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From the Faculty of Medicine
University of Sydney

Masters of Philosophy

PREDICTORS OF FIXATION FAILURE IN PERI-TROCHANTERIC FRACTURES

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CONTENTS

Abstract

Introduction

Successful treatment of hip fractures during the first operative episode is paramount in minimizing patient morbidity and socio-economic costs. Peri-trochanteric hip fractures are a sub-type of unstable intertrochanteric hip fractures which experience an increased rate of fixation failure. Although current literature suggests that successful surgical treatment of peri-trochanteric fractures is dependent on fracture pattern, quality of fracture reduction, implant choice and implant position, there is no agreement either to the relative importance of each or their inter-relationship. Consequently, the overall aim of this thesis was to assess the predictors of fixation failure and their relationship to each other in the treatment of peri-trochanteric fractures.

Methods

A retrospective review of 796 patients with peri-trochanteric fractures treated at a tertiary referral trauma centre between 2008 and 2012 was undertaken. Analysis of pre-operative, intra-operative and post-operative radiographs was performed using Centricity PACS. Analysis of potential confounding factors included age, gender, fracture classification, reduction quality, Cleveland zone, tip-apex distance, implant type (DHS versus short Gamma nail versus long Gamma nail), and fixation points in Gamma nails, specifically the lateral cortex, greater trochanter, and fit of the nail in the intramedullary canal at its narrowest point.

Results

Unstable fractures had a 7.6 (OR 3.0-19.6) times increased risk of fixation failure ($p < 0.001$), while fractures with a 'poor' grade of reduction had an 11.5 (OR 4.0-33.4) times increased risk of failure ($p < 0.001$). There was a direct relationship between fracture stability and grade of reduction ($P < 0.001$). While A TAD > 20 mm incurred a 2.2 (OR 1.7-2.73) increased risk of failure ($p<0.001$), it was not powerful enough to mitigate against fixation failure in the event of poor fracture reduction ($p<0.004$). Nail fit was noted to be a predictor of fixation failure, with a 10.3 (OR 8.1-28.4) times increased risk of failure if the nail filled < 70% of the intramedullary canal ($p<0.001$). There was no significant difference in choice of implant or increased rate of failure when using a DHS or Gamma nail except in reverse oblique type factures. Fixation points of the lateral cortex and greater trochanter were not associated with successful osteosynthesis.

Discussion

Unstable fracture type, poor fracture reduction, non optimal cephalomedullary screw positioning, and inadequate fit of IM recon nails in the intramedullary canal were predictors of fixation failure. These factors are closely inter-related: unstable fractures may be difficult to reduce which in turn leads to difficulty in achieving correct positioning of implants. A poorly reduced fracture will not be mitigated from fixation failure by correct positing of implants. Treatment of peri-trochanteric fractures should therefore be aimed at obtaining a high quality of fracture reduction prior to ensuring optimal lag screw position and intramedullary nail fit to maximize the success rate of osteosynthesis.

Introduction:

Demographics and Costs

Hip fractures in the elderly are frequent, with an estimated 16,518 hip fractures among Australians in 2006-07. [1] Almost three quarters of these occur in females, with an average age of 83. Due to the ageing of the Australian population the number of hip fractures is expected to increase. Of the 40 Australians who break their hip each day, less than 50% will return to their pre-injury level of functioning. [2] As the ability to undertake activities of daily living independently will be compromised, this may necessitate a move to residential aged care, leading to not only potentially reduced quality of life but also a considerable burden on the Australian health care system. No Australian data on the overall costs of hip fractures is currently available, however the estimated overall costs to society in the UK in 2000 was £726 million, with 67% in residential and social services, and 33 % in direct hospital costs. [3] Failed operative treatment is estimated to cost £ 10,000 per patient. [3] Thus successful treatment of hip fractures during the first operative episode is crucial in returning patients back to maximal function and decreasing socio-economic costs.

Aetiology

Most hip fractures in the elderly result from simple falls from standing. [4] Diminished bone strength because of osteopenia allows fractures to occur with smaller amount of energy. [4] Because of slowed reaction time, lack of shock absorbers such as fat or muscle that can dissipate the energy applied to the hip, and the fact that elderly people tend to fall to their side rather than forward because of diminished ambulatory speed, local force applied to the greater trochanter from a fall from standing height results in a fracture. [5]

Intertrochanteric Hip Fractures

Intertrochanteric hip fractures are extracapsular fractures of the proximal femur involving the area between the greater and lesser trochanters, see figure 1. The intertrochanteric region has an abundant blood supply which makes these fractures less

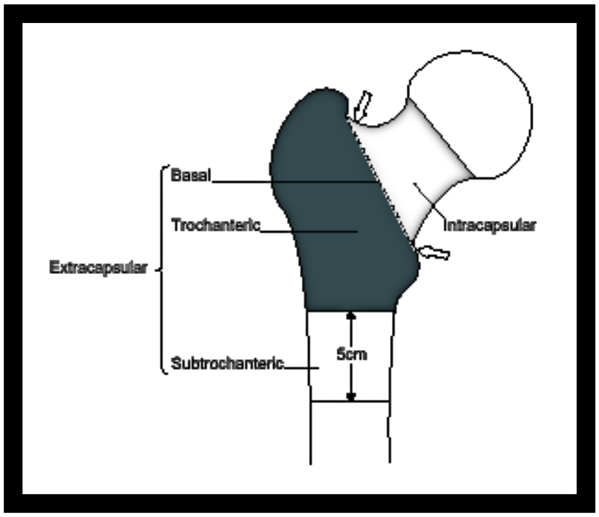

Figure 1: Diagram of extracapsular hip fracture

susceptible to nonunion and osteonecrosis than femoral neck fractures and more amenable to internal fixation. They account for approximately half of all hip fractures in the elderly. [6] 50-60% of these fractures extend distal to the lesser trochanter are described as having a subtrochanteric component and are termed unstable or "peri-trochanteric" fractures. [7]

Fracture Classification

A common classification system used in research is the alpha-numeric classification developed by the AO group. [8] The proximal femur represents bone region 31, intertrochanteric fractures are group A, and those that qualify as unstable are A2.2, A2.3 and the A3, see figure 2. The classification is based on the number and orientation of the fracture lines and does not account for the amount of displacement. [8]

Unfortunately this classification system for intertrochanteric fracture has poor reliability and reproducibility. A simplified classification system is the modified [9] system of Evans [10] based on fracture stability. Undisplaced (type 1), and intertrochanteric fractures with fracture of the lesser trochanter (type 2) are considered stable. Intertrochanteric fractures which have additional fracture of the greater trochanter with posteromedial comminution (type 3), or fractures with a intersubtrochanteric component, fracture of greater trochanter, posteromedial comminution with subtrochanteric component (type 4) or reverse oblique (type 5) are considered unstable, [9] see figure 3. A comparison with other grading systems has revealed that the modified Evans system has the best clinical predictive value regarding the reduction potential, and would, therefore, also indicate the likely risk of secondary displacement of the different fractures. [37]

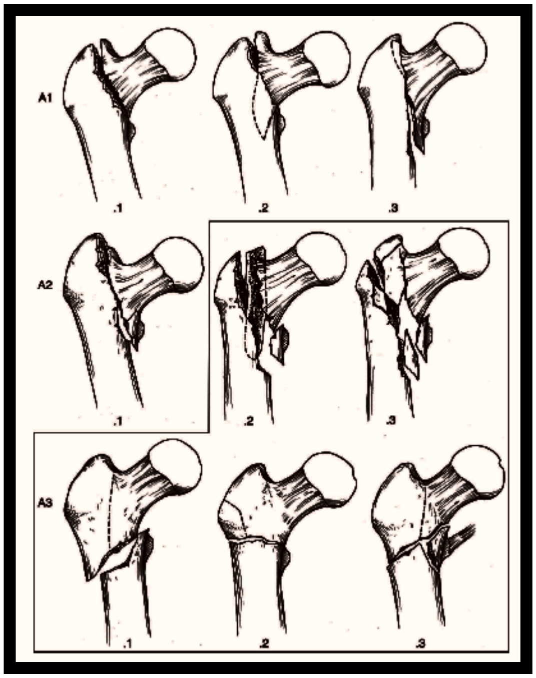

Figure 2: AO Classification of intertrochanteric hip fractures

Non Surgical versus Surgical Treatment

The goal of management of any hip fracture is to restore mobility while minimizing the risk of medical complications. Non surgical treatment of intertrochanteric fractures is reserved for patients with medical co-morbidities that place them at an unacceptable risk from surgical treatment and an anaesthetic. [11] Mortality rates in patients with severe medical co-morbidities is lower at 30 days in patients treated surgically, [12] however there is evidence demonstrating that patients can have equivalent outcomes with non surgical treatment when nursing care is excellent. [13] Since surgical treatment affords early mobilization and decreases risk of pressure sores, thromboembolism, cardiopulmonary problems, and need for beside physical therapy, operative treatment is recommended in nearly all patients. [12]

Surgical Treatment of Peri-trochanteric Fractures

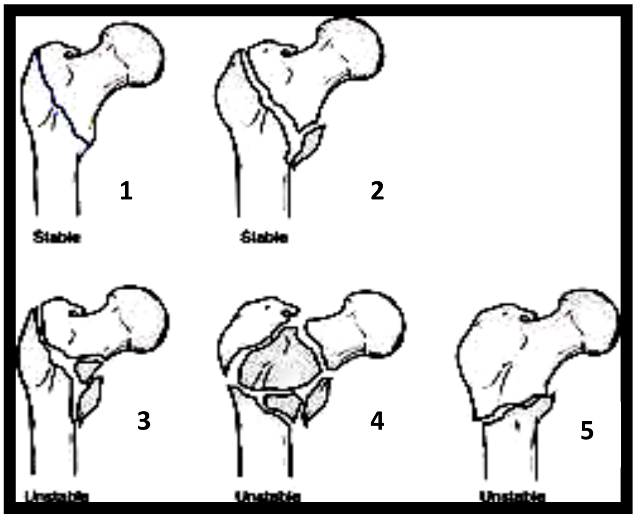

Figure 3: Modified Evans classification of intertrochanteric hip fractures

While surgical care of patients with intertrochanteric hip fractures has become the mainstay of treatment since the introduction of internal fixation in 1960, there are significant differences in failure rates between stable and unstable intertrochanteric hip fractures. [14, 15] Approximately 39% of hip fractures are peri-trochanteric, [16] and failure rates have been noted to be 50% higher with these unstable fracture patterns. [14, 15] Restoring mobility in patients with peri-trochanteric hip fractures has been determined to be dependent on 6 variables that affect the biomechanical strength of the fixation. [17] Surgeon independent variables are bone quality, fracture pattern, and fracture stability. [17] Surgeon dependent variables are quality of fracture reduction, implant choice and positioning of the implant. [17]

Quality of Fracture Reduction

Although fracture reduction should be assessed before the surgical procedure is begun, there is no common classification system for grading quality of hip fracture reduction. Fracture reduction is assessed by evaluating major fragment translation and angulation between the femoral shaft and head-neck fragment. Attention is paid to ensure that there are only a few millimeters of translation in the anteroposterior or lateral plane, and that neck shaft angulation is between 5° of varus (compared to the patient's anatomic neck shaft angle) and 20° of valgus.[7] More flexibility is permitted in the valgus direction as this reduces shortening that occurs with fracture fragment impaction, thus decreasing bending forces on the implant. [7] Angulation of more than 10° on the lateral view should not be accepted. [7] Possibly the reason that there is no universal classification system is that classifying fracture reduction is based largely on interpretation rather than well defined measurements. Even the simple three grade fracture reduction classification system of Baumgartner (see table 1) has been shown to be only moderately reliable. [18] Nevertheless, poor fracture reduction is associated with fixation failure. [7, 18, 19] Fracture reduction in an acceptable position is a pre-requisite prior to implantation of hardware for successful osteosynthesis. An implant will not reduce a fracture.

