The Design, Manufacture and Analysis of a New Implant for Fracture Fixation in Human and Veterinary Orthopaedic Surgery: The Bone Fastenerod

By

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This thesis is submitted to Dublin City University as the fulfillment of the requirement for the award of the degree of

Doctor of Philosophy

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Declaration

I hereby certify that this material, which I now submit for assessment on the programme of study leading to the award Doctor of Philosophy, is entirely my own work and has not been taken from the work of others save and to the extent that such work has been cited and acknowledged within the text of my work.

Signed: ____________ Date: 1/2/03

Name: W.T. McCARTNEY

ID Number: ____________

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And finally I must acknowledge the huge sacrifice my family have had to endure to enable me to complete the research

Dedication

I dedicate this work to my Mother and Father for always being there to help

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Nomenclature

Symbol	Definıtıon	Dımensıon
U	Ultımate yıeld	KN
E	Young's Modulus	mPa

Abbreviations

AO/ASIF	Associatıon for the Study of Internal Fıxatıon
DCP	Dynamıc Compressıon Plate
DSC	Dynamıc Condylar Screw
INAIL	Interlockıng naıl
1 1-2fd	1 1mm pıns, 2 0 mm screw
1 6-2 7fd	1 6mm pıns, 2 7 mm screw
1 6-3 5fd	1 6mm pıns, 3 5 mm screw
2 4-3 5fd	2 4mm pıns, 3 5 mm screw
4-4 5fd	4mm pıns, 4 5 mm screw
3 5clıp	3 5mm screw, opens top round bottomed clıp
G Naıl	Gamma Interlockıng Naıl
LCDCP	Lımıted Contact Decompressıon Plate
Pcfix	Poınt Contact Fıxator

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The design,manufacture and analysis of a new implant for fracture fixation in Human and Veterinary orthopaedic surgery: The bone fastenerod

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Abstract

Fracture fixation in humans and animals has troubled surgeons and scientists since first it was attempted right up to the present day At every milestone of achievement in the understanding and practice of fracture repair there has remained a significant problem left unresolved Of paramount concern is the preservation of blood vessels and soft tissues, avoidance of stress shielding and concentration, promotion of bone healing and a rapid return to function

However, matching these principles with the variables of degree and site of fracture/injury, age, size and status of patient, environmental and surgical factors is complex and difficult To be able to attempt to allow a surgeon to make decisions about every case, knowing that the implant choice does not constrain him but offers flexibility to aim for the ideal fixation for each case, the system must be modular The objectives were to produce an implant system that would satisfy the most up to date principles of fracture repair through design optimization, mechanical evaluation and testing for specific fracture types The design was called the bone fastenerod following the optimization and analysis procedures to indicate the origins of its basic formation

To begin with, the design of the fastenerod had to be optimized and this was achieved using bench testing, initially of selected designs followed by finite element analysis, which allowed a greater number of designs to be processed Once the optimum design had been found the process of manufacture had to be selected and various possible methods of manufacture were examined until the one most suitable was determined To analyze the fastenerod, the current industry standard implants that are used in the same clinical type settings were chosen for comparative testing Testing was performed using static and cyclic loading to failure with wood samples in four point, tensile, side, axial and torsional loading Specific fractures in dog, cat and horse bones were created and repaired using the fastenerod versus the best method currently available and tested in three point, tensile, axial, static loading to failure Also, specific fractures were created in human mechanical bones and tested using axial, cyclic and four point bending again, comparing the fastenerod with the best technology available The analysis revealed that in static loading the fastenerod was comparable to the industry standards for small implants but not comparable with the large human implants in the specific cases selected However, in the case of the cyclic loading to failure, the fastenerod performed better than the plate system of similar size, with the ultimate load to failure being higher and no stress concentration leading to implant fracture or failure Thus, the modular system of the bone fastenerod could now claim to provide fixation that could be flexible, less invasive and destructive to tissues, capable of greater choice of screw placement and stiff to level of choice whilst avoiding stress concentration and shielding On the basis of this analysis, the fastenerod system can proceed to full clinical trials

Chapter 1

Introduction

1 1 Fracture Management

Current standard methods of internal fixation of fractures are the same in human and veterinary orthopaedics Most major advances in the management of fractures were made by the AO / ASIF group based in Switzerland and America, and was formed by a group of Swiss surgeons in 1958 The AO / ASIF group defined the successful treatment of fractures based on the biomechanical principles of fracture repair, and was formed through the combination of orthopaedic surgeons, metallurgists and experts from the watch making industry

Figure 1 1 Bone healing under a cast

Together they founded a research laboratory in Davos, Switzerland and have remained in the forefront of the advances in the management of fractures since The aim of the group is to restore full function in as quick a fashion as possible in order to avoid the repercussions that occur from fracture disease Fracture disease is defined as complications such as muscle wastage, joint stiffness, soft tissue adhesions and osteoporosis arising when a limb is immobilised for a long period of time in a cast (Fig 1 1) Application of a cast for more than six weeks can lead to all the elements of fracture disease Return to full function is achieved by using the four techniques recommended by AO / ASIF

1. Atraumatic surgical technique
2. Perfect anatomical reduction of the fracture fragments
3. The avoidance of soft tissue trauma leading to adhesions and stiffness
4. Return to full function and rigid internal fixation

Figure 1 2 An intercondylar fracture of the elbow

Figure 1.3 Repair of fracture in Fig 1 2 using lag screws as part of fixation

Rigid internal fixation is accomplished by using compression techniques to reconstruct fractured bones (Figs 1 2 and 1 3)

Figure 1 4 A fracture of the anconeous

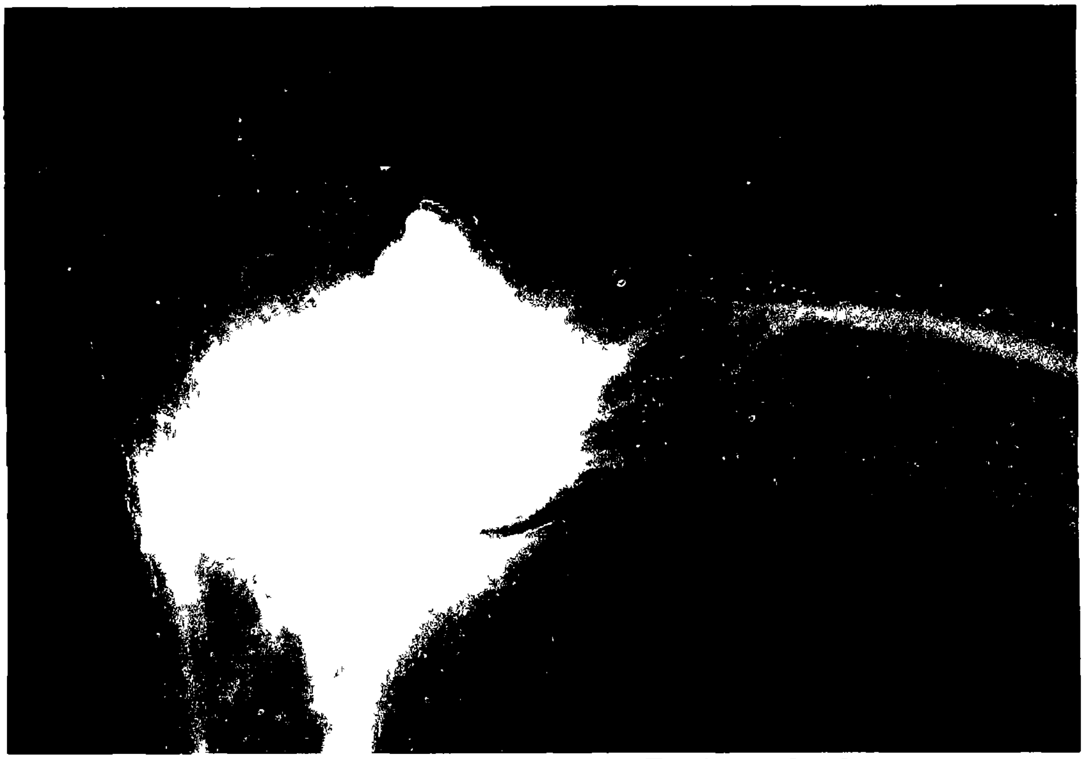


Figure 1.5 Repair of fracture from Fig 1 4 with a lag screw

This can take the form of functional compression with tension band wire, or axial compression with plate and wire techniques using the tension band principal by placing a plate on the tension side of the bone, and interfragmentary compression by use of lag screws (Figs 1 4 and 1 5)

Cerclage wires, neutralisation plates and external fixators can also be used Although the main thrust of the AO / ASIF techniques were based on rigid internal fixation and compression of fragments, there has been a change of attitude in recent years towards bridging osteosynthesis for diaphyseal fractures This is in line with thinking on biological osteosynthesis whereby the fracture area is bridged by metal work to reduce localised disturbance and to maintain its blood supply This can be done with a buttress or lengthening plate or with an interlocking nail Even though we do not achieve primary bone fusion using bridging osteosynthesis (Fig 1 60, the net effect of this is to master the objectives of the AO / ASIF in avoidance of fracture disease by a slightly different route.

Figure 1.6 An example of bridging osteosynthesis

The type of implants used for internal fracture fixation are in combination, or individually, AO bone screws, DCP (dynamic compression plate), pins, external skeletal fixators, interlocking nails and other specialist type plates.

1.2 Intramedullary Fixation

Intramedullary fixation is a method of repair whereby the implant is inserted into the medullary cavity of the bone (Fig 1.7). Some of the intramedullary devices used are Steinman pins, Rush pins, Kirschner wires, Kunstchner nails, interlocking nails plus other specialised human fixation nails. With the Steinman pin, which is a smooth pin, the stability of the fracture is dependant on the tightness of the pin fit within the intramedullary cavity to resist rotation (Fig 1.8). Muscle forces create functional compression and interlocking fragments can resist rotation Being at the centre of the bone, the pin is very resistant to bending forces but not to the rotational forces at the fracture site

