade (rather than screws) at the proximal end. The blade was designed with the intention of enhancing cut-out resistance as well as preserving bone.[32] The screw was controlled in rotation by a built-in internal set-screw proximally with two small arms that sat either side of an anterior and posterior flat (rather than round) surface of the lateral nail, as seen in Figure 4.5.

Figure 4.5 The TFN Helical Blade

Picture of the helical blade by TFN noting the flat anterior (and posterior) surface laterally for rotational locking. Source: Synthes.[31]

The next nail released was the PFNA in 2004 which saw the introduction of different short nail length options (170, 200 or 240mm) and a small reduction in proximal diameter (16.5mm). Uniquely it also introduced a lateral locking mechanism for the lag screw or blade, whereby the rotation of the blade or screw was limited by teeth that engaged an inner bolt within the barrel of the blade (Figure 4.6**)**. This ensured the barrel was unable to spin at the proximal aperture due to its ovoid cross-sectional shape. This was considered an improvement on the PFN which did not lock proximal rotation (though it had 2 cephalic screws) and the less convenient proximal method of locking the Stryker Gamma nail or Synthes TFN.

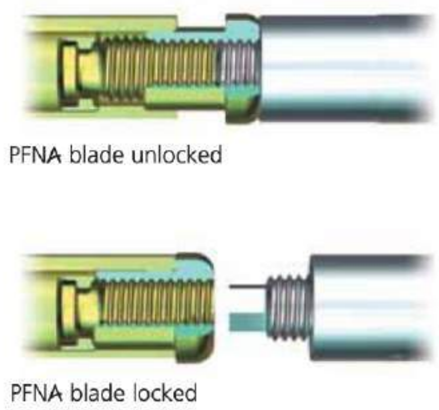

Figure 4.6 PFNA Lateral Locking Mechanism

Demonstration of the internal locking mechanism to prevent blade rotation. Source: Synthes Product Technique Guide.[54]

The TFNA (TFN-Advanced, DePuy Synthes, Oberdorf, Switzerland) was introduced to the global market in 2015 and is a TiMo (Ti-15Mo) Titanium-Molybdenum alloy.[33] This was the first time Ti-Mo had been chosen as the primary alloy in proximal femoral nails. The TFNA was first used in Western

Australia on the 1st March 2016 and is still currently in use locally and internationally. TiMo is said to provide improved fatigue resistance and strength compared to TAV (Ti-6Al-4V) and TAN (Ti-6Al-7Nb) alloys according to biomechanical testing data from DePuy Synthes Trauma.[44] TiMo has also been shown to have a lower elastic modulus compared to TAV (78 vs 112 GPa), suggesting it should behave more like the surrounding cortical bone.[41] It was assumed that the stronger alloy, combined with associated design changes, would result in a smaller nail diameter being acceptable without reduced overall construct strength. This would minimise bone loss during nail insertion. The TFNA offers both blade or screw fixation of the femoral head with sliding or static locking, with a built-in proximal set-screw similar to that used in the TFN.

Other introduced features of the TFNA include a 1.0m radius bow and a smaller proximal nail diameter of 15.66 mm thereby further preserving bone. The BUMP CUT™ design is said to improve fatigue strength and is a protuberance in the mid portion of the proximal aperture on the lateral side both on the anterior and posterior rims. The LATERAL RELIEF CUT™ was also introduced where the lateral portion of the proximal nail is progressively removed from proximal to distal leaving a flattened rather than cylindrical shape, again designed to preserve bone.[33] These features are shown in Figure 4.7.

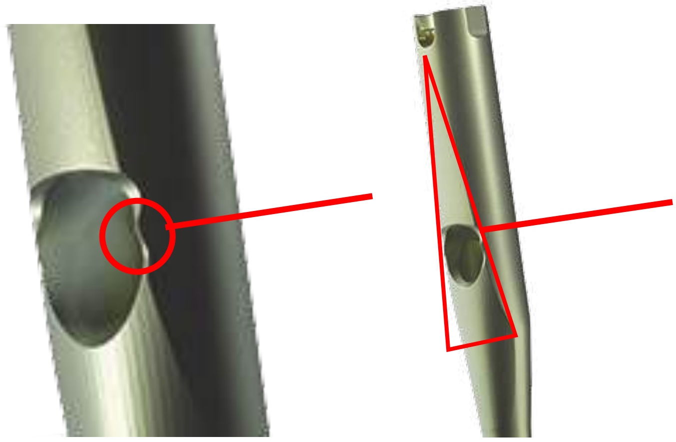

Figure 4.7 TFNA Bump and Lateral Relief Cuts

The BUMP CUT™ (left) and LATERAL RELIEF CUT™ (right) features of the TNFA. Source: Synthes.[44]

These features reduce the nail diameter around the level of the proximal aperture commensurate with nail size from 13.4 mm for a 9 mm diameter nail through to 15.2 mm for a 14 mm nail.[33] The volume of alloy within the wall of the proximal nail is further reduced compared to previous generations of nails by the presence of a cannulated built in set screw above the aperture and a threaded space below it to assist with device removal in case of implant breakage. This is comparatively shown in the laboratory photograph in Figure 7.2. The absence of a SIG like the Stryker Gamma3 also leaves a sharper outer margin of the proximal aperture.

4.3. Summary

A comprehensive review of some of the modern intramedullary nails used for proximal femoral fracture osteosynthesis outlines the significant changes that have occurred over time. Generally, implant manufacturers seek to preserve bone, reduce cut out and improve nail strength in a bid to reduce causes of fixation failure. This has been achieved by various combinations of reductions in proximal nail diameter, use of different lag screw devices, development of alternative alloys and alteration of overall nail design.

5. Results Chapter 2: Patterns of Local Proximal Femoral Nail Usage

5.1. Usage By Hospital

The total usage of nails is shown in Figure 5.1. This data should be read in conjunction with section 1.1 to understand that the FHHS and FSH health services merged/relocated in 2015 to become FSFHG. Their data are combined in the figures that follow.

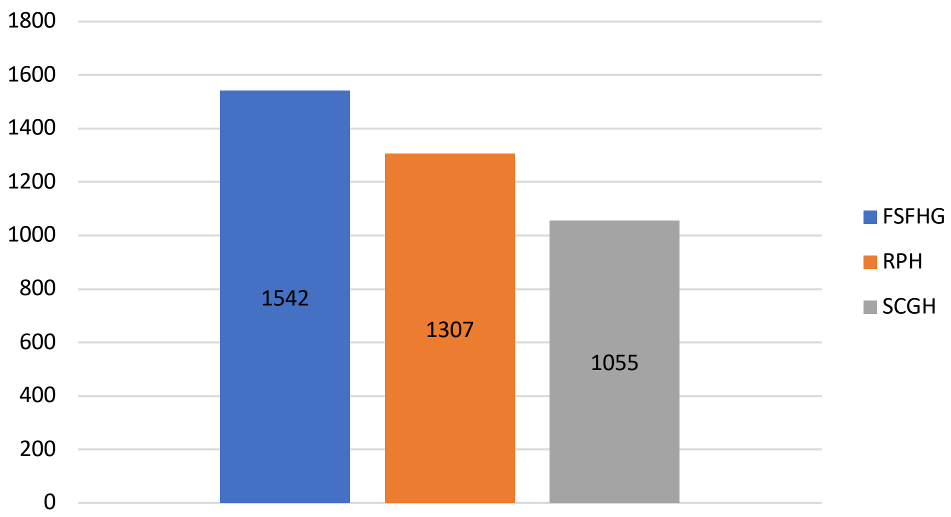

Figure 5.1 Total Number of Implanted Synthes Nails by Site

Tally of the total Synthes PFN, PFNA and TFNA implants used by each hospital group from 2001 to 2017

In Figure 5.2 the type of nail used at each site is examined as a proportion of all nails for that institution. Of note the Royal Perth Hospital made the decision to use very few TFNAs in recognition of their increased cost and continued to use the PFNA implant. This decision was made prior to the discovery of TFNA breakages.

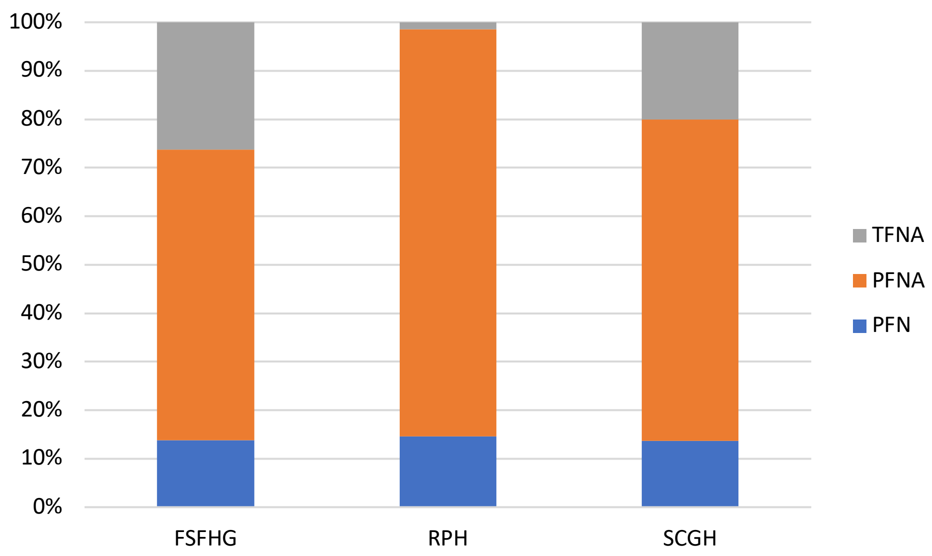

Figure 5.2 Use of different nails by site

The relative proportion of different nails used at each site as a stacked column chart.

5.2. Changes Over Time

In order to understand trends in usage both the volume of Synthes nails (as a surrogate of overall nail usage) and type of nail used were analysed across the years of data collection as seen in Figure 5.3 & Figure 5.4. Nails used until May 2018 were captured. Of note, 2018 was an incomplete year and therefore not included in the annual nail usage tally.