Table I: Baumgaertner grade of fracture reduction. [7]

Grade	**Angulation**	**Displacement**
Good	Normal or slight valgus alignment on AP x-ray, < 20° of angulation on lateral x-ray	< 4mm of displacement of any fragment
Acceptable	Meet criteria for a good reduction, but for either the alignment or the displacement, not for both	
Poor	Meets none of the criteria for angulation or displacement	

Implant Choice

Two types of implants are most commonly used in the treatment of intertrochanteric hip fractures: a compression hip screw with a side plate (dynamic hip screw) and an intramedullary nail with a cephomedullary sliding hip screw for reconstruction of the femoral neck (IM recon nail). Since the 1960s the dynamic hip screw (DHS) [44] has been the gold standard for osteosynthesis of intertrochanteric fractures as it allows for controlled fracture compression, [20] see figure 4. Biomechanical studies of the DHS have shown that calcar compression and lateral tensile strain are dependent on the fracture type and its quality of reduction in addition to the angle of the plate. [45] An anatomical reduction is superior to medial displacement or other non-anatomical reductions when tested to failure, while a 130 ° device has the highest compressive strain on the calcar in both stable and unstable


Figure 4: Illustration of dynamic hip screw implanted in a stable intertrochanteric fracture

fractures.[45] Failure of the DHS can occur with inaccurate placement of the screw within the head (causing screw cut out) or inadequate fracture reduction or excessive fracture collapse (causing plate breakage) exceeding the strain limits of the implant.[46]

Excessive fracture collapse and implant cut out has specifically been noted in the treatment of peri-trochanteric fractures with a DHS.[21] Consequently, IM recon nails have been advocated as an alternative in fixing peri-trochanteric fractures as the nail acts as an intramedullary buttress to prevent excessive shaft medialization, and their shorter lever arm decreases the tensile strain on the implant and reduces the risk of failure[22] see figure 5. Short nails (170 to 210mm) that allow jig guided distal interlocking as well as long nails that can be used to treat subtrochanteric fractures and intertrochanteric fractures with distal subtrochanteric extension are available. Long implant designs are useful when distal fracture extension cannot be bypassed effectively with short implants.

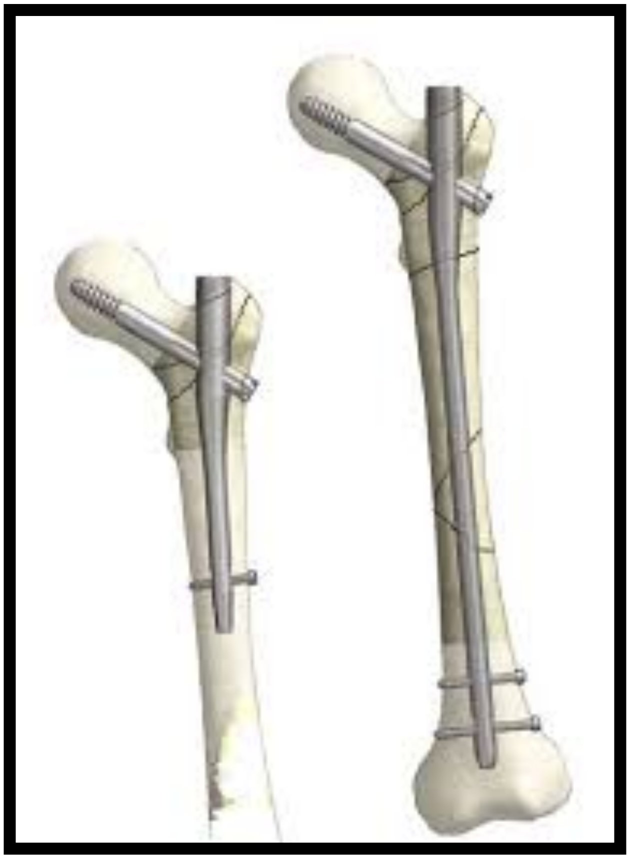

Figure 5: Illustration of short and long Gamma nails

The Gamma nail (Stryker, Mahwah, NJ) was originally designed in the 1980's by A. Grosse who developed an intramedullary nail that was locked proximally by a screw anchored in the femoral head.[47] The nail was inserted in a reverse fashion (left nail for right femur) and was used only in pathological fractures. Only a 130 º angle was available for the cervical screw, which was susceptible to breakage because of its small size (6.35 mm).[47] From this original prototype, a shorter nail (200 mm) with a larger cervical screw (12 mm) capable of sliding was developed and tested clinically at the end of 1986 as the first generation Gamma nail, named because of its shape to mimic the Greek letter.[47] Although these nails came in distal diameters of 16mm, 14mm and 12 mm, it was thought that the nail simply acted as a support for the cervical screw, and thus did not play the same role as a classic IM nail. The 16 mm and 14 mm nails were also rapidly abandoned to prevent intra-operative fracture upon its insertion. In certain bone morphologies (Asians and southern Europeans), even this diameter seemed excessive and an 11 mm distal nail was introduced. [47]

Early usage of the 1st generation Gamma nail gave birth to further modifications: (1) the 10º mediolateral curvature seemed too large, giving rise to a 3-point fixation phenomenon in which the nail could not be fully inserted because contact was made between the nail and the medial cortex in the subtrochanteric region, and the tip of the nail with the lateral cortex; (2) not both of the distal locking screw holes were required; and (3) there were no notable biomechanical differences between the size 12 mm and 11 mm nails. Thus a 2nd generation, "trochanteric" (TGN), nail was introduced which came with a mediolateral curvature of 4º, only in one diameter of 11 mm, only 1 distal locking screw option, and slightly shorter than its predecessor (180 mm versus 200 mm), [47] see figure 6. A long Gamma nail was also introduced to bypass fractures extending beyond 180 mm. Nails were fixed with a distal diameter of 11 mm in an effort to make the task of insertion easier and avoid the need of a mallet for insertion, thereby reducing the risk of intra-operative fracture. [47]

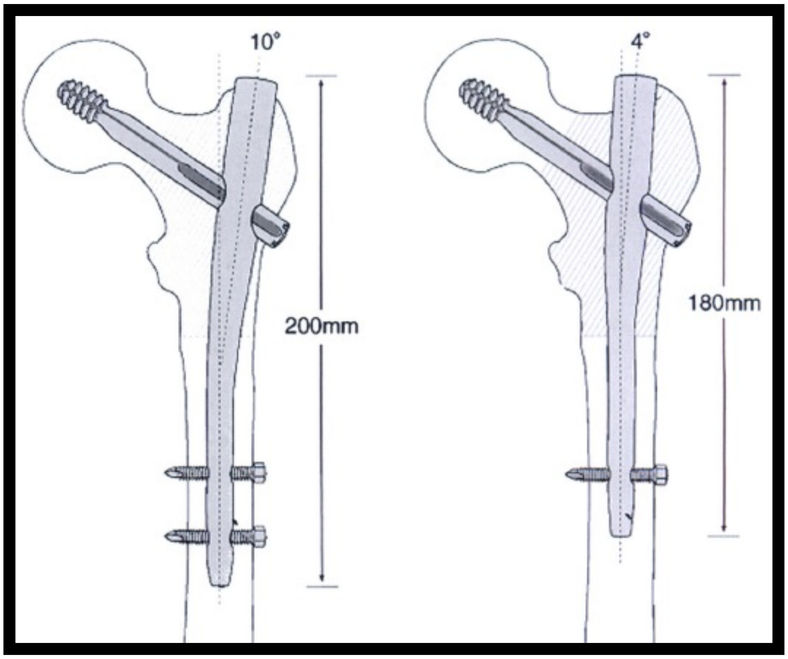

Figure 6: Illustration of 1st generation (left) and 2nd generation (right) Gamma nails

After 15 years of use, the second generation Gamma nail underwent further modifications in 1998; the diameter of the cervical screw was decreased from 12 mm to 10.5 mm, the diameter of the distal locking screw was changed from 6.5 mm to 5mm and the proximal diameter of the nail was decreased from 17 mm to 15.5 mm. [47] The radius of curvature was also changed from 3m to 2m, facilitating its insertion into the distal diaphysis. This 3rd generation nail was promoted since 2002 to be adaptable to all anatomies. See Figure 5.

Implant Position

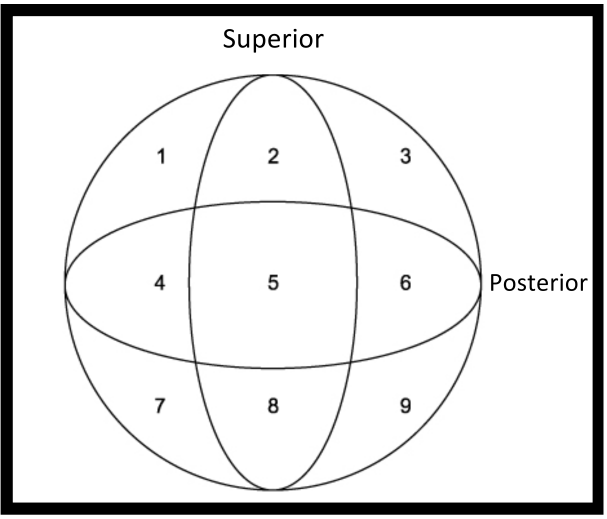

Figure 7: Diagram of the Cleveland zones. [41]

Despite the position of the lag screw within the femoral head having long been considered of vital importance for successful fixation, the methods of determining its best position has been inexact. Doherty [42] and Greider [43] both described the penetration of the screw on the number of turns necessary to advance the screw within the joint and its location as its distance (measured in screw diameters) relative to the central axis of the femoral head and neck on both anteroposterior (AP) and lateral (LAT) radiographs. Further studies on implant position described “safe zones” within the femoral head. [7] Zones within the femoral head were divided into superior, central and inferior segments on the AP view and anterior, central and posterior segments on the lateral view by Cleveland et al., [41] see figure 7. Mainds [30] and Thomas [31] reported that a central or inferior position on the AP view was best. Parker [32] revealed that there was significantly more frequent cutting-out when screws were placed superiorly or posteriorly.