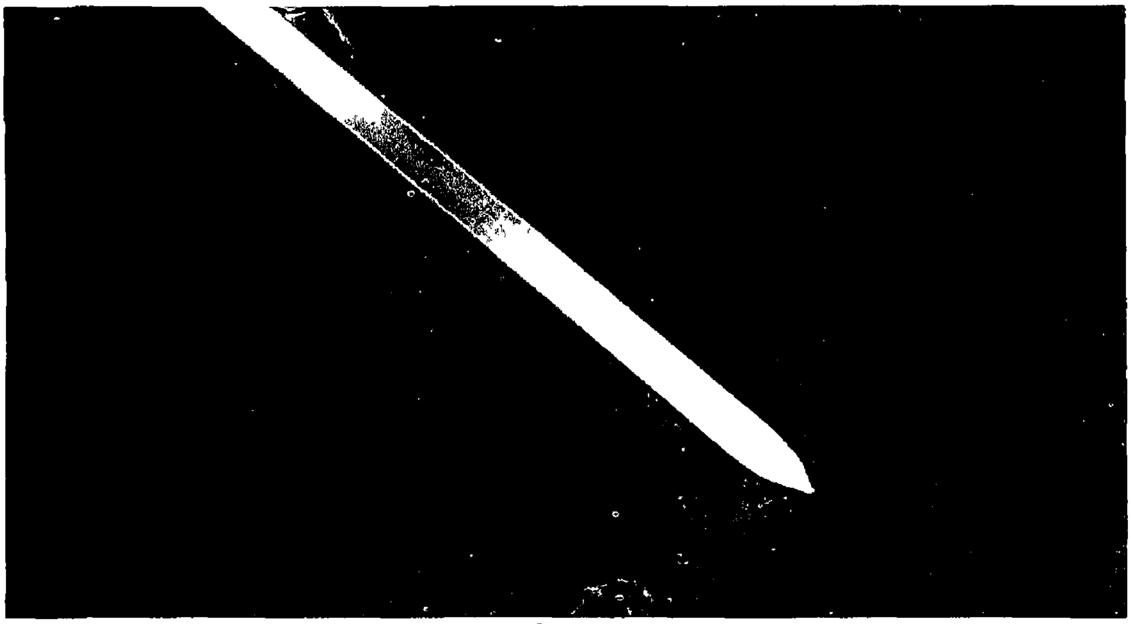


Figure 1.7 An example of intramedullary pinning

To overcome the rotational instability of the smooth nail, various types of pins were developed such as the clover leaf nail and the interlocking nails without which the only way to resist rotation would be to add on an external skeletal fixator (Fig 1 9)

Figure 1.8 A non union of a tibia treated using an intramedullary pin due to insufficient resistance to rotational forces

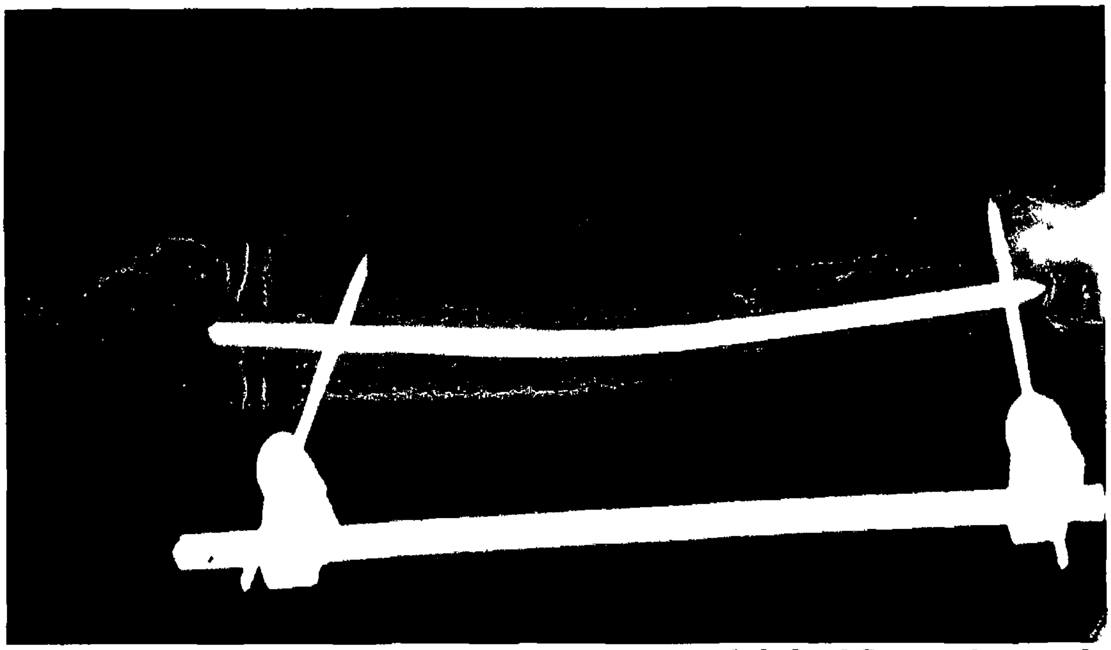


Fıgure 1 9 The combınatıon of a pın and external skeletal fixtaıon has good rotatıonal resıstance

Interlockıng naıls evolved as a modıficatıon of the Kuntschner naıl, whıch ıs basıcally an ıntramedullary pın secured ın posıtıon by proxımal dıstal transfixatıon screws whıch engage both cortıces of the bone to provıde rotatıonal stabılıty (Fıg 1 10, 1 11, 1 12) Thıs technıque ıs partıcularly useful ın complıcated long bone fractures, and ınterlockıng naıls are the current preferred method of fixatıon for most dıaphyseal fractures of the femur and the tıbıa ın humans

Fıgure 1 10 Fracture of the dıstal femur and proxımal tıbıa

Figure 1.11 Postop x-ray of fracture depicted in 1.10 with an anterior posterior view of the interlocking nail

Clinical application of the interlocking nail in dogs for the treatment of diaphyseal fractures of the humerus and the femur has given good results. To a certain extent, the current generation of interlocking nails has taken over from the traditional plate in many diaphyseal factures of the femur and tibia.

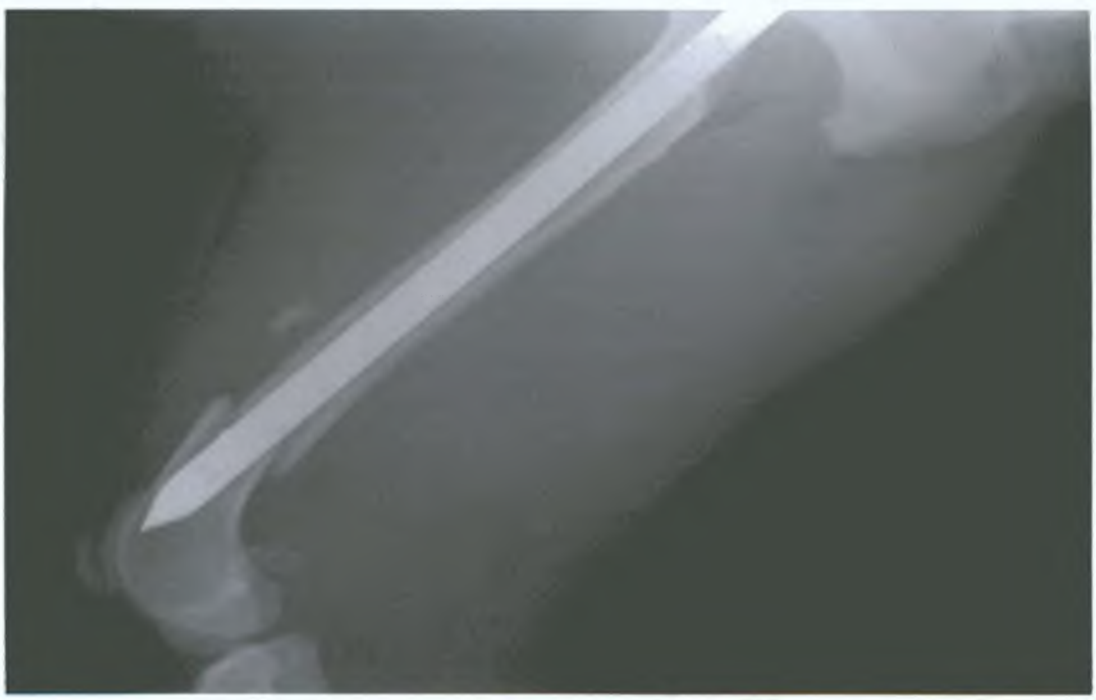


Figure 1.12 A lateral view of an interlocking nail for treatment of the fractured femur in Figure 1.10

Other forms of pin used for fixation are arthrodesis wires or Kirschner wires. These have a small diameter and can be short or long, and they are either used for cross pinning of some fractures in the immature or to hold small fragments in situ during fracture healing. They are also used in small bones such as the metacarpi (Fig 1.13 and 1.14), as temporary fixation and, in combination with lag screws, as second point fixation to resist rotation.

Figure 1.13 Multiple metacarpal fractures

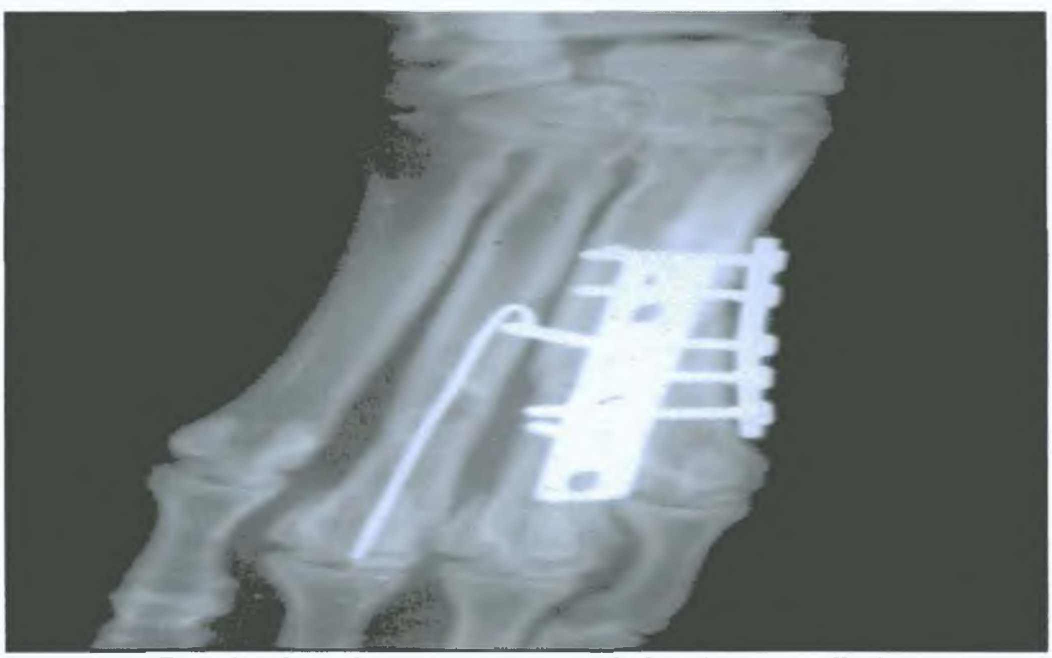


Figure 1.14 Repair of the fractures in Fig 1.13 showing a small pin being used

Rush pins are an old method of repair and are used mainly for fractures in or around the joint area and have a bevelled tip for ease of insertion so they can achieve a spring like action. This method was used in supracondylar fractures of the femur and humerus but is no longer popular.

1.3 External Skeletal Fixators

External fixators are basically pins piercing the skin, drilled into the bone to emerge at the other side where the pins are attached to an external bar (Figs 1.15 and 1.16). The use of external skeletal fixators to treat human injuries was first reported in 1897. Fixators specifically for animal use were designed in the late 1940s by Ehmer, based on a human design. The use of fixators declined following a high incidence of complications associated with the treatment of fractures during World War II. This was compounded by interest being drawn to the recent advances in the application of bone plates and screws in the treatment of fractures at that time.

