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Locking plates for distal femur fractures: Does an increased working length improve healing?

By

DR IAN M KOLLER

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Supervisors

Dr S Maqungo, Prof. J Walters

Department of Orthopaedic Surgery,

University of Cape Town

DECLARATION

I, *Dr Ian Koller* hereby declare that the work on which this dissertation/thesis is based is my original work (except where acknowledgements indicate otherwise) and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree in this or any other university.

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3. This dissertation is presented in a standard monograph format but it is also my intention to submit the research to a peer reviewed orthopaedic journal for publication.

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GLOSSARY OF ABBREVIATIONS

AO Foundation:	Arbeitsgemeinschaft für Osteosynthesefragen (Association for the Study of Internal Fixation)
ABP:	angular blade plate
CBP:	condylar buttress plate
DCS:	dynamic condylar screw
IM:	intramedullary
GSH nail:	Green-Seligson-Henry retrograde intramedullary nail
GSW:	gunshot wound
GPa:	gigapascal
LCP:	locked compression plate
LISS:	Less Invasive Stabilization System
MI(P)PO:	minimally invasive (percutaneous) plate osteosynthesis
MVA (P):	motor vehicle accident (pedestrian)
OTA:	Orthopaedic Trauma Association
SDR:	screw density ratio
TKR:	total knee replacement
UCT:	University of Cape Town
W/L:	working length

ABSTRACT

Purpose of study

Distal femur locking plates have become a very popular means of internal fixation because of their ability to provide stable distal periarticular fixation. In spite of this enthusiasm however several studies have reported significant problems with healing. In the distal femur it is recognized that locking plate fixation may be too rigid if used in certain configurations that limit the essential micro movement required for biological healing. Implant failure may arise from rigid configurations that cause excessive hardware stress concentrations. In an attempt to address these problems longer plates and an increased working length have been proposed to reduce construct rigidity. The purpose of our study is to investigate whether an increased working length translates into improved healing.

Description of method

We undertook a retrospective review of 64 suitable cases performed at our institution from April 2007 to February 2012. Case notes and X-rays were reviewed. Working length, plate to fracture zone ratios and working length to fractures zone ratios were calculated. Union was assessed radiographically. Multiple regression analysis was utilized with time to union as the dependent variable. The independent variables smoking, age, fracture severity and soft tissue injury as well as working length were included.

Summary of results

Mean time to union was 18.03 weeks (± 6.19). 14 delayed unions (21.8%), 3 nonunions (4.7%) and 1 implant failure were recorded. Multiple regression analysis identified an open fracture as the only significant risk factor $P=0.002$. Smoking showed a strong trend $P=0.07$ but working length did not show any significant influence over union ($P=0.341$) in this series.

Conclusion

Biomechanical studies have demonstrated increased flexibility of longer plates with an increased working length. In this study however, working length did not show any

correlation to union. In contrast, the risk factors known to prolong healing were the only significant independent variables that correlated with union times.

LITERATURE REVIEW

Objectives of the literature review

The objectives of this literature review are to gain an insight into the challenges present during the management of distal femur fractures. Visiting the earliest literature on the subject will allow me to track the evolution of management and the progression of surgical implant design that resulted in improved outcomes. The review will provide insight into the current management, potential complications and finally identify the most recent research pertaining to working length and its relationship to distal femur fracture healing.

Literature search strategy

Internet based search engines using numerous electronic databases, including Pubmed and Google Scholar were used to scan the English literature. The scope of the search included the English medical literature extending back to 1940. Article bibliographies were manually reviewed to identify relevant articles. Relevant veterinary studies were manually identified. Follow up searches of authors' names were performed to identify special interest threads. In two instances authors were contacted via email for direct commentary on their articles.

All articles were obtained in full and downloaded via the UCT library institutional access. Print articles were scanned and stored electronically.

Evolution of distal femur fracture management

Distal femur fractures are recognized as being difficult injuries to manage successfully. The short distal segment often with fracture extension into the knee joint, poor bone quality and large potential deforming forces from muscle action and weight bearing pose mechanical and surgical challenges.

The earliest reports on treatment noted varying results with conservative management consisting of traction followed by cast bracing or spica application.¹ Local complications of mal union, knee stiffness, and nonunion together with the systemic complications of prolonged bed rest led surgeons to explore operative means of treatment. Initial attempts at surgical management showed inferior results compared to conservative techniques. In 1967 Neer et al reviewed 110 fractures treated with either internal fixation by various means or conservatively and noted only 52% satisfactory results compared with 84% respectively.² They concluded that no category of distal femur fracture appeared amenable to internal fixation. Stewart et al arrived at a similar conclusion after comparing surgical and conservative methods of treatment³. Closer inspection of these studies however revealed significant bias. The more severe grades of fractures were treated surgically while minimally displaced fractures were managed conservatively. Further, it appeared that numerous different surgical techniques were employed from Blount angled blade plates to various pin or screw constructs. The X-rays presented in those studies show that most of the constructs were inferior biomechanically and demonstrated poor surgical technique.

The early challenges identified during open procedures included achieving rigid fixation, especially in the short distal metaphyseal fragment, dealing with intra articular involvement and multi fragmentary stabilization. During the 1960's and 1970's improvements in fixation devices and surgical technique began to swing the pendulum back in favour of open techniques. Schatzker et al in 1974 and Schatzker and Lambert in 1979 published results demonstrating the superiority of the AO principles of open reduction and internal fixation over both conservative treatment and other forms of internal fixation.^{4,5} It was also noted that age and bone quality has a significant effect on outcome. Healey and Brooker reported 81% vs 35% good functional outcome in favour of surgical management.⁶ Complications were 3 times higher and hospital stays were also significantly longer in the non surgical groups.⁶

Specific implants were designed in order to address some of these challenges. The arrival of the 95° angular blade plate (ABP) provided rigid fixation but was unforgiving with regards to mal alignment. Incorrect alignment of the seating chisel in the condyles was not correctable and no adjustment was possible after plate insertion.^{5,7} Another weakness was its difficulty in dealing with an intercondylar split as it required an intact condylar block for rigid fixation. The recommendation was to restore the block with an interfragmentary screw prior to blade insertion. With sound surgical technique good results were achievable however and the 95° angular blade plate remains in use today.

The dynamic condylar screw (DCS) introduced in 1980 was a more forgiving fixed angle device than the ABP. It still required intact or provisionally reduced condyles for insertion but was able to provide some compression via the lag screw. Its main weakness was instability in the sagittal plane as rotation could occur around the lag screw with knee motion resulting in loosening.⁶

In an attempt to deal with multi fragmentary fracture patterns, the condylar buttress plate (CBP) was developed. It was contoured to match the distal femur and could accept multiple lag screws through its flared distal end in order to compress comminuted condylar fragments. In order to achieve this versatility the CBP sacrificed stability. Its main weakness was that it was not a fixed angle device like the ABP or DCS and varus collapse was a problem.⁸ To overcome this problem Saunders et al proposed dual plating of both the medial and lateral sides to provide additional stability in comminuted fracture patterns.⁹ This required extensive exposure and periosteal stripping in a region of already compromised vascularity.

The advantages of intramedullary (IM) nailing techniques were recognized early on in the management of distal femur fractures. Insertion was through a limited incision without having to expose the fracture site. This avoided further disruption of the soft tissue envelope, affecting healing and potentially reduced the risk of sepsis. The earliest attempts at closed surgical management involved the use of Rush rods, Enders or Zickel nails. All these nails were too flexible to provide adequate stability and were not able to deal with comminution. Additional bracing or casting was required thus negating the advantages of surgical fixation. Many nails were also supplemented with

other forms of internal fixation. Although nonunion was low (0-2%), malunion and knee stiffness were a problem.¹⁰

As IM nailing of femur fractures became established, the technique was extended to include distal metaphyseal and even intercondylar fractures. The introduction of the interlocking nail by Grosse Kempf was a major step forward in controlling stability of the distal fragment especially in the rotational plane.¹¹ Initially only anterograde nailing was performed. Technical problems encountered were the distance of the locking screws from the end of the nail preventing secure fixation of very distal fractures. Yeung et al reported good results by modifying the nails, cutting off the distal 15mm, allowing very distal purchase.¹² The modern technique of retrograde nailing was first introduced in 1988 by Green with the introduction of the Green-Seligson-Henry (GSH) supracondylar intramedullary nail. Limb length equality, axial alignment and mechanical axis restoration were challenges reported.¹³ Union rates were very good however. Short nails, which terminated in the diaphysis, were thought to be adequate but stress risers with fracture at the proximal tip have led to the abandonment of short retrograde nail constructs. Salem et al reported in a 2006 series of 47 patients that there were no differences between anterograde and retrograde outcomes with regard to alignment.¹⁴ The use of blocking or Poller screws in the distal fragment aids alignment and increases construct stiffness.¹⁵ The weakness of intramedullary nailing is again dealing with comminution of the metaphysis and or intercondylar region. Intercondylar splits require prior fixation with lag screws, which can obstruct nail passage. The most recent retrograde nail designs have increased the number of interlocking screw options in order to provide maximum stability in a variety of fracture configurations.