In a landmark paper in 1995, Baumgaertner [7] devised a method to measure the distance of the screw tip from the apex of the femoral head, called the “tip-apex distance = TAD). (see figure 8) A TAD of less than 25 mm was significantly associated with a decreased risk of screw cut out (p=.0001). [7] More importantly, there was a direct relationship between an increased TAD and increased risk of the screw cutting out of the femoral head. In his retrospective review of 198 peri-trochanteric fractures, a TAD of < 30 mm had a 2% rate of cut out, compared with a 27% rate of cut out with a TAD > 30 mm, 36% rate of cut out with a TAD > 35 mm and a 60% rate of cut out with a TAD > 45 mm. [7] A follow up prospective study reinforced that

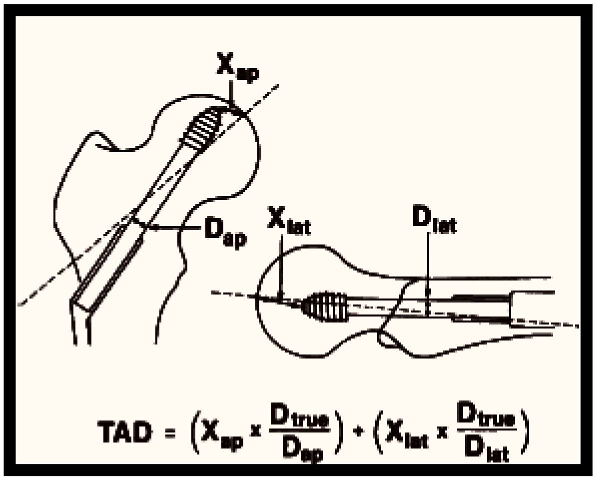

Figure 8: Technique for calculating the TAD: A superior placed screw is depicted in the AP, while a shallowly placed screw is depicted in the LAT. [7]

attention to ensuring the TAD is < 25 mm can reduce mechanical failures due to screw cut out from 8% to zero. [33] As this was a prospective study, the surgeons were aware of data collection so the Hawthorne effect may have applied where the outcome is influenced by the study itself. However further studies have supported that the TAD is the most reliable predictor against screw cut out. [18, 34] Furthermore the TAD measurement is not influenced by the experience of the observer likely because its measurement is based not on skillful interpretation but on simple, well-defined rules. [18] Since the TAD is easily measured on a picture archiving and communication system (PACS), [36] the use of the TAD is the most reliable method of ensuring optimum implant position. Most recent studies have suggested that a TAD should be kept < 15 mm to avoid lag screw cut out in DHS [19] and < 20 mm when using an IM recon device. [35] Moreover studies have shown that the TAD is independent from preferred safe zones in predicting screw cut out, and that previous considered safe zones do not significantly protect against screw cut out. [18] Interestingly, no studies have determined whether the average TAD is related to screw position; that is if the TAD is higher when the screw is in a vulnerable zone. Furthermore, no study has specifically investigated whether a shorter TAD is required for more unstable fractures and the relationship between the two.

Literature Review

DHS versus Gamma nail

Numerous studies have compared DHS versus IM recon nails and their results provide much controversy in the treatment of unstable intertrochanteric hip fractures. Utrilla et al. [23] found that postoperative ambulation was significantly improved (p = 0.017) in patients treated with a Gamma nail for unstable intertrochanteric fracture patterns in their level 1 study of 210 stable and unstable fractures. Fracture healing and intra- and post operative complication rates were not significantly different between the two groups. [23] Pajarinen et al. [24] showed that patients treated with IM nails for peri-trochanteric fractures had a significantly faster return to preoperative ambulation levels (p = 0.04) in a study of 108 patients, suggesting that IM recon nails provided faster restoration of walking ability than the DHS in patients with unstable fracture patterns. Fracture healing was similar between the two groups at 4 months. Guyer et al. [25] studied 100 patients treated with either a Gamma nail or a DHS and found that while no significant differences existed in terms of perioperative complications; a Gamma nail was preferable in unstable fracture patterns as the DHS group had 3 patients who experienced lag screw perforation during mobilization. Papasimos et al. [26] determined that screw cutout and fracture reduction were not statistically different between 120 prospectively randomized patients treated with a DHS or IM recon nail for unstable intertrochanteric fractures. Sadowski et al. [27] reported a significantly higher rate of implant failure (p=0.008) and non union (p =0.007) with a DHS in 39 patients treated with a DHS or IM nail for unstable reverse oblique peri-trochanteric fractures.

A number of studies have conversely advocated a DHS over an IM recon nail for unstable intertrochanteric hip fractures. Ahrengart et al. [28] revealed a higher incidence of cephalic position of the lag screw within the femoral head, screw cutout and intraoperative fracture in 426 randomized patients treated with a Gamma nail compared to DHS for intertrochanteric fractures. The authors recommended Gamma nails only for the severely unstable fracture patterns. [28] Baumgaertner et al. [29] found no significant difference between DHS and IM recon nails with regard to complications even when compared in unstable fractures. In the most recent Cochrane review by Parker and Handoll, most level 1 studies show that there are no significant differences in mobility, operating room time, blood loss, complication rates, union rates, or loss of reduction when comparing IM recon nails with DHS implants for intertrochanteric fractures, however analysis of level II studies show a preference for IM recon implants in osteosynthesis of unstable intertrochanteric hip fractures. [48]

Interestingly there has been an increase in the use of IM recon nails being used despite their superiority not being largely substantiated by scientific evidence. [53] The fixation rate using IM recon nails for intertrochanteric fractures increased from 3% to 67% between 1999 and 2006 in a study of candidates writing the Part II American Board of Orthopedic Surgery examination. [53] In view of the fact that current literature shows inconsistent treatment recommendations, additional studies are required which compare the IM recon nail with the DHS specifically in the most unstable fracture patterns.

Short versus Long Gamma nail

The use of short IM recon nails versus long IM recon nails in the management of peri-trochanteric fractures is also controversial. The higher complication rate reported in IM recon nails is often due to distal cortex fracture. [48] When the nail is hammered in forcefully, longitudinal fissures in the femur can occur that are not always noticed intra-operatively. Disparity between the design of the nail and the geometry of the bone and excessive tightening of distal locking screws can also cause iatrogenic injury. Since the distal part of the nail already produces a concentration stress at that site, further weakening of the bone can occur with a distal locking screw, thereby persuading many surgeons not to use a distal locking screw at all. Hesse favored use of a long Gamma nail after experiencing femoral shaft fractures distal to the implant in cases with a short Gamma nail as a mechanical complication just as often as screw cut out in a series of 498 patients. [49] Abram et al. [37] also reported the disuse of the short Gamma nail after 7 late distal femoral fractures in 43 patients. Bess and Jolly reported an 11.8 % rate of distal femoral fracture in 17 cases fixed with a short Gamma nail. [50] Lacroix reported an increase 57.8% risk of distal femoral fracture when hammering an awl to start the distal locking hole and a 35.7% increased risk when drilling additional holes due to missed previous attempts in a cadaver study of 10 femurs. Interestingly, the majority of distal femoral fractures have been reported in 1st generation devices. The modification of the Gamma nail to a 2nd generation and further 3rd generation device has been theorized to reduced the incidence of distal femoral fracture. This decrease in femoral fracture has been described by Børgul [51] who reported that changing from a short nail to a long nail decreased the number of femoral fractures 33 to 2. A recent study from Barton et al. [52] agreed with this finding, with no cases of intra-operative or post operative femoral fractures observed among 100 patients managed with a long Gamma nail for a peri-trochanteric hip fracture.

'Three- point' fixation

Recently the importance of implant position has been described in the Gamma nail for peri-trochanteric fractures. [37] Previous studies had shown that the only operative factor to predict failure in the Gamma nail is the TAD, [35] however Abram et al. [37] described that fixation points in the greater trochanter and lateral cortex in addition to an acceptable TAD was important in successful fixation, see figure 9. Multivariate analysis indicated that the TAD and the lateral cortex points were independent predictors of failure, but cortical contact in the greater trochanter was not significantly associated with mechanical failure. However despite the importance regarding the greater trochanteric cortical point, the lowest rate of failure (0.8%) was reported when all three points of fixation were positioned correctly. It was postulated that perhaps technical difficulty in achieving three points of fixation may be due to the

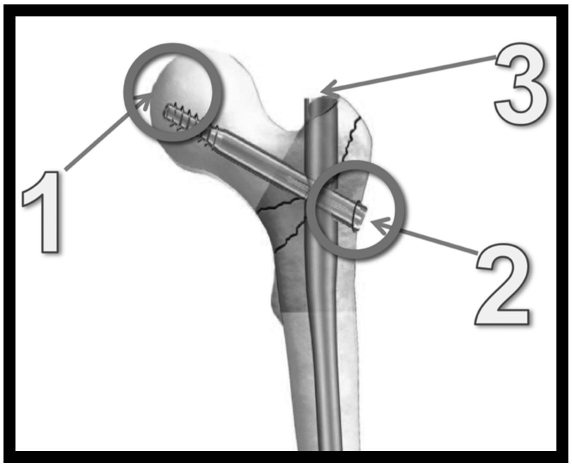

Figure 9: Schematic depicting 'three points of fixation' in a Gamma nail.

higher complication rate seen in some studies when using an IM recon nail for peri-trochanteric hip fractures. [37] The higher complication rate reported in IM recon nails is often due to distal cortex fracture. No study has yet determined the importance of intramedullary fit of IM recon nails in preventing mechanical failure.