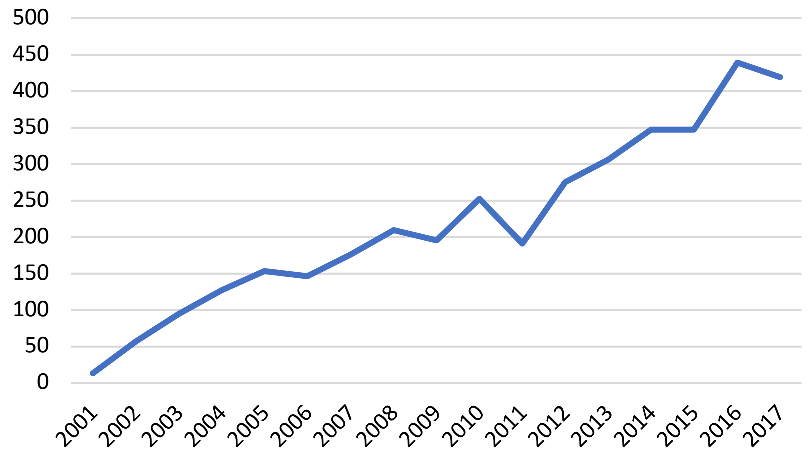

Figure 5.3 Number of Synthes Nails inserted

Line chart depicting total number of Synthes nails inserted in WA by calendar year

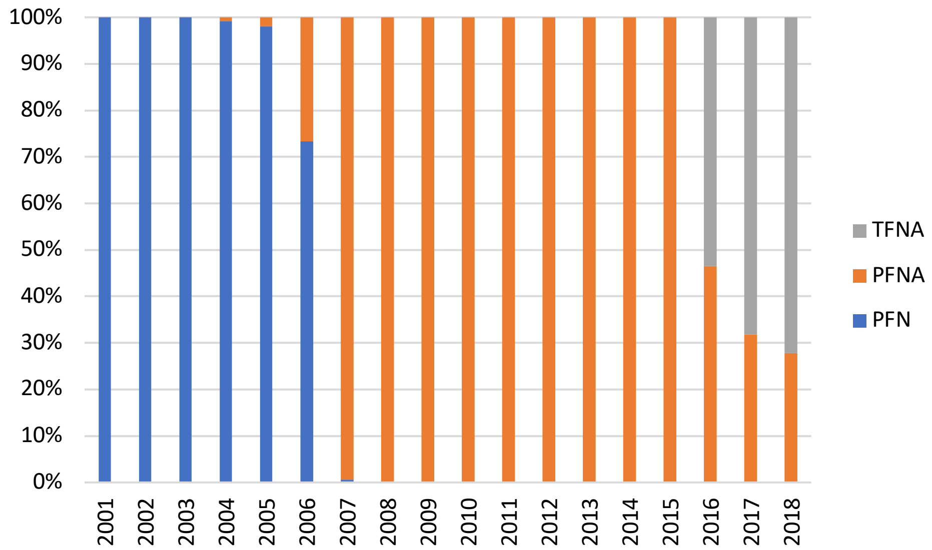

Figure 5.4 Relative Usage of the Different Nails

Stacked column chart depicting the relative usage of different Synthes nails over time.

We also decided to investigate the usage trends of short versus long femoral nails given that nails had expanded their indications to more simple proximal fracture types with their short options. Figure 5.5 demonstrates this over time whereas Figure 5.6 breaks this down by nail design.

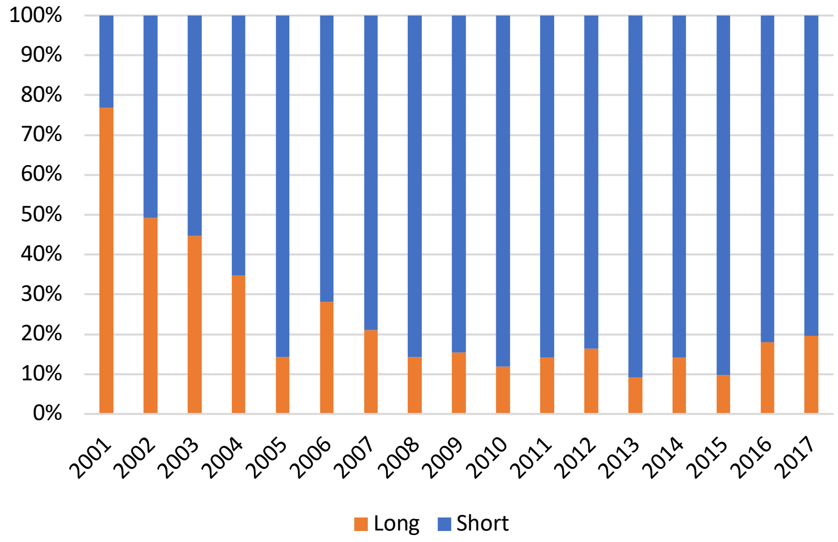

Figure 5.5 Proportion of Long and Short Nails by Year

Stacked column chart demonstrating proportion of nails by year and length

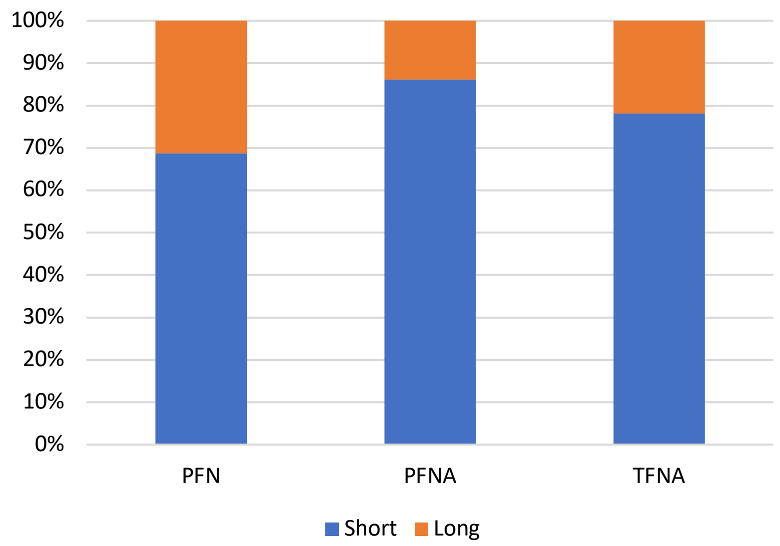

Figure 5.6 Length of Nail by Nail Type

Stacked column chart demonstrating proportion of each nail inserted that was long versus short in length

6. Results Chapter 3: Patient and Fracture Characteristics with Broken Nails

6.1. Patient Characteristics

At time of data collection there had been 16 reported cases of TFNA implant breakage in our region. Demographics and patient data are described in Table 6.1. There were no pathological fractures. Appendix B depicts the clinical information for individual cases.

Table 6.1 Summary of TFNA Breakage Patient Characteristics

*The values are given as the mean and the standard deviation, with the range in parentheses for continuous numerical data and the count with percentage in parentheses for categorical data. †Age is at time of implant breakage.

Parameter	Value*
Sex	F (11), M (5)
Age† *(yr)*	79.4 ± 9.3 (59 to 94)
BMI *(kg/m²)*	26.4 ± 3.3 (22 to 33)
ASA grade	2 (9), 3 (7)
Diagnosis	
Hip fracture	11 (69%)
Broken implant	5 (31%)
Mechanism	
Fall	12 (75%)
Atraumatic	4 (25%)
AO classification	
31A3	12 (75%)
31A2	2 (13%)
32A2	1 (6%)
32C3	1 (6%)

Post-operatively all patients had been allowed to weight bear as tolerated (as per best practice guidelines for management of proximal femoral fractures) with the use of a gait aid if required. Post-operative physiotherapy focused on functional rehabilitation including transfers, mobility, sitting out of bed, balance and falls risk reduction. Specific high load exercises such as straight leg raises or squats were not prescribed. Two patients with minimal displacement of the fracture despite nail breakage declined further surgery. Of the 11 revision nails used, there were 8 TFNAs, 2 AFNs (Antegrade Femoral Nail, DePuy Synthes, Oberdorf, Switzerland) and 1 PFNA (Proximal Femoral Nail Antirotation, DePuy Synthes, Oberdorf, Switzerland). There were 8 patients treated with a revision TFNA for nail breakage, of whom 3 returned with a breakage of the revision implant. These are cases 2, 4 and 11 returning as cases 9, 10 and 14 respectively in Appendix B.

6.2. Radiographic Assessment

Table 6.2 highlights the technical aspects and breakage information along with subsequent management. The AO/OTA fracture classification was predominantly intertrochanteric (reverse oblique), followed by multi-fragmentary pertrochanteric fractures and sub-trochanteric fractures. No breakages were seen with a simple pertrochanteric fracture pattern.

Table 6.2 Summary of Technical Features, Diagnosis and Outcomes

*The values are given as the mean and the standard deviation, with the range in parentheses for continuous numerical data and the count with percentage in parentheses for categorical data. †Assessed according to Baumgaertner's criteria[52].

Parameter	Value*
Reduction Quality†	
Good	10 (63%)
Acceptable	4 (25%)
Poor	2 (12%)

Reduction method Open Closed	 9 (56%) 7 (44%)
Nail length Long Short	 9 (56%) 7 (44%)
Time to breakage *(months)*	5.0 ± 2.2 (2.2 to 9.8)
Mechanism of breakage Atraumatic Fall	 14 (88%) 2 (12%)
Breakage site Proximal aperture Both apertures	 15 (94%) 1 (6%)
Diagnosis Delayed union Non union	 11 (69%) 5 (31%)
Management Revision nail Arthroplasty Nonoperative	 11 (69%) 3 (19%) 2 (12%)

All nails breakages occurred through the proximal aperture, with one nail additionally breaking at the distal aperture. Breakages had occurred with both the blade and screw options for head fixation, with blade fixation accounting for the majority of implants being inserted at time of data collection. Radiographs from Case 3 are shown (Figure 6.1 to Figure 6.4).

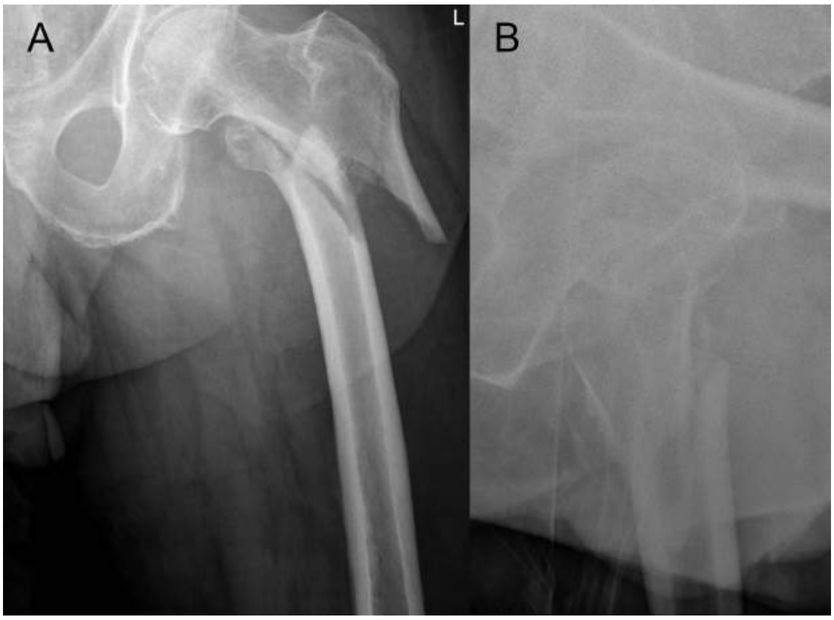

Figure 6.1 Pre-Operative X-rays for Case 3

Anteroposterior (A) and lateral (B) radiographs demonstrating the reverse oblique pattern proximal femur fracture.