Figure 1.15 Cat with fractured femur treated using external skeletal fixation (ESF)

Figure 1.16 Cat with fractured humerus treated using ESF

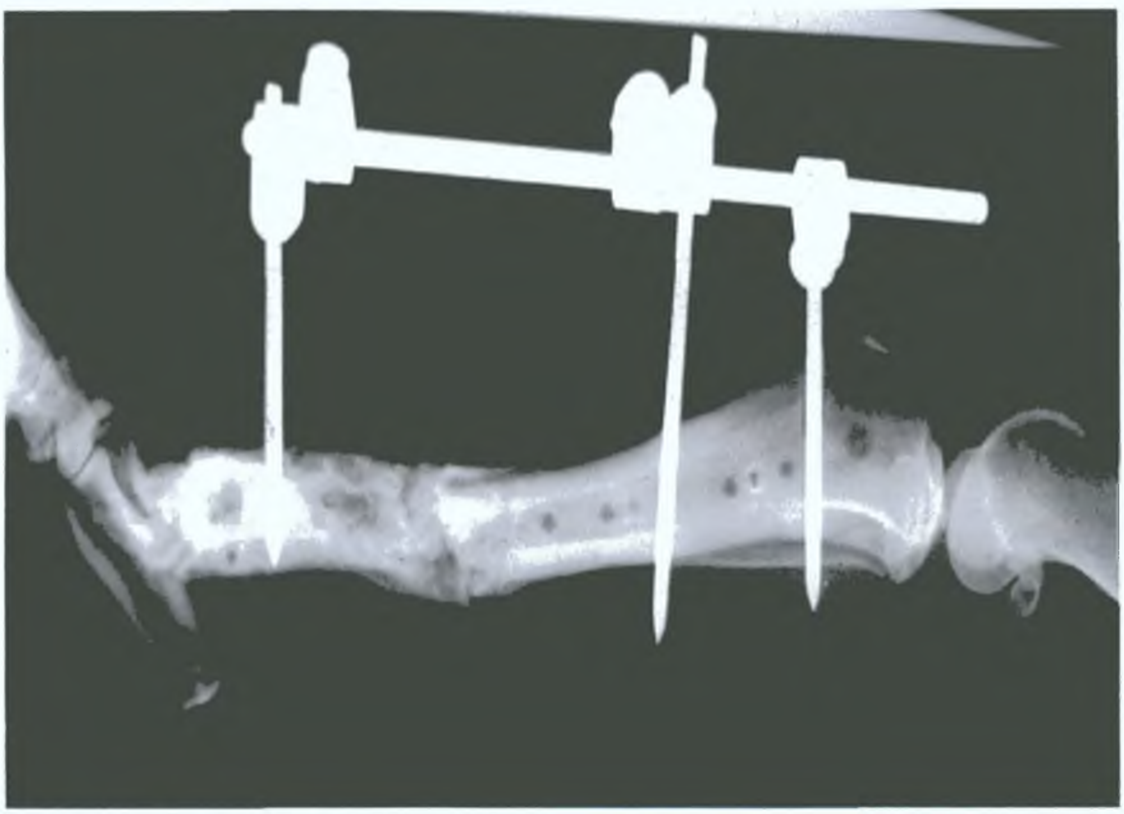


Figure 1.17 Radiograph of a tibia fracture treated using ESF. Note the ESF has been dynamised by removing pins in stages, hence the holes left in the bone

Figure 1.18 Cerclage wire used in conjunction with ESF

Extensive work since has allowed significant improvement in fixator design, in the materials used, the principles and techniques of application and subsequently a large reduction in complications As a result, surgeons have recently become more interested in their use in both human and veterinary orthopaedics Combining the ESF with other techniques such as cerclage wiring (Fig 1 18) also improved the success rate of the ESF,and also a major advantage of the ESF has been the ability to dynamise the fracture by gradually decreasing the stiffness of the ESf by removing pins (Fig 1 17) There are many different ways of using external skeletal fixation and each one has its own mechanical properties which should be chosen in particular for each fracture and when that choice is correct healing can be excellent (Fig 1 19) The ring fixators such as the Ilizarov system are extremely strong and involve circling the whole limb and use tensioned wires (Fig 1 20) They can be as strong as the strongest of the external fixators and are commonly used to correct growth deformities or to correct limb shortening

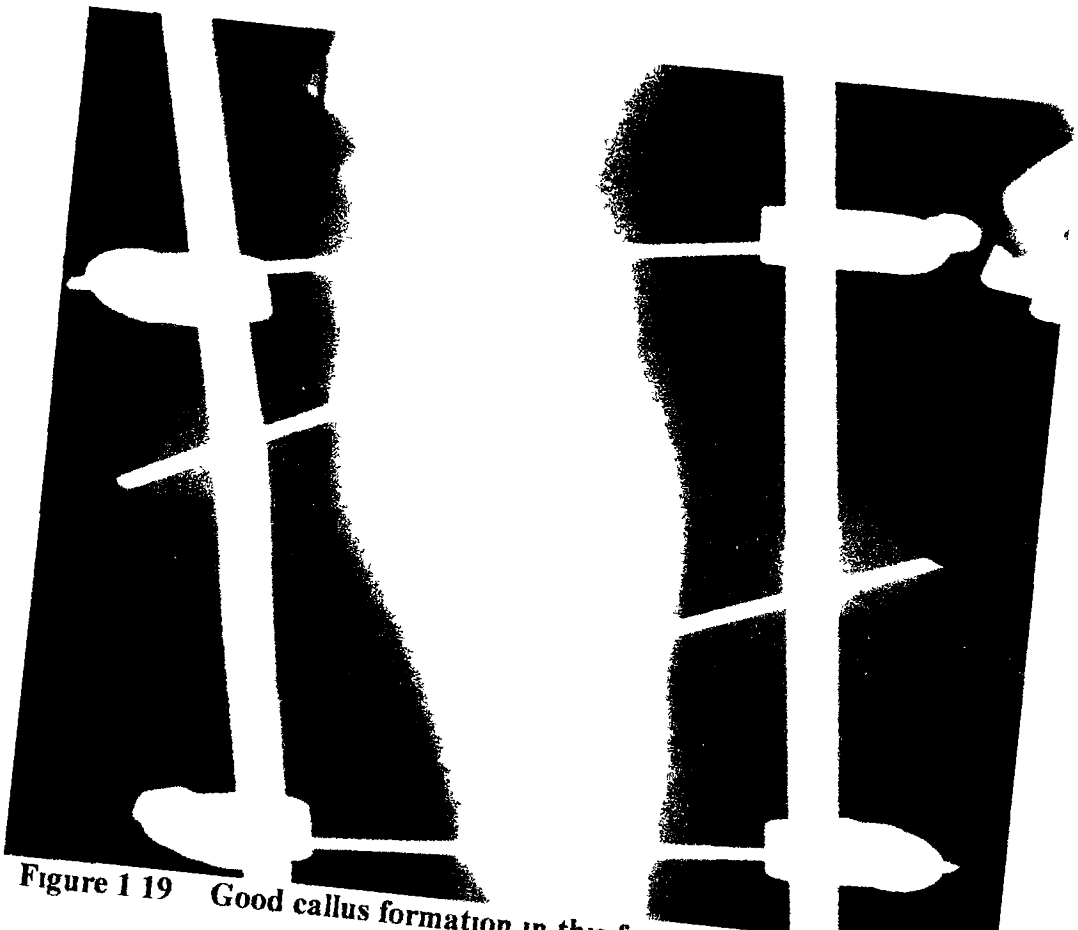


Figure 1 19 Good callus formation in this fracture treated using ESF

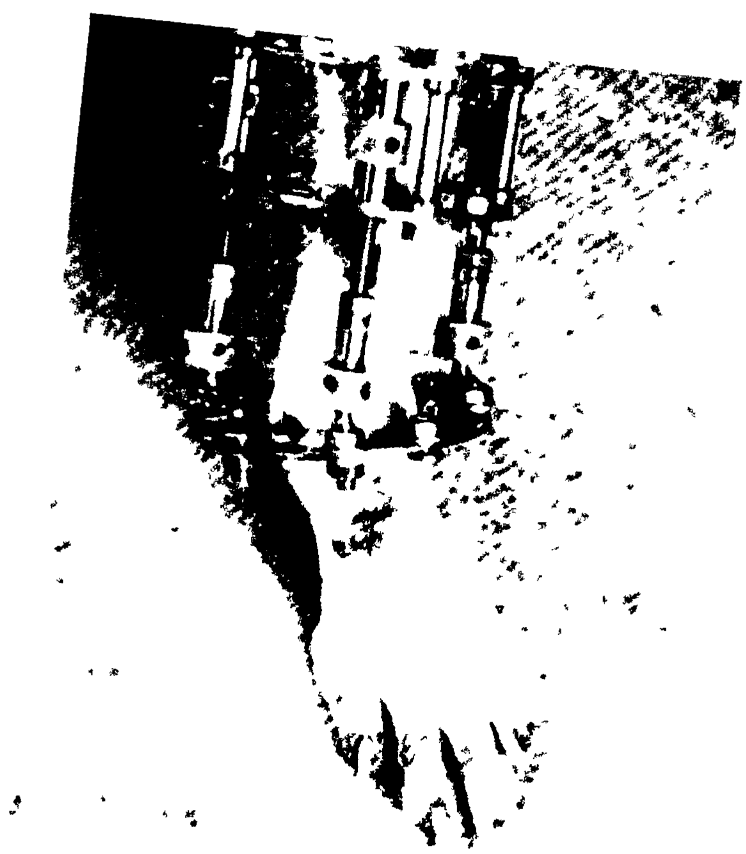


Figure 1 20 A ring fixator used to correct a limb deformity in a dog

1.4 Wire Techniques

Orthopaedic wire is made from monofilament stainless steel and is available in different sizes It is frequently used in combination with intramedullary pins in fracture fixation either to retain fragments in alignment or to provide rotational stability (Fig 1 21) Cerclage wiring would encircle the whole bone and provide compression at the fracture site, whilst other techniques such as hemicerclage wiring are used for holding fragments

