Neurovascular structures at risk from proximal locking of retrogade femoral nails

Thesis submitted for-
Degree of M.D., University of Glasgow

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UNIVERSITY
of
GLASGOW

CONTENTS

LEGENDS

DECLARATION

I hereby declare that this thesis has been composed by myself, that it has not been submitted in any previous application for a degree and that the general matter of this thesis is my own general composition.

Preliminary results from this project were read at the annual meeting of the British Association of Clinical Anatomists in December 2000 and this work was awarded the Conrad Lewin prize for the best presentation by a young scientist.

No benefit has been received by the author from any commercial party towards this thesis.

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DEDICATION

I would like to dedicate this work to my late father Abdul Haque who sadly passed away on the 1st of August, 2001 two months prior to the completion of this project, and my mother Zenib Bibi. They have both provided me with support and encouragement throughout my life and given me the desire to work hard.

I would also like to dedicate it to my dear long suffering and neglected wife Shameem, and my sons Shakeel aged 5, Qasim aged 2 and Atif aged 1 year. They have all provided me with tremendous love and hope in my moments of deep despair and given me strength to achieve my goals. For this I love and thank them unreservedly.

FOREWORD

It is with great happiness that I am writing this foreword which marks the end of a period in which I have devoted all my energy to a single project. The idea for this project arose from my first experience of retrograde femoral nailing. The operation (Patient 3, clinical cases) was carried out at Glasgow Royal Infirmary with Mr.P.J.James. The proximal anteroposterior locking was the most difficult and hazardous part of the procedure and resulted in several minutes of profuse sweating as I retracted ' big red, big blue and big white' away from the path of the drill and screws. From this experience arose the idea for this work. For this I am grateful to Mr. P.J.James.

There is a constant emergence of new implants in the management of fractures and it is important to assess these carefully to avoid potential complications with their use. On this note I leave you with the following verses.

As some delight most to behold;
        Each new device and guise,
So some in works of fathers old,
        Their studies exercise.

Perusing with all diligence,
        Books written long before,
Wherein they learn experience,
        To heal both sick and sore.

Which I allow in deed and word,
        In those that understand:
For otherwise it is a sword,
        Put in a mad mans hand.

Laufranke's Chirurgical Works 1565.

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I am extremely grateful to Dr.J.Shaw-Dunn for his constant advice, encouragement and never ending enthusiasm throughout the project. Without his support this project would almost certainly have come to an impromptu and premature end!!!

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My own skills of photography are restricted to ' point and shoot ' cameras and I am very thankful to Mr.A.Lockhart of the University of Glasgow Anatomy Department for help with the high quality digital photographs illustrated in the thesis.

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PREFACE

Femoral shaft fractures are caused by high-energy forces violent enough to fracture the strongest bone in the body. They can lead to 2 to 3 units of blood loss and approximately 40% of patients with an isolated femoral shaft fracture have an average transfusion requirement of 2.5 units of red cells (Lieurance et al 1992).

Femoral fractures can be both limb and life threatening and frequently occur in patients with multiple injuries (Bone at al 1989, Taylor et al 1994). The commonest causes are motor vehicle accidents, automobile-pedestrian accidents, falls from a height, or plane crashes. Approximately one fracture per week is seen in a large teaching hospital in the UK such as Glasgow Royal infirmary.

In the past femoral shaft fractures were virtually always treated by closed manipulative reduction and traction. This was sufficient to achieve and maintain gross anatomical realignment of the limb, but some deformity was inevitable.

Around the time of the second world war Küntscher introduced the technique of intramedullary nailing, which is now the treatment of choice for virtually all femoral shaft fractures (Kuntscher Küntscher 1965 , Kuntscher Küntscher 1968).

The ease and safety of the procedure has been greatly increased by the use of portable fluoroscopy equipment. Recent studies have shown that regardless of the severity of the patient's injury, fractures treated with intramedullary nailing had a significantly lower mortality rate and shorter length of stay in hospital than those treated by conservative methods (Fakhry et al 1994).

Conventional intramedullary femoral nailing involves insertion of an orthopaedic nail in an antegrade or downward manner from the greater trochanter at the proximal end of the femur (Hooper and Lyon 1988, Rothwell 1982, Winquist et al 1984). Interlocking screws are inserted across the femur and through the intramedullary nail at intervals using image intensification. These locking screws prevent both axial and rotational movement between the femur and nail. There are a number of drawbacks to the technique such as the risk of femoral neck fracture (Christie and Court-Brown 1988) and heterotopic ossification around the greater trochanter (Brumback et al 1988).

More recently, an alternative method for intramedullary femoral nailing has emerged and this has grown in popularity, particularly in the USA (Sanders et al 1993). This involves insertion of the femoral nail in a retrograde direction from the intercondylar fossa of the femur across the fracture site to the level of the lesser trochanter and avoids some of the complications associated with conventional nailing.

The Richards retrograde femoral nail (Smith & Nephew 1997) is one of a series of implants, designed specifically for this purpose. It is inserted into the medullary canal of the femur via an entry point in the intercondylar fossa, just anterior to the anterior cruciate ligament. This particular implant requires insertion of both proximal and distal interlocking screws for maximal axial and rotational stability.

The distal screws are inserted lateral to medial in a relatively safe area of the lower thigh using an external guide. The proximal locking screws by contrast are inserted 'freehand' at the level of the lesser trochanter in an anteroposterior direction using X-

To test this hypothesis we propose to;

4). Plan dissections to compare lateral to medial locking with anteroposterior locking, for use with a redesigned nail.

5). Finally we proposed a modified clinical trial of the redesigned nail. This would involve attaching the redesigned nail to the side of a volunteer's thigh and taking X-Rays in theatre to determine whether the redesigned nail could be adequately screened to allow its use in practice.

Section 1

PRINCIPLES OF FRACTURES

History

Humans have never been immune from injury, and the practice of bone setting was familiar to our most primitive ancestors. The earliest examples of the active management of fractures in humans were discovered at Naga-ed-Der (about 100 miles north of Luxor in Egypt) by Professor G.Elliot Smith during the Hearst Egyptian expedition of the University of California in 1903 (Browner et al 1998). Two specimens were found of splinted extremities. One was an adolescent femur with a compound comminuted midshaft fracture that had been splinted with four longitudinal wooden boards, each wrapped in linen bandages. A dressing pad covered in blood pigment was also found at the level of the fracture site. The victim is judged to have died shortly after injury, as the bones showed no evidence whatsoever of any healing reaction.

The second specimen was of open fractures of a forearm, treated by a similar method, but in this case a pad of blood-stained vegetable fibre (probably obtained from the date palm) was found adherent to the upper fragment of the ulna, evidently having been pushed into the wound to staunch bleeding. Again death appears to have occurred before any healing reaction had started (Browner at al 1998).

The Egyptians were known to be skilled at the healing of fractures and many healed specimens have been found. The majority of femoral fractures had united with shortening and deformity, but numbers of well-healed forearm fractures have been discovered.

Fractures

A fracture is a break in the structural continuity of bone. It may be a simple crack, a crumpling or a splintering of the cortex; more often however, the break is complete and the bone ends are displaced. If the overlying skin remains intact it is a closed (or simple) fracture; if the skin or one of the body cavities is breached it is an open (or compound) fracture; these are liable to contamination and infection.

Mechanism of fractures

Bone is a relatively brittle structure, yet it has sufficient strength and resilience to withstand considerable stress (Apley and Solomon 2001). Fractures result from:

1) A single traumatic incident.
2) Repetitive stress.
3) Abnormal weakening of the bone (a pathological fracture).

The majority of fractures are due to sudden and excessive force, which may be tapping, crushing, bending, twisting or pulling. With a direct force the bone breaks at the point of impact; the soft tissues are also damaged. Tapping (a momentary blow) usually results in a transverse fracture and damage to the overlying skin; crushing is more likely to cause a comminuted fracture associated with extensive soft-tissue damage.

When an indirect force is applied the bone usually breaks at a distance from where the force is applied; soft-tissue damage at the fracture site is not always present. The force may be

1) Twisting; which causes a spiral fracture

2) Bending; which causes a transverse fracture

3) Bending and compressing; which results in a fracture that is partly transverse but with separate triangular 'butterfly' fragment

4) A combination of twisting, bending and compressing, which causes a short oblique fracture.

5) Pulling; in which a tendon or ligament literally pulls the bone apart.

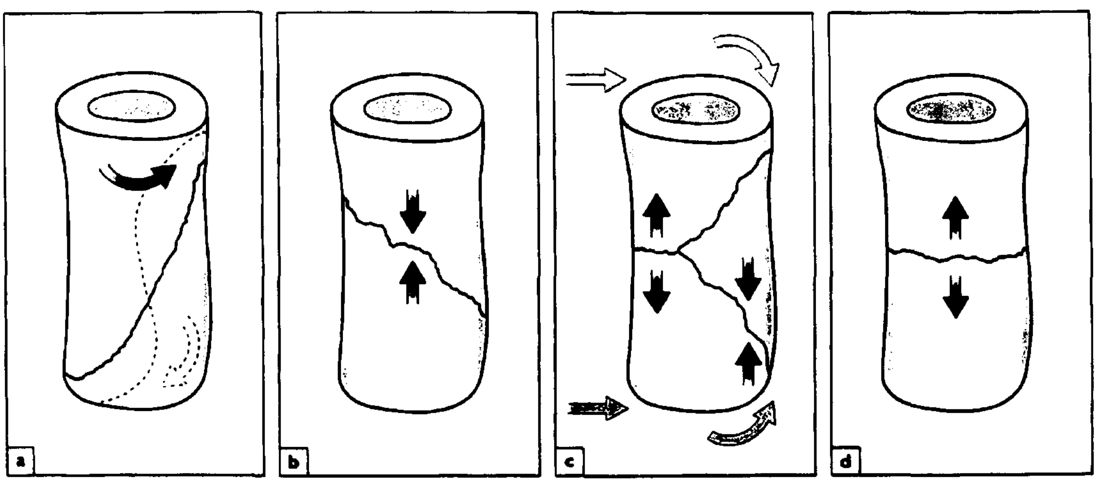

Fig.1.1 Mechanisms of injury. Apley and Solomon, 2001.

The above description applies mainly to the long bones. Cancellous bones, such as a vertebra or the calcaneum, when subjected to sufficient force, sustain a comminuted crush fracture. In some situations such as the knee or elbow, resisted extension may cause an avulsion fracture of the patella or olecranon; and in a number of situations resisted muscle action may pull off the bony attachment of the muscle.

Fatigue or stress fractures

Repetitive stress can lead to cracks developing in bone. Common sites include the tibia, fibula, or the metatarsals. This is seen especially in athletes, dancers and army recruits who go on long route marches.

Pathological fractures

Fractures may occur even with normal stresses if the bone has been weakened (e.g. by tumour) or if it is excessively brittle (e.g. in Paget's disease).

Types of fracture

Fractures are infinitely variable in appearance but for practical reasons they are divided into a few well defined groups (Apley and Solomon 2001).

Complete fractures

In a complete fracture the bone is broken into two or more fragments (Fig.1.2). If the fracture is transverse, the fragments usually remain in place after reduction. If the fracture is oblique or spiral it is less stable and tends to slip and redisplace even if the bone is splinted. In an impacted fracture the fragments are jammed tightly together and the fracture line is indistinct. A comminuted fracture is one in which there are more than two fragments; there is poor interlocking of the fracture surfaces and as a result these lesions are often unstable.

Incomplete fractures

Here the bone is incompletely divided and the periostium remains in continuity (Fig.1.2). In a greenstick fracture the bone is buckled or bent (like snapping a green twig); this is seen in children, whose bones are more elastic than those of adults. Greenstick fractures are easily reduced and heal quickly. Compression fractures occur when cancellous bone is crumpled. This happens in adults, especially in the vertebral bodies. Unless operated upon, reduction is impossible and some residual deformity is inevitable.

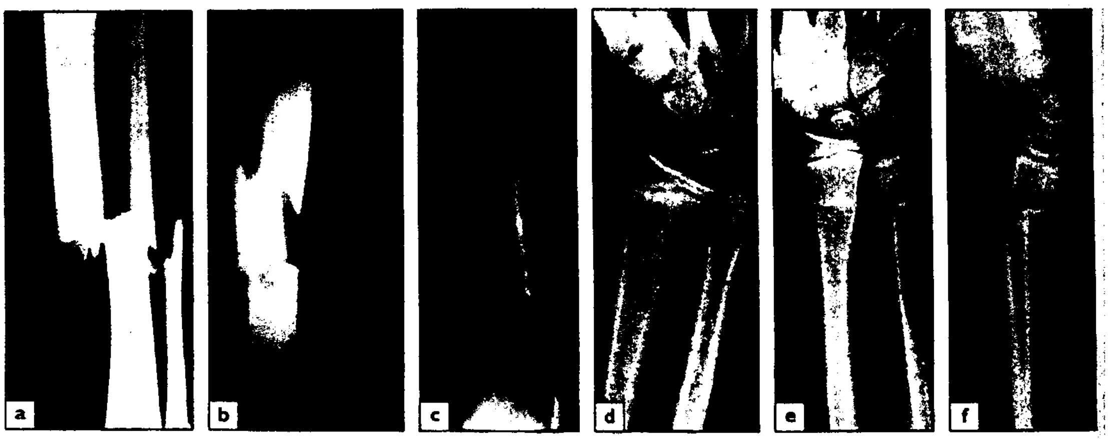

Fig.1.2 Varieties of fractures. Complete fractures: (a) transverse; (b) segmental; (c) spiral. Incomplete fractures: (d) buckle or torus; (e,f) greenstick. Apley and Solomon, 2001.

Classification of fractures

An alphanumeric classification of fractures, which can be used for computer storage and retrieval, has been developed (Muller et al 1991, Fig.1.3). The first digit specifies the bone:

1= Humerus

2= Radius / Ulna

3= Femur

4= Tibia / Fibula

and the second digit the segment

1= Proximal

2= Diaphyseal

3= Distal

4= Malleolar

A letter specifies the type of fracture

A= Simple

B= Wedge

C= Complex, for proximal fractures, and

A= Extra-articular

B= Partial articular

C= Complex articular, for distal fractures.

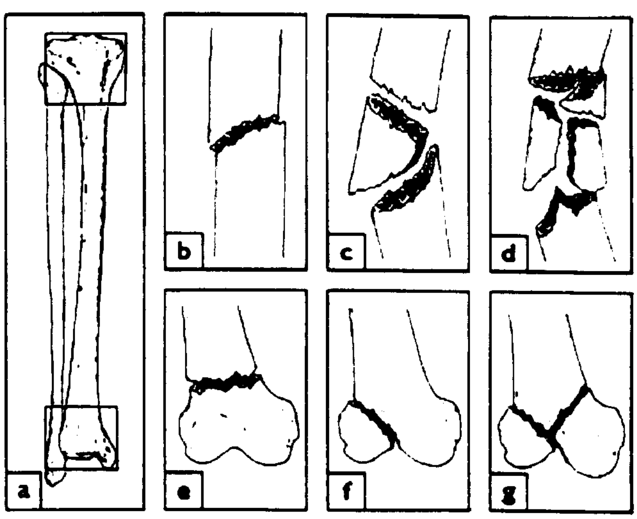

Fig.1.3 Mullers classification. (a) Each long bone has three segments- proximal, diaphyseal and distal; the proximal and distal segments are each defined by a square based on the widest part of the bone. (b,c,d) Diaphyseal fractures may be simple, wedge or complex. (e,f,g) Proximal and distal fractures may be extra-articular, partial articular or complete articular. Apley and Solomon, 2001.

Two further numbers specify the detailed morphology of the fracture. Although this classification system is comprehensive, there are reservations about its complexity and its reproducibility (Schipper et al 2001, Wainwright et al 2000). 'Tailored' classifications for specific fractures may be more useful for assessing prognosis and planning treatment (Blundell et al 1998).

How fractures are displaced

If a fracture is complete the fragments usually become displaced (Fig.1.4). This is usually due to a combination of factors; the force of the injury, partly by gravity and partly by the action of muscles attached to them. Displacement is usually described in terms of translation, alignment, rotation and altered length (Apley and Solomon 2001, Browner at al 1998).

Translation (shift)

The fragments may be shifted sideways, backwards or forwards in relation to each other, such that the fracture surfaces lose contact. The fracture will usually unite even if the ends are not perfectly apposed and indeed even if the bone ends lie side by side with the fracture surfaces making no contact at all.

Alignment (angulation)

The fragments may be tilted or angulated in relation to each other. Malalignment, if uncorrected, may lead to deformity of the limb.

Rotation (twist)

One of the fragments may be rotated on its longitudinal axis; the bone looks straight but the limb ends up with a rotational deformity.

Length

The fragments may be distracted and separated, or they may overlap, due to muscle spasm, causing shortening of the bone.

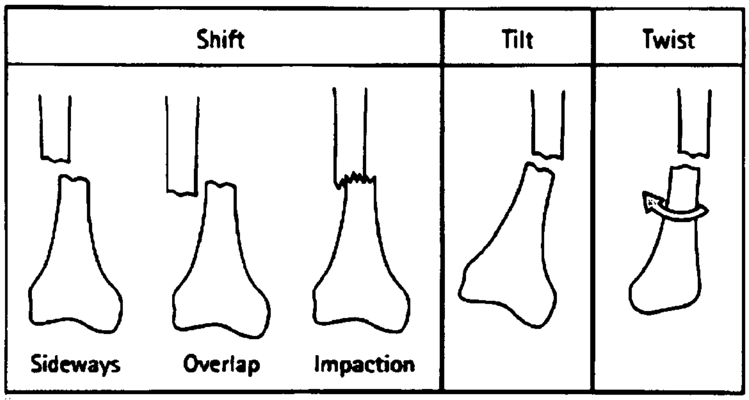

Fig.1.4 Fracture displacements; The different types of fracture displacements. Apley and Solomon, 2001.

Fracture healing

The process of fracture repair varies according to the type of bone involved and the amount of movement that takes place at the fracture site. In a tubular bone, and in the absence of rigid fixation, healing proceeds in five stages (Apley and Solomon 2001, McKibbin 1978, Fig.1.5).

1.Tissue destruction and haematoma formation

2.Inflammation and cellular proliferation

3.Callus formation

4.Consolidation

5.Remodelling

Contrary to popular belief, for a fracture to unite, complete immobilisation is not needed and may be detrimental.

Callus forms from the ends of a bone when a fracture occurs. This is termed the primary callus response and appears to be a very fundamental response of the bone to injury. This response is however short lived and finite. If bony contact between the bone ends is not made it will peter out. Because the response is finite, bridging of the fragments may not result from its activity alone (McKibbin 1978).

The bone then enters the phase of bridging external callus formation. This is a rapid process which involves widespread cellular activity between the bone fragments. Callus orientates itself towards the opposite bone fragment and this process leads to fracture union.

This part of the process is very dependant on mechanical factors and may be suppressed by rigid immobilisation (Anderson 1965, Schenk and Willenegger 1967). This suggests that its primary purpose is the arrest of movement between the two fragments. If satisfactory bridging of the fracture fragments is achieved, movement is arrested and the remodelling process can then proceed.

If the fracture is treated under circumstances of extreme mechanical rigidity then the process becomes profoundly altered (Anderson 1965, Schenk and Willenegger 1967). External bridging is suppressed and the healing is dependent on the activity of medullary callus and direct osteonal penetration. In this situation the dead ends of the bone are not resorbed but are recanalised by new Haversian systems, and where the fragments are in contact these systems actually cross from one fragment to the other. This process is termed primary bone healing (Schenk and Willenegger 1967).

Three examples of healing are illustrated in Fig.1.6. In (a) the fracture has been stabilised with a tightly fitting nail which prevented any movement and at 6 weeks there is little callus visible.

In (b) the femoral fracture has been stabilised by a nail which fitted loosely, permitting some movement and there is callus formation. In (c) the patient had cerebral irritation and thrashed about wildly; at 3 weeks there is excessive callus formation.

This shows that it is not mandatory for the surgeon to impose fracture immobility artificially- Nature can do this, with callus, and callus forms in response to movement, not to splintage (McKibbin 1978).

Fractures can unite by a number of different methods and we splint most fractures, not to ensure union but

1) To alleviate pain
2) To ensure that union takes place in a satisfactory position, and
3) To permit early movement and return to function.

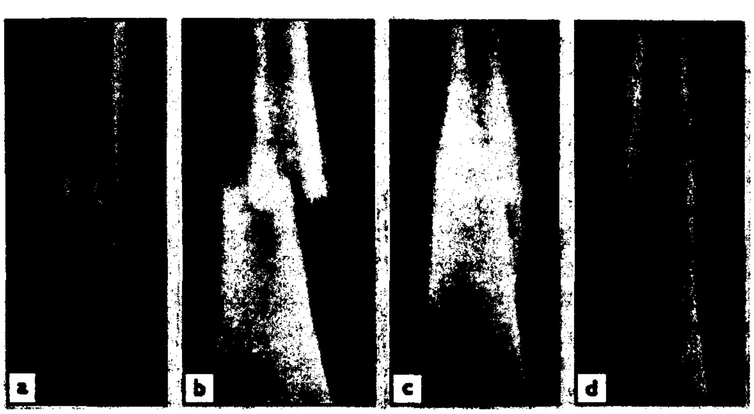

Fig.1.5 Fracture repair. (a) fracture; (b) union; (c) consolidation; (d) bone remodelling. The fracture must be protected until it has consolidated. Apley and Solomon, 2001.

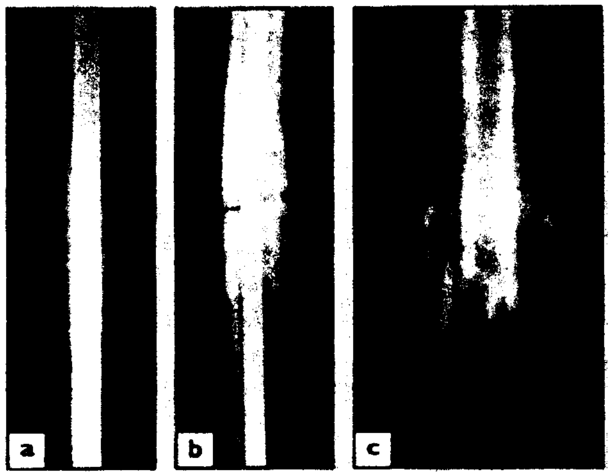

Fig.1.6. Callus and movement: (a) tightly fitting nail; (b) loosely fitting nail; (c) excessive fracture movement. Apley and Solomon , 2001.

FEMORAL SHAFT FRACTURES

Background

The femur is a long tubular bone that extends from the hip to the knee. It is not only the strongest but also the heaviest bone in the body. The femur consists of the three distinct parts: the shaft, or diaphysis, and two ends- a proximal and a distal metaphysis. The proximal metaphysis consists of the head of the femur, the neck of the femur and the greater and lesser trochanters (Fig.2.1). The distal femur consists of the distal metaphysis and the knee joint.

The shaft, or diaphysis, of the femur extends from the level of the lesser trochanter to the flare of the condyles. The femoral shaft is slightly bowed anteriorly (Fig.2.1) and is narrowest in the midshaft (Yoshioka et al 1987).

Its cross section is approximately circular except for a broad ridge of bone, the linea aspera, running down the middle of its posterior surface (Fig.2.1). The linea aspera is the attachment for many muscles, including the gluteus maximus, adductor magnus, adductor brecis, vastus lateralis, vastus medialis, vastus intermedius, and short head of biceps (Netter 1987).

Other muscles originate and insert proximally and distally on the femur. Large muscles (gluteus medius and minimus) attach to the greater trochanter. Several muscles attach on the distal femur with the large adductor muscle mass inserting on the distal medial aspect of the femur.

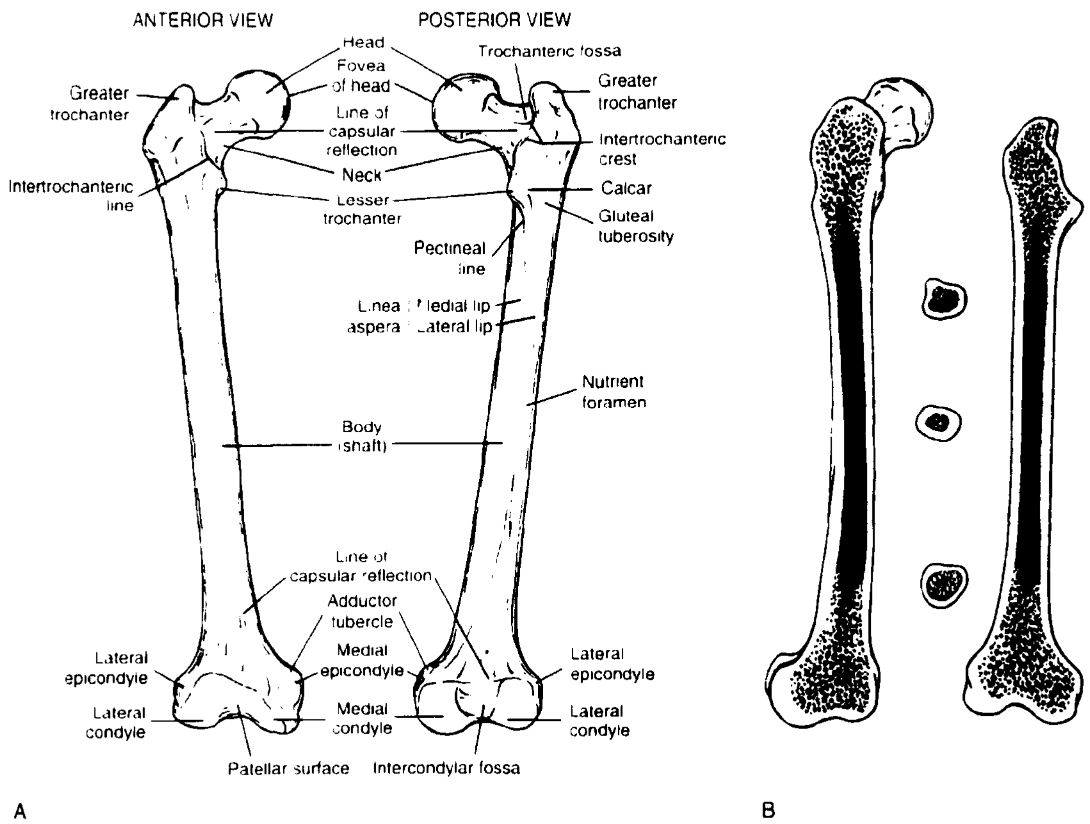

Fig.2.1 Femoral shaft with metaphysis, diaphysis, isthmus and shape of intramedullary canal.

The major function of the femur is as a structure for standing and walking. The best design for strength, particularly for axial loading and bending, is a tubular structure. The intramedullary canal of the femur is essentially trumpet shaped, opening both proximally and distally (Sofield 1951).

The blood supply of along bone usually enters the bone via metaphyseal arteries (Brookes et al 1961, Laing 1953). In addition the femur usually has a single nutrient artery that branches off the profunda femoris artery to penetrate the upper half of the diaphyseal cortex, close to the linea aspera.

The nutrient artery forms medullary arteries in the intramedullary canal that extend proximally and distally (Rhinelander 1968).

The superficial femoral artery and the profunda femoris artery surround the femur (Netter 1987). The profunda femoris artery branches off the main femoral artery just distal to the femoral head and runs distally along the posterior aspect of the femur. This artery sends a perforating branch to the proximal half of the femur as the nutrient artery to the femoral shaft.

The profunda femoris artery also sends penetrating arteries through the intramuscular septum to supply muscles that lie along the lateral side of the femur (Fig.2.2). The femoral artery enters the thigh under the inguinal ligament and courses down the medial border of the thigh.

The sciatic nerve and femoral nerve course through the thigh. The femoral nerve enters the thigh under the inguinal ligament and supplies the quadriceps femoris muscle. The sciatic nerve enters the thigh posteriorly under the piriformis muscle and is well protected from the bone by muscle as it runs through the thigh.

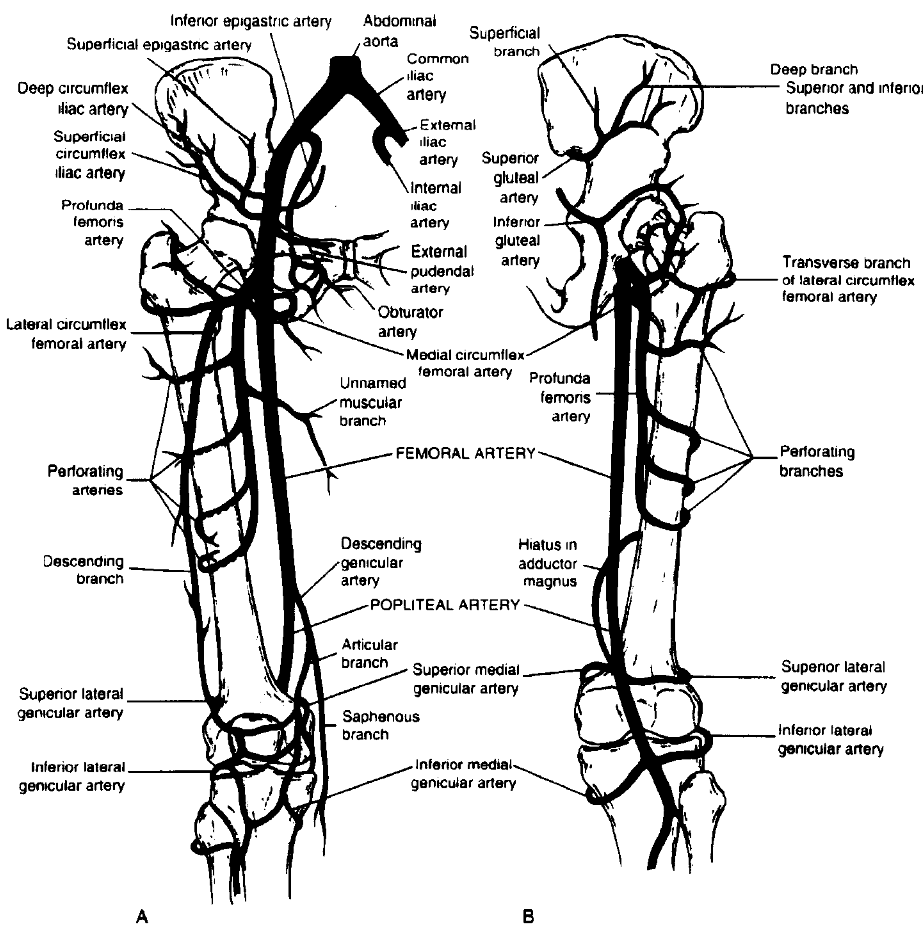

Fig.2.2 Blood supply to the thigh (AP cross section). A, Anterior view. B, Posterior view.

Incidence

Fractures of the femur, exclusive of hip fractures, occur at a rate of approximately 1 fracture per 10,000 people per year (Grazier et al 1984, Salminen et al 2000). The injury is more common in those younger than 25 years and older than 65 years. The incidence in these groups of patients is approximately 3 fractures per 10,000 persons. Femoral fractures result in restricted activity for an average of 107 days, with 69 of those days spent in bed. An average loss of 30 days from work or school has been reported (Grazier et al 1984). Currently the average length of stay in an most Glasgow teaching hospitals is approximately 10 days. This was before routine internal fixation of these fractures and has reduced since then. A similar incidence of 1.33 fractures per 10,000 population was found by Fakhry et al (1994).

According to studies from England and Scandinavia, the incidence of femoral shaft fractures in the elderly is increasing (Moran et al 1990, Partridge and Evans 1982). These fractures are commonly the result of low- to moderate-energy trauma. This increased incidence of fracture in the elderly can only partly be explained by the increased number of elderly persons in the general population.

Mechanism of Injury

Femoral shaft fractures are usually the result of major trauma. The cause of injury is often motorcar, motorcycle, or bicycle accidents and gunshot wounds (in the USA). Prehospital care (Border et al 1975) and resuscitation in the hospital have improved so that a larger number of severely injured patients survive injuries that would previously have been fatal (Bone et al 1989, Johnson et al 1985).

Gunshot fractures are different from those caused by blunt trauma. Low-velocity handgun and rifle injuries generally do well with minimal soft tissue debridement and routine fracture stabilization (Hollman and Horowitz 1990).

Table 1. Open Fracture Classification According to Gustilo (Gustilo et al 1984).

Type I	An open fracture with a clean wound less than 1 cm long.
Type II	An open fracture with a laceration more than 1 cm long without extensive soft tissue damage, flaps, or avulsions.
Type IIIA	Adequate soft tissue coverage of a fractured bone despite extensive soft tissue laceration of flaps, or high-energy trauma regardless of the size of the wound.
Type IIIB	Extensive soft tissue loss with periosteal stripping and bone exposure, usually associated with massive contamination.
Type IIIC	Open fracture associated with arterial injury requiring repair.

High-velocity rifle injuries and close-range shotgun blasts should be considered type IIIB or IIIC open fractures (Table 1). The above classification of open fractures is universally used.

Fracture patterns vary according to the direction and quantity of force absorbed and can be classified according to Winquist's classification (Winquist and Hansen 1980, Fig.2.3). A direct force applied perpendicular to the axis of the bone produces a transverse or short oblique fracture with local soft tissue trauma. A force applied to the femur in an axial direction may injure the hip or knee.

Elderly patients tend to sustain this fracture as a result of a rotational force, which creates a long oblique or spiral fracture with minimal comminution (Taylor et al 1994). The amount of comminution at the fracture site increases directly with the amount of energy absorbed by the femur at the time of injury (Browner at al 1998).

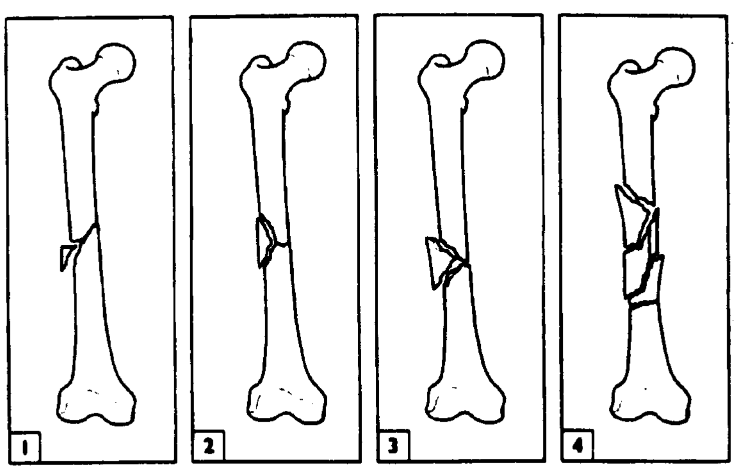

Fig.2.3 Femoral shaft fractures-classification. Winquists Classification reflects the observation that the degrees of soft tissue damage and fracture instability increase with increasing grades of comminution. In type 1 there is only a tiny cortical fragment. In type 2 the 'butterfly fragment' is larger but there is still at least 50% cortical contact between the main fragments. In type 3 the butterfly fragment involves more than 50% of the bone width. Type 4 is essentially a segmental fracture. Winquist and Hansen 1980.

Commonly Associated Injuries

Nerve Injuries

Peripheral nerve injuries associated with femoral shaft fractures are uncommon (Takami et al 1999) . The sciatic nerve is well protected by surrounding soft tissue situated between it and the femur. Extreme fracture displacement needs to occur before nerve injury is likely. Sciatic nerve injuries are seen due to direct, penetrating trauma (e.g. a gunshot wound or laceration). Femoral nerve injuries are similarly uncommon and the incidence has been reported as approximately 0.002% (Kluger et al 1994) Most neurological injuries associated with femoral shaft fractures arise from difficulties or problems with treatment rather than with the injury itself.

Vascular Injuries

Vascular injuries associated with femoral shaft fractures are also uncommon. The incidence is stated at approximately 0.1 to 2% of fractures (Cone 1989, Iannocone et al 1994, Kluger et al 1994). Although the commonest vascular injury reported is an intimal flap tear of the superficial femoral artery (Kluger et al 1994) injury to the profunda femoris has also been reported (Owers et al 1999)

The consequences of associated arterial injuries can be extremely serious and limb vascularity must be assessed carefully for all femur fractures. Blunt trauma resulting in a fracture of the distal femoral shaft can tear the femoral artery at the level of the adductor canal (Fig.2.4). This is the commonest site of injury to the artery as it is tethered by local soft tissue structures at this point. This may be an intimal tear with initially normal pulses followed by delayed occlusion of the artery (Porter 1968). Distal pulse pressures should be measured. Pressures lower than 0.9 times that of the upper extremities require further investigations such as angiography. This may be delayed (up to 24 hours) if distal pulses are present and the patient's vascular status can be closely monitored.