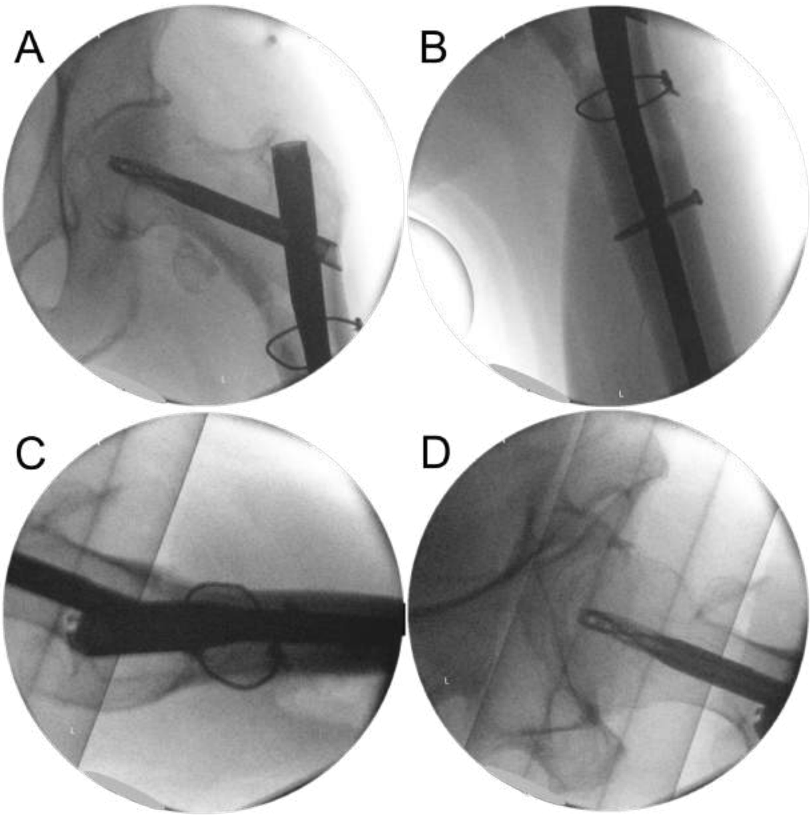

Figure 6.2 Intra-operative Fluoroscopic Images for Case 3

Intraoperative fluoroscopic radiographs at time of nail insertion.

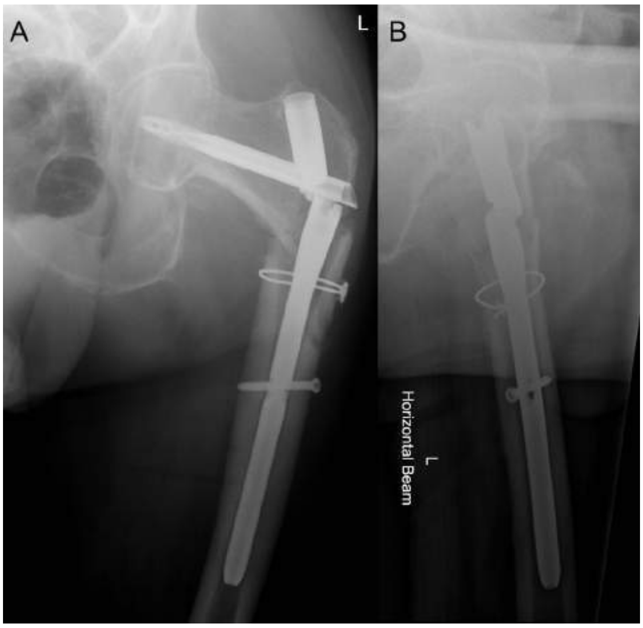

Figure 6.3 Implant Breakage in Case 3

Anteroposterior (A) and lateral (B) radiographs demonstrating implant breakage through the proximal aperture typical of this series

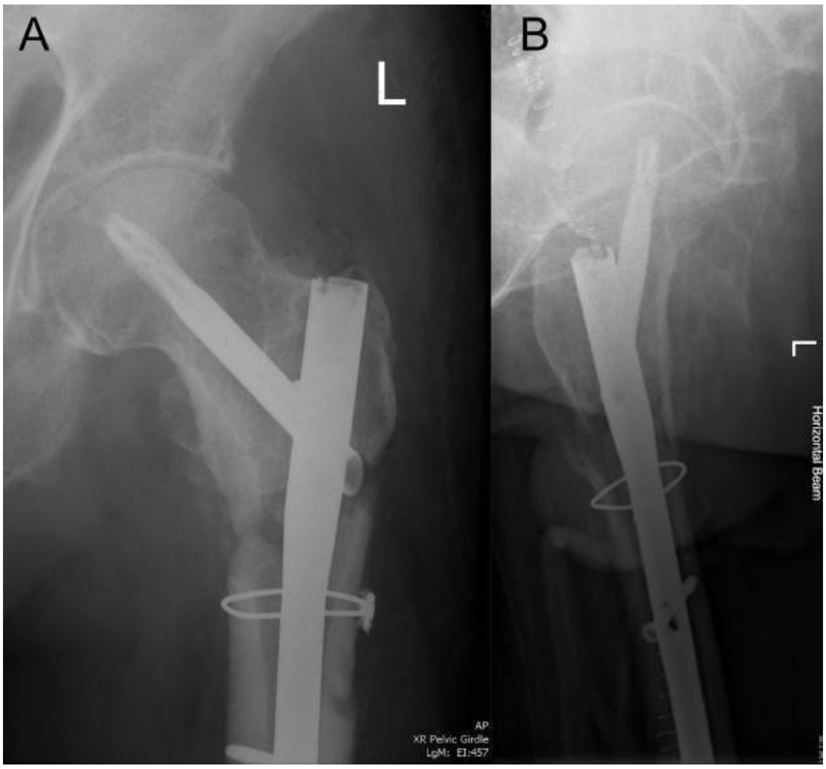

Figure 6.4 X-Rays Post Revision for Case 3

Anteroposterior (A) and lateral (B) radiographs following revision nailing

It is worth noting that two of the cases of breakage presented with very subtle plain film findings and required CT to confirm implant breakage as catastrophic failure had not yet occurred. It is likely that some of the patients that presented with catastrophic failure (fracture displaced) may have had a window of opportunity for diagnosis and revision before this stage and one patient in fact retrospectively was identified as having a minimally displaced implant breakage on earlier films (Figure 6.5).

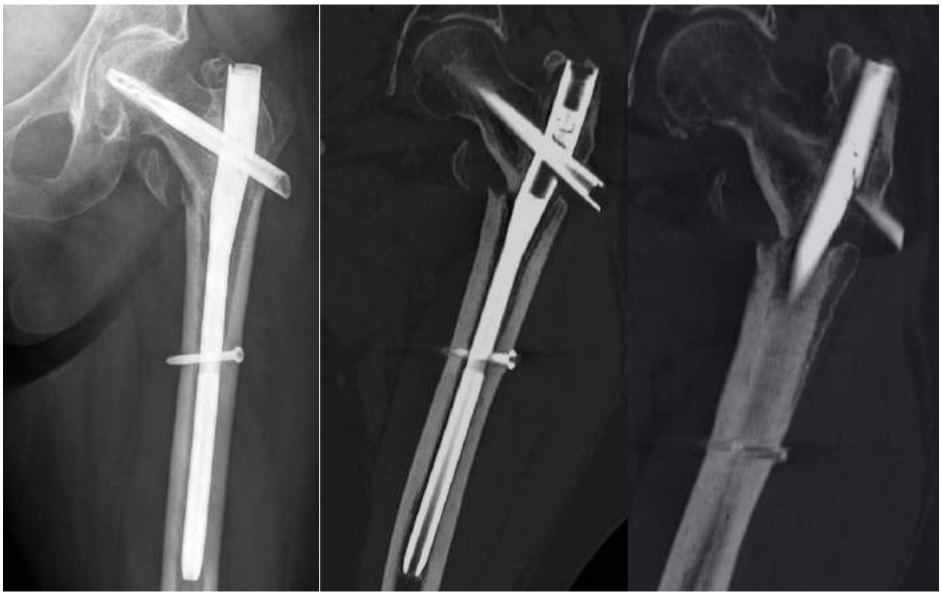

Figure 6.5 X-ray and CT of Case 1

Imaging demonstrating subtle radiographic malalignment and on CT confirmation of implant breakage

6.3. Summary

The characteristics of the patients are described, noting a female dominance, age of 70-90 years old and a relatively low ASA for the population and normal BMI. Predominantly unstable primary fractures were found to suffer implant breakage.

7. Results Chapter 4: Laboratory Investigation of Retrieved Nails

7.1. Macroscopic Analysis

Macroscopic analysis of the TFNA nails primarily revealed a tortuous crack failure path with all nails showing multiple secondary cracks stemming from the fracture surfaces. In this regard several nails had evidence of small fragments of alloy missing from the fracture surface, indicative of multiple crack pathways. In all cases, part of the failure path included fracture surfaces running parallel to the long axis of the nail (Fig. 6).

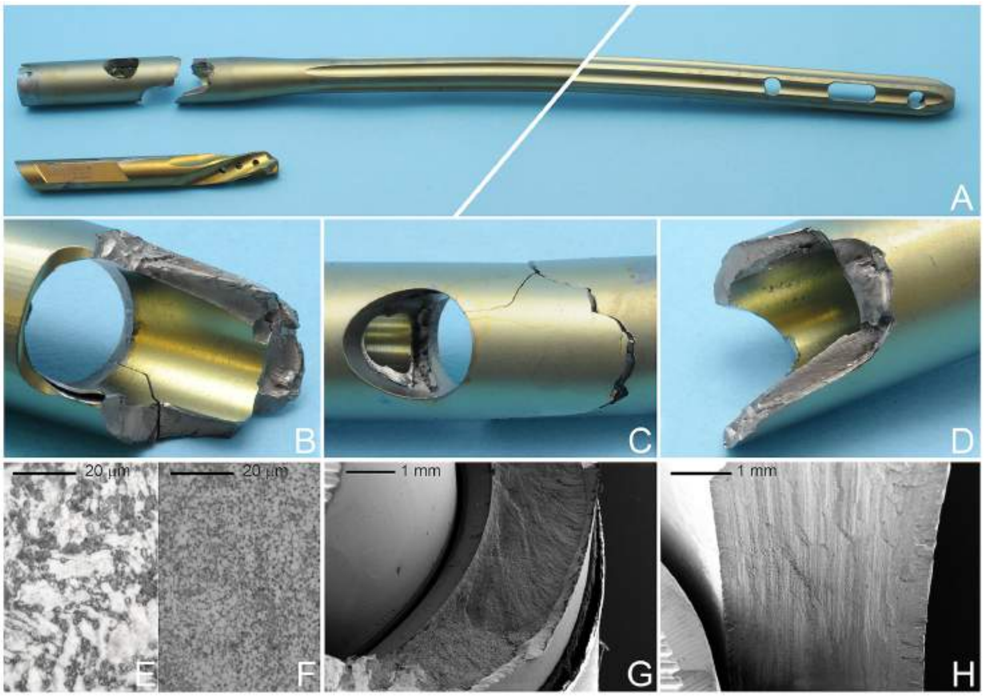

Figure 7.1 Appearance of a Typical TFNA on Retrieval Examination

Appearance of a typical fractured TFNA (A through D). Microstructures of the DePuy Synthes TFNA (E) and for comparison PFN (F) nails. SEM images of the horizontal (G) and vertical (H) fracture surfaces highlighting fatigue striations and a surface ridge.

In all devices the fracture origin was at the point of, or adjacent to the thinnest cross section of the nail, generally on the lateral aspect of the device associated with the LATERAL RELIEF CUT™ and BUMP CUT™ design features of the proximal hole. The nails showed typical intraoperative or insertional damage commonly found on intact nails retrieved for other diagnoses. These findings ranged from sight scratching to severe gouging of the proximal aperture in all but one case.

In comparison to previous generations of Synthes nails or to the Stryker Gamma nail, there appeared to be a significant macroscopic reduction in alloy volume around the proximal aperture as pictured in Figure 7.2. Examining the nail design there was no evidence of a SIG-like etching of the outer aperture as seen in Stryker Gamma nails and discussed in section 4.1.