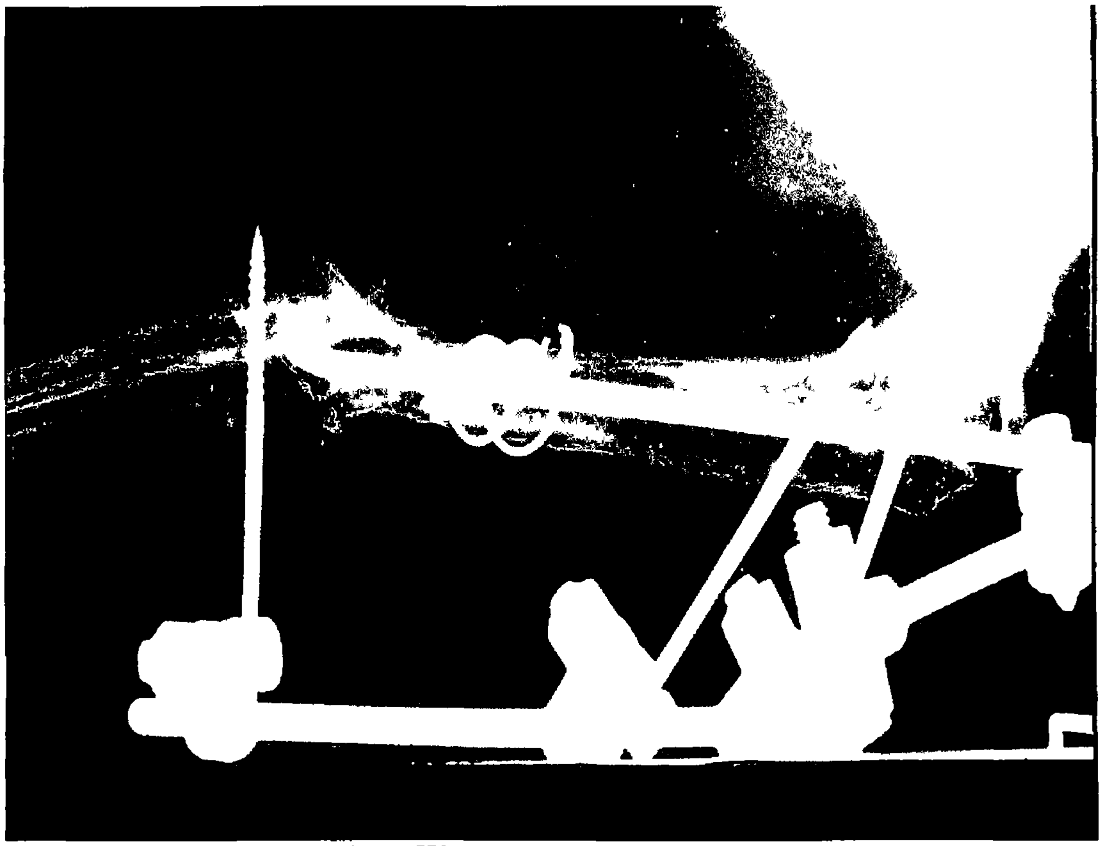


Figure 1 21 Wire used to hold bone fragments

The wire is also used in the tension band effect to repair avulsion fractures (Fig 1 22) Tension band wiring is an important technique in avulsion fractures, such as those of the tibial tuberosity, where the fragments are distracted by the pull of muscle and ligament Tension band acts and counteracts the tensile forces working on the fragments and redirects them to compress the fragments to the adjacent bone

Figure 1.22 A fracture repaired using the tension band wire technique

1.5 Screws and Plates

There are many different types of bone plates, ranging from the DCP plate, round hole plates, lengthening plates, reconstruction plates, T plates, L plates, H plates, cuttable plates, acetabular plates, etc.

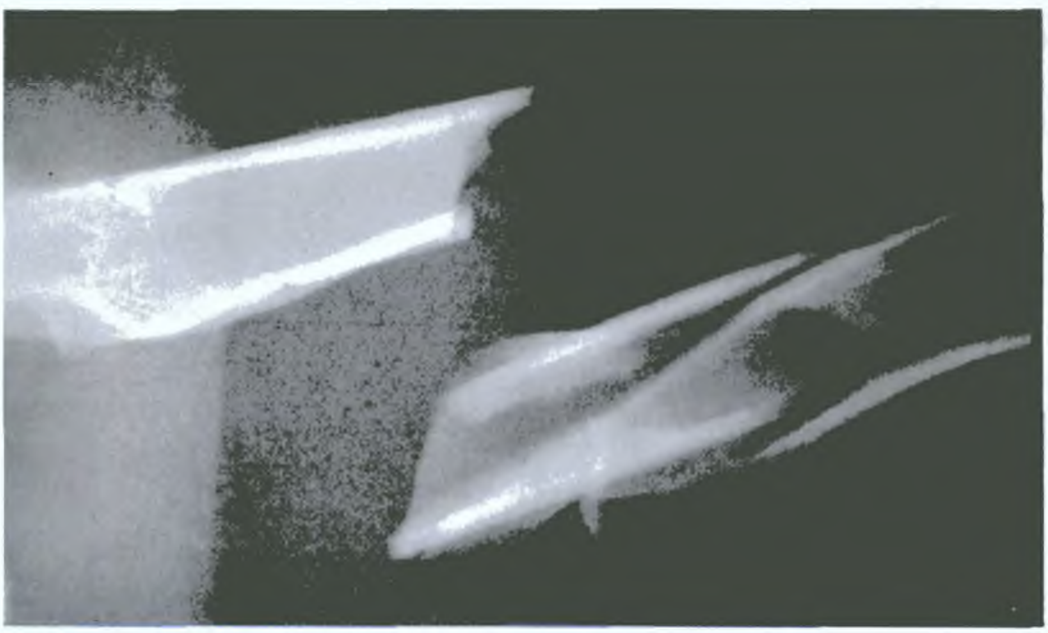


Figure 1.23 An example of a fractured femur in a large dog

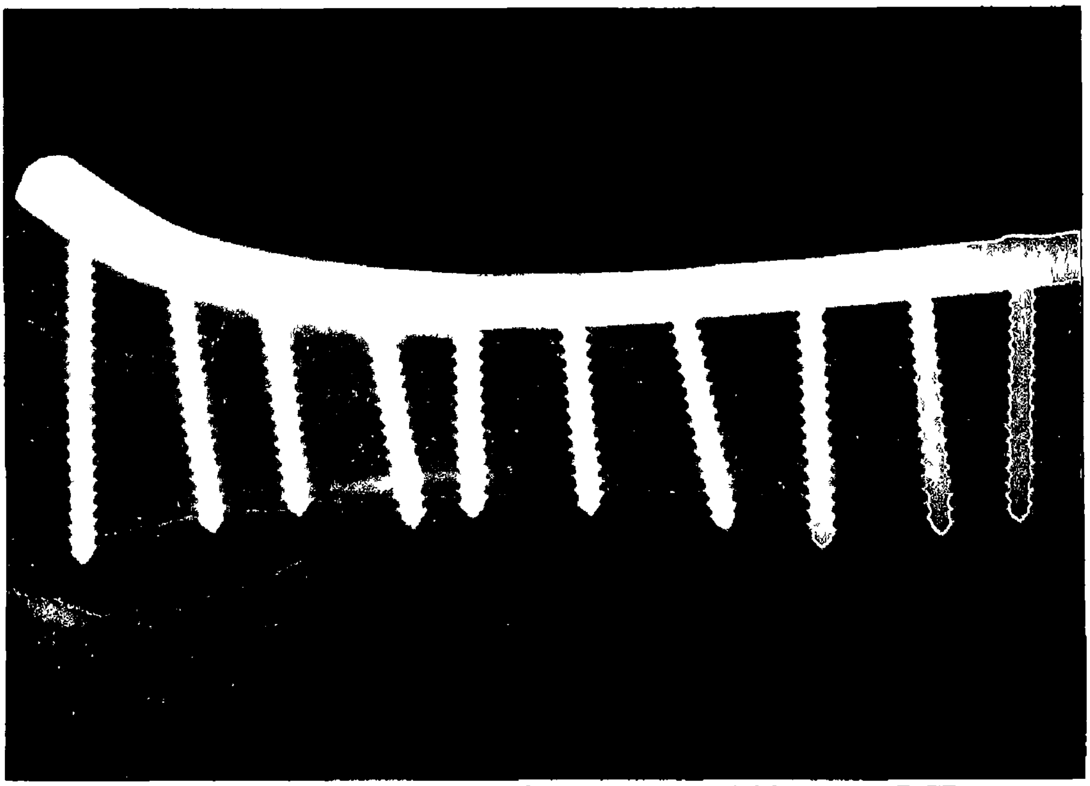


Fıgure 1 24 Repaır of the fracture ın Fıg 1 23 usıng a DCP

The DCP plate or the compressıon plate can be used to create axıal compressıon on short oblıque or transverse fractures A plate ıs always applıed on the tensıon sıde of the bone ın order to achıeve functıonal compressıon (Fıg 1 23 and 1 24)

Fıgure 1.25 Fracture of the dıstal radıus ın a very small dog

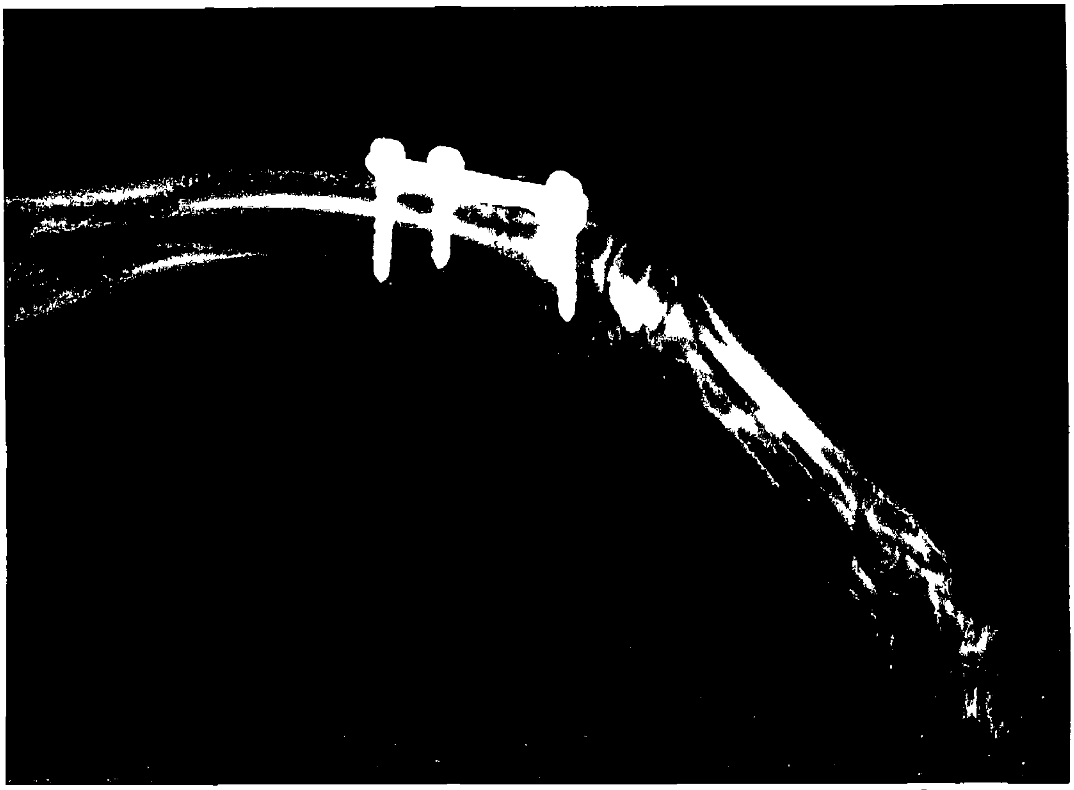


Figure 1 26 Repair of the fracture in Fig 1 25 using a T plate

Each bone has its own tensile side and the tensile side of certain bones has been established as follows (Fig 1 29),

- Cranial aspect of the proximal humerus,(Figs 1 27 and 1 28)
- Caudal aspect of the olecranon
- Lateral aspect of the proximal femur ,(Figs 1 31 and 1 32)
- Cranial medial aspect of the distal tibia