The management of arterial injuries is dependent on the degree of vascular insufficiency and the amount of time elapsed since injury. If the distal limb is clearly viable, the femoral shaft fracture should be stabilized initially and an arteriogram obtained thereafter. When there is clearly a problem with arterial supply, satisfactory arterial flow must be re-established within 6 hours if the limb is to be revived (Ashworth et al 1988).

Fig.2.4 Arteriogram shows a fracture of the distal third of the femur with an associated femoral artery injury at the level of the fracture. Browner at al, 1998.

When acute ischaemia of the lower extremity is associated with a femoral shaft fracture, a four-compartment fasciotomy of the lower leg may be performed along with arterial repair to prevent distal compartment syndrome in the calf resulting from reperfusion of ischaemic tissue (Connolly et al 1971). This includes virtually all cases of acute femoral arterial repair. Whenever the femoral artery injury is repaired, accompanying major venous injuries should be repaired as well. Sciatic nerve injuries in conjunction with arterial injury are generally caused by ischaemia, contusion, or stretching and seldom require exploration or surgical repair (Fried et al 1978).

Skeletal Injuries

Several musculoskeletal injuries are commonly seen in association with femoral shaft fractures. Proximal femoral injuries (femoral neck or intertrochanteric fracture), as well as hip dislocation, may occur. Such injuries are more common in patients with multiple injuries (Barquet et al 1987). It is important to be aware that the femur may be injured at more than one level. Imaging of femoral shaft fractures must include the entire femoral shaft as well as the hip and knee joints (Fig.2.5).

The femoral neck must be assessed with an AP radiograph of the pelvis and an adequate, lateral view of the femoral neck. Associated femoral neck fractures are missed in up to 30% of cases (Friedman and Wyman 1986, Swiontowski et al 1984, Swiontowski 1987). This is extremely important as failure to diagnose this injury and treat it appropriately increases the risk of avascular necrosis or non-union of the femoral neck.

Fig.2.5 Fracture of the femur associated with a femoral neck fracture (A and C). A Thomas splint ring obscures the view of the neck (B). An AP radiograph of the distal aspect of the same femur shows a fracture of the proximal tibia (B). Browner at al, 1998.

Knee injuries have been reported to occur in association with femoral shaft fracture in 15 to 55% of cases (Swiontowski 1987, Vangness et al 1993). Many patients with femoral shaft fractures have an ipsilateral knee effusion, which is suggestive of a major knee ligament injury. It is difficult to assess knee function and knee ligaments in the presence of an unstable femoral shaft fracture. Once fracture stability has been achieved by surgical treatment or fracture union, the ligaments of the knee can be examined.

The most appropriate time for assessment of the knee is on the operating room table immediately after femoral shaft fracture stabilisation. Appropriate treatment as necessary can then be carried out for knee ligament injuries. An arthroscopic examination of the knee performed in patients with femoral shaft fractures revealed a meniscal tear in 13 of 47 patients (Vangness et al 1993). A second study of 40 patients found significant injuries in 55% of the knees. Forty-eight percent had a partial and 5% a complete anterior cruciate ligament tear; 5% had a partial and 2.5% a complete posterior cruciate ligament tear; 12% had a medial meniscus injury; and 20% had a lateral meniscus tear (DeCampos et al 1994).

Ipsilateral tibial fractures are occasionally seen in conjunction with femoral shaft fractures. This injury pattern, the so-called floating knee (Fig.2.6), is suggestive of multiple injuries elsewhere (Johnson et al 1985, Karlstrom and Olerud 1977). This injury combination requires stabilisation of both the femoral shaft and tibial fractures to improve the final result and is one of the main indications for retrograde femoral nailing. Failure to stabilise either the femur or tibia can disturb knee function to an unacceptable degree. All patients with such fractures should be examined for multiple injuries because of the high frequency of injury to other body regions (Johnson et al 1985).

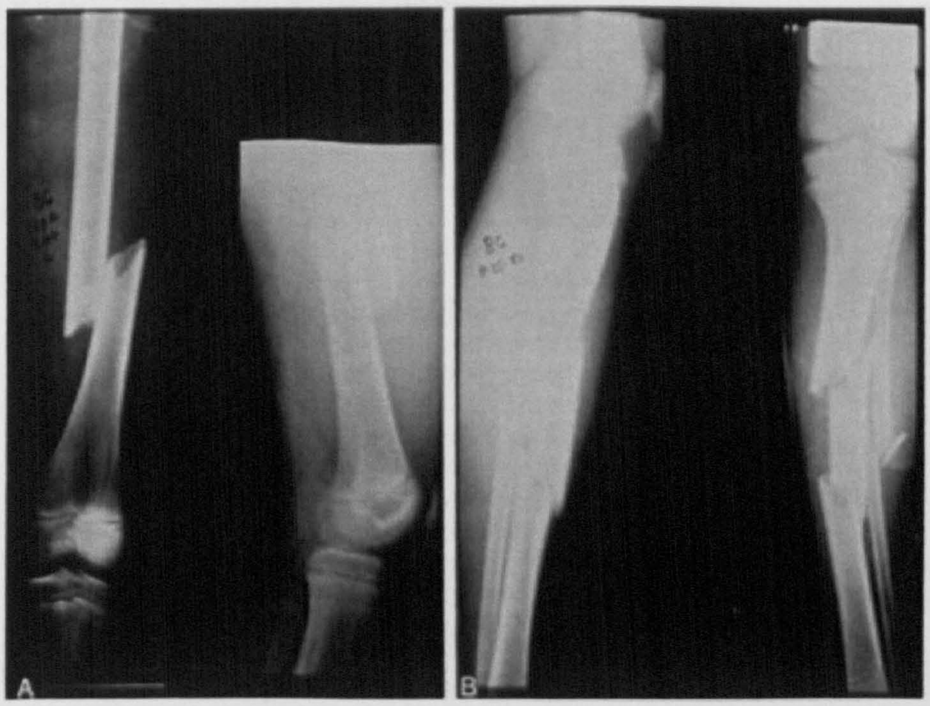

Fig.2.6 X-Ray of a 'floating knee'. Browner at al, 1998.

Open Fractures

Open femoral shaft fractures are seen regularly in trauma unit patients. In Winquist and co-workers' classic study of femoral shaft fractures from Harborview Medical Center in Seattle, open fractures occurred in approximately 16.5% of the 520 femoral shaft fractures treated (Winquist et al 1984). Of the 86 open fractures, 76 (88.4%) were type I open fractures (small skin wound with minimal or no stripping of soft tissue from bone). Although patients with open femoral fractures may have only small skin lacerations, the deep soft tissue injury can be significant (Lhowe and Hansen 1988).

METHODS OF FRACTURE STABILISATION

History of femoral shaft fracture management

Femoral shaft fractures were usually managed by closed methods until 1940. Non-operative treatment of these injuries involved closed reduction and traction as necessary to achieve and maintain gross anatomic realignment of the limb, accepting some deformity as inevitable. The limb was immobilised using a variety of different materials, historically including plaster, wood or bamboo splints, fabric stiffened with wax, and embalmer's fabric stiffened with gum. When plaster-of-Paris-impregnated gauze was developed in 1852 by Mathysen, it became the material of choice for immobilisation for fractures stable enough to be removed from traction (Mooney and Claudi 1975).

With the advent of radiographs in the late 1890s, it became apparent that simple, gross reduction and immobilisation of the fracture were not adequate for this injury. Consecutive femur fractures treated with Buck's skin traction at the University of Pennsylvania had an unsatisfactory result in 100% of cases (Browner at al 1998).

In the early 1900s, efforts were directed toward finding better ways to apply longitudinal traction to the femur to realign it and maintain length. Skeletal traction was devised for femoral fractures by Steinmann and Kirschner, both of whom developed techniques using pins or wires inserted into the femur to apply stronger longitudinal traction. This technique has been used with only minimal changes since the early 1900s.

The Thomas splint, developed in the late 1800s by Thomas in Great Britain, allowed for early ambulatory care of patients with femur fractures. It has been used for fractures of the femoral shaft since then. Only minimal modifications in the splint have been made since Thomas's original innovation. It has been used worldwide in conjunction with skeletal traction techniques.

A major advance in the care of femoral shaft fractures occurred in 1940 with the first nailing by Küntscher (Kuntscher Küntscher 1965). Although IM nailing had been attempted sporadically in the care of long bone fractures, it had not been generally accepted. With Küntscher's initial report in 1940 and subsequent experience, the trend began to change from non-operative to operative treatment of femoral shaft fractures (Bohler Bohler 1968). Excellent results of IM nailing were noted in 1945 when prisoners of war treated in Germany began returning to North America. This stimulated intense interest in the surgical treatment of femoral shaft fractures.

Various surgical techniques were tried, including Küntscher's technique of closed reduction and IM nailing (Bohler Bohler 1968, Burwell 1971), open reduction and IM nailing using various other designs of nails, and open reduction and internal fixation with plate and screws (Brav 1957, Fisk 1944, Huckstep 1972, Schneider 1968). As experience has been gained with various other forms of surgical treatment, including newer IM nail designs and plates, most orthopaedic surgeons have returned to Küntscher's original technique of closed reduction and IM nailing, using nails that remain similar to his original hollow cloverleaf-cross section nail (Clawson et al 1971, Klemm and Borner Borner 1986).

Femoral Fracture Stabilisation

Treatments currently described for femoral shaft fractures include (1) skeletal traction followed by cast brace application, (2) external fixation, (3) application of a compression plate with bone grafting and (4) closed IM nailing (Browner at al 1998).

Skeletal Traction

Skeletal traction is the most long-standing treatment of femoral shaft fractures (Buxton 1981, Peltier 1968). In an attempt to return the lower limb to its normal alignment, longitudinal traction with fracture immobilization using splints has been used since the time of the ancient Egyptians and Hippocrates.

Skeletal traction remains a common method for treating femoral shaft fractures throughout the world. Many orthopaedic surgeons use skeletal traction to immobilize femoral fractures before closed IM nailing. Virtually any closed or open femoral shaft fracture can be encouraged to heal with this mode of treatment. Skeletal traction as definitive treatment is however generally reserved for less-sophisticated medical communities and Third World nations where modern facilities and surgical care are not readily available (Johnson and Greenberg 1987).

Traction can reduce and hold most fractures in reasonable alignment, except those in the proximal third of the femur. Joint mobility can be maintained by active exercises. The main indications for traction are:

1. Fractures in children
2. Contra indications to anaesthesia and

3. Lack of suitable skills or facilities for internal fixation.

It is a poor choice for elderly patients, for pathological fractures and for those with multiple injuries (Browner at al 1998).

For femoral shaft fractures in children a number of management options are available. Skin traction without splintage is usually applied initially (Apley and Solomon 2001). Infants under 12 kg in weight are most easily managed by suspending the lower limbs from overhead pulleys (gallows traction), but no more than 2 kg in weight should be used and the feet must be checked frequently for circulatory problems (Fig.3.1). Older children are best suited to Russell's traction. A variable period in traction (approximately 5-10 days) can then be followed by the application of a spica cast which is retained until the fracture has united. An alternative method which is gaining in popularity is to use a flexible intramedullary nail.

Fracture union occurs within 2 to 4 weeks (depending on the age of the child) and at that stage a hip spica is applied and the child is allowed up. Consolidation is usually complete by 6 - 12 weeks.

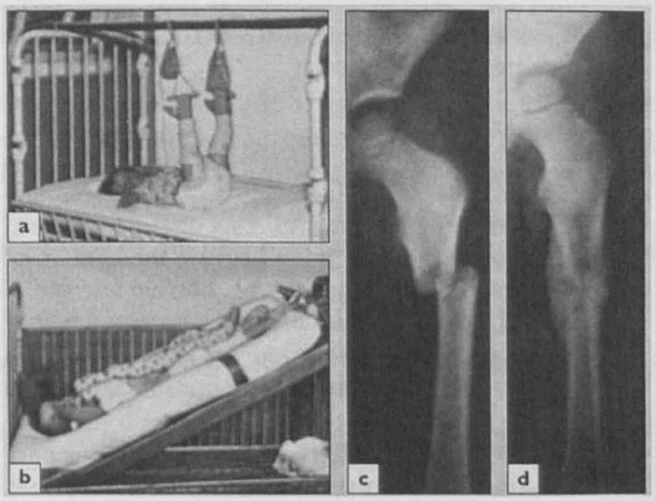

Fig.3.1 Femoral shaft fractures in children (a-d). Traction without a splint is certainly adequate in children, and skin traction is often sufficient. Apley and Solomon , 2001.

Skeletal traction technique

Adults (and older adolescents), require skeletal traction through a pin or tightly strung Kirschner wire behind the tibial tubercle or distal femur (Fig.3.2). Traction (between 8-10 kg for an adult) is applied over pulleys at the foot of the bed and the limb is usually supported on a Thomas splint. A flexion piece allows movement at the knee. However, a splint is not essential; indeed, skeletal traction without a splint (Perkin's traction) has the advantages of producing less distortion of the fracture and allowing freer movement in bed (Browner at al 1998). Exercises are begun as soon as possible (Apley and Solomon 2001).

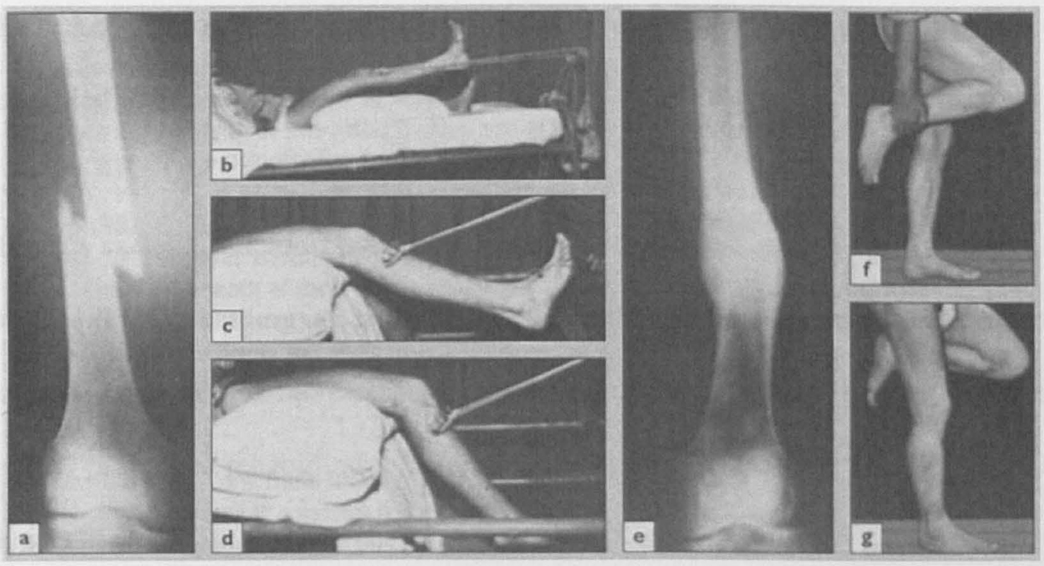

Fig.3.2 Femoral shaft fractures- traction. Even in the adult traction without a splint can be satisfactory, but skeletal traction is essential. The patient with this rather unstable fracture (a) can lift his leg and exercise his knee (b,c,d). At no time was the leg splinted, but clearly the fracture has consolidated (e), and the knee range (f) is only slightly less than that of the uninjured leg (g). Apley and Solomon, 2001.

Adults with femoral shaft fractures treated in traction generally require 6 to 8 weeks in the hospital. After 4 to 6 weeks in traction, and sufficient consolidation of the fracture so that its motion is no longer readily palpable, a spica cast or fracture brace can be applied with little risk of alignment loss.

The major fracture complication associated with skeletal traction is malalignment. This usually results in a varus deformity combined with internal rotation of the distal fragment. This has been well described by Neer et al (1967). In the supine patient, forces acting on the proximal femur cause abduction and external rotation of the proximal fragment.

The pull of the adductor magnus causes internal rotation and adduction of the distal fragment. If this deformity is not corrected, malunion will occur. As with all manipulative or traction methods of fracture reduction, the distal fragment must be aligned with the proximal, as the proximal fragment cannot be controlled. This can be achieved by appropriate positioning of the skeletal traction pin, and the direction of the applied force.

Although skeletal traction is still in common use, it is associated with a variety of complications, including inability to mobilize the patient, fracture malalignment, decreased knee motion, increased cost of medical care as a result of greater time in the hospital, prolonged rehabilitation, and patient inconvenience (Carr and Wingo 1973, Johnson et al 1985).

Diagnostic techniques such as computed tomography scanning, magnetic resonance imaging, ultrasound, and others that may be necessary are difficult for patients in traction. Limb length inequality (shortening) and rotational and angulatory malalignment problems may all occur (Carr and Wingo 1973, Johnson et al 1985). Their severity may be minimized by meticulous attention from physicians and staff during traction.

Cast Brace

The cast brace was developed as an alternative to immobilization of femoral shaft fractures in a plaster spica cast after 4 to 6 weeks of traction (Hardy 1983, Meggitt et al 1981). Traction followed by immobilization in a spica cast was blamed for significant difficulties with overall patient care, knee motion, and mobility. The cast brace provided for functional knee and hip motion after a period of traction and offered enough control of some fractures to reduce the time in traction and in hospital. Initially it was felt to be so successful that it came to be applied earlier and earlier after a period of skeletal traction.

The cast brace is most successful after an appropriate period of skeletal traction. Occasionally, the cast brace can be applied after 1 to 2 weeks of skeletal traction (Fig.3.3). The time in skeletal traction must be long enough to achieve adequate fracture consolidation. This is indicated by a pain-free stable fracture with evidence of callus formation on X-Ray. This signifies that enough stability is present to allow application of a cast brace.

The cast brace initially may carry up to 50% of the load applied in normal weight bearing (Mooney 1974). This rapidly decreases to 10 to 20% of the load applied in normal weight bearing as soft tissue atrophy occurs under the cast.

The cast brace is most successful for distal femoral shaft fractures and less so for more proximal fractures (Mooney and Claudi 1975). It is inappropriate for proximal third shaft fractures, as the cast achieves essentially no control of the fracture in AP or mediolateral bending. If a cast brace is desired for fractures in the proximal half of the shaft, it should have proximal control with a belt or pelvic band (DeLee et al 1981). Malalignment of proximal shaft fractures is extremely difficult to prevent with a cast brace.

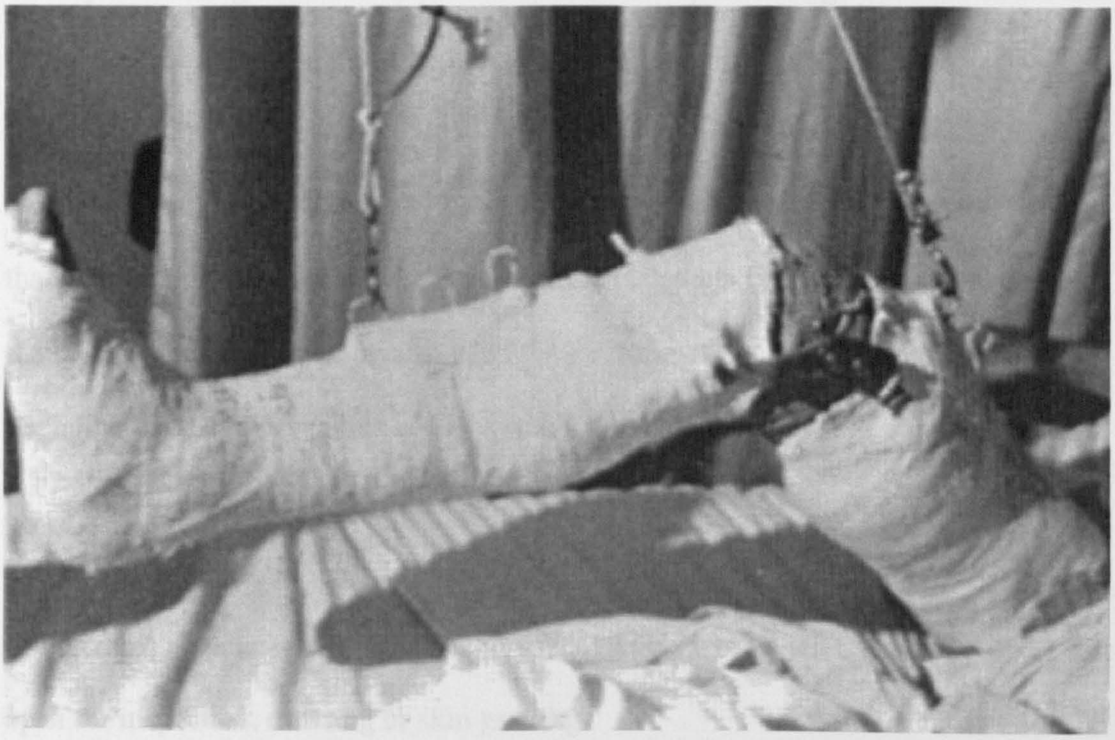

Fig.3.3 Cast Brace- being used in conjunction with skeletal traction. Browner at al, 1998.

Small amounts of malalignment and angulation (1° to 3°) can be corrected by wedging of the plaster cast. The use of a cast brace, as with other forms of traction application, requires acceptance of a certain amount of shortening (1 to 2 cm) and this may be unacceptable to some patients. The femoral shaft fracture can be expected to unite solidly at a period of 4 to 5 months after the fracture.

External Fixation

External fixators consist of modular components, which are assembled to form a stable construct of bone fragments, and an adjustable beam system. A fracture may be held by transfixing screws or tensioned wires, which pass through the bone above and below the fracture and are attached to an external frame.

By its very nature the modularity of the system renders it very versatile, which means that the potential uses are almost infinite. This is especially applicable to the tibia and the pelvis, but the method is also used for fractures of the femur (Fig.3.4 and 3.5), the humerus, the lower radius and even the bones of the hand.

External fixation is particularly useful for:

1) Fractures associated with severe soft tissue damage for which the wound can be left open for inspection, dressing or skin grafting.

2) Fractures associated with nerve or vessel damage.

3) Severely comminuted and unstable fractures which can be held out to length until healing commences.

4) Ununited fractures which can be excised and compressed; sometimes this is combined with elongation.

5) Infected fractures, for which internal fixation might not be suitable.

6) Severe multiple injuries in which early stabilisation reduces the risk of serious complications.

Apley and Solomon, 2001.

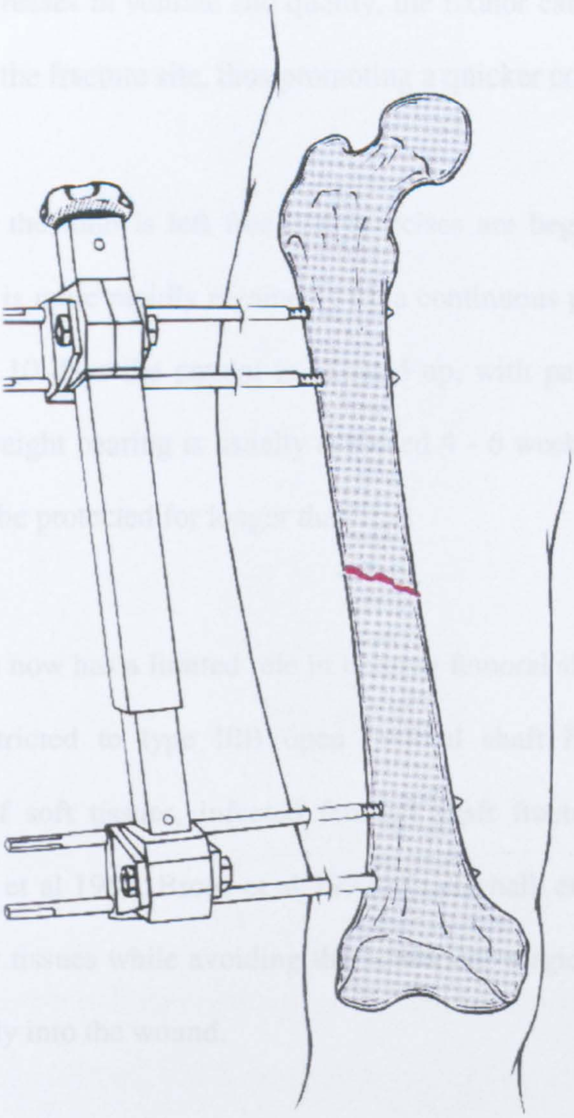

Fig.3.4 External fixation applied to the femur. Browner at al, 1998.

Union rates of over 90% have been reported (DeBastiani et al 1984) with external fixators. Like closed intramedullary nailing, external fixation has the advantage of not exposing the fracture site and small amounts of axial movement can be fed to the bone by allowing a telescoping action to occur in the fixator body (Browner at al 1998).

As the callus increases in volume and quality, the fixator can be adjusted to increase stress transfer to the fracture site, thus promoting a quicker consolidation.

Post operatively the limb is left free and exercises are begun as soon as possible. Knee movement is more rapidly regained with a continuous passive motion machine. After a week or 10 days the patient is allowed up, with partial weight bearing on crutches. Full weight bearing is usually achieved 4 - 6 weeks later, but comminuted fractures should be protected for longer than this.

External fixation now has a limited role in treating femoral shaft fractures and its use is generally restricted to type IIIB open femoral shaft fractures with extensive contamination of soft tissues, infected femoral shaft fractures, and infected non-unions (Alonzo et al 1989, Broos et al 1992, Gottschalk et al 1985). It allows the treatment of soft tissues while avoiding the additional surgical trauma of inserting a large foreign body into the wound.

It can be considered as a method of applying fixed but mobile skeletal traction (Marsh and Reagan 1986) and can also be used as a temporising device for rapid stabilisation of a femoral fracture in life- or limb-threatening circumstances (Broos et al 1992, Murphy et al 1988) as external fixation can be applied to a femoral shaft fracture in 30 minutes or less, especially if the fracture site is open.

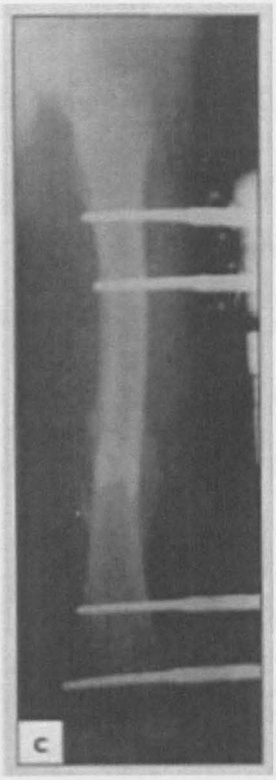

Fig.3.5 Femoral shaft fracture treated with external fixation. Apley and Solomon, 2001.

Its drawbacks include pin site problems (10-15% infection rates are to be expected), interference with quadriceps and knee motion, and limited ability to maintain fracture alignment until healing. Therefore, it should be used when other treatments are even riskier.

Plate Fixation

The reconstruction of a fractured bone by surgical and mechanical means is called osteosynthesis. Plating is a comparatively easy way of obtaining accurate fracture reduction and firm fixation (Fig.3.6 and 3.7). The technique gained popularity in the 1960s after publication of the AO (Arbeitsgemeinschaft fur osteosynthesesfragen) method (Murphy et al 1988, Wade 1970). The AO group designed a large compression plate for use in femoral shaft fractures. They also designed larger screws (4.5 mm) with larger core diameters that are about twice as strong as screws used previously in orthopaedic surgery. The method was popular at one time but went out of favour because of the high complication rate, including implant failure.

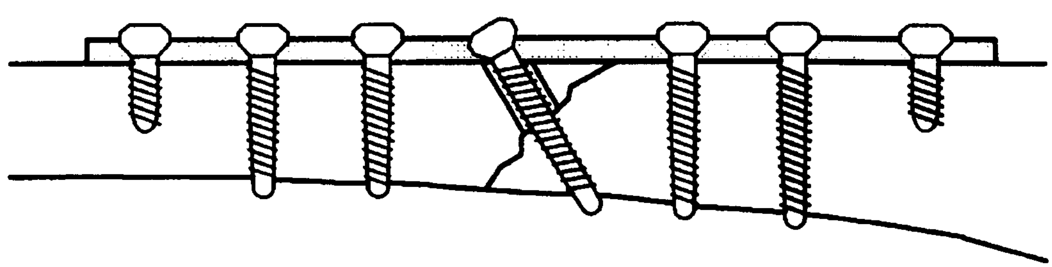

Fig.3.6 Plate fixation. AO Course Guide, 1998.

The main indications today are:

1. The combination of shaft and femoral neck fractures
2. The combination of shaft and distal femoral fractures.
3. A shaft fracture with an associated vascular injury.

Plate application to the femoral shaft, by necessity, requires an open surgical procedure, with at least some devascularisation of the femoral shaft occurring at the time of plate application. Fracture haematoma is typically evacuated as well. Both devitalisation of the shaft and evacuation of the fracture haematoma predispose plated fractures to delayed healing.

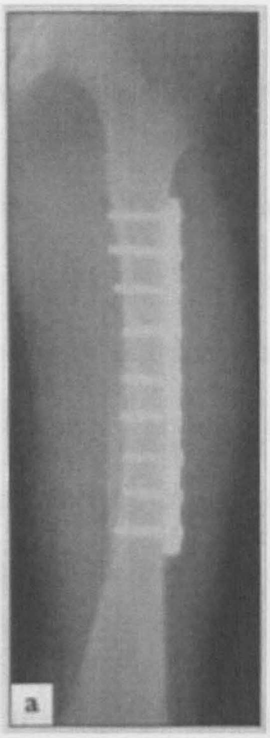

Fig.3.7 Femoral shaft fracture treated with plate fixation. Apley and Solomon, 2001.

The least destructive technique is indirect reduction using a femoral distractor. A single stout plate (Fig.3.7) is then applied to the lateral surface of the femur with at least 5 screws in each of the main fragments; bone grafts can be added on the medial aspect across the fracture if required. Severely comminuted fractures are simply bridged by a plate of suitable length (Fig.3.8).

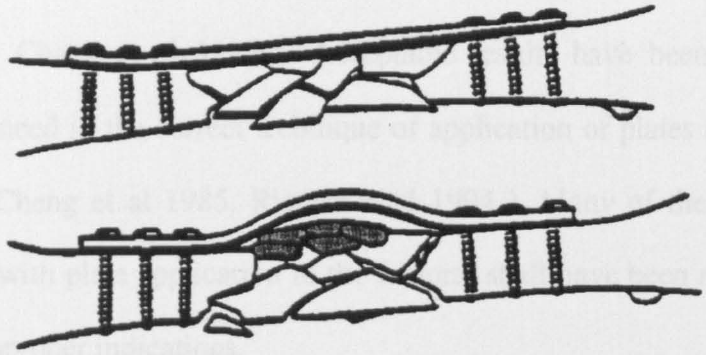

Fig.3.8 Bridging plate fixation. AO Course Guide, 1998.

A plate on the femoral shaft is at a distinct biomechanical disadvantage when compared with an IM nail. The plate is placed eccentrically on the femoral shaft. The line of application of weight-bearing forces has a resultant lever arm approximately 1 to 2 cm longer for plate fixation than with IM fixation. This places more stress on the plate, as the bending moment experienced by the plate or nail is directly related to the force of application and the distance of the implant from the force of application.

By design, a plate bears weight that would otherwise be transmitted by the bone (Mooney and Claudi 1975). Stress applied to the femur passes directly up the femoral shaft and bypasses the femur by means of absorption of stress through the distal screws into the plate and back into the femur through proximal screws. IM nails are, in general, weight-sharing devices that share stress with the femoral shaft as fracture healing occurs.

The combination of the mechanical disadvantage of the plate and the delay in fracture healing risks fixation failure, such as plate or screw breakage or loosening, before fracture healing as well as delayed refracture (Bostman et al 1989, Magerl et al 1979

). In spite of the disadvantages of plates, there are indications for their use in femoral shaft fractures (Cheng et al 1985). Acceptable results have been achieved by surgeons experienced in the correct technique of application of plates to the femoral shaft fracture (Cheng et al 1985, Riemer et al 1994). Many of the unacceptable results achieved with plate application to the femoral shaft have been related to poor technique and improper indications.

IM Nailing

A continuous improvement in nail design and the advent of image intensification in the operating room has allowed the technique of closed IM nailing to flourish. This allows the nail to be inserted into the medullary canal at a point distant from the fracture site, to be guided across the fracture, and then to be locked to the proximal and distal fragments.

IM nailing is claimed to be the best treatment for most femoral shaft fractures (Anastopoulos et al 1993, Bohler Bohler 1968, Winquist et al 1984) when appropriate facilities and expertise are available. With new nail designs that allow locking in the proximal and distal femur, it has become possible to nail virtually any fracture of the femoral shaft (Anastopoulos et al 1993, Cameron et al 1992, Christie et al 1988, Huckstep 1972, Klemm and Borner Borner 1986).

The indications for first-generation intramedullary fixation of fractures of the femoral shaft include fractures just below the lesser trochanter to within 6 to 8 cm of the articular surface of the distal femur. Type I and type II open femoral shaft fractures appear to pose no contraindication to closed IM nailing, provided the initial débridement is adequate. Controversy exists as to whether type III open femoral shaft fractures should be treated with immediate or delayed nailing after a period of wound care and traction. This decision is made by evaluating the wound.

Before the development of smaller, locked IM femoral nails, which can be inserted with little or no reaming, IM nail systems for the femur required reaming of the intramedullary canal. Reaming allows insertion of larger diameter nails (12 to 16 mm) that allow stable fixation of the femoral shaft (Hansen and Winquist 1979).

These large-diameter nails effectively prevent bending and loss of fixation of the fracture site, even with the application of significant amounts of stress, including weight-bearing ambulation. They are also of large-enough diameter that drill holes for durable locking bolts can be placed through the nail both proximally and distally, without significantly weakening the implant (Fig.3.9). Today, with improved design of interlocking nails, small-diameter nails (10 to 11 mm) are as strong as older large-diameter nails, allowing the use of these smaller nails with a decrease in reaming, with no increased risk of nail breakage.

Although reaming the medullary canal does damage the endosteal blood supply of the femoral shaft (Danckwardt-Lilliestrom 1969) which provides vascularity to the inner third of the cortex of the femoral shaft (Kessler et al 1986) it has been shown that as long as space remains within the intramedullary canal after insertion of the IM nail, this bone is revascularized by 6 to 8 weeks after reaming of the intramedullary canal (Rhinelander 1968).

Certainly, reaming of the intramedullary canal has demonstrated no major drawbacks for closed fractures of the femur and in fact may actually aid in fracture healing by deposition of small bone fragments within the fracture haematoma (Clartworthy et al 1998). A potential disadvantage of the loss of endosteal blood supply exists in IM nailing of open fractures or of fractures that require open surgical manipulation of the fracture fragments. In these instances, loss of periosteal as well as endosteal blood supply may predispose the fracture to delayed healing and a higher rate of infection. This concern has been borne out in clinical series (Green et al 1987). Other series of open fractures have demonstrated that at least type I and type II open fractures can be safely nailed early with no significant increase in complications (Brumback et al 1989).

Recent smaller-diameter nail designs allow the use of a strong, minimally reamed, locked IM nail for the femur. This nail would provide the mechanical benefits of a larger nail and allow stabilisation by locking, but with minimal or no reaming, which devitalises fragments of bone and may predispose open fractures to infection. Preliminary research has indicated that the use of these unreamed IM nails may indeed preserve some of the blood supply that is lost during reaming of the medullary canal (Brinker et al 1999).

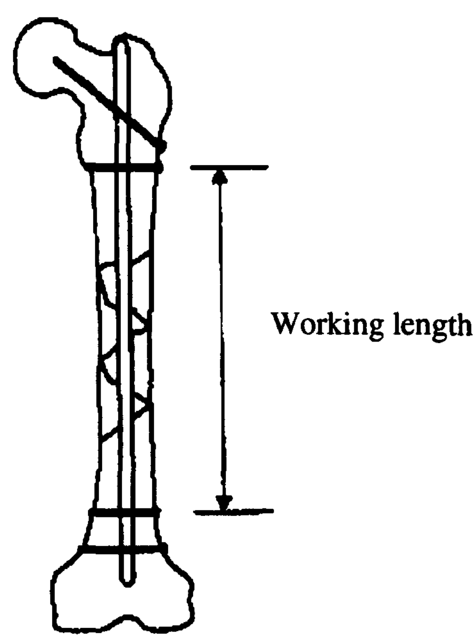

Fig.3.8 Locked femoral nail. The distance between the locking screws is the working length of the nail. AO course Guide, 1998.