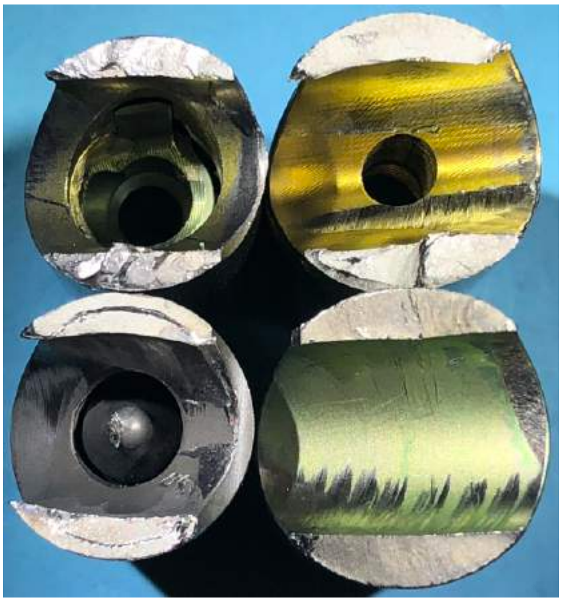

Figure 7.2 Cross Sectional Microscope Photograph of Broken Nails

Clockwise from top left: Synthes TFNA, Synthes PFNA, Synthes PFN and Stryker Gamma nails. Photo through proximal aperture, looking into proximal part of nail. Source: CITRA.

7.2. Microscopic Analysis

The phases (microstructure) of titanium alloys in the solid state can be alpha, beta or alpha-beta as discussed in section 1.3.4.2. In the present case the microstructure consisted of a fine alpha equiaxed in a beta structure (alpha-beta) which is indicative that the alloy had been worked in some way, as expected in the production of an intramedullary nail. Microscopic photos are seen in Figure 7.1.

7.3. Microhardness

The microhardness was evaluated by sequential tests traversing from the outer to inner diameter. Of note was a decrease in hardness from the outer surface to mid point of the cross section and then a slight increase at the inner surface.

7.4. Scanning Electron Microscopy (SEM)

SEM of the fracture surfaces was confounded by the tortuous fracture path with 'vertical/axial' fracture faces which contrasts to the more commonly observed planar fracture surface of other failed intramedullary proximal femoral nails. Fatigue striations were observed on all nails as expected, whilst a noticeable surface ridge was also present which correlated with the microhardness results. SEM images are included in Figure 7.1.

7.5. Segmental Nail Breakage

One case in particular demonstrated breakages through both the proximal and distal apertures, which had not been described previously in the orthopaedic literature Figure 7.3.

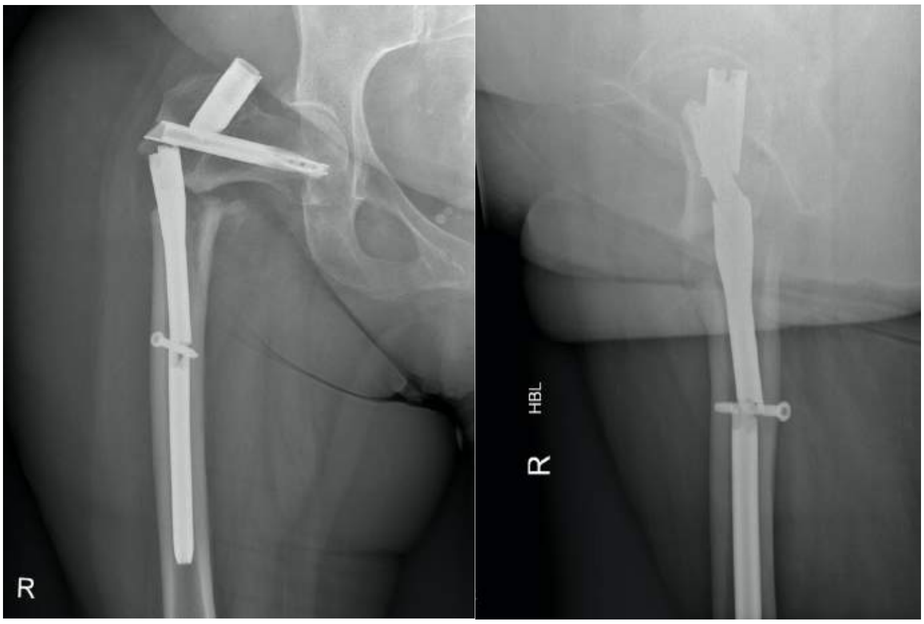

Figure 7.3 Post Breakage X-rays of Case 5

Segmental breakage of the proximal femoral nail is shown on AP (left) and lateral (right) radiographs

Analysis of the retrieved nail fragments illustrated an unusual pattern of fragmentation (Figure 7.4). The tortuous fracture path and missing fragments were characteristic of the titanium alloy and its inherent microstructure. It was hypothesised that the implant initially failed distally, suggesting that the proximal nail was not well supported, leading to increased bending loads at the level of the cross-locking screw.

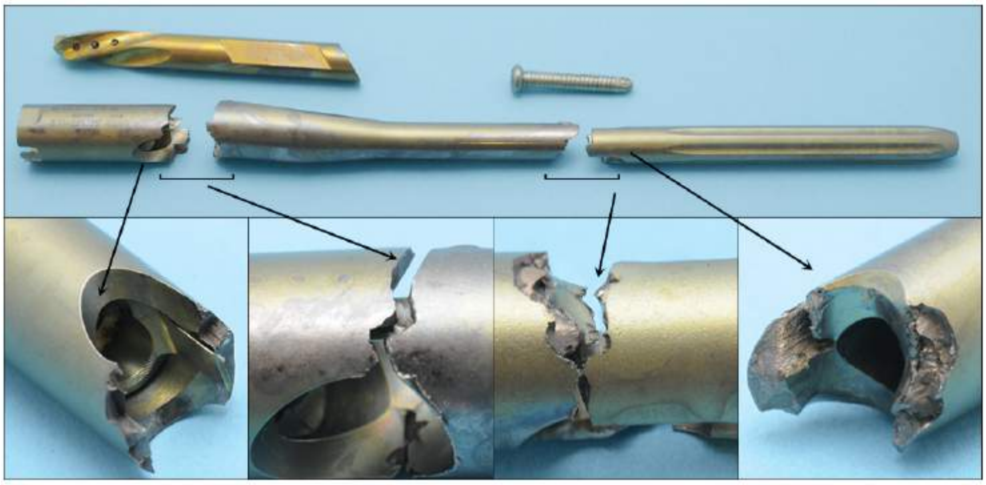

Figure 7.4 Case 5 Laboratory Photography

Segmental breakage of the nail is depicted

The extent of wear noted on the proximal nail surface further indicates that there was a significant amount of proximal micromotion. Finally, the distal aperture showed evidence of axial load, causing bending forces which likely contributed to the breakage at the distal aperture.

7.6. Summary

Novel findings of a unique fracture pattern and unusually large number of implant breakages are analysed. Macroscopic and microscopic images are provided to highlight the fragmentation and tortuous fracture path of the breakage.

8. General discussion

8.1. Summary of results

If proximal hip fractures pose the significant projected burden on the community discussed by Burge et. al., then a deeper understanding of nails used for fracture osteosynthesis and their potential modes of failure is critical to ensuring their ideal use.[3] This thesis covers a comprehensive review of design and material changes to modern proximal femoral nails over the past 20 years in a bid to explore possible reasons to explain a newly identified group of implant failures. This is followed by a unique analysis of implant usage patterns and trends covering a large population of patients and surgeons. Such information can be used to understand evolutions in management of hip fractures.

The thesis also analyses the demographics, radiographic findings and retrieval data of the largest series of nail breakages in the published English literature and is the first to perform a laboratory analysis on the new TFNA implant. The regular collection and analysis of implant breakages across a large yet geographically isolated population, combined with the presence of a centralised, independent implant retrieval centre underpins the strength of this study. These factors combine to produce a study that may be the early detection point of an implant issue that has not yet been recognised elsewhere.

8.2. Changes to Design and Metallurgy of Proximal Femoral Nails

Nails have evolved significantly since Küntscher and Pohl collaborated in the late 1930s.[23] Modern nails are highly engineered and therefore more costly, with numerous design features and intricate locking systems and jigs for minimally invasive insertion. As industry strives to refine implant design there is a clear progression towards reducing nail diameter in an effort to preserve bone, while simultaneously attempting to mitigate the inevitable loss of strength that accompanies cross sectional diameter reduction. We have seen this with design changes such as the introduction of the SIG on the lateral aspect of the Gamma nail (Figure 4.2) and the Bump Cut and Lateral Relief Cut (Figure 4.7) on the TFNA. Strength has also been sought from progressive alloy changes from stainless steel to titanium initially (less stiffness, closer modulus to host bone) and more recently through the use of different titanium alloys including TAN, TAV and Ti-Mo. Though some of the changes appear minor, it is important to understand the implications and potential pitfalls of each adjustment, both in isolation and as part of a new design/alloy combination.

The reduction of nail diameter from 17mm to 15.6mm over the iterations of Synthes nails with a superimposed further reduction of volume from a lateral relief cut may mean that failure risk is not fully mitigated despite the use of a theoretically stronger alloy and other associated design features. Additional design features such as the introduction of a flattened lateral edge of the proximal aperture like the SIG, may improve fatigue strength and potentially benefit the Synthes line of nails.

As there were multiple changes in prosthetic design that occurred simultaneously with a change in alloy choice for the TFNA a formal root cause analysis is difficult.

8.3. Patterns of Local Proximal Femoral Nail Usage

For the first time in Australia, this study has provided a large scale assessment of usage patterns for proximal femoral nails used to treat hip fractures. It was observed in our national hip fracture registry that Australia-wide the rate of IMN use in hip fractures has increased by 47% over a 5 year period.[36] This correlates with our findings of rapidly increasing use of nails in our region. From 2001 to 2017 annual Synthes nail use (as shown in figure 5.3) has risen from less than 50 to over 400 nails per year.

Figure 5.1 demonstrates relatively high volumes of nail usage at each of the 3 public tertiary orthopaedic hospitals across WA, each site using over 1,000 nails in the examined time period of 2001 – 2018. Furthermore Figure 5.2 demonstrates that by far the most commonly used nail of those examined has been the Synthes PFNA, which sparks interest given the relative paucity of retrieved PFNA nails at CITRA. This will be an avenue of further investigation in a planned future study. From 2015 to 2018 by far the majority of nails used were the Synthes TFNA in WA, however anecdotally this study has contributed to a partial change in practice since then.

When comparing short versus long nails, historically nailing was preserved for shaft fractures and highly unstable subtrochanteric femur fractures and thus long nails predominated. Proximal stable fractures would typically have been treated with a sliding hip screw device (Figure 1.3). This is evident at the commencement of data collection in 2001 where long nails constituted 75% of nails used during that year. By 2005 this was a minority of 10-30% of cases and has continued to be a progressive minority since (Figure 5.5), likely reflecting change in practice along with the expanding indications of short nails.

Given the incidence of breakages of the TFNA, it was postulated as to whether the newer nail in its short form was inappropriately being used where a long nail would be more appropriate. Figure 5.6 however demonstrates that a slightly higher proportion of long nails have been used since the introduction of the TFNA design compared to previous generations.