Figure 1 27 Fractured humerus in a 30 Kg dog

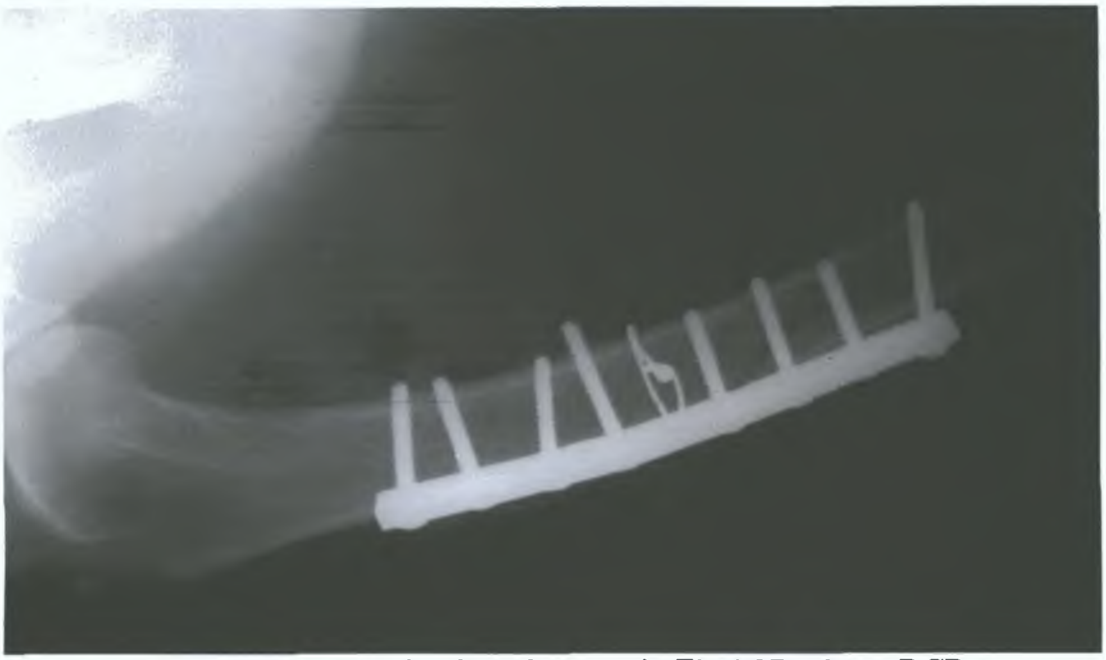


Figure 1.28 Repair of the fracture in Fig 1.27 using a DCP

Other areas that are thought to be the tension side but remain unproven are:

- Caudal aspect of the distal humerus (Fig 1.30).
- Cranial aspect of the radius (Figs 1.25 and 1.26).
- Lateral aspect of the distal femur.
- Cranial aspect of the tibia.

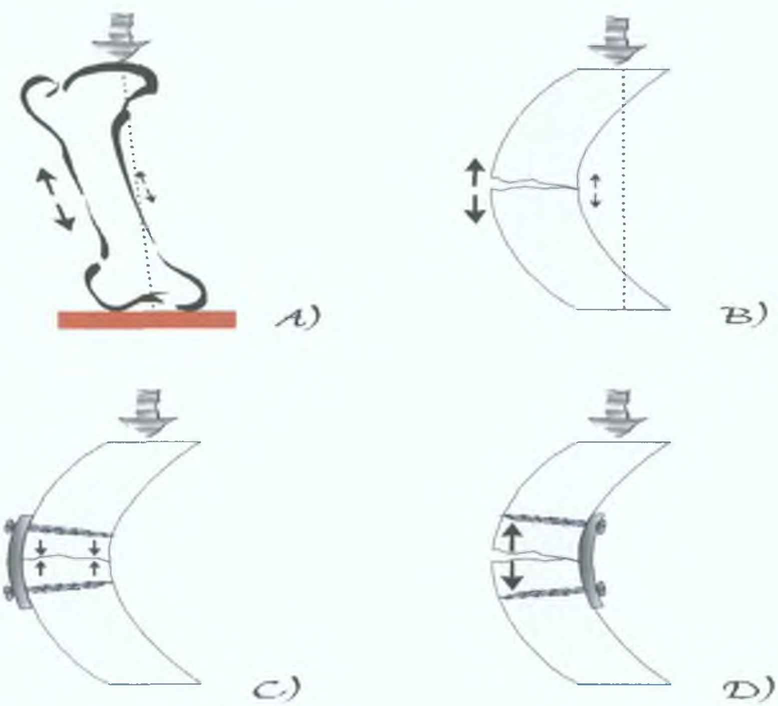


Figure 1.29 Diagramatic representation of the principle of the tension side vs. compressive side of a bone

Figure 1.30 Repair of intraarticular fractures requires compression techniques

Figure 1 31 Fracture of the proximal femur in a 40 kg dog

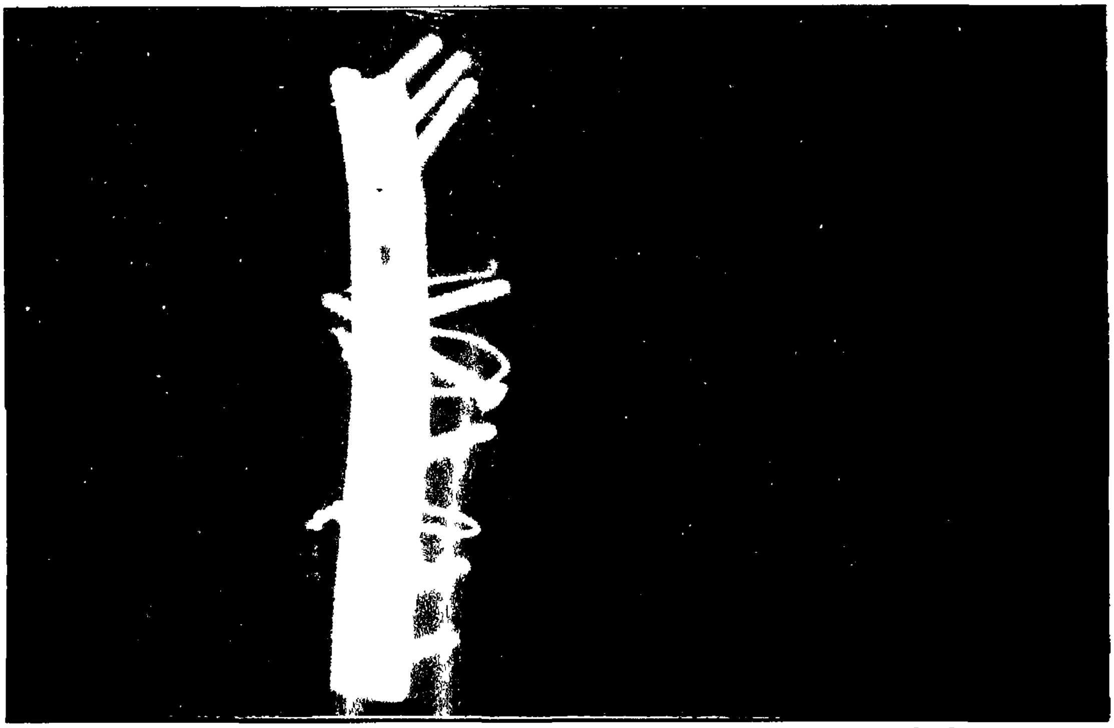


Figure 1.32 A combination of lag screws, cerclage wire and plating

Compression can be achieved using round hole plates on these tension surfaces of bones but there is a need for a special tensioning device that is applied to the end of the plate and essentially is attached to the bone, but its use is awkward and has been superceded by the dynamic compression plate circa 1973, (Figs 1 33 and 1 34)

Figure 1.33 Fractured distal radius / ulna in a racing greyhound

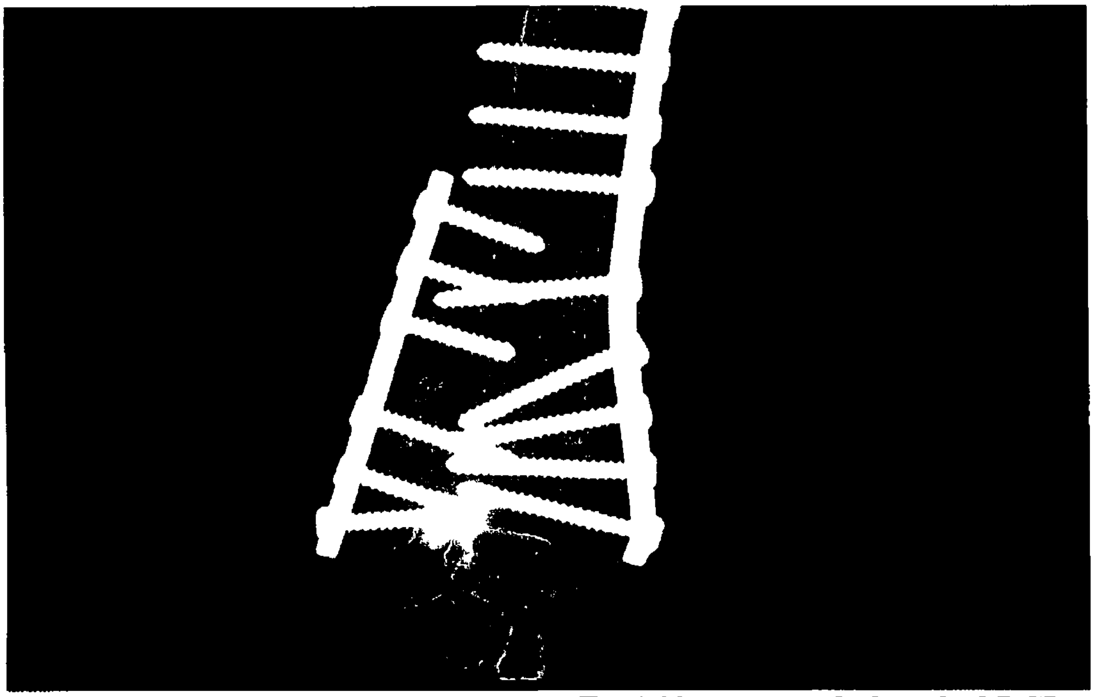


Figure 1 34 Repair of the fracture in Fig 1 30, using medial applied DCP

The design of the DCP plate is such that it has a spherical gliding hole This enables the screw ,which has a spherical head, to have a self compressing effect at the fracture site as the screw is driven into the hole The spherical geometry of the screw hole also ensures that there is a congruent fit between the screw and the plate in any position along the screw hole, by permitting a degree of tilt 25° long and 75° to each side between the screw and the plate (Figs 1 35 and 1 36)

Figure 1 35 Fracture dislocation of the hock in a working sheepdog

The DCP is ideal for treating multiple fractures of long bones, and fragments can be compressed together by the introduction of lag screws in the plate