Any surgeon performing closed IM nailing of femoral shaft fractures must have lockable IM nails available. Unlocked IM nails, such as the Kuntscher Küntscher nail, Sampson nail, Schneider nail, Hansen-Street nail, and the original AO IM nail, are now of historical interest only (Harper 1985, Schneider 1968). These nails provide longitudinal stability and achieve fixation of stable femoral shaft fracture patterns; transverse or short oblique midshaft fractures. They do not however provide any rotational stability. Their versatility is significantly limited and they do not allow the surgeon the full benefit of IM nailing techniques.

Intramedullary nailing technique

The standard operation is performed with the patient on his or her back or side and skeletal traction still in place (Browner et al 1998). The fracture is then reduced under X-ray control. The tip of the greater trochanter is identified through a gluteal muscle splitting incision and the cortex of the pyriform fossa perforated with a sharp bayonet and then, under fluoroscopic control, a guide rod is passed down the femur crossing the fracture.

If closed reduction cannot be achieved and repeated attempts to persuade a guide wire across the fracture site fail, a small exposure to achieve reduction is permissible. Flexible reamers are used to widen the medullary canal. A pre bent nail of suitable length and width (usually 1.5 mm smaller than the widest reamer used) is chosen; this is passed over the guide rod (or a second, stiffer, guide rod) and driven home under fluoroscopic control.

Stability is improved by using interlocking screws; all locking holes in the nails should be used as a single distal locking screw has been shown to fail significantly more often than two locking screws (Kniefel and Buckley 1996) . Often there is enough shared stability between the nail and fracture ends to allow some weight bearing early on. The fracture usually heals within 20 weeks and complication rates are low; sometimes malunion (more likely mal rotation) or delayed union (from leaving the fracture site over-distracted) occurs.

INTRAMEDULLARY NAILING

Introduction

Although intramedullary femoral nailing as a technique for treating fractures has been with us for over seventy years (Kuntscher Küntscher 1965, Kuntscher Küntscher 1968) it is still undergoing development. Modern nailing is a technique whereby the nail is inserted into the bone from the proximal end without disturbing the fracture site at all - the so called antegrade technique (Winquist et al 1984).

An alternative method for intramedullary nailing involves insertion of the nail from the distal end of the femur without disturbing the fracture site at all - the so-called retrograde technique (Patterson et al 1995, Sanders et al 1993). An X-ray image intensifier is essential in the operating room for this method of fracture fixation. It is a major improvement on old methods where the fracture site was opened by soft tissue dissection and the fracture end delivered into the wound for reaming and insertion of the nail - the so called open technique.

Both nail design and operative technique must be considered when planning a nailing system. Developments in design continue to take place, centred around whether it is necessary to widen the intramedullary canal by paring off (reaming) the inner surface of the bone (Hansen and Winquist 1979) or whether to use nails which are solid and of smaller diameter so that they may be inserted without damage to the inner blood supply of bones; unreamed technique (Krettek et al 1996).

Function of nails

The design and use of intramedullary nails has been effectively reviewed by Rowley et al (1998). An intramedullary nail functions as a form of internal splint, which stabilises long bone fractures. As intramedullary nails are sturdy implants, they are able to withstand a heavy load to the body well in any direction, rather like the bone itself. Limbs in which fractures have been treated by nailing can consequently be mobilised early after surgery, with partial weight bearing being allowed before bony union has occurred.

Design features of a nail

There are several factors that contribute to the effectiveness of the nail. The following three are important in design considerations:-

1 - The material of which it is made.

2 – The diameter of the nail.

3 - Its radius of curvature.

4 - Whether it is hollow or solid- and its wall thickness if hollow.

Materials of manufacture

The majority of nails are made of stainless steel because this material has good strength and stiffness characteristics. It is also easy to handle during the manufacturing process and therefore economical to use. It is also well tolerated by the body tissues. Titanium would be a good alternative material for nails. It is a little less stiff than steel and has very low toxicity. Unfortunately however, a nail made of titanium alloy is more susceptible to weakening, either if the hole is drilled across it, or if it is accidentally abraded during insertion allotting - a phenomenon known as notch sensitivity.

The shape and dimensions of a nail

Nails may be either solid or hollow and are supplied in a complete range of diameters and lengths so that an appropriate size can be chosen which will grip the inside of the medullary canal which is being nailed. Reaming is used to increase the size of the medullary canal so a larger and therefore stronger nail can be inserted along the length of its internal diameter.

This internal fit can be improved further if nails are curved to conform roughly to the shape of the bone for which they are designed - for example, femoral nails are gently curved in an arc over their whole length whereas the tibial nail has a sharper angulation one third of the way down from the top.

Hollow nails are less stiff in bending than solid ones. Their stiffness can be altered by making the walls thicker or thinner. The thicker the wall the stronger and stiffer the nail. The stiffness of a nail can be reduced by putting a longitudinal slot in the wall of the nail. This makes it much more flexible but does so at the cost of it losing somewhat overall bending strength and especially, torsional strength. Nail design, like that of any engineering structure, is always a compromise between including as many desirable properties as possible whilst trying to keep undesirable properties to a minimum. There are obvious advantages of having a somewhat flexible nail in that it will have a little give in it on insertion. This will make it easier to insert and allow the nail to undergo slight deformation to conform to the natural shape of the bone. Slight flexibility should not however compromise the ability of the nail to act as a rigid enough splint to support the broken bone.

The relationship between stiffness and strength is not a simple one. Both factors may be related mathematically to the diameter of the nail - for example, stiffness in bending is proportional to the diameter raised to the fourth power and the strength in bending varies with the third power of the diameter (Fig.4.1). This means that as nails get a little stronger they get considerably more stiff. Very stiff nails are not desirable as they may damage the bone if there is any discrepancy between the shape and size of the nail and that of the medullary canal into which it is inserted - this situation can arise because nails are of a standard shape and people are not, even after reaming!!!

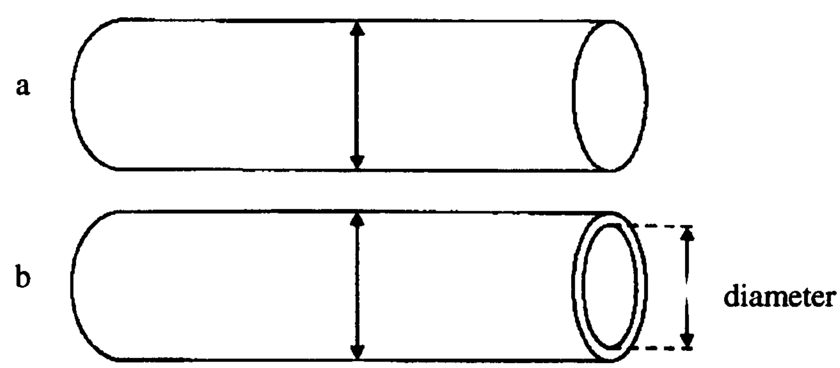

Fig.4.1 The relationship between diameter and bending stiffness in (a) a solid nail and (b) a hollow nail. AO Course Guide, 1998.

The aim of nail design is to gently curve the nail according to the bone involved and to slot the nail along its length. The wall thickness of 1.2 mm and the slot give an optimal balance between strength and flexibility. The slot allows the cross section of the nail to be compressed like a stiff spring inside the medullary canal. This promotes a tight fit between rod and bone. The presence of the slot reduces the stiffness of the nail. This has both positive and negative value. The reduced stiffness allows the nail to conform to minor discrepancies between itself and the medullary canal. This can ease insertion by allowing twisting to occur but does compromise the use of external aiming devices used to locate the distal locking holes.

Locking

The presence of paired holes, which are aligned at various angles to the long axis of a nail, permits cross interlocking. This provides the nail and bone construct with axial and rotational stability as the nail itself has no direct contact with the endosteal surface of the bone. It increases the working length (Fig.4.2) to the distance between the locking screws at either end of the nail (Christie et al 1998) and allows more comminuted fractures to be treated by intramedullary nailing.

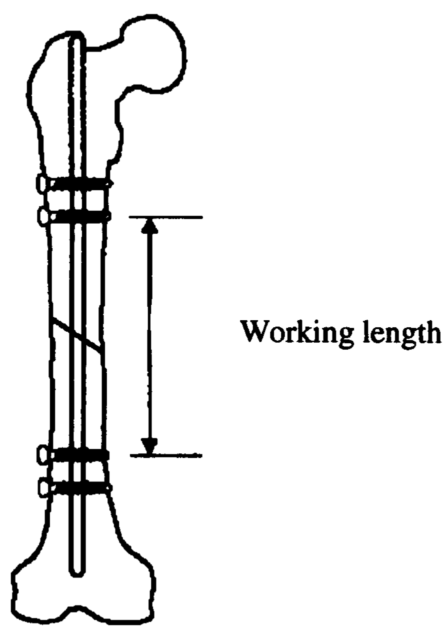

Fig. 4.2 Locked nail. The effect of locking screws is to increase the ability of a nail to prevent shortening of a comminuted fracture and to ensure that the nail can contribute to rotational stabilty to a predictable degree. AO Course Guide, 1998.

The locking holes may be round, as they are usually at the distal end, to accommodate a screw or bolt. The holes are slightly bigger than the thread diameter of the screw so that the cross fixation device can pass smoothly through the nail without damage to either. Some proximal holes may instead be slots, as in standard nails. This design feature permits slight axial movement of the bone and locking screw relative to the nail, but still prevents rotation. This allows a degree of fracture impaction and dynamic motion which encourages callus formation and rapid healing by allowing some load to be transmitted across the healing fracture site.

Proximal locking is achieved by passing screws through the aligned holes across the nail, guided by a jig, which attaches into the top of the nail. This is not possible however at the distal end, as the relatively flexible nail tends to twist and distort as it is hammered in to place. The position of the distal holes is therefore not precisely related to any jig attached to the other end of the nail.

Locking in the distal screw holes of the nail is achieved using X-ray image intensification. For safety reasons the image intensifier must have an image storing facility so that screening time can be kept to only a few seconds, thereby reducing the risk of radiation exposure to both surgeon and patient.

Dynamisation involves the removal of a set of screws during fracture healing to allow increased force across the healing callus. It is not usually done unless a hypertrophic delayed union occurs at four to six months. Routine removal of screws later in fracture treatment to ensure dynamisation is not usually necessary as the natural flexibility of the nail is sufficient to stimulate callus formation (Kempf et al 1985).

The contact between nail and bone

The length of the nail that transmits load from one fragment of the fractured bone to the other is known as the working length. This is an important concept because the stiffness of the nail in both rotation and bending is related inversely to its working length (Fig.4.3).

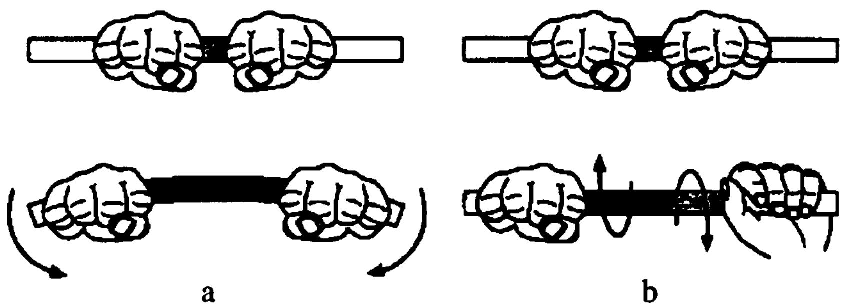

Fig.4.3 (a) bending; (b) torsion. AO Course Guide, 1998.

This means that an intramedullary nail, which has a firm grip on the endosteal surface of the bone immediately above and below a fracture, will have a short working length. In this situation the ability of the nail to resist bending and torsional forces will be high. On the other hand if a nail is inserted across a multi-fragmentary shaft fracture, the nail must be anchored to the bone by a cross locking screw.

If gripping of the bone is solely by virtue of the proximal and distal locking screws across the nail, it will have a longer working length, equal to the distance between the top and bottom locking screws (Fig.4.4).

This results in the nail being less able to resist bending and torsional forces. The longer the working length, the greater the relative movement between the main bone fragments.

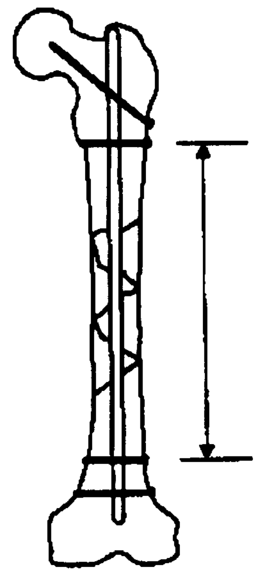

Fig.4.4 Working length. The effective working length of the nail depends on where there is contact between nail and bone. AO Course Guide, 1998.

Unreamed nails

Some shaping of the medullary cavity by reaming is necessary to accommodate the reamed nails safely. This damages the interior blood supply of the bone as has been shown in animal studies (Danckwardt-Lilliestrom 1969). If a fracture is extensive and there is a lot of soft tissue damage, there is a risk that the outer blood supply will also already be impaired. At best, this will delay healing and at worse may lead to bone death.

By using a smaller solid nail, reaming may be avoided (Krettek et al 1996). Solid nails have been introduced for this purpose. Even though an unreamed nail is thinner, the insertion of a nail is not always possible without reaming. Also because a firm contact between nail and bone is not the aim of this technique, cross locking is essential to control rotation and to transmit longitudinal load. The concept of an unreamed nail as a way of stabilising open fractures, in cases where severe injury to the outer blood supply is a distinct possibility, is now being actively explored. As yet there seems no evidence to extend the indications for unreamed nails to uncomplicated fractures, as the result of closed reamed nailings are so good - especially in the femur.

<u>Indications for use</u>

Prospective randomized studies have indicated that intramedullary nailing is the treatment of choice for virtually all closed diaphyseal fractures of the long bones of the lower extremity (Anastopoulos et al 1993, Brumback et al 1988, Cameron et al 1992, Winquist et al 1984).

Unless the fracture is a mid shaft fracture or a short / fracture treated with a tight fitting nail, all other fractures are treated with a reamed statically long nail. This includes:-

1 - All acute diaphyseal fractures / closed.

2 - Impending pathological fractures or pathological fractures.

3 - Delayed or non-union of the femur or tibia.

All open fractures of the femur are treated with statically locked reamed and intra medullary nailing unless there is no soft tissue coverage or severe contamination.

The main variables of a typical femoral nail are;

1 - Cross section.

2 - Wall thickness and nail diameter.

3 - The continuous longitudinal slot.

4 - The conical upper end with locking dove tail slot.

5 - The curvature of the nail.

1 - The cross section

A typical nail has a clover leaf cross section which maintains good contact with the bone whilst preventing excessive nail distortion when twisted (Fig.4.5). The various nails available come in different outer diameters from 9 to 18 mms (or occasionally larger). The diameter affects strength and so by increasing the diameter a little the strength is increased significantly.

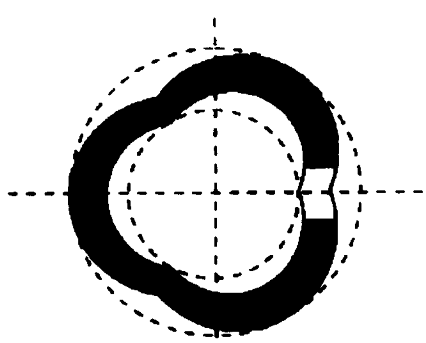

Fig. 4.5 The cloverleaf cross-section of a common nail design. AO Course Guide, 1998.

2 - The wall thickness

The wall is 1.2 mm thick which balances strength and flexibility - the longitudinal slot also affects the latter.

3 - The continuous longitudinal slot.

The presence of a slot makes the nail more flexible and deformable enough to make contact with the bone. This helps to distribute contact forces between bone and nail over as large an area as possible, and gains maximum interference (frictional) fit with the interior surface of the medullary canal.

4 -The conical upper end with dove tail slot.

The upper end of a nail has a conical female thread in it to accommodate a conical male threaded bolt, used to attach the insertion and extraction devices (Fig.4.6). As the conical bolt is driven home the continuous slot tends to open. In this part of the nail the slot follows the line of the dove tail, and so as the nail is spread under the force of the advancing bolt, the slot eventually jams preventing the nail from flaring open and ensuring solid contact between bolt and nail. Once the bolt has been removed the slot serves its functions to make the nail more flexible and deformable.

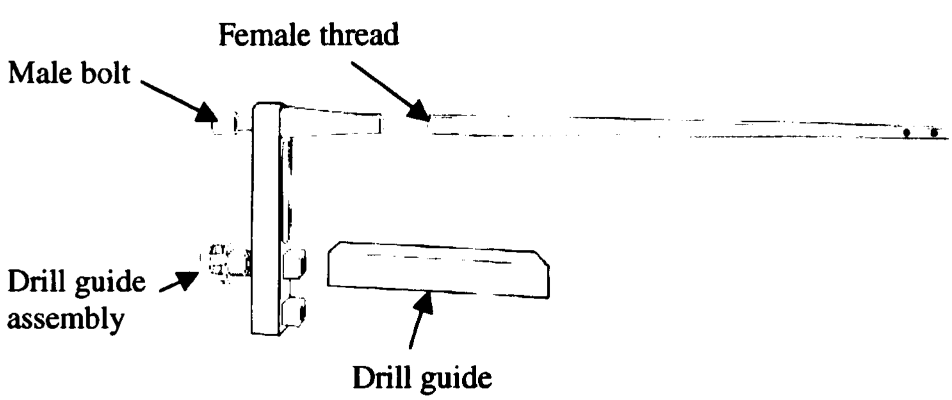

Fig.4.6 Drill guide assembly of a typical intramedullary nail. Manufacturers Handbook, Smith and Nephew, 1997.

If the slot did not go right to the top of the nail there would be an area of stress concentration at the junction of the stiff unslotted part and the flexible slotted, lower part. This would risk fatigue failure of the nail at this junction. The bolt must be inserted fully so as to lock the dove tail lest the bolt jump out under load; this could damage the threads, making later extractions impossible.

5 -The curvature of the nail

The average nail has a curvature which corresponds to part of the circumference of a circle which has a radius of 1500 mms, which reflects the average shaped femur. Nails come in different lengths as well as diameters. Nails of each radius of curvature are available in different longitudinal lengths.

RETROGRADE FEMORAL NAILING

Introduction

Soon after its introduction antegrade femoral nailing became the most popular and effective treatment of fractures of the femoral shaft (Brumback et al 1988, Winquist et al 1984). Distal interlocking is performed using a guide and proximal interlocking is performed 'freehand' using image intensification in a lateral to medial direction. Success rates of up to 98% (Brumback et al 1988) are reported with high rates of union, low rates of mal-union and a low prevalence of infection (Brumback et al 1988, Winquist et al 1984).

The disadvantages of antegrade nailing include heterotopic ossification around the hip, the routine requirement for a fracture table, longer time for setting-up in theatre and risk of femoral neck fractures (Brumback et al 1990, Steinberg and Hubbard 1993, Christie and Court-Brown 1988). Retrograde femoral nailing is a relatively new technique, which has the potential to eliminate these problems.

Where antegrade nailing is difficult or impossible retrograde femoral nailing is becoming more common with the introduction of implants specifically designed for this purpose. Its use has been advocated in the management of femoral shaft fractures in patients with ipsilateral peritrochanteric or acetabular fractures, polytrauma requiring multiple simultaneous procedures and in pregnancy (Sanders et al 1993, Patterson et al 1995, Moed and Watson 1995).

There are essentially two forms of retrograde femoral nails. These are the 'shorter' supracondylar nail (Fig.5.1) and the longer retrograde femoral nail (Fig.5.2). The Richards retrograde femoral nail is an example of the latter.

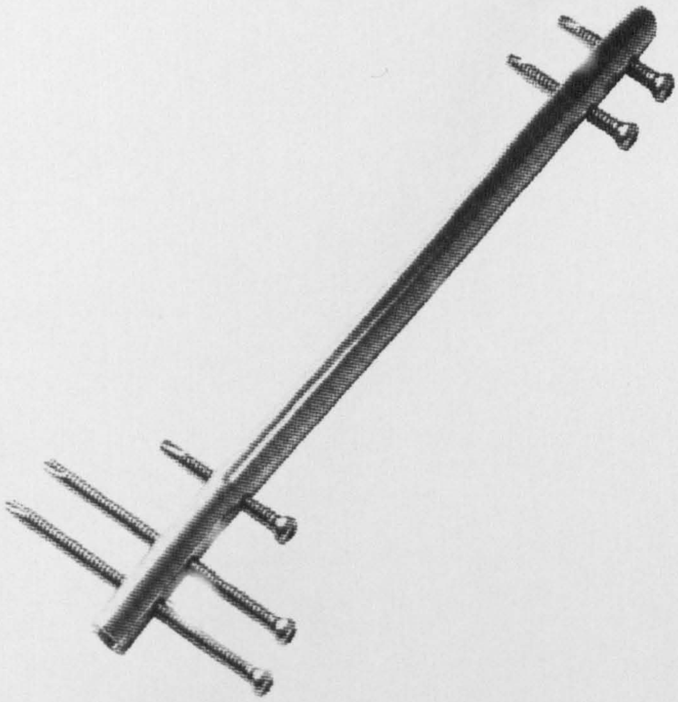

Fig.5.1 Supracondylar nail-used for supracondylar fractures of the femur. Maufacturers Handbook, Smith and Nephew, 1997.

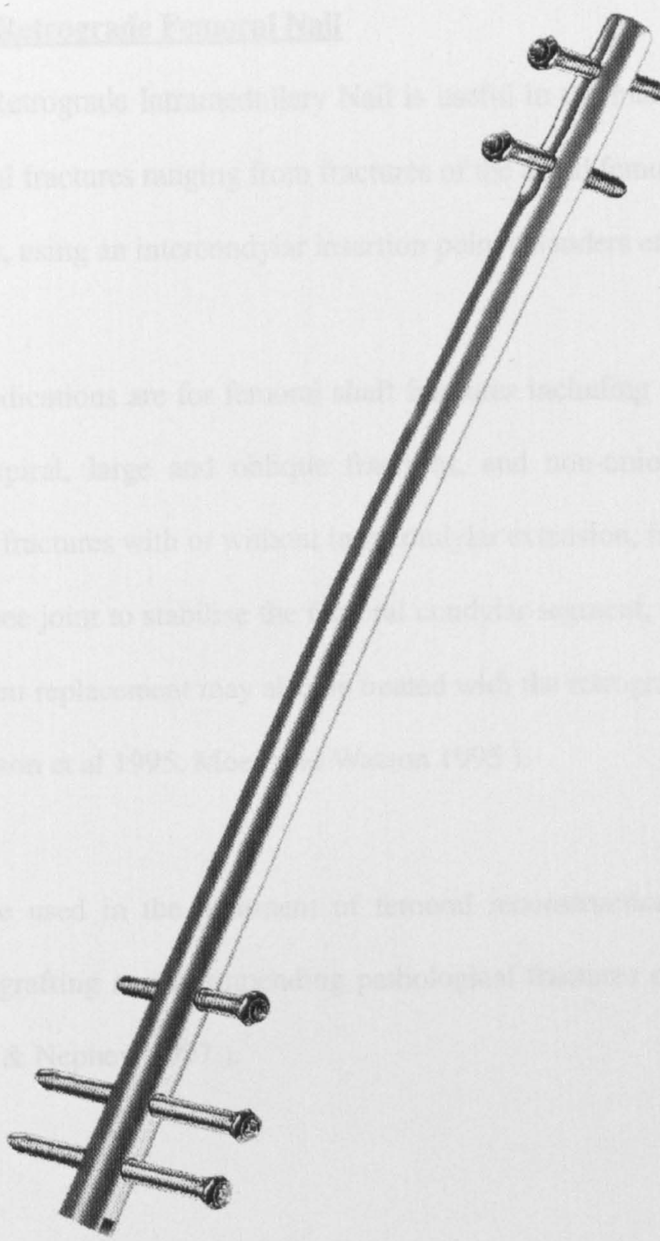

Fig.5.2 Richards retrograde femoral nail. Manufacturers Handbook, Smith and Nephew, 1997.

The Richards Retrograde Femoral Nail

The Richards Retrograde Intramedullary Nail is useful in the management of a wide range of femoral fractures ranging from fractures of the distal femur to fractures of the shaft (Fig.5.3), using an intercondylar insertion point (Sanders et al 1993).

The primary indications are for femoral shaft fractures including segmental, severely comminuted, spiral, large and oblique fractures, and non-unions and malunions. Supracondylar fractures with or without intracondylar extension, fractures that require opening the knee joint to stabilise the femoral condylar segment, and fractures above a total knee joint replacement may also be treated with the retrograde nail (Sanders et al 1993, Patterson et al 1995, Moed and Watson 1995).

It may also be used in the treatment of femoral reconstruction following tumour resection and grafting and in impending pathological fractures of the shaft or distal femur (Smith & Nephew 1997).

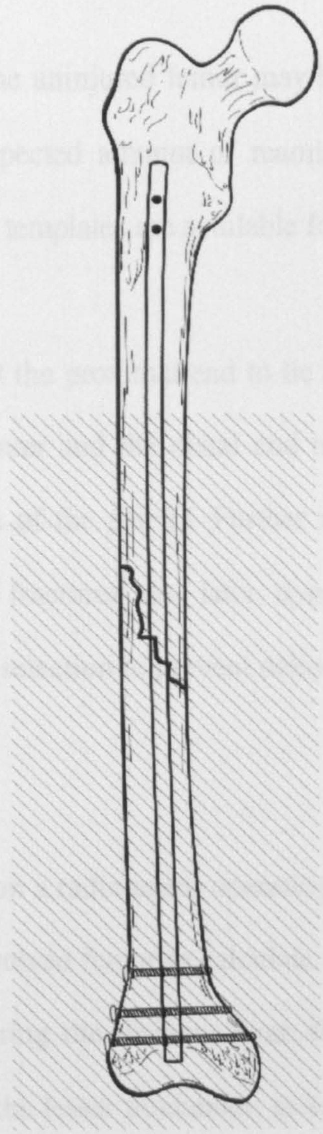

Fig.5.3 Femoral shaft fracture- treated with a retrograde femoral nail. Fractures in the shaded area may be treated using such an implant. Manufacturers Handbook, Smith and Nephew, 1997.

The Richards Retrograde Intramedullary Nail is a fully cannulated, closed section, stainless steel implant with outer diameters of 10-13mm. The nails are available in lengths of 30-48cm (in 2cm increments) and have five screwholes, accepting 5.0 mm fully threaded or 5.0 / 6.4 mm step screws of stainless steel. The nails are designed to permit the distal driving end to be countersunk below the level of the articular surface of the femur.

Preoperative planning

Preoperative radiographs of the uninjured femur may be used to estimate proper nail length and diameter; and expected amount of reaming (if desired) for severely comminuted fractures. X-Ray templates are available for preoperative planning.

The nail length should permit the proximal end to lie at approximately 1-2cm above the level of the lesser trochanter and the distal end to be countersunk so as not to interfere with the articulation of the patella. Further impaction is occasionally seen when severely comminuted fractures are later dynamised. This risk should be considered during nail length selection to prevent delayed migration into the knee.

Surgical Technique

The patient is placed supine on a radiolucent operating table using fluoroscopy and a radiolucent ruler on the uninvolved femur to calculate the length of nail required. The length is obtained by measuring the distance from the intercondylar notch to 1cm above the superior border of the lesser trochanter, as seen on the anteroposterior (AP) view.

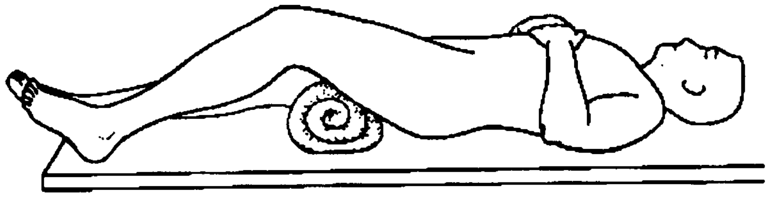

Fig.5.4 Patient positioning for retrograde femoral nailing. Manufacturers Handbook, Smith and Nephew, 1997.

In patients with bilateral injuries, a clinical estimation using this method can be obtained. A sandbag or pillow is then placed under the knee to flex the knee to 45 degrees (Fig.5.4). The entire limb is then prepared to the iliac crest. Fluoroscopic control should be used in association with the radiolucent extension table. The C-arm should also be draped and placed at the side of the table (Fig.5.5).

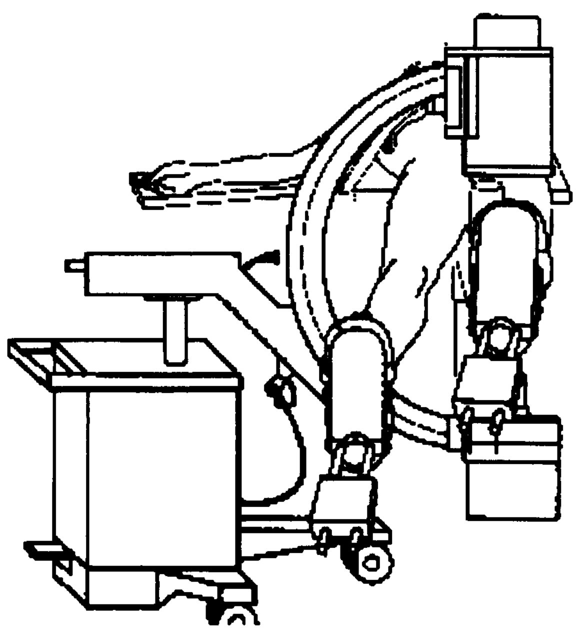

Fig.5.5 Positioning of the image intensifier for retrograde femoral nailing. The C-Arm of the image intensifier is brought in perpendicular to the femur from the opposite side to the fracture. Manufacturers Handbook, Smith and Nephew, 1997.

A midline incision and medial parapatellar approach is used. The patellar tendon is retracted laterally, and the anterior cruciate ligament is located by palpation. A guide pin is inserted in the notch, 1 cm anterior to the ligament, with the position verified fluoroscopically. On the lateral view the pin is placed so that it will lie in the centre of the femur between the anterior and posterior cortices (Fig.5.6). This is facilitated by placing the tip of the guide pin at the angulation produced by the medullary canal (Iannacone et al 1994, Patterson et al 1995) of the femur. An extraarticular entry portal through the medial femoral condyle at the junction between the distal femoral articular surface cartilage and the metaphyseal supracondylar flare (Sanders et al 1993, Swiontowski 1987) can also be used.

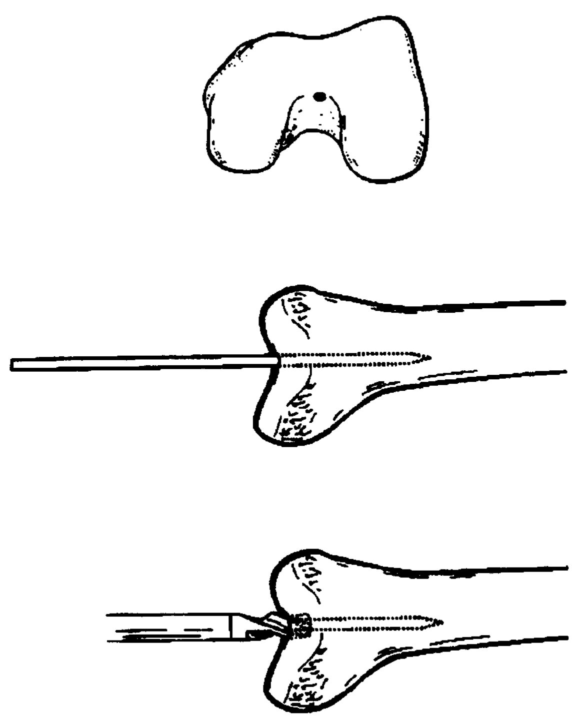

Fig.5.6 Femoral preparation for retrograde femoral nailing. Manufacturers Handbook, Smith and Nephew, 1997.

The guide pin is advanced into the medullary canal and across the fracture site for a distance of 10cm. A reamer is passed over the guide wire and advanced along the length of the wire (Fig.5.7). Both wire and reamer are then removed, and all loose fragments of bone are washed out of the joint. The medullary canal should be reamed 1.0 to 1.5 mm larger than the stated size of the nail which is to be inserted.

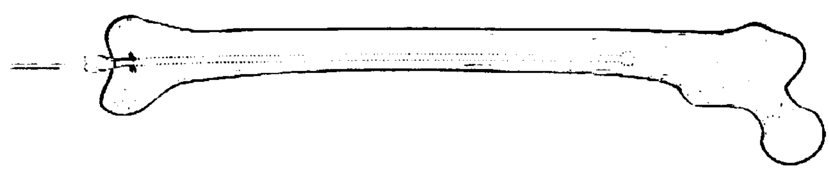

Fig.5.7 Reaming of the femur for retrograde femoral nailing. Manufacturers Handbook, Smith and Nephew, 1997.

Once reaming has been completed the nail is placed in the notch over the guidewire and advanced towards the fracture. With the patient paralysed to relax the muscles a knee roll is placed under the fracture. Reduction is accomplished by one of three methods;

1) Manual reduction with or without a small Steinman pin (Richards, Memphis, TN) in the posterior aspect of femoral condyle for traction.
2) A femoral distractor.
3) A sterile tourniquet can be used to facilitate reduction in much the same way as a paramedic uses an inflatable splint to reduce and align a fracture in the field.

After pulling the femur out to length, the tourniquet is inflated over the fracture and the nail is used to help in the reduction.

The nail is then driven across the fracture and seated at the level of the lesser trochanter (Fig.5.8). It should be countersunk 1-2 mm into the intercondylar notch beneath the articular surface.

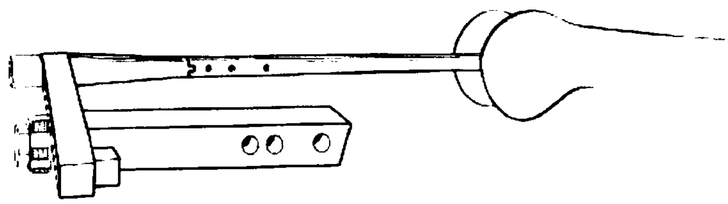

Fig.5.8 Nail insertion in retrograde femoral nailing. Manufacturers Handbook, Smith and Nephew, 1997.

For the shorter supracondylar nail both proximal and distal locking is performed using a guide through a relatively safe zone from a lateral to medial direction.

In using longer nails such as the Richards retrograde femoral nail the distal locking is performed using a drill guide assembly (Fig.5.9), through a relatively safe zone from a lateral to medial direction, but the proximal locking is performed percutaneously and freehand at the level of the lesser trochanter in an anteroposterior direction under image intensification.

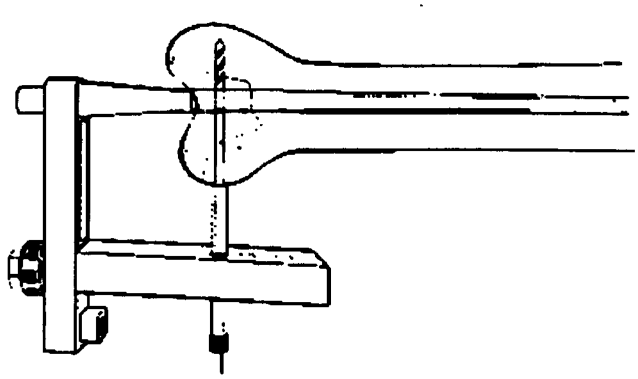

Fig.5.9 Insertion of the distal interlocking screws using the drill guide assembly. Manufacturers Handbook, Smith and Nephew, 1997.

The Richards retrograde intramedullary femoral nail like other nails provides fracture stability by acting as an internal splint for the femur. It does this by being in contact with the inner surface of the medullary canal of the femur. In the absence of any locking screws it would provide a degree of stability to the fracture which would include maintaining the alignment of the fracture.

It would not however provide any axial or rotational stability i.e. it would not prevent shortening or rotation at the fracture site. This would lead to decreased fracture stability which would lead to more patient discomfort and a greater incidence of complications of healing such as malunion with rotational deformity as well as limb length discrepancy.

Distal locking of this implant is a simple procedure as described above. This anchors the nail to the distal femoral fragment. In the absence of proximal locking this would still allow both axial and rotational movement at the fracture site and therefore on its own the above problems would persist. Proximal locking anchors the nail to the proximal femoral fragment at the level of the lesser trochanter. This increases fracture stability and prevents the fragments from both axial and rotational movements. This makes the patient more comfortable and also reduces the complications described above.