By the mid 1990's surgical management of distal femur fractures was well established and consistently provided superior outcomes to conservative treatment. There were however certain fracture patterns that still presented significant challenges. Highly comminuted fractures with intra articular involvement frequently produced worse results. Delayed union and nonunion was highest in this group as was loss of reduction. Elderly patients with osteoporotic bone fared the worst of all.^{16,17} With the increasing popularity of total knee replacements (TKR) especially in older patients periprosthetic fractures became more common. A very short, osteoporotic distal fragment containing the femoral prosthesis provides very limited room for fixation.¹⁸

Some implants depending on design can accommodate a retrograde nail but many such as the posterior cruciate substituting designs may not allow the passage of a nail due to the presence of the central cam.¹⁹ These fractures require internal fixation by other means such as a distal femur locking plate.

Epidemiology and classification of distal femur fractures

The definition of what constitutes a distal femur fracture varies in the literature. Variations arise due to the differing distances from the knee joint described. Qualitatively the fracture must involve the supracondylar region of the femur or “box”. The height of the box equals the width of the condyles. Fracture lines may extend proximally into the diaphysis or distally to involve the articular surface.

The largest epidemiological study was undertaken by the AO Foundation published in 2000. Distal femur fractures were noted to follow a bimodal pattern with one group of high energy fractures mostly from road traffic accidents occurring in young males and a second group of older patients, mostly female with osteoporotic fractures from low energy falls.²⁰

The classification most widely used and the one used in this study is the AO trauma classification. Seinsheimer proposed a similar classification in which he attempted to demonstrate the differing patterns associated with various epidemiological and prognostic groups.²¹ His classification is not widely employed in the literature.

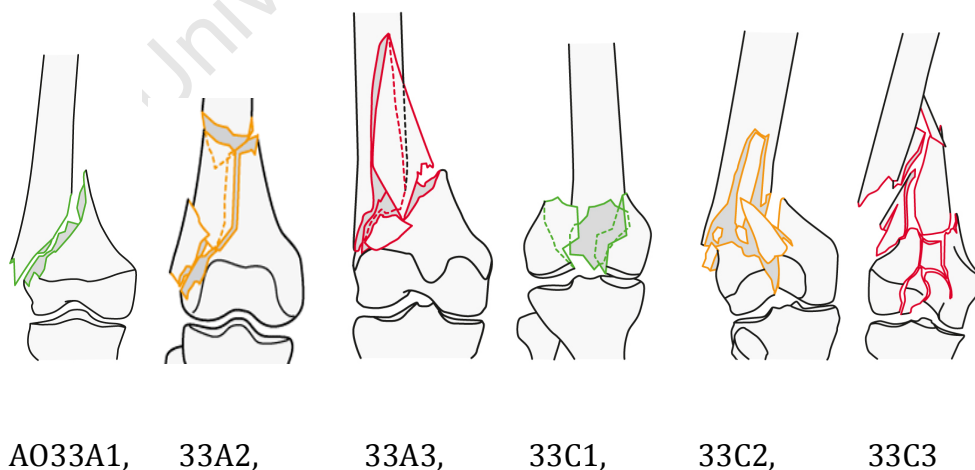


Fig 1. AO Classification-groups



Fig. 2 The “box “ defining the supracondylar region

Principles of fracture healing as they relate to surgical fixation of distal femur fractures

The physiological process of fracture healing requires some motion at the fracture site to allow mechanical induction of external callus formation. It also requires an adequate local blood supply to optimize the metabolic processes of bone formation. This is considered secondary or indirect healing and is how fractures heal with conservative management and with intramedullary nailing. In the 1960's the principles of open reduction and internal fixation were formalized. Rigid, anatomical surgical stabilization of fractures was considered essential for early joint motion to prevent stiffness and muscle wasting. Anatomical reduction of fracture fragments especially intra articular involvement was desired in order to minimize the late development of arthrosis. To achieve this, large dissections were performed. Interfragmentary compression was achieved via lag screws and neutralization plates were fixed with screws as close to the fracture as possible to maximize rigidity.²² This construct results in direct or primary bone healing. Due to the compression and absolute rigidity no micromotion is present for the mechanical induction of callus formation. The healing process skips the intermediate steps of tissue differentiation and resorption. The cutting cones and osteons cross the fracture and proceed directly to the internal remodeling of the Haversian system. The disadvantage of this rigid construct is that if anatomical reduction and compression are not achieved then there is a high risk of

delayed union. This is because of the high strain generated across the fracture gap. The strain theory states that a tissue cannot be produced under conditions that exceed the elongation at rupture.^{23,24} In the case of fracture healing, it refers to the osteoblasts involved in the remodeling process being disrupted.

In the distal femur especially in comminuted fractures it is often not possible or desirable to achieve primary bone healing, as it would require large dissections and further disruption of local blood supply. Technically it may be impossible to anatomically reduce all fracture fragments without completely devitalizing them. The current aims of distal femur fracture management are to bridge the fracture site restoring overall alignment while minimizing soft tissue disruption. This is achieved with an IM nail if the fracture pattern allows or with a distal femur locking plate.

Distal femur locking plate design and surgical technique.

In the late 1990's the plate and screw construct, now known as a locking plate, was developed that attempted to address the limitations of standard compression plating. Toggling between the screw and plate resulted in screw loosening and loss of fixation.²⁴ Other limitations were disruption of fracture zone blood supply and weak fixation in osteoporotic and metaphyseal bone. Locking plates or angular stable plates have a threaded screw plate interface providing an angular stable construct in the same manner as the ABP and DCS. They do not rely on compression between the plate and bone for stability.²⁵ This in turn allows preservation of the periosteal blood supply. Purchase in osteoporotic bone is superior to standard compression plating constructs as the plate and screws function as a single unit to resist pullout. They have been referred to as "internal external fixators" upon which their biomechanical principles are based.

The classic indications for locking plate use are with fractures that are periarticular and or involve osteoporotic bone.²⁶ In fractures of the distal femur these advantages of locking plates became immediately attractive. They offer superior distal fragment fixation via multiple angular stable screws arranged in a periarticular cluster. Intra articular fracture extension can be separately fixed or held through the plate as required. This is their biggest advantage over the retrograde intra medullary nail,

which is the other surgical modality currently in use for distal femur fracture management.

Recognition of the importance of blood supply in fracture healing led to the emergence of minimally invasive techniques known as minimally invasive percutaneous plate osteosynthesis (MIPPO).^{27,28} These procedures incorporate the concept of 'biological osteosynthesis' whereby the fracture zone is bridged, minimizing disruption to the fracture zone. The surgical incision is not made directly over the fracture but in the periarticular region proximally or distally. It is important not to confuse minimally invasive techniques with locking plate surgical technique. A locking plate can be applied using an open technique and an example of this is in distal radius fractures where anatomical reduction is desirable. Minimally invasive techniques have been applied to distal femur locking plate constructs to combine the advantages of both concepts to maximize healing potential. The first such system available was the Less Invasive Stabilization System(LISS) plate by Synthes (USA, Paoli, PA) followed by others such as the Perilock plate by Smith and Nephew.^{29,30} These plates are pre contoured to the lateral distal femur and are inserted with the aid of a targeting jig. Intra articular fracture extension is anatomically reduced under direct vision via arthrotomy and held with lag screws. The plate is then inserted in a retrograde fashion along the femoral shaft following a submuscular plane, bridging the fracture zone. The most important step is correct alignment of the plate to the lateral condyle as the precontoured plate is then used as a template to guide fracture reduction via indirect methods. Reduction is not required to be anatomic, the goal being restoration of alignment. Fluoroscopic guidance and percutaneous reduction tools assist with reduction. Finally proximal screws are inserted percutaneously via the targeter.