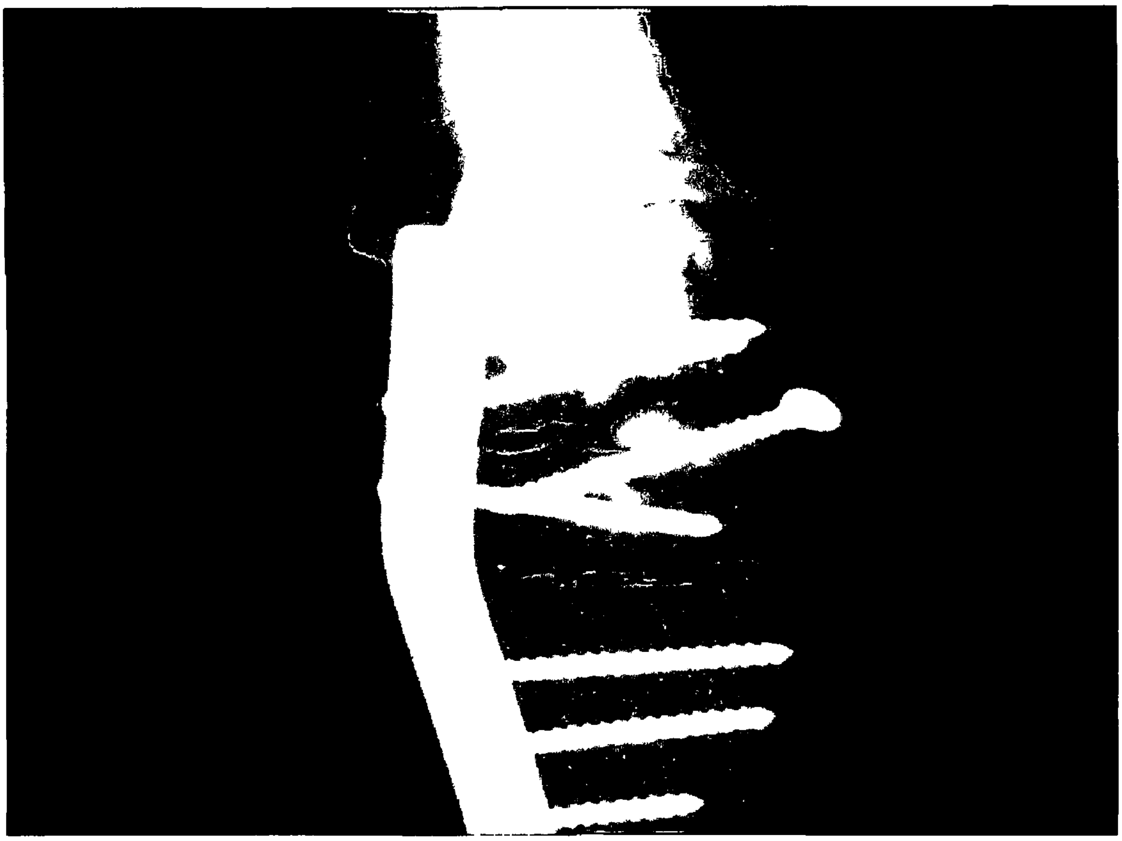


Figure 1 36 Repair of the Fracture in Fig 1 33

The size of a DCP relates to the diameter of the screw which is being used, so a 2 7 DCP is used for a 2 7 cortical screw and a 4 5 DCP takes a 4 5 screw The greatest fracture gap that can be closed with screws using a DCP (Fig 1 37) is as follows

- 2 7DCP will close a gap of 3 2 mm,
- 3 5 DCP will close a gap of 4 mm,
- 4 5 DCP will close a gap of 4mm
- 2 mm DCP can be used where a 1 5 or 2 5 screw is also available

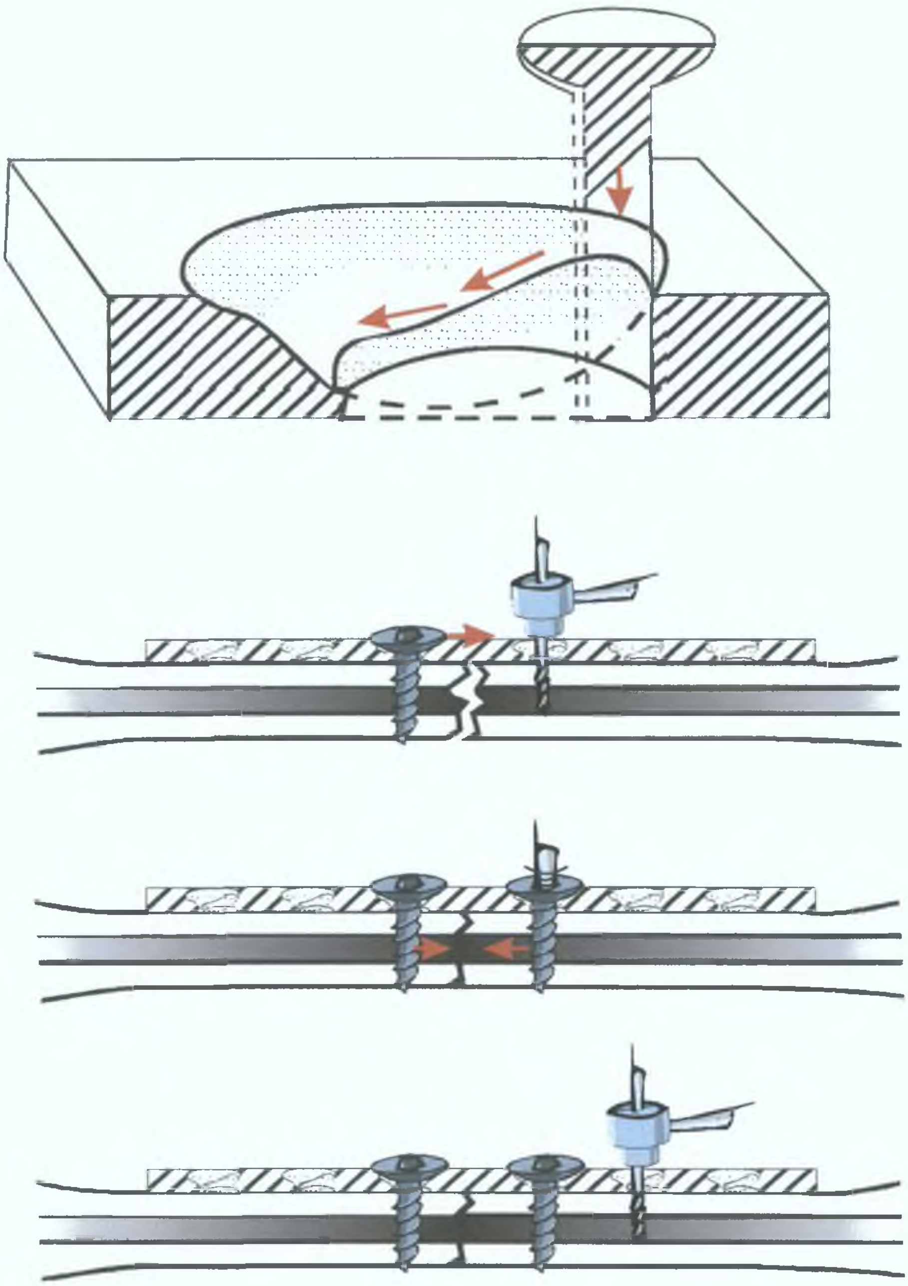


Figure 1.37 Diagram showing the spherical gliding hold providing compression at fracture site as used in applying a DCP

1.6 Specialised Plates

Specific fractures and site of fracture can be treated with specific plates designed solely for that site or purpose.These are commonly found in human orthopaedics and are expensive high technology implant systems in their own right(Figs 1.38 and 1.39)

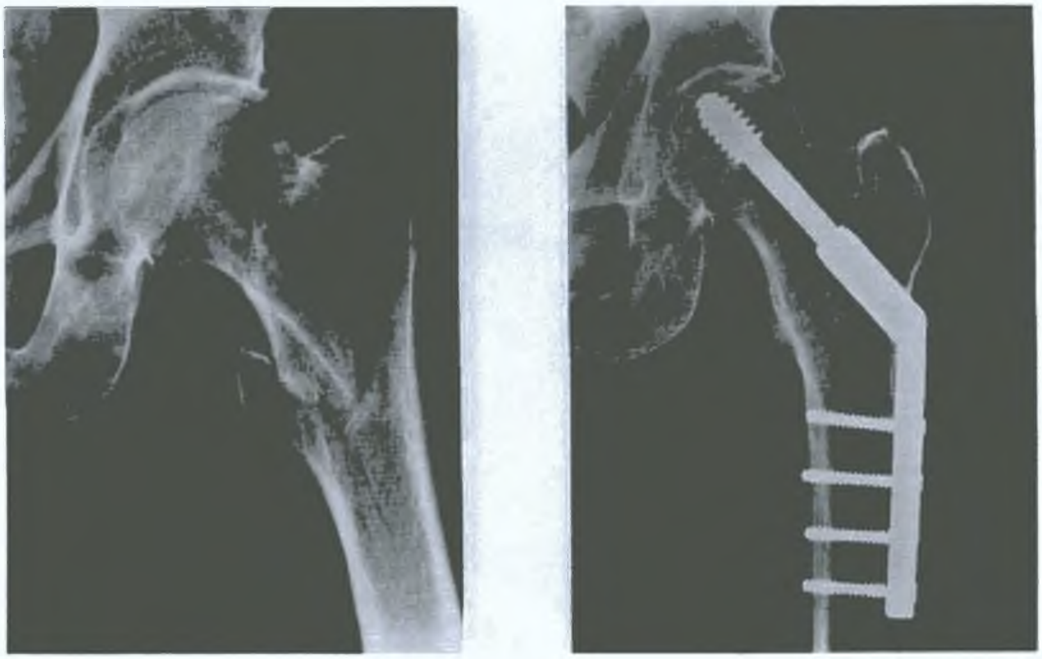


Figure 1.38 An example of repair of a fracture proximal femur with a dynamic hip screw system (courtesy of S padley)

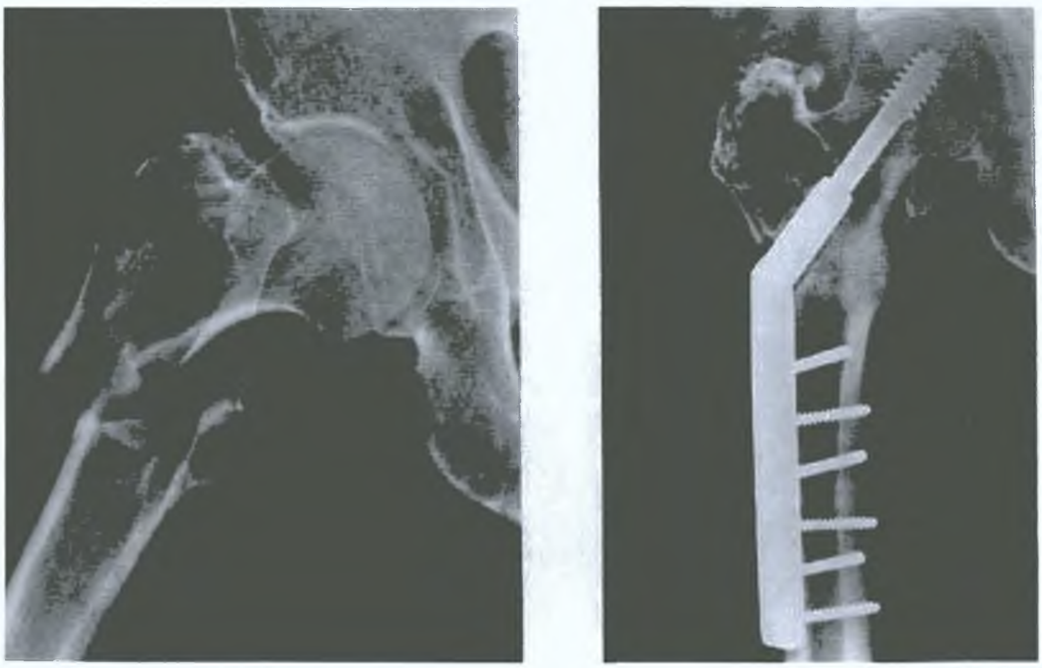


Figure 1.39 Fracture of the proximal human femur repaired with a dynamic conylar screw (courtesy of S Padley)