The anteroposterior locking is performed with the patient supine on a radiolucent fracture table. A sandbag is sometimes placed under the knee. The procedure is carried out under screening and the C-arm of the image intensifier is brought in from the side of the table, perpendicular to the long axis of the femur. The position of the proximal locking holes at the level of the lesser trochanter is identified using screening and the locking screws are then inserted in an anteroposterior direction under image intensification. The screws may be inserted either percutaneously or through a limited open incision at this level.

The insertion of the proximal screws is a difficult procedure for a number of reasons. Firstly and foremost the freehand technique is relatively imprecise and therefore a number of attempts may be required to drill the locking holes in the femur exactly over the holes in the nail. The anterior surface of the femur is convex and this makes it liable for the drill to slip off either medially or laterally injuring neighbouring structures. The proximity of the femoral neurovascular bundle is also a concern and the large number of branches arising from the femoral nerve, artery and vein have been shown by Riina et al (1998) to lie in this area of the proximal thigh in the region of the lesser trochanter.

Null Hypothesis

The anteroposterior locking is technically difficult. We feel that this aspect of the procedure is of concern due to the proximity of the femoral neurovascular bundle and therefore requires further investigation.

Our null hypothesis states that proximal anteroposterior locking screws can be inserted into the proximal femur through the thigh at the level of the lesser trochanter without damage to nerves and vessels. We aim to test this by carrying out dissections of cadaver limbs both with and without the investigative drill holes, which imitate the insertion of proximal locking screws.

Section 2

MATERIALS AND METHODS

Anatomical Examination of Cadavers

The lower extremities of 11 embalmed cadavers from the departmental teaching collection were selected for careful dissection and studied. These had been embalmed using the following standardised technique.

Cadavers bequested to the Department of Anatomy, University of Glasgow are initially embalmed using arterial injection and completed by spot injection. All nametags, hospital gown, jewellery and hair are first removed.

The carotid artery is identified and raised. It is then opened to accept a large bore cannula. Initially 3 litres of industrial methylated spirits are injected. This helps to stop rapid fixation of the blood and subsequent blockage of the arteries. 12 litres of embalming fluid (Cambridge formulation, Vickers Laboratories, Pudsey, UK.) is then injected using a Pierce Royal Bond Embalming pump at 9psi.

One litre of embalming fluid consists of;	Methylated Spirits 99%	625mls
	Phenol	125mls
	Formaldehyde 39%	75mls
	Glycerol	175mls.

Once the initial arterial injection has ceased, the cadaver is left overnight to allow the fixative to settle and any area of poor fixation is subsequently spot injected using an open ended cannula connected to the embalming pump. The cadaver is then tagged with a year and body number. It is placed in a clear plastic body bag with a paper label attached and stored in a fridge at a temperature of 4°C and left for at least 4 weeks before use.

Coloured latex can be injected into the arteries for special demonstrations of the arterial supply to particular organs. To do this 20 mls of ammonia in 100 mls of warm water is injected into the cadaver to neutralise the embalming fluid and this is immediately followed by the injection of 500 mls of latex solution. This consists of 50 mls white latex (Trylon Ltd, Wollaston, UK.) cold water and colour added, usually black Indian ink. Any artery can be used for this purpose as long as it is not blocked.

The specimens were dissected whilst still attached to the remainder of the body so as to try and simulate as normal an anatomical position as possible. Dissections were performed of the full length of the thigh and knee to study the position of the neurovascular structures of the femoral triangle- the femoral artery, femoral vein, the femoral nerve and their branches. Standard dissection techniques were followed using Zuckermann (1981) and Romanes (1986) as a guide.

Superficial anterior dissection

Initially a superficial dissection of the full length of the thigh was carried out to study the course of the femoral nerves and vessels. A skin flap was elevated from the medial aspect of the thigh over the region of the femoral triangle. This was extended distally and the flap elevated laterally. The superficial and deep fascia were removed exposing the sartorius and adductor longus muscles.

The femoral artery, vein and nerve were then dissected from proximal to distal and their various branches identified and followed to their destination.

Deep posterior dissection

On the same limb a deep dissection was carried out on the posterior side. Once again, a skin flap was elevated from the medial aspect of the thigh. This was reflected laterally and many of the superficial structures were removed or reflected in order to locate the deeper nerves and vessels. Particular care was taken to identify the sciatic nerve and the structures lying deep to this, such as the emerging medial circumflex artery.

Deep anterior dissection

This dissection was carried out in five specimens and was performed in a manner similar to the superficial dissection. It was carried out to study the deeper aspect of the thigh, and the paths of the structures identified in the superficial dissection. A skin flap was elevated from the medial aspect of the thigh and reflected laterally. The dissection however, was continued to a much greater depth at the front of the thigh by removing many of the superficial structures.

Great care was taken to expose the medial circumflex artery, profunda femoris artery and their deeper branches. The main muscular branches of the femoral nerve were also identified and followed to their destinations.

Superficial posterior dissection

This was carried out on the same limb on which the deep anterior dissection had been performed. This was carried out in a manner similar to the deep posterior dissection. A skin flap was elevated from the medial aspect of the thigh and reflected laterally.

Once all the anterior dissections had been completed three pins were inserted as reference points to allow measurements to be made between the neurovascular structures at risk and the position of the locking screws. The first pin was inserted into the midpoint of the lesser trochanter of the femur. The midpoint of the femur was identified at this level and the other two pins were inserted into the femur 12 mm above (proximal of the two AP locking screws) and 12 mm below (distal of the two AP locking screws) below this point. These pins were taken as the position of the AP locking screws and all subsequent measurements were made from the position of these pins.

Simulation of Retrograde Femoral Nailing

Simulation of retrograde intramedullary femoral nailing was carried out as an investigative procedure on the left limb of an undissected embalmed cadaver. This had been embalmed using a formalin free embalming solution, known as ' glyofixx'.

The length of nail required is normally obtained by either measuring the length of the femur (from the intercondylar notch to the level of the lesser trochanter) on preoperative X-rays of the contralateral femur or by intraoperative screening.

As it was not possible to determine the length of the nail required using this method in the dissecting room an alternative method had to be used. This was carried out by dissecting the contralateral limb to the one which was going to be operated upon. The femoral triangle was initially dissected to the level of the lesser trochanter. At the knee, the intercondylar fossa was dissected. Following this, a ruler was used to measure the distance from the lesser trochanter to the intercondylar fossa (Fig.6.1). The measurement obtained was 36.6 cm. The Richards nail which was closest to this length measured 36 cm, and this size of nail was ordered (Fig.6.2).

Fig.6.1 Determination of length of nail required for simulated retrograde femoral nailing.

The Richards retrograde intramedullary femoral nail has an anteroposterior curvature, which matches that of the femur (Fig.6.2). As previously stated the nail has five interlocking screws. Three of these are inserted in the supracondylar region of the femur from a lateral to medial direction. Two, are inserted at the level of the lesser trochanter in an anteroposterior direction (Fig. 5.2).

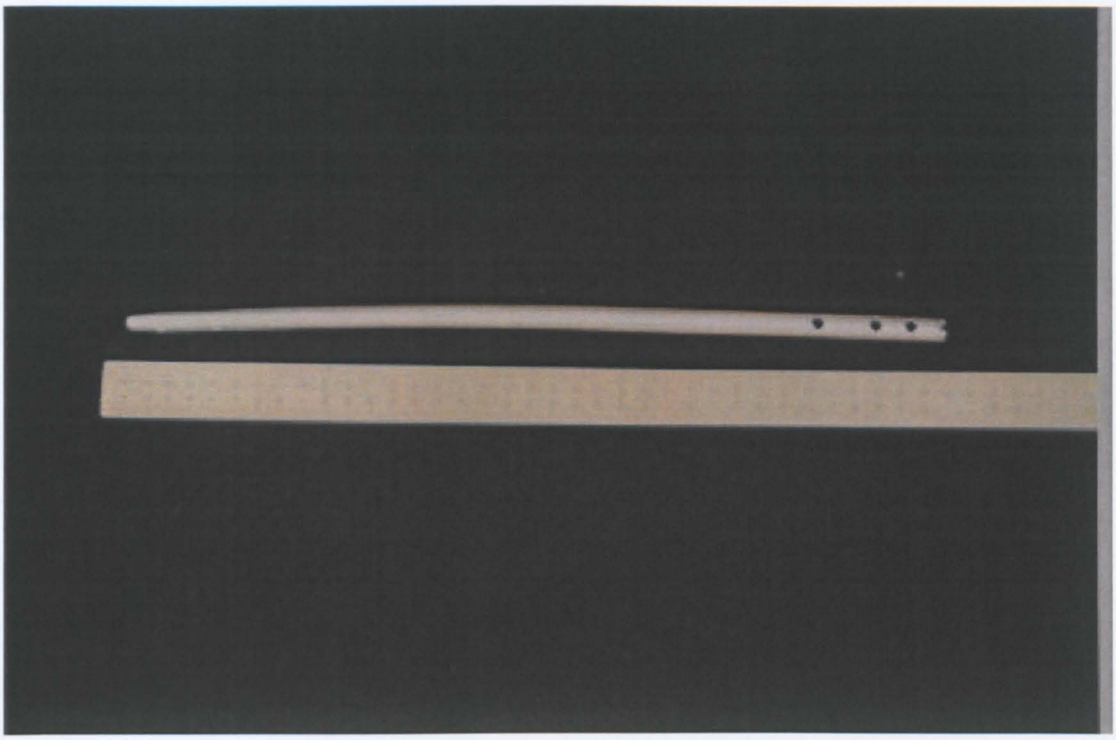

Fig.6.2 Richards retrograde femoral nail of appropriate length for simulated nailing.

The distal locking screws are inserted using the ' guide ' (Fig.5.9). The proximal screws are inserted freehand under ' image intensification '. As this technique was not available in the dissecting room an alternative method had to be used. In order to allow percutaneous anteroposterior locking to be performed a window was made in the proximal femur. A proximal to distal incision was made over the lateral aspect of the thigh. This was extended down to the surface of the lateral aspect of the femur. At the level of the lesser trochanter the lateral surface of the femur was cut and chipped away to create a window which measured about seven centimetres in length, revealing the medullary cavity (Fig.6.3). This would allow the surgeon to visualise where the drill would be in relation to the femur and the locking holes in the Richards nail.

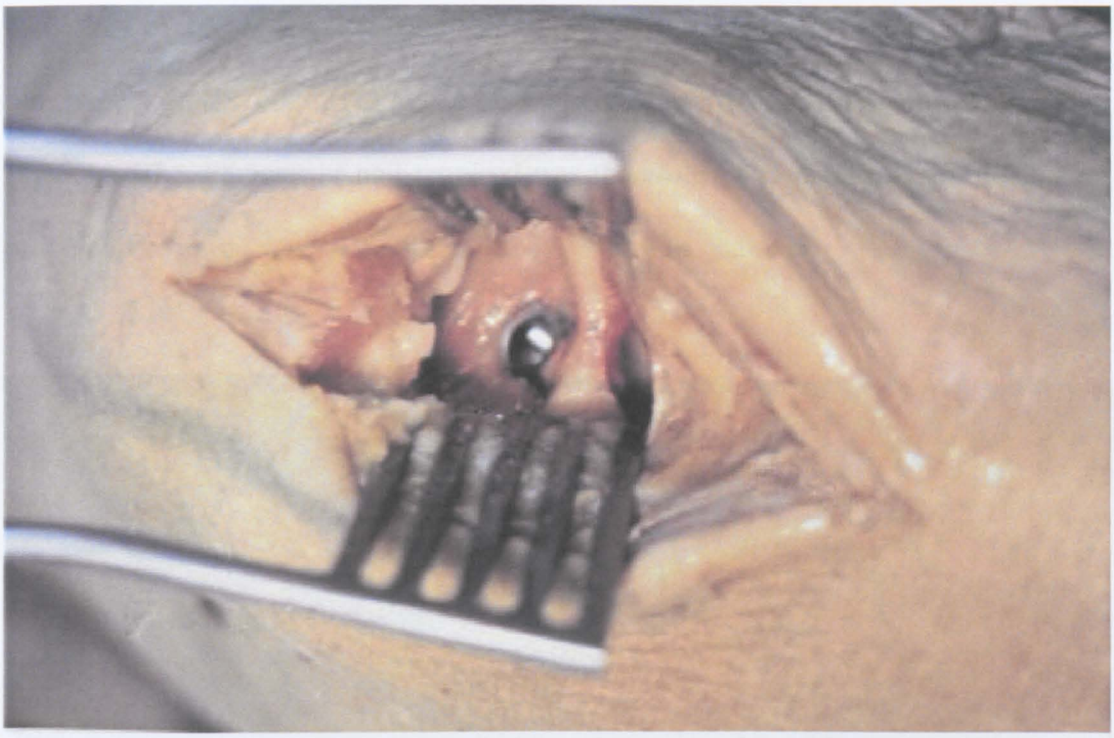

Fig.6.3 Windowed proximal lateral femur at the level of the lesser trochanter.

The simulated retrograde femoral nailing was performed on the intact left limb of the cadaver, the proximal femur of which had been windowed laterally. The nailing was carried out using a standard retrograde femoral operating technique (Smith and Nephew 1997). The knee was placed in a flexed position by inserting a stainless steel bowl under the popliteal fossa. A longitudinal skin incision was made over the medial border of the patella tendon. This was extended through subcutaneous fat and deep fascia and the patella tendon retracted laterally.

This allowed the intercondylar fossa to be visualised. An entry point using a hand reamer and steinman pin was made in the intercondylar fossa just anterior to the insertion of the anterior cruciate ligament. Once the entry point had been made, a guide wire was inserted into the medullary cavity of the femur (Fig.6.4). The medullary cavity was then reamed using powered flexible reamers starting from a 6.5 mm reamer, and going up to a size 12.5 mm diameter reamer in 1 mm increments (Fig.6.5). The diameter of nail required was therefore 11 mm. The exact dimensions of the nail required was 36 cm in length by 11 mm in diameter.

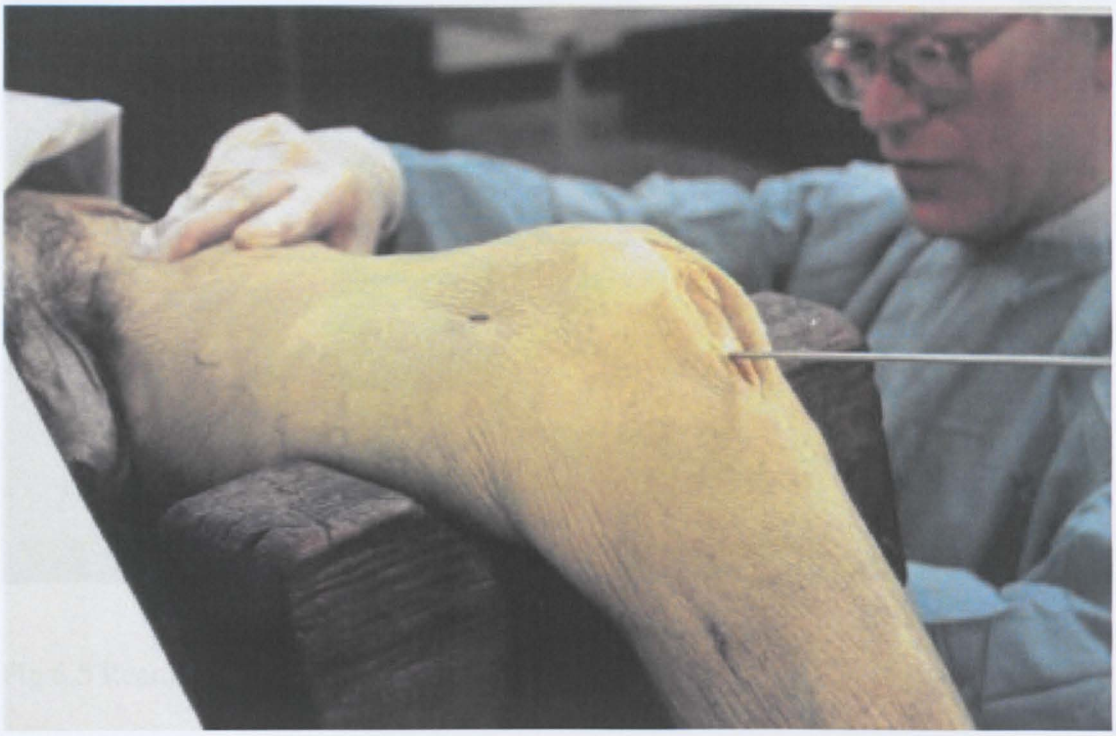

Fig.6.4 Guidewire being inserted into the medullary cavity of the femur in simulated retrograde femoral nailing.

The nail was then inserted with ease over the guide wire and was countersunk into the intercondylar fossa for 1-2 cm so that the proximal end was approximately 1 cm above the level of the lesser trochanter. This was followed by removal of the guide wire, whilst leaving the nail in place inside the medullary cavity. Under normal circumstances, a drill guide assembly is used for insertion of the nail into the medullary cavity as well insertion of the distal locking screws. However, in this case, the insertion of the distal locking screws was not being investigated, so no drill guide assembly was used. Instead, the nail was inserted freehand and countersunk.

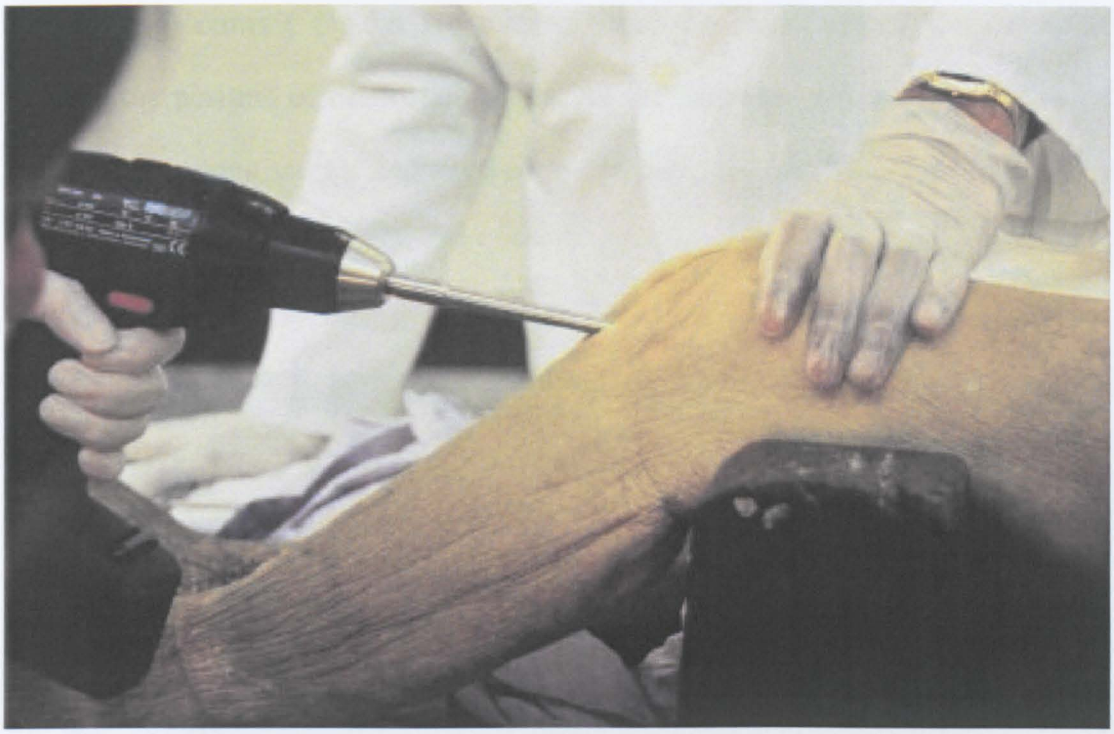

Fig.6.5 Reaming of the femur.

Normally, the distal locking screws are inserted at this stage of the procedure. For the purposes of this study the nail was only locked at the proximal end of the femur. Investigative drill holes were made at the exact position in which the locking screws would be placed at surgery. To enable external visualisation of their position, the position of the holes was temporarily marked by Steinman pins. Proximal locking was performed using a percutaneous technique. The Steinman pins were inserted into the anterior thigh through a small stab incision in the skin. The position of insertion was determined from the position of the locking holes which were visible through the windowed lateral femur.

The investigative drill holes were made through the anterior cortex of the femur, through the locking holes in the Richards nail and out through the posterior cortex of the femur. This procedure was repeated twice, as the Richards nail has two proximal A-P locking screws (Fig.6.6). Steinman pins were then inserted temporarily to indicate the position of the locking holes. As the Steinman pins were considerably longer than locking screws it allowed us to determine the potential risks to the many surrounding nerves and vessels.

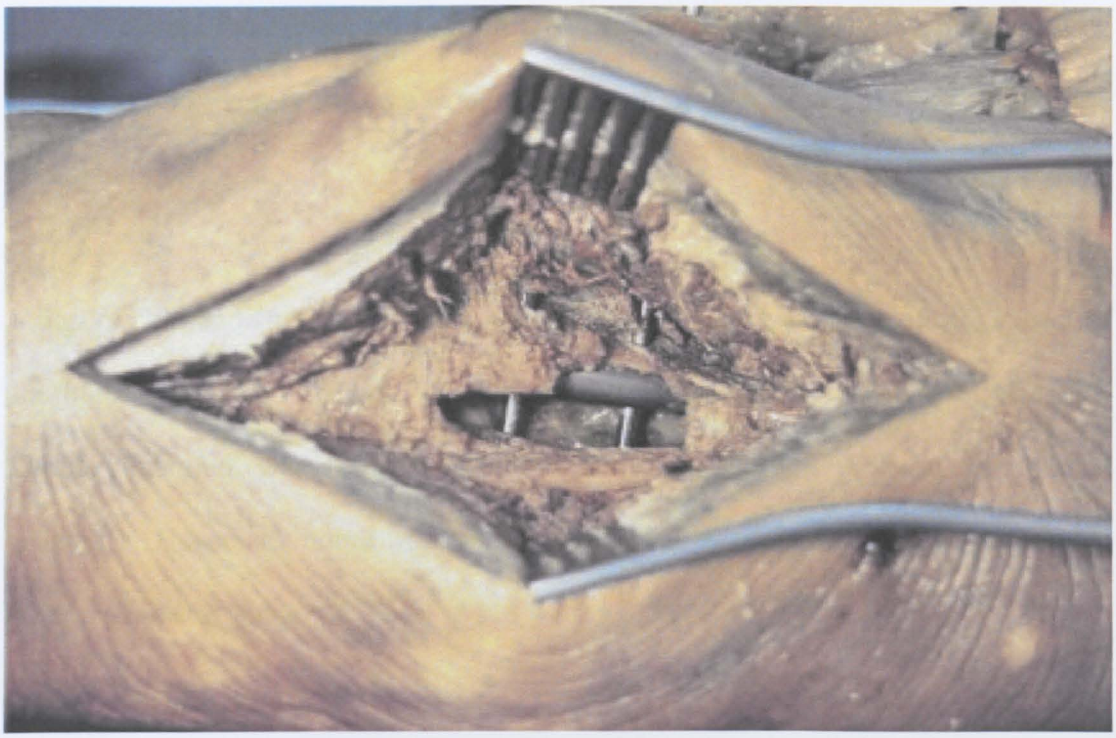

Fig.6.6 Position of the proximal interlocking pins seen in the windowed proximal lateral femur.

<u>Anatomical Examination of the Proximal (Anteroposterior) Interlocking Screws</u>

Dissections were performed of the both the anterior and posterior thigh to determine which if any structures were at risk from percutaneous insertion of the anteroposterior proximal locking pins.

A skin flap was reflected from the medial aspect of the thigh, and elevated laterally. An ' island ' of skin was, however, left around the Steinmann pins which indicated the position of the investigative holes. Careful dissection down to the deep fascia was then performed in order to determine if any cutaneous nerves were at risk. Once these had been identified they were removed.

The deep fascia was removed and the femoral sheath exposed. The femoral sheath was dissected to reveal the femoral neurovascular bundle. The femoral vein, artery and nerve were then dissected in a proximal to distal direction to provide the basic landmarks and identify the course and destination of their branches in relation to the steinmann pins.

A flap of skin and superficial fascia was reflected laterally on the posterior aspect of the thigh. Again, an ' island ' of skin was left around the investigative drill holes. Gluteus maximus was reflected laterally until its insertion point at the gluteal tuberosity. The sciatic nerve was identified and the followed distally by splitting the fascia which surrounded it.

<u>Dissections of the lateral thigh</u>

Four dissections were carried out of the lateral aspect of the thigh. These were performed with the limb still attached to the rest of the body. The hip and knee were in a position of 10-20 degrees of flexion with the limb in approximately 20 degrees of external rotation.

A skin flap was elevated from the lateral aspect of the thigh and reflected posteriorly. The superficial fascia was removed and the tensor fasciae latae identified. This was incised perpendicular to its long axis and reflected superiorly to expose the underliying vastus lateralis muscle. The neurovascular bundles to the tensor fasciae latae and vastus lateralis were identified and carefully dissected out in relation to the lateral surface of the femoral shaft at the level of the lesser trochanter.

Simulation of Retrograde Femoral Nailing Using Redesigned Nail

Retrograde femoral nailing was performed using a redesigned nail. The conventional Richards retrograde femoral nailing has anteroposteriorly directed proximal locking screws (Fig.6.7). Following our preliminary investigations it was decided to attempt proximal locking from a lateral to medial direction at the level of the lesser trochanter.

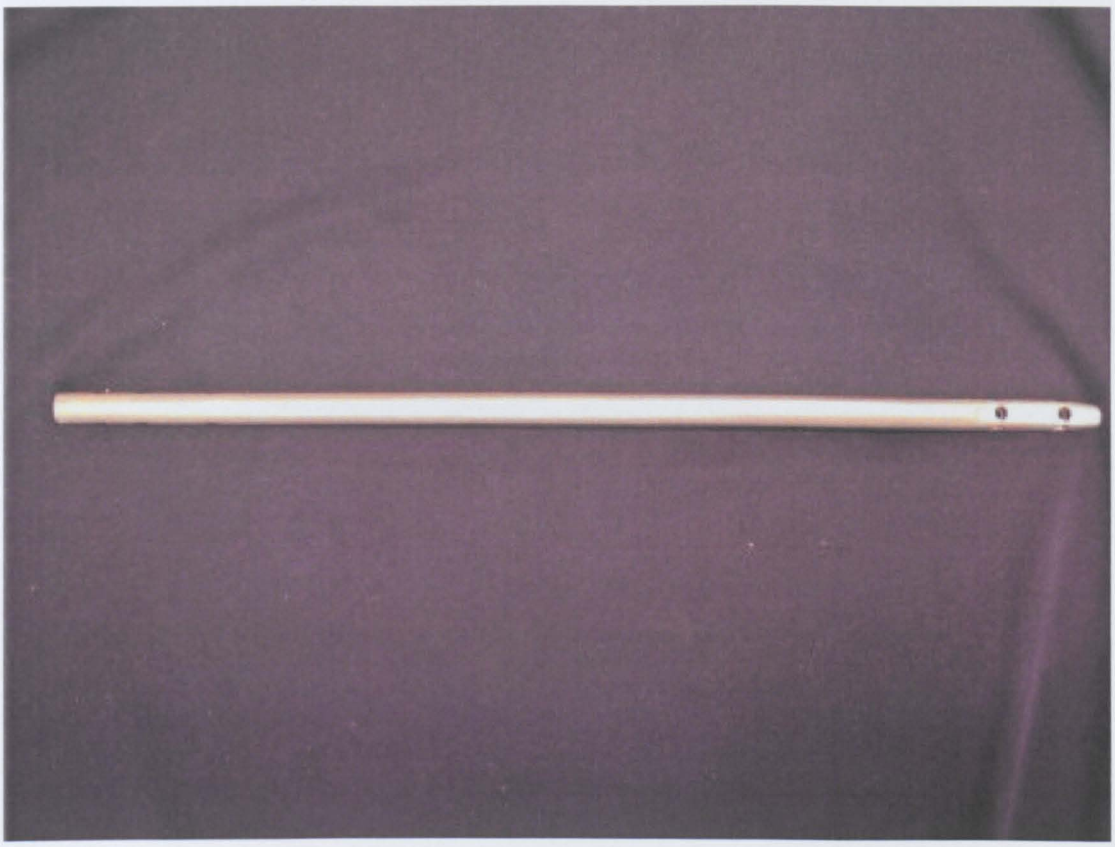

Fig.6.7 Standard Richards nail with anteroposterior proximal locking holes.

This was carried out using the standard procedure for retrograde femoral nailing which has been described above. The length of the femoral nail required was once again determined by dissection of the contralateral femur as previously described.

A standard Richards nail of appropriate length (38cm) was obtained and modified for the purposes of the study by the Department of Mechanical Engineering at the University of Glasgow (see Appendix). Two lateral to medial locking holes were drilled at the exact level of the pre-existing anteroposterior locking holes (Fig.6.8).

Fig.6.8 Modified Richards nail with lateral to medial proximal locking holes.

In order for proximal locking to be performed without image intensification a similar technique to that described previously was utilised. On this occasion a skin flap was elevated from the medial aspect of the anterior thigh and reflected laterally. The femoral triangle was dissected as before, identifying the femoral neurovascular bundles and their branches.

The anterior surface of the proximal femur was exposed by excising the overlying muscle. The anterior surface of the femur was then windowed by cutting and chipping away the anterior cortex until the medullary cavity was revealed (Fig.6.9).

Fig.6.9 Windowed proximal femur at the level of the lesser trochanter.

This allowed the surgeon to visualise where the drill would be in relation to the femur and the proximal locking holes, which would now be in the horizontal plane.

Retrograde femoral nailing was then performed using a standard technique. The nail was inserted freehand through an entry point in the intercondylar notch once reaming had been performed and was countersunk below the articular surface. Distal locking was not carried out for the purposes of this study and only proximal locking from a lateral to medial direction was performed.

To enable external visualisation of their position, the actual locking screws were replaced by investigative drill holes. Steinmann pins were temporarily inserted to mark the position of the drill holes. Proximal locking was performed using a percutaneous technique. The drill holes were made into the lateral aspect of the femur through a small stab incision in the skin. The position of insertion was determined from the position of the locking holes, which were visible through the windowed anterior femur (Fig.6.9).

The holes were then drilled through the lateral cortex of the femur, through the locking holes in the Richards nail and out through the medial cortex of the femur. This procedure was repeated twice, as the Richards nail has two proximal locking screws. Steinmann pins were inserted temporarily through the drill holes to show their position. As the Steinmann pins were considerably longer than locking screws it allowed us to determine the potential risks to the many surrounding nerves and vessels.

Three specimens on which deep anterior dissections had been performed were then chosen for further investigation of the lateral to medial locking screws. Investigative holes were made in the proximal femur from a lateral to medial direction. These were made at the level of the lesser trochanter and approximately two centimetres below. Steinmann pins were inserted temporarily and left proud of the medial femoral cortex.

Anatomical Examination of the Proximal (lateral to medial) Interlocking Screws

Dissections were performed of the both the lateral and medial thigh to determine which if any structures were at risk from percutaneous insertion of the proximal locking pins in a lateral to medial direction.

A skin flap was reflected from the lateral aspect of the thigh, and elevated posteriorly. An ' island ' of skin was, however, left around the Steinmann pins. Careful dissection was performed in order to determine if any cutaneous nerves were at risk. The superficial fascia was then removed and the fascia lata identified.

This was incised perpendicular to its long axis and reflected superiorly to expose the underlying vastus lateralis muscle. The neurovascular bundles to the tensor fasciae latae and vastus lateralis were identified and carefully dissected out in relation to the proximal interlocking pins. The limbs were also dissected medially and the obturator nerve and its branches identified and dissected out as well as the obturator artery.

Trial of Redesigned Nail In Theatre Using Image Intensification

A nail similar to that used for lateral to medial proximal locking screw insertion was used during this part of the study, As the nail was not licensed for actual implantation during surgery a formal surgical trial was not possible. It was therefore decided to attempt to simulate proximal interlocking in a lateral to medial direction.

This was carried out on volunteers following approval of the project by the Ethics of Research Committee (Forth Valley Health Board). The nature and purpose of the procedure was explained to the volunteers as well as the risks of X-Ray exposure and informed consent obtained.

In theatre the volunteers were placed supine on the fracture table. The C-arm of the image intensifier was then placed directly over the proximal femur in an anteroposterior direction (Fig.6.12). Screening was carried out and the level of the lesser trochanter identified.

Under image intensification the redesigned nail was taped to the lateral aspect of the thigh in line with the shaft of the femur (Fig.6.10). The proximal end of the nail was positioned so that the proximal locking hole was situated at the level of the lesser trochanter (Fig.6.11).

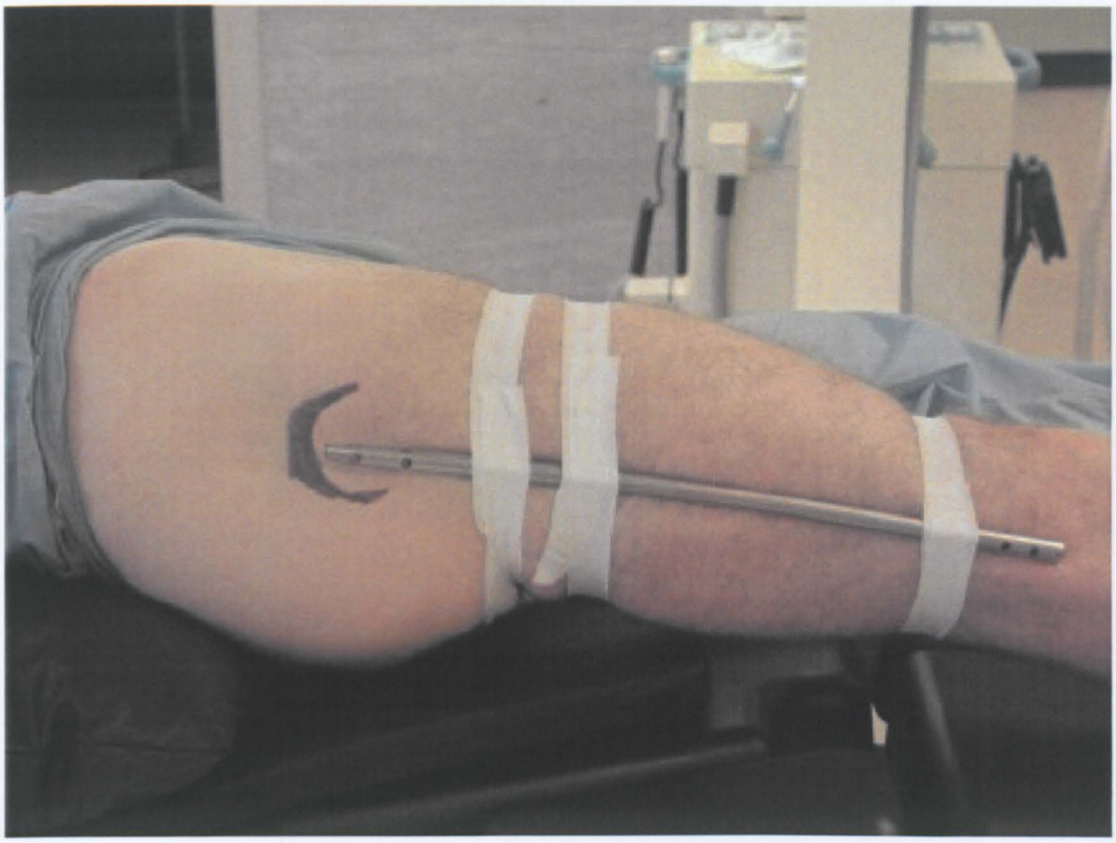

Fig.6.10 Modified nail taped to the lateral aspect of thigh for screening using the image intensifier.

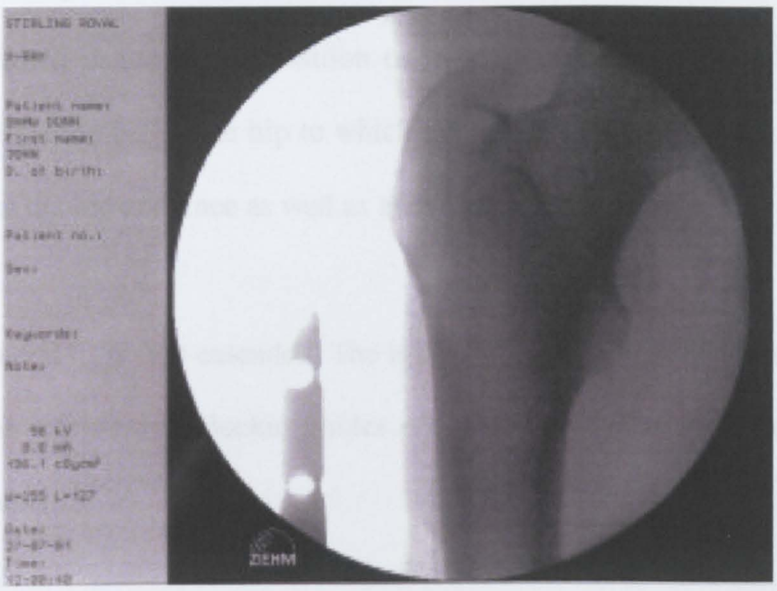

Fig.6.11 X-Ray showing the locking holes of the modified nail to be at the level of the lesser trochanter.

