Periprosthetic Fracture after Total Hip Arthroplasty: Treatment and Outcomes

Dr. Sumedha Suriyaarachchi Amarasekara
U5080650

Supervised by:

Professor Paul N Smith
Dr. Diana M Perriman

Date of submission – September 2016

A thesis submitted for the degree of
Master of Philosophy
of the
Australian National University

S**umedha Suriyaarachchi Amarasekara** hereby declare that this submission is my own work and that it contains no material previously published or written by another person except where acknowledged in the text. Nor does it contain material that has been accepted for the award of another degree or diploma in any university.

In addition, ethical approval from the ACT Health and the Australian National University, Human Ethics Committee was granted for the studies presented in this thesis. Subjects were required to read a subject information document and informed consent was gained prior to data collection.

Sumedha Suriyaarachchi Amarasekara

As supervisor of Dr. Sumedha S. Amarasekara's Master of Philosophy work, I certify that I consider his thesis 'A twelve year review of periprosthetic fractures following total hip arthroplasty: The TCH experience' to be suitable for examination.

Signed ______________________________

Date _____________________

Professor Paul N Smith
MedicalSchool
College of Medicine Biology and Environment
AustralianNationalUniversity

ACKNOWLEDGMENTS

This thesis has been the culmination of time, resources and ideas of many people. I would like to single out Dr, Diana Perriman, my immediate supervisor. Without her input across the desk, room, suburb, state, country and continent this thesis would not be in your hands today. THANK YOU for all your help and advice Diana; I know the preceding sentence is the topic sentence and should be on the top, but please indulge me this one time.

I would like to thank Professor Paul Smith for his insight and guidance, providing the necessary frame work across the multitude of institutions and departments, and agreeing to be my thesis supervisor for this MPhil which was a series of 'firsts'. I would also like to thank Jennie Scarvell who helped me get started, the staff at TORU for making it possible for me to do this thesis as a part-time student, with special thanks to Belinda Payne and Joe Lynch for their help in collating the patient data and Wendy Riley from the ANU for keeping me in line with my administrative obligations.

From the TCH, I would like to Thank Gloria Spyropolous for her help in coding and providing me with continuous access to the TCH patient files, the Department of Radiology and the Department of IT for providing access to the patient's radiographs and allowing me access to the hospital data while 'off site' respectively.

From The ADFA, Dr. Krishna Shankar for organizing the time and resources for the mechanical study to be carried out, advice on conducting the series of experiments, and his final report providing the data (table and figures) of the biomechanical study. Alan Fien for his insight on the biomechanical study and providing me with the laboratory time to validate the jig when none existed! Ahmed, my thanks to you for spending time ironing out the issues of the jig construction and running the tests on a tight schedule. My heartfelt thanks go to Marcos de Almeida, my constant companion and technical advisor in the specimen preparation. I would also like to thank Stuart Gay, Robert Clark and David Sharp for their work behind the scenes to make sure that everything ran smoothly.

I would like to thank Angelo Iezzi, research fellow from the Centre for Health Economics, Victoria, for his support and analysis of the AQOL data and the AOANJRR for providing the data on THA prostheses types used in the clinical study.

I would like to thank Poorna for tinkering with the issues I had in formatting this thesis. Last but not least, I would like to thank my mother who has being encouraging me to do an MPhil from the time I could read and write, and my wonderful wife Sherine, who has supported me during this whole process, making certain I was meeting my deadlines (with a range of incentives and disincentives). I am sure she had a secret pact with Diana!

ABSTRACT

Treatment of periprosthetic fractures (PPF) following total hip arthroplasty (THA) is seldom easy, often complex and always expensive. Although international data on periprosthetic fracture outcomes have been reported, there has been no published Australian data. We therefore sought to examine the long-term outcomes of patients treated in our centre and to compare them against previously published data from other centres outside Australia. By so doing we hoped to evaluate our performance and, more importantly, reflect on current surgical practice with respect to periprosthetic fracture treatment and its effectiveness. Another focus for this thesis was the testing of different fixation constructs with a view to examining potential opportunities for improving patient outcomes. The resulting body of work contained in this thesis includes a review of the literature, a retrospective cohort study and a biomechanical study. The questions examined include: what is known about PPF (Chapter 2), how our experience and outcomes in a regional centre compare with other published data (Chapter 3), how newer methods of fracture fixation compare with other established methods (Chapters 4 and 5) and finally, how we should manage this challenging problem in the future (Chapter 6).

A review of the literature revealed that although PPF following THA is an uncommon complication, the number is increasing with the increase in THA procedures being performed. PPF are more common in uncemented prostheses than in cemented prostheses and in revision surgery than in primary surgery. Currently, the Vancouver classification system is most commonly used by clinicians when treating this group of fractures. This classification is based on the relationship of the fracture position to the prosthesis, the stability of the prosthesis and the amount of host bone loss. The best results have been achieved in Vancouver B_2 PPF where a stem revision is required, whereas results after Vancouver B_1 PPF where the stem is not normally revised, have been less successful. Vancouver C fractures have been reported to result in surprisingly poor outcomes.

Over the twelve-year period of the retrospective cohort study, 51 patients were treated at the Canberra hospital for 56 PPF of the femur following THA. There were four Vancouver B_1 fractures, four Vancouver C fractures and one Vancouver B_2 fracture fixation failures. At the time of writing this thesis 29 deaths were recorded and failure of PPF fixation was the most common surgical complication. The biomechanical study was designed to examine the effectiveness of a new cable/plate system (SuperCable, Kinamed Inc., Camarillo, CA, USA) which claims to overcome the slippage and fretting

encountered when using metal cables. The experiment used 12 synthetic femurs which had been obliquely sectioned at the midshaft. These were used to compare three fixation constructs: an 8-hole plate with, SuperCables, steel cables and screws. The specimens were tested under compression compression cyclical loading up to 10,000 cycles at 1 Hz with maximum and minimum loads of 2.2kN and 0.2kN respectively. At the end of 10,000 cycles the average displacement of the fracture gap was the largest for SuperCable fixation, while it was the least for screw fixation, being 243μm and 3μm, and 144μm and 0μm for the relative vertical and horizontal displacement respectively. The corresponding values for fracture gap displacement for steel cable fixation was 35μm and 55μm. Conversely, the cable migration was least marked for SuperCables. From their original location, SuperCable migration varied by a magnitude of 82 to 173 μm, while the steel cable migration varied by a magnitude of 173μm to 225μm. It is suggested that the increased movement at the fracture site as reflected in the magnitude of the measured displacement of the fracture gap, implies a greater potential for secondary healing with SuperCable fixation but this hypothesis needs clinical evaluation.

The results of this thesis indicate that our clinical and patient reported outcomes are comparable to the international literature. It also suggests that the clinical outcomes in the treatment of Vancouver B_1 and C fractures are suboptimal and new treatment paradigms are probably required. Our biomechanical testing suggests important implications in terms of fracture healing and possible earlier weight bearing in patients with PPF. Finally, we suggest the need for a national or international registry to monitor progress in future PPF outcomes.

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ABBREVIATIONS

Acronym	Meaning
ACT	Australian Capital Territory
ADFA	Australian Defense Force Academy
AQoL-6D	Assessment of Quality of Life -6 Dimensions
AOANJRR	Australian Orthopaedic Association National Joint Replacement Registry
ASA	American Society of Anaesthesiologists
CAD	Computer Aided Design
CATIA	Computer Aided Three-dimensional Interactive Application
ICU	Intensive Care Unit
IM	Intramedullary
IMU	Inertial Measurement Unit
IT	Information Technology
OHS	Oxford Hip Score
PPF	Periprosthetic fracture/s
TCH	Canberra Hospital
THA	Total Hip Arthroplasty
TORU	Trauma and Orthopaedic Research Unit
WOMAC	Western Ontario McMaster University Osteoarthritis Index

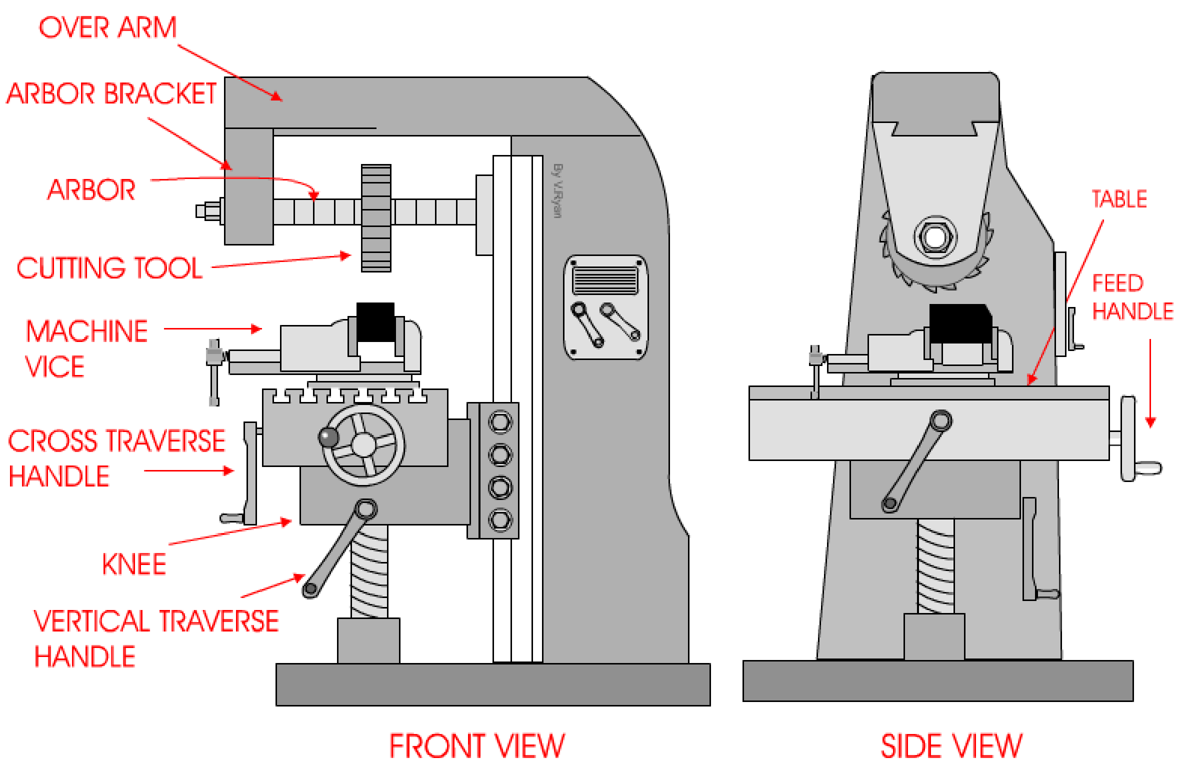
Glossary

Arbor: Rotating device on the milling machine on to which the cutting blades are mounted (See milling machine).

Milling: Is the machining process of using rotary cutters to remove material from a workpiece by advancing (or feeding) in a direction at an angle with the axis of the tool.

Milling machine: The machine used for milling (See milling)

Milling machine diagram with parts named.



CHAPTER 1

INTRODUCTION

Treatment of periprosthetic fractures (PPF) following total hip arthroplasty (THA) is seldom easy, often complex and always expensive. THA is a very successful procedure but its success cannot be measured without considering the complications that can ensue. PPF are a very serious complication requiring complicated surgery with variable results (Beals and Tower 1996). The number of THA performed every year is increasing due to an aging population and the demands of a younger population who have increased expectations of a better quality of life (Singh 2011). The number of complications and therefore also PPF, are concomitantly increasing due to this increase in THA and accompanying change in the type of arthroplasty (Lindahl 2007). Although the rate of PPF is reported to be relatively low at between 1% and 5% (Lindahl, Oden et al. 2007) the consequences can be devastating with reports of significant disability and prolonged rehabilitation times (Phillips, Boulton et al. 2011).

The success of THA for the relief of painful arthritis of the hip has been demonstrated (Chang, Pellisier et al. 1996). The British orthopaedic surgeon, John Charnely, was knighted for his pioneering work on the development of hip arthroplasty in the early 1960's. Since that time the number of THAs performed has steadily increased, making it is one of the commonest elective orthopaedic procedures in the world today. The Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) at the time of its inception in the year 2000 reported 14,193 primary total hip replacements (AOANJRR 2001). The 2014 AOANJRR annual report, the outcome of 280,522 primary conventional total hip replacements. This represented an additional 29,675 cases compared to the previous year. (AOANJRR 2014[1]). The increase in the number of hip replacements for just that year was, in fact, more than double the entire number of hip arthroplasties that were done 15 years ago.

An increase in the average life expectancy of the population has further fueled this increase in THA. Looking at this from an Australian perspective, it can be seen that the life expectancy in the 1960's (1960 -1962) was approximately 68 years for a male and 74 for a female. The life expectancy 50 years later (2011-2013) is 80 and 84 for males and females respectively (AIHW 2016). This increase in life expectancy has not been symmetrical across the board for all ages. It is skewed in favour of the aged. The number of Australians aged 55 years or older in 2001 was 4.2 million and this is expected to increase to 7.2 million in 2021 -a percentage increase from 22 % to 31% of the population (ABS 2013).

This rise in the life expectancy has enormous implications in terms of hip arthroplasty. Firstly, there is a substantial increase in the over 75 age group that are requiring hip arthroplasty that did not exist 25 years or so ago. Secondly, the average age that patients undergo hip replacement is 67 years and therefore a prosthesis now has to last longer. Thirdly, based on the survivorship rates for hip replacements (i.e. how long a hip replacement will remain in situ, before it fails and needs to be revised) more people will eventually need a revision of their hip, if not a second revision as well.

Compounding these above issues are the increasing demands in terms of function that patients place on the prosthetic system. Data reveals that over a third of primary THRs are done for those under the age of 65 (AOANJRR 2015). These younger and more active patients have greater demands in terms of activity and work which potentially lead to earlier wear of the prosthesis. The operation that was devised to alleviate pain and immobility in the elderly low demand patient now has to deliver a painless mobile hip expected to work at a higher level.

A further complicating factor is the obesity epidemic which society is now experiencing (Swinburn, Sacks et al. 2011). The primary cause for degenerative osteoarthritis is wear and tear of the articular surfaces, which is a function of the overall force (which is related to a person’s weight) being transmitted across the hip joint(Ganz, Leunig et al. 2008). Obesity only compounds this issue (Cooper, Inskip et al. 1998, Harms, Larson et al. 2007, Vasarhelyi and MacDonald 2012). Firstly, by increasing the number of joint arthroplasties needed for a given population. Secondly, the risk of revision is significantly increased in the morbidly obese (Lubbeke, Katz et al. 2007, Hanna, McCalden et al. 2017).

Osteoporosis is another important factor that plays a role in PPF. It is known fact that osteoporosis is associated with an increase rate in hip fractures (Cummings and Melton III 2002). The treatment of osteoporotic fractures is also associated with an increase rate in complication of fracture fixation and failure (Barrios, Broström et al. 1993). It has been estimated that in 2012, 4.74 million Australians over the age of 50 have osteoporosis or osteopenia or poor bone health. This is estimate is expected to rise to 6.2 million by 2022 (a

31% rise) (Watts, Abimanyi-Ochom et al. 2013). Therefore on the one hand there will be an increasing number of hip arthroplasties being performed due to the increasing number of hip fractures secondary to osteoporosis and on the other hand an increasing number of PPF following hip arthroplasties (performed for all causes) due to osteoporosis in an ageing population. Additionally, the treatment of PPF will be further complicated by increased failure rate due to osteoporotic bone (Augat, Simon et al. 2005).

The increase in the number of hip arthroplasties has also been associated with a change in the type of hip arthroplasty that is being performed (Wyatt, Hooper et al. 2014). In the 1960’s Charnely had introduced the cemented hip arthroplasty. Over time cementless and hybrid forms of fixation for hip arthroplasties have been developed. Currently the number of cementless total hip arthroplasties that are performed is increasing. According to the AOANJRR 2015 report the use of cementless fixation has increased from 51.3% in 2003 to 63.2% in 2014. Cement fixation and hybrid fixation has declined from 13.9% to 4.4% and 34.8% to 32.4% respectively (AOANJRR 2015). This has important implications in the occurrence of periprosthetic fractures of the hip.

The increase in periprosthetic fractures is thought to be associated with the increase in the use of cementless hip arthroplasty (Lindahl 2007). In a cemented hip arthroplasty, the cement is considered to act as a grout in the bond between the host bone and the prosthesis. In cementless arthroplasty the prosthesis is meant to fit tightly into the femoral canal (press fit) to establish stability between the prosthesis and the bone to enable bony ingrowth. Therefore in a cementless prosthesis there is more force and pressure created in the femoral canal, both during the process of reaming and the insertion of the femoral prosthesis, which in turn leads to an increased incidence of intra-operative periprosthetic fractures.

With time, periprosthetic fractures which were a rare occurrence following hip arthroplasty have become a much commoner complication. In the 2004 AOA NJRR annual report, 937 hip arthroplasty revisions were reportedly due to periprosthetic fractures, accounting for 8.3% of the revisions (AOANJRR 2004). In the 2014 AOA NJRR annual report, 1576 revisions were reported for periprosthetic fractures, which had overtaken infection to become the third commonest reason for revision hip arthroplasty, accounting for 17.5% of the revisions (AOANJRR 2014[2]). Though this is also a reflection of a possible decrease in hip revisions due to other causes, it is important to note that this accounts for only those periprosthetic fractures that resulted in a hip revision arthroplasty. All other periprosthetic fractures that did not require a hip revision arthroplasty are not accounted for in this statistic and therefore the true incidence of periprosthetic fracture is likely to be considerably higher.

The treatment of periprosthetic fractures is complex. The patients are elderly and have multiple co-morbidities. Conventional screw and plate fixation of fractures cannot always be used due to the presence of the femoral component within the intramedullary canal of the femur. Hence different methods of fixation, such as those which utilize cables and plate constructs need to be used. At times the hip replacements involved in the periprosthetic fracture need to be revised using special prosthetic components which are expensive. Surgery is often lengthy leading to a longer post-operative stay and a lengthier rehabilitation (Phillips, Boulton et al. 2011). The treating surgeons need to have experience in both in fracture fixation as well revision hip surgery.

These periprosthetic fractures following hip arthroplasty due to their complex nature therefore need specialized treatment. As discussed earlier, although the incidence of periprosthetic fractures has been increasing they are still fairly uncommon. An average orthopaedic surgeon performing 150 to 200 hundred hip replacements annually will not encounter more than a few of these in a year. Therefore these fractures are best treated in tertiary level referral hospitals by a dedicated group of trained orthopaedic surgeons. In such a unit the number of these fractures fixed over a decade still would be in the hundreds rather than the thousands.

The number of periprosthetic fractures that are prevalent at any given time, will be determined by the number of hip replacements, which in turn is determined by the number of people in a given population. Most of the main cities in the world have a population of over 5 million. In Australia, Sydney and Melbourne are on the verge of achieving this target in the not too distant future. Furthermore, Australia despite its first world status has one of the least dense population to land ratios in the world. Almost half of the Australian population is widely dispersed around the shoreline of the continent. Transport of patients across an entire continent is not practical. Regional centres need to be established and even then based on population figures gaining expertise in an uncommon procedure becomes more difficult.

Based on what we know about periprosthetic fractures, how does the Australian experience fit in? Do our centres have the same number of periprosthetic fractures that are prevalent in other centres? Do we have the similar outcomes? How do our patients fare? These were the questions that intrigued me. “A twelve year review of periprosthetic fractures: The TCH experience” is a thesis that seeks the answers for these questions.

CHAPTER 2

LITERATURE REVIEW OF TREATMENT OF PERIPROSTHETIC FRACTURES

2.1 AETIOLOGY AND EPIDEMIOLOGY OF PERIPROSTHETIC FRACTURES

The true incidence of PPF is difficult to estimate. Hip arthroplasty registers in different countries provide prevalence estimates of these fractures and their trends. However, not all fractures are captured. The Australian Orthopaedic Association National Joint Registry (AOANJRR) records only THA revisions, therefore PPF fractures which do not result in a revision do not get recorded. The rate of PPF is affected by patient demographics, the number of revised patients in the fracture group, the use of cemented or uncemented prostheses and finally, the follow-up regimen used to detect loosening/osteolysis leading to a decision to revise before fracture (Lindahl 2007).

Periprosthetic fractures (PPF) can involve either the acetabulum or the femur (or both) and can be classified as intraoperative or postoperative. The incidence of both of these fractures is higher in revision than in primary procedures and is further increased with the use of uncemented components (Masri, Meek et al. 2004). The occurrence of periprosthetic acetabular fractures is much rarer than femoral fractures so there is very little data available about them. Therefore most of the literature relates to periprosthetic fractures of the femur. Since this study only involves PPF of the femoral component, the following literature review has been confined to this area.

Intra-operative PPF of the femur occur more commonly in revision THA than primary THA (Johansson, McBroom et al. 1981, Berry 2003) with a higher incidence associated with the use of uncemented prostheses (Fitzgerald, Brindley et al. 1988, Morrey and Kavanagh 1992, Masri, Meek et al. 2004). The increased impaction forces associated with uncemented fixation increases the risk of femoral PPF (Haddad, Masri et al. 1999). The increase of PPF during revision surgery is associated with the rigors of having to remove the existing stem, with or without the cement mantle, inserting a new stem and dealing with any accompanying bone loss. Berry (1999) comparative rates of 1% (238 of 23,980) versus 7.8% (497 of 6349) for PPF during primary and revision procedures from the Mayo Clinic Joint Registry data. The majority of the primary THR fractures occurred in procedures using uncemented stems, 5.4% (170 of 3121) compared with 0.3% of cemented stems (68 of 20,859) (Berry 1999). This higher incidence in uncemented stems is also supported by other authors (Fitzgerald, Brindley et al. 1988, Morrey and Kavanagh 1992). The increased incidence with uncemented components applies also to revision procedures with 3.6% (175 of 4813) occurring with cemented components compared to 21% (322 of 1536) in uncemented revisions (Berry 1999).

There are a number of aetiological factors which to PPF of the femur. These include undiagnosed intra-operative fractures, fractures from osteolysis secondary to stress shielding, and fractures that occur secondary to bone loss and loosening (Haddad, Masri et al. 1999). The incidence of these fractures appears to be growing with increased deployment of hip replacement technology as it improves in terms of longevity and is used for more and younger patients (Garbuz, Masri et al. 1998, Lindahl 2007). Specifically, the introduction of uncemented stems which improve utilization of scarce theatre time (by elimination of the use of cement) over the past 10 years has also undoubtedly contributed to the increasing incidence of femoral PPF (Wyatt, Hooper et al. 2014).

A minimal trauma episode is the most common cause of post-operative periprosthetic fracture but other causes include undiagnosed osteolytic defects and major trauma. Minor trauma has been attributed to 84% to 88% of PPF (Adolphson, Jonsson et al. 1987, Beals and Tower 1996). Undiagnosed osteolytic defects have been assumed in up to 50% of cases based on insidious pain in the absence of any traumatic event (Lewallen and Berry 1998). Major trauma has been reported in 8% in cases (Cooke and Newman 1988).