1.7 <u>Screws and Pins</u>

The combination of screws and pins has been possible for a long time and its principle is older still.However general acceptance of its merits remains virtually unchanged in that surgeons decline to try out any methods of use due to lack of faith in the principle and the technique largely because there is no significant laboratory data to support its widespread use The fixclip has been marketed by way of peer driven clinical experience mainly by one surgeon but remains on the fringes of orthopaedic surgery

1 8 Stress Concentration

An orthopaedic plate has a non-uniform stress distribution due to the frequent round or spherical holes for the screws that are found along its length The holes represent a geometrical discontinuity in the plate, and the average stress will be higher at the vicinity of the discontinuity or stress raiser Stress concentration at the edges of the hole is high and decreases with distance from the hole However, the distances between holes are small because the maximum number of holes possible is usually created to allow as many screws as possible to be inserted into the bone An example of the clinical consequences of stress concentration is depicted in Figure 1 40-1 42 were one screw hole has been left unfilled as it is located directly over the fracture site

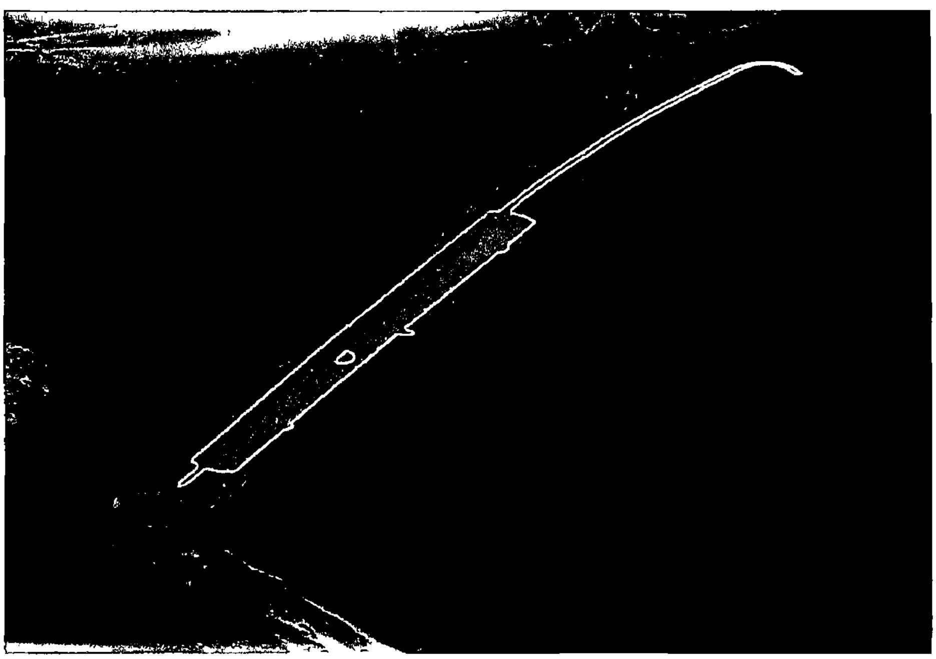


Figure 1 40 X-ray of tibia showing empty screw hole over fracture site

This stress raiser leads to implant fatigue fracture A further consequence of stress concentration is that when a plate is removed the holes in the bones may take up to a year to fill in and represent a stress raiser during their lifetime, and hence may lead to a refracture at the old screw hole

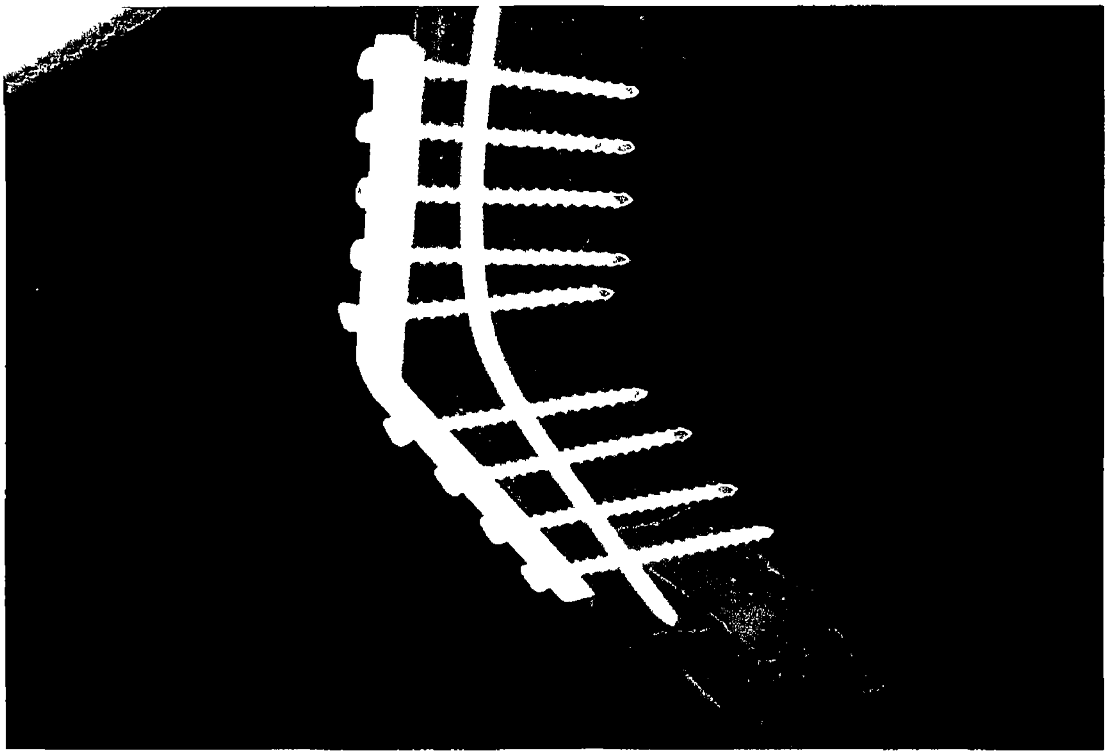


Figure 1 41 Bending of the plate at screw hole

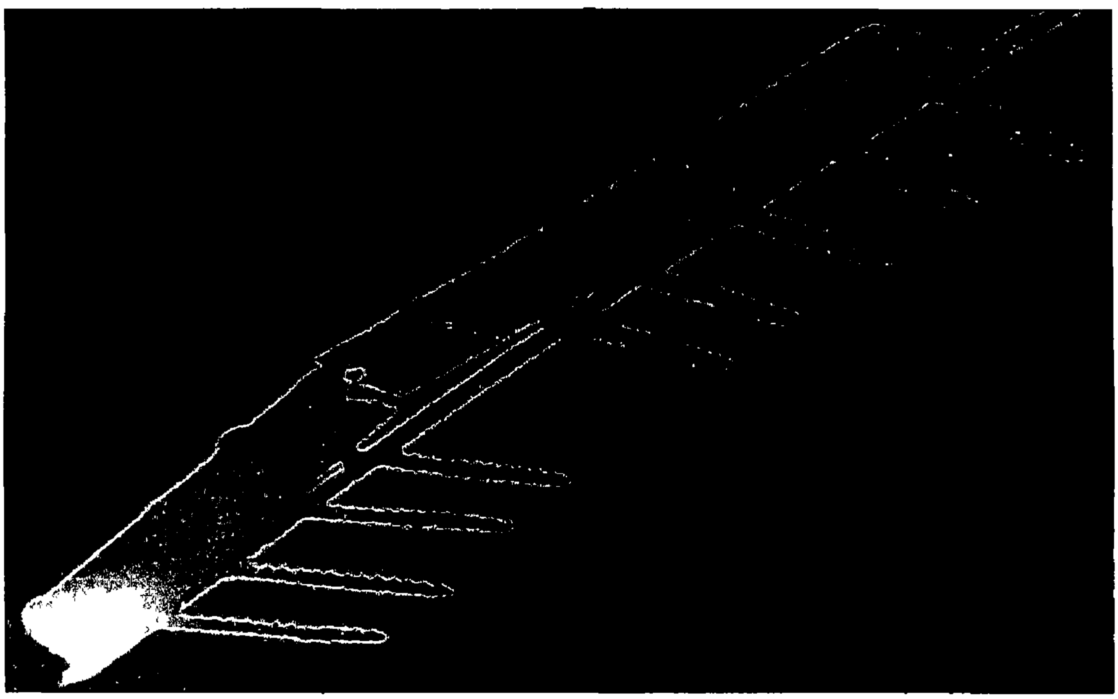


Figure 1.42 Eventual fracture of the plate over the screw hole with the fracture not yet healed

1 9 Stress Shielding

When a bone is protected from normal loading by an implant, the remodeling associated with the loading process leads to a weaker bone due to the lower stress that it experiences as a result of the stress shielding and damage to the vasculature (Fig 1 43) The end result is a more porous bone with fewer osteocyte filled lacunae An example of stress shielding is shown in Figure 1 44, where the central area of the plated radius/ulna is darker (osteopaenic) then the ends, indicating decreased tissue density and hence increased bone porosity