Early outcomes and complications

Early results of the use of locking plates were favorable.^{29,30,31,32} Nonunion ranged from 0-9%, delayed union 0-7%.^{33,34} Of particular interest was the incidence of varus collapse in the mechanically unstable comminuted fracture patterns. Syed et al reported only 1 patient (4%).³² Biomechanical studies quickly emerged comparing locking plate stability to IM nailing, the ABP and DCS. Results showed that locking

plates are superior in resisting deformity under axial loads and are only slightly weaker than IM nails under torsional loads.^{35,36}

On the back of these favorable early results locking plates became the implant of choice for many surgeons. Amongst the successes there were some clear failures. Kregor in his 2001 study noted 5% implant failure in 103 cases.²⁹ Sommer in 2004 reported on 4 cases with broken plates and Vallier in 2006 presented 6 cases of implant failure.^{37,38} What was not clearly understood were some of the mechanical factors regarding locking plate constructs that optimize fracture healing.

Two patterns of implant failure have emerged from the literature. Early failure, occurring in the first few weeks to months post op, is considered to be related to technical factors such as poor patient compliance with restricted weight bearing or inferior surgical technique. Late failure, occurring after what would be considered the expected time to union is related to the healing process. As with all orthopaedic constructs used to treat fractures, implant integrity is a race against time. If the bone does not unite the implant will eventually fail. The rate at which this occurs depends upon the forces acting on the construct and the construct's ability to withstand the repetitive loading over time.

Biological or secondary bone healing requires micro motion for callus formation. Motion at the fracture site results from reversible deformation of the bridging plate under cyclic load. Biomechanical analysis of locking plates noted that their stiffness is an order of magnitude greater than external fixators and comparable to conventional compression plating under axial load.³⁹ Stiffness of this magnitude is considered to be too great to allow adequate micro motion required for callus generation (0.2-1mm).⁴⁰ There are many factors that regulate the stiffness of the locking plate construct. Plate factors include dimensions of the plate and material used. Stainless steel (SS) and titanium are the materials currently in use. Titanium has a Young's modulus of elasticity of +/-110GPa and stainless steel 200 GPa. In contrast bone ranges from 10 GPa for trabecular bone up to 30 GPa for cortical bone. Clearly both metals are more rigid than bone but titanium is closer to bone in its mechanical properties than stainless steel. Titanium also has a higher yield stress than SS and has superior fatigue resistance.⁴¹ Gaines reviewed this in 2008 and found a significant difference in non union between the titanium 7% and stainless steel 23% (P=0.05) groups.⁴²

Working length

The working length of the plate refers to the unsecured section of the plate that bridges the fracture. The margins are defined by the most distal screw in the proximal fragment and the most proximal screw in the distal fragment. The location of the screws regulates the working length. Stoffel in 2003 in biomechanical testing of the locked compression plate (LCP, Synthes) demonstrated that the omission of one screw on either side of the fracture site almost doubled the flexibility.⁴³ Increased flexibility results in greater motion at the fracture site for the same load. The increased working length also distributes stress over a greater area thus decreasing stress concentrations in the plate and minimizing the chance of fatigue failure with cyclic loading^{43,44}.

A difficult question to answer is what the appropriate working length for a given fracture should be. The introduction of minimally invasive plate osteosynthesis (MIPO) has allowed longer plates to be used without greatly increasing the surgical insult. Gautier in his paper divided the plate into three zones; the proximal zone, the middle fracture zone and the distal zone.. He empirically proposed that the overall plate length or “plate span width “should be three times the fracture zone length for comminuted fractures and 8-10 times in simple transverse fractures.⁴⁴ The 4th zone to consider is the working length. Gautier did not state how long the working length should be in relation to the fracture zone.. The fracture zone and the working length are not necessarily the same. The fracture zone may be short in simple transverse fractures but may also be extensive in severely comminuted fractures. The working length is always equal to or greater than the fracture zone. The only way the working length can be shorter than the fracture zone is if compression screws are placed within the fracture zone which is against biological healing principles.

The recommendations for plate length and technique have mostly been made on models of diaphyseal fractures with proximal and distal zones that are unconstrained in length.⁴³ The distal femur however presents a different scenario. The distal zone is constrained by the knee joint distally and the fracture proximally. The fracture zone is mostly metaphyseal. The proximal zone is unconstrained and can be altered by plate length and screw location. The significance of this is that the working length usually

cannot be extended distally past the edge of the fracture zone and any manipulation of working length must occur by omitting screws proximal to the fracture zone.

The second recommendation that Gautier made concerned the number of screws used for fixation. The “screw density ratio” (SDR) is calculated by dividing the total number of screw holes available in the plate by the number of screws used.

He proposed that SDR be used as a proxy for working length. Again he empirically recommended ratios of between 0.4-0.5. While this SDR provides a guideline for overall screw use it is less useful in guiding screw placement. Mechanical characteristics of the construct can be significantly altered by varying screw location while maintaining the same screw density ratio. Where the screws are placed is more important than how many are used. In distal femur fractures especially those involving the joint the priority is to obtain anatomic reduction of any intra articular extension and adequate distal purchase to prevent varus collapse. As many screws as are required to achieve this are used.

Returning to the working length the two most important factors to consider are how long the working length relative to the fracture zone should be and how long should the proximal zone be. The single most important screw is the first screw proximal to the fracture zone. This screw determines the working length. Placing the screw just proximal to the fracture zone will result in a short working length. In comminuted fractures the fracture zone may be large and placing the first screw close to the proximal margin of the fracture zone ie making the working length equal to the fracture zone may provide sufficient flexibility.

In the clinical setting there are two different construct scenarios. The first is a simple transverse or short oblique fracture with a small fracture zone bridged by the plate. Making the working length equal to the short fracture zone will result in a very stiff construct^{39,43,44} This may result in implant failure due to high stress concentrations or poor healing due to lack of fracture site micro motion. Here it is proposed that making the working length longer than the fracture zone (large working length to fracture zone ratio) minimizes these complications.

The second clinical scenario is a comminuted fracture with a large fracture zone. In such circumstances smaller working length to fracture zone ratios may be more

appropriate. Employing the same ratios that are used in the first scenario may not be necessary or physically possible due to femur or plate length. The possibility of making a construct too flexible and therefore unstable has not to date been reviewed in the literature. Stoffel noted that in large fracture gaps there was no further reduction in plate stress beyond a working length of four holes.⁴³

The proximal zone length is governed by the location of the first screw that divides the working length zone and the proximal zone for any given plate length. The strength of fixation in the diaphyseal bone is determined by bone quality, type of screw (locked or unlocked), number of screws and length of the proximal zone. The cantilever effect of lengthening the proximal zone reduces the pullout load on the most proximal screw thus reducing the risk of proximal zone failure.⁴⁴ Again it becomes more important where you place the screws rather than how many are used. A proximal zone length of 6 holes with 3 screws filling alternate holes has superior pullout resistance to a 3 hole length filled with 3 screws. In healthy cortical bone there is no clinically significant difference in pullout resistance between locked and unlocked screws but using unlocked screws may make the construct stiffer⁴⁵. There is no added mechanical advantage beyond four screws.⁴²

Is there a problem with fracture healing?

A comprehensive review of distal femur locking plates and potential problems with healing was performed by Henderson recently.⁵² The systematic review noted an incidence of problem healing was as high as 32%. Nonunion rates were from 0% to 19%. Henderson included delayed union, nonunion and implant failure under the collective term of problem healing.

There are many biomechanical studies and review papers discussing locking plate use but there are very few clinical distal femur studies comparing working length and healing outcomes. In an abstract of the OTA annual meeting 2009, Ricci presented the findings of a large multi center study of 305 patients looking at risk factors for complications including nonunion and implant failure. The only independent risk factor for nonunion was diabetes. Technical risk factors for implant failure were analyzed and on those findings he proposed recommendations for plate length, screw

density ratio.⁴⁶ He recommended a combined fracture zone and proximal zone length of no fewer than 10 holes with 5 or more proximal screws and a screw density ratio of less than 60%. To date the findings have not been published in a peer reviewed journal.