8.4. Patient and Fracture Characteristics with Broken Nails

Similar to other published cohorts of nail breakages, the patients in this series were found to have mostly unstable fracture patterns, producing more significant stresses for the implanted nail. No simple pertrochanteric type fractures (AO 31-A1) have thus far had implant breakage, with highly unstable reverse oblique fractures representing the majority of failures. Whilst a direct comparison wasn't performed between breakage and non-breakage cohorts it is postulated that reverse oblique intertrochanteric (AO 31-A3) fractures should be added to the list of nail breakage risk factors identified by Johnson et. al..47 It is possible that reduction quality is not as important a contributor to implant failure as previously thought, given the significant majority of fractures were well reduced in this series (Table 6.2).

The mean time to failure of 5 months appeared briefer than has been previously observed in our implant retrieval database and will be further analysed in a future study. The cohort also had a near normal mean BMI, consistent with Johnson et. al. suggesting that lighter and by correlation more active and healthy patients, are at risk of implant breakage due to a higher number of cyclical loads being placed through the implant.[47]

In our experience of 8 revision patients whereby a broken intramedullary nail was treated with a revision TFNA implant, a greater than 1 in 3 risk of repeat implant breakage was observed. Other implant choices may be advisable in a revision setting, including nails with a greater alloy volume around the proximal aperture or if appropriate direct conversion to arthroplasty.

Given the subtle nature of some of the implant breakages on plain film radiographs, (Figure 6.5) patients presenting with persistent pain despite apparently unremarkable plain radiographs should be considered for 3-dimensional computed tomographic (CT) scans to investigate occult implant fractures. An unstable fracture pattern that is known to be high risk for delayed union should also be kept under closer surveillance, and increase the surgeon's level of suspicion in the context of pain.

8.4.1. Segmental Nail Breakage

The first case in the literature of segmental nail breakage in a proximal femur fracture is reported in this study. The 3 other cases of segmental femoral nail breakage described by Mazzini et al, Kouvidis et al, and Sivananthan et al were all in distal diaphyseal fractures, and none involved 2 screw apertures. [49-51] Figure 7.4 shows the fracture characteristics which were suggestive of a staged failure on microscopic examination of fatigue lines.

8.5. Laboratory Investigation of Retrieved Nails

Regarding the mechanics of fracture in this device, it became apparent from the laboratory evaluations that the fracture pathway is considerably different from retrieved intramedullary nails that have been evaluated in CITRA for more than 40 years. Whilst all the fractures have initiated at the thinnest cross-sectional location and on the lateral aspect of the nail, consistent with other devices, there are multiple crack pathways, some of which led to loss of small 'fragments' of metal from the fracture surface. In addition, none of the retrieved devices other than the TFNA have had a fracture pattern whereby a planar crack has arrested, changed planes by 90 degrees, progressed, arrested and then change planes again by 90 degrees until final failure. It is hypothesised that a superimposed substructure of alpha and beta phases in the microstructure are leading to arresting of the crack pathways and changing of direction.

A theory considered for contribution to implant breakage was that malalignment of the aiming device for the stepped reamer for the proximal screw or blade may have caused intraoperative damage to the proximal aperture in the nail, thereby predisposing the nail to failure. Although such damage was indeed seen in this series, it appears to be commonly present in almost all previously retrieved intramedullary nails including those without fracture and in isolation does not fully explain the breakages. The microhardness and SEM results confirmed surface hardening and a surface ridge which demonstrate that the alloy had been anodised, an expected finding.

It is possible that the observed breakages are the culmination of a combination of factors including alloy change, design and potentially an increased susceptibility to insertional damage to the proximal nail around the screw aperture.

8.6. Strengths and Novelty of the findings

The regular collection and analysis of implant breakages across a large yet geographically isolated population with the availability of a centralised, independent implant retrieval centre underpins the strength of this study. This is further supported by the willing collaboration of the three health services , that provided a complete and comprehensive data set for investigating both nail insertions and failures.

8.7. Limitations of the study

A limitation of the study is that the data was collected retrospectively. As previously outlined, the rate of return of failed prostheses is felt to be high due to a long history of collaboration, a positive local culture and regional interest. However, there may be implants that have not been returned that subsequently narrow the spectrum of what is analysed and reported.

A further limitation is the exclusion of other nail brands in the assessment of intramedullary nail insertions state-wide, which would have provided a broader picture of nail usage patterns given the Stryker Gamma nail is not infrequently used. The focus of the study was deliberately limited to compare the different generations of nails from the single company with by far the largest usage in our region. This ensured ease of following modifications to implant design, evolution in the use of alternative alloys and streamlined correlation with failure patterns.

8.8. Clinical implications

This study has already been the subject of widespread international interest, and was named one of the top 10 most read articles of the American Journal of Bone and Joint Surgery (JBJS) in 2019. The research has resulted in the formation of new local guidelines for the treatment of different fracture patterns with different nail designs and in some institutions the use of TFNA has diminished of even been discontinued pending further analysis.

It is opinion of the authors that the key messages from this study are:

In unstable fracture patterns (subtrochanteric, reverse oblique) that are at high risk for non-union and subject the nail to significant forces, alternative implants may need to be considered.

If a TFNA is used there should be consideration of close clinical and/or radiological surveillance until confirmed fracture union in order to diagnose a potentially failing implant and intervene prior to breakage if revision is required.

Whilst a direct comparison wasn't performed between breakage and non-breakage cohorts it is postulated that reverse oblique intertrochanteric (AO 31-A3) fractures should be added to the list of known nail breakage risk factors.

8.9. Future work

A systematic review of the literature will be undertaken to further define what may be considered an acceptable rate of implant breakage for a given prosthesis. This will then inform a breakage rate comparison study linking the insertion data to the full CITRA retrieval log of implants.

Time to failure appears to be more rapid in the TFNA and this will be directly compared in a further investigation.

Ideally, a prospective randomised controlled trial between the different brands and models of implants would more definitively answer the question of which implants have a higher breakage rate. Such a study would also benefit from looking at all modes of failure with an overall failure rate, as implant cut out and loss of position are alternative failure modes with very similar consequences such as pain and likely revision surgery for the patient.

The authors have received formal feedback from DePuy Synthes that surgeon error is a likely contributor to local rates of implant failure through damage to the proximal aperture during the insertion of a cutting drill. This would be an analysis amenable to more in-depth investigation as it is a novel field that has not before been reported on nor explored, and would include an assessment of 'normal' insertional damage during the appropriate insertion of a nail in a clinical fracture fixation setting.

Finally, if there is a difference in fatigue resistance or strength between implants, then a cyclical loading test run by an independent facility such as CITRA would be a sound biomechanical method to directly compare nail behaviour under experimental conditions.

8.10. Conclusions

This thesis explores the historical and more recent evolution of nail development and regional usage patterns. It provides a comprehensive assessment of a range of recent implant failures from both a clinical and laboratory/biomechanical perspective. It should increase the level of awareness of the international orthopaedic community with regards to the features and mode of breakage of the novel TFNA implant. Changes to the nail design and/or alloy may have contributed to this series of observed breakages. We advise vigilant clinical and radiological surveillance of patients with unstable hip fracture patterns who undergo osteosynthesis with a TFNA and recommend against revising a broken TFNA to a second TFNA implant which appears to have a higher than acceptable rate of re-breakage.

References

1. Australian Bureau of Statistics (ABS). [cited 2020 March 21st]. Available from: https://www.abs.gov.au/

2. World Guides. [cited 2020 March 21st]. Available from: http://www.world-guides.com/australia-continent/australia/western-australia/perth/perth_maps.html

3. Burge R, Hughes BD, Solomon DH, Wong JB, King A, Tosteson A. Incidence and Economic Burden of Osteoporosis - Related Fractures in the United States, 2005 - 2025. Journal of Bone and Mineral Research. 2007 Mar 01;22(3):465-475. Available from: https://asbmr-onlinelibrary-wiley-com.ezproxy.surgeons.org/doi/full/10.1359/jbmr.061113 https://asbmr.onlinelibrary.wiley.com/doi/full/10.1359/jbmr.061113 doi: 10.1359/jbmr.061113

4. Williamson S, Landeiro F, McConnell T, Fulford-Smith L, Javaid MK, Judge A, et al. Costs of fragility hip fractures globally: a systematic review and meta-regression analysis. Osteoporosis international : a journal established as result of cooperation between the European Foundation for Osteoporosis and the National Osteoporosis Foundation of the USA [Meta-Analysis]. 2017 Oct;28(10):2791-2800. Available from: http://link.springer.com/10.1007/s00198-017-4153-6 doi: 10.1007/s00198-017-4153-6

5. Close J, Harris I. ANZHFR Annual Report. Australian & New Zealand Hip Fracture Registry. 2019. Available from: https://anzhfr.org/2019-annual-report/

6. Large TM, Adams MR, Loeffler BJ, Gardner MJ. Posttraumatic Avascular Necrosis After Proximal Femur, Proximal Humerus, Talar Neck, and Scaphoid Fractures. J Am Acad Orthop Surg. 2019 May 29;27(21):794-805. Available from: http://Insights.ovid.com/crossref?an=00124635-201911010-00002 doi: 10.5435/JAAOS-D-18-00225

7. Kaplan K, Miyamoto R, Levine BR, Egol KA, Zuckerman JD. Surgical management of hip fractures: an evidence-based review of the literature. II: intertrochanteric fractures. J Am Acad Orthop Surg [Review]. 2008 Nov;16(11):665-673. Available from: http://content.wkhealth.com/linkback/openurl?sid=WKPTLP:landingpage&an=00124635-200811000-00007 doi: 10.5435/00124635-200811000-00007

8. Kukla C, Heinz T, Berger G, Kwasny O, Rosenberger A, Vecsei V. Gamma Nail vs. Dynamic Hip Screw in 120 Patients over 760 Years - A Randomized Trial. Acta Chirurgica Austriaca. 1997;29(5):290-293.

9. Adams CI, Robinson CM, Court-Brown CM, McQueen MM. Prospective randomized controlled trial of an intramedullary nail versus dynamic screw and plate for intertrochanteric fractures of the femur. Journal of orthopaedic trauma. 2001 Aug;15(6):394-400. Available from: http://eutils.ncbi.nlm.nih.gov/entrez/eutils/elink.fcgi?dbfrom=pubmed&id=11514765&retmode=ref&cmd=prlinks

10. McMillan TE, Stevenson IM. Subtrochanteric fractures of the hip. Orthopaedics and Trauma. 2016 [cited 2019/12/31];30(2):109-116. Available from: https://doi.org/10.1016/j.mporth.2016.03.005 doi: 10.1016/j.mporth.2016.03.005

11. Franklin JL, Winquist RA, Benirschke SK, Hansen ST, Jr. Broken intramedullary nails. J Bone Joint Surg Am. 1988 Dec;70(10):1463-71.