Causes of Fixation Failure

Successful operative fixation does not always correlate with a successful functional outcome. [38] Rehabilitation programs and preoperative co-morbidities are independent predictors of functional outcome. [38] Therefore mechanical complications such as loss of fixation, femoral shaft fracture, and nonunion are often used as objective qualifiers when determining successful surgical treatment. These mechanical complications will henceforth in this thesis be termed 'failures of fixation' or 'fixation failure'. Migration of the lag screw with cut-out from the femoral head remains the most common cause of fixation failure. [18] Most studies report cut-out rates from 4-20%, with increased rates seen in the most unstable fractures. [7] A review of severe unstable fractures (Modified Evans 5) revealed a 56% failure rate for DHS fixation. [14] The use of IM recon nails in this fracture subtype has been suggested to lower loss of proximal fixation. [14] A complication of IM recon nails in treating peri-trochanteric hip fractures, however, is femoral shaft fracture. Femoral shaft fracture can occur at the time of implantation or postoperatively, but has been almost completely limited to short intramedullary fixation. Improvements in operative technique and newer generation nails have shown to decrease the rate of iatrogenic femoral shaft fracture from 12% to 3%. [29, 39] Nonunion after peri-trochanteric fracture is a less common complication than hardware failure, with most rates at 1 to 2%. [40] Most reports of nonunion are associated with instability or loss of reduction, with unstable fracture patterns and loss of a medial calcar buttress most at risk. While most authors agree that fracture fixation failure is a combination of fracture type, grade of reduction, implant choice, and implant position, there is no clear consensus either to their inter-relationships or to the relative importance of each. In view of that, the predictors of fixation failure in treatment of peri-trochanteric hip fractures require further investigation.

Hypotheses

The aim of this thesis is to investigate the predictors of fixation failure in peri-trochanteric hip fractures when using a DHS or Gamma nail at a tertiary referral trauma centre. The null hypotheses specifically are:

(1) There is no difference in fixation failure when using a DHS or Gamma nail for peri-trochanteric hip fractures.
(2) TAD is not a predictor of fixation failure in peri-trochanteric hip fractures
(3) A shorter TAD does not improve fixation success with increasingly unstable peri-trochanteric hip fractures.
(4) The average TAD is not related to zone position of the screw
(5) There is no difference in fixation failure when using a short or long Gamma nail for peri-trochanteric hip fractures.
(6) The intramedullary fit of a Gamma nail is not a predictor of fixation failure in peri-trochanteric hip fractures
(7) Fixation points of the lateral cortex and greater trochanter are not predictors of fixation failure in peri-trochanteric hip fractures.

Methods

Study Cohort

A retrospective review of all peri-trochanteric hip fractures treated with a DHS or Gamma nail between 2008-2012 at the author's institution, a tertiary referral trauma facility, was performed. A list of all hip fractures treated by internal fixation was identified by searching the ICD 10 codes for: (1) 47519-00 - internal fixation of fracture of trochanteric or subcapital femur, (2) 47531-00 - closed reduction of fracture of femur with internal fixation, and (3) 47528-01 - open reduction of fracture of femur with internal fixation. Exclusion criteria for the study included: (1) inadequate radiographs for analysis, (2) prophylactic fixation, (3) death within 30 days, (4) pathological fracture, (5) peri-prosthetic fracture, (6) segmental fracture, (7) polytraumatized patients (Injury Severity Score ≥9) and (8) fixation device other than a Gamma nail or DHS, resulting in a total of 516 peri-trochanteric fractures for radiographic analysis, see figure 10.

Analysis of pre-operative, intra-operative, and post-operative radiographs was undertaken using Centricity PACS software. Fracture patterns were graded by the modified system [9] of Evans. [10] The quality of the reduction was graded as good, acceptable or poor according to Baumgaertner classification. [7] Fixation of the head of the femur was graded according to the Baumgaertner TAD [7] and classified satisfactory if < 25 mm. The diameter of the lag screw in the DHS (12.5 mm) and Gamma nail (10.5 mm) were used to correct for radiological magnification. The location of the screw head was classified as per the 9 zones described by Cleveland et al. [41] The proximal tip of the nail was classified as satisfactory if in contact with or protruding beyond the cortex of the greater trochanter. The position of the lag screw at the lateral femoral cortex was classified as satisfactory when the screw was in contact or protruding beyond the lateral femoral cortex. The fit of the nail was measured as a percentage the intramedullary canal occupied at its narrowest point combined on the AP and lateral views. Examples of inadequate positioning for each of these points are shown in figure 11.

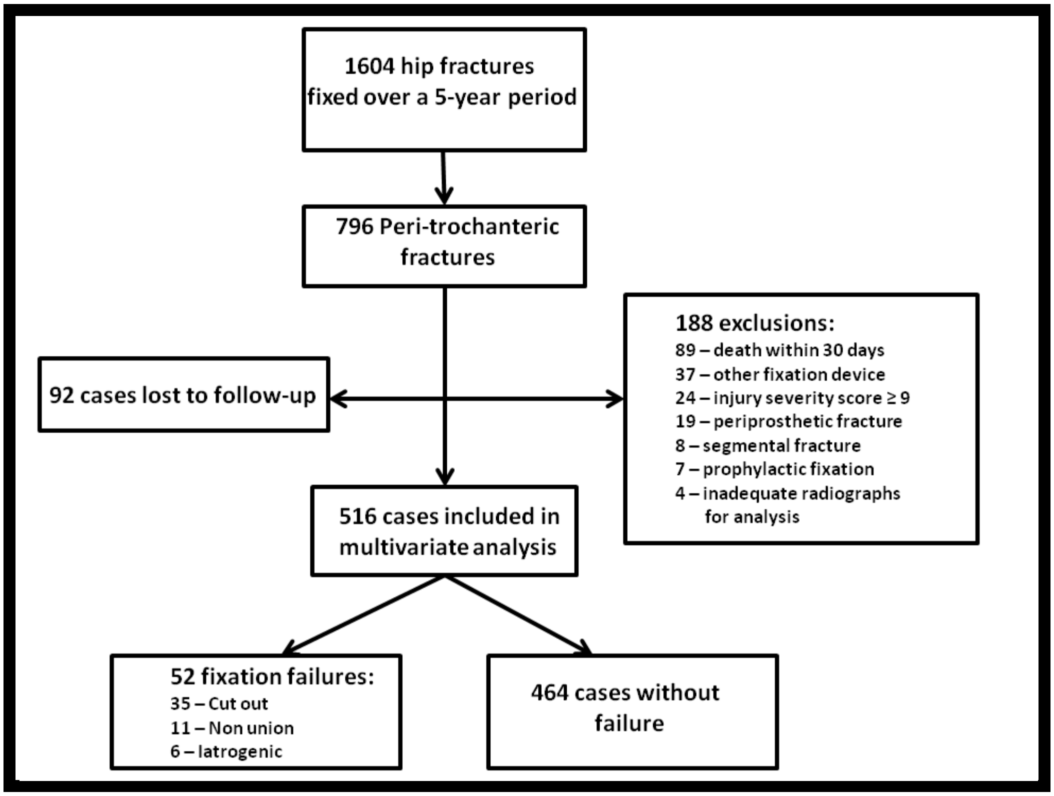

Figure 10: Consort flow diagram of the cohort

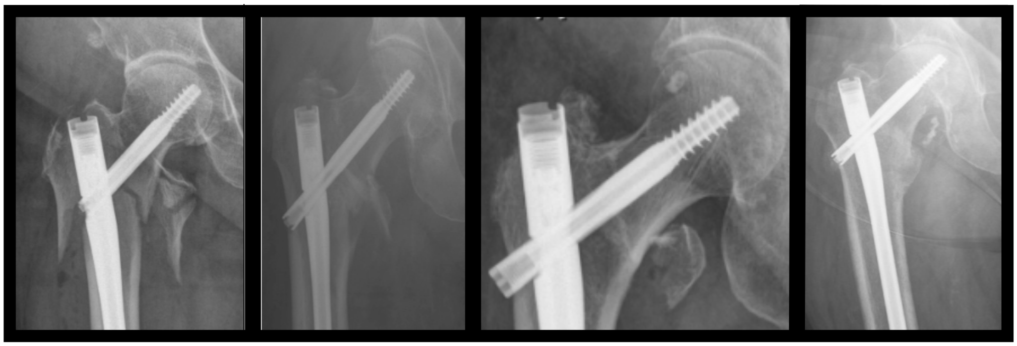

Figure 11: Radiographs of inadequate proximal femoral fixation points with (A) lag screw short of the lateral cortex (B) end cap of nail distal to greater trochanter (C) TAD > 25 mm, and (D) poor nail fit

Mechanical failure of fixation was defined as loss of fracture reduction by appearance of either: (1) migration of the lag screw within the proximal fragment (failure due to screw cut out), (2) fracture through the nail or plate (fatigue failure due to non union), (3) fracture of the distal locking screws (failure due to subsidence) or (4) intra-operative iatrogenic fracture requiring revision.

Our institution's policy is that all patients are routinely followed up at 3 months, and those who are mobile and pain-free are discharged at that visit, although radiological union will not be evident at this stage. As a tertiary referral centre, patients who subsequently develop pain or complications are referred back to the department for further imaging and assessment. For the purposes of this study, all cases were followed up to the most recently recorded clinical episode, with follow-up calculated as being from the date of surgery to this most recent episode.

Ethics Approval

This study was given Human Research and Ethics Committee approval following the guidance of the National Research and Ethics Committee, project number 462/13.

Statistical Analysis

Statistical analysis was performed with use of SPSS version 21 (SPSS, Chicago, Illinois) on a personal computer. Univariate logistic regression analysis of potential confounding factors (age, gender, fracture classification, reduction quality, Cleveland zone, tip-apex distance, and implant type (DHS versus short Gamma nail versus long Gamma nail) was performed using a Pearson's chi-square test to compare differences among categorical variables by evaluating frequencies within the groups by the method of cross tabulation. Before analyzing continuous variables, the data sets were tested for normality by performing the Shapiro-Wilk test. When distribution was considered to be normal, for independent samples the Students T test was used, otherwise the Mann-Whitney test was used. Those factors that appeared to affect failure rates, with a p-value of <0.1 were then included, and adjusted for in a multivariate regression analysis. Each of the 4 Gamma nail fixation points was added into this model in turn, to establish their effect on risk of failure. In addition the Gamma nail fixation points were included in the model together, so that independence between points could be established. Statistical significance was ascribed when the p-value was < 0.05.