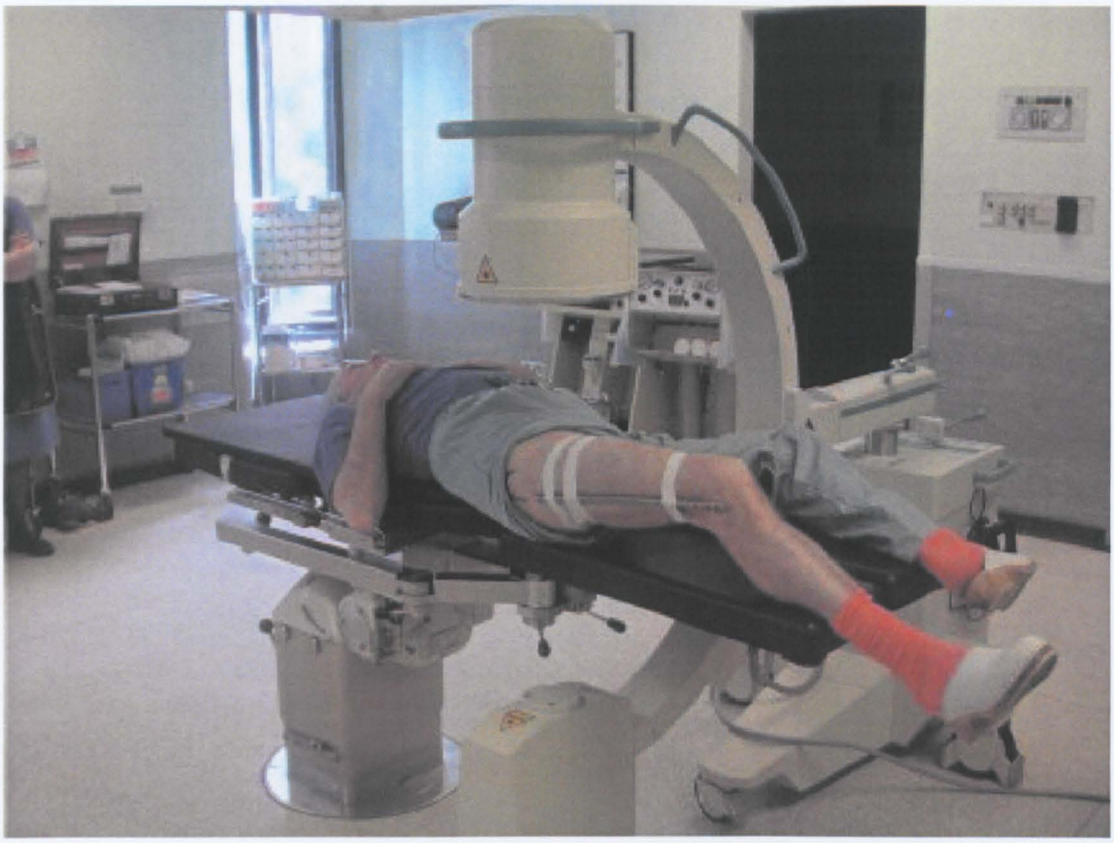

Fig.6.12 Position of the image intensifier to confirm the level of the proximal locking holes.

Screening of the proximal thigh was carried out in two positions. In the first volunteer it was performed in the supine position on a standard theatre table (Fig.6.13). A sandbag was placed below the hip to which the femoral nail was taped. This leg was then flexed at the hip and knee as well as abducted at the hip.

The contralateral limb was extended. The image intensifier was then positioned to try and visualise the proximal locking holes of the redesigned nail at the level of the lesser trochanter.

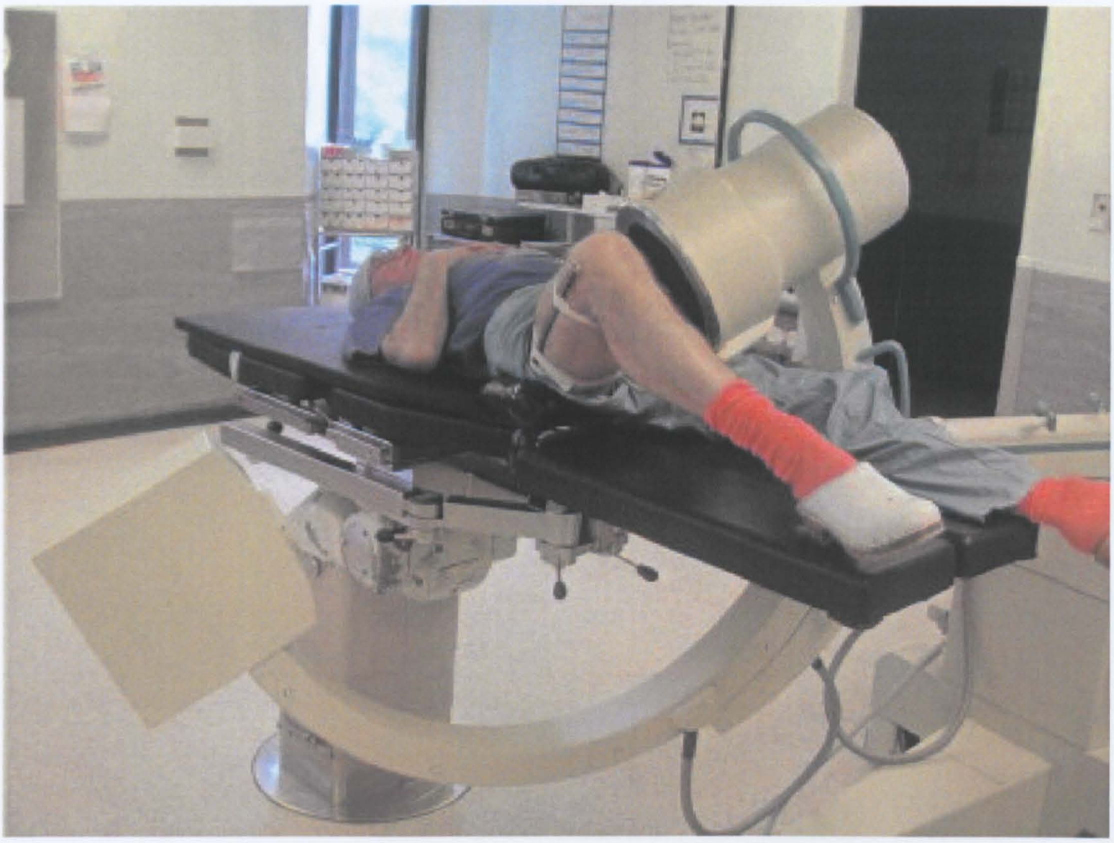

Fig.6.13 Position of the C-arm of the image intensifier to screen the proximal locking holes with the volunteer on a standard theatre table.

In the subsequent two volunteers screening was carried out with the limbs placed in traction with the limb which was undergoing simulated ' nailing ' fully extended (Fig.6.14). The contralateral limb was abducted and flexed at both the hip and knee.

The C- arm was once again positioned over the proximal femur, but on this occasion in the horizontal position to allow screening to take place from lateral to medial. Image intensification was then used to determine if the proximal locking holes could be visualised completely i.e. viewed as round holes, in order to allow proximal locking of the Richards nail from a lateral to medial direction.

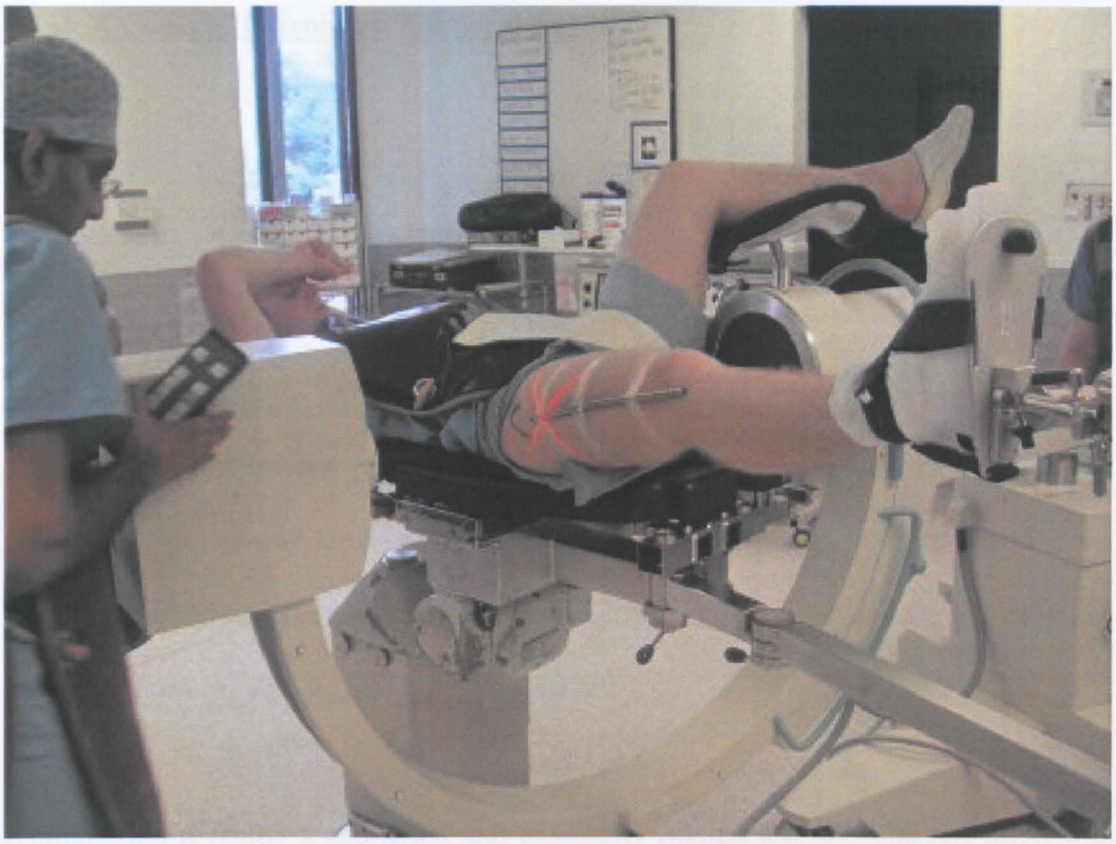

Fig.6.14 Position of the C-arm of the image intensifier to screen the proximal locking holes with the volunteer in traction.

Retrograde Femoral Nailing in Clinical Cases

Below are case histories of four patients who presented to hospital with femoral shaft fractures and were treated with intramedullary retrograde femoral nailing. The procedure was carried out as previously described in Chapter 5.

The patients were all placed supine with a bolster under the knee. A medial parapatellar incision was used and the patella retracted laterally. The intercondylar notch was breached using a bone awl and a guidewire inserted into the femur across the fracture site. The medullary canal was reamed and the appropriate length of nail inserted. Distal locking was carried out using the jig and proximal AP locking was carried out freehand under image intensification.

Clinical Cases of Retrograde Femoral Nailing

Patient 1

Details	Initials:	A.M
	Unit No.:	370410
	D.O.B. :	17.7.15

This 85 year old woman was initially admitted to hospital under the care of the physicians for investigation of recurrent falls at home. Unfortunately whilst in hospital, she fell again and injured her left leg. She complained of severe pain in her left leg and was unable to weightbear on the left leg.

Examination revealed a shortened and externally rotated left leg. The left thigh was very swollen and she was tender over the distal femoral shaft. She was unable to move the left hip or knee actively because of severe pain, and passive movements were also extremely painful. There was no distal neurovascular deficit and she had no other injuries.

X- Rays showed a fracture of the left distal shaft of femur which was significantly displaced (Fig.6.15). She was given adequate analgesia and a femoral nerve block inserted using 1 % Lignocaine and 0.5 % Marcaine. Her left leg was then temporarily immobilised in a Thomas splint prior to surgery the following day.

Fig.6.15 Pre-operative X-Rays of patient 1 showing an oblique fracture of the left distal femur.

She underwent intramedullary retrograde femoral nailing using the technique described above. As the Richards nail was not available a similar implant manufactured by Biomet was used. This is almost identical to the Richards nail, and has two proximal AP locking screws which are inserted freehand. Unlike the Richards nail which has three distal locking screws this nail has only two. However, as these were not being investigated the nail was a suitable replacement for the Richards nail. The nail required for this patient was 280 mm in length and 12 mm in diameter. Distal locking was performed percutaneously using the drill guide assembly. Proximal locking carried out freehand below the level of the lesser trochanter through a small open incision in an AP direction using image intensification.

Patient 2

Details	Initials:	P.M.
	Unit No.	880816
	D.O.B.	23.5.81

This 19 year old man was admitted to hospital after being assaulted with a blunt instrument. He had been hit on the head and also struck on the right thigh. On admission he was alert and orientated. He complained of severe right thigh pain and had been unable to weightbear following the assault. On examination he had a Glagow Coma Score of 15. His right thigh was very swollen and tender over the midshaft of the femur. He was unable to move the hip or knee actively because of pain and passive movements were also very painful. There was no distal neurovascular deficit.

X-Rays revealed a displaced fracture of the midshaft of the femur (Fig.6.16). He was given adequate analgesia and a femoral nerve block inserted. The right leg was temporarily immobilised in a Thomas splint and he was taken to theatre the following day and underwent retrograde femoral nailing as above. Once again a Biomet nail was used and the length of nail inserted was 380 mm in length and 12 mm in diameter. Distal and proximal locking was carried out as described above.

Fig.6.16 Pre-operative X-Rays of patient 2 showing a spiral fracture of the right distal femur.

Patient 3:

Details	Initials:	A.T
	Unit No.	208639
	D.O.B.	10.10.31

This 69 year old man was initially brought in to the accident and emergency department after falling following excessive alcohol intake. He could not recollect the exact mechanism of injury but felt he may have fallen down some stairs.

Following the fall he had been unable to weight bear on his right leg and complained of severe thigh pain. On examination his right thigh was swollen and tender. He was unable to move his right hip or knee actively because of pain and passive movements were also painful. There was no distal neurovascular deficit. X-Rays showed a fracture of the distal shaft of the right femur with a longitudinal extension into the knee joint (Fig.6.17).

His right leg was temporarily immobilised in a Thomas splint and he was taken to theatre the following day for internal fixation of the femoral shaft fracture. This was treated initially with a 'short' supracondylar nail.

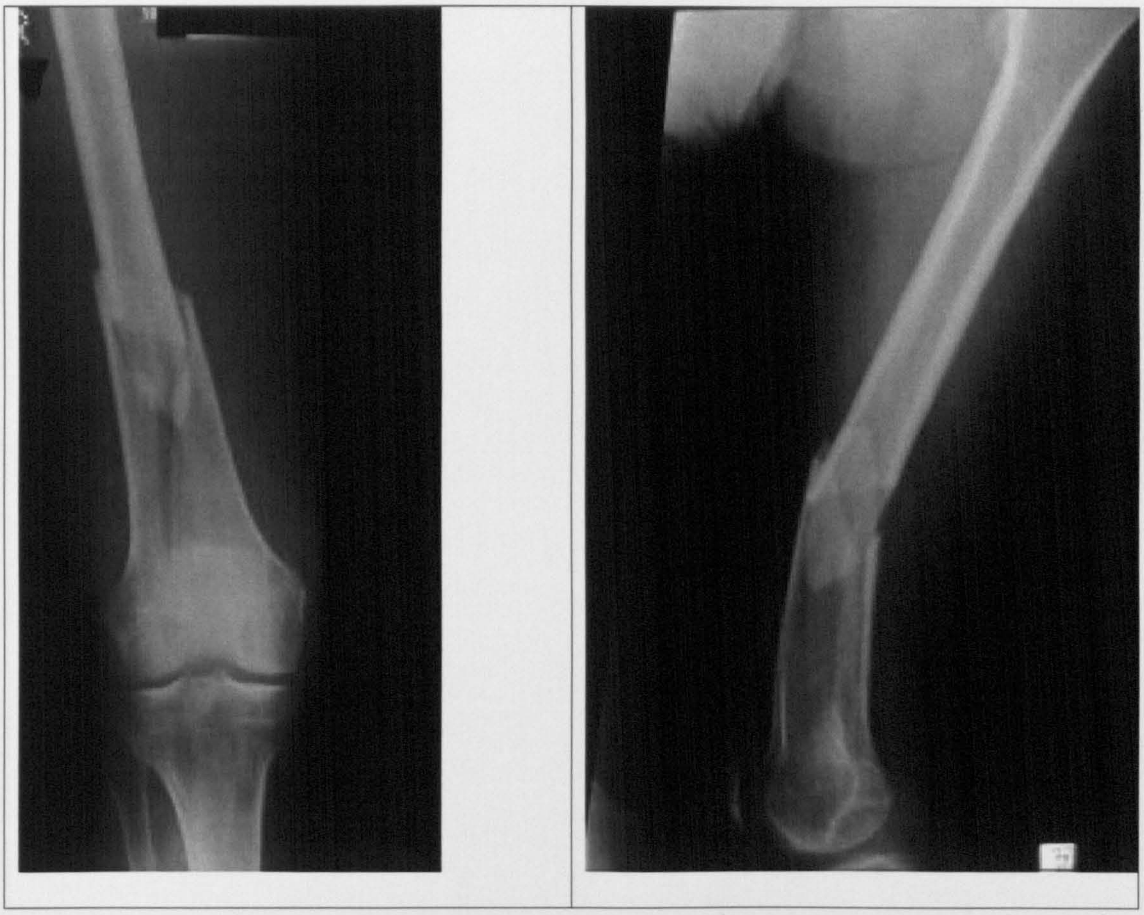

Fig.6.17 Pre-operative X-Rays (1) of patient 3 showing a comminuted fracture of right the distal femur.

He was mobilised partial weight bearing post-operatively and discharged home. Unfortunately, he was then readmitted a few days later following a further fall after excessive alcohol intake. The exact mechanism of injury was unclear and he once again complained of right thigh pain and inability to weight bear.

Examination revealed his right thigh to be swollen, tender and deformed. There was no distal neurovascular deficit and X-Rays of his femur showed a peri-prosthetic fracture at the tip of the supracondylar nail (Fig.6.18).

Fig.6.18 Pre-operative X-Rays (2) of patient 3 showing a periprosthetic fracture of the right femur.

He was taken to theatre the following day and an exchange nailing carried out with insertion of a Richards retrograde femoral nail. Distal locking was carried out using a guide and proximal locking was performed freehand.

Patient 4

Details	Initials:	V.M.B
	Unit No.	1501682
	D.O.B.	14.01.30

This 70 year old man presented to the accident and emergency department complaining of pain in his left thigh and knee. He was unable to weightbear due to the pain and gave no history of trauma. He was noted to have a past history of prostatic cancer.

On examination he was noted to have swelling over the left distal thigh and knee. He was tender over the distal femur and movements of the knee were very painful. There was no distal neurovascular deficit. X-rays of the left femur and knee revealed a supracondylar fracture of the femur (Fig.6.19). Given the patients past medical history and clinical presentation the fracture was presumed to be pathological.

He was given adequate analgesia and initially immobilised in a long leg plaster cast. In view of his past medical history a bone scan was arranged. This revealed widespread skeletal metastases with an area of increased uptake in the supracondylar region of the left femur and confirmed the fracture to be pathological in nature.

He subsequently received a course of radiotherapy to the left femur prior to undergoing retrograde femoral nailing of the left femur using the technique described above. Distal locking was carried out using the drill guide assembly and proximal locking performed through a small open incision and a single screw was inserted.

Fig.6.19 Pre-operative X-Rays of patient 4 showing a supracondylar fracture of the left femur.

Section 3

RESULTS

Anatomy of the Neurovascular Structures of the Thigh

Dissections of the anterior aspect of the thigh showed the topography of the femoral triangle, the course of the femoral nerve and vessels through the proximal thigh, and in particular, their relationship to the femur at the level of the lesser trochanter.

The femoral triangle was found to be a depressed area, which was located in the upper thigh. It is bordered by sartorius laterally, the adductor longus medially and the inguinal ligament superiorly (Fig.7.1). The femoral vessels were found to be in the deepest part of the femoral triangle. The femoral nerve lay lateral to the artery and began to divide near the base of the triangle. The femoral artery entered the femoral triangle at the midinguinal point separated from the head of the femur by the psoas tendon and emerged on the anteromedial surface of the thigh. As the femoral artery leaves the boundaries of the femoral triangle, it lies on adductor longus but dissections show that it is close to the medial surface of the femur.

Figure 7.2 shows the deep dissection of the anterior thigh. Sartorius is partially reflected laterally to expose the many branches of the femoral nerve and artery passing behind and through the muscle.

Deeper dissections on the other specimens showed the main branches of the femoral artery, the profunda femoris artery and the lateral and medial circumflex arteries (Figures 7.2 and 7.8-7.12). The lateral and medial circumflex arteries, in most cases, arise directly from the profunda femoris (Figure 7.2).

Fig.7.1 Femoral triangle; Superficial dissection of the femoral triangle (right side). The triangle is bordered by the medial border of sartorius (A) and the medial border of adductor longus (B). Above is the inguinal ligament (C). In the centre is the femoral artery (D). Medially lies the femoral vein (E) receiving the saphenous vein (F) and laterally the profunda femoris artery (G), which has an unusually high origin. Branches of the femoral nerve (H) fill the lateral angle of the triangle. On the lateral side of the thigh are the tensor fasciae latae (I) and rectus femoris (J).

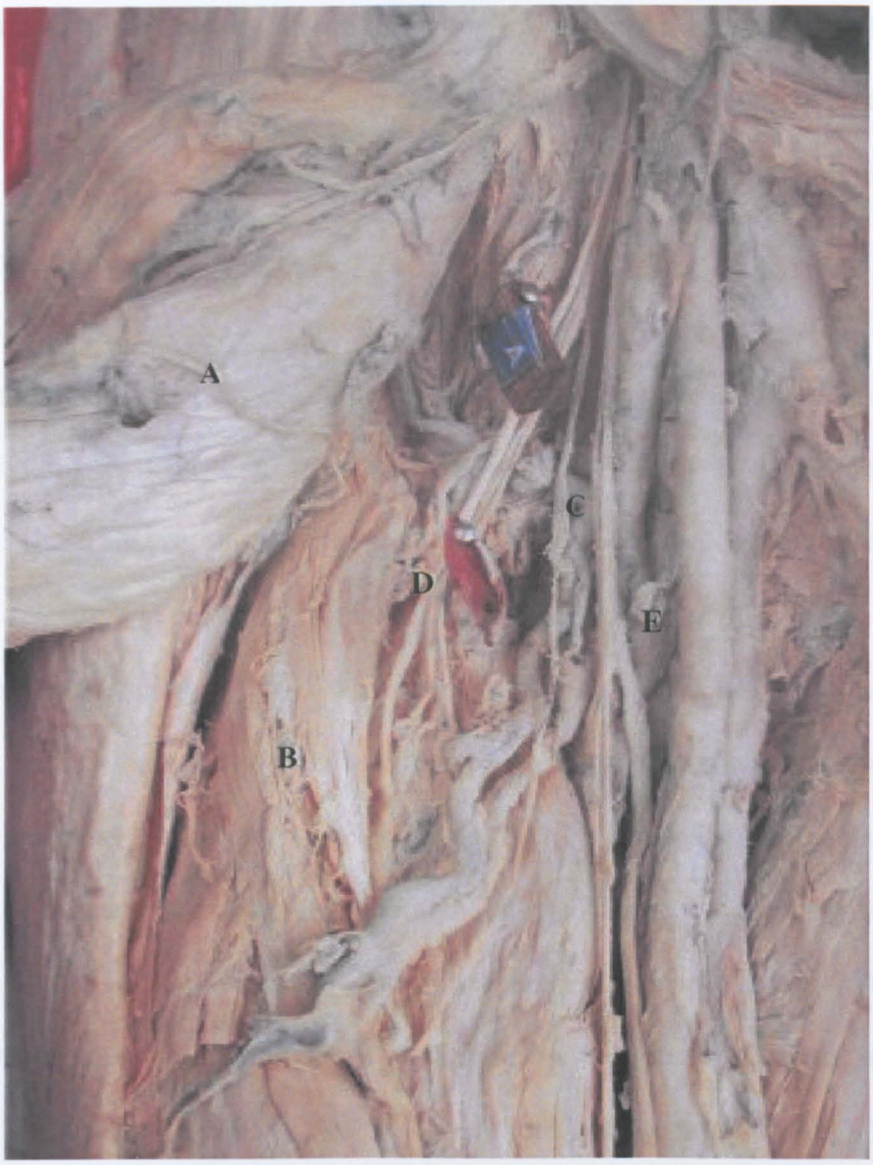

Fig.7.2 Deep anterior dissection; This demonstrates a deeper dissection on the specimen shown in fig.7.1. The sartorius muscle (A) has been reflected. On the surface of rectus femoris (B) are the descending and transverse branches of the lateral circumflex femoral artery (C) and the muscular branch of the femoral nerve to vastus lateralis (D). The medial circumflex femoral artery (E) can be seen coursing deeper into the thigh.

The medial circumflex artery is seen in Figure 7.2, as it courses deeper into the thigh, where it branches to give an ascending branch. This goes on to supply the head of the femur. It also gives off a transverse branch, which supplies the hamstring muscles of the thigh.

The lateral circumflex artery runs laterally between the branches of the femoral nerve, before dividing into its three branches; the ascending, transverse, and descending branches. These are best seen in Figure 7.6, on the simulated nailing specimen.

After the femoral artery emerged into the femoral triangle, about 1cm distally, the profunda femoris branched off its lateral surface. The profunda femoris artery is the principal artery supplying the muscles of the thigh. It arises in the femoral triangle from the posterolateral surface of the femoral artery. It then runs medially and lies to the medial side of the femur and descends close to the femur (Fig. 7.3). Three perforating arteries arise from the profunda femoris artery in the proximal half of the thigh. It eventually terminates as the fourth perforating artery (Fig. 7.3). The perforating arteries spiralled downwards around the femur and ended in the vastus lateralis muscle and emerged at the back of the femur. These perforators and their branches supply the vastus lateralis, the adductor muscles, and the hamstring muscles of the thigh, and run close to the linea aspera.

The femoral nerve (L2 – L4) is the primary nerve of the anterior thigh (Figures 7.1 and 7.2). It enters the femoral triangle behind the inguinal ligament and lateral to the femoral sheath, containing the femoral artery and vein. It then divides into numerous muscular and cutaneous branches which fan out about 2 cm from its origin (Figures 7.1, 7.2 and 7.8-7.12) .

Fig.7.3 Perforating arteries; The profunda femoris artery (A) gives off the first, second and third perforating arteries (B,C,D) and continues as the fourth perforating artery below (E).

There are three prominent branches, the saphenous, the branch to vastus medialis and a lateral branch to vastus lateralis. The most relevant nerves in this investigation are the nerve to vastus lateralis (Figures 7.2 and 7.6), and the lateral cutaneous nerve of the thigh which is an independent branch of the lumbar plexus (Fig.7.5).

The femoral vein is the most medial of the structures in the femoral triangle and lies medial to the femoral artery in the femoral sheath. It also, like the femoral artery has an extensive network of sizeable muscular tributaries. Before leaving the femoral triangle to enter the pelvis it received blood from the profunda femoris vein and the great saphenous vein (Fig.7.1).

Deep and superficial dissections of the posterior thigh clearly showed the path of the sciatic nerve (Fig.7.4). The sciatic nerve left the pelvis via the greater sciatic foramen curving downwards midway between the greater trochanter and the ischial tuberosity as it passed through the gluteal region. It lies deep to gluteus maximus, crossing in turn, obturator internus, the gemelli and quadratus femoris which separate the nerve from the hip joint. Here it encountered the posterior cutaneous nerve of the thigh medially, running just medial to the inferior gluteal vessels (Fig.7.4), and continued distally, deep to the long head of biceps. Further distally, it sends branches down the middle of the posterior thigh, immediately deep to the deep fascia.

Fig.7.4 Dissection of the posterior thigh. This shows the sciatic nerve (A) and the posterior cutaneous nerve of the thigh (B). The bony landmarks illustrated by C and D are the greater trochanter and the ischial tuberosity.

Dissection of the Femoral triangle after Simulated Nailing

Systematic dissection of the area where the investigative holes had been drilled for proximal anteroposterior locking produced some dramatic findings. The dissection revealed the course of the femoral vein, artery, and nerve and their various branches in relation to the path of the investigative drill holes.

The lateral cutaneous nerve of the thigh was identified in close proximity to the drill holes, which represented the locking screws. It was located adjacent to the drill holes as it ran from proximal to distal. At its closest point it passes 1.2 cm medially to the holes (Fig.7.5). It also gives off a small branch which runs 1.5 cm distal to the drill holes (Fig.7.5).

A deeper dissection exposed the femoral nerve and its branches as they fan outwards. Fig.7.6 also shows clearly the branches of the femoral nerve, which supply vastus lateralis, and the path of the lateral circumflex artery, as they pass the pathway of the drill holes obliquely (Fig.7.6).

The results of the dissections in four other specimens are shown in Figures 7.8-7.12.

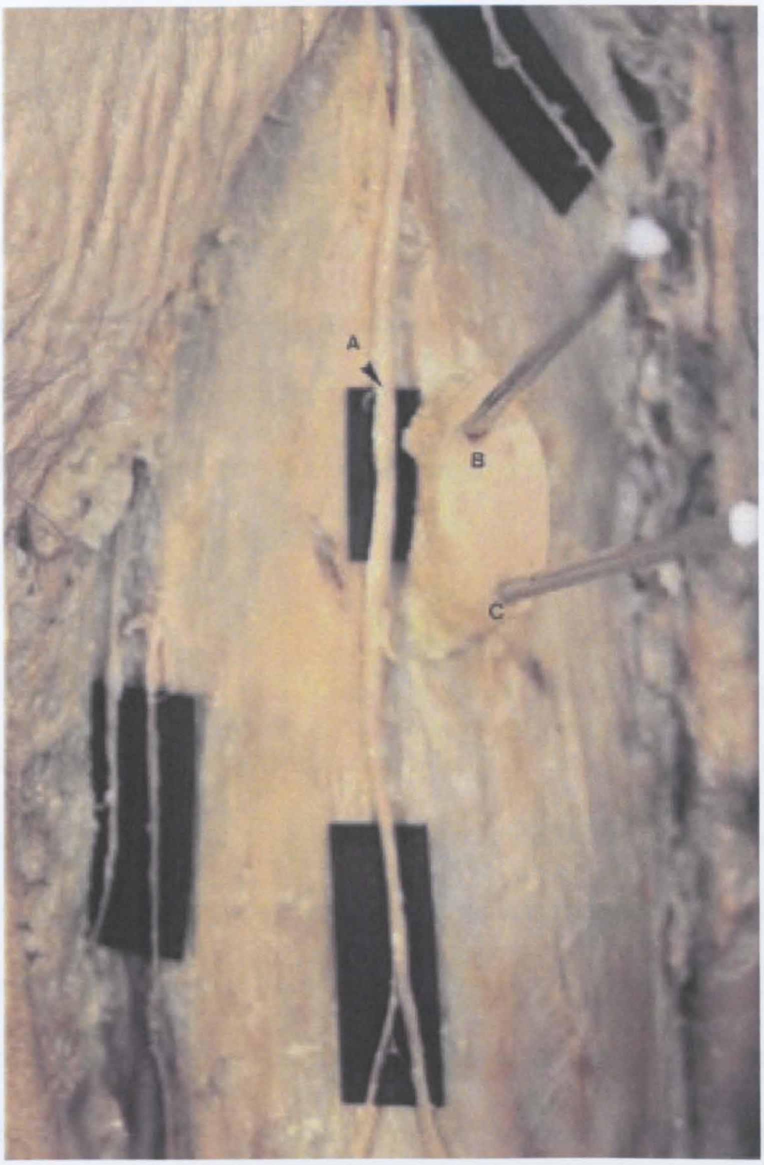

Fig.7.5 Superficial dissection of the left thigh. The lateral cutaneous nerve of the thigh (A) lies on the fascia lata. On the lateral side is an island of skin with the investigative drill holes, simulating the position of the proximal locking screws (B,C). On the medial side is another cutaneous nerve.

The nerves to vastus lateralis in particular run directly through the area of the investigative drill holes and at one point are in direct contact with the distal pin (Fig.7.6). The ascending branch of the lateral circumflex artery runs 4.2 cm from the most proximal drill hole whereas the transverse branch of the lateral circumflex artery passes through vastus lateralis 1 cm above the proximal drill hole. The larger descending branch and its accompanying veins descend medially to the drill holes at a distance of 1.6 cm from the proximal drill hole and only 1 cm from the distal of the two drill holes.

Figure 7.7 shows a deep dissection of the posterior aspect of the same specimen. Gluteus maximus has been reflected laterally, and the steinmann pins have been temporarily driven through the thigh and the investigative drill holes to show their relationship to the sciatic nerve. The sciatic nerve was found deep to the gluteus maximus muscle as it emerged from the greater sciatic foramen. The sciatic nerve and the accompanying gluteal vessels pass 3 cm medially to the more proximal hole, and 2.2cm medial to the more distal of the two holes, before disappearing behind biceps femoris.

Fig.7.6 Deep dissection of the left thigh after simulated nailing. This shows the descending branch of the lateral circumflex femoral artery (A) coursing towards the distal locking hole and the transverse branch (B) passing close to the proximal hole. A lateral branch of the femoral nerve (C) gives rise to muscular branches to vastus lateralis (D) which can be seen coursing towards the island of skin with the two investigative drill holes (E,F).

Fig.7.7 Posterior dissection of the left thigh after simulated nailing showing the sciatic nerve (A) and the accompanying gluteal vessels (B) lying medial to the locking holes (C,D).

Fig.7.8 Anterior dissection (4) of the right thigh; showing the position of the locking holes (A,B) and the femoral vein (C), artery (D), and nerve (E). The branches of the femoral nerve (F) can be seen passing close to the locking holes.

Fig.7.9 Anterior dissection (5) of the left thigh; showing the position of the locking holes (A,B) and the femoral vein (C), artery (D), and nerve (E). The branches of the femoral nerve (F) can be seen passing close to the locking holes.

Fig.7.10 Anterior dissection (6) of the right thigh; showing the position of the locking holes (A,B) and the femoral vein (C), artery (D), and nerve (E). The branches of the femoral nerve (F) can be seen passing close to the locking holes.

Fig.7.11 Anterior dissection (7) of the right thigh; showing the position of the locking holes (A,B) and the femoral vein (C), artery (D), and nerve (E). The branches of the femoral nerve (F) can be seen passing close to the locking holes.