12. Miyamoto RG, Kaplan KM, Levine BR, Egol KA, Zuckerman JD. Surgical management of hip fractures: an evidence-based review of the literature. I: femoral neck fractures. J Am Acad Orthop Surg [Review]. 2008 Oct;16(10):596-607. Available from: http://content.wkhealth.com/linkback/openurl?sid=WKPTLP:landingpage&an=00124635-200810000-00005 doi: 10.5435/00124635-200810000-00005

13. Roberts KC, Brox WT. AAOS Clinical Practice Guideline: Management of Hip Fractures in the Elderly. J Am Acad Orthop Surg [Review]. 2015 Feb;23(2):138-140. Available from: http://eutils.ncbi.nlm.nih.gov/entrez/eutils/elink.fcgi?dbfrom=pubmed&id=25624366&retmode=ref&cmd=prlinks doi: 10.5435/JAAOS-D-14-00433

14. Geiger F, Zimmermann-Stenzel M, Heisel C, Lehner B, Daecke W. Trochanteric fractures in the elderly: the influence of primary hip arthroplasty on 1-year mortality. Arch Orthop Trauma Surg. 2007 Dec;127(10):959-966. Available from: http://eutils.ncbi.nlm.nih.gov/entrez/eutils/elink.fcgi?dbfrom=pubmed&id=17899138&retmode=ref&cmd=prlinks doi: 10.1007/s00402-007-0423-7

15. Gormeli G, Korkmaz MF, Gormeli CA, Adanas C, Karatas T, Simsek SA. Comparison of femur intertrochanteric fracture fixation with hemiarthroplasty and proximal femoral nail systems. Ulusal travma ve acil cerrahi dergisi = Turkish journal of trauma & emergency surgery : TJTES. 2015 Dec;21(6):503-508. Available from: http://eutils.ncbi.nlm.nih.gov/entrez/eutils/elink.fcgi?dbfrom=pubmed&id=27054643&retmode=ref&cmd=prlinks

16. Tang P, Hu F, Shen J, Zhang L, Zhang L. Proximal femoral nail antirotation versus hemiarthroplasty: a study for the treatment of intertrochanteric fractures. Injury. 2012 Jun;43(6):876-881. Available from:

http://eutils.ncbi.nlm.nih.gov/entrez/eutils/elink.fcgi?dbfrom=pubmed&id=22169013&retmode=ref&cmd=prlinks doi: 10.1016/j.injury.2011.11.008

17. AO Surgery Reference. 2020 [cited 2020 January 1st]. Available from: https://www2.aofoundation.org/wps/portal/surgery

18. Born C, Pidgeon T, Gilbert T. 75 Years of Contemporary Intramedullary Nailing. Journal of Orthopaedic Trauma. 2014;28:S1-2.

19. Müller-Daniels H. Evolution of Implants for Trochanteric Fracture Fixation: The Engineer's Point of View. In: Leung K-S, Taglang G, Schnettler R, Alt V, Haarman HJTM, Seidel H, et al., editors. Practice of Intramedullary Locked Nails: New Developments in Techniques and Applications. Berlin, Heidelberg: Springer Berlin Heidelberg; 2006. p. 139-144.

20. Bartoníček J, Rammelt S. The history of internal fixation of proximal femur fractures Ernst Pohl—the genius behind. 2014;38(11):2421-2426. Available from: https://dx.doi.org/10.1007/s00264-014-2320-3 doi: 10.1007/s00264-014-2320-3

21. The Küntscher Society. 2020 [cited 2020 January 3rd]. Available from: https://www.kuentschersociety.org/the-society/gerhard-kuentscher.html

22. Küntscher G. Die Marknagelung von Knochenbrüchen. Klinische Wochenschrift. 1940;19(33):833-835. Available from: https://dx.doi.org/10.1007/BF01774565 doi: 10.1007/bf01774565

23. Küntscher G. The Intramedullary Nailing of Fractures. Clinical Orthopaedics and Related Research®. 1968;60:5-11. Available from: https://journals.lww.com/clinorthop/Fulltext/1968/09000/The_Intramedullary_Nailing_of_Fractures.2.aspx

24. Pierach CA. Give me a break: Gerhard Kuntscher and his nail. Perspectives in Biology and Medicine. 2014;57(4):361.

25. Ernst Pohl (medical technician) - Wikipedia. Karger 1986, ed .: K. Klemm; 2020 [cited 2020 January 3rd]. Available from: https://de.wikipedia.org/wiki/Ernst_Pohl_(Medizintechniker)

26. Stryker Website: Our History. 2020 [cited 2020 January 3rd]. Available from: https://www.stryker.com/us/en/about/history.html#nineteenninety

27. Zickel RE. A new fixation device for subtrochanteric fractures of the femur: a preliminary report. Clin Orthop Relat Res. 1967 Sep-Oct;54:115-23. Available from: https://www.ncbi.nlm.nih.gov/pubmed/5589594

28. Femoral Neck System (FNS). Johnson and Johnson Medical Devices; 2020 [cited 2020 January 3rd]. Available from: https://www.jnjmedicaldevices.com/en-EMEA/product/femoral-neck-system-fns

29. Why One Million Gamma Nails Have Been Implanted Worldwide. Stryker Trauma. 2006:1-2. Available from: https://www.yumpu.com/en/document/read/25072032/one-million-gamma-nails-flyer-stryker

30. AO Foundation. 2020 [cited 2020 January 4th]. Available from: https://www.aofoundation.org/

31. TFN Surgical Technique. DePuy Synthes. 2016.

32. PFNA Proximal Femoral Nail Antirotation Surgical Technique. DePuy Synthes. 2015:1-82. Available from: https://www.jnjmedicaldevices.com/en-EMEA/product/proximal-femoral-nail-antirotation-pfna

33. TFNA - TFN Advanced Surgical Technique. DePuy Synthes. 2016 Sep 23:1-100. Available from: https://www.jnjmedicaldevices.com/en-US/tfn-advancedr-proximal-femoral-nailing-system-tfna

34. PFN Proximal Femoral Nail Surgical Technique. DePuy Synthes. 2016:1-29. Available from: http://synthes.vo.llnwd.net/o16/LLNWMB8/INT%20Mobile/Synthes%20International/Product%20Support%20Material/legacy_Synthes_PDF/DSEM-TRM-0714-0122-1_LR.pdf

35. Allen WC, Piotrowski G, Burstein AH, Frankel VH. Biomechanical Principles of Intramedullary Fixation. Clinical Orthopaedics and Related Research®. 1968;60:12-20. Available from: https://journals.lww.com/clinorthop/Fulltext/1968/09000/Biomechanical_Principles_of_Intramedullary.3.aspx

36. Boulton C BT, Borgon V, Cromwell D, Johansen A, Rai S, Stanley R, Tsang C, Wakeman R, Williams A. National Hip Fracture Database (NHFD) annual report 2015: Physicians RCo; 2015. Available from: https://www.nhfd.co.uk/nhfd/nhfd2015reportPR1.pdf

37. Lambers A. Quarterly Orthopaedic Audit. Western Australia, Australia; 2018.

38. The 2020 National Prostheses List [resource]. Australian Government Department of Health; 2019 [updated 2019-12-19; cited 2020 January 4th]. Available from:

https://www1.health.gov.au/internet/main/publishing.nsf/Content/health-privatehealth-prostheseslist.htm

39. Gotman I. Characteristics of metals used in implants. Journal of endourology (Online). 1997;11(6):383-9. Available from: https://www.liebertpub.com/doi/abs/10.1089/end.1997.11.383

40. Stainless Steel and Titanium in Surgical Implants. AZO Materials; 2012 [updated 2012-09-26; cited 2020 January 5th]. Available from: https://www.azom.com/

41. Bălţatu MS, Vizureanu P, Tierean MH, Minciună MG, Achiţei DC. Ti-Mo Alloys Used in Medical Applications. Advanced Materials Research. 2015;1128:105-111. p. 105. doi: 10.4028/www.scientific.net/AMR.1128.105

42. V2A Steel. Rime Metals; 2016 [updated 2016-11-25; cited 2020 January 5th]. Available from: https://www.rime.de/en/wiki/v2a-steel/

43. Bell T. Characteristics of and Uses for Austenitic Stainless Steel. The Balance; 2020 [cited 2020 January 5th]. Available from: https://www.thebalance.com/metal-profile-austenitic-stainless-2340126

44. TFNA Value Analysis Brief. DePuy Synthes. 2016 Jun 30:1-28. Available from: http://synthes.vo.llnwd.net/o16/LLNWMB8/INT%20Mobile/Synthes%20International/Product%20Support%20Material/legacy_Synthes_PDF/DSEM-TRM-0515-0375-1_LR.pdf

45. Froes FH. Titanium: Alloying. In: Encyclopedia of Materials: Science and Technology (Second Edition): Elsevier; 2001. p. 9361-4.

46. Bojan AJ, Beimel C, Speitling A, Taglang G, Ekholm C, Jonsson A. 3066 consecutive Gamma Nails. 12 years experience at a single centre. BMC Musculoskelet Disord. 2010 Jun 26;11:133. Available from: https://www.ncbi.nlm.nih.gov/pubmed/20579384 doi: 10.1186/1471-2474-11-133

47. Johnson NA, Uzoigwe C, Venkatesan M, Burgula V, Kulkarni A, Davison JN, et al. Risk factors for intramedullary nail breakage in proximal femoral fractures: a 10-year retrospective review. Ann R Coll Surg Engl. 2017 Feb;99(2):145-150. Available from: https://www.ncbi.nlm.nih.gov/pubmed/27659368 doi: 10.1308/rcsann.2016.0297

48. Sitthiseripratip K, Van Oosterwyck H, Vander Sloten J, Mahaisavariya B, Bohez ELJ, Suwanprateeb J, et al. Finite element study of trochanteric gamma nail for trochanteric fracture. Medical engineering & physics. 2003

Mar;25(2):99-106. Available from: http://eutils.ncbi.nlm.nih.gov/entrez/eutils/elink.fcgi?dbfrom=pubmed&id=12538064&retmode=ref&cmd=prlinks

49. Pretell Mazzini J, Rodriguez Martin J, Resines Erasun C. Removal of a broken intramedullary femoral nail with an unusual pattern of breakage: a case report. Strategies in Trauma and Limb Reconstruction. 2009 Sep 24;4(3):151-155. Available from: http://link.springer.com/10.1007/s11751-009-0066-z doi: 10.1007/s11751-009-0066-z

50. Kouvidis GK, Galanakis IA, Hadjipavlou AG. Three-Part Broken Intramedullary Nail Reconsideration: A Case Report and Review of the Literature. 2009 Jan;66(1):E4-E8. Available from: https://insights.ovid.com/crossref?an=00005373-200901000-00045 doi: 10.1097/01.ta.0000221707.40720.7d

51. Sivananthan KS, Raveendran K, Kumar T, Sivananthan S. A simple method for removal of a broken intramedullary nail. Injury. 2000 Jul;31(6):433-434. Available from: http://linkinghub.elsevier.com/retrieve/pii/S0020138300000152 doi: 10.1016/S0020-1383(00)00015-2

52. Baumgaertner MR, Curtin SL, Lindskog DM. Intramedullary Versus Extramedullary Fixation for the Treatment of Intertrochanteric Hip Fractures. Clinical Orthopaedics and Related Research. 1998 Mar;348:87-94. p. 87???94. Available from: https://insights.ovid.com/crossref?an=00003086-199803000-00015 doi: 10.1097/00003086-199803000-00015

53. Trochanteric Gamma Locking Nail - Operative Technique. Stryker Trauma. 2003:1-32.

54. PFNA Proximal Femoral Nail Antirotation Surgical Technique. DePuy Synthes. 2005:1-46. Available from: https://www.rch.org.au/uploadedFiles/Main/Content/ortho/PFNA-Proximal_Femoral_Nailing-A_System.pdf

Appendices

Appendix A: Publication

Implant Fracture Analysis of the TFNA Proximal Femoral Nail

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

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

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

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

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

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

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

Disclosure: This research was supported by an Australian Government Research Training Program (RTP) Scholarship through the University of Western Australia Master of Surgery program and was undertaken in collaboration with the Orthopaedic Research Foundation Western Australia (ORFWA). On the **Disclosure of Potential Conflicts of Interest** forms, *which are provided with the online version of the article,* one or more of the authors checked "yes" to indicate that the author had a relevant financial relationship in the biomedical arena outside the submitted work and "yes" to indicate that the author had other relationships or activities that could be perceived to influence, or have the potential to influence, what was written in this work (http://links.lww.com/JBJS/F172).