Risk factors for PPF include disorders which decrease bone strength or integrity, or promote conditions where excessive forces are exerted on the bone (Table 2.1). These disorders can be either direct, due to processes that affect the bone quality and/or quantity, or indirect where the bone is subjected to decreased muscle forces resulting in decreased bone density. Excessive forces in conditions such as epilepsy can also contribute to fractures in an already weakened bone. Osteoporosis is the most obvious risk factor for PPF, as it is for all fractures (Russell 2013). Rheumatoid arthritis is a recognized risk factor for PPF (Poss, Ewald et al. 1976) due to the prolonged steroids use.

Table 2.1 Risk factors for intra-operative and post-operative PPF (Haddad, Masri et al. 1999)

Osteoporosis
- Primary
- Secondary to steroids and other medication
- Female sex

Osteopenia
- Rheumatoid arthritis
- Osteomalacia
- Paget's disease
- Osteopetrosis
- Osteogenesis imperfecta
- Thalassemia

Neuro-muscular disorders
- Parkinsonism
- Neuropathic arthropathy
- Poliomyelitis
- Cerebral Palsy
- Myasthenia Gravis
- Seizures
- Ataxia

Previous hip surgery
- Stress risers within the cortex
- Screw holes
- Plates

Associated hip surgery such as osteotomy

Revision Arthroplasty

Loose prosthesis

Localized osteolysis

Cortical perforation
- Narrow femoral canals
- Developmental dislocation of the hip

Juvenile Rheumatoid Arthritis

Pre-existing areas of femoral bone loss

2.2 CLASSIFICATION SYSTEMS

2.2.1 Classification of femoral fractures

Fracture patterns are not always the same and therefore classification systems are needed for communication, treatment decisions, and outcome assessment. The classification system is used as a tool to formulate a treatment plan for a given fracture and also provides a mechanism for comparison of outcomes across equivalent groups.

The earliest attempt at classifying PPF was made by Parrish and Jones in 1964 (Parrish and Jones 1964). Nine periprosthetic fractures were individually described and classified into 4 categories, based on the level of the fracture: at the level of the intertrochanteric region, proximal femur, mid shaft and distal shaft of the femur. The femoral prosthesis is mentioned in the description of the fracture, but no direct attempt was made to relate the prosthesis to the fracture pattern. It is interesting to note that the index THA for all the cases was a fracture of the femoral neck. This was at a time before the advent of the Charnely hip and there was still no well recognized and accepted procedure to deal with degenerative osteoarthritis.

In the decade spanning from 1980 to1990 several classification systems were introduced that took fracture patterns and the implant stability into consideration. By this time THA was being performed on a regular basis for degenerative osteoarthritis of the hip. PPF of the hip were becoming recognized as a serious complication and classifications were introduced to deal with intra-operative fractures as well as postoperative fractures. These classifications unlike that of Parrish and Jones, related the fracture to the level of the prosthesis, rather than to an anatomical location the femur. The classifications were made according to the type of stem (cemented or uncemented), level of the fracture and the fracture pattern and the stability of the stem. Table 2.2 and 2.3 show a summary of the existing classification systems of this time. None of these classifications encompassed all aspects of the PPF in regards to formulating a rational approach in the treatment pattern, and the multitude of classifications do indicate that none of these classifications were close to being ‘ideal’. The Johansson classification system that included both intraoperative and postoperative fractures, with its simplicity was the most popular classification system till the mid nineteen nighties (Johansson, McBroom et al. 1981).

Table 2.2 Intra-operative classification of periprosthetic fractures following THA

Name of classification	**Classification**				**Year and type of prosthesis**
Johansson (Johansson et al., 1981)	Type I	Type II	Type III		1981
	Proximal to the tip	Around the tip	Distal to the tip		Cement and uncemented
Mallory (Mallory et al., 1989)	Type I	Type II	Type III		1989
	Proximal to lessor trochanter	Distal to lessor trochanter but no closer than 4cm to the tip of the stem	More distal than type II		Uncemented stems
Schwartz (Schwartz et al., 1989)	Proximal complete	Proximal incomplete	Distal incomplete minimally displaced and displaced	Distal complete	1989 Uncemented stems
Stuchin (Stuchin, 1990)	Type I	Type II	Type III	Type IV	1990
	Proximal to the tip	Around the tip	Related to stress riser	Not otherwise classifiable	Uncemented stems

Table 2.3 Post-operative classification of periprosthetic fractures following THA

Name of classification	Classification				Year of classification
Johansson (Johansson, McBroom et al. 1981)	Type I Proximal to the tip	Type II Around the tip	Type III Distal to the tip		1981
Bethea (Bethea, DeAndrade et al. 1982)	A Below the tip	B Around the stem	C Comminuted		1982
Cooke and Newman(Cooke and Newman 1988)	Type 1 Comminuted	Type 2 Oblique or spiral around the stem	Type 3 Transverse below the tip	Type 4 Oblique below the tip	1988
Roffman and Mendes(Roffman and Mendes 1989)	Stable prosthesis	Loose prosthesis			1989

In the mid nineteen nighties two classification systems were introduced- the Beals and Tower classification (Beals and Tower 1996) and the Vancouver classification system (Duncan and Masri 1995). The Beals and Tower classification took almost all elements of the fracture into account; the level of the fractures, fracture pattern and stability of the implant and also looked at treatment options. However, the classification was not simple and failed to take in to account the host bone stock. In contrast the Vancouver classification was a simple classification system (applying to both intra-operative and post-operative periprosthetic fractures) that encompassed both cemented and uncemented stems and noted the stability of the implant as well as the host bone stock, which had major implications in the treatment options (Table 2.4 and 2.5).

Table 2.4 Vancouver, post-operative classification of periprosthetic fractures following THA

Location of the fracture		Status of the stem	Bone stock	Classification
Trochanteric region	Involving Greater trochanter	Well fixed		A_G
	Involving lesser trochanter	Well fixed		A_L
Diaphyseal in relation to the femoral stem		Well fixed, stable stem	Good	B_1
		Stem involved and loose	Good	B_2
		Stem involved and loose	Poor	B_3
Distal to the stem		Not applicable		C

Table 2.5 Vancouver, intra-operative classification of periprosthetic fractures following THA

Location of the fracture	Nature of the fracture		
	Cortical perforation	Undisplaced linear crack	Displaced fracture
Trochanteric region	A_1	A_2	A_3
Diaphyseal in relation to the stem	B_1	B_2	B_3
Distal to the stem	C_1	C_2	C_3

The Vancouver classification system (Duncan and Masri 1995) is currently the most widely-used and only validated classification system for femoral PPF of the hip. The Vancouver system classifies fractures according to fracture pattern, stability of the implant and the available bone stock. Both the post and intra-operative classifications have a similar nomenclature giving the system consistency. This system has been subject to reliability and validity testing in both North America and Europe (Brady, Garbuz et al. 2000, Rayan, Dodd et al. 2008, Naqvi, Baig et al. 2012). Intra-observer agreement is reported to range between 0.73 and 0.83 with an inter-observer agreement of 0.61 to 0.64 by kappa analysis, indicating substantial agreement between observers (Brady, Garbuz et al. 2000).

2.3 TREATMENT OF PERIPROSTHETIC FRACTURES

Treatment of periprosthetic fractures following THA is dictated by a host of factors e.g. fracture pattern, comminution, stem fixation, stem loosening, osteolysis etc...The Vancouver classification, which is currently the most popular classification, guides the treatment according to the anatomical site, fixation of the stem (well fixed or loose), the available bone stock and as to whether the fracture was sustained intra-operative or post-operative.

However, it is pertinent to understand that in intra-operative fractures, it is the time of diagnosis that matters the most because intra-operative fractures diagnosed post–operatively are managed differently to those that are diagnosed during the surgery.

The other significant factor that is not considered in the Vancouver classification but influences treatment, is the nature of the stem fixation. Is it a cemented stem or an uncemented stem? The use of cement imposes an additional factor to consider when making decisions about the management of PPF. This will be discussed in detail in section 2.3.1.1B

PPF can also occur due to implant loosening secondary to aseptic osteolysis, which occurs due to wear debris (Holt, Murnaghan et al. 2007, Kurtz, Gawel et al. 2011, Pal, Quah et al. 2011). Management of these fractures involves complex reconstructions and from a practical point of view belong under the category of a ‘failed arthroplasty’ (Scuderi 2014). This aspect is considered to be beyond the scope of this literature review and as such has not been discussed.

2.3.1. Periprosthetic fractures of the femur

Currently the Vancouver classification system is the most popular classification system that is used in the treatment of periprosthetic fractures of the femur following THA.

2.3.1.1A Vancouver A (post-operative):

Vancouver A fractures are confined to the trochanteric region of the femur and are not in direct contact with the femoral stem.

Type A_G fractures involve the greater trochanter are usually stable and can be treated with protected weight bearing for 6 to 8 weeks. Trochanteric fractures that have moved less than 2cm can be treated non-operatively (Brun and Maansson 2013). Fractures with more than 2.5cm displacement or trochanteric non-union that result in instability or weakness will need internal fixation. Fractures associated with significant femoral osteolysis secondary to polyethylene wear, should be considered for a formal limited acetabular revision conjunction with bone grafting and fixation of the femur.

Type A_L fractures are rare, usually minor and inconsequential. If these fractures involve a large portion of the femoral calcar and are considered to be major, they should be considered as Vancouver B fractures and may require a revision THA to avoid impending implant instability issues.

2.3.1.1B Vancouver B (post-operative)

Vancouver B fractures are confined to the area of the femoral stem and the fracture is in direct contact with the femoral stem. In Type B_1 fractures the stem is stable, in Type B_2 the stem is unstable and in Type B_3 there is an associated loss of bone in addition to the unstable stem.

2.3.1.1B_1 Vancouver B_1

The challenge in the treatment of these fractures is the proximal fixation of the fracture. Standard plates and screws are not desirable as the screws tend to violate the cement/stem interphase in a cemented stem, and are difficult to insert if a canal filling uncemented stem is present. Several options for open reduction and internal fixation of these fractures have been described without any single method being favoured.

Cable plate systems offer the options of both screw fixation as well as circumferential cables, mitigating the need for screws in unsuitable areas. The Ogden plate (Zimmer) was one of the first designs to be used in the cable plate system (Zenni, Pomeroy et al. 1988). Since then several plate systems have been introduced successfully with reported fracture union rates of

100% (Xue, Tu et al. 2011, Apivatthakakul, Phornphutkul et al. 2012, Ebraheim, Sochacki et al. 2013).

However, there have also been poor results with these systems with reported union rates as low as 40% (Tsiridis, Narvani et al. 2005). The failure rates of the plate cable system have been attributed to bio-mechanical drawbacks in the application of the plate; the biological being related to the application process of cables and the mechanical being related to the cable properties (Bryant, Morshed et al. 2009). The cables have to be applied circumferentially which entails stripping the soft tissues of the bone circumferentially depriving the bone of its blood supply and then need to be tightened (tensioned) which leads to further interference of the periosteal blood supply. Both these biological effects are thought to result in a diminished blood supply leading to a decreased potential in fracture healing (Ricci, Bolhofner et al. 2005, Bryant, Morshed et al. 2009). Mechanical issues are that: stainless steel cables have limited ability to maintain compression with progressive loss of tension (Menard, Emard et al. 2013), monofilament cables are prone to breakage and multifilament cables tend to undergo fatigue failure and fray (Steinberg and Shavit 2011, Lenz, Perren et al. 2013).

To compensate for the biological issues of metal plates, cortical strut grafts have been used on their own or in conjunction with a plate system as another option. Since the first report of cortical strut grafts in 1989 (Chandler and Penenberg 1989) they have been used consistently (Chandler and Tigges 1998, Haddad, Duncan et al. 2002, Virolainen, Mokka et al. 2010). Studies have shown that the cortical strut grafts get incorporated in to the fracture process (Chandler and Tigges 1998). Strut grafts, if used on their own are placed on the anterior and lateral aspect of the fracture and are held by cerclage wires, and when used in conjunction with a plate are placed anteriorly to the femur to augment the plate (Masri, Meek et al. 2004). The use of a single strut graft is biomechanically weaker than a cable plate and has shown to have an unacceptable failure rate when compared with augmenting of cable palate anteriorly or used as two strut grafts on their own (Haddad, Duncan et al. 2002, Haddad and Duncan 2003, Tsiridis, Haddad et al. 2003). There has also been a study that advocated the use of a strut graft and a plate, as being superior to the use of plates alone (Buttaro, Farfalli et al. 2007). These results have been collaborated by biomechanical studies as well (Zdero, Walker et al. 2008). The advantages of the strut grafts is that they can be customized to fit any femur (independent of the intramedullary prosthesis), have the allograft sharing module of the femur and augment host bone stock and strength (Haddad, Duncan et al. 2002).

Despite excellent results in some series cortical strut grafts are not without their disadvantages. Placement of the strut grafts involve further stripping of the femur. The application of a single plate requires stripping of the lateral aspect of the femur. Therefore to apply a second ‘plate’ requires the additional stripping of the anterior aspect leading to almost 50% or more loss of soft tissue cover –hence the vascularity of the femur. This process is considered to have a detrimental effect on fracture healing, leading to a delayed union or failure of the construct. The second concern is the increased risk of infection due to the devascularisation process and addition of foreign material (Ricci, Bolhofner et al. 2005, Bryant, Morshed et al. 2009). In a recent systemic review of periprosthetic fracture fixation caution has been advocated in the use of cortical strut grafts due to these complications (Moore, Baldwin et al. 2014).

To overcome the problems of standard plate / screw application, plate /cable systems and strut grafts, recent developments in plate technology have been utilized. These are placement of eccentric screw holes in the plate and locking plate technology. Plates with eccentric screw hole positions offer cortical-cortical fixation with minimal invasion into the medullary cavity. These plates can be applied in a ‘standard fashion’ on the lateral aspect of the femur. However, since the screw holes are eccentric and are placed towards the edge of the plate, they provide secure fixation to the bone, without disruption of the stem fixation by offering ‘cortical-cortical’ screw fixation, as opposed to the cortical-medulla-cortical fixation of a standard screw. Locking plates offer superiority (over standard plates) in the overall construct for fixation of osteoporotic bone, as well unicortical fixation of screws that once again mitigates the need for interfering with the stem fixation (Frigg 2003, Wood, Naudie et al. 2011). Recent plates such as the NCB plate (Zimmer) uses the locking technology in combination with eccentric screw hole positioning giving a versatile plate for the fixation of these Vancouver B_1 fractures (White 2013). However there is a paucity of studies evaluating the new eccentric screw technology.

For Vancouver type B_1 fractures, it is now recommended that regardless of the method of treatment, which could be standard /locking plates, cable plate systems, strut allografts or a combination of these, the fracture site should be bone grafted with morselized bone (Masri, Meek et al. 2004).

Currently there seems to be a move to further divide the B_1 fractures with a stem revision being advocated for short oblique fractures at the tip of the stem and fractures that extend to the medial cortex of the shaft as these are considered to be more unstable (Matharu, Pynsent et al. 2012). It must be also noted that good results have been obtained by revising all Vancouver B_1 fractures, though this is not a widely used practice (Fawzy, de Steiger et al. 2009).

2.3.1.1B_2 and 2.3.1.1B_3 Vancouver B_2 and B_3

The general principle in governing these fractures is the same i.e. an unstable stem, hence they have been discussed together. A revision hip arthroplasty is required for both Vancouver type B_2 and B_3 periprosthetic fractures as the stem is unstable. Type B_3 fractures pose an additional challenge due to the associated bone loss due to aseptic osteolysis.

The most important criteria in revision arthroplasty is bypassing the fracture by at least two diameters of the femoral shaft at the level of the fracture. The original data for this came from a canine study (Larson, Chao et al. 1991) which since then has been confirmed in clinical studies as well (Stuchin 1990, Morrey and Kavanagh 1992). It is pertinent to note that in the original canine study, which evaluated cemented stems to failure in torsion, a two diameter bypass was noted as the most optimum distance i.e. the results for a three diametre bypass were inferior to a two diametre bypass.

Review of results, with the exclusion of impacting grafting, indicate that uncemented revisions are more successful than cemented revisions. Beals and Tower reported on 102 interventions (93 patients) for periprosthetic fractures of the femur from 30 surgeons (Beals and Tower 1996). Regardless of the fracture site it was shown that uncemented revisions (n=28) had a better outcome than cemented (n=13, P=0.01) revisions. Uncemented revisions had no complications in 80% of the cases while cemented revisions had complications in 39% of the cases. The non-union and new periprosthetic fracture rate was 3% and 7%, and 31% and15% for uncemented revisions and cemented revisions respectively. The superiority of uncemented revisions over cemented revisions have been shown in other studies as well (Mont and Maar 1994, Schmidt and Kyle 2002, Berry 2003).

Extensively porous coated stems show a high rate of union and stable fixation and have been shown to be better than the earlier proximally coated uncemented stems (Springer, Berry et al. 2003). Fully coated, modular, fluted tapered stems have been used successfully in the treatment of B2 and B3 fractures with over a 90% union rate (Abdel, Lewallen et al. 2014).

In these cases it was noted that there was an increase in the cortical index and the medial and lateral cortical thickness over time. This was most pronounced in those with moderate osteoporosis with the use of thinner stems (under16mm) (Garcia-Cimbrelo, Garcia-Rey et al. 2011).

Impaction grafting in conjunction with cemented revision for periprosthetic fractures of the hip have proven to show results that are comparable to uncemented revisions with 100% survival at 10 years (Schreurs, Arts et al. 2006). Impaction grafting has been used successfully for treating bone loss in Vancouver B3 fractures (Lee, Nelson et al. 2010). Tsidris retrospectively reviewed 144 fractures with B2 and B3 fractures. Impaction grafting with a long stem achieved higher union rates than long stem revision alone (odds ratio = 4.07; 95% CI 1—15; p = 0.035) (Tsiridis, Narvani et al. 2004). Long stem cemented revisions in the elderly have shown to be very successful allowing immediate weight bearing with no further revisions or radiographic evidence of the implant being loose at final follow up (Corten, Macdonald et al. 2012).

Vancouver B_3 fractures often require the use of structural allograft replacement of the proximal femur within allograft-prosthetic-composite revision, a tumour prosthesis, or a custom implant (Masri, Meek et al. 2004). These fractures belong for all practical purposes under the category of a ‘failed arthroplasty’.

2.3.1.1C Vancouver C (post-operative):

Vancouver type C fractures can be treated with standard open reduction and internal fixation methods for a distal femur (Corten, Vanrykel et al. 2009). Efficient fixation for these fractures have been demonstrated both with standard and locking plate technology, current evidence not being able to demonstrate superiority of any single plate system (Baba, Kaneko et al. 2013, Moore, Baldwin et al. 2014).

2.3.1.2. Intra-operative periprosthetic fractures of the femur:

Treatment of intra-operative fractures of the femur are based on the individual subtypes which are an extension of the existing Vancouver classification (Duncan and Masri 1995). Subtype 1: representing a simple cortical perforation; subtype 2: representing an undisplaced linear crack; and subtype 3 representing a displaced, or unstable fracture.

2.3.1.2A Vancouver A intra-operative subtypes:

Subtype A_1: Cortical perforation

These fractures are unlikely to affect the stability of the stem. If bone graft is available locally (i.e. acetabular reamings) the recommendation is to treat it with simple bone graft or if not, then to be ignored.

Subtype A_2: Undisplaced linear crack

These fractures occur at the time of proximal broaching or stem insertion. These can be treated with cerclage wiring, which should be done as soon as the fracture is noticed to avoid further propagation of the fracture.

Subtype A_3: Displaced or unstable fracture of the proximal femur or greater trochanter

These include inadvertent trochanteric fractures or proximal cortical perforation of the calcar femoral at the time of insertion of proximally coated femoral stems. Fractures of the trochanter should be fixed in order to achieve stability at the end of the procedure, the means of fixation being immaterial (Masri, Meek et al. 2004). A diaphyseal fitting uncemented stem should be used if the split disrupts the integrity of the metaphyseal region (Mont and Maar 1994). In revision surgery as a diaphyseal fitting stem is used in most instances, these fractures do not require any further special treatment.

Another fracture that occurs in revision surgery with an extended femoral osteotomy, is a fracture at the base of the trochanter, at the time of tightening the wire/cable on reducing the osteotomy to be fixed. This fracture can be potentially avoided by using a narrow strut graft along the lateral aspect of the femur to prevent the wire /cable cutting though the underlying weakened bone (Masri, Meek et al. 2004).

2.3.1.2B Vancouver B intra-operative subtypes:

All intra-operative Vancouver B subtype fractures are treated on the principle that, the fracture should be bypassed by two cortical diameters with a longer stem (Larson, Chao et al. 1991) and that it is advisable to consider cerclage fixation below the fracture prior to the insertion of the stem. If the fracture cannot be by passed with a stem, then it should be bypassed with a cortical strut and the fracture be bone grafted at that time. In addition to this for Subtype B_2 fractures cerclage wires are needed to secure the fracture. In cases where the Subtype B_2 fracture is only recognized postoperatively a period of 6 weeks to 3 months of protected weight bearing is recommended while Subtype B_3 fractures should be exposed, reduced and fixed according to their configuration. Oblique or spiral fractures can be treated as Subtype B_2 equivalents with cerclage fixation, while transverse fractures should be secured with one or two strut grafts.

2.3.1.2C Vancouver C intra-operative subtypes:

These are uncommon intra-operative fractures. These are treated on the same principles that apply for Vancouver subtype B, where due to the location of the fracture, it cannot be bypassed by a stem. In Subtype C_2, long spiral fractures with inherent stability may not require a cortical strut graft, while plate fixation is needed for the Subtype C_3.

CHAPTER 3

RETROSPECTIVE REVIEW OF PERIPROSTHETIC FRACTURES AT CANBERRA HOSPITAL -A 12 YEAR REVIEW

3.1 INTRODUCTION

Periprosthetic fractures (PPF) following total hip arthroplasty (THA) are a very serious complication requiring complex surgery with variable results (Beals and Tower 1996). The number of PPF are increasing as a result of an increase in the number of THAs being performed (Berry 2003), an aging population living longer (Singh 2011) and changes in practice resulting in more cementless arthroplasties being done (Lindahl 2007). All of these factors are being further exacerbated by the obesity epidemic we are now facing (Swinburn, Sacks et al. 2011) and also the problem of osteoporosis in the elderly population (Wade, Strader et al. 2014).

PPF, once a rare occurrence following hip arthroplasty, have become a much commoner complication. In 2004, the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) reported 937 hip arthroplasty revisions for periprosthetic fractures, accounting for 8.3% of the revisions. In 2014 the AOANJRR reported 1576 revisions for periprosthetic fractures, which had overtaken infection to become the third commonest reason for revision hip arthroplasty, accounting for 17.5% of all revisions. It is important to note that PPF that did not require a hip revision arthroplasty are NOT accounted for in this statistic and therefore the actual number is highly likely to be higher.

PPF are a complex and difficult problem to treat. Although the rate of PPF is relatively low at between 1% and 5%, the consequences can be devastating with reports of significant disability and extensive rehabilitation times (Lindahl, Oden et al. 2007). An average orthopaedic surgeon performing 150 to 200 hundred hip replacements during a year will not encounter more than a few in a year. Therefore, it has been suggested that these complex fractures are best treated in tertiary level referral hospitals by a dedicated group of trained orthopaedic surgeons (Phillips, Boulton et al. 2011). There have been no data reported for Australian patients to date. The aim of this study therefore, was to describe an Australian cohort in terms of fracture types, modes of treatment, length of stay, rehabilitation times, complications and outcomes. In order to do this a retrospective review of PPF treated in a single unit is presented.