Univariate logistic regression was used to calculate the predicted probability of cut-out for each observed tip-apex distance value. The receiving operating characteristic (ROC) curve for the mean tip apex distance was used to calculate the area under the curve (C-statistics), and the best threshold value of the tip apex distance was used to predict screw cut-out. The differences in the mean tip apex distance in the groups of the modified Evans classification system and Cleveland zones were tested with use of one-way analysis variance (ANOVA).

Source of Funding

There was no external funding source used for this study

Results

Demographic Data

Out of the 1604 hip fractures identified, 796 were noted to be peri-trochanteric. 92 patients (12%) were excluded on the basis of incomplete radiographic follow up. Other patients excluded were: 7 patients who underwent prophylactic fixation, 19 patients with periprosthetic fractures, 37 patients who had a fixation device other than a Gamma nail or DHS, 8 patients with segmental fractures, 24 patients with an injury severity score ≥ 9, 89 patients who died within 30 days and 4 patients with post operative radiographs inadequate for analysis. After exclusions 516 patients with peri-trochanteric hip fractures were suitable for our study. Most individuals were female (69.4%). Mean age was 80.8 ± 13.6. Of the 516 peri-trochanteric hip fractures, there were 52 failures of fixation (10.2%). There was no difference in age or sex in regard to fixation failure, see table II.

Implant Choice

DHS versus Gamma nail

A DHS was implanted in 69.4 % of hip fractures (n=358) while the Gamma nail was used in 30.6% of cases (n=158). In treatment of stable intertrochanteric fractures (n=213), a DHS was used significantly more frequently than a Gamma nail (84.5% versus 15.5%, respectively; $p<0.001$). In treatment of unstable peri-trochanteric hip fractures (n=303) there was no overall statistical difference between use of DHS or Gamma nail (58.7% versus 41.3%, respectively, $p=0.945$), except for Evans type 5 fractures (n=40) where 85% were fixed with a Gamma nail versus 15% fixed with a DHS, $p <0.001$. A Gamma nail was itself used more commonly to treat unstable peri-trochanteric hip fractures (79.1% in unstable versus 10.9% in stable fractures), $p <0.001$.

There were a total of 10.1% fixation failures (n=52) with no overall difference in fixation failure with the use of a DHS or Gamma nail (10.3% versus 9.5%, respectively, $p=0.770$). There was a

Table II: Overall Characteristics according to Fixation Failure in all Patients

Characteristic	**Total**	**No Failure**	**Failure**	**P-value**
Age, mean±SD		81±14	80±14	0.509
Implant Type				0.945
- DHS	358	321 (89.7%)	37 (10.3%)	
- Long gamma	77	70 (90.9%)	7 (9.1%)	
- Short gamma	81	73 (90.1%)	8 (9.9%)	
Grade of Reduction				<0.001
- Excellent	143	139 (97.2%)	4 (2.8%)	
- Good	315	289 (91.7%)	26 (8.3%)	
- Poor	58	36 (62.1%)	22 (37.9%)	
TAD (mm) median ±SD	516	20±7	30±9	<0.001
Mean (±SD) Nail fit	158	84±6%	58±6%	<0.001
Evans Class				<0.001
- 1	125	120 (96%)	5 (4.0%)	
- 2	88	88 (100%)	0	
- 3	68	62 (91%)	6 (8.8%)	
- 4	195	158 (81%)	37 (19%)	
- 5	40	36 (90%)	4 (10%)	
Lateral Cortex				0.536
- Yes	116	106 (91.4%)	10 (8.6%)	
- No	42	37 (88.1%)	5 (11.9%)	
GT Fixation				0.234
- Yes	104	92 (64.3%)	1(80.0%)	
- No	54	51 (35.7)%	3 (20.0%)	
Cleveland Classification				
				0.085
- SA				
- CA	1	1	0	0%
- IA	18	16	2	11.1%
- SC	8	6	2	25.0%
- CC	20	16	4	20.0%
- IC	327	301	26	8.0%
- SP	45	42	3	6.7%
- CP	9	7	2	22.2%
- IP	64	57	7	10.9%
	24	18	6	25.0%
Total	**516**	**464**	**52**	**10.1%**

significantly higher rate of fixation failure in patients with an Evans Type 5 fracture treated with a DHS (33.3%, 2/6) versus a Gamma nail (2/34, 5.9%, P=0.003). There were no significant differences rates of fixation failure within the other Evans grades of fractures, see table III.

Short versus Long Gamma nail

Short and long Gamma nails were used in similar frequency when treating peri-trochanteric hip fractures overall, with 51.3% and 48.7% of the 158 implants, respectively. However in treatment of stable intertrochanteric fractures (n =33), short Gamma nails were used more than two times as frequently as long Gamma nails (69.7% versus 30.3%, respectively; p=0.017). In treatment of unstable peri-trochanteric hip fractures (n=125) there was no overall statistical difference between use of a short or long Gamma nail (58.7% versus 41.3%, respectively, p=0.438), except for Evans type 5 fractures (n=34) where 79.4% were fixed with a long Gamma nail versus 20.6% fixed with a short Gamma nail, p =0.001.

There were a total of 15 cases of fixation failures, with no overall difference in fixation failure with the use of a short or long Gamma nail (9.9% versus 9.1%, respectively, p=0.380). For Evans type 4 fractures treated using Gamma nails, 6 of 44 short nails failed (14%) versus 6 of 33 long nails (18%), p = 0.626. For Evans class 5 fractures treated using Gamma nails, 2 of 7 short nails failed (28.6%) versus 1 of 27 long nails (3.7%), p= 0.101, see table III.

Both short and long implants incurred two iatrogenic causes of failure amongst the total 15 cases of failures of fixation. Both iatrogenic causes of the long implants were due to distal femoral perforation, while the iatrogenic causes of failure in the short Gamma nail group were due to propagation of the fracture beyond the length of the implant, requiring revision to a long Gamma nail.

Fracture type

Unstable peri-trochanteric hip fractures were associated with a significantly higher rate of fixation failure than stable hip fractures. Fractures with an Evans grade of ≥ 3 had a 7.6 (OR 3.0-19.6) times increased risk of fixation failure (p <0.02), see table II.

Quality of Fracture Reduction

Fracture reduction had a significant effect on fixation failure (p<0.001). Fractures with an ‘acceptable’ grade of reduction incurred a 2.9 (1.0-8.4) times increased risk of fixation failure

Table III: Implant choice and fixation failure stratified by grade of modified Evans classification.

	Modified Evans Classification					**Overall**
	Stable		**Unstable**			
	1	2	3	4	5	
Implant Choice (Total)	**125**	**88**	**68**	**195**	**40**	**516**
DHS	110	70	54	118	6	358
Gamma nail	15	18	14	77	34	158
P-value	*<0.001*		*0.380*		*<0.001*	
Short Gamma nail	11	12	7	44	7	81
Long Gamma nail	4	6	7	33	27	77
P-value	*0.017*		*0.438*		*<0.001*	
Fixation Failure (Total)	**5**	**0**	**6**	**37**	**4**	**52**
DHS	5	0	6	24	2	37
Gamma nail	0	0	0	12	3	15
P-value	NE		0.191	0.403	*0.003*	
Short Gamma nail	0	0	0	6	2	8
Long Gamma nail	0	0	0	6	1	7
P-value	NE		NE	0.626	*0.101*	

NE = Not estimable because of zero events

Table IV: Univariate and Multivariate odds ratios and associated 95% CIs of Risk Factors for Fracture Fixation Failure

	Univariate		Multivariate Adjusted for modified Evans class and Quality of Reduction	
	OR (95% CI)	*p-value*	OR (95% CI)	*p-value*
Grade of Reduction 'Acceptable'	2.9 (1.0-8.4)	*0.047*		
Grade of Reduction 'Poor'	11.5 (4.0-33.4)	*<0.001*		
Evans Class ≥3	7.6 (3.0-19.6)	*< 0.02*		
TAD >20 mm	2.2 (1.70-2.73)	*0.001*	6.4 (2.9-14.1)	*<0.0001*
Nail fit	10.3 (8.1-28.4)	*<0.001*	29 (3-100)	*<0.0001*
Lateral cortex	0.69 (0.22-2.18)	0.536	0.4 (0.1-1.6)	0.464
GT	2.22 (0.60-8.22)	0.234	1.6 (0.5-5.5)	0.177

(p = 0.047), while fractures with a 'poor' grade of reduction had an 11.5 (4.0-33.4) times increased risk of failure (p <0.001), see table II.

Implant Position

Tip-apex Distance

Overall, the TADs of those cases that underwent cut out (30 ±9 mm) was significantly higher than those that had uneventful healing (20 ±7 mm), (p<0.001). To estimate a threshold value that can predict cut out, we used an ROC curve. The criterion for cutting out was at the 20.0 mm level. Sensitivity was 91.4% and specificity was 53.6%. The area under the curve was 0.80 (SE 0.04) , see Figure 11). At the 25 mm level, the sensitivity and specificity were 57.1% and 77.3%, respectively. At the 15 mm level, the sensitivity and specificity were 100% and 18.3%, respectively. We chose the 20 mm value as the threshold for cut out because it gave the best balance of predictive values. Figure 12 shows the predicted probability of cut out with ascending TAD. The odds ratio of the TAD adjusted for modified Evans classification and screw position per 5 mm TAD increase was 2.15 (95% CI 1.70 to 2.73), p <0.001

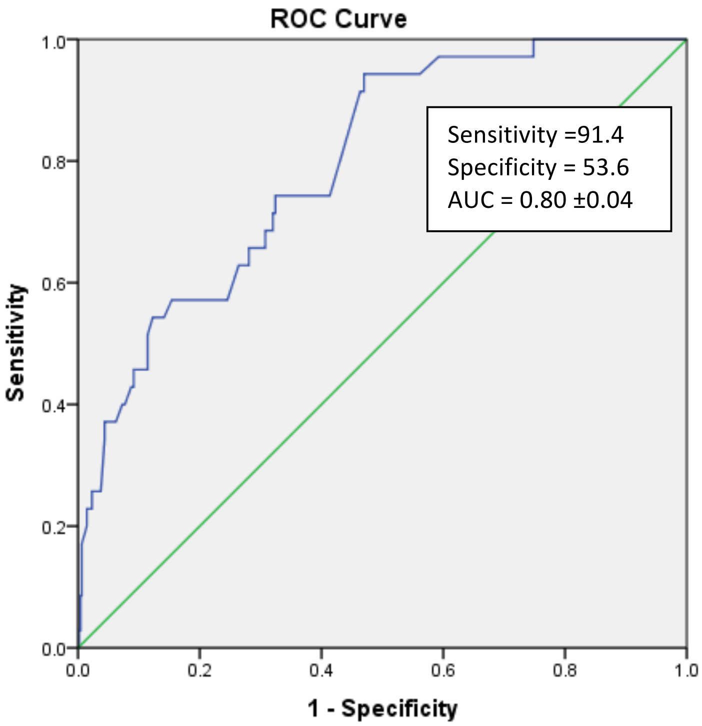

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Figure 12: The predicted probability of cut out with ascending TAD