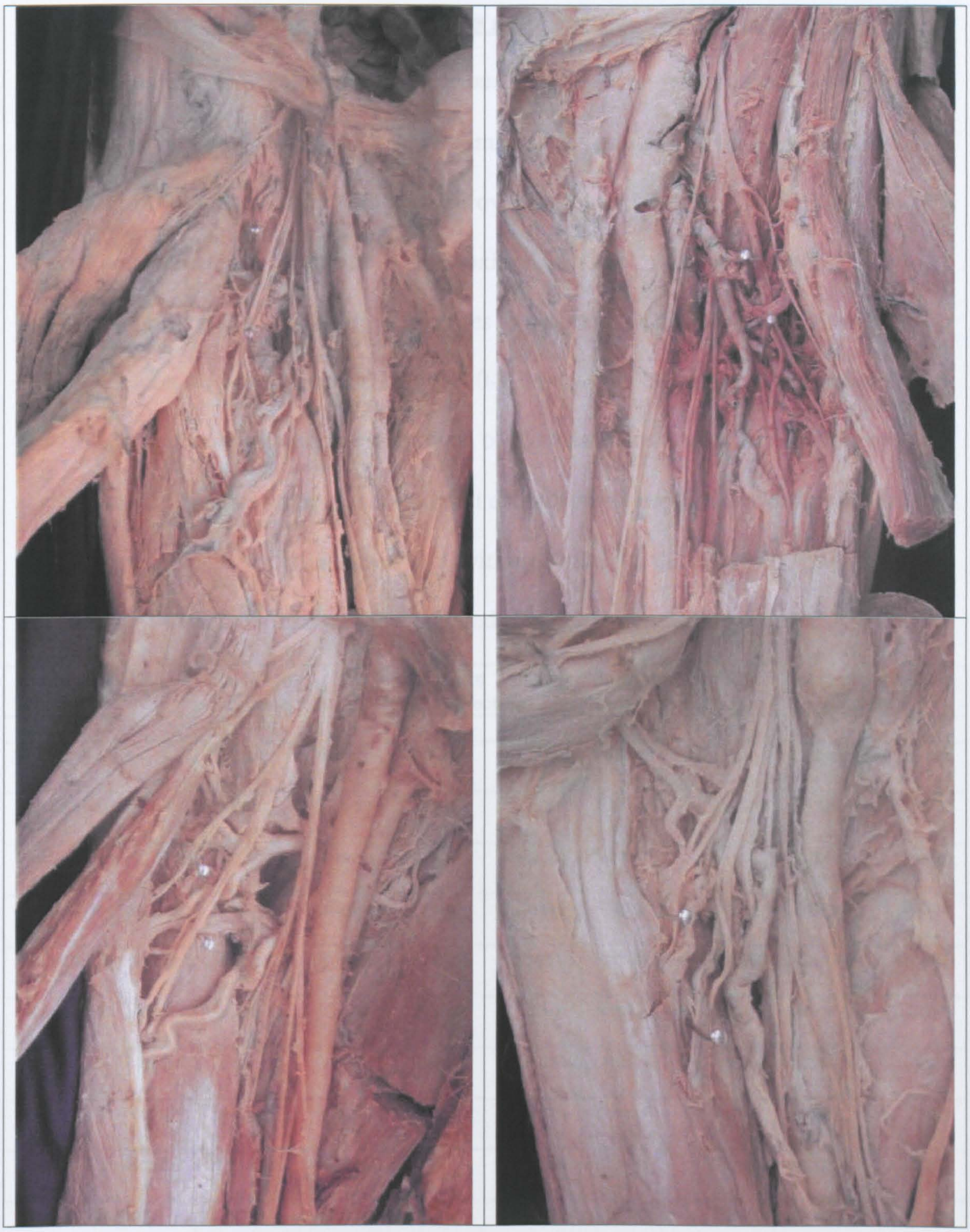

Fig.7.12 Collage of deep anterior dissections of the thigh showing the femoral vein, artery and nerve and the proximity of their branches to the position of the locking holes.

Distances between locking screw positions and neurovascular structures

The measurements carried out on the various specimens show that there are a large number of nerves and vessels in close proximity to the position of the locking screws. In total 25-30 branches of the femoral neurovascular bundle were identified within a 4sq.cm area around the position of the proximal locking screws (Tables 2 and 3). The structures at greatest risk were the nerves to vastus lateralis, medialis, intermedius and rectus femoris which were all between 0-12mm of the locking screws. The nerve to vastus lateralis and the transverse branch of the lateral circumflex femoral artery in some of the dissections were in fact in direct contact with one of the investigative drill holes. Posteriorly the sciatic nerve was within 20mm of the locking screw (this measurement was performed on the simulated retrograde nailing specimen).

Neurovascular Structures	Specimen 1 (Sup ant. dissection)		Specimen 2 (Deep ant. dissection)		Specimen 3 (Sim. nailing dissection)		Specimen 4 (Deep ant. dissection)	
	Ref 1	Ref 2	Ref 1	Ref 2	Ref 1	Ref 2	Ref 1	Ref 2
Femoral vein	35mm	40mm	40mm	53mm	48mm	58mm	41mm	50mm
Femoral artery	15mm	21mm	25mm	32mm	22mm	30mm	21mm	28mm
Femoral nerve	42mm	50mm	42mm	60mm	30mm	40mm	38mm	50mm
Profunda femoral artery	12mm	20mm	15mm	35mm	48mm	63mm	25mm	39mm
Gt.Saphenous vein	55mm	80mm	60mm	88mm	35mm	40mm	50mm	69mm
Nerve to Vastus medialis	7mm	7mm	10mm	12mm	8mm	10mm	8mm	10mm
Nerve to Vastus Intermedius	2mm	4mm	3mm	3mm	6mm	6mm	4mm	4mm
Nerve to Vastus Lateralis	5mm	2mm	8mm	7mm	2mm	0mm	5mm	3mm
Nerve to Rectus Femoris	2mm	2mm	5mm	8mm	12mm	12mm	6mm	7mm
Saphenous nerve	25mm	30mm	30mm	37mm	35mm	37mm	30mm	35mm
Nerve to sartorius	25mm	30mm	35mm	40mm	30mm	40mm	30mm	37mm
Med circ. femoral artery	35mm	52mm	38mm	56mm	44mm	48mm	39mm	52mm
Lat. circ. femoral artery	2mm	15mm	5mm	15mm	0mm	15mm	2mm	15mm

Table 2. Distances between locking screws and nerves and vessels.

Neurovascular Structures	Specimen 5 (Deep ant. dissection)		Specimen 6 (Deep ant. dissection)		Specimen 7 (Deep ant. dissection)		Average Distance	
	Ref 1	Ref 2	Ref 1	Ref 2	Ref 1	Ref 2	Ref 1	Ref 2
Femoral vein	40mm	50mm	36mm	40mm	53mm	64mm	36mm	51mm
Femoral artery	25mm	35mm	17mm	22mm	33mm	25mm	23mm	28mm
Femoral nerve	32mm	40mm	40mm	48mm	30mm	40mm	36mm	47mm
Profunda femoral artery	15mm	23mm	13mm	20mm	25mm	32mm	22mm	28mm
Gt.Saphenous vein	50mm	60mm	55mm	65mm	60mm	70mm	52mm	58mm
Nerve to Vastus medialis	2mm	3mm	4mm	4mm	5mm	0mm	5mm	5mm
Nerve to Vastus Intermedius	3mm	10mm	2mm	3mm	5mm	5mm	3mm	4mm
Nerve to Vastus Lateralis	3mm	0mm	3mm	0mm	8mm	0mm	4mm	2mm
Nerve to Rectus Femoris	5mm	10mm	2mm	0mm	8mm	8mm	5mm	6mm
Saphenous nerve	15mm	18mm	20mm	23mm	23mm	27mm	21mm	25mm
Nerve to sartorius	30mm	33mm	25mm	28mm	27mm	30mm	25mm	29mm
Med circ. femoral artery	30mm	38mm	36mm	50mm	35mm	40mm	31mm	39mm
Lat. circ. femoral artery	3mm	5mm	10mm	10mm	22mm	23mm	6mm	12mm

Table 3. Distances between locking screws and nerves and vessels.

Anatomy of the Nerves and Vessels of the lateral thigh

Systematic dissection of the lateral aspect of the proximal thigh was carried out in four specimens. These demonstrated that there were no significant superficial nerves and vessels in the subcutaneous layer (Fig.7.13). The dissections also showed that there were no structures entering the vastus lateralis superficially (Fig.7.14).

There were however two leashes of nerves and vessels entering the deep surface of vastus lateralis. The proximal of these consist of the transverse branch of the lateral circumflex femoral artery and the accompanying vein (Fig. 7.15). These cross the anterior surface of the femur about 2-3cm below the level of the lesser trochanter and come to lie over the lateral surface about 4cm below the level of the lesser trochanter before entering the deep surface of vastus lateralis.

The distal of the two leashes consists of the descending branch of the lateral circumflex femoral artery and accompanying vein as well as the muscular branch to the vastus lateralis (Figures 7.18-7.25). These cross the anterior surface of the femur about 5-6 cm below the lesser trochanter and come to lie over the lateral surface of the femur about 7cm below the lesser trochanter before entering the deep surface of the femur.

Medially the main trunks of the femoral vein, artery and nerve lie anterior to the lesser trochanter and medial femoral cortex. This is where the drill holes for the lateral to medial locking screws would be made. Three to four cm medial to the lesser trochanter lie the obturator nerve and its anterior and posterior branches (Figures 7.26-7.30).

Fig.7.13 Superficial dissection of the lateral aspect of the left thigh showing tensor fasciae latae (A).

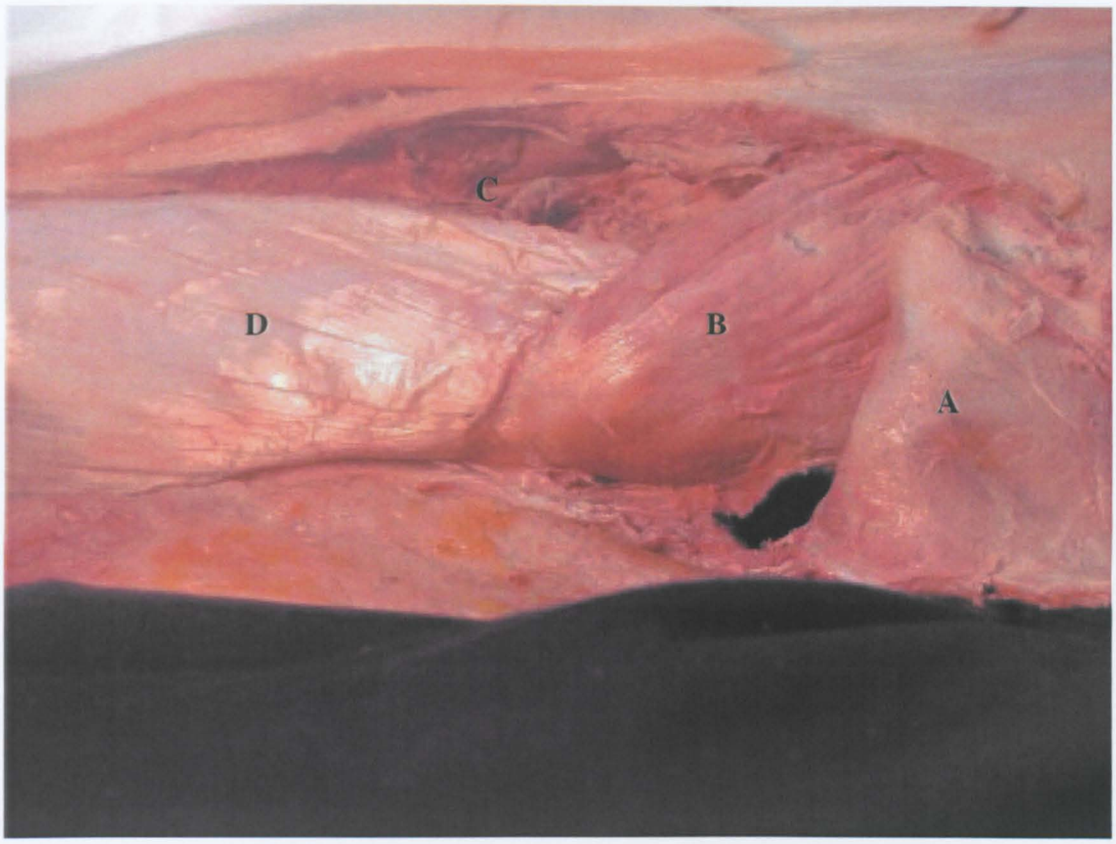

Fig.7.14 Deeper dissection (1) of the lateral aspect of the left thigh showing tensor fasciae latae (A) reflected proximally. Gluteus medius and minimus (B) can be seen to insert into the greater trochanter of the femur. The transverse branch of the lateral circumflex femoral artery (C) is seen to enter the deep surface of vastus lateralis (D).

Fig.7.15 Preliminary dissection (1) of the lateral aspect of the left thigh showing tensor fasciae latae (A) reflected proximally. Gluteus medius and minimus (B) can be seen to insert into the greater trochanter of the femur. The transverse branch of the lateral circumflex femoral artery (C) is seen to enter the deep surface of vastus lateralis (D) distal to the lateral to medial locking holes (E,F).

Fig.7.16 Preliminary dissection (2) of the lateral aspect of the right thigh The descending branch of the lateral circumflex femoral artery (A), accompanying vein and the muscular branch of the femoral nerve (B) can be seen to enter the deep surface of vastus lateralis (C) several centimetres distal to the lateral to medial locking holes (D,E).

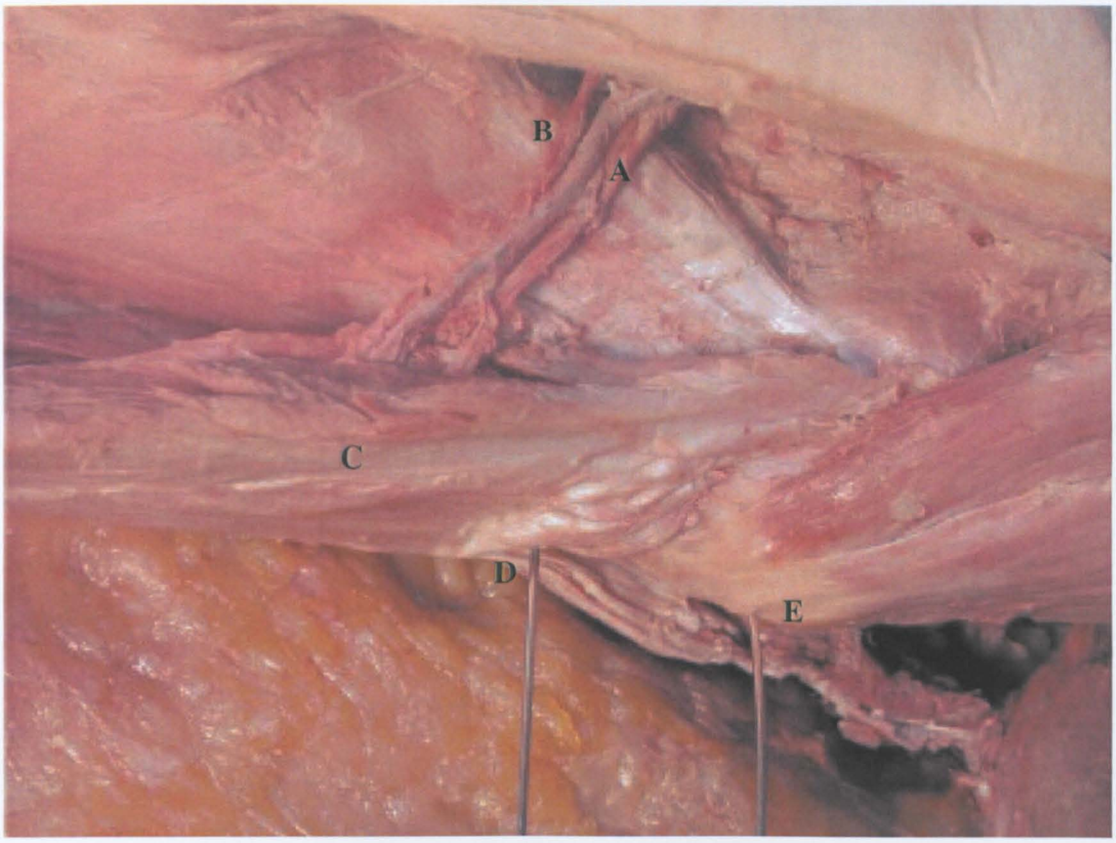

Fig.7.17 Preliminary dissection (3) of the lateral aspect of the left thigh. The descending branch of the lateral circumflex femoral artery (A), accompanying vein and the muscular branch of the femoral nerve (B) can be seen to enter the deep surface of vastus lateralis (C) several centimetres distal to the lateral to medial locking holes (D,E).

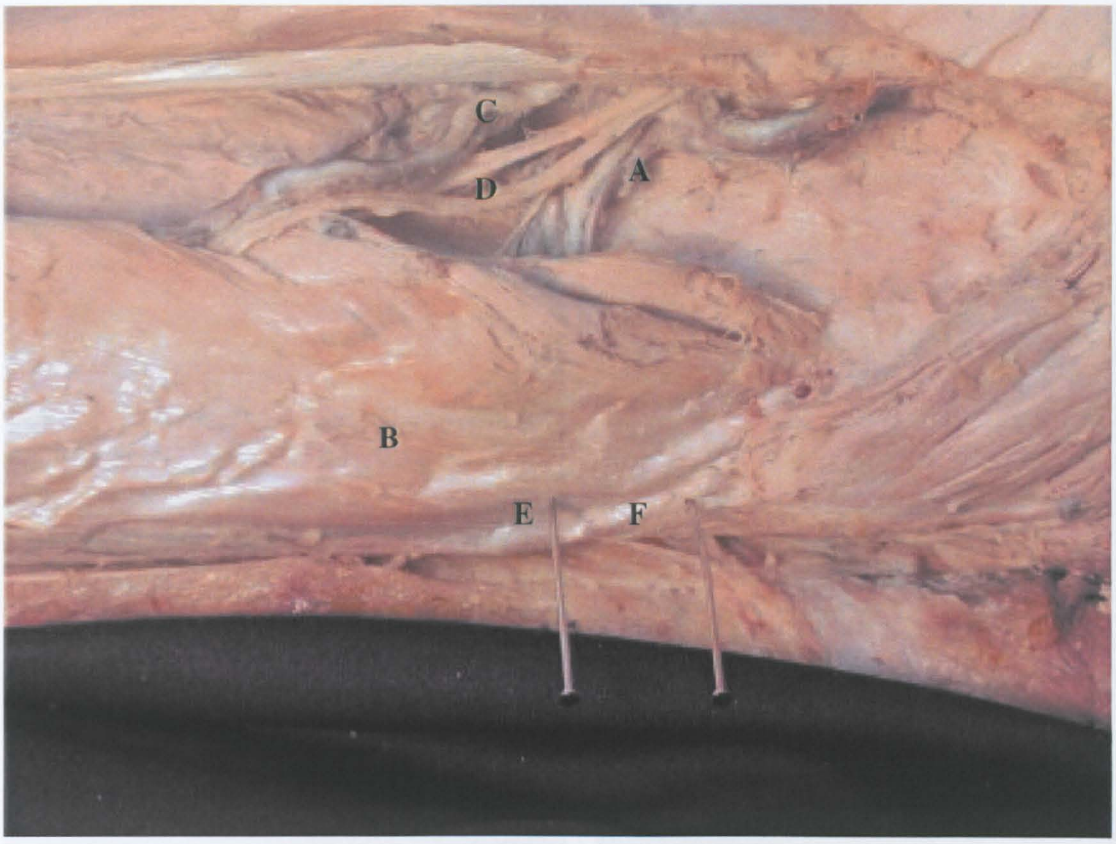

Fig.7.18 Preliminary dissection (4) of the lateral aspect of the left thigh The transverse branch of the lateral circumflex femoral artery and accompanying vein (A) can be seen to enter the vastus lateralis (B) at level of the distal locking hole (E) whilst the descending branch (C) and the muscular branch of the femoral nerve (D) can be seen to enter the deep surface of vastus lateralis several centimetres distal to the lateral to medial locking holes (E,F).

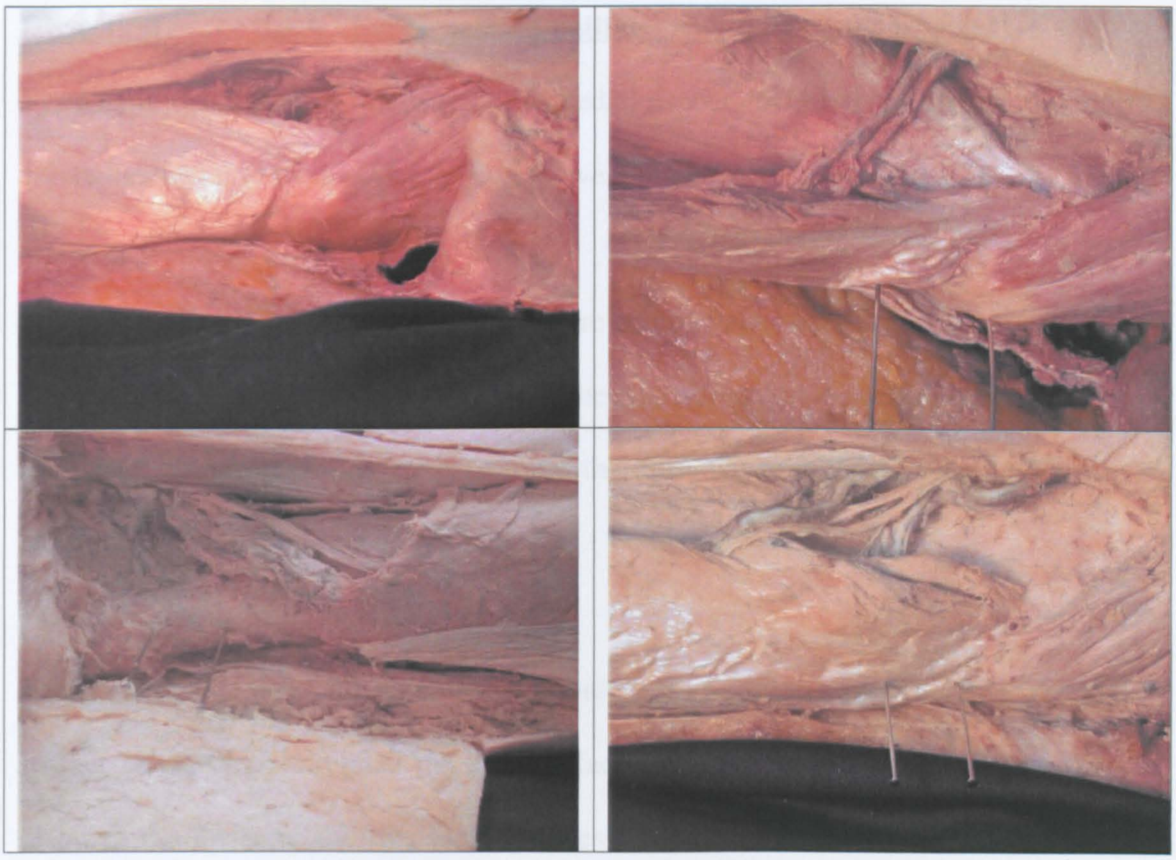

Fig.7.19 Collage of preliminary lateral dissections (1-4).

Dissection of the thigh after simulated nailing using redesigned implant

Systematic dissection of the lateral and medial aspects of the thigh around the area where the lateral to medial locking screws were placed was carried out.

Superficial dissection showed that there were no cutaneous nerves at risk (Fig.7.13). Deeper dissection revealed the course of the transverse and descending branches of the lateral circumflex femoral vessels and the muscular branch to vastus lateralis in relation to the lateral to medial locking pins (Figures 7.20-7.25).

The transverse branch and accompanying vein were found to course over the anterior surface of the thigh and enter the deep surface of vastus lateralis approximately 3cm distal to the lower of the two locking holes (Figures 7.20-7.25). The descending branch of the lateral circumflex femoral artery and accompanying vein and the nerve to vastus lateralis entered the deep surface of vastus lateralis further distal still, approximately 6cm distal to the lower of the two locking holes (Figures 7.20-7.25).

The main trunks of the femoral vein, artery and nerve lie anteromedial in the anterior thigh at a significant distance from the locking holes as do the rest of their branches (Figures 7.26-7.30).

Dissection of the anteromedial thigh showed that the investigative drill holes emerged from the lesser trochanter and medial cortex of the femur posterior to the femoral nerves and vessels, lying approximately 3cm posterior to these (Figures 7.26-7.30).

The obturator nerve and artery and their associated branches were found to lie approximately 3-4 cm from the lesser trochanter and medial femoral cortex (Figures 7.26-7.30). These were in the line of the investigative drill holes but several centimetres from the point at which the drill holes emerged from the femur.

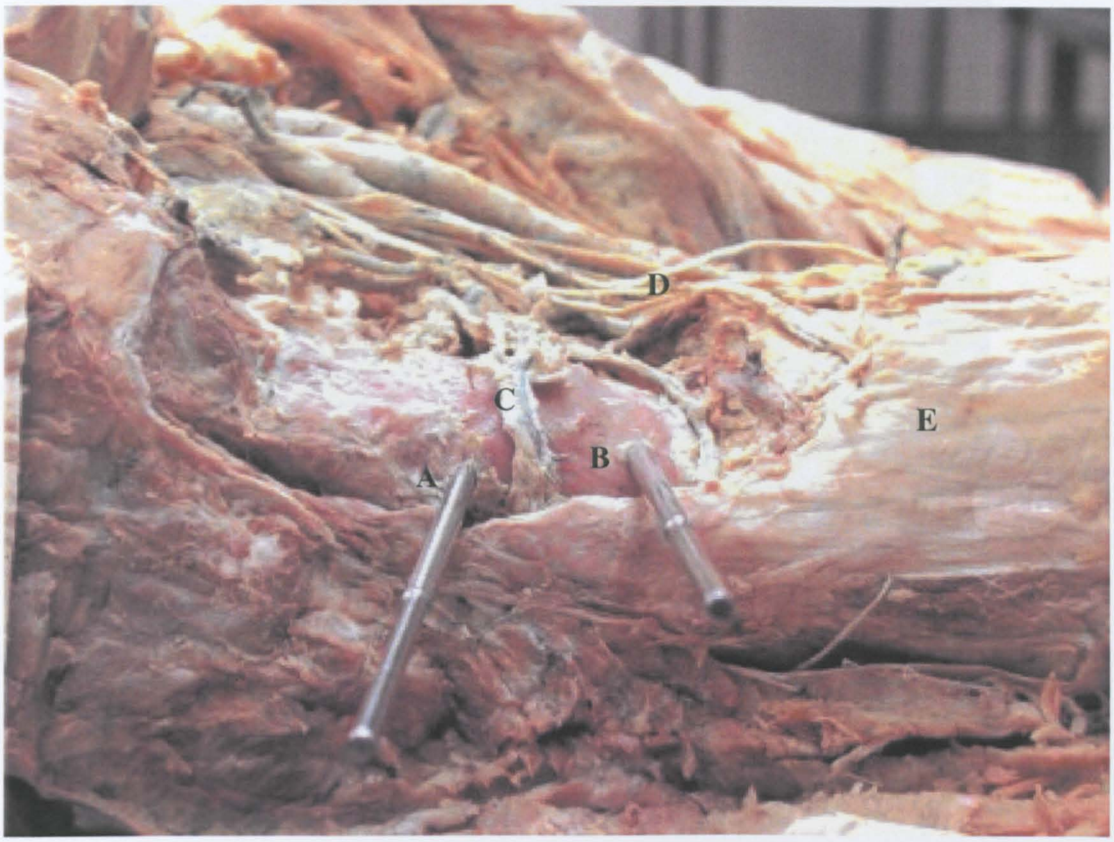

Fig.7.20 Deep dissection of the lateral aspect of the right thigh after simulated femoral nailing with lateral to medial locking. The position of the locking holes is marked by the steinmann pins (A,B). The transverse branch of the lateral circumflex femoral artery (C) can be seen lying on the lateral surface of the femur in between the two locking holes. The muscular branch of the femoral nerve (D) enters the deep surface of vastus lateralis (E) distal to the locking holes.

Fig.7.21 Deep dissection of the proximal thigh (right) after simulated femoral nailing with lateral to medial locking. The position of the locking holes is marked by the steinmann pins (A,B) which pass through the proximal locking holes of the retrograde femoral nail (C) which is visible in the windowed proximal femur (D). The transverse branch of the lateral circumflex femoral artery (E) can be seen lying on the lateral surface of the femur between the two locking holes. The muscular branch of the femoral nerve (F) enters the deep surface of vastus lateralis (G) distal to the locking holes.

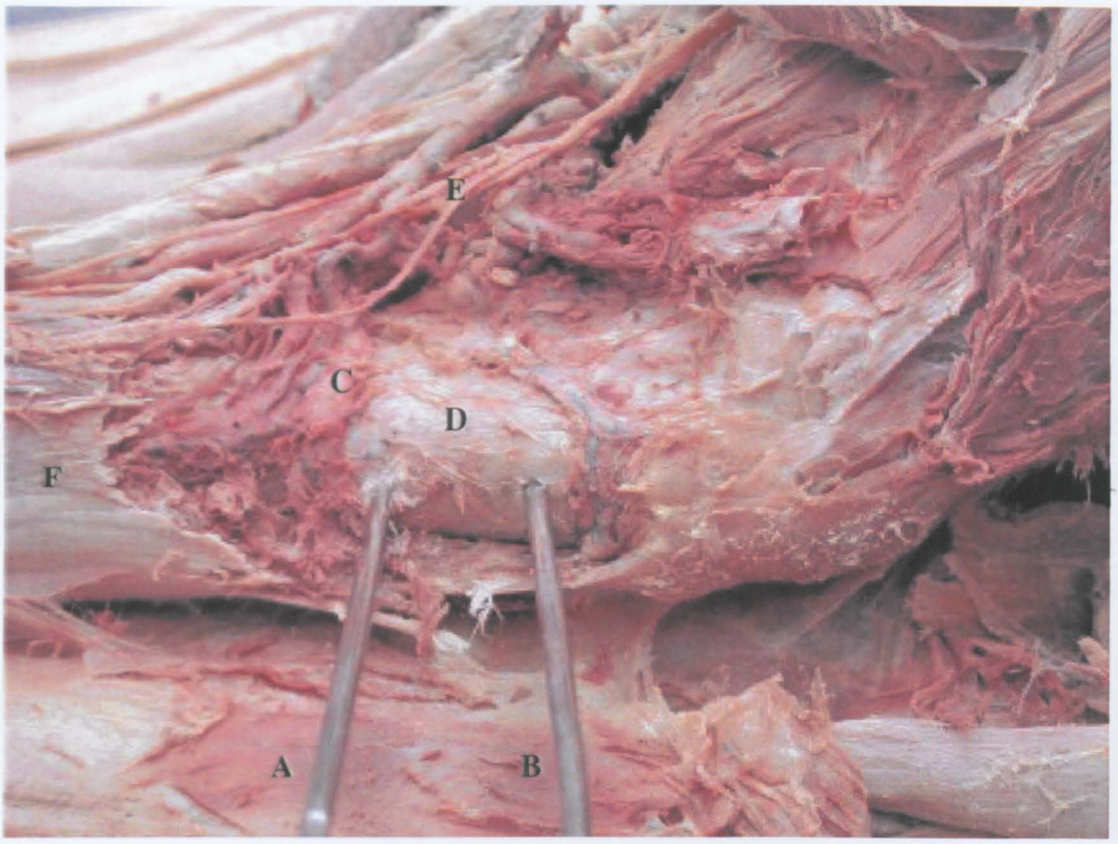

Fig.7.22 Deep dissection (2) of the lateral thigh (left) after simulated lateral to medial locking. The position of the locking holes is marked by the steinmann pins (A,B) which mark the position of the proximal locking holes of the redesigned retrograde femoral nail. The transverse branch of the lateral circumflex femoral artery and accompanying vein (C) can be seen lying on the lateral surface of the femur (D) distal to the two locking holes. The muscular branch of the femoral nerve (E) enters the deep surface of vastus lateralis (F) distal to the locking holes.

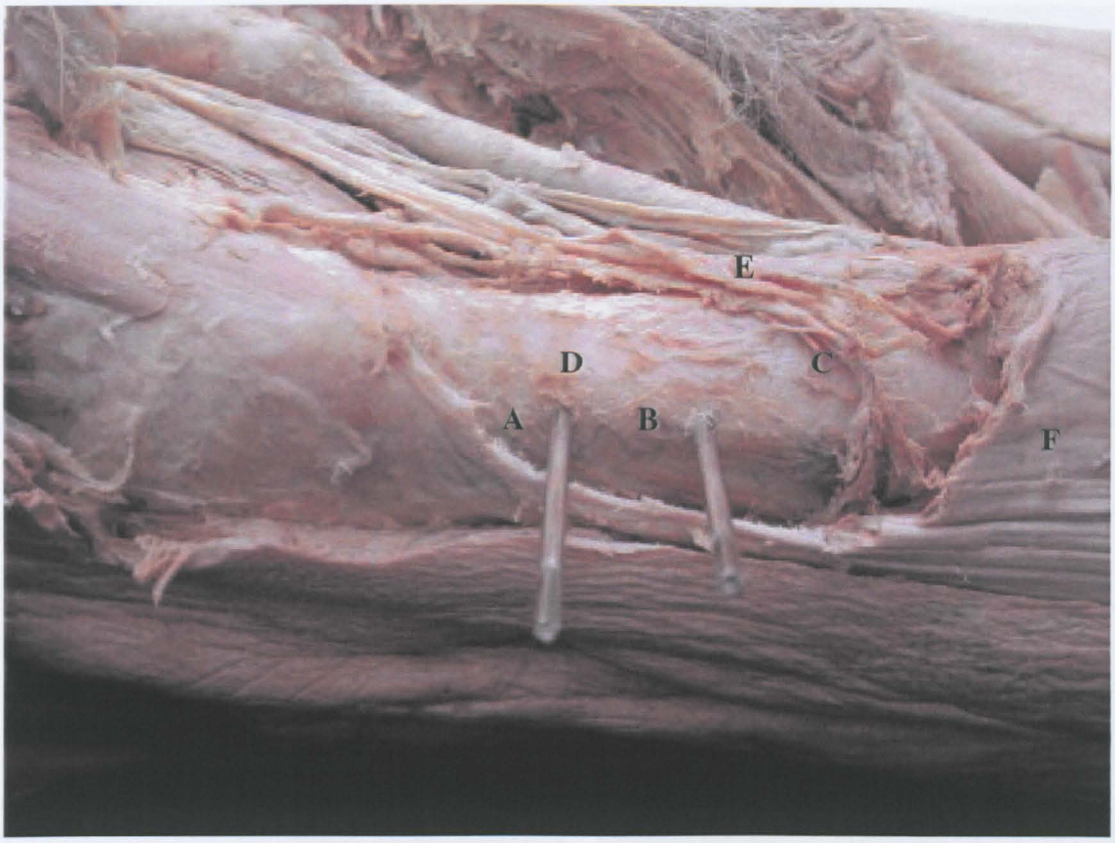

Fig.7.24 Deep dissection (4) of the lateral thigh (right) after simulated lateral to medial locking. The position of the locking holes is marked by the steinmann pins (A,B) which mark the position of the proximal locking holes of the redesigned retrograde femoral nail. The descending branch of the lateral circumflex femoral artery and accompanying vein (C) can be seen lying on the lateral surface of the femur (D) several centimetres distal to the two locking holes. The muscular branch of the femoral nerve (E) enters the deep surface of vastus lateralis (F) also several centimetres distal to the locking holes.

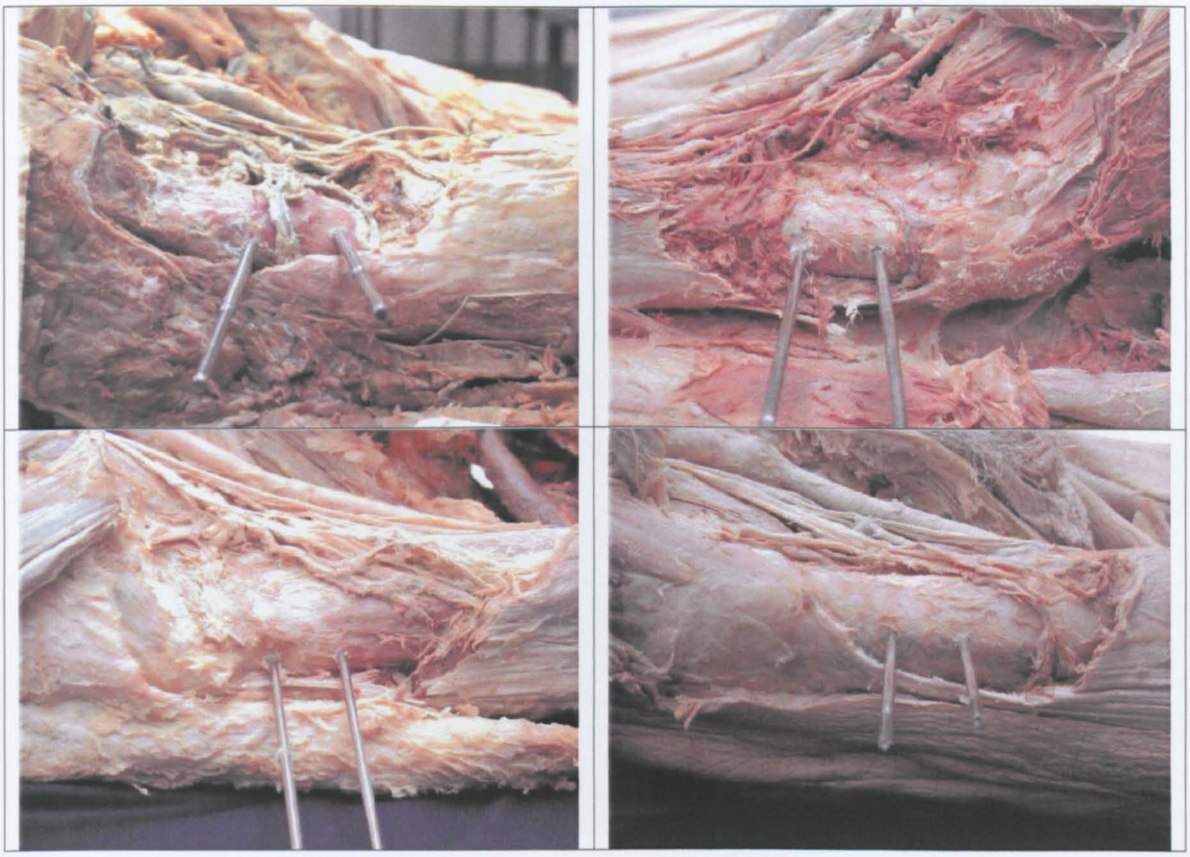

Fig.7.25 Collage of deep dissections of the lateral aspect of the thigh after simulated lateral to medial locking.