Lugan in 2010 performed volumetric callus mapping as a means of measuring healing in locking plate fixation of distal femur fractures⁴⁷. Periosteal callus formation is a marker of secondary bone healing. He noted that lateral locked plates produce asymmetrical and inconsistent callus formation. He also compared the effect of working length and plate material on callus formation. There was a very weak correlation between medial callus at 6 weeks and working length. Follow up at 12 and 24 weeks showed no correlation. Further he noted that 40% of the cases produced very little ($< 20\text{mm}^2$) callus even at 6 months. Titanium produced significantly more callus than stainless steel constructs.

Bottlang also in a 2010 review of 70 patients noted a 19% non union rate and no significant difference in working length between the non union and union groups.³⁹

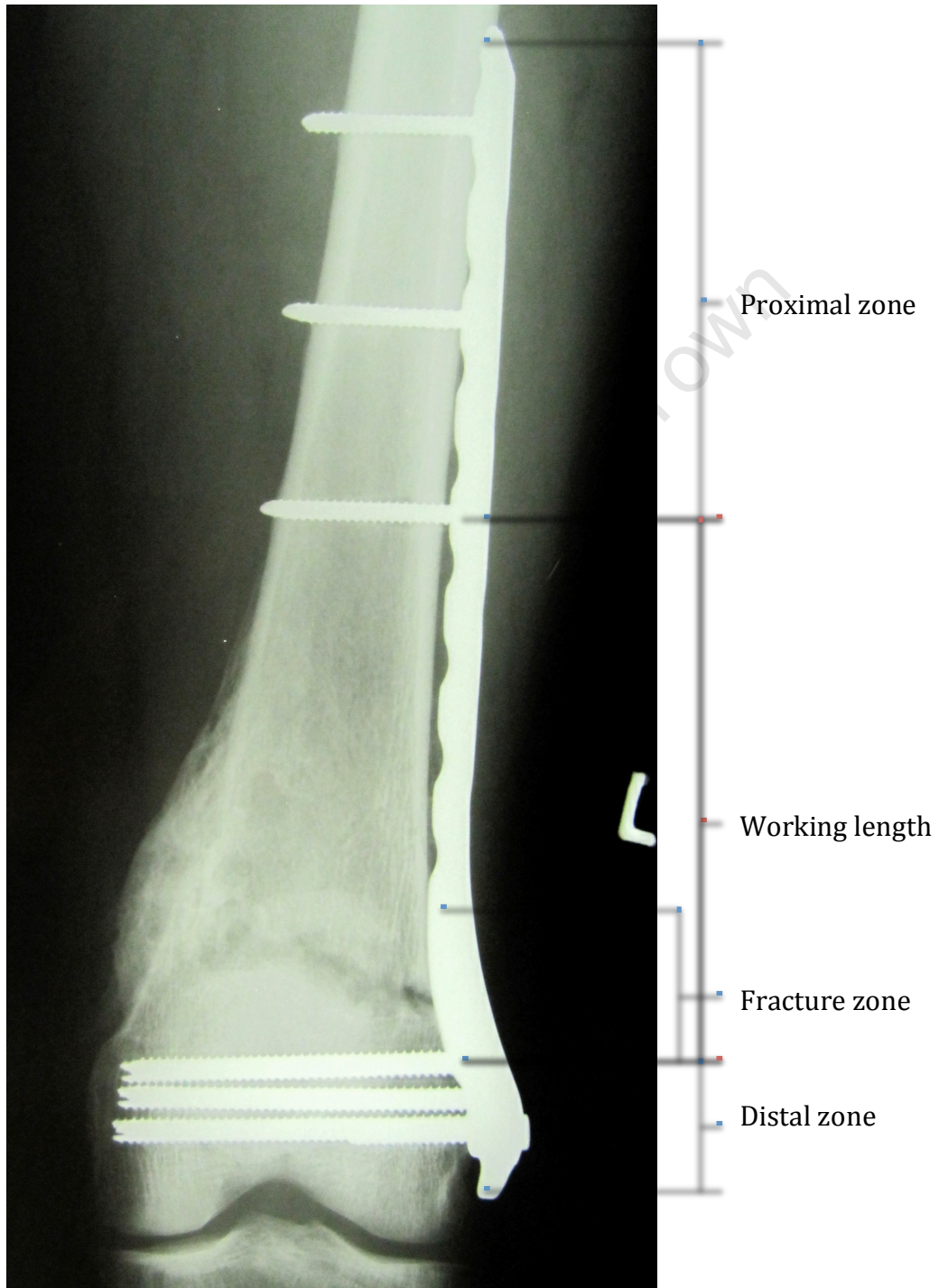
These last 3 studies represent the current clinical evidence for working length and its affect on healing. The findings are conflicting and no significant conclusion can be drawn from these studies. Of caution is the observation that the studies of Lugan and Bottlang appear to be very similar in materials and method and they are both co-authors of each others papers. Possibly there is some overlap of the data samples.

Summary

The literature shows that distal femur fracture management has progressed a long way from the early days of conservative management. It also shows however that these fractures remain challenging in spite of the recent advances in orthopaedic techniques and implants. The recent literature has identified concerns about prolonged healing and its proposed relationship to plate working length. The theory that increasing the working length will improve the healing rate has not been widely tested in the literature to date and this represents an area of active research. Other interventions that potentially improve healing besides working length represent areas of future research potential.

The aim of this study is to identify whether there is a relationship between working length and fracture healing. The null hypothesis to be tested is that greater working lengths are not able to improve distal femur fracture healing.

Fig 3. Anatomy of a distal femur locking plate construct



LOCKING PLATES FOR DISTAL FEMUR FRACTURES: DOES AN INCREASED WORKING LENGTH IMPROVE HEALING?

Materials and methods

A retrospective review of 126 consecutive distal femur fractures treated by locking plate between April 2007 and February 2012 were identified for inclusion in the study. The indication for locking plate fixation is a distal femur fracture not amenable to IM nail fixation specifically those fractures that are too comminuted or are too distal to obtain adequate stability. Cases were identified through the theatre case records, and cross referenced with company implant invoice data bases to ensure a complete series.

Inclusion criteria:

All skeletally mature patients with distal femur fractures who underwent locking plate fixation at our institution between April 2007 and February 2012.

Exclusion criteria:

- Partial articular fractures, AO 33 type B: these plates have been used in a buttress or anti glide fashion and there is no working length to consider.
- Pathological fractures: The healing of pathological bone is unpredictable and is dependent on successful treatment of the underlying condition.
- Incomplete or missing notes or X-rays preventing adequate data acquisition
- Inadequate follow up: minimum 6 months
- Skeletally immature patients

Ethics committee approval was obtained (270/2011), case notes and X-rays were reviewed. Of 126 cases identified, 64 were suitable for analysis. A proforma was drawn up to capture relevant data (see appendix A).

Parameters measured were the following:

Demographic data

- Age
- Gender

Medical history

- Presence of diabetes
- History of smoking

Fracture characteristics

- Mechanism of injury
- Classification (AO)
- Fracture pattern (descriptive)
- Soft tissue injury - open or closed fracture

Details of surgery

- Details of implant
 - Manufacturer
 - Metal type
 - Length (holes and millimeters)
- Details of surgical technique
 - Distal zone: length (mm), holes available, holes filled
 - Fracture zone: length (mm), holes available, holes filled
 - Proximal zone: length (mm), holes available, holes filled

 - Working length: length (mm), holes available, holes filled
 - Zone distal to working length: length (mm), holes available, holes filled
 - Zone proximal to working length : length (mm), holes available, holes filled
- Reduction: alignment in coronal and sagittal plane

Outcome

- Duration of follow up
- Time to radiological union

Complications

- Sepsis
- Loss of alignment
- Delayed union
- Non union
- Implant failure

Parameters recorded were based on factors known to influence bony union such as smoking, severity of injury and diabetes.

In order to account for magnification error when measuring the X-rays the locking plate template provided by the implant manufacturer was used. The length of the plates and the distance between each screw hole was shown on the template in millimeters. Knowing the distances between the screw holes from the template and measuring the fracture lines in screw hole increments on the post op X-ray, the precise length of each zone could be calculated.

Fractures that had intra articular extension fixed with interfragmentary screws to restore the “box” were treated as their extra articular equivalents with regard to fracture zones. Once restored, the distal zone did not contribute to the fracture zone or working length.