The specific questions addressed in this study were:

1. How many patients with PPF are treated in a regional orthopaedic tertiary referral hospital over a period of 12 years?

2. What were the demographics of this patient cohort (age, sex, place of residence, mechanism of fracture?

3. What fracture types presented for treatment and when did they occur with respect to their index or revision procedure?

4. What surgical treatment methods were used according to fracture type?

5. What were the outcomes in terms of mortality, length of stay (acute and rehabilitation), complications, time to union and patient reported outcomes.

3.2 METHODOLOGY

Ethical approval for this study was obtained from the Australian National University (human ethics protocol 2012/704) and the ACT Health Human Ethics Committees (ETHLR.12.129).

We retrospectively reviewed all admissions for PPF following THA between January 1st 2000 and December 31st 2012. The hospital medical record system was used to retrieve the patient data using the ICD10 codes S72.3, fracture shaft of femur and T84.0, mechanical complication of internal joint prosthesis. Patients with intra-operative and postoperative fracture as well as readmissions for failed previous PPF fixations were all included in the study. Patient outcomes were only possible for patients still living. The fractures were classified according to the Vancouver classification (Duncan and Masri 1995) (Duncan and Masri 1995) (see Chapter 2, section 2.2). The AOANJRR was consulted for each prosthesis with respect to whether it was primary or revision and whether it was cemented or not.

Details of the fractures and treatment were ascertained according to the operative notes and available radiology. The medical record was also used to obtain data regarding peri-operative morbidity via the American Society of Anaesthesiologists (ASA) scores, blood transfusion frequency and number of units, Intensive Care Unit (ICU) stay, complications and acute and rehabilitation length of stay . Time to fracture union was taken as the time to discharge from follow-up clinic with documentation of clinical or radiological union. Patient reported outcomes were assessed using the Oxford Hip Score (OHS), the Western Ontario McMaster University Osteoarthritis Index (WOMAC) and the Assessment of Quality of Life -6 dimensions (AQOL-6D) –utility score.

The OHS is a validated 12 item questionnaire that addresses the patients’ level of functional disability in regard to the hip joint (Dawson, Fitzpatrick et al. 1996). The responses are weighted from 1 to 5, with a minimum score of 12 and a maximum of 60. The lower the score the better the outcome. The WOMAC is a validated questionnaire addressing primarily the disease process of the hip (Bellamy and Buchanan 1984, Bellamy, Buchanan et al. 1988). The score is the addition of individual scores for three categories: pain (5 questions), stiffness (2 questions) and physical function (17 questions). The responses are weighted from 0 to 4, with a minimum score of 0 and a maximum of 68. The lower the overall score the better the outcome. The AQoL-6D is a validated questionnaire that assesses quality of life of patients in 6 dimensions: independent living, relationships, mental health, coping, pain and senses (Richardson, Peacock et al. 2012, Allen, Inder et al. 2013). The responses to 20 questions covering these 6 dimensions are combined using a weighted scoring algorithm to create a single utility score. Sub-dimensions can also be represented with an individual score but we did no use these in this study. The utility score is scored between 0 and 1 with 1 being the maximum outcome score.

The questionnaires were posted to the patients with a covering letter, information about the study and a self-addressed return envelope. Incomplete questionnaires (or where clarification was needed) were completed by the researcher via a follow up phone call.

Statistical Analysis: This is an observational study and only descriptive statistics were used, apart from a single comparison of ASA scores using unpaired Students t-tests with the assumption that a probability less than 0.05 constituted significance. Confidence intervals for the differences are reported. Patient demographic and treatment data are presented as either a frequency or mean ± standard deviation (range). Length of stay and rehabilitation time are reported as mean ± standard deviation (range). Complications are reported as a percentage. Patient reported outcomes are given as the range, median, mean, Standard Deviation and are also graphically presented as box-plots which demonstrate the median within the 25th to the

75th quartiles with whiskers spanning the 95% confidence intervals and outliers represented as individual points.

3.3 RESULTS

Demographics

A summary of the demographics is given in Table 3.1

Over the twelve year period studied, 51 patients were recorded as having sustained a PPF of the femur following THA. There were 18 males and 33 females in the study population. The average age was 79 ± 13 (29 to 95) years. No periprosthetic acetabular fractures were recorded over this time. There were 56 periprosthetic fractures in total which were fixed by 17 surgeons. These included: 2 Vancouver A_G fractures, 15 Vancouver B_1 fractures (inclusive of 2 previous periprosthetic fracture fixation failures), 15 Vancouver B_2 fractures (inclusive of one intra-operative fracture- Subtype B_2) , 3 Vancouver B_3 fractures and, 21 Vancouver C fractures (inclusive of 3 intra-operative fractures-Subtype C_2 and one previous PPF fixation failure).

The date of the index procedure was not known in 8 cases. For the remainder the average age of survival for the THA was 7.4 ± 6.6 (13 days to 27) years. Forty four fractures were associated with a primary THA (inclusive of 4 Austin Moore prostheses) and 12 were associated with a revision THA. Thirty one femoral stems were uncemented, 17 were cemented and in eight, the type was not recorded (3 Vancouver C and 5 Vancouver $B_{1)}$. Data from 21 patients were available from the AOANJRR which was cross checked for accuracy of index procedures.

Twenty three of the PPF were due to a mechanical fall. There were three presentations following a road traffic accident, stroke and ongoing pain (Previous Vancouver B1 fixation). The mechanism was not documented in 25 of the presentations (excluding the four intra-operative fractures). Thirty patients were independent in activities of daily living. Three were documented as not being independent, while their status was not documented in 8. Sixteen patients were documented as using an aid (stick or walker) for mobilization. Four used a wheelchair. Forty were documented as living in their own home, three in retirement villages and nine in nursing homes.

Table 3.1 Demographics of the study cohort: age, sex distribution, number of PPF with subtypes, survival time since index procedure with arthroplasty type, stem type, mechanism of fracture, residency status, degree of independence , number alive at the time of the study and time since fracture fixation for the living.

Demographics of cohort	Frequency
Number of patients	51
Age	79 ±13 (29-95) years
Sex (M:F)	13:38
Number of fractures	56
Vancouver subtypes	
A_G	2
B_1	15^{α}
B_2	15^{β}
B_3	3
C	21^{π}
Hip Survival at time of PPF$^{\mu}$	7.4 ±6.6 (13 days to 27) years
Type of hip arthroplasty	
Primary hip arthroplasty	44
Revision hip arthroplasty	12
Type of stem	
Cemented	17
Uncemented	31
Not documented	8
Mechanism of fracture	
Simple fall	23
Other $^{\delta}$	3
Undocumented	25
Place of residence	
Own home	40
Residential village	3
Nursing home	9
Independent in ADL : Dependent	30 :3
Mobility	
Using a walking aid	16
Wheelchair bound	4
Alive at time of study	22
Time since fracture for the living	8 ±3.87 (3.3 to 13.8) years

$^{\alpha}$ inclusive of two previous fixations
$^{\beta}$ inclusive of one intra-operative fracture
$^{\pi}$ inclusive of three intra-operative and one previous fracture fixation
$^{\mu}$ index procedure time not known in 8 cases
$^{\delta}$ road traffic accident, stroke and ongoing pain following previous fracture fixation

Fifteen patients were transferred from other hospitals following PPF, fourteen were direct admissions to the Canberra Hospital, while the mode of admission was not documented in 22 of the patients. Thirty four patients were discharged or re-transferred to their original hospital. One patient who was previously living independently was discharged to a nursing home. A further 11 patients were transferred to rehabilitation care. The discharge plans were not documented in 5 patients. The fractures were treated (with one exception) according to the guidelines suggested by the Vancouver classification system. I.e. internal fixation for B_1 and C subtypes and femoral stem revision with further plate fixation for B_2 and B_3 subtypes. Within these guidelines a variety of methods were used in the fixation of these fractures (Table 3.2).

Table 3.2 Fixation methods showing number of periprosthetic fractures fixed according to the Vancouver classification. P = Plate, CP = Cable Plate, C = Cable, LS = Lag Screw, ST = Strut Graft, ALG = Allograft, AUG = Autograft, OP = Osteogenic Protein. Methods where fixation failed and the corresponding numbers according to the Vancouver classification are underlined.

Fixation method	**Vancouver Classification**				
	B_1	**B_2^{α}**	**C^{Ω}**	**B_3^{β}**	**A_G**
P+C	1		2		
CP+C	2	2		1	
CP + LS+C	3				
CP +LS +ST+C	2	1	1		
P +LS+C	1		3		
CP +P+C	1				
P+ST+ALG+OP+C	1 +1				
CP+ST+ALG+C	1				
CP+ST+AUG+C	1				
P+ST+C	1	1	1		
CP +ST		1+1			
C		5			
LS+C+ALG+AUG+OP		1			
C+ALG		1			
C+ST		1			
CP+ST+AUG			1		
P			1+3		
P +C			1		
CP+ST+AUG +OP			1		
CP+LS			1		
CP			1		1
P+LS			2		
P+LS+AUG			1		
P+C +ALG+OP			1^{δ}		
CP+ST+OP			1		
CP+ST+ALG+AUG				1	
CP+ST+ALG				1	
Conservative			1^{δ}		1

$^{\alpha}$ In addition to the above fixation all B_2 PPF apart from one were treated with revision of the femoral stem. The intra-operative fracture Subtype B_2 fixation was abandoned due to an intra-operative cardiac arrest and has not been included here. This B_2 periprosthetic fracture did not have a femoral stem revision.

$^{\Omega}$ The intra-operative Subtype C_2 fractures are included here as well.

$^{\beta}$ In addition to the above fixation all B_3 PPF had revision of the stem and cup.

$^{\delta}$ Following the fixation of the PPF, the patient was noted to have sustained a further V_c type fracture following fall at a clinic visit, which was managed conservatively.

Outcomes

Mortality and Morbidity

At the time of writing this article 29 deaths were recorded in the study population. The average survival of the patient cohort after their first PPF fixation was 8.0 ± 3.9 (3.3 to 13.8) years. Seven deaths occurred within the first year and two of these were during the inpatient stay. Both of these patients were ASA 4. One developed rapid atrial fibrillation that led to congestive cardiac failure leading to an episode of acute pulmonary oedema resulting in death; the other sustained an intra-operative myocardial infarction, resulting in the fixation procedure being abandoned. The patient later died in ICU. The average ASA for the 43 patients in whom it was recorded was 2.7 ± 0.6. The ASA scores of the survivors were significantly lower (2.6 ± 0.6) than those who succumbed (3.1 ± 0.7) following a PPF fixation (P = 0.02, 95% CI of difference 0.83-0.92). A third of the patients (17/51) were admitted to the ICU, the average ICU stay being 1.6 ± 0.8 (1 to 4) days. Eighty percent of the patients (41/51) had blood transfusions, the average transfusion being 4.5 ± 3.5 (1 to 16) units. Only 6 patients did not have any post-operative concerns. The rest had at least one medical/surgical event that prolonged their stay in hospital e.g. breathlessness and low urine output. Over 50% (27/51) had a definitive diagnosis associated with their post-operative event (e.g. pneumonia, urinary tract infection and myocardial infarction) which required specific management. The average acute stay was 19 ± 19 (4 to 90) days and the average rehabilitation stay was 42 ± 29 (14 to 90) days. Follow-up details were available for 20 of the admissions (Table 3.3).

Table 3.3 Mortality, ASA, ICU admissions, blood transfusions, complications, acute stay and rehabilitation stay for all patients with periprosthetic fractures (N=51).

Mortality and morbidity	Frequency
Deaths total	29
Inpatient$^{\alpha}$	2
Within the first year	5
ASA$^{\beta}$	
Total	2.7 ± 0.6
Living at the time of the study	3.1 ± 0.7 P=0.02 (95% CI 0.83-0.92)
Dead at the time of the study	2.6 ± 0.6
ICU admissions	17
Stay in ICU	1.6 ± 0.8 (1 to 4) days
Number of patients transfused	41
Number of blood transfusions	4.5 ± 3.5 (1to 16) units
In patient complication$^{\Omega}$	
No complications	6
Minor complications$^{\mu}$	18
Major complications$^{\pi}$	27
Acute in patient stay	19 ±19 (4 to 90) days
Rehabilitation stay	42 ±29 (14 to 90) days

$^{\alpha}$ Both of these patients were ASA 4. One developed rapid atrial fibrillation that led to congestive cardiac failure leading to an episode of acute pulmonary resulting in death, the other sustained an intra-operative non ST segment elevated myocardial infarction, resulting the fixation procedure being abandoned and succumbed later in ICU.

$^{\beta}$ Not recorded in 8 patients; 5 from the living group and 3 from the dead group

$^{\Omega}$All complications excluding PPF fixation failure, dislocations, surgical site infection and DVT included.

$^{\mu}$ These are medical /surgical events that prolonged the in-patient stay, but did not lead to a definitive diagnosis i.e. breathlessness, low urine output,

$^{\pi}$ These were events that led to a definitive diagnosis that required a specific management plan with the involvement of another speciality i.e. pneumonia, urinary tract infection, myocardial infarction

Fracture Union

The average time to fracture union (excluding failure of the initial PPF fixation) was 7.9 ± 5.2 (1.5 to 18) months.

Failure of fixation

Failure of PPF fixation was the single biggest complication of this series (Table 3.2). Nine patients had failure of PPF fixation including three in whom previous fixation had failed. All of the failed patients presented with ongoing pain within one year of the initial fixation (2 to 9 months). There were four Vancouver B_1 fractures, four Vancouver C fractures and one Vancouver B_2 fractures. Five of the fixations re-presented with a fracture through the plate and/or struts (two Vancouver C and three Vancouver B_1 fractures). The remaining four presented with progressively increasing pain in the presence of a clinically non-united fracture. In six patients a single procedure resulted in a successful fixation; one required two procedures, one required three procedures and one required four before a successful fixation was achieved.

Surgical Complications

There were a total of three wound infections, of which two were deep periprosthetic infections requiring lifelong antibiotics. One patient had all the metalware removed after 10 months due to a Klebsiella deep wound infection. Two patients had dislocations following revision arthroplasty. In one patient this led to a second revision arthroplasty after 4 dislocations. Four patients had deep vein thrombosis and were treated uneventfully.

Patient Reported Outcomes

Of the 51 patients identified, 22 were alive at the time of the study and of these 18 patients responded and returned the WOMAC, OHS and AQoL-6D questionnaires. The range, median and mean of the patient related outcomes are tabulated (Table 3.4) and graphed (Figures 3.1-3.3). Not all questionnaires were completed. The WOMAC questionnaire was not completed by one patient. The OHS questionnaire was excluded in one patient because her answers reflected her disability due to Parkinson's disease but her hip was not problematic. A further 2 patients did not respond to the OHS questionnaire, while one patient did not answer both the OHS and the AQol- 6D questionnaires.

Table 3.4 Results of patient reported outcome scores for the WOMAC, Oxford and AQol

Vancouver Classification	Patient reported outcome		
	WOMAC$^{\alpha}$ (N = 17)	OHS$^{\beta}$ (N = 14)	AQol-6D$^{\Omega}$ (N = 17)
B_1 (5 patients)			
Range	4-39	27-46	0.85-0.94
Median	21	43	0.89
Mean	19.2	38.6	0.84
B_2 (6 patients)			
Range	2-55	17-52	0.09-0.9
Median	27	41.5	0.73
Mean	27.8	29.5	0.66
B_3 (1 patient)	49	26	0.32
C (6 patients)			
Range	2-42	12-40	0.29-1
Median	31	33	0.71
Mean	27.2	36.3	0.64
Total			
Range	2-55	12-52	0.09-1
Median	27	38	0.85
Mean	26.4	34.1	0.67
Standard Deviation	17.7	12.6	0.3

$^{\alpha}$ one Vancouver subtype B_2 did not respond to the questionnaire

$^{\beta}$ two Vancouver subtype $B_1$and one Vancouver subtype B_2 did not respond to the questionnaire

$^{\Omega}$ one Vancouver subtype B_1 did not respond to the questionnaire

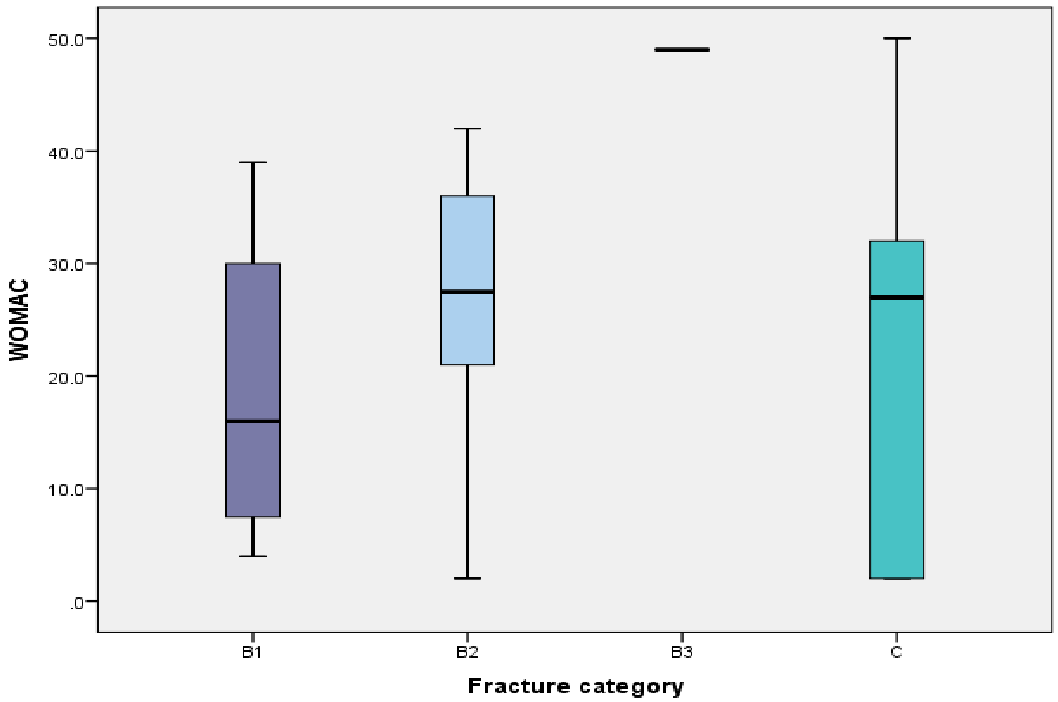


Figure 3.1 Box-plot depicting median and 95% confidence intervals of WOMAC scores according to the Vancouver PPF classification (B_1 N=5, B_2 N=6, B_3 N=1, C N=6). The score reflects three domains: pain (5 questions), stiffness (2 questions) and physical function (17 questions). Maximum score is 96. The lower the overall score the better the outcome.

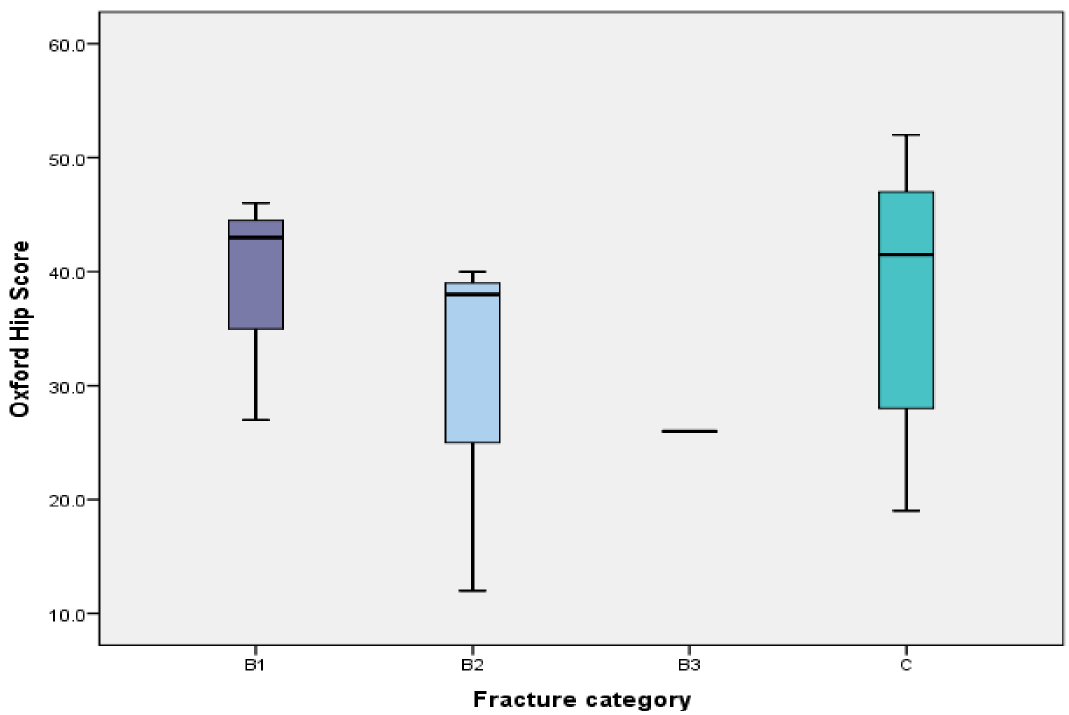


Figure 3.2 Box-plot depicting median and 95% confidence intervals of OHS of responses according to the Vancouver PPF classification (B_1 N=5, B_2 N=6, B_3 N=1, C N=6). The score is calculated using the responses from 12 questions. Minimum score is 12 with a maximum of 60. Higher the score the better the outcome.

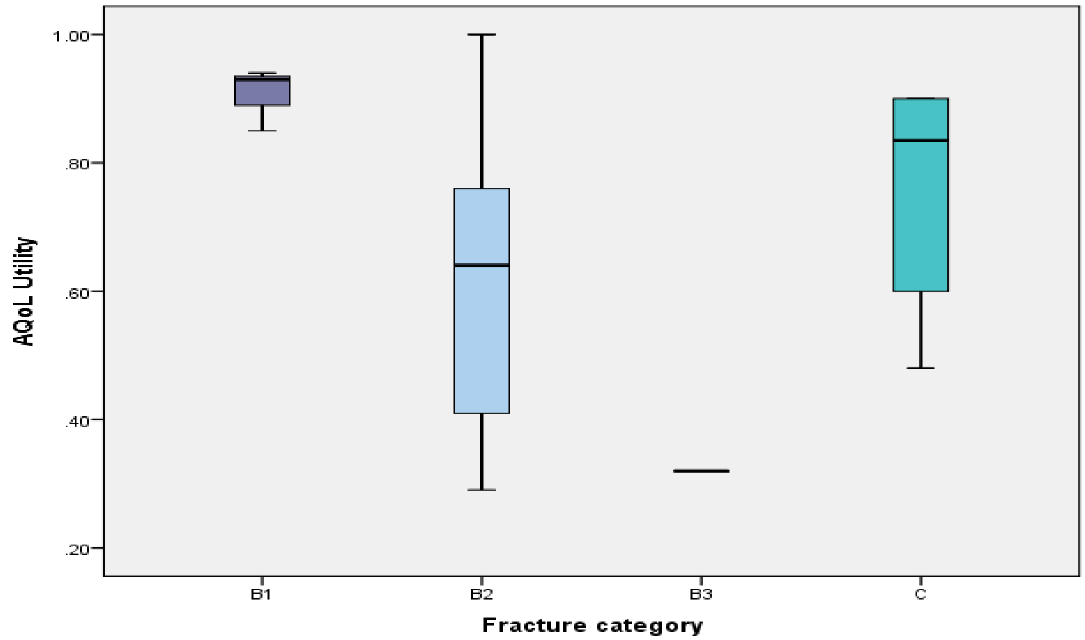


Figure 3.3 Box-plot depicting median and 95% confidence intervals of AQOL-6D scores of responses according to the Vancouver PPF Classification (B_1 N=5, B_2 N=6, B_3 N=1, C N=6). The score is calculated according to the responses to 20 questions and presented as a fraction (range 0 to 1). The higher the fraction the better the outcome.