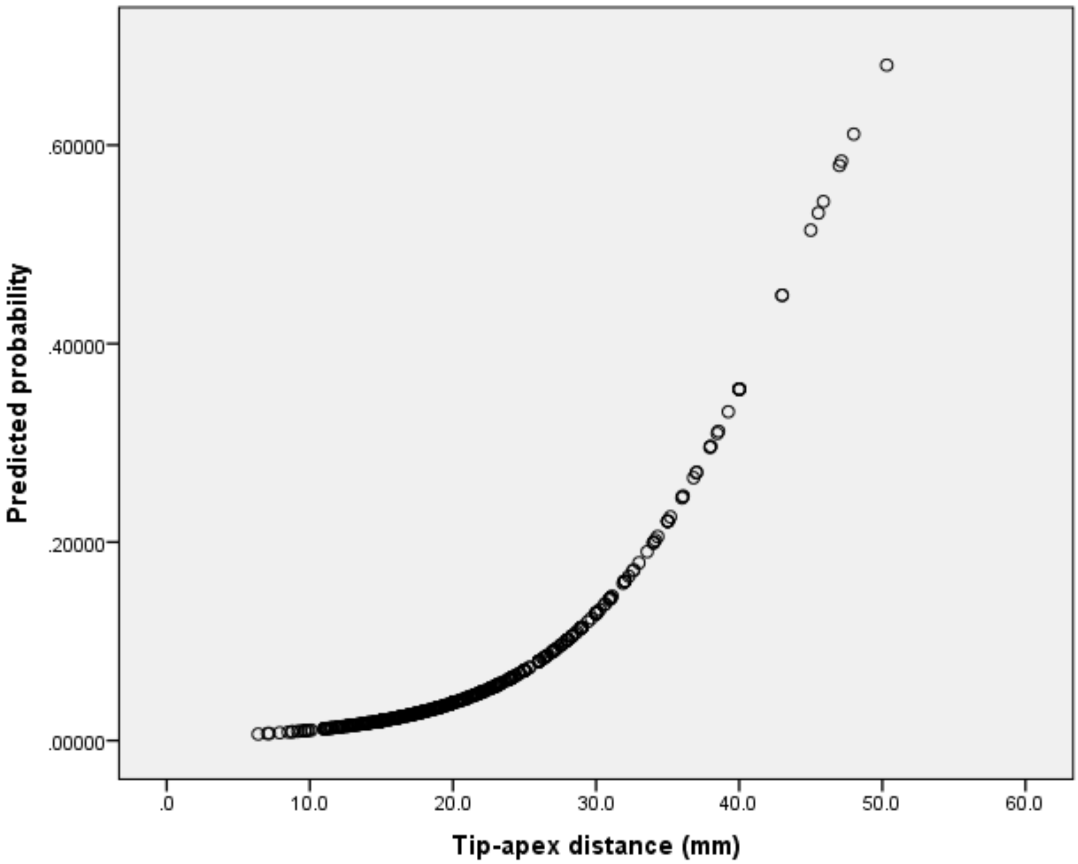

Figure 13: Predicted probability of screw cut out with ascending TAD

The Kruskel-Wallis nonparametric ANOVA test showed that there was no significant difference (p= 0.354) amongst the TAD of the 5 different modified Evans classifications. The median TAD was for each of the classifications in shown in table V. There was no significant interaction between the effects of modified Evans grade (stable versus unstable) and TAD on the odds of cut out (p=0.259). In other words a shorter TAD did not show to protect against cut out with an increasing modified Evans grade.

Table V: Average TAD in implants stratified by grade of modified Evans classification

	Modified Evans Classification					**Overall**	***P-value***
	Stable		**Unstable**				
	1	2	3	4	5		
TAD threshold mm (cut out vs. no cut cut)	**20.1 (±8.4)**	**20.3 (±6.7)**	**20.9 (±7.8)**	**20.0 (±6.9)**	**21.7 (±8.8)**	**20.0 (±7)**	**0.259**

Cleveland Zone

As evaluated according to the zones described by Cleveland et al. [41] and used by Kyle et al. [9], lag screws were found to have been placed in all nine possible locations within the femoral head. Screws cut out from eight of the nine zones, see figure 13. Screws were most commonly placed in the centre-centre zone (327/516 = 63.4%) and least frequently in the superior-anterior zone (1/516 = <1%),(p <0.001) . The highest rates of screw cut out occurred in the inferior-anterior (1 of 8 screws), inferior posterior (3 of 21 screws), superior-posterior (2 of 9 screws), and superior central (4 of 20 screws) zones. The rate of cut out in any of these peripheral zones was significantly higher than the rate in the centre-centre zone (p <0.025), however the placement of screws in any of the other 4 zones, that is the placement of 88.2% of all screws, had no predictive significance with regards to fixation failure (p= 0.085), see table II.

When cut out of the screw was regressed against both the tip-apex distance and the zone in which the screw had been placed, none of the zones had any predictive significance for cut out (p =0.662), whereas the TAD remained a strong predictor of fixation failure (p <0.001). In other words, placement of a screw in a peripheral position resulted on average in a larger TAD.

Lateral cortex

Inadequate fixation of the lateral cortex point was not associated with an increased failure of fixation when using a Gamma nail (p = 0.536). In fact the majority of fractures (66.7%) whose osteosynthesis failed had adequate fixation of the lateral cortex. On the other hand, the majority of fractures (74.1%) who had successful healing also had adequate fixation of the lateral cortex, see table IV.

Greater Trochanter

Inadequate fixation of the greater trochanter was not associated with an increased fixation failure when using a Gamma nail (p = 0.234). Moreover 80% of fractures whose osteosynthesis failed had an adequate fixation point in the greater trochanter. In the subset of successfully healed fractures, there was a preponderance of cases (64.3%) with adequate fixation in the greater trochanter, see table IV.

Nail Fit

The fit of the nail in the intramedullary canal was significantly associated with fixation failure, with those cases with successful healing having a nail occupying 84 ± 6 % of the canal, compared to those that incurred fixation failure 58 ± 6% (p <0.001). More importantly, there was a direct relationship between increased nail fit and decreased risk of fixation failure. When the size of the nail occupied greater than 70% of the intramedullary canal, there were no cases of fixation failure when using a Gamma nail, irrespective of Evans classification or grade of fracture reduction, see table IV.

Multivariate Analysis

Multivariate regression was employed to test the effects of the 4 fixation points on fixation failure after adjusting for modified Evans grade and quality of reduction. The odds ratios for the TAD and nail fit were 6.4 and 29, respectively, which were highly statistically significant ($P < 0.001$ and $p < 0.0001$) (Table 9). The lateral cortex and greater trochanter fixation points were not significantly associated with failure ($p = 0.464$ and $p = 0.177$), see table IV.

Discussion

Published literature on the factors affecting fixation failure in the treatment of peri-trochanteric proximal femoral fractures include: (1) fracture type, (2) quality of reduction, (3) implant choice (sliding hip screw versus IM recon nail), (4) TAD and position of screws within the femoral head, and (5) three-point fixation when using an IM recon nail. [21] In this study we investigated the relative importance and the inter-relationships of these factors by studying the reliability of the modified Evans classification, the three grade Baumgaertner fracture reduction classification, the TAD measurement, the Cleveland femoral head dividing system in DHS and Gamma nail implants, and the fixation points of the lateral cortex and greater trochanter in Gamma nails. We have introduced the concept of nail fit as a further predictor of failure specific to the Gamma nail.

Fracture type and Quality of Reduction

The type of peri-trochanteric fracture has long been believed to affect the success rate of its surgical treatment. [14-16] Our study supports this well held belief, quantifying that unstable fractures have a significant 7.6 (OR 3.0-19.6) times increased risk of fixation failure ($p < 0.02$). It is also known that poor fracture reduction increases the risk of fixation failure. [14-16] Our study also confirmed this relationship, as fractures with an ‘acceptable’ grade of reduction incurred a 2.9 (1.0-8.4) times increased risk of fixation failure ($p = 0.047$), while fractures with a ‘poor’ grade of reduction had an 11.5 (4.0-33.4) times increased risk of failure ($p < 0.001$),

An unstable fracture type and poor fracture reduction though may be inter-related; that is an unstable fracture may incur an increased risk of fixation failure because they may be more difficult to reduce. This study is the first to confirm that this inter-relationship does exist, revealing that there was a significantly increased rate of ‘poor’ fracture reduction amongst cases with unstable fracture patterns (84.5% = 49/58) compared to those cases with stable fracture patterns (15.5% = 9/58), p <0.001.

Our study, unfortunately, is unable to ascertain whether the increased risk of fixation failure is in itself an inter-relationship between fracture type and quality of reduction, or if it is in fact due to a third factor – fracture settling. Fracture settling is defined as the degree of uncontrollable medialization of the distal fracture fragment relative to the proximal one. [54] Fracture settling is minimal in stable fracture types because of their inherent stability. This inherent stability has been thought to be reliant on the posteromedial wall. [55] Comminution along the calcar and posterior fragments leads to a deficit along the medial arch, allowing medial displacement during fracture healing – a predisposition for varus collapse [55] In fact the probability of fixation failure has been reported to be proportional to the degree of medialization. [54] When the distal fragment medializes > 90%, fixation failure is inevitable. [54]

Recently however the integrity of the lateral wall has been recognized as the key determinant in fracture settling. The superolateral part of the distal fracture fragment, which corresponds to the lateral part of the greater trochanter, anchors to the proximal fragment and prevents medial displacement. [56] It has recently reported that the thickness of the lateral wall contributes significantly to post-operative lateral wall fracture, with a threshold value of 20.5 mm for risk of developing a secondary lateral wall fracture. [56] Fracture of the lateral wall occurs in modified Evans type 4 and 5 fractures or during reaming for the insertion of the cephalomedullary lag screw. When there is no intact lateral wall to act as a buttress, medialization and subsequent fixation failure is likely as the screw runs out of length within the barrel, and the implant becomes fixed. It is postulated that the IM recon nail is more appropriate than a DHS in the unstable fractures which inherently have a greater risk of medialization because the centromedullary position of the nail acts as a buttress against uncontrollable medialization. [56]

Implant Choice

DHS versus Gamma nail

Although a cephalomedullary implant such as a Gamma nail may provide a biomechanical advantage over a DHS in fixation of peri-trochanteric hip fractures, they have not been noted to be used more frequently. [48] Our results agree with the latest Cochrane review, [48] with no overall statistical difference in the treatment of unstable peri-trochanteric hip fractures between use of a DHS (58.7%) or Gamma nail (41.3%), p=0.945). A DHS was used significantly more frequently than a Gamma nail (84.5% versus 15.5%, respectively; p<0.001) in the treatment of stable intertrochanteric fractures. Again this finding is in keeping with the latest Cochrane review, which states that the DHS has such excellent results as the gold standard, that it would be "perhaps immoral to try to improve its outcomes in treatment of stable intertrochanteric fractures". [48]

Our results, however, showed a significant predilection for using a Gamma nail (85%) instead of a DHS (15%) in the treatment of modified Evans type 5 fractures, $p < 0.001$. The lateral wall is by definition broken in these reverse oblique and transverse type fractures belonging to this category, and undergoes uncontrollable medialization. In fact an IM recon nail implant is now recommended for this specific subtype of fracture as the failure rate is 40% when fixed with a DHS implant. [48] Our results again agree with these studies, revealing a significantly higher rate of fixation failure when a modified Evans type 5 fracture was treated with a DHS (33.3%) compared to a Gamma nail (5.9%), $p = 0.003$.