The standard follow up care consisted of visits conducted at 2, 6, 12 and then every 6 weeks until union. Complications required deviation from this schedule. In order to assess progression to union and identify complications serial X-rays were assessed from each out patients follow up. Images were reviewed by the author and callus bridging 3 cortices on 2 views was used to confirm union.^{48,49} Nonunion was defined as no evidence of progressive healing for 3 consecutive months after a minimum 6 months. Delayed union was defined as union that occurred after 20 months. Malunion

was defined as malalignment of the anatomical axis of the femur of more than 10 degrees in the coronal plane or 15 degrees in the sagittal plane.

Data analysis

All data was captured on an excel spreadsheet (©Microsoft Corporation). Descriptive analysis was performed on the data using embedded statistical functions within excel. Additional analyses utilized StatPlus: mac LE. 2009 (© 2010 AnalystSoft Inc.)

Bone healing is a complex process with many influencing factors. This is the reason for the choice of multiple regression as the analysis tool. Time to union was used as the dependent variable (DV). The following were considered as independent variables (IV) on the X axis:

- Screw density ratio,
- Working length,
- Working length to fracture zone ratio
- Plate to fracture zone ratio
- Age,
- Diabetes,
- Fracture severity (AO classification)
- Sepsis
- Smoking
- Soft tissue Injury (open or closed fracture)

Results

126 cases were identified for inclusion in the study

- 12 AO type B fractures excluded
- 1 pathological fracture (TB osteitis)
- 20 cases had incomplete data available (inadequate notes/missing X-rays)
- 29 did not meet minimum follow up period of 6 months(6 deaths, 23 lost to follow up)

64 cases remained that were suitable for analysis

Demographic data:

Males	40 (62.5%)
Females	24 (37.5%)
Mean age	44,3yrs range 67 (15,8 – 83yrs)

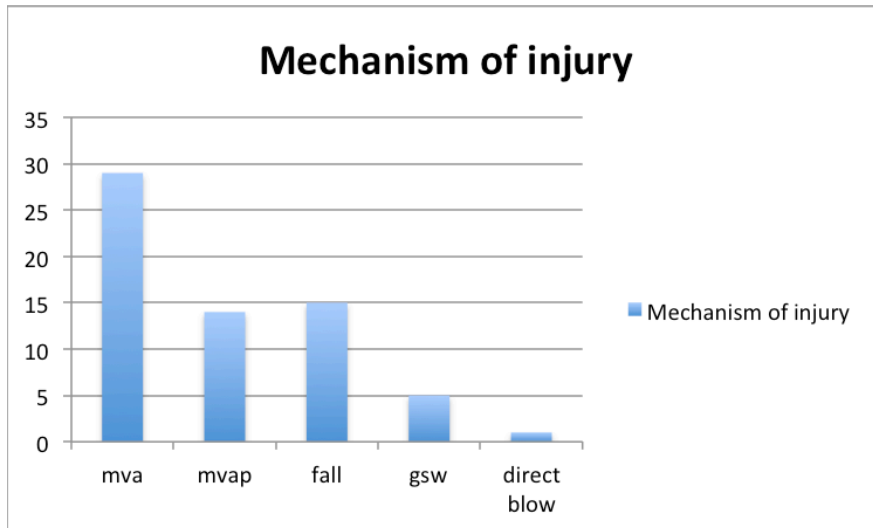
Relevant medical co morbidities:

• Smokers	26	(40.6%)
• Non smokers	26	(40.6%)
• Not recorded	12	(18.8%)
• Diabetics	4	(6.3%)
• Non diabetics	60	(93.7%)

Fracture characteristics:

Mechanism of injury

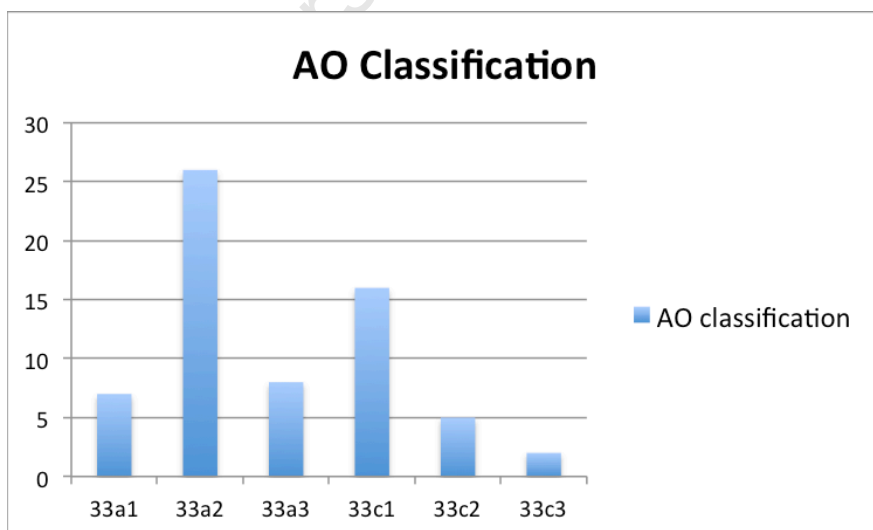
• MVA	29	(45.3%)
• MVAP	14	(21.8%)
• Fall	15	(23.5%)
• GSW	5	(7.8%)
• Direct blow	1	(1.6%)



Graph 1. Case frequency as per mech. of injury

AO classification:

- 33A1 7 (10.9%)
- 33A2 26 (40.6%)
- 33A3 8 (12.5%)
- 33C1 16 (25%)
- 33C2 5 (7.9%)
- 33C3 2 (3.1%)



Graph 2. Case frequency as per AO classification

Fracture pattern descriptive classification:

- Transverse 12 (18.6%)
- Oblique 26 (40.6%)
- Spiral 5 (7.9%)
- Comminuted 21 (32.9%)

Soft tissue injury:

- Closed 59 (92.2%)
- Open 5 (7.8%)

Details of surgery

- Details of plate:
 - Metal type
 - Stainless steel 54 (81.5%)
 - Titanium 10 (18.5%)
 - Mean length 204mm +/- 49.11, 8.7 holes

Table 1. Details of surgical technique: (Mean values)

Zone	Length (mm) +/- std dev	Holes available	Holes filled
distal zone	31.5 +/- 13.26	5.3	4.6
Fracture zone	58.5 +/- 37.42	2.4	0
Proximal zone	116 +/- 33.0	5.8	3.6
Distal to W/L *	31.5 +/- 13.26	5.3	4.6
Working length (W/L)	87.5 +/- 45.87	3.8	0
Proximal to W/L	86.5 +/- 23.47	4.6	3.7

* The distal zone and distal to W/L zone are the same

- Mean screw density ratio (SDR): 0.49

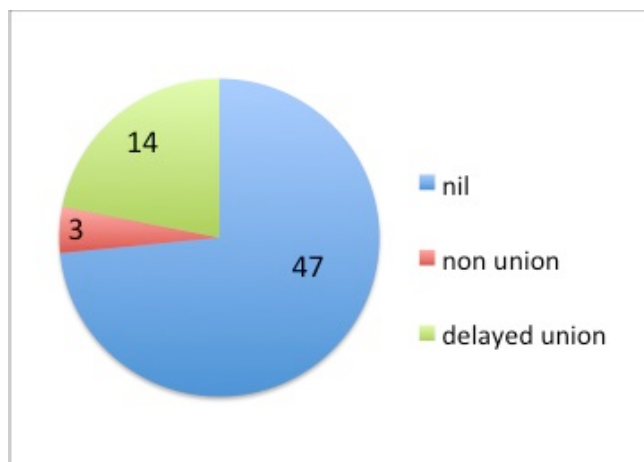
Reduction:

- Restoration of alignment : 1 valgus and 1 varus malreduction

Table 2. Healing Outcomes

	Count	Percentage	Mean (weeks)	Std dev.
Union	47	73.5%	14.77	2.68
Delayed union	14	21.8%	24.46	4.07
Nonunion	3	4.7%	48.9 *	6.89*
Combined union	64	100%	18.05	6.19
Problem healing	17	26.6%	29.5	10.9

* 2 of the non union cases united after revision plating and bone graft. The third patient, a complex case, who also had deep sepsis was offered and accepted an above knee amputation at 53 weeks.



Graph 3. Healing outcomes

Other complications:

- Sepsis: 3 (4.7%)
- Late loss of alignment 0 (see below)
- Implant failure: 1 (20° varus due to bent plate)
- Mean follow up time 30.6 weeks (std dev. 19.6)

Analysis of results

The decision as to which covariates to include in the analysis was based upon literature demonstrating an influence over fracture healing.⁴³ These were prioritized based on whether they were felt to be major or minor prognostic contributors.