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

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

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

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

Materials and Methods

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

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

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

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

Results

Patient Cohort

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

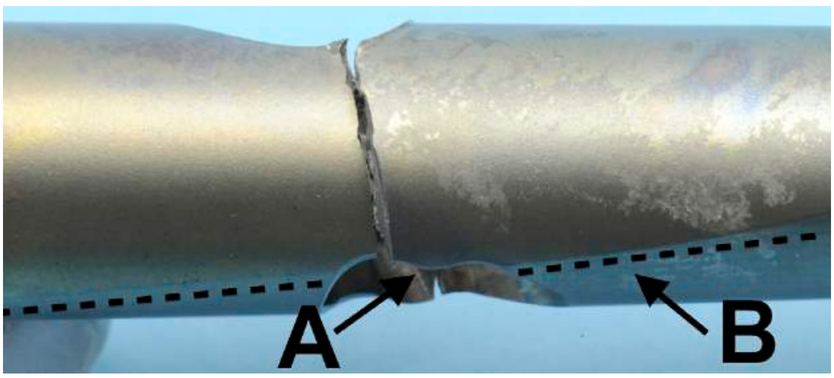

Fig. 1
Photograph of the anterior surface of the proximal portion of a broken nail. "A" indicates the BUMP CUT, and the dashed line ("B") indicates the LATERAL RELIEF CUT.

Fracture and Treatment

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

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

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

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

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

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

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

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

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

Implant Analysis

Macroscopic Analysis

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

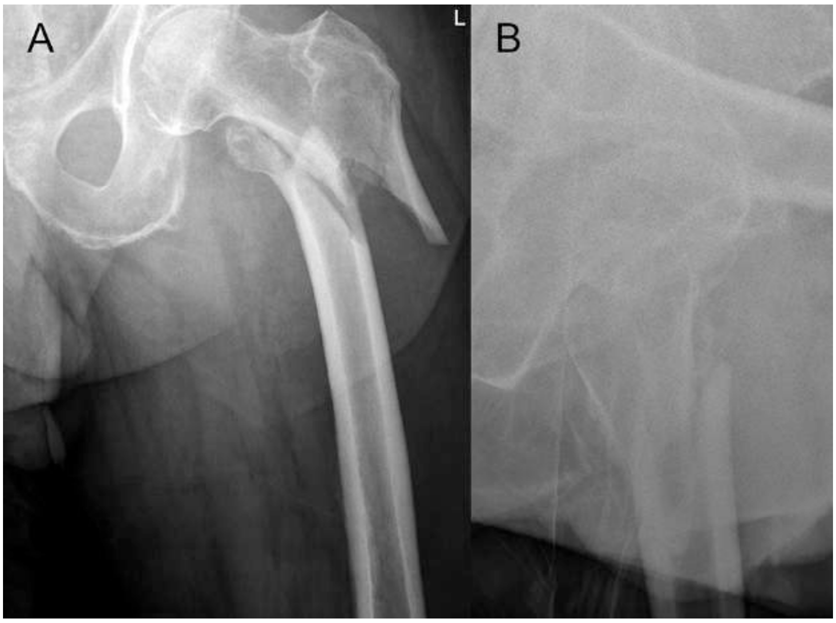

Fig. 2
Anteroposterior (**Fig. 2-A**) and lateral (**Fig. 2-B**) radiographs demonstrating a proximal femoral fracture.

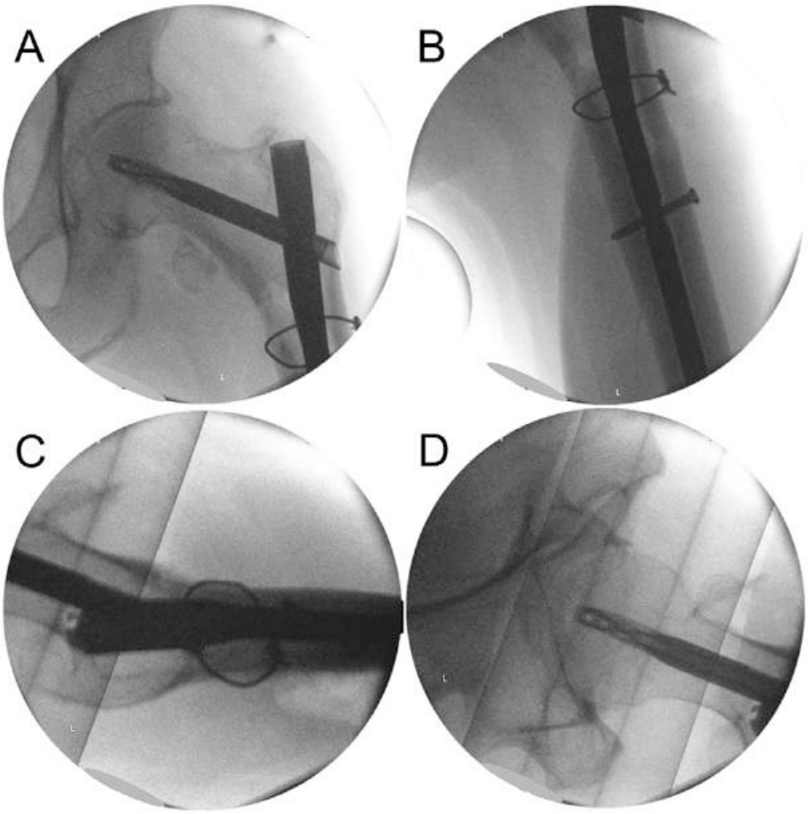

Fig. 3
Intraoperative fluoroscopic radiographs at the time of nail insertion.

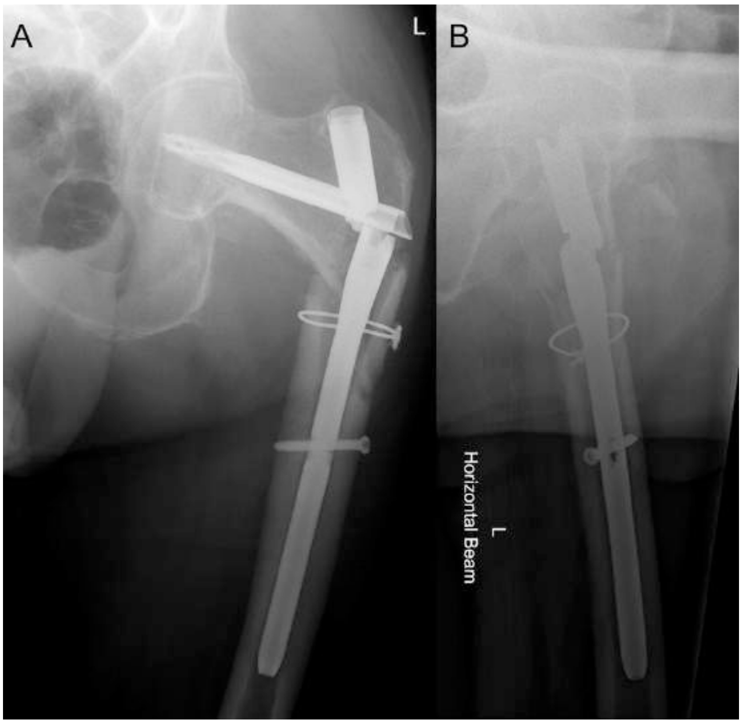

Fig. 4
Anteroposterior (**Fig. 4-A**) and lateral (**Fig. 4-B**) radiographs demonstrating implant breakage.

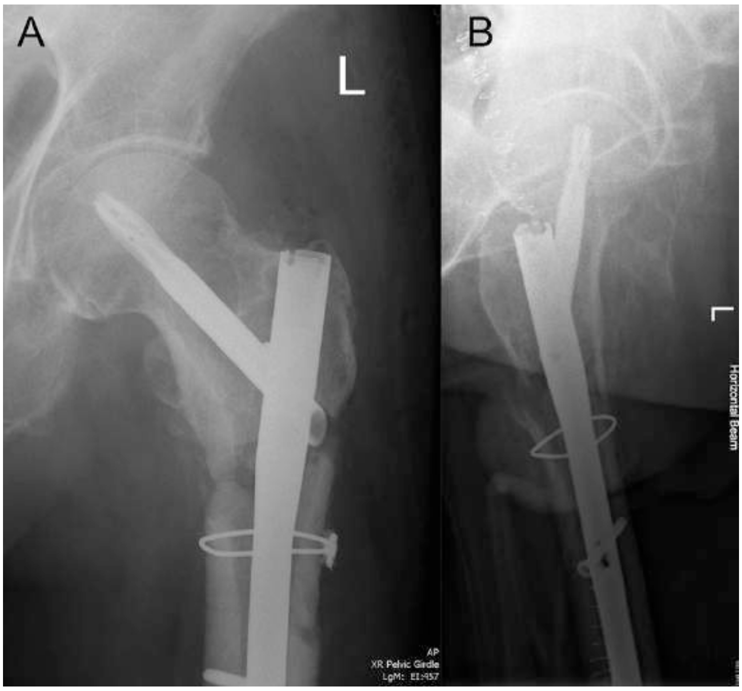

Fig. 5
Anteroposterior (**Fig. 5-A**) and lateral (**Fig. 5-B**) radiographs following revision nailing.