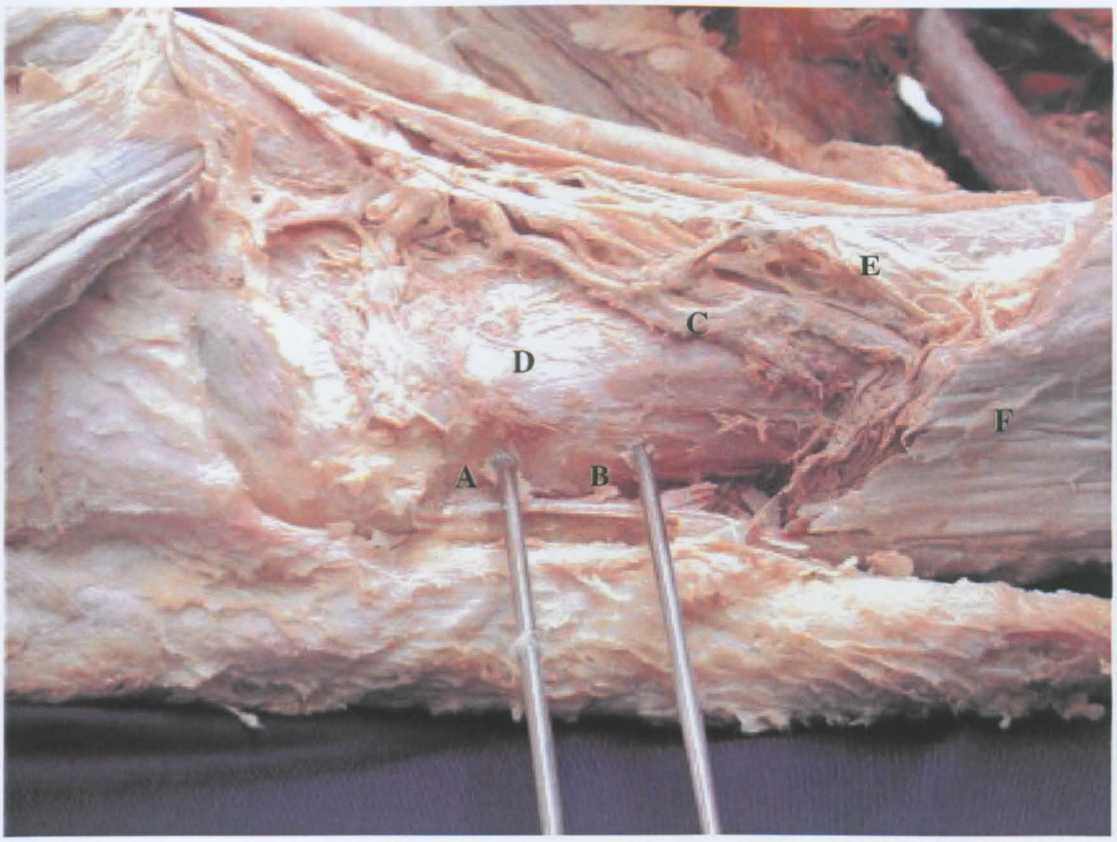

Fig.7.23 Deep dissection (3) of the lateral thigh (right) after simulated lateral to medial locking. The position of the locking holes is marked by the steinmann pins (A,B) which mark the position of the proximal locking holes of the redesigned retrograde femoral nail. The descending branch of the lateral circumflex femoral artery and accompanying vein (C) can be seen lying on the lateral surface of the femur (D) several centimetres distal to the two locking holes. The muscular branch of the femoral nerve (E) enters the deep surface of vastus lateralis (F) also several centimetres distal to the locking holes.

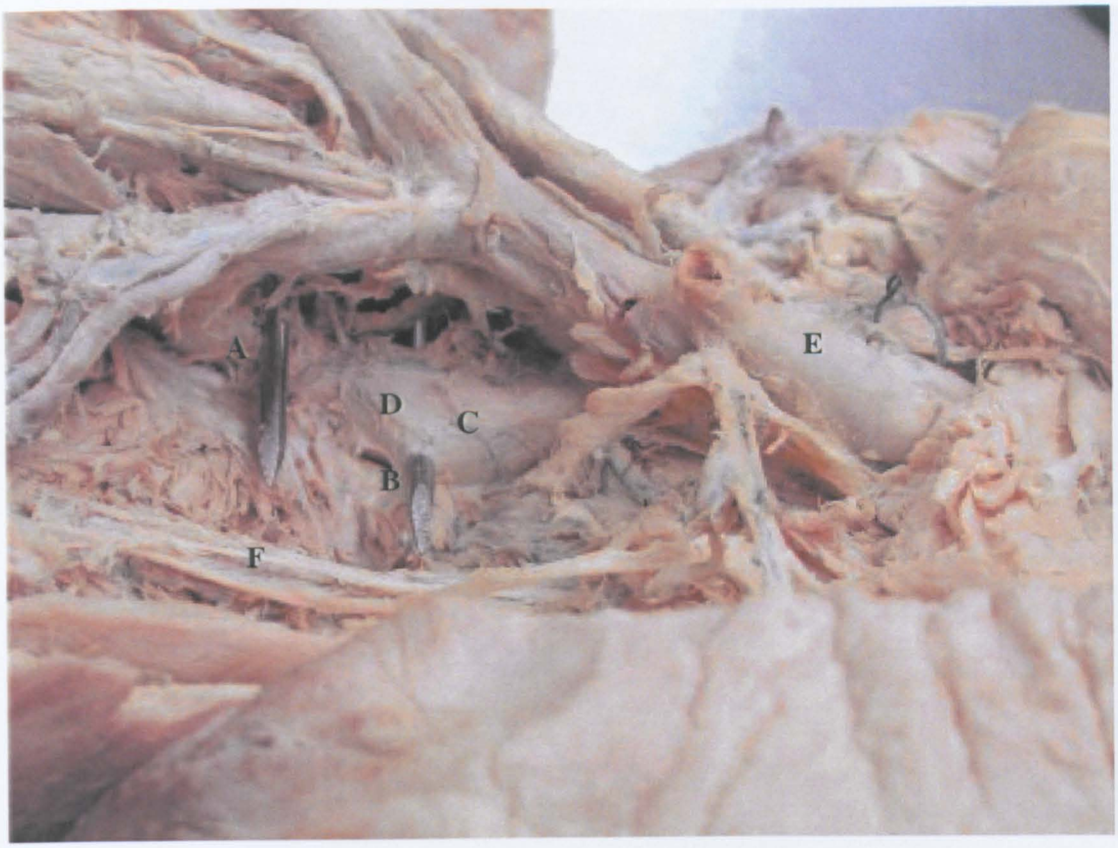

Fig.7.26 Deep dissection of the medial aspect of the left thigh (1) after simulated lateral to medial locking. This shows the locking pins (A,B) emerging from the lesser trochanter (C) and medial femoral cortex (D) behind the femoral artery, vein and nerve (E) and stopping short of the obturator nerve (F).

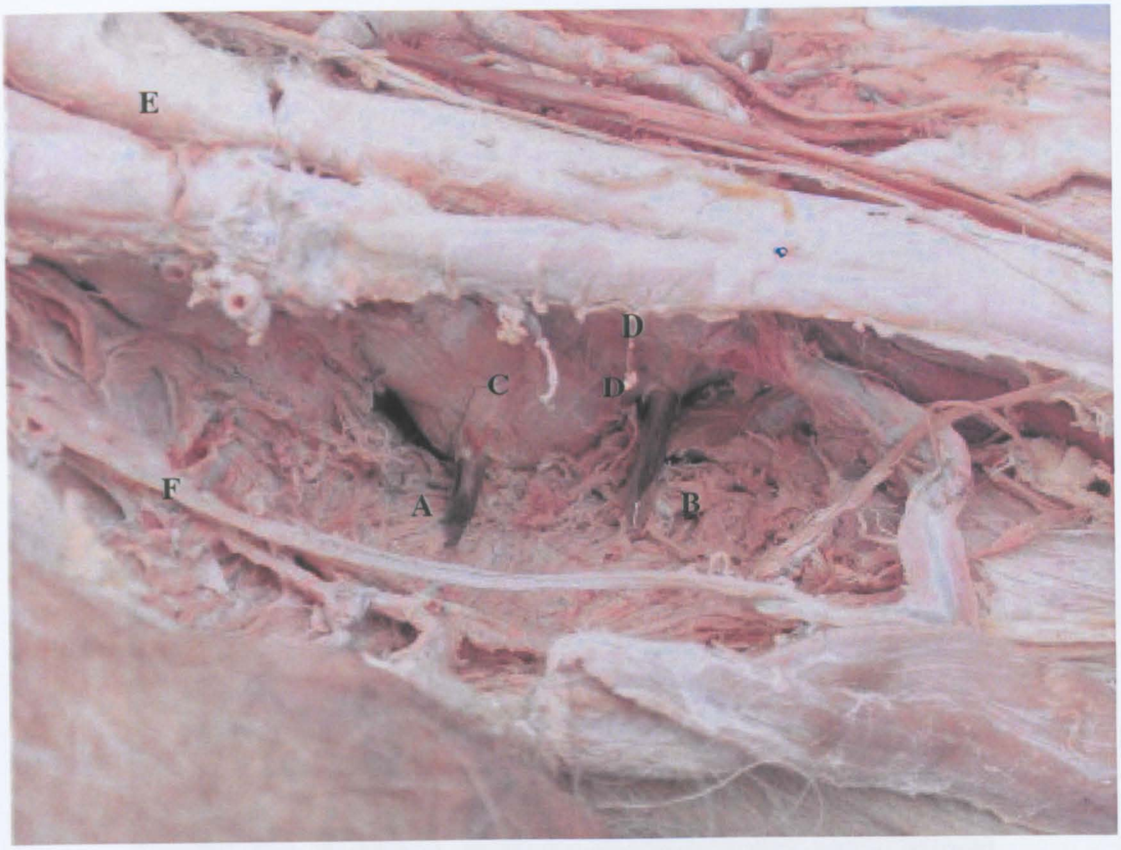

Fig.7.27 Deep dissection of the medial aspect of the right thigh (2) after simulated lateral to medial locking. This shows the locking pins (A,B) emerging from the lesser trochanter (C) and medial femoral cortex (D) behind the femoral artery , vein and nerve (E) and stopping short of the obturator nerve (F).

Fig.7.28 Deep dissection of the right thigh (3) after simulated lateral to medial locking. This shows the locking pins (A,B) emerging from the lesser trochanter and medial femoral cortex behind the femoral artery (C), vein (D) and nerve (E) and stopping short of the obturator nerve (F).

Fig.7.29 Deep dissection of the right thigh (4) after simulated lateral to medial locking. This shows the locking pins (A,B) emerging from the lesser trochanter and medial femoral cortex behind the femoral artery (C), vein (D) and nerve (E) and stopping short of the obturator nerve (F).

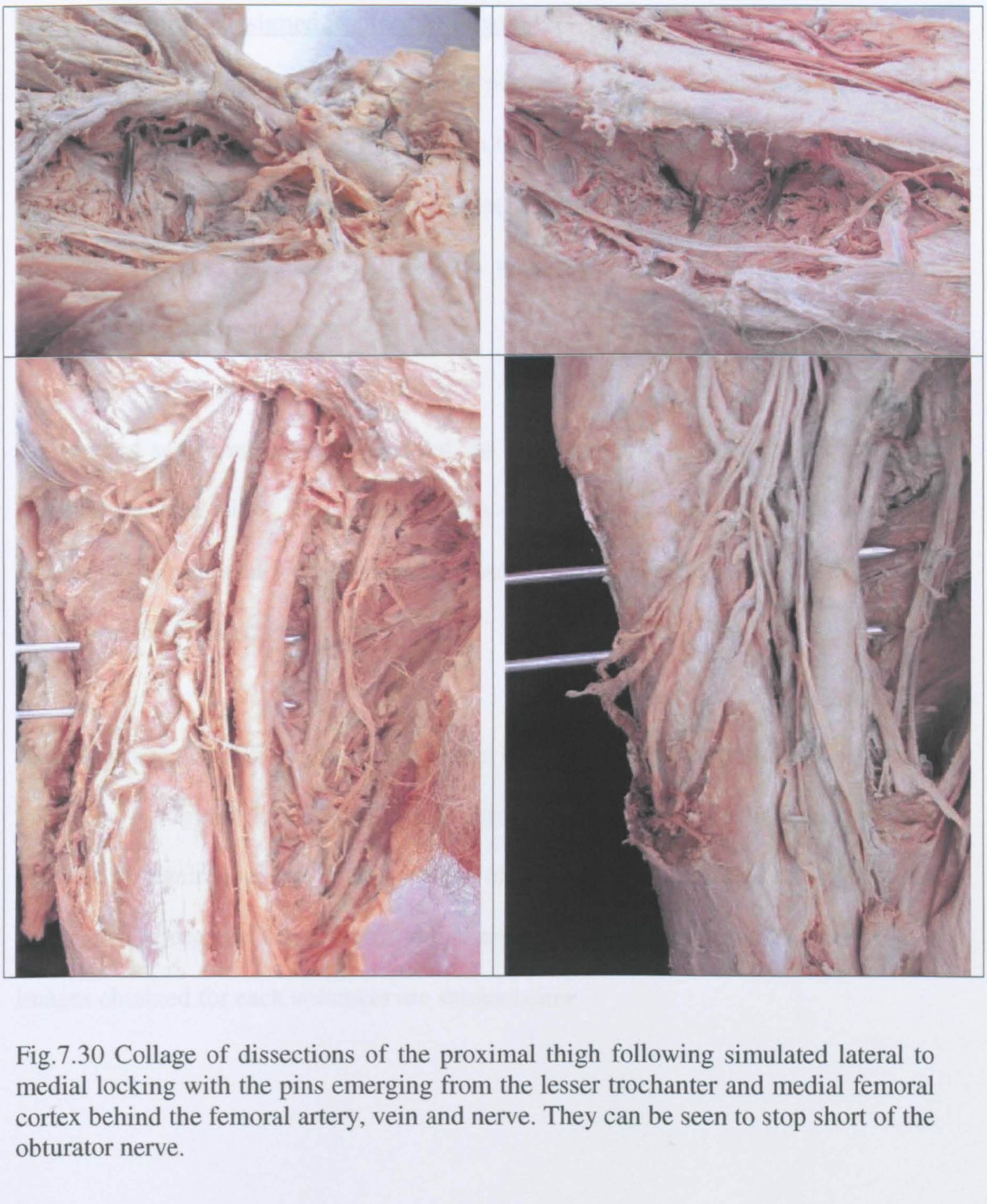

Fig.7.30 Collage of dissections of the proximal thigh following simulated lateral to medial locking with the pins emerging from the lesser trochanter and medial femoral cortex behind the femoral artery, vein and nerve. They can be seen to stop short of the obturator nerve.

Surface trial of redesigned implant in theatre

A surface trial of the redesigned nail was performed in theatre on three volunteers. Screening was carried out with the limbs in two different positions (Fig.6.13). With the volunteers in a supine position on a standard fracture table adequate screening of the proximal locking holes was obtained with the C-arm in an oblique position relative to the proximal femur.

The second screening position involved the volunteer being placed in traction on a standard fracture table (Fig.6.14). In this case it was possible to obtain adequate images of the proximal femur and locking holes with the C-Arm horizontal in relation to the proximal femur.

X-rays were taken of the proximal femur using an image intensifier in all three volunteers (Figures 7.31-7.36). These demonstrated that in all three cases it was possible to obtain adequate X-Ray images of both the proximal locking holes of the redesigned retrograde femoral nail with lateral to medial locking holes. The X-Ray images obtained for each volunteer are shown below

Volunteer 1

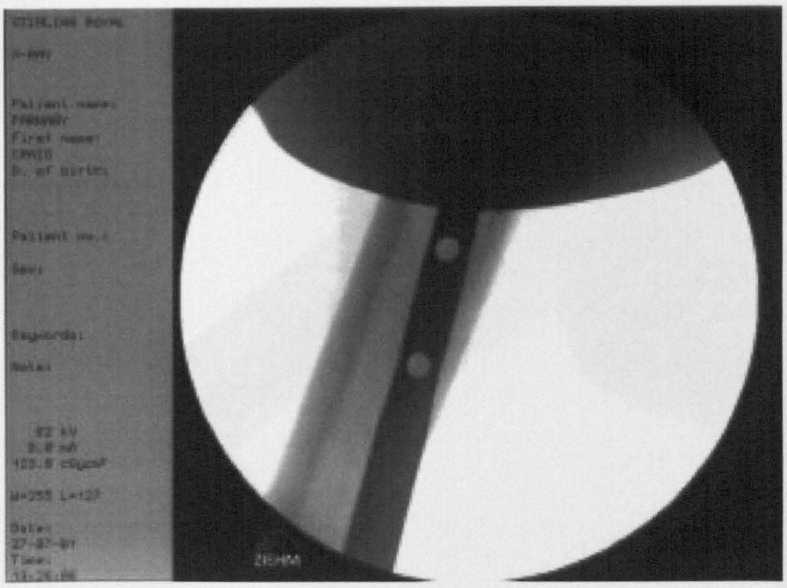

Fig.7.31 X-Ray image of volunteer 1 showing both proximal locking holes of the redesigned nail.

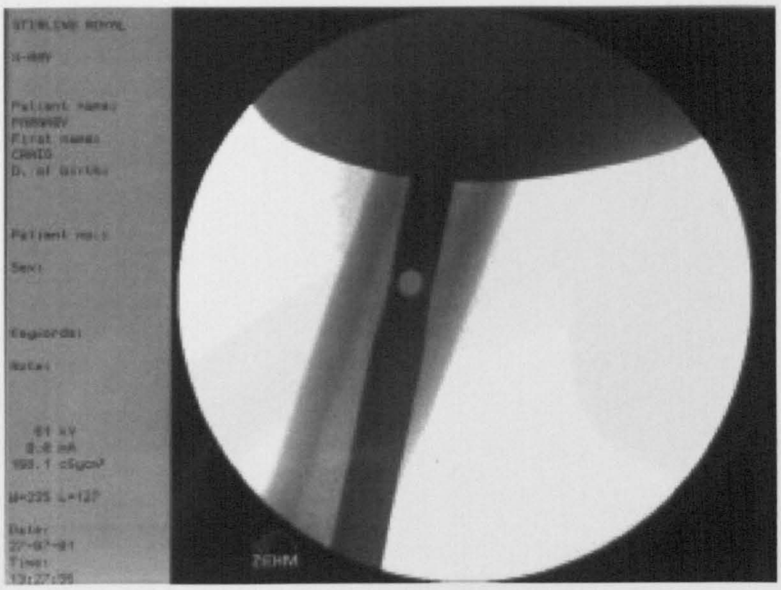

Fig.7.32 X-Ray image of volunteer 1 showing the distal of the two proximal locking holes of the redesigned nail.

Volunteer 2

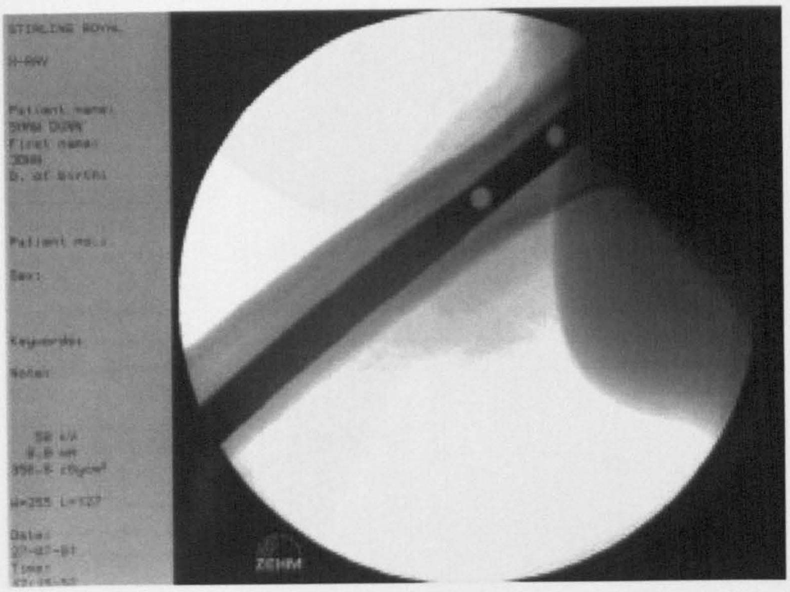

Fig7.33 X-Ray image of volunteer 2 showing both proximal locking holes of the redesigned nail.

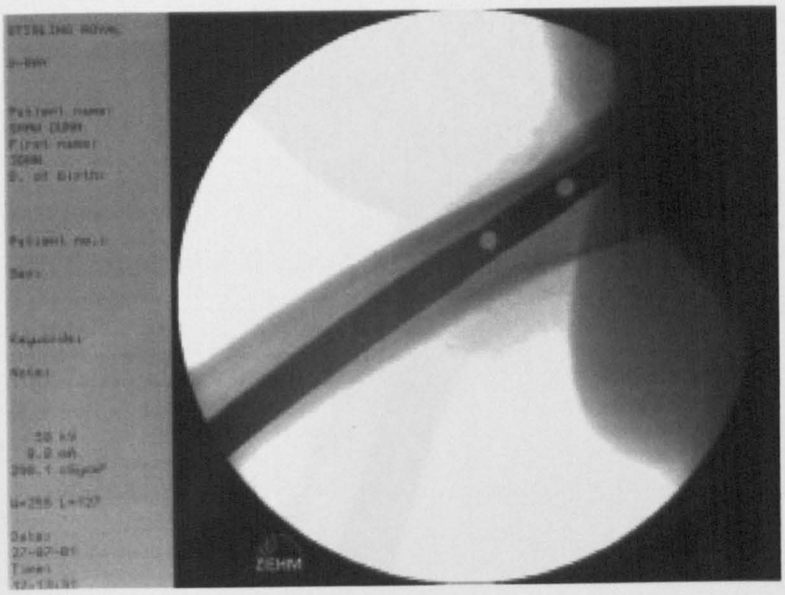

Fig.7.34 X-Ray image of volunteer 2 showing both proximal locking holes of the redesigned nail.

Volunteer 3

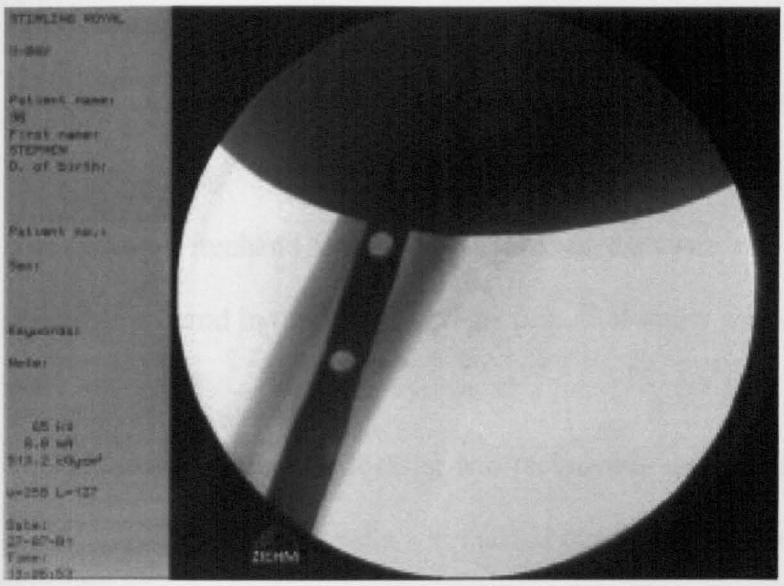

Fig.7.34 X-Ray image of volunteer 3 showing both proximal locking holes of the redesigned nail.

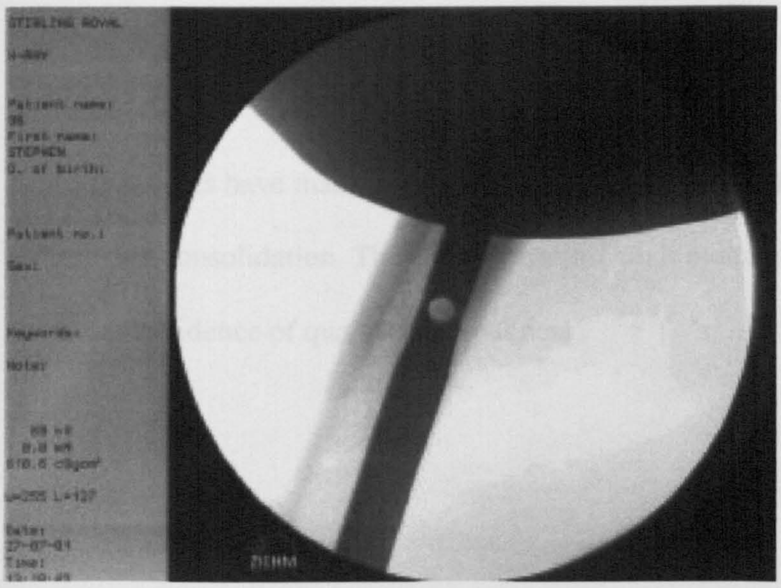

Fig.7.36 X-Ray image of volunteer 3 showing the distal of the two proximal locking holes of the redesigned nail.

Results of Clinical Cases of Retrograde Femoral Nailing

Retrograde femoral nailing was performed in all of the clinical cases using the standard technique which has been described previously. Distal locking was performed using the drill guide assembly and proximal locking was carried out in all cases using a freehand technique. In three of the cases two proximal locking screws were inserted and in the fourth a single proximal screw was inserted.

In all four cases proximal locking was technically difficult and in view of the risk to underlying nerves and vessels was carried out through a small open incision directly over the level of the locking holes. This allowed the nerves and vessels to be retracted away from the path of the drill and locking screws. The precise location of the proximal wound can be identified in two of the cases (Figures 7.38 and 7.40) by the presence of staples over the region of the proximal locking holes.

All four patients have made good progress and have proceeded to satisfactory fracture healing and consolidation. There have been no gross neurovascular complications and no clinical evidence of quadriceps weakness.

Patient 1:

Fig.7.37 Post-op X-Rays of patient 1 showing that the femoral fracture has been stabilised with a retrograde femoral nail. Two proximal anteroposterior locking screws have been inserted to increase stability.

Patient 2:

Fig.7.38 Post-op X-Rays of patient 2 showing that the femoral fracture has been stabilised with a retrograde femoral nail. Two proximal anteroposterior locking screws have been inserted through a small open incision (staples visible over the proximal femur).

Patient 3:

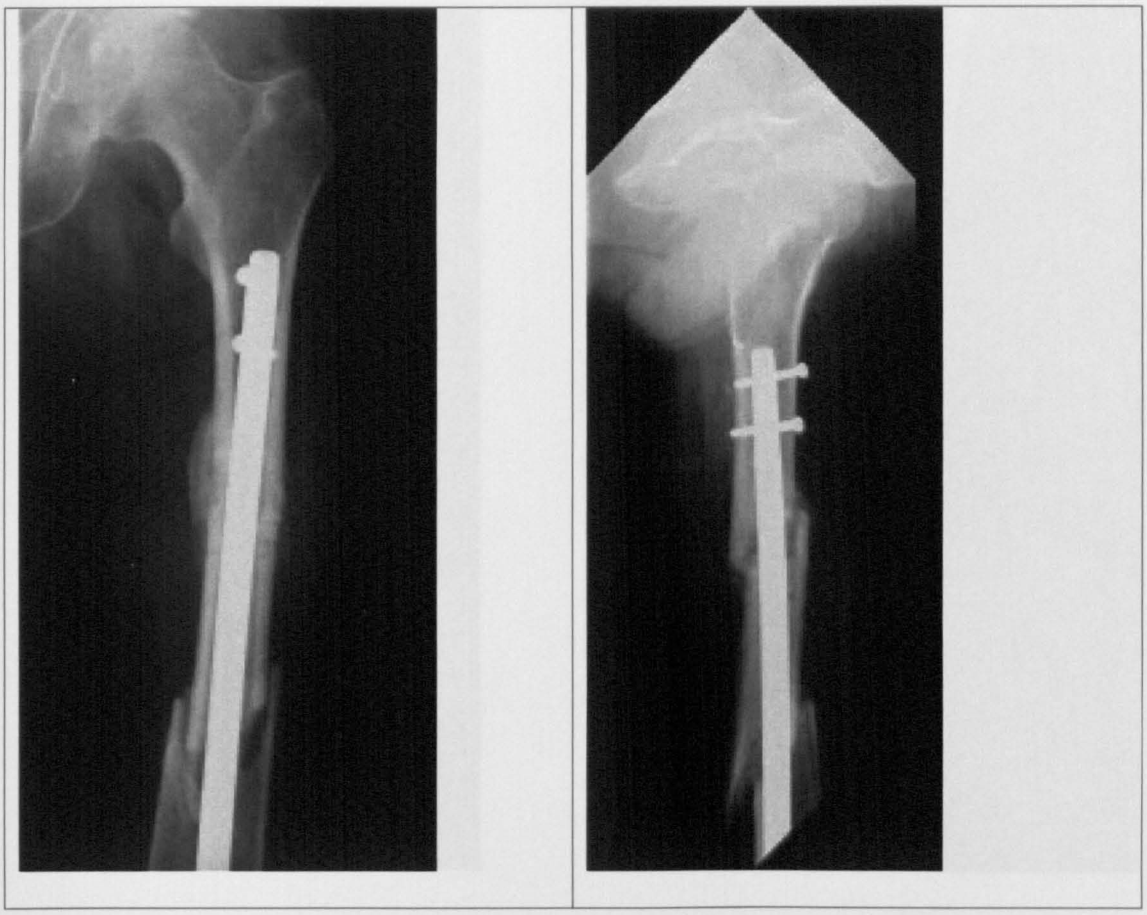

Fig.7.39 Post-op X-Rays of patient 3 showing that the femoral fracture has been stabilised with a retrograde femoral nail. Two proximal anteroposterior locking screws have been inserted to increase stability.

Patient 4:

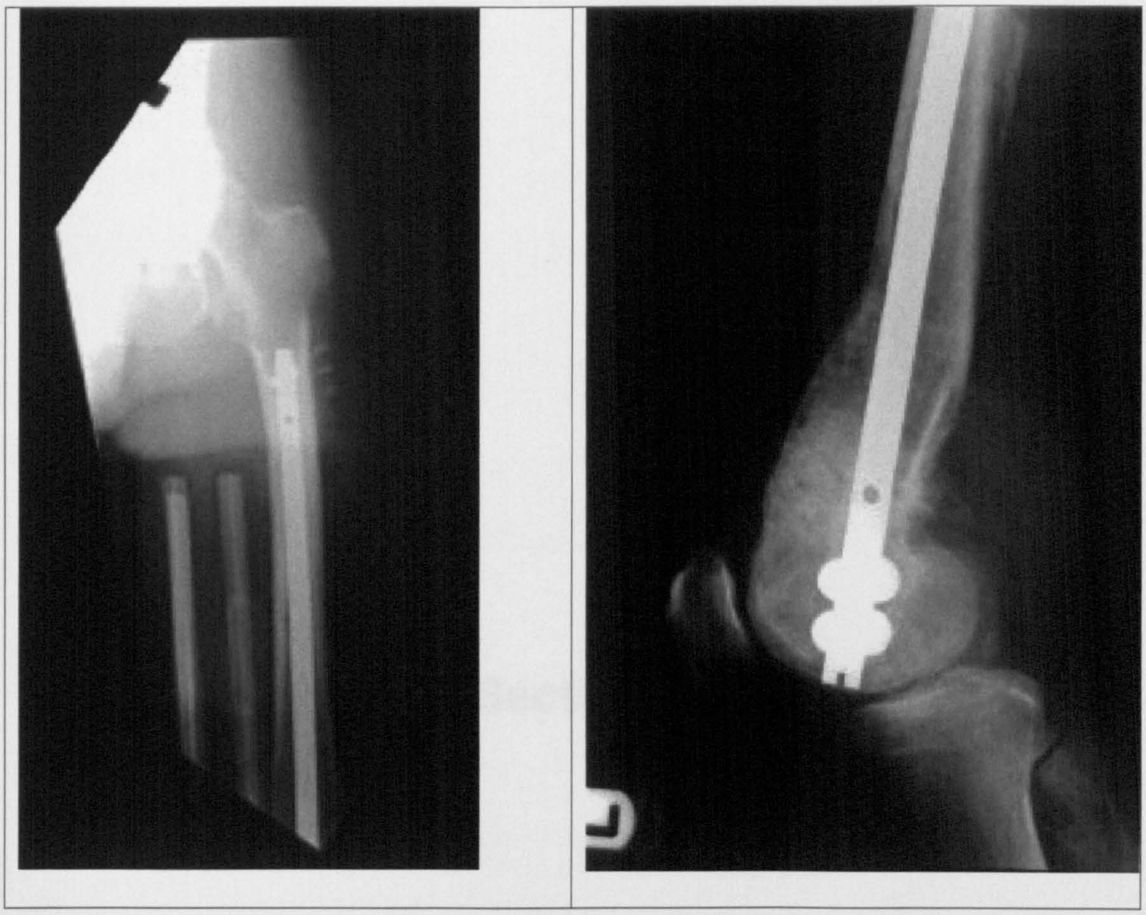

Fig.7.40 Post-op X-Rays of patient 4 showing that the femoral fracture has been stabilised with a retrograde femoral nail. A single proximal anteroposterior locking screw has been inserted through a small open incision (staples visible over the proximal femur).

Section 4

DISCUSSION

1). Statement of Principal Findings

The plan of the discussion is based on that recommended by Smith (1999) in a British Medical Journal 'Leader' article.

The original hypothesis which this project set out to test was that the "proximal anteroposterior locking screws of retrograde femoral nails can be safely inserted in the proximal end of the femur without damage to nerves and vessels".

Once the initial dissection and simulated femoral nailing had been performed it was clear the femoral artery, vein and nerve lay several centimetres medial to the path of the locking screws and were therefore not at direct risk. Posteriorly the sciatic nerve is not directly at risk as it runs medial to the locking screws

However the superficial dissection revealed that the lateral cutaneous nerve of the thigh and its branches passed extremely close to the position of the locking screws.

At a deeper level three other muscular branches of the femoral nerve were at a distance of 0 – 12 mm from the position of the locking screws and were therefore also at significant risk of being damaged from screw insertion. The closest of these was the nerve to vastus lateralis which at one point was in direct contact with one of the investigative drill holes. These findings led to the investigation of alternative paths for the locking screws and to the formation of a second null hypothesis that " the nerves and vessels of the upper thigh are at risk from proximal locking screws inserted in a lateral to medial direction in the upper thigh".

To test this new hypothesis a second series of dissections and simulated nailing using a specifically modified Richards nail were carried out. These results showed that this hypothesis could be rejected. The closest structures to the proximal lateral to medial locking screws were the transverse branch of the lateral circumflex femoral artery and the muscular branch to the vastus lateralis. These were both several centimetres from the locking screws making this a significantly safer procedure than anteroposterior locking. Although damage to the transverse branch of the lateral circumflex femoral artery is a possibility this is significantly less likely than with an anteroposterior approach. If this artery was damaged at this site, it could be easily exposed using a direct lateral approach to the femur allowing any haemorrhage to be controlled quickly.

Finally although the lateral to medial direction is safer, it is also much more awkward physically and it seemed possible that the image intensifier, drill and locking holes could not be lined up in this position

To test this a surface trial of the redesigned nail, with X-Ray screening of volunteers at the level of the lesser trochanter was set up. This shows that it should be possible to lock the nail in a lateral to medial direction at the level of the lesser trochanter.