3.4 DISCUSSION

The aim of this study was to describe an Australian patient cohort treated for PPF of the hip following THA in a single institution in terms of fracture types, modes of treatment, mortality and morbidity including length of acute and inpatient rehabilitation stay, time to union, complications and patient reported outcomes. The most important findings of this study were that PPF fixation has a high risk of failure, a prolonged length of hospital stay and, despite a high complications rate and an acceptable quality of life.

In this study the failure rate was 11% for all fractures from primary fixations between 2000 and 2012 (6/53). This rate is on the high side compared to other reports which range between 2.5% and 32% (Table 3.5). A lower failure rate was reported for studies involving single/limited surgeon series (Fawzy, de Steiger et al. 2009, Mukundan, Rayan et al. 2010, Park, Kim et al. 2011) compared to multi-institution and multi surgeon series (Zuurmond, van Wijhe et al. 2010, Holder, Papp et al. 2014)(Table 3.5). The present study involved multiple surgeons (N=17) but a single institution. Therefore, our series is most comparable to that reported by Holder et al. who reported a rate of 14% which is similar to ours. The reason for this disparity is unclear but it seems reasonable to suggest that for best results these fractures should be treated by a dedicated team of surgeons in a selected number of tertiary referral institutions (Phillips, Boulton et al. 2011).

Another factor which may influence the failure rate, and should be considered when comparing rates, is the relative fracture type. Vancouver Subtype B_1 is the fracture which is most controversial in terms of management. As discussed in Chapter 2, B_1 fractures can be fixed in a number of ways but are prone to failure (Moore, Baldwin et al. 2014). In the present study the same proportion of Vancouver C type fracture failed as B_1 type fractures. Interestingly, the same phenomenon was present in all of the other reported series with the exception of Mukundan et al. (2010). Therefore, it may be that fixation of Vancouver C fractures is not as straight forward as we currently assume. Although Vancouver C fractures are treated as normal femoral fractures, in fact they are not amenable to intra-medullary nails and therefore can only support a plate system. Rigid plate systems are associated with delayed healing (Uhthoff, Poitras et al. 2006) and therefore, if these patients were treated in this way an increased failure rate may have ensued.

Table 3.5 Studies showing outcome in terms of time of fracture union and failure of fracture fixation according to Vancouver classification of PPF, ratio of primary to revision hip arthroplasties and cemented to cementless stem fixation.

Study	Number of fractures in each study according to the Vancouver classification with the number of PPF fixation. Failures presented as a fraction for that sub type.					Ratio of primary to revision arthroplasty	Ratio of cemented to cementless stems	Average time to fracture union in months	Fixation Failure Rate Failures/ Total N (%)
	A	B1	B2	B3	C				
Zuurmond RG, ,et. al., 2010^	3	2/14	8/26$^{\beta}$	7	11/21	62:38	87:13	35/66*	23/71 (32%)
Fawzy E, et. al., 2009~	-	5	28	-	7	-	-	3.5	1/40 (2.5%)
Mukundan C, et. al., 2010l>	1	2/7	1/42	17	5	79:21	76:24	4	3/72 (4%)
Holder N, et. al., 2013<	4/11	2/15	24	2	2/4	96:4	30:70	15	8/56 (14%)
Park SK, et. al., 2011 `	-	10	3	1	1/4	95:5	39:61	6.3	1/18 (6%)
Kinov P, et. al., 2015	4$^{\alpha}$	1/16	14	14	1/12	95:5	56:44	4.1	2/56 (4%)
Current series, 2016$^{\Omega}$	2	2/13	1/15	3	3/20	79:21	35:65	7.9	6/53 (11%)

* 6 months postoperative fracture consolidation was evaluated in surviving patients

^ The study included results from two institutions.

$^{\beta}$ Includes operations for pseudo arthrosis, plate breakage or infection

~ All fractures were treated with an Oxford Trimodular femoral stem. Vancouver subtype of failure not mentioned

> Single surgeon series from one institution

< Intra-operative fractures excluded

` Single surgeon series, Out of 41 PPF only 18 were available for the study

$^{\alpha}$ Treated conservatively

$^{\Omega}$ Excluding the three previous PPF fixations (two B_1 and one C) that pre-date the series

PPF results in very long inpatient stays which are at least double that of a primary hip replacement acute stay and four times the rehabilitation stay. For patients in this study the average acute stay was 19 ± 19 (4 to 90) days and the average rehabilitation stay was 42 ± 29 (14 to 90) days in this study. After primary THA acute stay is usually around 8 days after which some patients have up to 10 days inpatient rehabilitation (Bozic, Wagie et al. 2006). We cannot compare our length of stay data with the other studies documented in Table 3.5 because they were not recorded, however, a study looking into the financial cost of treating PPF fixation following THA recorded an average stay of 39.3 days. A separation for acute and rehabilitation stays was not done in this study and a significant cost increase was noted when the stay was greater than 30 days ($P< 0.0001$) (Phillips, Boulton et al. 2011).The financial implications of these extended inpatient episodes are not difficult to appreciate with acute bed stays at our institution averaging $2,000 per day.

The results of this study compare quite favourably to reported outcomes from other periprosthetic fracture studies (Table 3.6), though they are not comparable to the results of a primary THR. The expected mean OHS following THR has been reported as 37.6 ± 9.2 on a scale from 0 to 48 (Murray, Fitzpatrick et al. 2007). Therefore by converting our results to a 0-48 scale (by subtracting 12) the mean OHS for our patients was 22.1 ± 12.6 which is significantly lower than an uncomplicated THR. Despite this, the OHS range for the present study was 0 to 40 with a median of 26 (converted to a 0-48 scale) so there were some very good individual outcomes. Also, when the pre-operative mean for a primary THR is considered (14.7 ± 7.3; (Murray, Fitzpatrick et al. 2007) it is clear that our patients were likely to have been better after fracture fixation than before THR. The AQoL-6D utility score of a normal healthy population over the age of 75 has been reported as 0.75 ± 0.02 (Richardson, Peacock et al. 2012). Therefore the AQoL-6D results from this study 0.67 ± 0.3 with a median of 0.85 compare quite favourably.

Table 3.6 Comparison of patient reported outcomes (WOMAC, OHS, AQol-6D and Harris Hip Score) between study groups. Not available (N/A)

Study	Number of fractures in each study according to the Vancouver classification					OHS	WOMAC	AQol-6D	Harris Hip Score
	A	B_1	B_2	B_3	C				
Zuurmond RG, et. al., 2010[β]	3	14	26	7	21	27.8 (12-57)	N/A	N/A	N/A
Fawzy E, et. al., 2009	-	5	28	-	7	30 (22-46)	N/A	N/A	N/A
Mukundan C, et. al., 2010	1	7	42	17	5	N/A	N/A	N/A	N/A
Holder N, et. al., 2013	11	15	24	2	4	N/A	N/A	N/A	N/A
Park SK, et. al., 2011	-	10	3	1	4	N/A	N/A	N/A	92 (84 -98)
Kinov P. et. al., 2015	4	16	14	14	12	N/A	73.7 (50-86)	N/A[Ω]	81.3 (52-91)
Current series, 2016	2	15	15	3	21	34.1 ± 12.6 (12-52)	26.4 ± 17.7 (2-55)	0.67 ± 0.3 (0.09-1)	N/A

[Ω] SF-8 physical component 41.3 (33.1-56.7) and mental component 44.1 (30.4-62.2)

[β] Zuurmond et al also noted that those who developed femur related complications had a worse score (P=0.02).

PPF fixation is associated with a high mortality and morbidity. This study had a high mortality rate with 7 deaths occurring within the first year and 29 deaths (out of 51) being recorded at the time of the study. However, this is most probably a reflection of the morbidity of the patients rather than a reflection of the PPF fixation process as the ASA scores of the survivors were significantly lower (ASA 2.6 ± 0.6) than those who succumbed (ASA 3.1 ± 0.7) following a PPF reconstruction (P = 0.02). Other studies have recorded similar mortality rates; Zuurmond et al. recorded seven deaths within the first year following surgery and a

45% mortality overall (Zuurmond, van Wijhe et al. 2010), while in a separate study 11/39 (28%) deaths were noted at the last follow up (Fawzy, de Steiger et al. 2009).

In this study the major complication rate was 27/51 (54%). This included conditions such as MI, UTI and pneumonia though excluding complications related to the surgery i.e. loosening, infection, dislocations, non-unions and failure of fixation. Other studies have reported variable but lower complication rates including 48% (Zuurmond, van Wijhe et al. 2010), 24% (Mukundan, Rayan et al. 2010) and 31% (Holder, Papp et al. 2014). However, the complication rates reported in these studies, with the exception of Zuurmond RG, et.al. 2010 are only related to the surgery. If we compare our surgically related complications the rate reduces to 14/51 (27%) which is comparable to those reported in other studies.

Time to union for the present study was in the mid-range compared to other studies but the heterogenicity of the patient population needs to be considered when interpreting this data. The average time to union in this series was 7.9 months compared with between 3.5 months and 15 months in the other series (Table 3.5). The ratio of primary THA to revision hip arthroplasty, cemented to cementless stems and PPF types (according to the Vancouver classification) differ significantly between the different studies, which needs to be taken into consideration when comparing the outcomes (Table 3.5).

Although all of the other series reported classifying and treating their fractures using the Vancouver system, there was a noticeable lack of detail with respect to reporting the precise fixation method employed. Within the guidelines set by the Vancouver system, over 25 different combinations of plates, cable plates, lag screws, strut grafts, autografts, allografts and osteogenic protein were used in this study. Most other studies however, although following the same principles, recorded limited variation in treatment methods. It is difficult to ascertain if this was actually due to a limited number of fixation methods or if different fixation methods were categorized together i.e. internal fixation with strut grafts included all types of plate fixation, screws and cables in addition to strut grafts. If we are to improve our understanding of this difficult and relatively rare condition, it is imperative that precise reporting is made.

The duration of the study period, number of patients, male to female ratio and survival of the prosthesis in this study is comparable to most other institutional studies (Table 3.7).

Table 3.7 Institutional studies showing duration of study period, number of patients, average age of the study population, ratio of female to males and duration of survival of the prosthesis prior to PPF.

Study	Duration of study period in years	Number of patients	Average age of the study population in years	Ratio of female to males	Duration of survival of the prosthesis in years, prior to fracture
Zuurmond RG. et al.2010,^	13	79	73.4	72:28	6.3
Fawzy et al. 2009	7	40	76	62:38	9.3
Mukundan C et al.2010	10	72	74.2	71:29	6.7
Holder N. et al. 2013	4.5	45	78	67:33	NA
Park SK. et al. 2011	16.5	18	58.8	44:56	4.1
Kinov P. et al. 2015	9	56	64.7	71:29	6.2
2016 Current series	12	51	79	65:35	7.4

^ The study included results from two institutions

` Out of 41 periprosthetic fractures only 18 were available for the study

This study should be interpreted in light of its potential limitations. First, the numbers were small but this is case for all reported series because of the rarity of the condition. However, the data presented will help to inform a potential meta-analysis in the future. The data was not accrued prospectively and therefore there was a significant amount of missing data. In this study nearly 50% of the patients came from outside the region. The data was very difficult to retrieve in these cases. This is probably the experience of other tertiary referral hospitals throughout Australia. It would seem therefore, that a registry would be ideal for this type of rare condition. A national registry would allow us to capture patient and radiographic information as well as outcome data prospectively in meaningful numbers. In addition the problem of loss to follow up of patients transferred from other hospitals might be overcome.

Imprecise or deficient recording has probably led to loss of information available for reporting. For instance, it is extremely unlikely that the only intra-operative PPF identified over this 12 year period, occurred during revision of post-operative PPF. The possible explanation for this is that intra-operative fractures during a primary THA or Revision were not coded as such and therefore were not identified.

The results of this study indicate that PPF results in considerable disability in spite of a systematic approach to its management. The failure rate is relatively high and of particular note is the unexpected rate of failure of Vancouver C type fracture fixation. Because, the treatment of these fractures is difficult and the failure rate is high, they should arguably be fixed by peri-prosthetic fracture specialist surgeons. The significant failure rate should be further explored in future studies and for this it is proposed that a national registry is required.

CHAPTER 4

VALIDATION OF A MECHANICAL JIG FOR THE BIOMECHANICAL STUDY

4.1 INTRODUCTION

Biomechanical testing with highly accurate and sensitive mechanical testing stations is recognized as the technique of choice for comparing different methods of fracture/prosthesis fixation (Gardner, Silva et al. 2012). The strength of this method is that the laboratory conditions mitigate the inherent biological variations that accompany a clinical study. However, this strength can be undermined where the methods employed result in a lack of consistency of specimen preparation. Therefore, in order to produce valid and reliable results, it is imperative that the experiments are designed to ensure optimal consistency in the preparation of each specimen.

The methods that have been used for the biomechanical testing of femoral fracture fixation are very precise and clear (Dennis, Simon et al. 2001, Fulkerson, Koval et al. 2006, Ahmad, Nanda et al. 2007, Brinkman, Hurschler et al. 2011), however, none have described how they sought to achieve consistency in their fracture patterns or plate position preparations or how they validated their preparation method. Indeed, in one instance where the authors have provided a picture of their specimen preparation, there is evidence of significant variation in the fracture angle and position achieved (Figure 4.1) (Dennis, Simon et al. 2000).

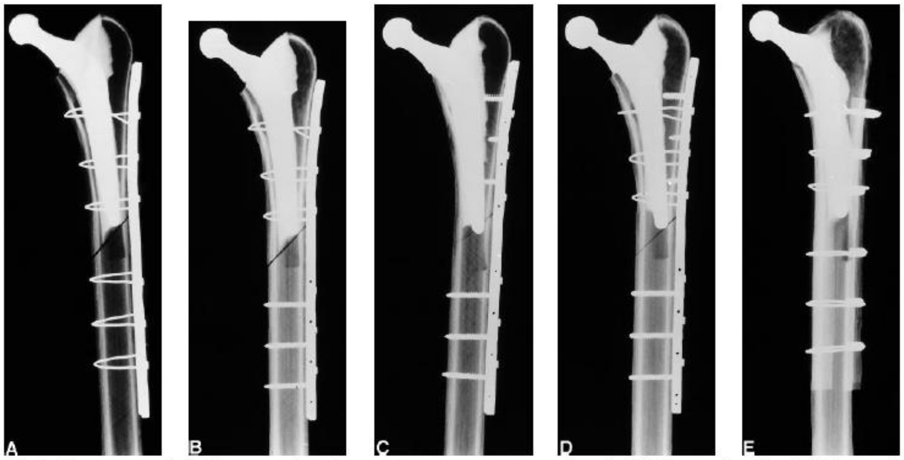


Fig. 1. X-ray views of the 5 periprosthetic fracture fixation constructs evaluated. (A) Plate with cables. (B) Plate with proximal cables and distal bicortical screws (Ogden concept). (C) Plate with proximal unicortical screws and distal bicortical screws. (D) Plate with proximal unicortical screws and cables and distal bicortical screws. (E) Two allograft cortical strut grafts with cables.

Figure 4.1 Illustration of the variation in angle and position of the femoral cuts in a mechanical testing study of femoral fracture fixation (from Dennis, Simon et al. 2000 with Permission from Churchill and Livingstone).

Furthermore, these studies did not acknowledge that the possible variation in fracture and fixation preparation could impact upon the outcome of these studies where the specimen number is usually limited because of the expectation of high levels of consistency.

There is therefore a need for a validated method for producing consistent fracture model in preparation for biomechanical testing. This study aimed to test whether a mechanical jig was effective in both producing precise and reproducible cuts in synthetic femurs and accurate and reproducible positioning of plate and cable/screw fixations.

To achieve a consistency, the following four parameters needed to be reproducible for a given fracture fixation

1. Position of the cut
2. Angle of the cut
3. Position of the plate on the femur.
4. Reduction of the fracture in terms of the magnitude of the fracture gap

The fundamental concept underpinning the jig design was to construct an apparatus which was effective at: holding a synthetic femur securely, providing a frame within which a reproducible cut could be made and, providing a stable environment for reduction of the fracture and the application of the plate.

4. 2 METHODOLOGY

4.2.1 Designing the jig

A mechanical jig was designed by first drawing a detailed sketch (Figure 4.2). A three dimensional (3D) model of the jig was then constructed using CATIA (Computer Aided Three-dimensional Interactive Application, Dassault Systemes SE, Velizy-Villacoublay, France) software. The CAD (Computer Aided Design) models of a synthetic femur (Large size, 4th generation synthetic femur, Sawbones®, WA, USA)) and a titanium 8 hole plate (straight 240mm, 35-220-2010, Kinamed Inc., Camarillo, CA, USA) were used to test the configuration of the jig (Figure 4.3). Moulds (epoxy resin) of both the proximal and distal ends of the femur were made to accurately locate the femur in the jig (Figure 4.4).

Using the CAD models of the synthetic femur a detachable distal intramedullary rod was designed and constructed. This rod was advanced up the distal femoral medullary canal to provide axial stabilization of the femur on the distal mould prior to engagement of the proximal mould (Figure 4.2- item 13, and Figure 4.4).

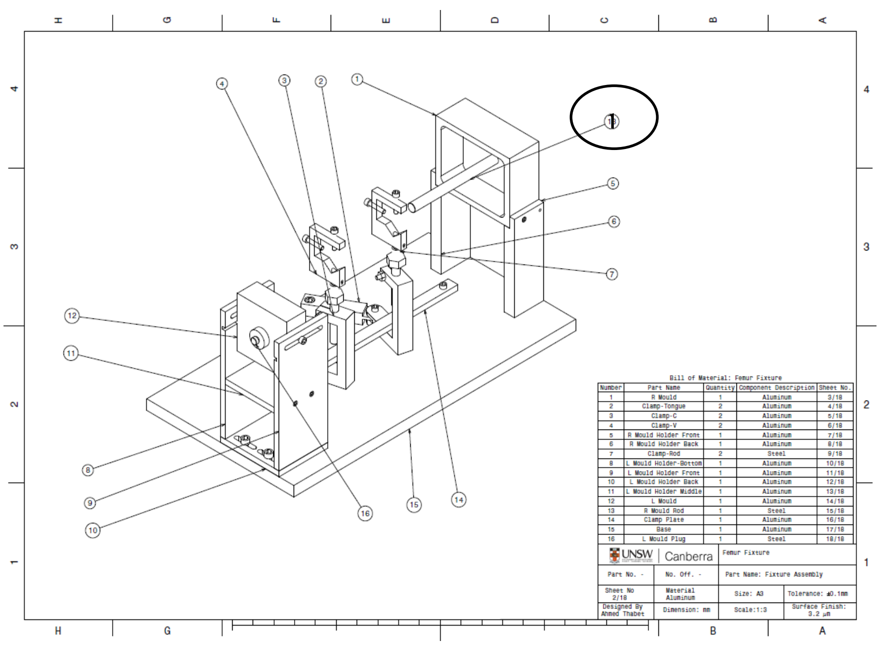


Figure 4.2 Sketch/design of mechanical jig.

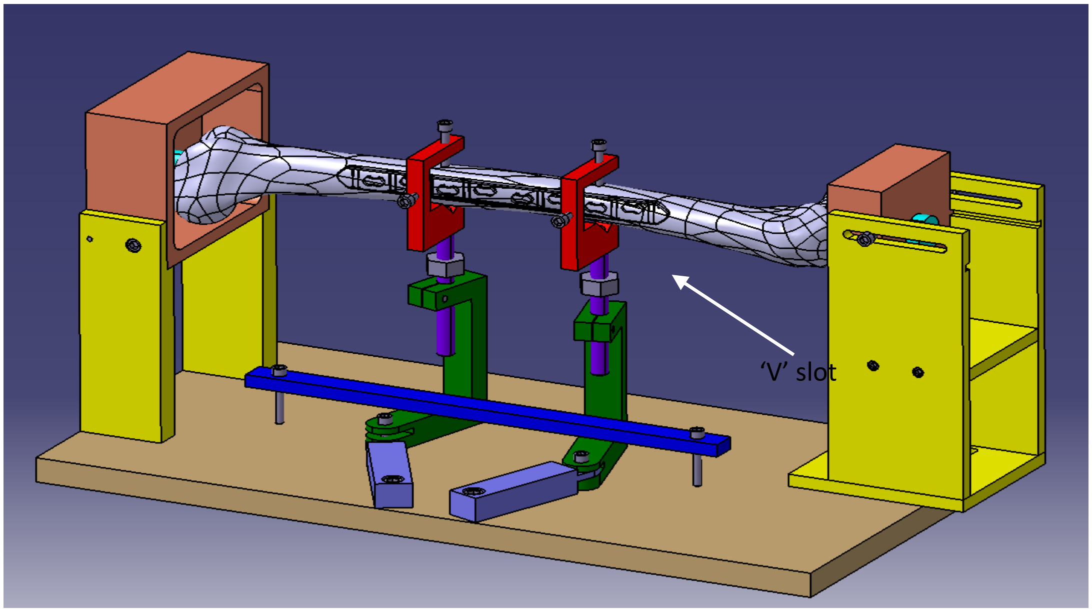


Figure 4.3 3D model of the jig with CAD models of the femur and plate included for optimisation of the design. The femur is orientated with the anterior aspect superiorly, the distal femur shown to the left. The femur is resting in the 'V' slot.