Short versus Long Gamma nail

Our results did not support the decline in the usage of short Gamma nails in favour of long Gamma nails as reported by recent literature. [37,48,49,51,52] Short and long Gamma nails were used in similar frequency when treating peri-trochanteric hip fractures overall, with 51.3% and 48.7% of the 158 implants, respectively. The increased risk of fixation failure with use of a short IM nail has all but been eliminated as shown in a recent meta-analysis of 25 prospective randomized trials by Bhandari et al. [57] This may be due to the fact that there does not seem to be significant differences amongst the short and long third generation nails. [58]

Despite both the short and long Gamma nails sharing similar biomechanical properties, short Gamma nails were used significantly more frequently ($p=0.017$) in the treatment of stable intertrochanteric fractures, while long Gamma nails were used significantly more frequently ($p = .001$) in the treatment of modified Evans type 5 fractures. Undoubtedly the use of a guided gig to aid insertion of the distal cortical screw quickens the operative time when using a short Gamma nail, thereby encouraging its use amongst surgeons as opposed to a long Gamma nail whose distal locking screws must be inserted freehand with help of image intensification.

There was no significantly higher rate of fixation failure in patients with an Evans type 5 fracture treated with a short versus a long Gamma nail, $p=0.101$. The causes of fixation failure of the two type 5 fractures treated with a short Gamma nail was due to iatrogenic causes – propagation of the original fracture beyond the length of the short Gamma nail. Hence the increased failure rate incurred with the short Gamma nail was not error of the implant itself.

There were no significant differences in rates of iatrogenic injuries among the DHS and Gamma nail implants. ($p=0.0586$). This finding is again in keeping with current literature that suggests iatrogenic injury has reduced with newer design nails. In fact when iatrogenic injuries do occur now, they are almost exclusively as a result of poor operative technique.

Position of Screw within the Femoral Head

Like many studies since Baumgaertner's landmark paper in 1995, [7, 13, 19, 20] our study showed that the risk of screw cut out grows exponentially with an increasing TAD. Studies on TAD since 1995 have varied on the exact threshold value, with some studies stating 15 mm for a DHS [19] and 20 mm for an IM recon nail. In our study there was no significant difference in screw cut out threshold for a DHS or Gamma nail, $p = 0.785$. We chose 20 mm as the best threshold for screw cut out because it gave the best overall predictive value. We chose 5mm as increments to base our predicted probability of screw cut out because clinically, it is the smallest scale that is likely to be able to be detected on an image intensifier. From a threshold of 20 mm, for every 5 mm increase risk of screw cut out approximately doubles, $p<0.001$.

It is commonly believed amongst surgeons that when treating an unstable fracture, a smaller TAD would be more protective against screw cut out. Our study showed that this is not the case. A shorter TAD did not show to protect against screw cut out with an increasing modified Evans grade, $p =0.259$. While the importance of a short TAD is not in dispute, we have shown that it is not powerful enough to mitigate against failure in the face of a malreduced unstable fracture, $p = 0.004$. In fact of those fractures with poor reduction that went on to fixation failure, 22.7% had a TAD < 20 mm, see figure 14.

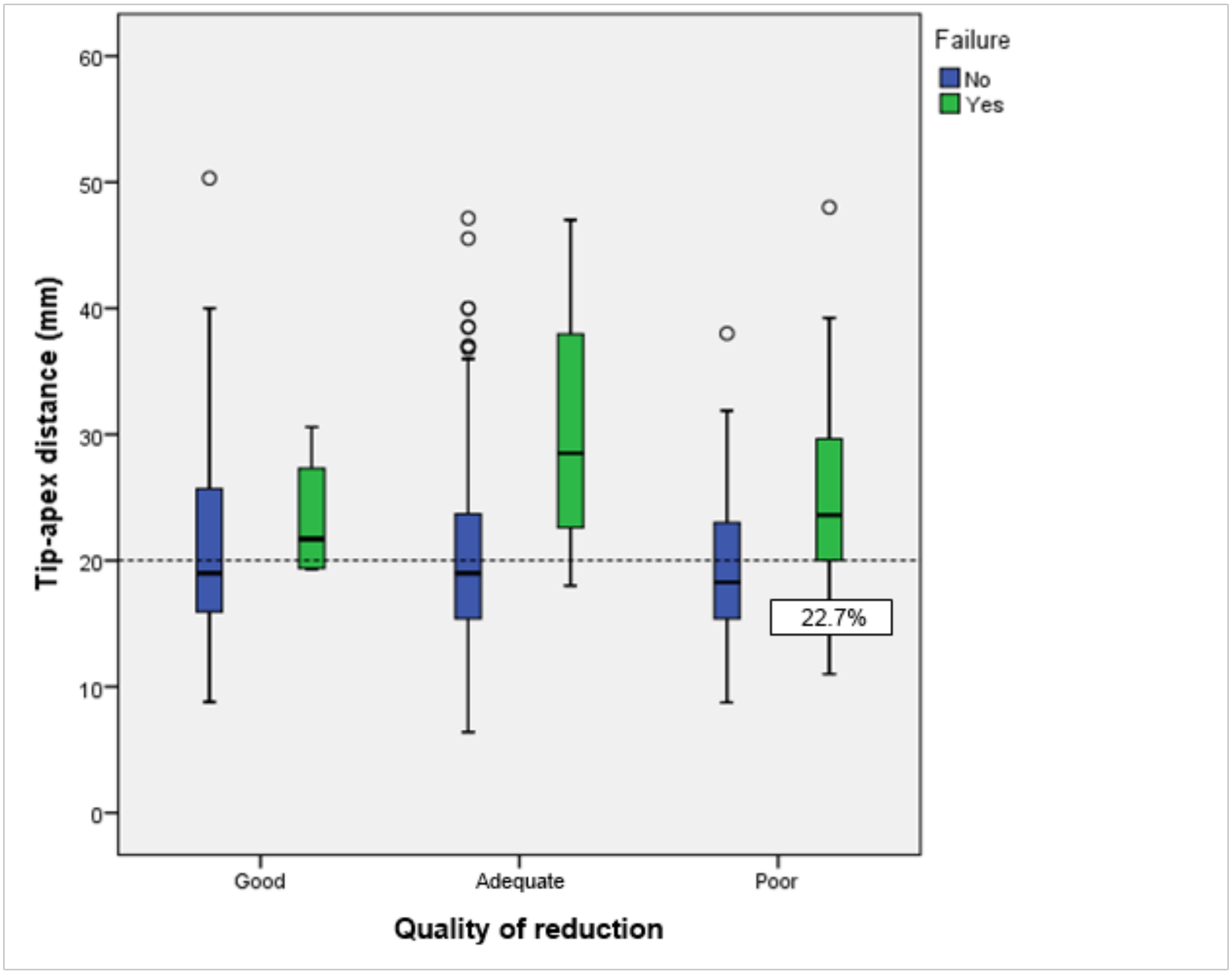

Figure 14: Fixation failure stratified according to quality of reduction and tip-apex distance

While it has been well established that the TAD is of vital importance in predicting screw cut out, the exact position of the screw in the femoral head needs refining. Previous studies have stated that the inferior and posterior screw positions were best, while others reported the inferior-posterior position does not significantly protect against screw cut out. Still other studies have reported that the central-central, inferior-anterior, and inferior-central positions contribute significantly to protect against screw cut out. Our study showed that no specific zone protects the screw from cutting out of the femoral head, p= 0.085. In fact screws that were placed in peripheral zones that were reported to be protective against cut out in previous publications had a significantly increased risk of cut out in our study, p <0.025. We believe the reason for this finding is because the TAD is independent to the screw position for predicting cut out. More so, we discovered that if a screw is placed in a peripheral zone then it will on average have a higher TAD. This is because the TAD measurement takes into account both the location and depth of penetration of the screw. An eccentrically placed screw will have a higher TAD than a concentrically based screw. Clinically screw placement is evaluated in two-dimensions with screw cut out occurring with varus collapse of the femoral head and superior migration of the lag screw. In vivo, however a rotational force is acting on the femoral head during gait. [60, 61] Obtaining a short TAD by placing the screw deep and central within the femoral head gives a fracture the best chance of union as it reduces the risk of rotation of the femoral head and neck around the screw (small torsional moment) that can occur when a screw is eccentrically placed. [65, 66]

'Three-point' Fixation

We examined the recently published concept of 'three-point' fixation when using a Gamma nail. by Abram et al.[37] who reported that successful osteosynthesis was significantly dependant on obtaining fixation of the lateral cortex with the set screw in addition to an optimal TAD. Although the greater trochanter fixation point was not an independent predictor of fixation failure unlike the lateral cortex and TAD points, when all three fixation points were positioned adequately, the failure rate was < 1%. [37] Our findings caused us to conclude otherwise. We found that obtaining a lateral fixation point was not associated with an increased rate of successful osteosynthesis. Modified Evans type 4 and 5 fractures patterns by definition do not have an intact lateral wall. Not uncommonly after reaming for the cephalomedullary screw some modified Evans type 3 fracture patterns do not have an intact lateral wall either. The concept of 'three-point' fixation original introduced by Charnley is to have three points of stable fixation in order to secure the unstable fracture. If the lateral wall is missing then by definition it is an unstable area and is not able to be relied upon as a fixation point in obtaining three points of fixation. It is noted that of the 16 cases of fixation failures reported by Abram, ten cases were modified Evans grade 4 or 5. Out of these ten cases, 8 were deemed to have inadequate fixations points. Unfortunately these 10 cases would not have had a stable lateral wall to act as an area of fixation to begin with. Our study included 111 cases of modified Evans type 4 and 5 fractures and 83.5% of them had adequate fixation of the lateral cortex. Hence a third point of fixation must be at play in order to obtain 'three points' of fixation.