Non modifiable prognostic factors

Major contributors:

- Fracture severity
- Smoking
- Soft tissue injury (open/ closed fractures)
- Diabetes
- Sepsis

Minor contributors:

- Age

Modifiable prognostic factors

Potential modifiable factors were considered to be the surgical technique with which the fracture was treated. There is very little literature examining this aspect of management and many recommendations are empirical or extrapolated from other regions.

- Working length
- Plate material (stainless steel vs titanium)
- Plate length to fracture zone ratio
- Working length to fracture zone ratio
- Screw density ratio

Multiple linear regression analysis was used to run various combinations of variables against time to union. The data count of 64 meant that only 5 variables could be used. Scatter plots were used to screen for simple linearity prior to inclusion in the analysis. SDR and working length demonstrated significant multi-collinearity ($r^2=0.69$) and therefore SDR was removed from the analysis (essentially duplication). Sepsis (3, 4.6%) and diabetes (4, 6.25%) were rare events and did not show any linearity in our series therefore they were not included. None of the modifiable factors demonstrated any simple linearity against time to union.

The regression analysis model which produced the best fit to the data is shown below:

Table 3. Outcome of regression analysis

Regression Statistics			<i>p-level</i>	<i>H0 (5%) rejected?</i>
<i>R</i>	0,692	Open fractures	0,002	<i>Yes</i>
<i>R Square</i>	0,479	smokers	0,072	<i>No</i>
		Age at injury	0,118	<i>No</i>
		# severity (AO)	0,241	<i>No</i>
		WL mm	0,346	<i>No</i>

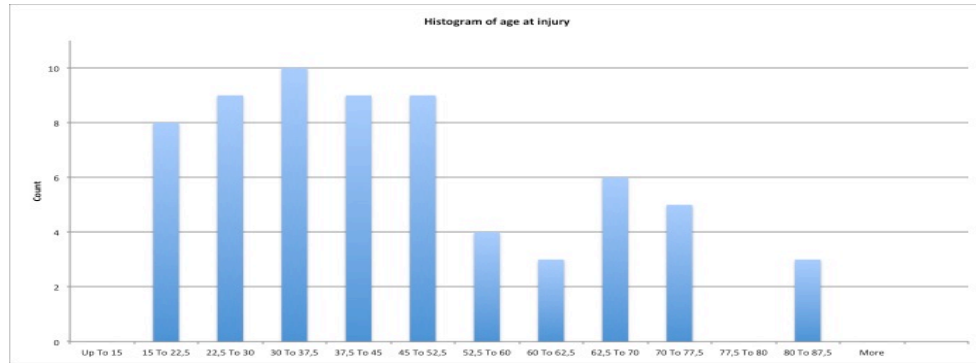
Discussion

Locking plates for distal femur fractures have provided solutions to challenging presentations but some uncertainties remain about optimal surgical technique required to maximize healing potential.

Descriptive data

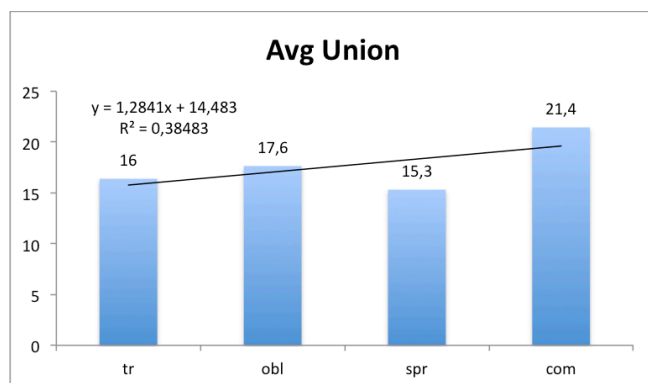
One of the weaknesses of a retrospective study is the lack of control over data collection. This study had a 50% case exclusion percentage which immediately raises questions over the representivity of the data sample. Loss of files, X-rays and patients to follow up remains a major challenge for researchers in our local environment.

The histogram of age at time of injury is consistent with the bimodal distribution pattern reported in the literature.

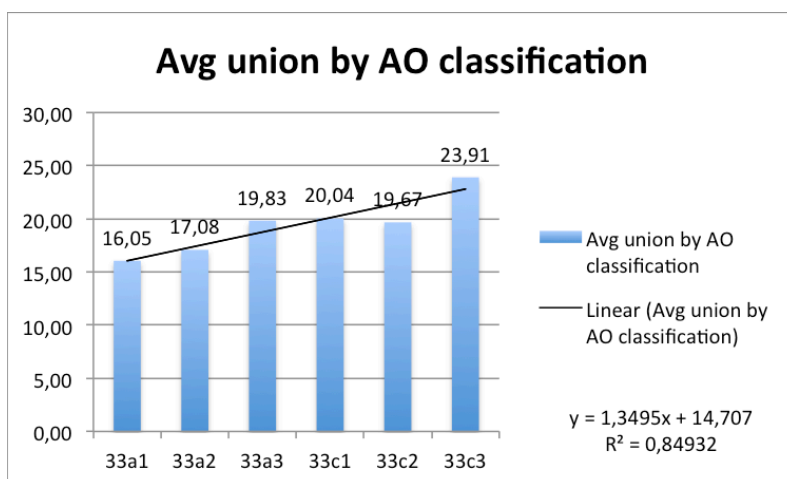


Graph 4. Histogram of age at time of injury

Fracture severity is considered to be a major contributor to delayed union. The mean union times of the descriptive fracture patterns supports this. The AO classification system in general has a progression of fracture severity through the classification system. Again this is supported by the mean union times of the data set. On the basis of this simple linear correlation, the AO classification was used as a surrogate for fracture severity in the regression analysis but It was not significant however ($p=0.241$). Ricci found The 33A3 pattern to be a significant independent risk factor for implant failure. The only implant failure in this study was also in a 33a3 pattern when the plate bent in the fracture zone (working length 110mm). The femur still went on to unite. It was recorded that the particular patient was not compliant with restricted weight bearing, a recommendation that Button made in 2004 to reduce implant failure.⁵⁰



Graph 5. Mean union time by fracture pattern



Graph 6. Mean union by AO classification

Among the covariates that were recorded, the deep sepsis rate of 4.7 % is consistent with the 5% recorded by Ricci et al in the largest series to date . In his series however he had a diabetic incidence of 19% against this study's 6.8%

Considering the percentage of high energy mechanisms (66%) there was a low number of open fractures (5, 7.8%). The gunshot wounds were treated as closed fractures as there were no high velocity injuries. In the regression analysis however open fractures were the only variable found to be a significant independent risk factor for delayed healing (P=. 0.002)

Smoking is well recognized to delay bony healing and in this study it was second only to open fractures in its influence over union times and approached significance (p=0.07). There were quite a few cases where smoking status was not recorded (12, 18.75%) and this may have influenced the outcome. Statistically though the fact that the recorded incidence was 50% (26 smokers) it reduced the impact of the missing data.

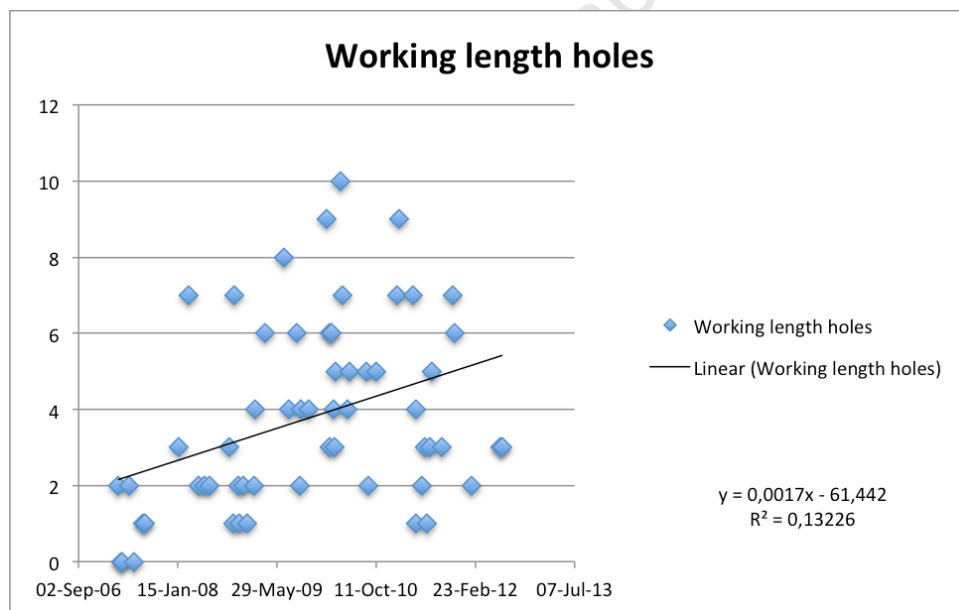
There was only 1 periprosthetic knee fracture in the data set unlike many other studies where the these fractures are much more common. These fractures are particularly challenging and higher rates of healing difficulty are encountered.