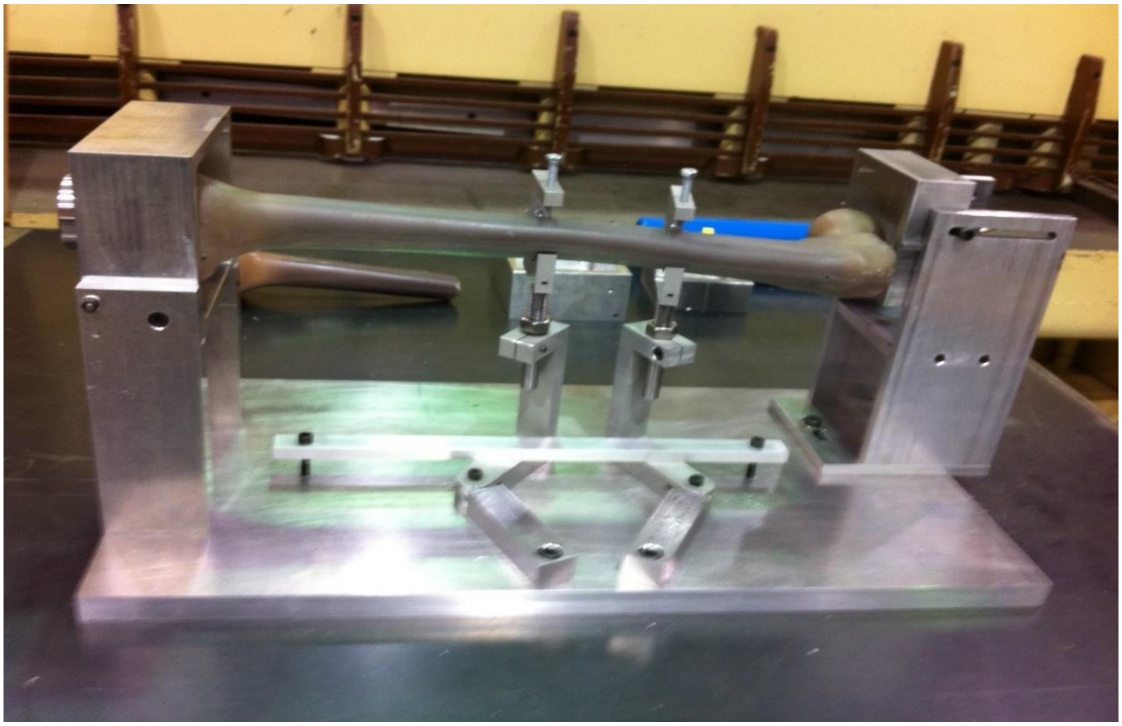


Figure 4.4 Mechanical jig with the femur located in epoxy moulds distally (left) and not yet located proximally (right)

The specimens were prepared (located in the jig, cut, reduced and plated) by a single operator.

4.2.2 Cutting the femur

The mechanical jig consisted of a base, a fixed distal femoral mould (with a detachable intramedullary rod), a mobile proximal femoral mould, and adjustable clamps to secure the femoral shaft and plate. (Figure 4.4).

The femurs were secured by first fitting them into the fixed distal mould so that the anterior surface was orientated superiorly. The distal intramedullary rod was then advanced to secure the femur in position. The proximal mobile mould, which moved orthogonally in the horizontal plane, was then engaged with the femoral head and locked in place so that axial compression was applied (Figure 4.4).

The two clamps were designed to hold the femur on either side of the fracture and to secure the plate onto the femur. The clamps were mounted on arms that could be moved in a horizontal plane (parallel to the long axis of the femur) while the clamps themselves could be moved vertically (perpendicular to the long axis of the femur) and rotated around this vertical axis. Their purpose was firstly, to secure the femur while the cut was being made and secondly, to secure the plate onto the reduced femur in a consistent position. As a result of the 3D modelling it was determined that the femur had to rest on the bottom of the clamps in a ‘V’ shaped slot and the plate had to rest on the horizontal bar (above the ‘V’ slot) to ensure a consistent relationship between the plate and the femur (Figure 4.3).

An oblique cut from lateral to medial in a proximal to distal direction was made by precisely locating the jig on the platform of a milling station so that it was at 60^0 to the long axis of the femur. The platform of the milling station was calibrated to ensure that the jig was located precisely in the same position relative to the arbor for each cut. An electronic edge finding probe (accuracy of 0.01mm) was used to locate and relocate the position of the distal mould in relation to the milling machine arbor to within 0.5mm[1]. The cut was made by a 152mm diameter, 1.5mm thick rotating slitting saw mounted on a stub arbor on the milling machine.

[1] Though conventionally one speaks of ‘moving the probe’ in reality the probe/arbor remains stationary and the moving element is the milling machine platform.

4.2.3 Reducing the 'fracture' and applying the plate in the jig

For this study[2] 12 left synthetic femurs (with a simulated midshaft fracture) were fixed with an 8-hole plate which was specifically designed to be used with SuperCables: 5 with screws (4.5mm compression screws, 35-230-45XX, Kinamed Inc., Camarillo, CA, USA), 5 with synthetic cables (SuperCable® cerclage cable assembly with Titanium clasp, 35-100-1010, Kinamed Inc., Camarillo, CA, USA) and, 2 with steel cables (1.7mm, 298.801.01S , Synthes, West Chester, PA, USA)). A separate plate was re-used for each fixation series i.e. 3 plates for three types of fixation.

Prior to cutting the femur two parallel lines were drawn on the femoral shaft to enable accurate realignment of the 'fractured' shaft prior to plating (Figure 4.5). The mould lines (Figure 4.8) that were present on the medial and lateral aspects of the synthetic femoral shaft also assisted in confirming the reduction of the fracture. For each type of fixation, the plate was placed laterally on the femur and positioned to allow optimal fixation for that particular type of fixation. The plate was then marked at the level of the cut to enable reproduction of the plate position in the subsequent fixations for that type (Figure 4.5). At this point the femur was located in the 'V" slot and the plate was supported on the horizontal bar section of the clamps (Figure 4.6).

After the plate was applied, the position of the clamps were marked on the base of the jig because each fixation type required a different clamp position. Therefore the clamp position (both horizontally and vertically) was defined for each fixation type.

[2] The number of femurs and the fixation types were selected for the subsequent biomechanical study

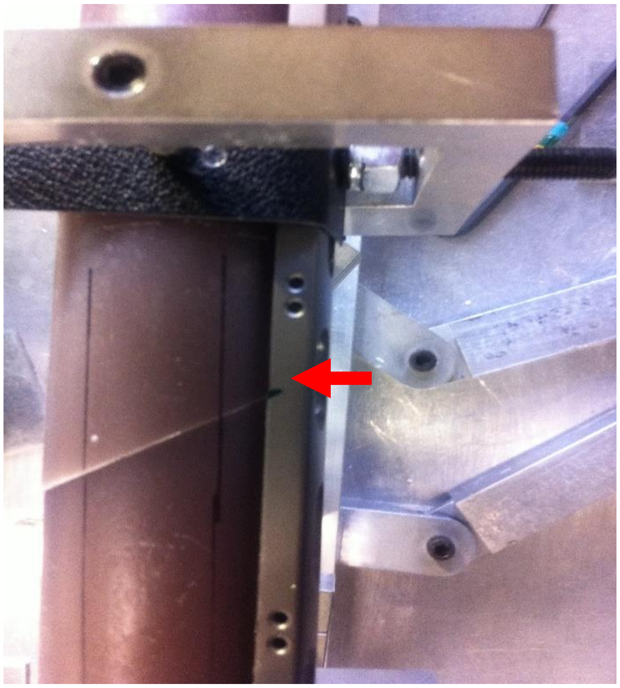


Figure 4.5 A mark (red arrow) was made on the plate which lined up with the fracture reduction for screw fixation. Parallel marks were made on the femur to achieve a consistent reduction. Titanium plate showing two sets of two holes on either side of the red arrow

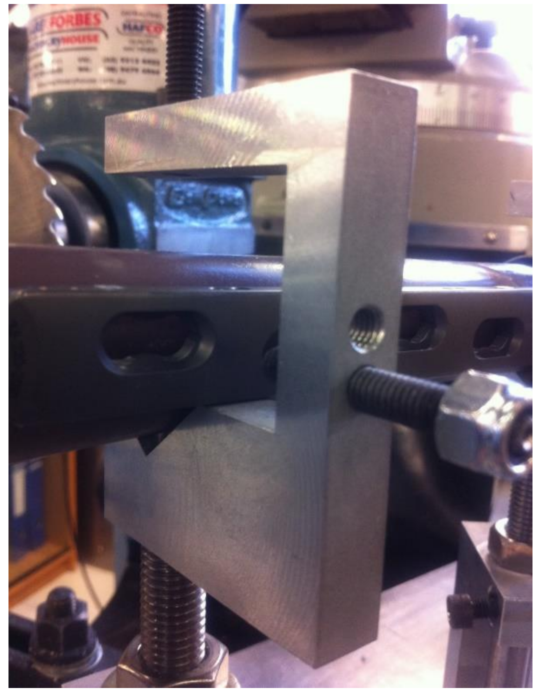


Figure 4.6 The plate was supported on the horizontal bars of the clamp to ensure a consistent position of the plate on the femur. The femur rests in the 'V'-slot of the clamp

4.2.3 Applying the fixation and testing

The titanium plate used for all of the fixation strategies was designed for use with the SuperCables in that it had eight sets of two holes for threading of eight double loop cables.

SuperCables

The SuperCables (4 proximal and 4 distal) were passed through the dedicated double hole configuration on the sides of the plate to form a double loop (Figure 4.5, above and below the red arrow). The cables were then tensioned according to the manufacturer's instructions for a healthy adult i.e. tensioned to 530N marked 'Hi' on the Kinamed tensioning instrument.

Steel cables

The steel cables were applied through one hole only because they are conventionally used as a single loop. In the central four pairs of holes the cables were threaded through the holes closest to the fracture. The outer four cables were threaded through the outermost holes. The cables were then tensioned according to the manufactures instructions to the 50 (50kg) mark using the Synthes tensioning device.

Screws

Non-locking screws (4 proximal and 4 distal) were used with axial compression being applied first, before securing the remaining screws. In order to reproduce surgical conditions screws were tightened according to feel, till a solid end point was felt (as one would do during surgery).

Thereafter the fixed specimens were subjected to mechanical testing (see Chapter 5).

4.2.4 Validation of the jig

Validation of the mechanical jig was done by measuring the consistency of the: position of the cut, angle of the cut, plate position on the femur and the overall fracture reduction gap (allowing for the different modes of fixation). The position of the cut and the angle of the cut could only be measured after the testing of each specimen because the fixation had to be dismantled for the measurements to be done.

The position of the cut and the measurements to calculate the angle of the cut were measured using an edge finding probe with an accuracy of 0.01mm. The plate position was measured manually using an electronic Vernier calliper with an accuracy of 0.01mm. The fracture reduction gap was measured using a computer controlled Canon EOS 60D camera (Canon, Òta, Tokyo, Japan) with 16 MB (4608x3456) pixels per frame, which captured high resolution photographs. These photographs were analysed to give the measurements, using the image processing tool, Inertial Measurement Unit (IMU) in Matlab (Mathworks®, Natick, Massachusetts, USA)

Measurement of the position of the cut

Following the mechanical testing (and dismantling of the fixation), the distal cut ends of the femur were mounted in the jig in order to measure the level of the cut.

The position of the cut for SuperCable 2 was the reference measurement against which all others were measured for the degree of consistency.

The measurements were made using an edge finding probe mounted on the milling station arbor. The probe was located at a set point in relation to the distal femoral mould that located the femur. The probe was used to measure the distance from the arbor to the most proximal point of the cut on the distal segment. For each subsequent femur, the measurements were started from the same set point. Therefore the differences in these measurements reflected the differences in the length of the distal femur segments and the variation in the position of the cut.

Measurement of the angle of the cut

The intention was to accurately cut each femur at an angle of 60^0. The accuracy of the cut was examined using inverse trigonometric functions. In a right angle triangle, the acute angles can be calculated as the inverse Tangent of the opposite side over the adjacent side. Therefore, starting on the cut surface of the femur, a line running parallel to the long axis of the femur and a line running perpendicular to the long axis of the femur intersect on the cut surface of the femur, creating a right angle triangle where the cut surface of the femur is the hypotenuse (Figure 4.7). Therefore the inverse Tangent function of the opposite over the adjacent sides gives the angle of the cut. These measurements were made using the edge finding probe to measure the distances of the horizontal and vertical sides of the triangle.

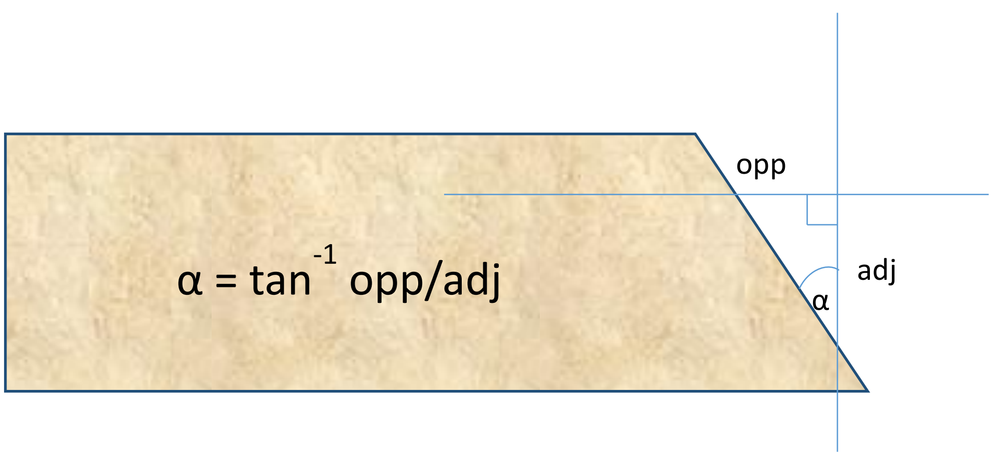


Figure 4.7 Method for calculating the accuracy of the angle of the cut using trigonometry. The measurements of the opposite and adjacent sides were measures using the edge finding probe.

Measurement of the position of the plate on the femur

In order to determine how successful the jig was in maintaining the plate position during fixation the plate position was measured both before and after fixation. A proximal and a distal measurement were taken. A 3.1mm drill bit was inserted into the proximal pinhole underneath the greater trochanter (Figure 4.8). The proximal measurement was a linear distance between the edge of the drill bit where it contacted the femoral surface to the proximal tip of the plate. The distal measurement was made in the same way from the pinhole in the lateral epicondyle to the distal tip of the plate.

Figure 4.8 A 3.1mm drill bit has engaged the proximal pin hole. The electronic Vernier calliper measured the distance from the edge of the drill bit to the tip of the plate (shown with an arrow). The pin hole is situated between the 'mould' lines.

Measurement of the fracture reduction gap

Before commencement of fatigue testing, images were captured using a computer controlled Canon EOS 60D camera with 16 MB (4608x3456) pixels per frame of the femur, with a 0.2kN compressive force. The vertical gap between the left and right edges of the fracture were measured using the image processing tool, Inertial Measurement Unit (IMU) in Matlab and averaged to give the measurement of the fracture gap.

4.2.5 Statistical Analysis

Descriptive statistics including mean ± SD, range, maximum and minimum values were used to compare the data.

Note. Details relating to the individual specific steps in the setting up of the jig can be found in Appendices I.

4.3 RESULTS

Of the twelve femur specimens tested, only eight were used for the validation of the position and the angle of the cut and eleven for the plate position and fracture gap. SuperCable 1 was excluded because of technical errors experienced during the first specimen preparation. Three further specimens were unavailable for measurement of the position and the angle of the cut because the intact specimen was required for a further study and they were therefore not dismantled.

4.3.1 The position of the cut

The absolute mean variation in the position of the cut was 0.28 ± 0.26 mm. The range of the variation was 0.95mm (-0.74 to +0.21). The maximum deviation from the reference measurement (SuperCable 2) was 0.74mm and a minimum deviation was 0.01mm (Table 4.1).

Table 4.1. Measurements of the variation in the position and the angle of the cut

Construct	Variation in cut position mm	Cut angle in degrees
SuperCable 2	0.00*	59.75
SuperCable 3	0.05	60.35
SuperCable 4	0.47	60.0
Steel cable 1	0.01	60.0
Screw 1	0.21	60.05
Screw 2	0.74	60.35
Screw 3	0.33	60.05
Screw 4	0.12	60.2
Absolute Mean	**0.28**	**60.05**
SD	**0.26**	**0.2**

Note. *The variation on the position of the cut was referenced off the SuperCable 2 construct. The cut angle was derived trigonometrically

4.3.2 Angle of the cut

The mean angle of the cut was $60.05^0 \pm 0.2^0$. The range was of 0.55^0 with a maximum angle of 60.35^0 and a minimum angle of 59.75^0 (Table 4.1).

4.3.3 The position of the plate

The mean absolute movement of the plate before and after fixation was 0.71±0.66mm. The steel cables demonstrated the least movement (0.33±0.32) during fixation and the screw fixation demonstrated the most (0.87±0.87) (Table 4.2).

Table 4.2. Measurements (mm) of the plate position before and after fixation with absolute mean differences in position and standard deviation of the difference for each construct and overall.

Construct	Position	Before	After	Abs. Diff	Mean Abs Diff	SD
SuperCable 2	Proximal	64.57	64.78	0.21		
	Distal	85.07	85.86	0.79		
SuperCable 3	Proximal	65.27	64.56	0.71		
	Distal	86.76	86.98	0.22		
SuperCable 4	Proximal	65.16	64.67	0.49		
	Distal	85	85.74	0.74		
SuperCable 5	Proximal	62.77	61.22	1.55	0.69	0.43
	Distal	88.22	89.01	0.79		
screw 1	Proximal	71.94	69.53	2.41		
	Distal	80.52	78.11	2.41		
screw 2	Proximal	69.99	69.85	0.14		
	Distal	80.76	81.85	1.09		
screw 3	Proximal	69.41	69.8	0.39		
	Distal	81.31	81.8	0.49		
screw 4	Proximal	67.12	67.27	0.15		
	Distal	82.48	83.43	0.95		
screw 5	Proximal	68.26	68.59	0.33	0.87	0.87
	Distal	82.35	82.02	0.33		
steel cable 1	Proximal	63.87	63.53	0.34		
	Distal	84.42	85.2	0.78		
steel cable 2	Proximal	63.87	63.78	0.09		
	Distal	84.94	84.82	0.12	0.33	0.32
All Constructs					**0.71**	**0.66**

Note. Abs. Diff = Absolute Difference between the before (Proximal) and after (Distal) fixation measurements. SD = standard deviation of the absolute difference.

Table 4.3. Measurements of the fracture gap (μm). Left and right side and average fracture gap, with the mean and SD for each construct and overall.

Construct	Left (μm)	Right (μm)	Average gap (μm)
SuperCable 2	473.15	457.63	465.39
SuperCable 3	521.14	343.73	432.435
SuperCable 4	549.13	557.7	553.415
SuperCable 5	519.18	654.68	586.93
Mean	**515.65**	**503.43**	**509.54**
SD	**31.46**	**133.44**	**72.59**
screw 1	422.2	443.85	433.025
screw 2	304.63	480.16	392.395
screw 3	350.42	505.16	427.79
screw 4	390.78	480.18	435.48
screw 5	355.87	470.68	413.275
Mean	**364.78**	**476.01**	**420.39**
SD	**44.38**	**22.06**	**17.86**
steel cable 1	486.38	398.8	442.59
steel cable 2	490.53	420.7	455.615
Mean	**488.46**	**409.75**	**449.10**
SD	**2.93**	**15.49**	**9.21**
All constructs Mean	**442.13**	**473.93**	**458.03**
All constructs SD	**81.66**	**82.07**	**59.18**

4.3.4 The fracture gap

The mean fracture gap was 0.46 ± 0.06mm (458.03µm). The range was 0.19mm with a maximum gap of 0.59mm (586.93µm) and a minimum gap of 0.39mm (392.4µm). The mean gap on the left and right side of the fractures were 0.44 ±0.08mm (442.13µm) and 0.47 ± 0.08 mm (473.93µm) respectively (Table 4.3).

4.4 DISCUSSION

Laboratory testing of fracture fixation is an established method of investigating different fixation methods. For conclusions to be valid, it is imperative that the specimens tested are prepared consistently in order to avoid bias in the results due to inconsistencies from specimen preparation (Gardner, Silva et al. 2012).The purpose in the construction of this mechanical jig was to reduce the degree of variation that we had encountered when preparing the specimens with generic workshop instruments. The aim of this study was to measure the degree of variation in the specimen preparation when using a bespoke mechanical jig to control the fracture cut position and angle, and the fracture segment position during fixation.

Our results showed that the mechanical jig achieved a high level of accuracy and precision. The position of the cut was within a millimetre (mean variation was 0.16 ± 0.32 mm with a range of 0.95mm) for the 12 specimens fixed. The angle of the cut was accurate to within a degree and the variation in the angle was less than a degree (mean $60.05^0 \pm 0.2^0$ with the range 0.55^0). The mean absolute variation in the plate position (i.e. movement of the plate during the fixation process) was less than 1mm (0.71 ± 0.66mm, range 0.09 to 2.41mm). The mean fracture gap following reduction (and fixation) was 0.46 ± 0.06mm (range 0.39 to 0.59mm).

The results of this study lead us to believe that the jig ensured adequate consistency between specimens for comparative studies of femoral fracture fixation. However, there were some limitations in terms of study design and the design of the jig. Although we have measured the accuracy and consistency with which we can prepare the specimens in the jig, we do not have data from a ‘non-jig’ sample with which to compare our results. Although these data would have been ideal, our resources did not enable us to do this work. However, having attempted to prepare the specimens without a jig, we are confident that the jig resulted in superior accuracy and consistency.

The jig was superior to other non-bespoke methods of preparing the femur but there are a number of ways in which the design could be further improved.

1. The proximal fragment was unstable during the repositioning of the clamps due to the symmetry of the mould (corresponding to the femoral head). The jig would be enhanced by the addition of stabilising mechanism for the proximal fragment.

2. The clamp design interfered with a smooth reduction and fixation of the plate. The clamps had a dual function: to hold the reduced femur fragments in place and to secure the plate to the femur during the fracture fixation. The plane of the clamps (the axis through which the screw was tightened to secure the plate to the femur) needed to be perpendicular to the femur to maintain the consistent relationship between the femur and the plate, by the femur resting on the bottom 'V' and the plate resting on the horizontal bar of the clamp. Therefore a slight adjustment of one function led to a disruption of the other. Ideally the clamps could be re-engineered to allow independent functions.

In conclusion, we have demonstrated that the use of a mechanical jig results in minimal variation between synthetic femur samples prepared for a comparative fracture fixation study. Previous studies have not described how accurate preparation was achieved or the degree of variation between specimens. In this study, for the first time, we have quantified the variation between samples prepared for fixation using a bespoke mechanical jig. It is suggested that future studies should employ a similar method when preparing specimens for comparison.

CHAPTER 5

MECHANICAL TESTING OF PLATE WITH SUPERCABLES VERSUS STEEL CABLES AND SCREWS

5.1 INTRODUCTION

Treatment of periprosthetic fractures following total hip arthroplasty is seldom easy, often complex and always expensive (Phillips, Boulton et al. 2011). A Vancouver B_1 periprosthetic fracture requires fixation of the bone around a stable component. Although the recommended treatment for Vancouver B_1 fractures is open reduction and internal fixation, a single method of fixation has yet to gain universal acceptance (Moore, Baldwin et al. 2014). Cable plate systems have been reported to result in both excellent and poor outcomes in terms of performance and complication rates (Ricci, Bolhofner et al. 2005, Tsiridis, Narvani et al. 2005). One mechanism by which the construct can fail is thought to be due to the loosening of the metal cables secondary to micro-motion and displacement (Ritter, Eizember et al. 1991). This micro motion is thought to be due to interposition of soft tissue between the cable and the bone at the time of fixation as well as bone resorption. Other mechanisms which can lead to failure include, fraying of the cable ends and metal debris production from metal on metal interactions. A further consequence of metal cable use is that of injury to the surgical team from puncture injuries caused by the cut wire ends (Silverton, Jacobs et al. 1996).