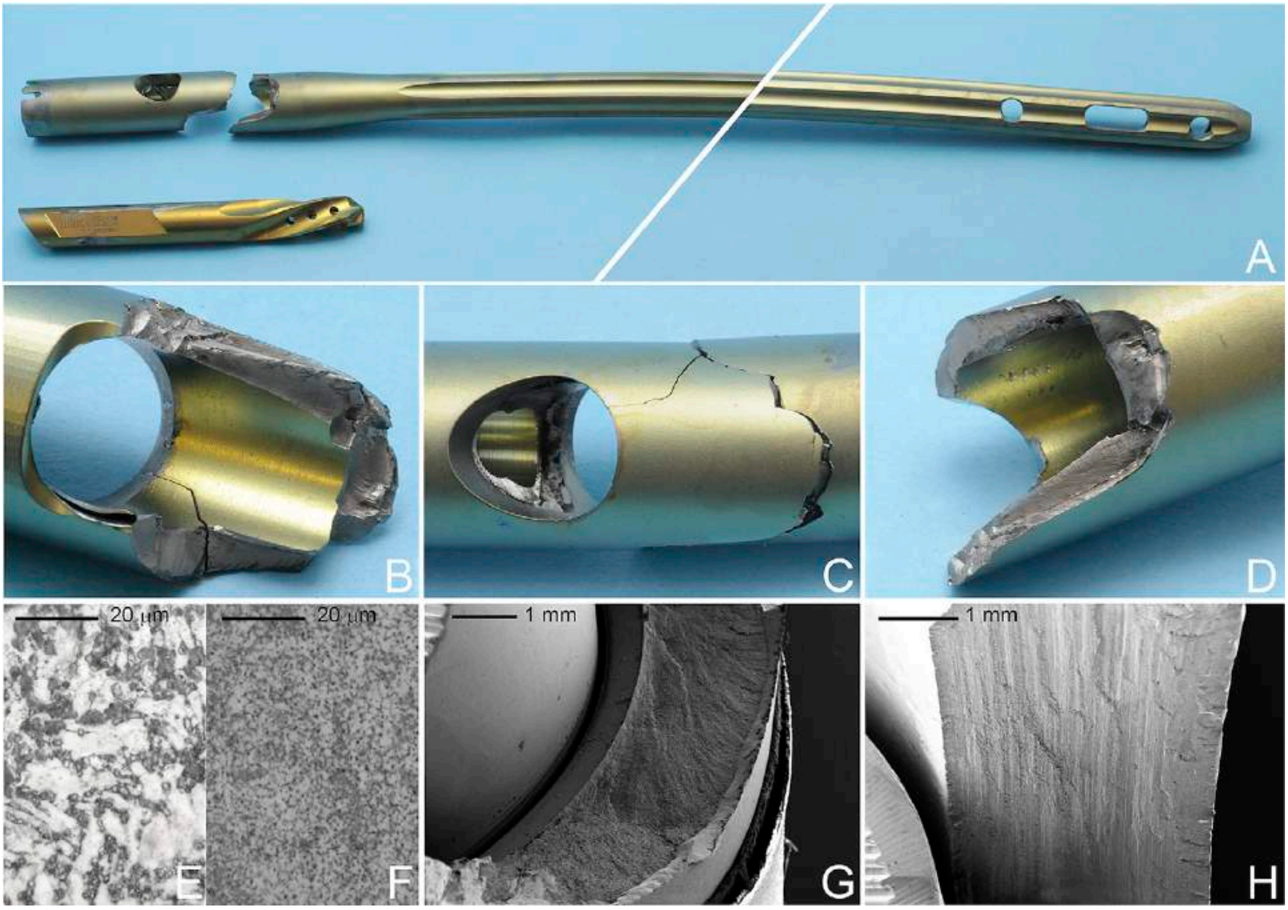

Fig. 6

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

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

Microscopic Analysis

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

Microhardness

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

SEM Analysis

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

Discussion

This investigation included an analysis of demographic information, radiographic findings, and retrieval data from the largest series, to our knowledge, of proximal femoral nail breakages in the published English literature and was the first study that we are aware of to involve laboratory analysis of the TFNA implant. The regular collection and analysis of cases of implant breakage across a large yet geographically isolated population through the availability of a centralized, independent implant retrieval center underpins the strength of this study. As a result, our findings may represent the early detection of an implant issue that has not yet been recognized elsewhere.

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

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

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

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

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

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

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

Appendix

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

Note: The authors recognize the heads of departments and theatre data managers at Fiona Stanley Hospital (Mr. Andrew Mattin), Sir Charles Gairdner Hospital (Prof. Richard Carey Smith), and Royal Perth Hospital (Mr. Alan Prosser) for their collaboration and provision of orthopaedic implant data. Laboratory analysis and data were provided by our centralized implant retrieval laboratory, the Centre for Implant Technology and Retrieval Analysis (CITRA), Western Australia.

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References

1. Williamson S, Landeiro F, McConnell T, Fulford-Smith L, Javaid MK, Judge A, Leal J. Costs of fragility hip fractures globally: a systematic review and meta-regression analysis. Osteoporos Int. 2017 Oct;28(10):2791-800. Epub 2017 Jul 26.

2. Burge R, Dawson-Hughes B, Solomon DH, Wong JB, King A, Tosteson A. Incidence and economic burden of osteoporosis-related fractures in the United States, 2005-2025. J Bone Miner Res. 2007 Mar;22(3):465-75.

3. Schipper IB, Steyerberg EW, Castelein RM, van der Heijden FHWM, den Hoed PT, Kerver AJ, van Vugt AB. Treatment of unstable trochanteric fractures. Randomised comparison of the gamma nail and the proximal femoral nail. J Bone Joint Surg Br. 2004 Jan;86(1):86-94.

4. Lee KB, Lee BT. Complications of femoral pertrochanteric fractures treated with Proximal Femoral Nail (PFN). J Korean Fract Soc. 2007 Jan;20(1):33-9.

5. Johnson NA, Uzoigwe C, Venkatesan M, Burgula V, Kulkarni A, Davison JN, Ashford RU. Risk factors for intramedullary nail breakage in proximal femoral fractures: a 10-year retrospective review. Ann R Coll Surg Engl. 2017 Feb;99(2):145-50. Epub 2016 Sep 23.

6. DePuy Synthes. TFN-Advanced Proximal Femoral Nailing System: surgical technique. 2017 Dec. http://synthes.vo.llnwd.net/o16/LLNWMB8/US%20Mobile/Synthes%20North%20America/Product%20Support%20Materials/Brochures/3936_DSUSTRM06140109-7_TFNA_Core_rev1.pdf. Accessed 2019 Jan 24.

7. DePuy Synthes. TFN-Advanced Proximal Femoral Nailing System value analysis brief. 2016. http://synthes.vo.llnwd.net/o16/LLNWMB8/INT%20Mobile/Synthes%20International/Product%20Support%20Material/legacy_Synthes_PDF/DSEM-TRM-0515-0375-1_LR.pdf. Accessed 2019 Jan 24.

8. Bălțatu MS, Vizureanu P, Țierean MH, Minciună MG, Achiței DC. Ti-Mo alloys used in medical applications. Adv Mat Res. 2015;1128:105-11.

9. Kellam JF, Meinberg EG, Agel J, Karam MD, Roberts CS. Introduction: fracture and dislocation classification compendium-2018: International Comprehensive Classification of Fractures and Dislocations Committee. J Orthop Trauma. 2018 Jan;32(Suppl 1):S1-10.

10. Baumgaertner MR, Curtin SL, Lindskog DM, Keggi JM. The value of the tip-apex distance in predicting failure of fixation of peritrochanteric fractures of the hip. J Bone Joint Surg Am. 1995 Jul;77(7):1058-64.

11. U.S. Food and Drug Administration. 510(k) premarket notification. 2016. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K160167. Accessed 2018 Nov 18

12. Okazaki Y, Gotoh E. Comparison of fatigue strengths of biocompatible Ti-15Zr-4Nb-4Ta alloy and other titanium materials. Mater Sci Eng C. 2011 Mar;31(2):325-33.

13. Barzilai S, Toher C, Curtarolo S, Levy O. Molybdenum-titanium phase diagram evaluated from ab initiocalculations. Phys Rev Mater. 2017;1(2):023604.

Appendix B: Patients with TFNA Breakage

Patient and radiographic factors for the cases of TFNA implant breakage

Case	Sex	Age* *(yr)*	BMI *(kg/m²)*	ASA	Diagnosis	Mechanism for Index Injury	AO	Reduction	Method	Cable	Implant	Time *(m)*	Mechanism of Breakage	Site	Diagnosis	Revision Implant†
1	F	70	24	2	Hip fracture	Mechanical fall	31A 2.2	Good	Closed	No	125°, 235x10mm, 100mm blade	8.6	Atraumatic	Proximal aperture	Non-union	130°, 235x12mm, 95mm blade + cement (TFNA)
2	F	77	27	2	Hip fracture	Mechanical fall	31A 3.3	Acceptable	Open	Yes	125°, 235x11mm, 105mm blade	3.4	Atraumatic	Proximal aperture	Delayed union	130°, 380x14mm, 110mm blade + cement (TFNA)
3	M	87	25	3	Hip fracture	Mechanical fall	31A 3.1	Good	Open	Yes	125°, 235x11mm, 105mm blade	2.8	Atraumatic	Proximal aperture	Non-union	130°, 235x12mm, 105mm blade (TFNA)
4	F	72	24	3	Hip fracture	Mechanical fall	31A 3.3	Good	Open	Yes	125°, 360x12mm, 90mm blade	3.6	Atraumatic	Proximal aperture	Delayed union	130°, 360x14mm, 85mm blade + cement (TFNA)
5	F	59	33	2	Hip fracture	Atraumatic	31A 3.2	Good	Closed	No	125°, 235x10mm, 85mm blade	5.6	Mechanical fall	Proximal + distal	Non-union	125°, 320x11mm, 90mm blade (TFNA)
6	F	89	29	2	Hip fracture	Mechanical fall	31A 2.2	Good	Closed	No	125°, 235x10mm, 90mm blade	6.5	Atraumatic	Proximal aperture	Delayed union	Non-operatively managed
7	F	94	30	3	Hip fracture	Mechanical fall	31A 3.1	Good	Open	Yes	130°, 360x12mm, 85mm screw	3.9	Atraumatic	Proximal aperture	Delayed union	130°, 360x12mm, 85mm screw (TFNA)
8	M	79	22	3	Broken PFNA	Mechanical fall	31A 3.3	Good	Open	No	130°, 235x12mm, 110mm screw	3.8	Atraumatic	Proximal aperture	Delayed union	400x14mm, 115 & 105mm recon screws (AFN)
9	F	77	27	2	Broken TFNA	Atraumatic	31A 3.3	Good	Closed	No	130°, 380x14mm, 110mm blade	2.3	Atraumatic	Proximal aperture	Delayed union	360x14mm, 115 & 120mm recon screws (AFN)
10	F	72	24	3	Broken TFNA	Atraumatic	31A 3.3	Acceptable	Open	Yes	130°, 360x14mm, 85mm blade	4.6	Atraumatic	Proximal aperture	Non-union	Total hip replacement (Zimmer ZMR)
11	M	74	28	2	Hip fracture	Mechanical fall	31A 3.3	Poor	Closed	No	130°, 360x10mm, 105mm blade	2.2	Atraumatic	Proximal aperture	Delayed union	125°, 380x12mm, 85mm blade (TFNA)
12	F	82	22	2	Hip fracture	Mechanical fall	31A 3.3	Good	Open	Yes	125°, 380x11mm, 95mm blade	5.6	Atraumatic	Proximal aperture	Delayed union	130°, 360x12mm, 85mm blade (TFNA)
13	F	79	22	2	Hip fracture	Mechanical fall	31A 3.3	Acceptable	Closed	No	125°, 235x11mm, 105mm blade	3.8	Atraumatic	Proximal aperture	Delayed union	125°, 200x12mm, 105mm blade + cement (PFNA)
14	M	75	28	2	Broken TFNA	Atraumatic	31A 3.3	Poor	Open	Yes	125°, 380x12mm, 85mm blade	5.4	Mechanical fall	Proximal aperture	Delayed union	Total hip replacement (Zimmer ZMR)
15	F	90	31	3	Hip fracture	Mechanical fall	32C 3i	Acceptable	Open	Yes	125°, 380x11mm, 90mm blade	7.2	Atraumatic	Proximal aperture	Delayed union	Non-operatively managed
16	M	92	26	3	Broken PFNA	Mechanical fall	32A 2a	Good	Closed	No	130°, 380x14mm, 100mm blade	9.8	Atraumatic	Proximal aperture	Non-union	Total hip replacement (Zimmer ZMR)

FIN.