Surgical technique

The lack of guidelines governing surgical technique meant that there was a wide variation in length of plate used and screw configurations. General recommendations

have been made for the use of longer plates and longer working lengths in response to the healing complications experienced. The mean working length in this study was 3.8 holes (87mm). The literature has not reported clearly on mean working lengths used but the case series' discussing implant failure have shown images of very short working lengths either 0 or 1 hole. This study did not have reveal any implant breakages suggesting that the working lengths were long enough to reduce cyclic loading stresses or the plates were strong enough to withstand them until union.

The scatter plot of date of injury vs working length has shown a mild but significant linear correlation $r = 0.337$ $r^2 = 0.13$ ($p = 0.007$) suggesting that as the surgeons at our institution became more familiar with these relatively new implants they were modifying their surgical technique. As the analysis has shown however this has not translated into any difference in union times in this study. This is in agreement with Bottlang's findings in 2010 where he used volumetric callus mapping as a surrogate for healing measured against bridging span (working length) $r = 0.04$ $P = 0.4$.³⁹



Graph 7. Scattergram of working length vs date of surgery

Working length as an absolute value measured against union has not demonstrated any significant correlation. Working length is not independent of the nature and magnitude of the fracture zone. A large fracture zone will always result in a large working length. The nature of the fracture zone may also differ even though it has the same length. A severely comminuted fracture zone will have no load sharing ability under all

conditions of plate flexion until sufficient callus forms. A long spiral fracture bridged with the same working length may allow some load sharing if the plate flexes sufficiently and the fracture edges appose each other. The relevance of this is that there will be differing plate stresses for the same working length. In the comminuted fracture the stress will continue increasing whereas it will decrease upon fracture gap closure in the spiral fracture⁴⁰.

Screw density ratio has been proposed as a surrogate for working length and an empirical value of 0.4-0.5 reported by Gautier as desirable. Our SDR average of 0.49 appears consistent with recommendations. The linear correlation coefficient $r = -0.83$ with $r^2 = 0.69$ obtained from the data set confirms this strong correlation. When measured against union it consequently does not show any significant independent relationship ($r^2 = 0.0068$)

Titanium vs stainless steel

Bottlang did however note that the titanium plates produced a significantly increased volume of callus (68%) over the stainless steel plates.³⁹ In this study only 10 titanium plates were used and most of them within the last year because of consignment requirements. There was no difference in healing. This is an area for future research as the majority of distal femur plates now being inserted at our institution are titanium and a study with greater numbers may be able to demonstrate significant differences.

Mean healing time

In our study the mean healing time of 18.05 weeks appears to be longer than most other studies. We postulate that it may have been affected by our sampling frequency. Our standard follow up was at 2, 6, 12, 18 weeks with X-rays obtained at each visit. If at 12 weeks the fracture did not meet the criteria for union then the next assessment that could report union would have been around 18 weeks and possibly with more frequent X-rays the time to union would have been reduced. This is a clear limitation of our study. Other factors that may have affected the assessment are the metaphyseal location of the fractures and the presence of the lateral plate obscuring a cortex. Due to the way that metaphyseal fractures heal with creeping substitution of trabeculae in direct contact and intramembraneous ossification, little external callus is produced. This makes radiological assessment of metaphyseal union more difficult than

diaphyseal fractures as noted by McClelland et al in 2006.⁵¹ Other factors influencing this study may be the high percentage of smokers (50%) compared to other quoted figures such as 25% in Ricci's study.

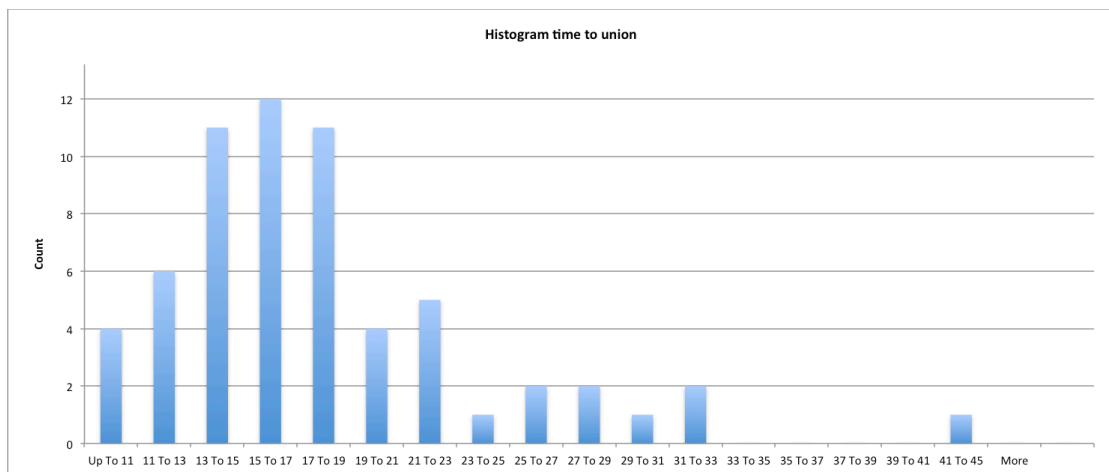
Further breakdown of the healing times shows that the mean healing time of the fractures with uneventful union of 14.3 weeks was as expected. Interestingly there was not one recorded intervention of bone grafting amongst the delayed union (14 patients, 24.5 weeks) group and perhaps more aggressive intervention of those with risk factors for delayed union may have reduced this group. Henderson in his review notes that bone grafting itself presents difficulties when attempting to analysis healing rates. Planned early bone grafting would prevent delayed union which may have otherwise occurred. Ricci excluded these cases from his analysis because they were such confounders.

Problem Healing

Our results of "problem healing" (26%) are in agreement with those noted in the largest review on the subject published to date by Henderson et al.⁵² One of the biggest factors affecting the results of any published outcome study on fracture healing are the definitions and criteria used to describe union, delayed union and nonunion. Fracture union is a gradual process and identifying the tipping point of when a fracture is considered to be united is to an extent a factor of the sampling frequency. It is not practical nor ethical to X-ray a fracture frequently enough to precisely identify the time of healing. Conversely assessing the patient every 8 weeks will result in a less accurate assessment of time to union. Most orthopaedic surgeons agree that the combination of clinical and radiological features provides the most accurate assessment of union.⁵³ This was unfortunately not possible in our study. Initially it was planned to asses both clinical and radiological parameters of union but early on it became apparent that the notes lacked sufficient detail in most cases to allow for any analysis of clinical union therefore the study was based on radiological assessments of union only.

The concept of delayed union is even harder to define as the literature shows⁵⁴. Qualitatively it is described as a fracture that takes longer to unite than would normally be expected but that there are signs of progressive healing as apposed to a

non union where there are no signs of progression towards healing for 3 consecutive months after a minimum period, usually 6 months. Quantitatively 12 weeks has been most widely used for the lower limb based on work done with regards to stiffness of healing fractures over time. Henderson in his review regarded union longer than 12 weeks as delayed union but does not record what the various studies used as their criteria. Reviewing multiple papers discussing delayed and non union shows that there is a wide range of opinion from 4 to 24 weeks with a median of 12 weeks.^{48,55} This includes the upper and lower extremity. In this study it was decided to use a cut off of 20 weeks for delayed union. This was decided upon because of the post op follow up sequence. It was expected that most fractures would have united without complication between the 12 and 18 week visits. The 18 week follow up was often not precisely 18 weeks and therefore by selecting 20 weeks we would allow for those without them being classified as a delayed union.