Alternative solutions to metal cables have been developed. A non-metallic iso-elastic cable (SuperCable®, Kinamed Inc., Camarillo, CA, USA) was introduced to the market in 2004. It was marketed as having overcome the problems that are encountered with metal cables (Sarin VK 2005). This cable consists of a nylon core and jacket of Ultra High Molecular Weight Poly Ethylene (UHMWPE) braided fibers. Clinical studies have shown favorable results with the use of non-metallic cables (Sarin VK 2005, Ting, Wera et al. 2010). However, a recent biomechanical study has demonstrated that non-metallic cables fail at lower loads than metal cables (Frisch, Charters et al. 2015) but the loads to which the samples were subjected to achieve failure, were higher than would be expected during normal walking

Previous studies however, have tested these cable systems as cerclage systems alone. There have been no studies that have analyzed their performance in the context of a cable plate system, which is how they are predominately utilized in the treatment of Vancouver B1 fractures. Further, no previous studies have measured the degree of fracture site displacement which occurs after fixation using cables and plates.

The purpose of this study therefore, was to compare the performance of SuperCable/plate fixation to a screw/plate and steel cable/plate fixations in terms of fracture gap displacement and cable migration. 'That synthetic cables would not slip as much as metal cables and would provide equivalent stability in terms of preventing fracture site displacement during the first 10,000 full weight-bearing steps'

5.2 METHODOLOGY

For this study 12 left synthetic femurs (Large size, 4th generation synthetic femur, Sawbones®, WA, USA) with a simulated oblique midshaft fracture were fixed with an 8-hole plate (Titanium, straight 240mm, 35-220-2010, Kinamed Inc., Camarillo, CA, USA). In 5 specimens the plate was secured using screws (4.5mm cortical compression screws, 35-230-45XX, Kinamed Inc., Camarillo, CA, USA), in a further 5 synthetic cables (SuperCable® cerclage cable assembly with Titanium clasp, 35-100-1010, Kinamed Inc., Camarillo, CA, USA) were used, and in 2 steel cables (1.7mm, 298.801.01S , Synthes, West Chester, PA, USA) were used. A separate plate was re-used for each fixation series i.e. 3 plates for three types of fixation. The study was conducted by two operators, one for preparation of the specimens and the other for testing of the specimens.

The titanium plate used for all of the fixation strategies was designed for use with the SuperCables in that it had eight sets of two holes for threading of eight double loop cables.

The SuperCables (4 proximal and 4 distal) were passed through the dedicated double hole configuration on the sides of the plate to form a double loop. The cables were then tensioned according to the manufacturer's instructions for a healthy adult i.e. tensioned to 530N marked 'Hi' on the Kinamed tensioning instrument. The steel cables were applied through one hole only because they are conventionally used as a single loop. In the central four pairs of holes the cables were threaded through the holes closest to the fracture. The outer four loops were threaded through the outermost holes. The cables were then tensioned according to the manufacturer's instructions to the 50 (50kg) mark using the Synthes tensioning device. Non-locking screws (4 proximal and 4 distal) were used with axial compression being applied first, before securing the remaining screws. In order to reproduce surgical conditions screws were tightened according to feel, till a solid end point was felt (as one would do during surgery).

A simulated fracture was created by making a 60° angle cut to the anatomical axis of the femur running distally from lateral to medial at the mid-diaphyseal point of the femur, which was measured at 235mm from the tip of the greater trochanter. An angled cut was chosen to enhance slippage of the cut surfaces on one another. The 60° angle was chosen to create a situation where an inter-fragmentary lag screw would not be used. The direction of the cut, which ran distally from lateral to medial, was chosen to avoid the laterally placed plate functioning as a buttress. The cut was made using a 152mm diameter and 1.5mm thick rotating slitting saw mounted on a stub arbor on the milling machine.

To ensure consistency in the creation of a fracture and subsequent plating, a mechanical jig was designed and validated (Chapter 4). After fixation with one of the three constructs described above, the specimens were mounted in a servo-hydraulic mechanical testing machine (Shimadzu Servo hydraulic Test machine, Shimadzu, Kyoto 604-8511, Japan) at 12° to the sagittal axis in adduction (0° rotation and 0° flexion). The specimens were pre-loaded to 0.2 kN after which they were subjected to cyclic sinusoidal loading with a maximum compressive force of 2.2kN and minimum of 0.2kN at 1HZ for up to 10,000 cycles. The same moulds that were used for the jig were used to mount the femur.

The aim was to reproduce the force pattern that would occur during early rehabilitation following a periprosthetic fracture fixation. The forces used for testing were based on Bergmann (Bergmann, Deuretzbacher et al. 2001). The femur was mounted to simulate a weight-bearing mid-stance position during a slow-walking gait pattern. In this position the hip is in 12° of adduction with 0° of flexion and 0° of rotation. Bergman et al calculated that peak hip contact forces in this position were 250% of body weight, which translates to 2.2kN for a 90kg adult (representative weight for the synthetic femur). In keeping with slow walking a 1Hz cycle was chosen with a total of 10,000 cycles to be tested equating to 20,000 steps of rehabilitation.

In testing, the upper head of the loading unit is fixed and its height could be adjusted using a vertical columns and four screwed bolts. This head is connected to a 50kN load cell to measure the load during testing. The lower platen of the machine is connected to the servo-hydraulic actuator (MOOG servo-hydraulic actuator, New York, 14052, USA) which is moved by the control unit to provide the sinusoidal loading set (within a maximum range of ± 25 mm). The controller is run through a PC with a lab-designed code using Lab View software to control the motion of the actuator, loading rate and the machine limits.

For measuring the displacement of the fracture gap and the cables a computer controlled Canon EOS 60D camera(Canon, Òta, Tokyo, Japan) with 16 MB (4608x3456) pixels per frame was used to capture high resolution photographs, which were analyzed using the image processing tool, Inertial Measurement Unit (IMU) in Matlab(Mathworks®, Natick, Massachusetts, USA). The aluminum housings of the upper and lower moulds were marked with reflecting strips to be used as references to track the displacements of different points on the femur sample (also marked with reflecting strips) and the cables (also marked with reflecting strips) (Figure5.1).

Figure 5.1 Femur mounted with reflective strips (visible on upper and lower mould) in servo-hydraulic test machine with MOOG controller. Canon Camera with image processing (left computer screen).

Displacement of the fracture gap was measured after every 1000 cycles while cable position was measured at the end of 10,000 cycles. Photographs were taken of the sample before commencing the test and at intervals of 1000 cycles, for which the loading was stopped briefly. The photographs were taken with load set to its minimum value of 0.2kN in each case.

Consistency of the reduction was assessed by measuring the fracture gap. From the images recorded (magnified) with the minimum load before the commencement of fatigue testing, the vertical distance between the left and right edges of the fracture were measured and averaged to give the fracture gap.

Cable migration was calculated as the difference in the distance between a fixed reference point on the aluminum housing and the cable positions before and after 10,000 cycles. The cables were numbered from1 to 8, proximal to distal.

Displacement of the fracture gap was defined as the relative difference in displacement between the proximal femur segment and the distal femur segment. This was divided into a vertical and a horizontal component. To calculate the vertical component, the distance between a reference point on the proximal femur segment close to the fracture site and a reference point on the aluminum housing was measured. The same two points were measured after a 1000 cycles. The difference between the two gave the displacement of the proximal femur segment (Figure 5.2). The same method applied to the distal half gave the displacement of the distal segment. The difference between the two provided the vertical displacement of the fracture. The same principle was applied in the horizontal direction to calculate the relative horizontal displacement of the fracture gap. The calculation was always done with subtraction of the proximal half from the distal half. Therefore a positive value indicated reduction of the fracture gap while a negative value indicated an increase of the fracture gap.

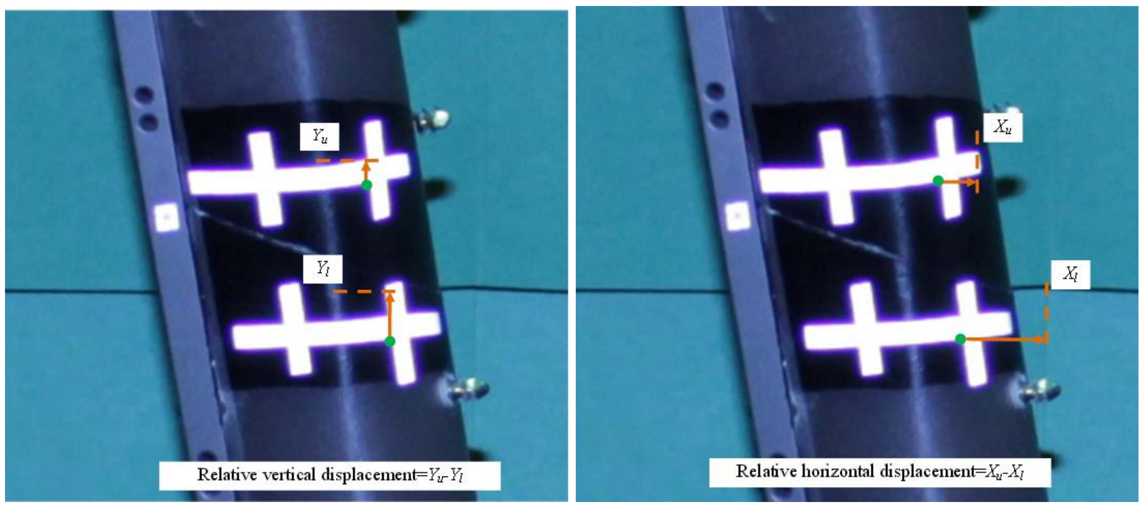


Figure 5.2 Shows the mounted femur with reflective strips used in the calculation of the fracture displacement. The green dots with arrows show displacement of reference points in the proximal and distal femur. Y_1 –Y_u = difference in relative displacement of the reference points i.e. displacement of the fracture gap in the vertical direction. Likewise X_1-X_u = displacement of the fracture gap in the horizontal direction.

Statistical analysis:

Displacement of the fracture gap and cable migration were plotted using the mean of the data to compare the results.

5.3 RESULTS

Fracture Site Displacement

SuperCables demonstrated the most displacement in both the vertical and horizontal directions. There was a clear delineation between the three fixation conditions with screw fixation allowing the least fracture gap displacement, followed by steel cables and the most displacement was demonstrated in the SuperCable samples (Figure 5.3 and 5.4).

The maximum average relative vertical fracture gap displacement for plate/screw fixation, was initially 18 µm after the first thousand cycles, and thereafter reduced and stabilized around 3µm over the next 9000 cycles (Figure 5.3). In regards to the horizontal displacement a maximum of 20 µm occurred at the 4000 cycle mark after which it decreased to 0 µm by 10,000 cycles (Figure 5.4).

The maximum average relative fracture gap displacement (in both vertical and horizontal directions) for SuperCable fixation was much greater than for screw fixation. The relative vertical fracture displacement reached its maximum in the first 1000 cycles at 263µm, and although the displacement was variable at subsequent measurements, it was 243µm when measured at 10,000 cycles (Figure 5.3). The relative horizontal fracture displacement was 101µm at 2000 cycles, and fluctuated to a maximum of 144µm at 10,000 cycles (Figure 5.4).

The steel cable fixation demonstrated fracture gap displacement magnitudes that were much closer to the screw fixation measurements. The relative vertical fracture gap displacement reached 25 µm in the first 1000 cycles rising to a maximum at of 35 µm at around 8000 cycles (Figure 5.3). The relative displacement in the horizontal plane had a similar pattern, with the corresponding figures being 39 µm and 55 µm respectively (Figure 5.4).

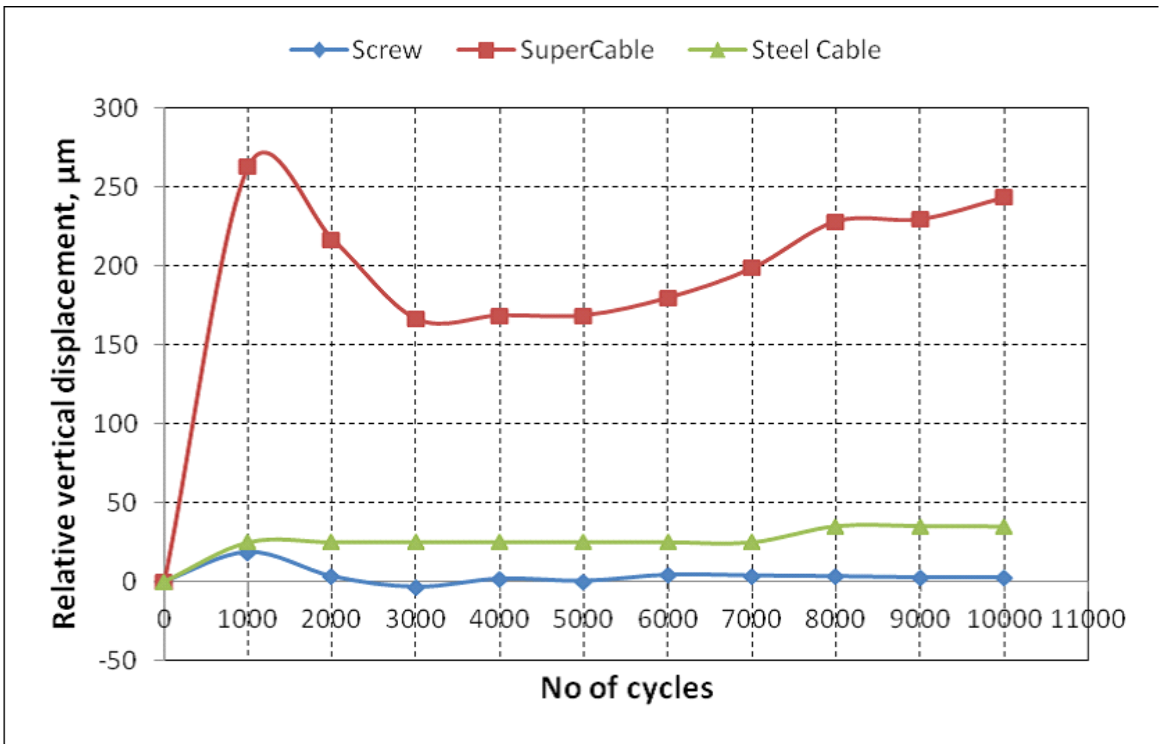


Figure 5.3 Comparison of average relative vertical displacement between the fracture surfaces (fracture gap) of femur samples repaired with screws, SuperCables and steel cables.

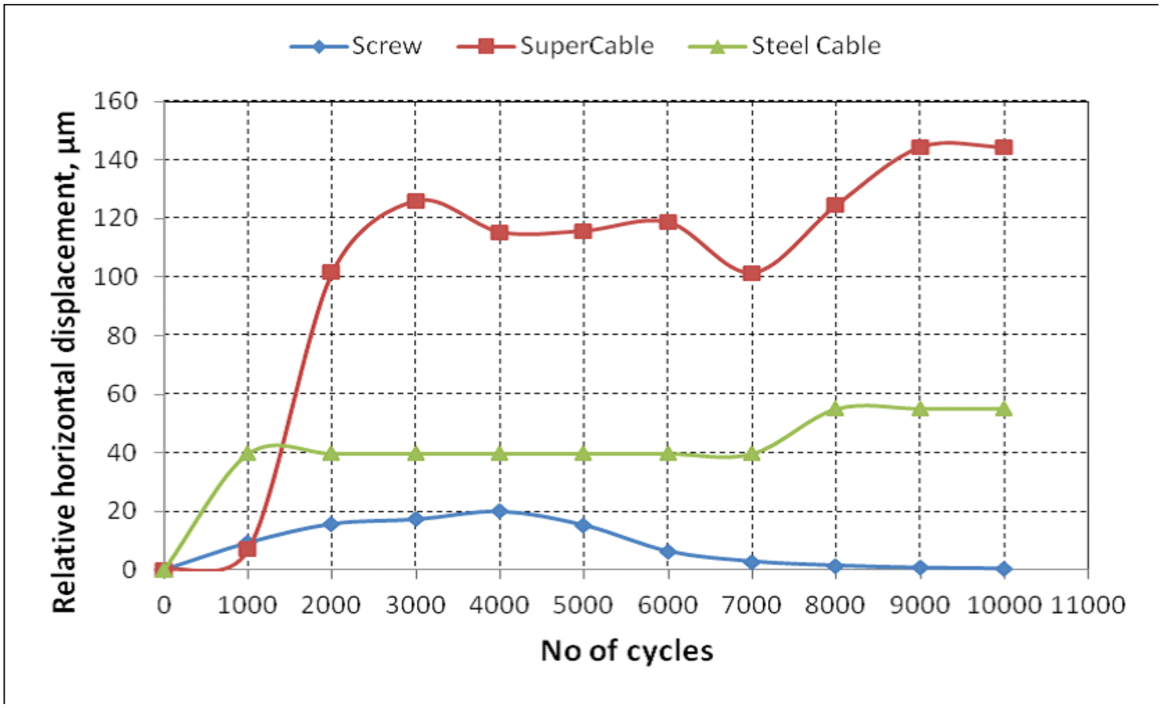


Figure 5.4 Comparison of average relative horizontal displacement between the fracture surfaces (fracture gap) of femur samples repaired with screws, SuperCables and steel cables

Cable Migration

The SuperCables showed less cable migration compared to steel cables. SuperCable migration was affected by the individual distance of each cable to the fracture site, while steel cable migration was affected by whether the individual cables were fixed proximally or distally to the fracture site. SuperCable displacement from their original location varied by a magnitude of 82 to 173 µm. SuperCables further to the fracture site migrated less than those closer to the fracture site, in both the proximal and distal fracture segments. The steel cable displacement from their original location varied by a magnitude of 173µm to 225µm. The steel cables in the proximal fracture segment migrated less (173µm to 174µm) than those in the distal fracture segment (212µm to 225µm) (Figure 5.5).

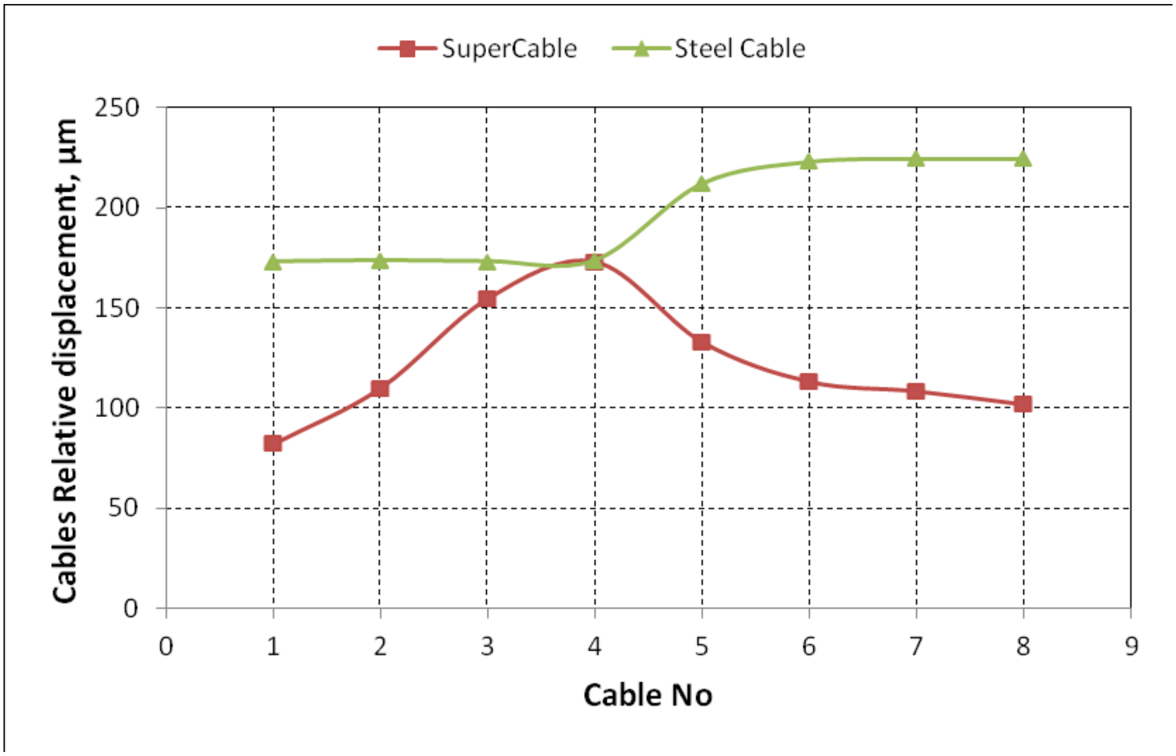


Figure 5.5 Comparison of average displacement of individual cables on femur samples repaired with SuperCables and steel cables.

There were no failures of fixation. All specimens were examined after testing and were deemed stable. However, it was noted that the most proximal steel cable in both specimens, had lost tension and was relatively loose.

5.4 DISCUSSION

SuperCables have been introduced as an alternative to steel cables for the fixation of periprosthetic fractures. The purpose of this study was to compare the performance of SuperCable/plate fixation to a screw/plate and steel cable/plate in terms of fracture gap displacement and cable migration. The hypothesis was that the SuperCables cables would not slip as much as metal cables but would provide equivalent stability in terms of preventing fracture site movement. In this study we found that the SuperCable/plate construct allowed more movement at the fracture site but, cable migration was less than steel cables.

Primary and secondary healing

Periprosthetic fracture fixation strategies need to promote optimal healing of bone. Bone can heal in two ways: primary and secondary. Primary healing is direct healing of bone by Haversian remodeling both in contact areas (contact healing) and noncontact areas (gap healing). This occurs in rigid compression plating of fractures. Secondary healing differs from primary healing in that it involves an intermediate stage of fibrous healing prior to ossification. This healing occurs with non-rigid fixation. The difference in these healing patterns is explained by the interfragmentary strain theory of Perren (Perren 1979). According to this theory, the type of healing is dictated by the strain on the fracture site. Inter-fragmentary strain is defined as the ratio of the relative motion of the fracture fragments to the 'original fracture gap'. Granulation tissue can tolerate up to a 100% strain, fibrous tissue and cartilage can tolerate appreciably less, while compact bone can tolerate up to a 2% strain only. Therefore with rigid fixation, if the strain generated is less than 2%, primary healing occurs. On the contrary, less rigid fixation which allows movement at the fracture gap, encourages secondary healing which results in a faster union than Primary healing (Sarmiento, Mullis et al. 1980, Sarmiento, McKellop et al. 1996). This movement which occurs at the fracture site, which is beneficial to healing is referred to as micro motion (Kenwright, Richardson et al. 1986).

Strain theory in the context the three fixation methods

In this study we found that screw fixation allowed minimal movement, followed closely by steel cables whereas SuperCables allowed considerable movement to occur at the fracture site. The amount of displacement with SuperCables was nearly 100 times greater than the screw fixation. This degree of displacement would suggest that SuperCable fixation could not be conducive to primary healing. However, we know from clinical studies that healing does take place with SuperCable fixation (Ting, Wera et al. 2010). It is pertinent to note that according to Perren's strain theory, strain is inversely proportional to the fracture gap. Therefore if the fracture gap is small the strain is higher and vice versa. The fracture gap was larger for the SuperCables, but only by 25% (Chapter 4). However, by virtue of the elastic nature of the SuperCables, the fracture gap could have varied during loading thereby reducing the strain and promoting secondary healing. On the other hand, the screw fixation would have remained rigid, and primary healing would be the only healing mechanism possible, while steel cable would have been conducive to secondary healing.