Nail Fit

We believe this third fixation point may be the fit of the nail in the intramedullary canal, see figure 15. The fit of the nail in the intramedullary canal was seen to be significantly associated with fixation failure, with those cases with successful healing having a nail occupying 84 ± 6 % of the canal, compared to those that incurred fixation failure 58 ± 6% ($p < 0.001$). More importantly, there was a direct relationship between increased nail fit and decreased risk of fixation failure. When the size of the nail occupied greater than 70% of the intramedullary canal, there were no cases of fixation failure when using a Gamma nail, irrespective of modified Evans classification or grade of fracture reduction. Moreover in multivariate analysis the fit of the nail was seen to be an independent predictor of successful osteosynthesis, much like the TAD is in preventing screw cut out.

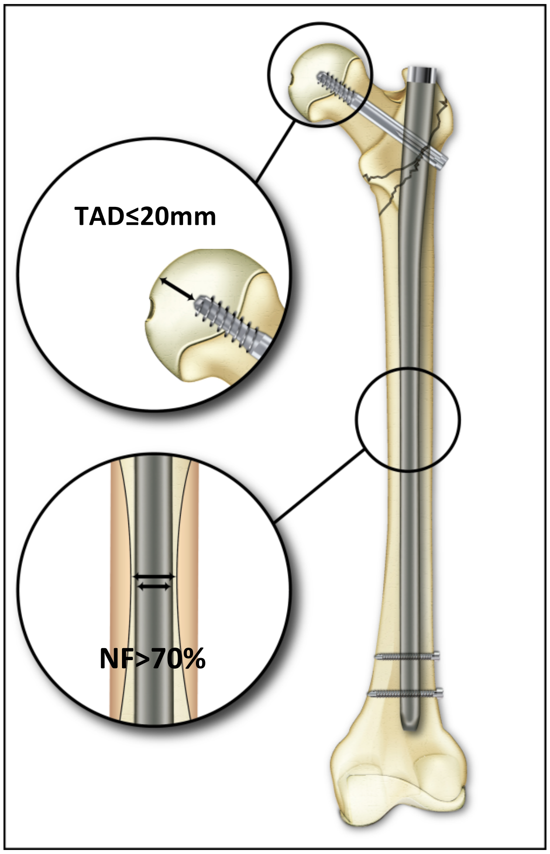

Figure 15: Nail fit –measured as the percentage of the intramedullary canal occupied by the nail at the narrowest point of the intramedullary canal.

A number of reasons may explain why nail fit was seen to be an independent predictor of fixation failure. Firstly the fit of prosthesis is directly related to union when treating fractures of long bones. [65] If the nail is not sized appropriately to the patient's intramedullary canal then a hypertrophic non union can arise by too much fracture micro motion. [66] An interfragmentary strain hypothesis predicts that fracture healing will only occur if the interfragmentary motion divided by the fracture gap width is less than the fracture strain of the bone. [66, 67] In secondary fracture healing movement of the fragments should be kept small (amplitude 0.2-1 mm) and fracture gaps should be < 2 mm. [66] Not surprisingly aseptic non unions are have been reported to be successfully treated in 72 to 100% of cases by simple exchange nailing – that is removing the old nail, reaming the canal to a bigger size and introducing a larger diameter nail to increase fracture stability by decreasing the amount of micro motion at the fracture. [68] In fact all cases of non union seen in our study were due to a nail sized less than 50% of the intramedullary canal, independent of the grade of reduction or modified Evans grade of fracture.

The concept of sizing an implant to fit intramedullary anatomy is a critical concept in arthroplasty. In-growth of a non cemented, press fit implant is directly related to the fit of the implant. [69] Less than 40 microns of micro motion is needed for optimal in-growth of bone on implants. [70] Greater than 150 microns of motion predisposes the implant to fibrous encapsulation. [70] We believe a similar phenomenon occurs during non union of the proximal femur. Excessive micro motion of the intramedullary implant does not allow sufficient stabilization of the distal fragment to the proximal fragments, leading to non union. Moreover use of an IM recon nail that does not fit the intramedullary canal does not maintain adequate fracture reduction, see figure 16. Although IM recon nails have the biomechanical advantage of a shorter lever arm to decrease the tensile strain on the implant and prevent excessive shaft medialization, they need to fit the intramedullary canal to stabilize the distal fragment. Poor intramedullary canal fit when using a nail will compromise fracture reduction, thereby putting undue strain on the nail that can then fail after its repetitive fatigue strength has been exceeded.

Figure 16: Adequate reduction of modified Evans type 5 fracture not maintained due to poor nail fit, leading to medialization of the distal fragment, non union and nail breakage.

Secondly, ensuring fit of the nail to occupy >70% of the intramedullary canal may decrease rotational forces. Previous biomechanical studies have described large rotational moments on the femoral head during gait due to AP forces. [60, 61] This multi planar mechanism of axial loading and rotational moments during gait thereby leads to screw cut out.[62, 63] The fact that cut out of a screw has recently been shown to usually occur in a superior-anterior direction further supports the rotational theory of screw cut out.[64] In modified Evans type 4 fractures there is instability in the greater trochanter, posteromedial calcar, and lateral wall, predisposing not only towards excessive medialization, but also subsequent fixation failure by excessive rotation as there will be no fixation contact points available in the greater trochanter or lateral wall. In fixation of every fracture there is a race between fracture union and fixation failure. If the intramedullary component of an IM recon nail does not provide a secure fixation point the implant can undergo varus tilt as the fracture settles, medializes, and rotates – thereby leading to screw cut out, see figure 17.

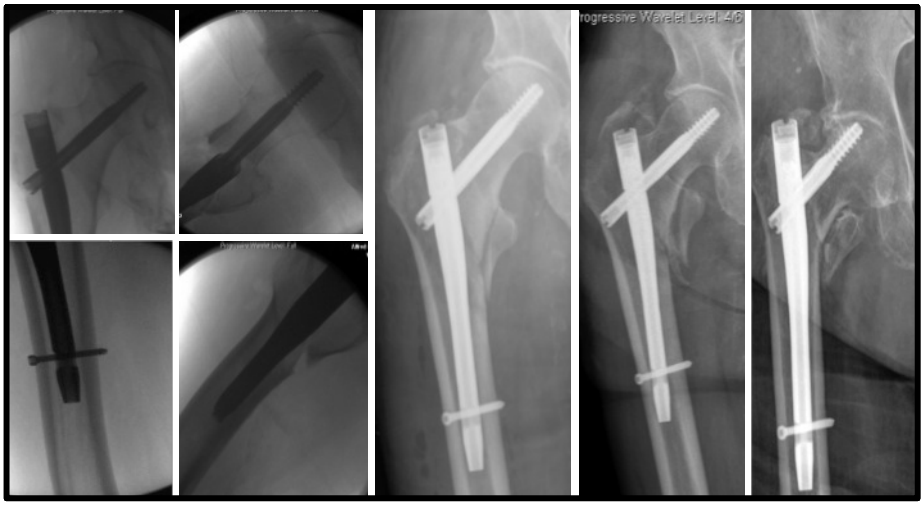

Figure 17: Progressive varus tilt and rotation in short Gamma nail with poor nail fit, leading to progressive varus collapse and screw cut out

It has been shown that increasing the diameter of titanium nails increases their strength and thereby union rate when used as intramedullary devices in paediatric fractures.[59] Indeed the strength of a device is directly proportional to square of the radius. Larger diameter nails have increased fatigue strength.[59] Larger distal diameter Gamma nails of 16 mm and 14 mm seen in 1st generation implants were originally abandoned due the increased rate of intra-operative femoral fracture. In hindsight this higher rate of iatrogenic injury was due more to the fact that 1st generation nails had a lateral curvature of 10 degrees. Larger diameter nails were unable to be inserted because of the ‘three-point loading’ phenomenon. Reverting to one size of 11 mm diameter as a one fix solution for all femurs to ease their insertion means that the intramedullary component does not fit all femurs. The isthmus of the proximal femoral canal has been observed to be 14.09 ± 2.81 mm. [71] With ageing the femur expands and the diameter of medullary canal increases, [72] thereby further predisposing 11 mm diameter Gamma nails to poor intramedullary fit. The fact that there is wide discrepancy in femur anatomy is well recognized and accommodated for in hip arthroplasty. [71] Pre-operative templating in hip arthroplasty has been shown to be crucial in its surgical success. Pre-operative templating in treatment of peri-trochanteric fracture fixation should likewise improve their outcomes. A 3rd generation Gamma nail with a 13 mm distal diameter has recently been introduced into the Australian market. A study investigating the rate success rate incorporating both the 11 mm and 13 mm diameter nails would be interesting to further investigate the concept of nail fit on peri-trochanteric fracture fixation success.

Study Limitations

This study on predictors of fixation failure in peri-trochanteric fractures incorporates a large consecutive series, enabling statistically supported statements. The fact that this study was undertaken at a tertiary referral centre is also a strength of the study as cases that have failed are more likely to referred back to the unit, which regularly performs revision procedures of cases referred by other hospitals where they had undergone their primary procedure. On the other hand, the retrospective nature of this study leads to some limitations caused by loss of follow up, no method of determining seniority of operating surgeon as the facility is a teaching hospital, and inconsistent radiographs.

Conclusion

This study has identified 4 variables associated with increased risk of fixation failure: unstable fracture type, poor fracture reduction, non optimal cephalomedullary screw positioning, and inadequate fit of IM recon nails in the intramedullary canal. These factors are interdependent – unstable fractures may be difficult to reduce which in turn leads to difficulty in achieving correct positioning of implants. Fracture reduction in an acceptable position is a pre-requisite prior to implantation of hardware for successful osteosynthesis. An implant will not reduce a fracture. Never-the-less, the TAD and nail fit have been shown to be predictors of fixation failure. Surgeons confronted with peri-trochanteric proximal femoral fractures should therefore be aware of the difficulties in treating these fractures and their fracture personalities. Every effort should be made to optimize controllable variables of fracture reduction, TAD and the intramedullary fit of the implant whenever possible.

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