Graph 8. Histogram of union times

Loss of alignment and malunion.

As noted above this study only had 1 case of malunion (20° varus) secondary to a bent plate. Strictly this is an implant failure, as the patient required an osteotomy, even though the patient went on to unite uneventfully. Of particular relevance, there were no cases of varus collapse due to poor control of the distal fragment. This is one of the major advantages of locking plates and it has been demonstrated here again.

Strengths and weaknesses

This study represents one of the larger studies performed on distal femur fracture management. It provides an in depth analysis of the various components that make up specifically a distal femur locking plate construct and considers not just absolute working length but its relationship to the fracture zone.

It is a retrospective review and suffers from a 50% case exclusion percentage. This potentially introduces bias and also weakens the power of the study. The inability to combine a clinical assessment of union with the radiological assessment as planned weakens the assessment. Blinding and multiple reviewers would have improved the accuracy of assessment. The inherent discrepancies surrounding the definitions of union, delayed and nonunion are not unique to this study. The frequency of follow up dictated the frequency of X-ray assessment and a prospective study would aim to improve on this study's 6 week cycle. There are obvious cost and ethical implications of large scale weekly X-rays of patients and while ideal from a research perspective may not be achievable in our local environment.

Conclusion

Fractures of the distal femur can be challenging to manage successfully. The addition of the distal femur locking plate to the surgeon's armory has provided an implant that offers superior control of the distal fragment, the one component of these fractures that is the most challenging to stabilize. The concerns in the literature about the incidence of healing difficulties have been supported by the findings in this study. The ability of an increased working length to independently reduce the union time has not been shown. What has been confirmed is that the risk factors known to prolong bone healing such as open fractures were significant contributors to the healing difficulties seen in this study. When present, these should be optimized and if healing difficulties are anticipated early intervention should be planned. The limitations of this study have highlighted the need for future large prospective studies that are adequately powered utilizing validated and standardized measures of bone healing. Interventions other than increasing working length that maximize healing potential should be explored as it appears that working length may be limited in its ability to significantly improve healing.

Distal femur locked plate study

case no. _____

□

Pt sticker or details:

Rel. med. Hx:

Diabetic smoker

□

Fracture characteristics

AO classification: _____ Date of injury: _____

Side : right left Open closed

Mechanism: fall MVA GSW direct blow

Pattern: transverse oblique spiral
comminuted

□

Plate characteristics

Brand: _____ SS titanium

Length: _____ diaphyseal holes, _____ mm

Prox to # zone: _____ holes, _____ holes filled, _____ mm

Fracture zone: _____ holes, _____ holes filled, _____ mm

Distal to fracture zone: _____ holes, _____ holes filled, _____ mm

Prox screws : locking non locking

□

Outcome

Fixation: adequate inadequate: follow up duration _____

If inadequate why:

1. screw density ratio 2. # zone to plate ratio

3. # alignment 4. Plate positioning

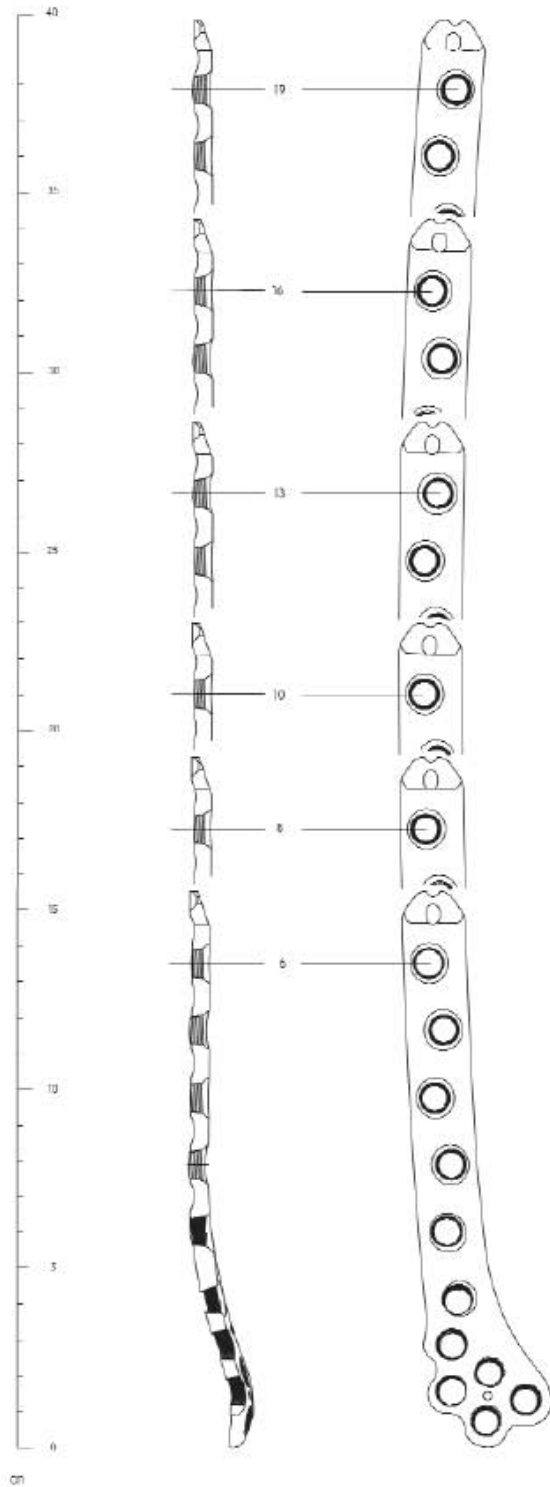
Time to full WB: (include date): _____

Time to radiological union in weeks (include date): _____

Complications: delayed union non union sepsis plate failure

Screw failure loss of alignment

Perilock stainless steel distal femur plate template



PERI-LOC 4.5mm Distal Femur Plating Preoperative Template
Cat No. 7118-0915

Titanium plate templates

Titanium Distal Femur LISS Plates for Left Femur **AO ASIF**

Note: Plates for right femur on other side.

Titanium Distal Femur LISS Plates (this view for left femur)
[AO 236 series]

AP View

422.290 Titanium Screw Hole Insert, 5 mm
 422.302 6.0 mm Titanium Locking Screw, 25 mm
 422.283 6.0 mm Titanium Locking Screw, 40 mm
 422.284 6.0 mm Titanium Locking Screw, 55 mm
 422.285 6.0 mm Titanium Locking Screw, 65 mm
 422.286 6.0 mm Titanium Locking Screw, 75 mm
 422.287 6.0 mm Titanium Locking Screw, 90 mm

Lateral View

422.348 13 holes 316 mm
 422.345 7 holes 236 mm
 422.341 9 holes 195 mm

Illustrations actual size (0% magnification)

For use only with the Original AO ASIF System of Instruments and implants. AO ASIF is a registered trademark of SYNTECH GERMANY and SYNTECH AUSTRALIA. www.aofoundation.org



Femoral Plates, Sterile

Cat. No.	Description		
8141-30-106	6 Hole Right	179.4 mm	
8141-30-109	9 Hole Right	233.5 mm	
8141-30-112	12 Hole Right	287.6 mm	
8141-30-115*	15 Hole Right	341.7 mm	
8141-30-118*	18 Hole Right	395.8 mm	
8141-31-106	6 Hole Left	179.4 mm	
8141-31-109	9 Hole Left	233.5 mm	
8141-31-112	12 Hole Left	287.6 mm	
8141-31-115*	15 Hole Left	341.7 mm	
8141-31-118*	18 Hole Left	395.8 mm	

**POLYAX KNEE FRACTURE SYSTEM
DISTAL FEMORAL LOCKING PLATE**

THIS TEMPLATE IS FOR ESTIMATION PURPOSES ONLY. ACTUAL SIZE SHOULD BE DETERMINED BY THE SURGEON.

13 HOLES 13 HOLES
 6 HOLES 6 HOLES
 9 HOLES 9 HOLES

LENGTH	ORIG. PART NUMBER	AO 236 PART NUMBER	AO 236 PART NUMBER
179mm	8141-30-106	8141-31-106	8141-31-106
233mm	8141-30-109	8141-31-109	8141-31-109
287mm	8141-30-112	8141-31-112	8141-31-112

LEFT SIDEVIEW, RIGHT ON OPPOSITE SIDE.

DePuy

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University of Cape Town