The relationship between fracture gap and fragment movement

A small fracture gap combined with micro motion at the fracture site promotes the best healing. Animal model studies (as well as clinical experience) have shown that the smaller the fracture gap the better the healing (Jagodzinski and Krettek 2007). The smallest fracture gap with the smallest interfragmentary movement showed the best healing (Claes, Augat et al. 1997). A one millimeter fracture gap had the best healing in comparison to a 2mm and a 6 mm gap, with a fracture motion amplitude of 0.2 to 1mm (Claes, Heigele et al. 1998). This fracture motion occurred naturally i.e. during mobilization. This lead to the belief that induced micro motion at the fracture site will further enhance healing in bones. This concept was proven in further studies (Goodship and Kenwright 1985, Kenwright, Richardson et al. 1991) with the additional evidence that in oblique fractures, shear motion leads to more callus and more stiffness (Park, O'Connor et al. 1998). Apart from the strain generated, it was noted that the strain rate also influenced fracture healing. At a strain rate of 400mm/second the greatest amount of periosteal callus was noted though a strain rate of 40mm/second showed a greater degree of consolidation and radio density of the fracture gap (Goodship, Cunningham et al. 1998). Furthermore, these studies have demonstrated that axial motion, though beneficial earlier in fracture healing, is detrimental towards the latter stages of fracture healing (Goodship, Cunningham et al. 1998). In the absence of any compression with external splinting, both steel cable and SuperCable fixation would have led to secondary fracture (bone) healing in a clinical scenario (Perren 1979, Aro and Chao 1993). Applying these conditions to the study fixations, it can be seen that both steel cable and SuperCable fixation fall well within the accepted limits of displacement and fracture gap for secondary bone healing. In this regard, extrapolating fracture gap displacement to movement, SuperCables produce a better axial 'micro movement' than steel cables and it is interesting to note that for the first 1000 or so cycles in SuperCables, axial (vertical) movement is the primary type of movement recorded.

In our study, in contrast to the steel cable and SuperCable fixations, the screw fixation incorporated axial compression. Direct primary bone healing has been demonstrated with fracture gaps of up to 0.8 mm (Aro, Kelly et al. 1990) and under conditions where absolute rigidity was not established i.e. unfixed fractures (Perren 1979, Chao, Aro et al. 1989). The compression applied to the fracture via the screw/plate fixation led to a more rigid construction that would favour primary bone healing in a clinical scenario. Bone on bone contact was established in all specimens during the fixation process though an average fracture gap of 0.42 mm still occurred. There was a vertical compression of the fracture gap of 3μm per1000 cycles. Extrapolating displacement for movement, it can be seen that these values were well within the suggested 2% of interfragmentary strain, which is consistent with promotion of direct primary bone healing.

Cable migration

The fracture gap displacement was greater in SuperCables than steel cables, even though they displayed less cable migration, which seems paradoxical. A possible explanation for this is that the SuperCables allowed movement to occur without migration along the shaft because of their inherent elasticity. This explanation is further strengthened by the migration pattern of the SuperCables. The cables closest to the fracture showed the most of migration while those furthest away from the fracture showed the least amount migration.

At the end of testing it was noted that the most proximal steel cable was loose in both steel cable specimens whereas this was not the case in any of the SuperCable specimens. This would seem to indicate that SuperCables have better tension retaining abilities than steel cables, though it is difficult to be certain since there were only two steel cable specimens tested. The abrupt increase in the fracture gap displacement of steel cables in the horizontal and vertical measurements around 7000 cycles may have corresponded to the point of loss of tension in the most proximal steel cable.

Justification for the study design.

Synthetic femurs were used because they were easily available, easier to store, less expensive and do not pose any biohazards. Furthermore with a limited number of specimens being tested, they offer consistency in physical properties unlike the biological variations of cadaveric femurs (Cristofolini, Conti et al. 2010). Synthetic femurs have been validated for their physical properties (Heiner 2008) and have been used in several studies (Dennis, Simon et al. 2000, Talbot, Zdero et al. 2008, Zdero, Walker et al. 2008). However, it has been postulated that the bone-implant properties of synthetic femurs are not comparable to osteoporotic femurs (> 60 years) and results should only be used in the interpretation of healthy adults using standard synthetic femurs (Basso, Klaksvik et al. 2014). The synthetic femurs (and forces) used in this study correspond to healthy male adults. Therefore the results need to be treated cautiously in extrapolation for an osteoporotic group.

A cut angle of 60 degrees running superolateral to inferomedial was used in this study. The rationale to create shear forces and avoid the buttressing effect of a laterally placed plate has been used previously (Zdero, Walker et al. 2008). Previous studies have used an angle of 45 degrees (Dennis, Simon et al. 2000, Dennis, Simon et al. 2001, Fulkerson, Koval et al. 2006). An angle of 60 degrees was chosen in this study because, in practice a lesser angle would have been fixed with a lag screw.

A 2.2kN force (equivalent to 250% of the body weight) was used in 12 degrees of adduction (0 degrees of flexion and rotation) based on Bergmann et al (Bergmann, Deuretzbacher et al. 2001) to simulate the kinetics of a mid-stance position in slow walking. These values have been used in other studies (Wilson, Frei et al. 2005, Moazen, Jones et al. 2011). Other investigators have used different angles and forces to simulate single leg stance. Adduction angles from 5 degrees through 11 degrees and 15 degrees to 25 degrees have been used with no justification as to why a particular value was chosen (Panjabi, Trumble et al. 1985, Dennis, Simon et al. 2000, Dennis, Simon et al. 2001, Heiner and Brown 2001, Fulkerson, Koval et al. 2006, Talbot, Zdero et al. 2008, Zdero, Walker et al. 2008). Likewise forces ranging from 200 N up to 2670N have been used, with references being given for some of the values (Dennis, Simon et al. 2000, Han 2000, Dennis, Simon et al. 2001, Fulkerson, Koval et al. 2006, Talbot, Zdero et al. 2008, Zdero, Walker et al. 2008). Therefore though conclusions can be drawn from within a study, direct comparison between these studies is difficult.

The specimens used in this study were subjected to a cycling frequency of 1Hz for 10,000 cycles. This profile was used to simulate the period of early mobilization following a periprosthetic fracture fixation. Average fracture healing time of 3 months corresponds to approximately 150,000 to 250,000 cycles (Gardner, Silva et al. 2012). Most studies have used a frequency of 3Hz and up to 100,000 of cycles (Fulkerson, Koval et al. 2006, Talbot, Zdero et al. 2008). Three Hz corresponds to a fairly brisk walk (6 steps per second) which is an unrealistic gait speed in the immediate post-operative period following a fixation of a periprosthetic fracture. Furthermore, as callus forms and healing progresses, the forces across the fracture fixation device decreases. Therefore testing cycles beyond the immediate post-operative period become less relevant (Gardner, Silva et al. 2012). A cyclical frequency of 1Hz is closer to the normal post-operative mobilization frequency and provides a more realistic basis for testing.

In this study displacement of the fracture site was used as an indirect measurement of the stiffness of each construct The fixation was not evaluated directly in terms of stiffness of the construct as has been done in other studies (Dennis, Simon et al. 2000, Dennis, Simon et al. 2001, Fulkerson, Koval et al. 2006, Ahmad, Nanda et al. 2007). Determining a hierarchy of stiffness with testing to failure is of less relevance in physiological healing, provided that the fixation device does not fail under the physiological testing parameters as witnessed in this study.

Limitations

This study has several limitations primarily related to the constraints of mechanical testing. Apart from the vertical and horizontal loads to which the hip is subjected during mobilization, there is torsional moment. This torsional moment was not replicated in this study because the mechanical testing station did not have that facility. The fracture gap displacement at the end of each 1000 cycles was measured in this study, as opposed to the actual fracture movement. Serial measurements of the maximum fracture displacement (and fracture gap) under the peak force would have given data that had important biological implications as noted above. Only two steel cable specimens were tested as opposed to 5. This was due to resource limitations with the cost of the steel cables exceeding our budget. However, the 2 specimens were consistent and we think representative.

Conclusions

This study has demonstrated that different fixation types lead to distinctly different types of ‘fracture behaviour’. The SuperCable specimens demonstrated more fracture site displacement but the magnitude was within the constraints of effective secondary bone healing with micro-motion osteosynthesis. There is evidence that secondary healing results in better healing (Chao, Aro et al. 1989, Jagodzinski and Krettek 2007, Gardner, Silva et al. 2012). It is possible that the behaviour pattern of SuperCable in this regard has important biological implications for promoting fracture repair in the challenging environment of PPF.

CHAPTER 6

CONCLUSIONS

6.1 MAJOR IDEAS AND MAIN FINDINGS OF THE THESIS

Introduction

The final chapter of this thesis brings together the main ideas (and findings) that came out of chapters 3 (retrospective clinical study) and 5 (the mechanical testing study).The practical issues of preparation of the synthetic femur fracture specimens which led to the design and construction of a mechanical jig, are also discussed. Suggestions and ideas for future studies are ultimately made.

6.1.1 Retrospective review of PPF of Canberra hospital-a 12 year review

The results of this first Australian retrospective review of outcomes following PPF indicate that our success rates are similar to those previously reported. However, the impact of Vancouver C fractures has potentially been previously under-appreciated. Although most of the literature discusses the complexity of treating Vancouver B fractures, the results of this study, as well as other studies (Zuurmond, van Wijhe et al. 2010, Park, Kim et al. 2011, Holder, Papp et al. 2014, Plamen Kinov 2015) indicate that Vancouver C fractures also present an equivalent rate of PPF fixation failure. It is a well-recognized dictum that in the treatment of Vancouver C PPF, one can ignore the prosthesis and just treat the fracture (Duncan and Masri 1995). However, the results appear to be suboptimal when this approach is followed. This is perhaps not surprising given that fixation of a femoral fracture with an intramedullary (IM) nail is known to result in better outcomes than plate fixation (Uhthoff, Poitras et al. 2006). In a Vancouver C fracture, plate fixation is currently the treatment used for these fractures, because of the canal being occupied by the prosthesis. The possibility of using a retrograde IM nail has not been discussed in the literature and to our knowledge it is not used clinically. Practically speaking there would appear to be a substantial risk of creating a significant stress riser which may lead to further fractures using this strategy. However, there may be potential for a modified nail design or a mixed method using a retrograde nail and a plating construct. In any case, further biomechanical studies aimed at improving our management of this fracture would seem to be indicated.

The treatment of PPF may be improved by the establishment of Regional centres. It is well established that the treatment of rare conditions is improved when managed by a specialist centre (Heudel, Cousin et al. 2014). It is clear that gaining significant expertise in this uncommon procedure is difficult. Although the incidence of PPF is increasing, it is still relatively rare and an orthopaedic surgeon performing 150 to 200 hundred hip replacements annually will not encounter more than a few PPF in a year. In our study, over a 12 year period 56 fractures were fixed by 17 surgeons using over 25 different combinations of plates, screws, cable plates, cables, strut grafts, allografts, auto grafts and osteogenic proteins. The majority of these surgeons treated less than three fractures over the 12 year period of the study. For this reason, PPF are arguably best treated in a tertiary level referral hospital by a dedicated team of specifically trained orthopaedic surgeons with a research capability. In such a unit the number of these fractures fixed over a decade would still be in the hundreds rather than the thousands, but consolidating this data is essential if we are to improve outcomes.

It is therefore suggested that a registry of PPF is needed to accurately capture outcome data following PPF in Australia. The existing AOANJRR does not capture those fractures that fall short of a joint revision. This PPF registry would enable the results from all over the country to be consolidated and analyzed. Such a register may also enable the evaluation of novel interventions such as a more effective way of treating Vancouver C fractures as discussed above. In order to achieve this agreed outcome instruments would need to be developed.

6.1.2 Validation of a mechanical jig for the biomechanical study

Our investigation into the utility of a mechanical jig for biomechanical fracture testing indicated that a jig should be utilized for these studies. We were the first to design and build a mechanical jig to ensure consistency in the preparation of specimens by ensuring a consistent: position of the cut, angle of the cut, position of the plate on the femur and reduction of the fracture in terms of the magnitude of the fracture gap. Biomechanical testing utilizes a limited number of specimens and therefore in order to produce valid and reliable results, it is imperative that the experiments are designed to ensure optimal consistency in the preparation of each specimen. Our results showed that the mechanical jig achieved a high level of accuracy and precision. The position of the cut and variation in the plate position (i.e. movement of the plate during the fixation process) was within a millimetre. The angle of the cut was accurate to within a degree and the maximum variation in the fracture gap within each subset of fixation was less than 0.1 mm. We were therefore able to compare our fixation methods knowing what our margins of error were. This has not been the case for previous studies.

6.1.3 Biomechanical study

In our study of the behavior of various plate constructs we found that SuperCables were the most likely to promote secondary fracture healing. It is known that less rigid fixation, which allows movement at the fracture gap, encourages secondary healing and faster union (Sarmeinto et al, 1980, 1996). The SuperCable-plate constructs allowed movement of the fracture which was within the constraints of effective secondary bone healing with micro-motion osteosynthesis. In PPF, metal-ware breakage and non-union are the most common reasons for failure. Therefore, faster union would result in better outcomes. Metallic cable plate constructs are commonly used in clinical practice for PPF fixation. The results of our study showed that they were surprisingly stiff but not as immobile as the screw/plate construct. Therefore, it is possible that metallic cable-plate constructs are not stiff enough to effectively promote primary healing, but too stiff for a good secondary healing response. However, this is still unknown. Metal cable migration and loosening over time was observed in this study, especially the most proximal cable. For effective secondary healing relative stability is required by six weeks (Jagodzinski M, et. al., 2007). Metal cables may not comply with this requirement since the construct actually loosens over time. Therefore, it is possible that metal cables may not be the ideal construct for PPF fixation and their use might be a reason for some of the failures seen in both our retrospective clinical study and those described in the literature. The findings of this study support the investigation of SuperCables and plates for the treatment of PPF in the future.

Based on our study immediate weight bearing or at least protected weight bearing should be encouraged in patients following PPF fixation. It is well known that following internal fixation of fractures, there is a race between fracture healing and metalware failure (Ferreira, Marais et al. 2014). Therefore it follows that if one were comparing different methods of fixation; superiority (for a given aspect) of one over the others from a practical perspective is only relevant, if one fails outside the physiological test parameters and the others fails within it. If all fail outside the physiological parameters (i.e. the bone has healed) any construct will do, and if all fail within the physiological parameters (i.e. metal ware failure) none of them is strong enough. In our bio-mechanical study there were no failures in any of the constructs during the testing of 10,000 cycles. Therefore from a weight bearing perspective all of our constructs were 'equal'. In almost all instances following fixation of PPF in our study there was an extensive period of non-weight bearing i.e. at least 6 weeks. Weight bearing is an important stimulus for the healing of fractures. Given that the single most important complication resulted from a delayed/non-union of PPF, it would seem advantageous to commence early weight bearing following fixation of PPF. Our biomechanical study was undertaken on well reduced, 60 degree oblique femoral midshaft fracture models. Therefore the conclusions made with respect to weight-bearing are limited to fractures with similar properties.

6.2 LIMITATIONS OF THIS THESIS

6.2.1 Retrospective review of PPF of Canberra hospital-a 12 year review

The main limitation of the retrospective clinical study was that it was retrospective in nature. The lack of precise data stems from this fact. There is also the aspect of deficient record keeping i. e entry of operative codes. As mentioned earlier, it is extremely unlikely that the only intra-operative PPF identified over this 12 year period, occurred during revision of post-operative PPF.

6.2.2 Validation of a mechanical jig for the biomechanical study

There was no comparison of the current (free hand) method of specimen preparation against specimen preparation by a jig. Though the jig did deliver a very high degree of consistency in specimen preparation and the existing literature provides evidence of variation in specimens when prepared free handedly, we did not have a comparison to make this a bias free study.

The proximal mould and the clamp system was not conducive for a smooth fracture reduction and plate fixation and these should be modified.

6.2.3 Biomechanical study

Measurement of the residual fracture gap displacement at the end of each 1000 cycles did not give a true representation of the actual fracture movement during the cycling process.

Measuring the fracture gap displacement also does not allow any meaningful data in regard to the strain generated during the cycling as well, which has important implications in terms of fracture healing potential.

Testing up to 50,000 to 75,000 cycles would have given a more realistic assessment of the construct behavior, which would have corresponded to 6 to 8 weeks of early rehabilitation time. This would be especially valid for the cable constructs as the fracture gap was noted to be increasing towards the end of 10,000 cycles and especially so with metallic cables, as the most proximal cable was noted to be loose after 10,000 cycles.

We were not able to add a torsional moment (which is part of a normal gait pattern) to the testing protocol as the testing station did not have this facility, and we only had two metallic cable constructs for fixation due to resource limitation.

6.3 DIRECTIONS FOR FUTURE STUDIES

6.3.1 A 'comparative validation' of the mechanical jig

We demonstrated that our jig delivered a high degree of accuracy in specimen preparation. However, we did not have a comparative set of samples to prove that this difference in specimen preparation was significantly different. Therefore we propose a comparative study of specimen preparation using the mechanical jig and free hand.

6.3.2 Mechanical testing at a higher frequency

Given that laboratory time and human resources are two of the most expensive 'commodities', a decrease in time of the laboratory testing process will have a major impact on laboratory-based research. At 1 Hz, 8 hours of testing equals 28,800 cycles. Therefore testing a construct for 50 to 75000 cycles would take two to three days of laboratory work, which is 4 to 6 weeks of testing for 15 specimens. This is a significant and expensive amount of laboratory time and human resources. A frequency of 1Hz was chosen for this study to replicate a frequency that would be the closest to a gait pattern during rehabilitation following PPF fixation. However, in a purely mechanical study, unlike in a clinical study, the bone does not participate in the healing process. Therefore, the frequency rate of testing should not make an impact on the results, unless it affects the mechanical/physical properties of the construct system. Therefore in order to test whether there is an effect due to frequency in biomechanical bone constructs, a set of femurs with fracture fixation should be compared after testing at 1 Hz and 10 Hz. If there is no significant difference between the two sets of data testing at 10 Hz could be adopted.

6.3.3 Repeat the mechanical testing study

Although the results of the mechanical testing study revealed some useful insights, there are some avenues for additional study that could be pursued. The inclusion of a torsional moment would better equate to normal human weight bearing. Ideally we would have included equal numbers of specimens in each subset but this required additional financial resources. Increasing the number the number of cycles tested to mimic at least 6-8 weeks of weight bearing might reveal more about the longevity of each construct. Finally, measurement of the fracture movement, as opposed to residual fracture displacement, would provide more precise estimations of the absolute fracture site displacement distances as opposed to comparative intermittent resting positions. Very high speed video capture would be required to make these measurements.

These studies have provided a framework on which further testing of different fracture patterns and different fixation methods could be explored.

6.3.4 Further clinical studies and a registry

Given the results of the biomechanical study, a clinical randomized controlled trial of SuperCable and plate fixation compared to conventional metal cable and plate fixation should be conducted. However, given the rarity of PPF it would take considerable time to run such a trial and it is possible that the introduction of a PPF registry might prove to be better way to investigate outcomes after PPF. In the same way that the AOANJRR evaluates arthroplasty outcomes that have a below average performance; fixation methods in PPF could be evaluated. However, it should be acknowledged that there is sometimes a disparity between registries and randomized controlled trial results due to the effect of confounders which are not well controlled in registry data. On the other hand, the numbers of patients entered into registries allows for a better understanding of the patient population treatment trends (Graves 2010).

6.3.5 For validation of finite element testing

Finite element testing is a computer based method of predicting outcomes in regard to mechanical behavior based on the physical properties of the tested specimens. The data generated in these studies could be used to evaluate the accuracy of finite element testing models. These newer models could be then used more confidently to predict further outcomes.

6.4 CONCLUDING REMARKS

In conclusion the studies which comprise this thesis have allowed us to better understand the challenges of PPF treatment for both the surgeon and the patient, and also to test a potential improvement in surgical technique. Our clinical results have proved to be comparable to others reported internationally in terms of distribution of fracture types and outcomes. From our biomechanical studies we hypothesize that treatment of these fractures may be more successful if they are managed using a secondary healing paradigm. Larger multi-national studies and/or a registry are arguably required to better understand how to most effectively treat this condition. Finally, the establishment of specialist centres charged with managing periprosthetic fractures would assure the best possible outcomes for this vulnerable and challenging group of patients.

Appendix I describes the steps taken to ensure a consistent position and angle of the cut, reduction of the ‘fracture’ and fixation of the plate using the mechanical jig.

Setting up of the Milling Machine (Turret Milling Machine, Model: BM-1500V)

Please refer to the glossary for details of the milling machine.

The milling machine was set up with its base to the wall. The platform/table ran horizontally in front of the machine (Figure 1). The arbor attachment is perpendicular to the machine, with the blade attachment being parallel to the platform’s long axis. These settings were confirmed to be so, using the standard procedure for setting up the milling machine.

There was a dedicated milling station for the entire series of experiments. Once the station was set up it was not disturbed apart for two occasions. On these occasions the whole procedure was redone from start to finish.

Figure 1. Milling machine used in the study. The platform runs horizontally (red arrow) with the arbor (black arrow) perpendicular to the machine platform. The cutting blade has not been attached to the arbor.

Setting up of the Jig

This procedure was needed to ensure that a 60 degree cut to the long axis of the femur was made, as the cutting saw, which is mounted on the arbor of the milling machine remaining parallel to the long axis of the platform/table of the milling machine.

The jig was placed on the platform of the milling station. Thereafter the entire jig was orientated that its longitudinal axis (which is parallel to the femoral bone anatomical axis) is at 60 degrees to the longitudinal axis of the platform using the following steps.

1. The protractor was set to 60° visually and confirmed to be at 60° using a magnifying glass. This setting was locked in place and not disturbed throughout the experiment series.
2. The protractor was placed on the side of the platform with its base touching the long side of the platform along its entire length.
3. Then two parallel blocks were placed side to side (along their long axes) and tapped gently till they were secure along the entire length of the ruler of the protractor, once again using vision and touch as the discriminator.
4. The jig was placed on the platform in an orientation that the proximal femur (head end) would be pointing to the milling machine and the distal femur (trochlear end) away from the machine. The anterior surface of the femur would be facing up and the posterior surface of the femur facing down.
5. The jig was then positioned with its long side touching the parallel bars, and then gently tapped into place, until there was no gap seen and felt between the side of the jig and the parallel bars, while maintaining the relationship of the parallel bars to the protractor (ruler) and the protractor to the base of the platform (Figure 2).
6. The jig was then locked in place using 2 bolt clamps on the opposite side to the protractor.
7. It was confirmed physically that the jig was secure with these two bolt clamps in place and that the required orientation had not changed.
8. The protractor and the parallel bars were removed and a further two bolt clamps were placed on this side as well (Figure 3).