2). Strengths and Weaknesses of Study

i) Weaknesses

Simulated operations and dissections on embalmed cadavers can lead to various problems in interpretation and correlation.

Many of the bodies donated are those of elderly people, and the average age of the cadavers used in our project was 82 years. This contrasts significantly with the occurrence of femoral shaft fractures which are most frequently seen in the 25-30 age group (Grazier et al 1984). As a result a number of other factors come into play.

The muscles surrounding the femur are much thinner in the elderly patient (Aniansson et al 1984, Trappe et al 2001) than in the younger individual in whom femoral shaft fractures are most commonly seen, although the degree of muscle wasting can be reduced by regular training (Grimby et al 1992). The increased muscle mass in a young patient could make the insertion of locking screws a more technically difficult procedure in the younger patient and therefore neurovascular injury is more likely.

The texture and pliability of cadaver tissues differs from tissues in living individuals and there is certainly less elasticity in cadaver tissue. This would make it more liable to be directly injured by the locking pins, as it is less liable to be pushed away by the inserted pins.

In addition to this the appearance of blood vessels in cadavers can also be altered. The arteries often contain air after death and the veins become very dilated, as they contain more blood than in normal life due to the fixation procedure. This increases their diameter and makes them more liable to injury during simulated nailing procedures.

The cadavers are fixed in the typical anatomical position, in which the limb is often slightly hyperextended. All the standard dissections were performed in cadavers with fully extended or hyperextended limbs while the operation would be performed with the hip and knee flexed. Therefore there is a possible discrepancy in the position of the nerves and vessels especially when measurements have been made.

The clinical cases reported were of patients treated with standard retrograde femoral nailing. No postoperative investigations such as electomyography were performed to confirm that none of the branches of the femoral nerve had suffered subclinical damage during proximal locking.

Finally, in an ideal situation a prospective clinical trial of the redesigned nail would be performed to compare both its biomechanics and its results in clinical practice with those of the standard Richards retrograde femoral nail. This was not possible as the nail was not licensed for clinical use and therefore a simulated procedure was carried out. This is, of course not completely realistic as the nail was taped to the side of the thigh and not inserted into the femur. Therefore, the position in which the screening was performed was not the same as it would be in an implanted nail leading to potential error i.e. screening an implanted nail may lead to an inadequate image of the proximal locking holes which may not allow locking to be carried out.

ii) Strengths

Against these can be set considerable strengths. The study was carried out largely in a laboratory setting which made it possible to identify with greater accuracy the structures which were at greatest risk of being damaged in the much less favourable environment of the operating room.

The demonstration of anatomical detail was also aided by the fact that there is no bleeding from embalmed cadaver tissue. This contrasts to living tissue which bleeds profusely on dissection and leads to obscuring of anatomical detail with subsequent risk of accidental damage to important anatomical structures.

We tried to cancel the effect of variability by carrying out several dissections of each position of anatomical and clinical interest i.e. the anterior, lateral and medial aspects of the thigh. These were performed with and without simulated nailing (Figures 7.12, 7.19, 7.25, 7.30 and Tables 2 and 3).

One of the strengths of the study is that although the topographical observations were made on an artificially extended limb, the simulated nailing and proximal locking was performed with the limb in exactly the same position as it would be in clinical practice, i.e.with the hip and knee flexed by 15-20 degrees.

This should theoretically lead to greater correlation between the results obtained in cadavers and those which are likely to be obtained in clinical practice.

3). <u>Results in Relation to Other Studies</u>

A) Retrograde Femoral Nailing With Percutaneous AP Locking

i) Normal Anatomy

The femoral artery is the main artery of the lower limb and entered the thigh behind the midinguinal point and gave off its main branch the profunda femoris artery- the principal artery of the thigh. It usually has its origin from the common femoral artery approximately 4.4cm from the inguinal ligament (Siddharth et al 1985). In our dissections it had its origin approximately 3-4cm below the inguinal ligament in most of the dissections but in one case it arose from the common femoral artery only 1cm below the inguinal ligament.

Once the profunda has given origin to the circumflex femoral arteries it passes posteriorly between pectineus and adductor longus, and descends close to the femur, posterior to adductor longus. Here the first three perforating arteries arise and the vessel continues as the fourth perforating artery from a point a little below the middle of the thigh (Fig.7.3). The perforating arteries give muscular branches to the thigh muscles.

The lateral circumflex is the largest branch of the profunda femoris artery and supplies structures on the lateral side of the thigh. It usually arises from the profunda but may branch directly from the common femoral artery (Kadir 1991, Perera 1995, Siddharth et al 1985). In the present series it arose from the common femoral artery in 3 dissections and from the profunda femoris artery in 4 dissections.

It ends by dividing into ascending, descending and transverse branches. It can be a site of atherosclerotic aneurysm formation (Feldman and Berguer 1981) and more recently it has been utilised in coronary artery bypass grafting (Faidutti 1996) as well as bypass grafting of severe common femoral and distal profunda femoris atherosclerotic disease (Gradman 1992).

The medial circumflex femoral artery may similarly arise from the common femoral artery or the profunda femoris (Kadir 1991, Perera 1995, Siddharth et al 1985). In our series it arose from the common femoral artery in 3 dissections and the profunda femoris artery in 4 dissections. It gives branches to the adjacent muscles and a supply to the hip joint through the acetabular notch (Gautier et al 2000). Its deep branch may be damaged in posterior approaches to the hip and this is a potential cause of iatrogenic avascular necrosis of the head of the femur (Gautier et al 2000).

The lateral cutaneous nerve of the thigh is an important nerve which has its origin from the lumbar plexus (L2,3) and enters the thigh posterior to or through the lateral part of the inguinal ligament and crosses the lateral angle of the femoral triangle. In our simulated nailing dissection it was found to be at significant risk from the insertion of the anteroposterior locking screws and at its closest point it was only 1.2cm from the position of the locking holes.

As well as anterior cutaneous branches it also has a posterior branch which pierces the deep fascia first and passes backwards to supply an area of skin over the greater trochanter. The remainder of the nerve pierces the deep fascia lower down. It descends to the lateral side of the patella sending branches to the skin of the anterior and lateral surface of the thigh. The nerve has also been identified as a potential donor for facial nerve repair (Zhao et al 1995).

Variation is a common theme in accounts of the upper thigh and its extremities. Our simulated nailing and dissections show that in a very small series there is little major variation in the overall anatomy of the neurovascular structures of the proximal thigh (Figures 7.12, 7.19, 7.25, 7.30 and Tables 2 and 3). What can clearly be seen from this is the proximity of the nerves and vessels to the position of the locking screws.

One example of the presence of anatomical variation of the proximal thigh is the origin of the medial and lateral circumflex arteries which can be seen to arise from both the femoral artery (Fig. 7.6) or the profunda femoris (Fig.7.2) (Kadir 1991).

However, the existence of this variability does not directly affect clinical practice as it is unpredictable, cannot be foreseen or guarded against and in either case the structures are still in close proximity to the path of the locking screws and therefore remain at significant risk.

ii) Posterior Structures at Risk

The sciatic nerve is a posteromedial structure which runs medial to the locking screws. At its closest point it is approximately 2.2cm from the distal of the two locking screws and is therefore not directly at risk from screw insertion. The nerve could however be put at risk if the drill or screw were to be placed or angled too medially during insertion. This could potentially cause the sciatic nerve to be wrapped around the drill or screw with resultant damage.

Although the manufacturers handbook (Smith & Nephew 1997) did not acknowledge the possibility of damage to the anterior neurovascular structures, it did, warn that caution should be exercised when drilling the proximal holes, so as to avoid plunging too far through the bone, and ' wrapping ' the sciatic nerve at the back.

To date there have been no reports of sciatic nerve damage in clinical practice. Sanders et al 1993 described the management of 29 femoral shaft fractures using the retrograde technique. Proximal locking was carried out using a freehand technique at the level of the lesser trochanter from an anterolateral to posteromedial direction. This would put the sciatic nerve in the direct path of the locking screws making it more liable to injury. However, no complications were reported with regard to this.

iii) Anterior Structures at Risk

The results obtained during the course of this study confirm that there are a large number of branches of the femoral vein, artery and nerve in the region of the lesser trochanter. Approximately 25 – 40 branches were identified; some of these were tributaries of larger branches arising directly from the femoral neurovasculature. The closest of the structures were the branches of the femoral nerve, which were at a distance of 0–12 mm from the position of the proximal locking holes. The closest of the branches was the muscular branch to the vastus lateralis which in some of the specimens was in direct contact with the locking screws.

Branches of the femoral nerve were found to cross the femur both above and below the level of the lesser trochanter and are therefore at potential risk from locking at either level.

An anatomical study carried out (Riina et al 1998) drew attention to concerns over the safety of insertion of the proximal AP locking screws. This study involved cadaver dissections in sixty specimens, of the anterior aspect of the proximal thigh in which the branches of the femoral nerve and artery were located, counted and followed to their destinations. The position of each branch was recorded as the distance from the piriform fossa to where it crossed the femur anteriorly. If a structure did not cross the anterior femur its closest point to the femur was then recorded.

Riina et al (1998) reported that in all specimens, all the branches of the femoral artery (numbering between 8 and 19) crossed the femur distal to the lesser trochanter at a level of more than 10 cm from the piriform fossa. The femoral artery itself was found to run medial to the femur throughout its course. The number of femoral nerve branches found in each specimen ranged from four to twelve. The total number of branches of the femoral nerve, artery and vein identified in our study cannot be directly compared to those results obtained by Riina et al (1998) as they do not take into account the branches of the femoral vein, however the number of branches based on his identification of the branches of the femoral artery and nerve would appear to be similar.

Riina et al (1998) also concluded that in 70 % of the specimens, between one and four of the femoral nerve branches crossed the femur proximal to the lesser trochanter. Our own findings confirm that there are branches of the femoral nerve crossing the femur both above and below the level of the lesser trochanter. From this study the authors were able to conclude that the femoral artery itself was safe from injury unless a drill bit or screw strays medially during placement. The branches of the femoral artery were only thought to be at risk if the locking screws were placed below the level of the lesser trochanter.

Riina et al (1998) concluded that the branches of the femoral nerve were at greater risk, regardless of the level of locking. However, the likelihood of damage would be minimised by placing the locking screws above the level of the lesser trochanter.

iv) Potential Effects of Neurovascular Injury

The susceptibility of nerves to injury has been demonstrated by several case reports of nerve injury due to routine venipuncture (Horowitz 1994) as well as routine administration of intramuscular injections (Schnatz et al 1999, Haber et al 2000). Therefore, injury to a nerve in the path of a drill or screw is most definitely possible.

The lateral cutaneous nerve of the thigh is an important nerve which arises from the lumbar plexus above the inguinal ligament. It passes behind the lateral third of the inguinal ligament to enter the thigh and supply the skin over the anterolateral surface of the thigh. Compression of the nerve as it passes through the ligament is implicated in meralgia paresthetica (Aszmann et al 1997) in which patients usually present with a syndrome of pain or dysasthesia, or both, in the anterolateral thigh caused by entrapment or neuroma formation of the lateral cutaneous nerve of the thigh (Williams and Trzil 1991).

In our simulated nailing specimen, at its closest point the lateral cutaneous nerve of the thigh was only 1.2cm from the locking screws (Fig.7.5). It is therefore at significant risk of being damaged. It may simply be bruised, partially or completely divided with varying consequences and symptoms similar to those seen in meralgia paresthetica (Williams and Trzil 1991).

The most commonly used classification of traumatic nerve injuries is the one introduced by Seddon during the Second World War (Seddon 1943). He classified nerve injuries into three basic types: neurapraxia, axonotmesis, and neurotmesis. Neurapraxia is a mild injury that produces a physiologic block to conduction rather than an identifiable anatomic lesion. Motor fibres tend to be affected more than sensory fibres, and electrophysiological responses are normal.

The observation that nerve conduction changes markedly after various types of nerve injury has been the basis of several theories based on neuroma formation and sprout outgrowth. (Devor 1983, Melzack and Wall 1965, Wall and Gutnick 1981).

The injury may result from localized ischaemic demyelination, and spontaneous recovery usually occurs. Axonotmesis results from a greater degree of injury or stretch and involves interruption of the axon and myelin sheath; however, the endoneurial tubes remain intact, allowing the regenerating axons to reach their proper peripheral connections. Total loss of neurological function occurs, but because of the intact endoneurial tubes, spontaneous recovery is possible although the degree of recovery is variable (Bowden 1951, Deitch and Grimes 1984). Because Wallerian degeneration occurs distal to the site of injury, the electrical responses are identical to those of denervation.

Neurotmesis is the most severe form of nerve injury. The nerve is either completely severed or so seriously injured that spontaneous regeneration or recovery is impossible. The sensory fibres have their cell bodies in the dorsal root ganglia, just outside the spinal cord. When a nerve fibre is transected, the distal portion degenerates completely, for it is now separated from its cell body. The endoneurial tube and Schwann cells surrounding the fibre remain intact, except of course at the point of injury. As the distal fibre degenerates, it is absorbed by neighbouring cells.

At the same time, the proximal portion of the fibre begins its regeneration of about 3mm growth daily until the fibres reach their original destination. If, however, the architecture is such that the sprouts do not find intact tubes nearby, they are surrounded by an area of tissue injury and inflammatory response. Multiple sprouts are sent out by each axon in an unsuccessful attempt to find the familiar endoneurial structures. The end result of failed regeneration is called a neuroma and includes fibrous tissue and fine nerve sprouts trapped therein (Melzack and Wall 1965).

Wall and Gutnick (1981) have investigated the properties of these regenerating sprouts. Several unusual properties were observed that may play a role in the pathogenesis of reflex sympathetic dystrophy. First, these sprouts are extremely sensitive, even to light pressure stimulation. This is the basis for Tinel's sign, in which gentle tapping over a neuroma or sprouts produces a strong, shocklike pain. Second, some of these fibres originating in the neuroma are capable of generating impulses in the absence of any obvious stimulation.

Damage to the lateral cutaneous nerve would at a minimum lead to altered sensation over the lateral aspect of the thigh, the extent of this is difficult to ascertain due to sensory overlap from other cutaneous nerves. In addition painful neuroma formation could occur and in extreme cases hyperexcitability of the nerve cell bodies may lead to symptoms similar to reflex sympathetic dystrophy (Sunderland 1976).

Damage to the femoral nerve has been reported following various surgical procedures such as inguinal hernia repair (van Hoff et al 1985), abdominal rectopexy (Infantino et al 1994), anterior lumbar interbody fusion (Papastefanou et al 1994) as well as many others (Hudson et al 1979). The patients usually present with leg pain, diminished sensation over the anterior surface of the thigh and knee and quadriceps weakness (Infantino et al 1994, van Hoff et al 1985).

Our investigations have shown that the femoral nerve itself is situated several centimetres from the position of the locking screws and is therefore not directly at risk. However the symptoms of femoral nerve palsy give us an indication of the spectrum of problems which may be seen if any of its branches were to be damaged; leg pain, reduced sensation over the anterior surface of the thigh and knee and quadriceps weakness (Infantino et al 1994, van Hoff et al 1985).

The quadriceps femoris is the powerful extensor of the knee and consists of four individual muscles. These muscles receive their nerve supply from separate branches of the femoral nerve which arise in the femoral triangle approximately 2cm below the inguinal ligament.

Our study showed that there are four muscular branches of the femoral nerve within 12mm of the locking screws. These are the branches to quadriceps femoris. The closest of these is the branch to vastus lateralis which in some cases was in direct contact with the locking screws.

Vastus lateralis is the largest of those in the Quadriceps group and its primary function is to assist vastus intermedius and vastus medialis in extending the knee. Damage to its nerve supply would result in its partial or complete paralysis leading to weakened knee extension as would interference with its vascular supply due to ischaemia and fibrosis. Isolated paralysis of the vastus lateralis due to nerve damage caused by injection of intramuscular analgesics has previously been described in the literature (Haber et al 2000) with resulting weakness of quadriceps and therefore knee extension.

Isolated weakness of quadriceps femoris has also been described and can occur in a clinical variant of Becker Muscular dystrophy (Wada et al 1990), motor neuron disease, polymyositis (de Graaf and Hewlett 1982) as well as sporadically (Danielis et al 1991). Patients present with progressive weakness and wasting localised to the quadriceps (Danielis et al 1991) with weakened knee extension. There have also been case reports of isolated vastus laterlis wasting leading to a lesser degree of weakened knee extension (Haber et al 2000).

Damage to the various branches of the femoral nerve which supply the quadriceps would therefore be very significant. In some cases weakness of the muscle may be subclinical and asymptomatic (Wada et al 1990, Weale et al 1996) but it could also lead to partial or complete paralysis of the quadriceps resulting in weakened knee extension similar to that seen in isolated quadriceps myopathy (Danielis et al 1991, Wada et al 1990).

v) Clinical Results

A study by Moed and Watson (1995) used the Alta femoral nail, which is specifically designed for retrograde insertion. It has two proximal locking holes for subtrochanteric AP locking, and two distal locking screws for lateral to medial insertion. The AP locking screws were inserted using the freehand technique, facilitated by the use of a C- arm fluoroscopy unit. Twenty-two fractures were managed using the technique of retrograde femoral nailing described above.

The only complications reported by Moed and Watson (1995) was a lack of full knee motion in two patients. This failure was attributed to associated damage to the femoral nerve at the time of injury (caused by a gunshot) in one patient, and the knee joint at the time of surgery in the second patient.

There is no reference by the authors to any risks associated with the insertion of the proximal screws, and they report no complications resulting directly from the AP screws. This may be due to the fact that locking may have been performed at a level significantly lower than the level of the lesser trochanter where there are fewer structures to be damaged. Locking below the level of the lesser trochanter is however unsatisfactory as it reduces the working length of the nail therefore not all of the femoral shaft is stabilised. Our study examined the region of the lesser trochanter and is therefore not directly comparable.

Sanders et al (1993) described the management of twenty-nine fractures using the retrograde technique. Proximal locking was carried out using a freehand technique at the level of the lesser trochanter from an anterolateral to posteromedial direction. He reported no complications attributable to the insertion of the proximal screws. He also fails to state whether insertion was performed using a percutaneous or open technique.

A number of other clinical studies have been carried out using the retrograde technique. Patterson et al (1995) described the management of seventeen patients using the technique with proximal anteroposterior locking carried out freehand. He reported no neurovascular problems but fails to state whether it was carried out using a percutaneous or open technique.

Damage to the femoral artery has been reported in total hip replacement from retractor injury, thermal injury from methylmethacrylate or direct penetration from polymer or gouging during acetabular preparation (Aust et al 1981, Nachbur et al 1979). The consequences of vascular injury to the femoral artery or its branches can be severe and in some cases may result in significant lower limb ischaemia leading to an above knee amputation (Nachbur et al 1979).

More recently there has been a case report of arterial injury during retrograde femoral nailing of a femoral shaft fracture (Coupe and Beaver 2001). In this case, injury to a branch of the profunda femoris has been reported during placement of the anteroposterior locking screw. The patient developed postoperative hypovolaemia with a significant reduction in the haemoglobin level. An angiogram showed damage to a branch of the profunda femoris artery and the patient subsequently required arterial embolisation to control the bleeding.

This report reinforces our own findings which highlight the potential danger to neurovascular structures from anteroposterior locking at the level of the lesser trochanter and suggests that more accounts of injury may be published as the number of cases treated with retrograde femoral nailing begin to increase.

Conclusion

It is rather astounding, given our findings and those of Riina et al (1998) that the results of several previous studies indicate that their has been only one neurovascular complication associated with proximal anteroposterior locking of retrograde femoral nails (Coupe and Beaver 2001). This may be due fact that retrograde femoral nailing has only been carried out in relatively small numbers to date or because in life the neurovascular structures glide away from the path of the screws.

In some cases proximal locking may have been carried out as an open procedure and this in itself would reduce the risk of neurovascular damage. It is also well documented that minor neurological damage may not be picked up by clinical examination and requires formal assessment using nerve conduction studies (Weale et al 1996). On the other hand the lack of neurovascular complications may simply be down to ‘ damn good luck ‘.

This study and the work of Riina et al (1998) demonstrates that there are a large number of structures potentially at risk from this procedure and the consequences of neurovascular injury could be extremely serious. Having seen the anatomy of this region one could never feel safe with percutaneous proximal anteroposterior locking.

B) Alternatives to Percutaneous Proximal AP Locking

The options of dealing with these potential problems vary from either modifying the technique of percutaneous proximal anteroposterior locking or altering the direction of the locking screws. In order to avoid the many anterior branches of the femoral neurovascular bundle proximal anteroposterior locking could be carried out either above the level of the lesser trochanter, or several centimetres below as there are fewer branches at this level.

i) Altering the Level of Proximal AP Locking

If locking were carried out above the level of the lesser trochanter, the risk of neurovascular injury would be reduced. The working length of the nail would be increased. This would however, cause concentration of stress at the femoral shaft and neck junction (see Fig.6.18). This is not desirable as subsequent injuries i.e. minor falls would most probably lead to a fracture at this point.

Locking carried out several centimetres below the level of the lesser trochanter would also increase the safety of the procedure (as in Fig.7.37) due to the fewer number of neurovascular structures at this level. However this would reduce the working length of the nail and would also alter the biomechanics of the nail and femur construct reducing its stability. If the nail were used in this way it would have no real advantages over the standard shorter supracondylar nail.

ii) Open AP Locking

An alternative to this is to carry out proximal locking as an open procedure. The position of the proximal locking holes could be identified using the image intensifier. A small incision could be made over this point and blunt dissection used to identify the anterior cortex of the femur.

This would allow the neurovascular structures to be identified and retracted away from the path of the drill and screws. Although this is a safer technique than percutaneous locking there is still the risk of injury caused by either slippage of the instruments or a traction injury due to excessive retracting. Proximal locking in all the clinical cases previously described was carried out as an open procedure.

iii) Locking in a Different Direction

A third option would be to alter the direction of the proximal locking holes of the retrograde femoral nail to allow them to be inserted along a safer path. At present the position of the locking holes is anteroposterior. This could be altered to anterolateral to posteromedial or lateral to medial.

Our initial dissections showed that the sciatic nerve is a posteromedial structure and we can therefore eliminate the former option. We therefore feel that the ideal option would be to consider redesigning the nail with lateral to medial locking replacing the anteroposterior locking.

C) Locking in a Lateral to Medial Direction

i) Anatomy of the Lateral Side of the Thigh

Dissections of the lateral thigh carried out in four cadavers demonstrated that there were no significant cutaneous nerves at the level of the lesser trochanter over the lateral thigh. The only structures identified were the muscular branch to vastus lateralis which was about 2-3cm from the level of the locking holes and the transverse branch of the lateral circumflex femoral artery. This was also situated about 2-3cm from the locking holes.

ii) Simulated Nailing with Lateral to Medial Proximal Locking

Simulated nailing with lateral to medial proximal locking performed in four cadavers demonstrated that there were few structures situated over the lateral aspect of the thigh at the level of the lesser trochanter. No structure was damaged by placement of the locking screws.

The nearest structures were the transverse branch of the lateral circumflex femoral artery and the muscular branch to vastus lateralis. These were both several centimetres from the locking screws making this a significantly more safer procedure than anteroposterior locking. Although damage to the transverse branch of the lateral circumflex femoral artery is a possibility this is significantly less likely than with the anteroposterior approach. If this artery was damaged at this site, it could be easily exposed using a direct lateral approach to the femur allowing any haemorrage to be controlled quickly. Medially the locking screws emerged into the substance of the adductor muscles behind the femoral artery, the profunda femoris and the femoral nerve and several centimetres short of the obturator nerve.

These findings are supported by a recent radiological study carried out by Brown et al (2001). This study involved carrying out pelvic CT and MRI scans of patients with femoral shaft fractures. The aim of the study was to evaluate the course of the femoral sheath, neurovascular complex, and the sciatic nerve as they passed through the proximal thigh. The study concluded that at the level of the lesser trochanter lateral to medial screw insertion would be safer than anteroposterior screw insertion.

iii) Clinical Trial

It was anticipated that lateral to medial locking at the level of the lesser trochanter might not be possible because of potential difficulties in screening this area with the image intensifier. The image intensifier would have to be lined up with the drill and the locking holes of the nail (Grover and Wiss 1995, Hajek et al 1993, Levin et al 1987). In order for an adequate image to be obtained the affected hip would have to be abducted and the unaffected hip would require to be flexed and abducted out of the way of the image intensifier.

Our initial doubts however proved unfounded as it was possible to obtain adequate images of this area using two different screening positions without any real difficulties. The C-Arm was placed in a horizontal or slightly oblique position and perpendicular to the femur at the level of the lesser trochanter.

The patient can be positioned either supine with a bolster under the hemipelvis of the affected side or alternatively in traction with the unaffected limb flexed at the hip and knee and abducted out of the way. The insertion of lateral to medial screws using this technique could be performed without compromising the nail biomechanics or fracture stability.

4). Meaning of Results for Clinicians

i) The potential problems associated with percutaneous proximal anteroposterior locking have been suggested by our findings. The clinical results of retrograde femoral nailing are good so far but its use is potentially hazardous.

ii) This leads us to ask the question whether there should be any role for retrograde femoral nailing in the management of femoral shaft fractures. Conventional antegrade femoral nailing is the most popular treatment for femoral shaft fractures (Anastopoulos et al 1993, Cameron et al 1992, Christie et al 1988, Winquist et al 1984) but has a number of disadvantages including the risk of femoral neck fracture (Christie and Court-Brown 1988) and heterotopic ossification (Steinberg and Hubbard 1993).

Retrograde femoral nailing avoids these and it is potentially quicker to set up in theatre, can be used in multiple trauma and pregnancy (Moed and Watson 1995, Patterson et al 1995, Sanders et al 1993). It is also particularly useful for the management of patients with 'floating knee' injuries (Ostrum 2000, Gregory et al 1996).

It would therefore be naïve to discard such a potentially useful technique for femoral shaft fracture stabilisation and the answer to our initial question is a resounding yes.

Options

There appear to be two possible options, which would retain the advantages of retrograde femoral nailing, but reduce the risk of nerve and vessel damage at the proximal end of the femur. These are;

1.Anteroposterior locking under direct vision: which is easy but still risky.

2.Redesign of the nail with lateral to medial locking: which is more difficult but probably safer.

Conclusions

The null hypothesis, which was proposed at the beginning of this investigation suggested that proximal AP locking screw insertion at the level of the lesser trochanter is safe, is rejected. The dissections have conclusively shown that there are a large number of neurovascular structures at this level which are at potential risk from the insertion of AP locking screws.

A second null hypothesis- that the nerves and vessels of the upper thigh are at risk from proximal locking screws inserted in a lateral to medial direction has also been disproved. This new path seems to offer increased safety with little obvious disadvantage.

Following redesign of the nail, we feel that it would be an improved prosthesis. Because of its enhanced safety and the use of the more conventional lateral to medial locking technique it would be more user friendly and hence more popular in the management of certain patients with femoral shaft fractures.

The principal conclusions of this investigation may be summarized thus:-

1.Percutaneous proximal anteroposterior locking is potentially hazardous to the nerves and vessels of the upper thigh.

2.The lateral cutaneous nerve of the thigh is at risk from anteroposterior locking.

3.The nerve supply of quadriceps is at risk of being injured.

4.Lateral to medial locking is probably a safer procedure.

5.Redesign of the nail is possible allowing lateral to medial locking.

6.Surface trial of the redesigned nail has been successful.

5). Unanswered questions, speculation & future work.

The surface trial of the redesigned retrograde femoral nail proved successful indicating its potential use in theory. However in order for accurate clinical assessment of its use to be carried out it is necessary to carry out a formal randomised clinical trial using such an implant. This requires the redesigned nail to be licensed for clinical use and ethics committee approval to be obtained to allow its use to be assessed in a formal clinical trial.

APPENDICES

i) Digital Photography

All the photographs displayed in this project were taken with a high quality digital camera. The camera used was the Nikon Coolpix 990. The resolution setting for all the photographs was 640 by 480 pixels.

Once the photographs had been taken they were downloaded to a desktop computer and stored as jpeg. files. They were then adjusted to the correct size using a photographic software package. The software package used was Paintshop Pro version 6.01.

Following this they were incorporated into the text documents using Microsoft Word 97 and labelled appropriately.

ii) Supporting letters for ethics committee approval

WEST OF SCOTLAND HEALTH BOARDS

DEPARTMENT OF CLINICAL PHYSICS AND BIO-ENGINEERING

Director:
Professor A T Elliott
BA, PhD, DSc, CPhys, FinstP

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Health Physics Service

CJM/MC/096

20 July 2001

Mr A Mohammed
110 Broomhill Road
Glasgow
G11 7AS

Dear Mr Mohammed

RADIATION DOSE FROM EXPOSURE IN PROPOSED RESEARCH PROJECT

I have carried out an assessment of the radiation dose that would be received from the two exposures proposed in this project. The assessment was made for two exposures of the right hip taken from the inner aspect of the right leg with the legs apart. The dose to the most sensitive organs would result almost entirely from scattered radiation and this has been added to the dose to muscle and bone tissue with appropriate weighting factors to determine the effective dose.

The assessment has been carried out for the Zeihm Exposcop 8000 mobile image intensifier, serial number 3781, at Stirling Royal Infirmary and is based on measurements made on 20th June 2001.

It is estimated that the effective (whole body) dose to an individual subject would be 0.005 mSv, with the dose to the skin of the irradiated area, 1 mGy.

This dose is about one-quarter of that received from a chest X-ray or that received from natural background radiation in one day. The risk of fatal cancer resulting from this exposure is of the order of 1 in 4 million.

The risk from a radiation dose at this level is trivial. The International Commission on Radiological Protection state that "the level of benefit needed as the basis for approval of investigations with risks at this level will be minor and would include those investigations expected only to increase knowledge". Thus, provided that useful information will be obtained from the study, I see no reason why it should not go ahead.

Under the Ionising Radiation (Medical Exposure) Regulations 2000, it will be necessary for the procedure to be justified by a practitioner, who would normally be a qualified radiologist.

The X-ray tube should be positioned and the procedure performed in a manner to minimise the radiation dose to the gonads and I would recommend that lead drapes should be used for this purpose. The assessment that I have made assumes that such protection is in place and if it is not possible to protect the gonads, then the effective dose received would be double the value quoted.

The Regulations also require a "dose constraint" to be set for all individual biomedical research exposures. I would recommend that an entrance surface dose of 5 mGy be employed. This would allow up to 10 exposures to be made with gonad shielding in place and up to five without it. This constraint must be seen as an upper limit and the minimum number of exposures, i.e. two, should be taken under normal circumstances.

....../......

I hope that this provides all the information that you require. Please contact me if you require any clarification.

Yours sincerely

Colin J Martin

Colin J Martin (Dr)
Head of Health Physics

c.c. Mrs A Crowe, RPS, Stirling Royal Infirmary.
Dr J Robertson, RPA.

STIRLING ROYAL INFIRMARY

Stirling Royal Infirmary, Livilands, Stirling FK8 2AU.
Telephone: 01786 434000 Fax: 01786 450588

To Whom It May Concern:

I write to support Mr A Mohammed in his application to the Ethics Committee concerning his MD thesis.

The request for radiation has been discussed with Dr Martin, Acting Radiation Protection Adviser at the Medical Physics Department of Glasgow University who considers the proposed dose to be of negligible risk. Informed consent will, of course, be required of the volunteer subjects but as they are all Medically trained they should already be aware of the level of risk from the radiation involved.

The doses delivered to each subject will be recorded and archived.

Yours faithfully

Peter McDermott
Consultant Radiologist

24 July 2001

iii) <u>Volunteer information sheet</u>

STIRLING ROYAL INFIRMARY

Stirling Royal Infirmary, Livilands, Stirling FK8 2AU.
Telephone: 01786 434000 Fax: 01786 450588

TRIAL OF REDESIGNED FEMORAL NAIL

Volunteer Information Sheet

Date 24/07/01: Version 1

You have been asked to participate in a study looking at a redesigned femoral nail. This is a metal implant which is used for the treatment of fractures of the thigh bone (femur).

The study will involve taping a metal nail (rod) to the side of your thigh and taking two X-Rays of your thigh. This will be carried out in theatre with you lying on an operating table.

You will be exposed to X-Rays during the procedure. The dose of X-Rays will be equivalent to those received from normal background radiation in one day or a quarter of that received from a chest X-Ray. The risks of developing fatal cancer from this exposure are negligible and of the order of 1 in 4 million.

Although you will not benefit directly from this study, the outcome may help in the future management of patients with fractures of the thigh bone (femur).

Should you wish to withdraw from the study, you may do so at any stage.

iv) **Volunteer consent form**

STIRLING ROYAL INFIRMARY

Stirling Royal Infirmary, Livilands, Stirling FK8 2AU.
Telephone: 01786 434000 Fax: 01786 450588

Centre Number: :
Study Number:
Patient Identification Number for this trial:

CONSENT FORM

Title of Project: TRIAL OF REDESIGNED FEMORAL NAIL

Name of Researcher: MR.ASLAM MOHAMMED MB ChB, FRCS.
SPECIALIST REGISTRAR (ORTHOPAEDICS)
STIRLING ROYAL INFIRMARY

Please initial box

1. I confirm that I have read and understand the information sheet dated 24/07/01 (version 1) for the above study and have had the opportunity to ask questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. ☐
3. I agree to take part in the above study. ☐

Name of Patient	Date	Signature
Name of Person taking consent (if different from researcher)	Date	Signature
Researcher	Date	Signature

1 for patient; 1 for researcher; 1 to be kept with hospital notes

v) **Ethics committee approval**

FORTH VALLEY HEALTH BOARD

AJH/ksh/2002moh

1st August 2001

Mr A Mohammed
110 Broomhill Road
GLASGOW
G11 7AS

Dear Mr Mohammed

RE: Radiation Dose From Exposure In Proposed Research Project

Thank you for your application for the above study and for attending the Forth Valley Ethics of Research Committee meeting on 26 July to present details of the X-rays that you intended to take on Friday 27 July.

As you are already aware the Committee is happy for this to go ahead and grants ethical approval to this part of your study. I telephoned Dr McDermott on Thursday 26 July to let him know this outcome.

The project must be started within three years of obtaining notification of ethical approval. You should follow the protocol agreed and advise this committee of any changes made. Any alterations or amendments to the study protocol will require prior approval from Forth Valley Ethics of Research Committee. You should also provide the committee with an annual progress report each year on the anniversary of approval of your project

Please ensure that the Committee are advised when the study has been completed, with if appropriate, any notification for publication of results.

You will no doubt realise that whilst the Committee has given approval for your project on ethical grounds, it is still necessary for you to obtain management approval, if you have not already done so, from the relevant Clinical Director and/or Chief Executives of the Trusts in which the work will be carried out.

The Committee wishes you success with your MD.

Yours sincerely

Eileen Holliday

Dr A J Holliday
Secretary to Ethics of Research Committee

33 Spittal Street, Stirling, FK8 1DX
Telephone: 01786 -457251
Facsimile: 01786 - 451474

vi) **Modifications to retrograde femoral nail**

The objective was to drill two holes in a tubular stainless steel component supplied and described to as a "nail". The holes had to be drilled through the diameter of the nail in the same lateral positions as two existing holes, but perpendicular to them.

An accurate measurement was taken of the diameter of the two existing holes using a shadowgraph and two steel pins of the same diameter inserted into these holes. The pins were 50mm longer than the diameter of the nail so as to protrude from the holes by 25mm on either side of the nail.

The nail was then held in a dividing head and adjusted so that the pins were approximately vertical. The dividing head was then fixed to the table of a milling/drilling machine and "trued" to the machining heads of the machine. A device called a "clock gauge" was then used to make fine adjustments to the radial position of the nail by measuring the position of the steel pins above and below the nail with reference to a fixed datum point.

Once satisfied that the pins were vertical, the "chuck" holding the nail was rotated through ninety degrees. A device known as an "edge finder" was then used to accurately position the correct size of drill bit and the holes were drilled. The job was completed by removing any sharp edges around the holes.

vii) **Surface trial using image intensifier and fracture table**

The image intensifier used for the surface trial of the retrograde femoral nail was the Ziehm Exposcop 8000, Serial No. 3781. An average of three X-Rays were taken for each volunteer. This resulted in whole body radiation dose of approximately 0.0005mSv, with the dose to the skin of the irradiated area approximately 1mGy.

This is equivalent to the amount of natural background radiation received in one day or one quarter of the radiation dose received from a chest X-Ray.

The surface trial was carried out with the volunteer lying on a Maquet fracture table, Model No.112047, Serial No.267, Stlerlen-Maquet, Rastadt, Germany.

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