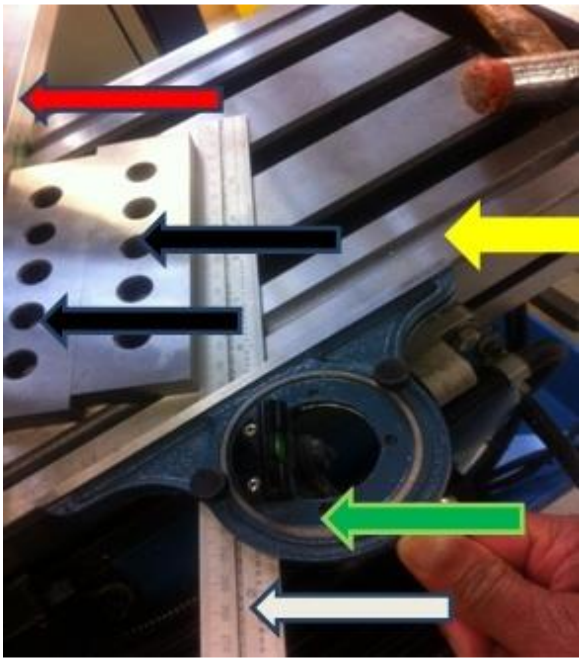


Figure 2. Protractor (green arrow) set at 60 degrees being applied to the platform (yellow arrow). The ruler of the protractor (white arrow) is in contact with the two parallel blocks (black arrows), which are in contact with the base of the jig (red arrow).

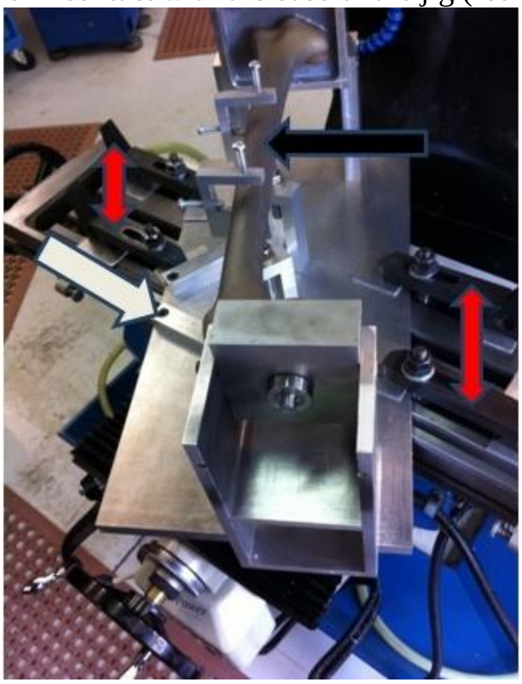


Figure 3. Final position of the mechanical jig secured to the platform with 4 bolt clamps (red double headed arrows) showing the femur (black arrow) in its correct orientation to obtain 60 degree cut across the long axis of the femoral shaft. The saw blade will be cutting parallel to the platform (in the direction of the white arrow) of the jig.

Setting up of the femur in the Jig[3]

The distal end of the femur was placed in the distal mould (12), which is fixed to the base (15). The intra-medullary rod (13) was then advanced till it engaged the femoral canal. A few gentle taps were given by a mallet to secure the rod.

Thereafter the proximal mould base (10) was moved transversely till the mould (12) lined up with the femoral head. At this point the mould base was secured to the base of the jig by tightening the screws of the mould base. Thereafter the proximal mould was advanced till it engaged on to the femoral head. Manual pressure was applied to the proximal mould, while the screws were tightened (on the proximal mould) to maintain the position (Figure 4).

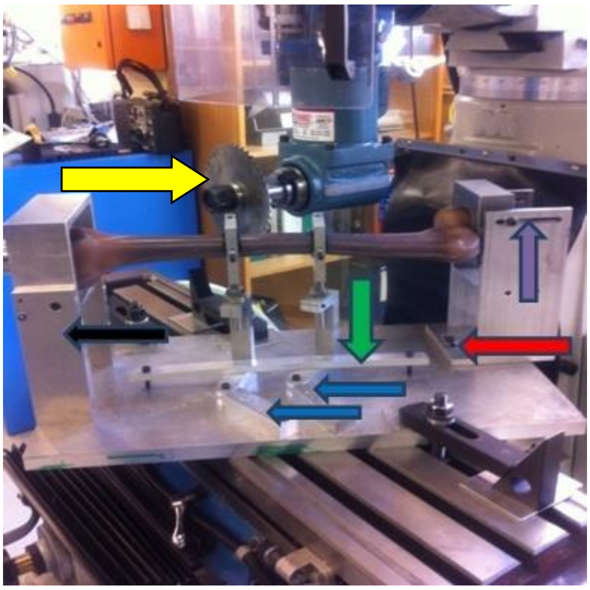


Figure 4. The femur is placed in jig in preparation to be cut. The distal mould (Black arrow) position is fixed. The proximal mould base can be moved transversely to line up with the femur, by moving the mould base, then secured in position by tightening the screws in the base (red arrow). The proximal mould can be moved axially to engage the femoral head along the grooves on either side (purple arrow). The horizontal bar (green arrow) is secured across the hinged base of the clamps (blue arrows). Please note the saw blade (yellow arrow) mounted on arbor, indicating the direction of the femur cut.

It was confirmed that the femur was secure by feel and by vision. Thereafter the specially designed proximal and the distal clamps were secured on to the femur. These clamps had a hinged base (2) that was movable in a horizontal plane on the base of the jig. A

[3]Please refer to Appendix II for a detailed diagram of the mechanical jig. Please note that the original nomenclature of the jig parts have been changed in order to aid the description. Reference has been made to the original nomenclature within brackets to help identify the part if need be i.e. distal mould (12) refers to the numbered part 12 in the diagram of the mechanical jig in appendix II.

horizontal bar (14) was designed to go over the hinged base to provide additional security and reduce the effect of vibration during cutting the femur (Figure 4). From this base a perpendicular strut (3 and 7) gave rise to a c-arm (4) designed to secure the femur as well as position the plate on the femur. The c-arms could be moved vertically up and down as well as rotated around their vertical axis. The c-arms of these clamps were elevated till the inside 'V' on the base of the c-arm clamps was in contact with the femoral shaft. Each c-arm had a horizontal and a vertical screw. The vertical screw was to secure the femur on to the c-arms, while the horizontal screw secured the plate on to the femur (Figure 5).

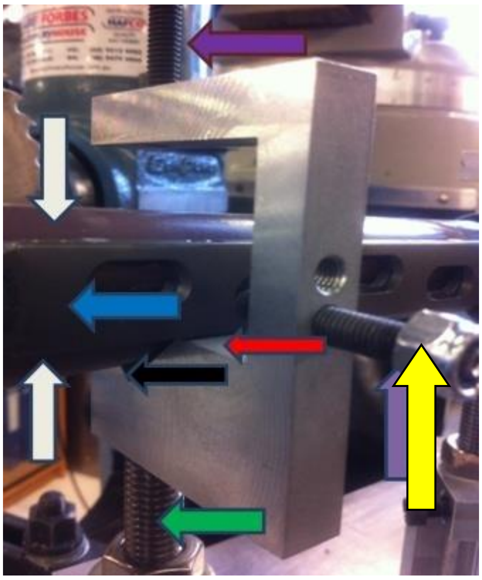


Figure 5. C-arm clamp on adjustable perpendicular strut (green arrow). The femur (white arrows) is resting in the 'V' position at the base of the c-arm clamps (black arrow). The plate (blue arrow) is resting on the horizontal base/bar of the c-arm clamps (red arrow). The horizontal screw (yellow arrow) coming out of the vertical bar of the c-arm clamp secures the plate on to the femur, while the vertical screw (purple arrow) coming off the top transverse bar of the c-arm clamp secures the femur on to the clamps.

Visual confirmation was done to ensure that the saw blade could cut through the femur without coming into contact with either of the clamps (Figure 4). The position of the hinge base of the clamps was marked on the base of the jig in this position to ensure reproducibility throughout the series of experiments (Figure 6).

A final visual/tactile check was done to confirm that the jig and the femur were secure and the screws were tightened.

Cutting of the Femur

The midpoint of the femur was determined as the midpoint between the tip of the greater trochanter and the highest point of the trochlear groove. This was measured at 235mm from the tip of the greater trochanter.

Using the controls of the milling machine the saw blade was lined up with this point.

An electronic edge finder probe[4] (accuracy of 0.01mm) was used to reference this point from the bottom left edge of the distal femur mould of the jig. The coordinates for this point were 42.905 on the Y-axis of the milling machine. This reference point was maintained for all subsequent femurs within an accuracy of .05cm. i.e. range from 42.9cm to 42.91cm.

A final check was done to ensure that the femur was secure in the jig and the jig secure on the milling station. Proper safety precautions were observed and the femur was cut. The cut was made by a 152mm diameter, 1.5mm thick, rotating slitting saw mounted on the stub arbor.

N.B. Firstly the midpoint of the femur was measured and marked only for the very first femur. This served as a point of reference (on the Y-axis) to facilitate a reproducible and accurate cut for the rest of the series.

Secondly it should be noted that the other two axes (X and Z) are irrelevant with regard to ensuring reproducibility of the consistent Y-axis running through the original point of reference, as the probe is locked in place. However, a consistent Z point was maintained to ensure that the saw blade made contact with the femur in a consistent relationship.

Reducing the fracture

Once the femur was cut the surrounding saw dust was vacuumed.

The proximal clamp that was holding the femur was loosened and the proximal mould was advanced till the fracture gap was reduced. The parallel lines that were drawn prior to cutting the femur were realigned in the reduction process. There were two ‘mould’ lines that ran on the lateral and medial aspect of the femur that were created during the

[4] It is conventional to speak of moving the probe, though in reality the probe/arbor is stationary, and it is the milling station platform that moves.

process of manufacturing the synthetic femurs. The alignment of these lines was used as well to assess the alignment of the reduced femur (Figure 6 and 7).

This reduction was also assessed by feeling for a step in the fracture.

Positioning the plate

The femur was resting in the ‘V’ base of the c-arm clamp. The horizontal screws were loosened and the plate was then rested on the horizontal bar section on the base of the c-clamp (Figure 5). This ensured a consistent relationship between the femur and the plate position in an anterior-posterior direction.

Thereafter the plate was moved till the ‘appropriate midline’ of the plate was in the optimal position for fixation. This position varied between the screw and cable fixation.

The bases of the clamps were also moved, as the original position of the clamps when cutting the femur, was not the optimal position for holding the plate on to the femur, during the fixation process.

Thereafter the horizontal screws (and the vertical) were tightened. The relationship between the femur, plate and the jig was reconfirmed visually.

The plate was marked on its superior (anterior) border where it met the fracture line so it could be positioned in the same place relative to the fracture. This now ensured that the plate was positioned consistently in a superior-inferior direction (Figure 6) as well. Also the position of the clamps was marked on the base of the jig, so this position could be reproduced consistently (Figure 6).

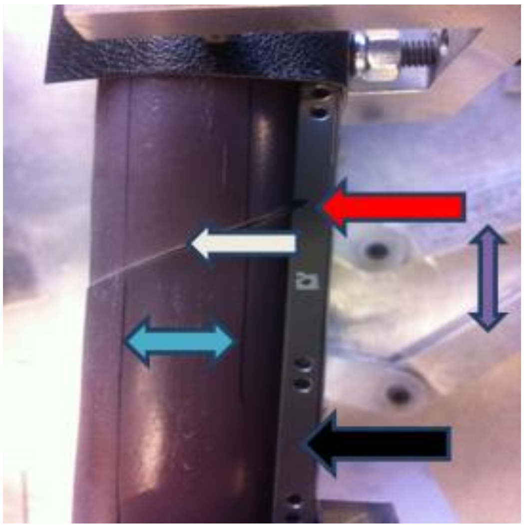


Figure 6. Fracture (white arrow) has been reduced aligning the two parallel lines (blue double headed arrow), marked before cutting the femur. The plate (black arrow) has been positioned with its midpoint marked (red arrow) in relation to the fracture line to ensure consistent position throughout each series of fixation. The hinged clamp bases can be seen on the base of the jig (purple double headed arrow).

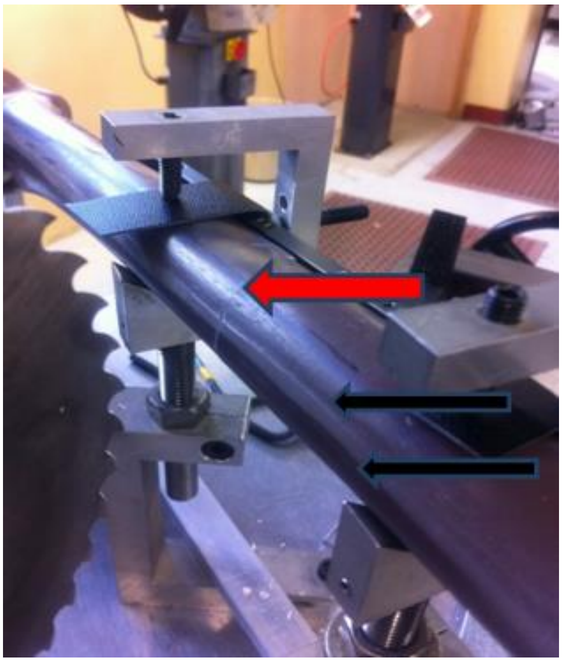


Figure 7. The mould lines (black arrows) that are running on the medial side of the synthetic femur can be seen to be aligned after the reduction of the femur fracture/cut (red arrow).

For each subset that was tested the same plate was used. i.e. three plates for three types of fixation: SuperCables, screws and steel cables.

The plate and clamp positon was the same for both sets of cable fixation while it was different for the screw fixation.

Plate position measurements

Three measurements were taken to verify the positon of the plate on the femur. Only two of these were used for the study. These measurements were taken using an electronic Vernier caliper (accurate to 0.01mm). There were two proximal measurements and one distal measurement.

The synthetic femurs had a ‘pin hole’ proximally on the lateral surface beneath the greater trochanter extending through to the head and another ‘pin hole’ distally through the epicondyles. A 3.1mm drill bit was inserted into the proximal pinhole. The proximal measurements were taken from the edge of the drill bit where it contacted the femoral surface; the measurements were to the proximal tip of the plate and the intersection of the bottom edge of the triangular tip of the plate with the top mould line of the femur (Figure 8). For the distal measurement the drill bit was inserted into the pinhole over the lateral epicondyle of the femur. The distal measurements were taken from the edge of the drill bit where it contacted the femoral surface to the distal tip of the plate.

Application of SuperCables

The SuperCables (4 proximal and 4 distal) were passed through the dedicated double hole configuration on the sides of the plate to form a double loop (Figure 8). The cables were tensioned according to the manufacturer’s instructions for a healthy adult i.e. tensioned to 530N marked ‘Hi’ on the Kinamed tensioning instrument.

The width of the clamp arms obscured the screw and cable holes, so that only four SuperCables could be applied once the plate was secured, without changing the clamp arm position.

Therefore four SuperCables were applied first. Thereafter sequentially the distal and proximal clamp arms were loosened and rotated to get access to the remaining holes.

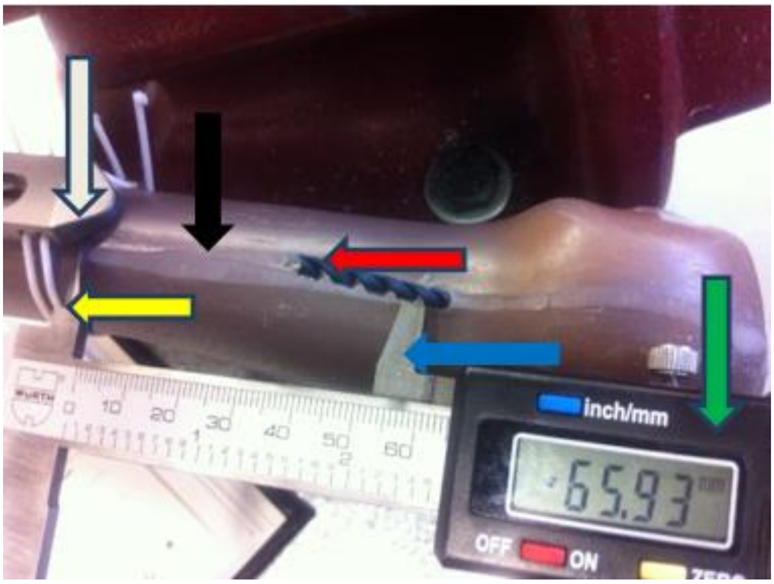


Figure 8. The 3.1mm drill bit (red arrow) is positioned in the proximal ‘pin hole’. The electronic Vernier caliper (green arrow) is placed on the femur with one of its jaw (blue arrow) in contact with the drill bit and the other jaw (yellow arrow) tip at the intersection of the bottom edge of the triangular tip of the plate (white arrow) and the top mould line of the femur (black arrow). A double loop of SuperCables is seen to the left of the yellow arrow.

Initially the two most proximal, the most distal and fifth distal SuperCables were applied in order of most proximal, most distal, second most proximal and fifth distal. Thereafter the distal clamp was loosened and the second to most distal SuperCable was applied. The clamp was retightened and the proximal clamp loosened and the fourth most proximal SuperCable was applied. The clamp was retightened. The same process was repeated for the remaining distal and proximal SuperCables (Figure 9).

Application of the screws

Axial compression was used in the application of the screws. The screws were tightened according to the torsional feel. The clamps only obscured one proximal and distal set of screw holes.

Therefore on the proximal side the two screws nearest to the fracture were applied first starting distally and moving proximally. Thereafter the nearest distal screw to the fracture line was applied with axial compression.

Thereafter the sixth distal screw followed by the most proximal screw and the most distal screws were applied.

Thereafter the proximal clamp was released to apply the second most proximal screw. The clamp was re-applied and the distal clamp was released to apply the seventh distal screw (Figure 9).

Application of the steel cables

The steel cables were applied through one hole only because they are conventionally used as a single loop. In the central four pairs of holes the cables were threaded through the holes closest to the fracture. The outer four cables were threaded through the outermost holes. The cables were then tensioned according to the manufacturer's instructions to the 50 (50kg) mark using the Synthes tensioning device.

Only one set of cable holes on either side was obscured by the clamps.

The closest cables to the fracture site were applied proximally and distally in that order, followed by the second most proximal cable and the most distal cable; then the most proximal cable and the sixth distal cable.

Clamps were loosened and retightened proximally and distally, to apply the third proximal and seventh distal cable respectively (Figure 9).

Figure 9 . Fixed synthetic femurs from left to right : SuperCables, steel cables and screws.

APPENDIX II

Design of mechanical jig.

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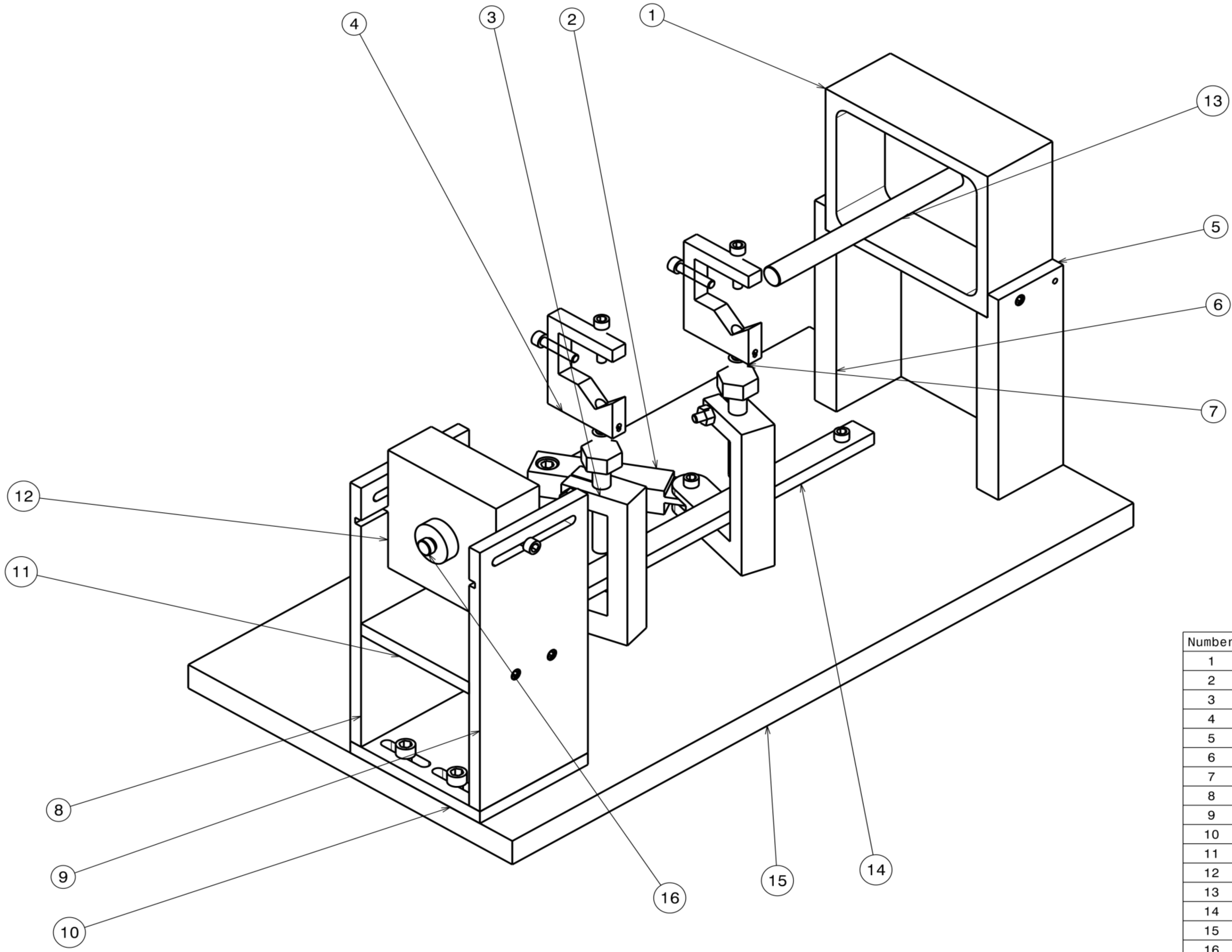

Bill of Material: Femur Fixture

Number	Part Name	Quantity	Component Description	Sheet No.
1	R Mould	1	Aluminum	3/18
2	Clamp-Tongue	2	Aluminum	4/18
3	Clamp-C	2	Aluminum	5/18
4	Clamp-V	2	Aluminum	6/18
5	R Mould Holder Front	1	Aluminum	7/18
6	R Mould Holder Back	1	Aluminum	8/18
7	Clamp-Rod	2	Steel	9/18
8	L Mould Holder-Bottom	1	Aluminum	10/18
9	L Mould Holder Front	1	Aluminum	11/18
10	L Mould Holder Back	1	Aluminum	12/18
11	L Mould Holder Middle	1	Aluminum	13/18
12	L Mould	1	Aluminum	14/18
13	R Mould Rod	1	Steel	15/18
14	Clamp Plate	1	Aluminum	16/18
15	Base	1	Aluminum	17/18
16	L Mould Plug	1	Steel	18/18

UNSW Canberra		Femur Fixture	
Part No. -	No. Off. -	Part Name: Fixture Assembly	
Sheet No 2/18	Material Aluminum	Size: A3	Tolerance: ±0.1mm
Designed By Ahmed Thabet	Dimension: mm	Scale:1:3	Surface Finish: 3.2 μm

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