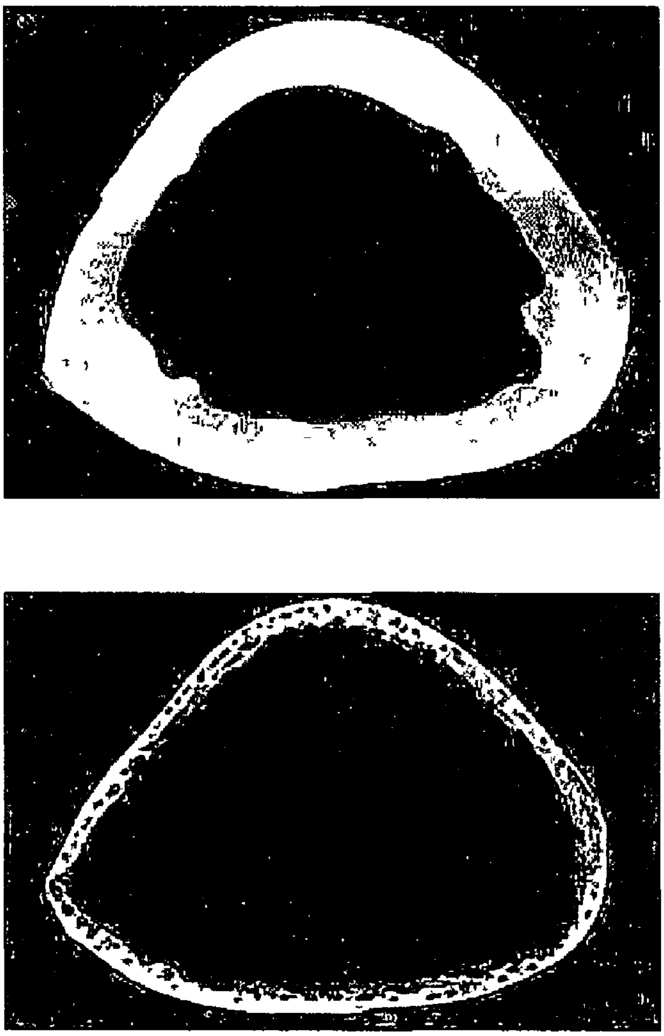


Figure 1.43 Lanyon , Rubin and Baust (156) showed that if a bone is not loaded there is significant bone loss compared to normal in an avian ulna

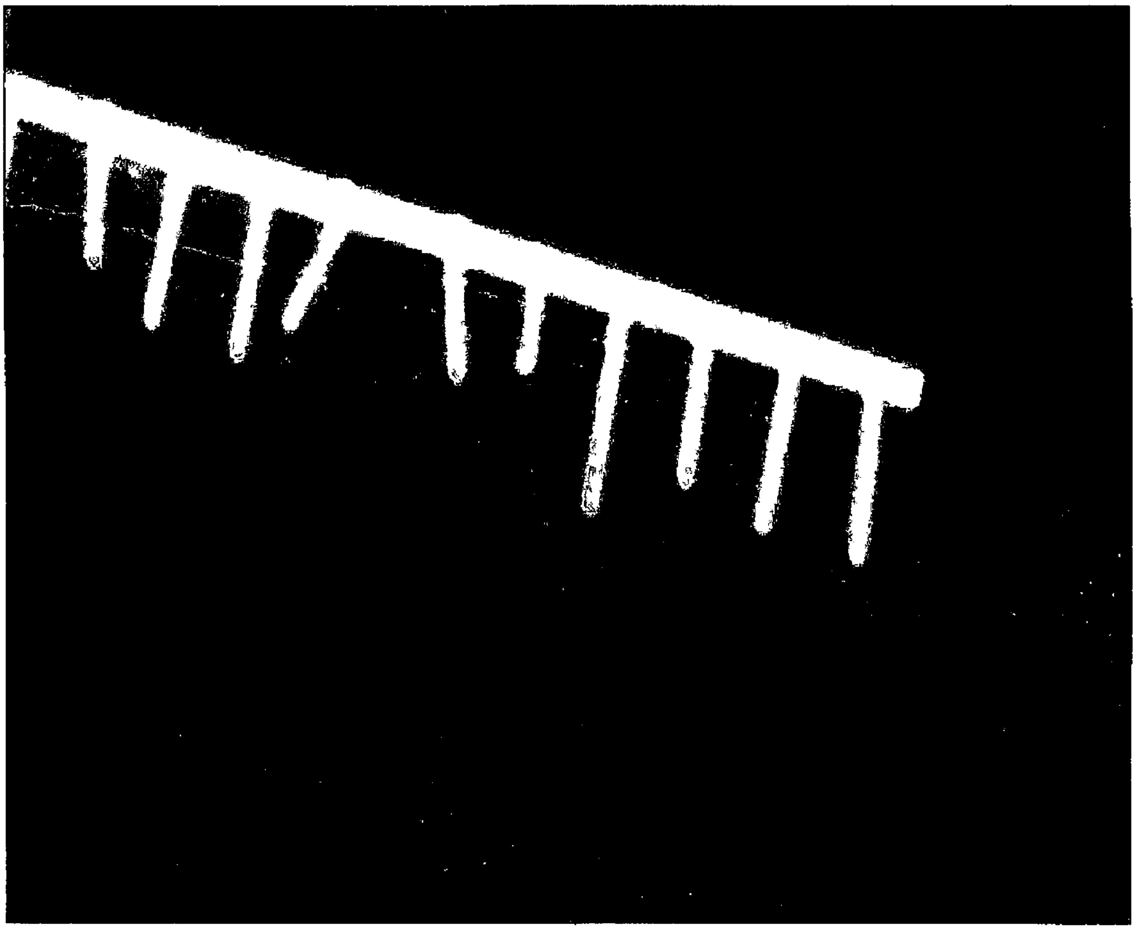


Figure 1.44 Rarefraction of bone under the plate due to stress protection(compare whteness of bone at middle and at ends)

1.10 Blood Supply to Bone

It is important to fully appreciate the relevance of osseous vasculature as it plays a vital role in healing and also in the interaction with implants (Fig 1 45) The normal make up and flow patterns are depicted in Fig 1 46, and it worth noting that the blood by and large flows centrifugally Changes in the osseous vasculature are due to the screw insertion, alteration to vascular drainage, rigidity of the plate and the amount of surface contact between the bone and the plate

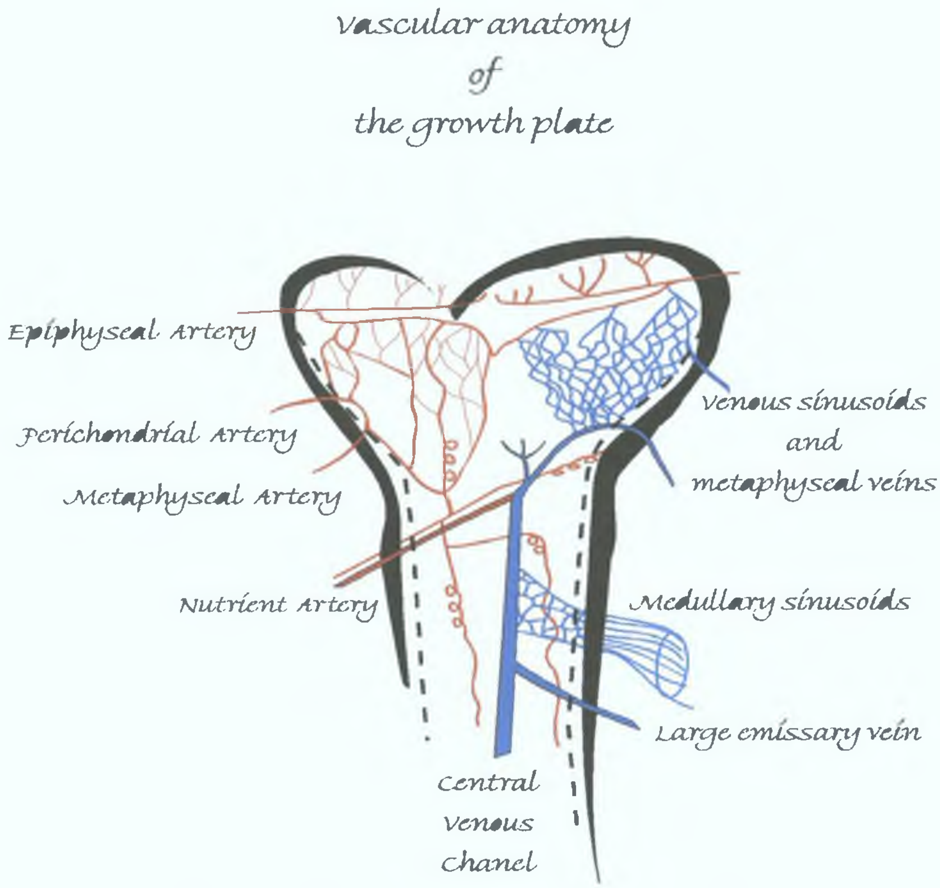


Figure 1.45 Blood supply to a typical bone

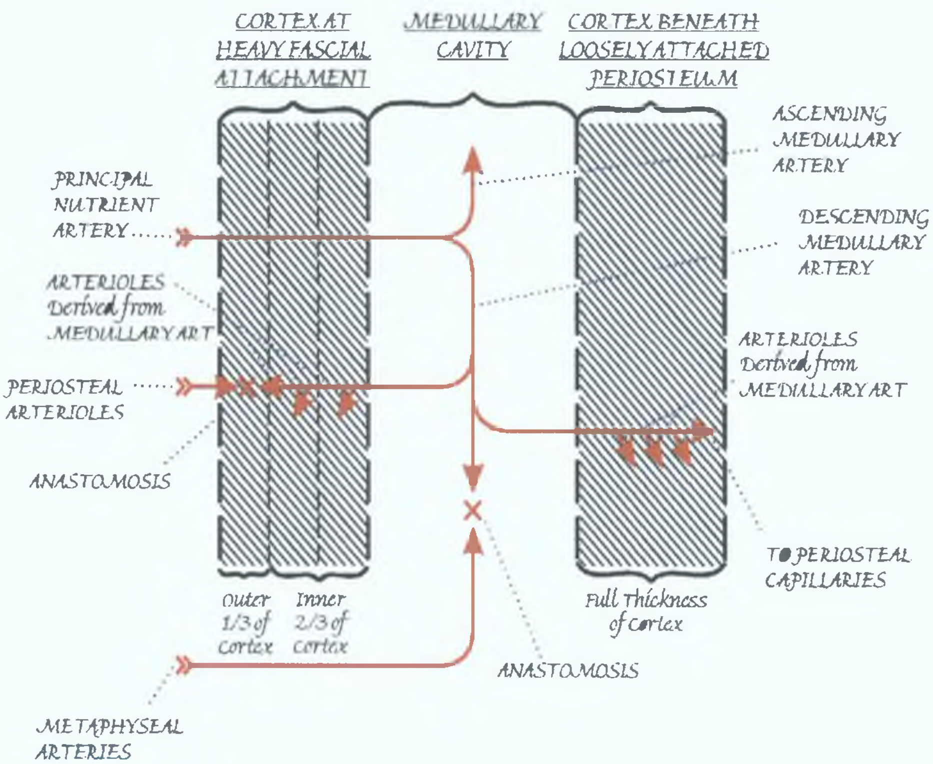


Figure 1.46 Close up view of blood supply to a typical bone

1 11 Material Properties of Bone

Bone is composed of two different forms of structural organisation Firstly, there is cortical compact bone in the mid part of the bone, otherwise called the diaphysis, cortical bone also forms a thin shell around the bone ends Secondly on the articular ends of the long bone, cancellous or trabecular bone is in the metaphysis or epiphysis and is continuous at the inner surface of the cortical shell Cancellous bone is a three dimensional network of bony plates and columns that divide the interior volume of bone into interconnecting pores of different dimensions, producing a structure of varying porosity and density The classification of bone tissue as cortical or cancellous is based on the degree of bone porosity and density, with cortical bone being the type that is not porous, but dense The behaviour of cortical bone under loading is different to cancellous bone and also to the type of load(Fig 1 47)

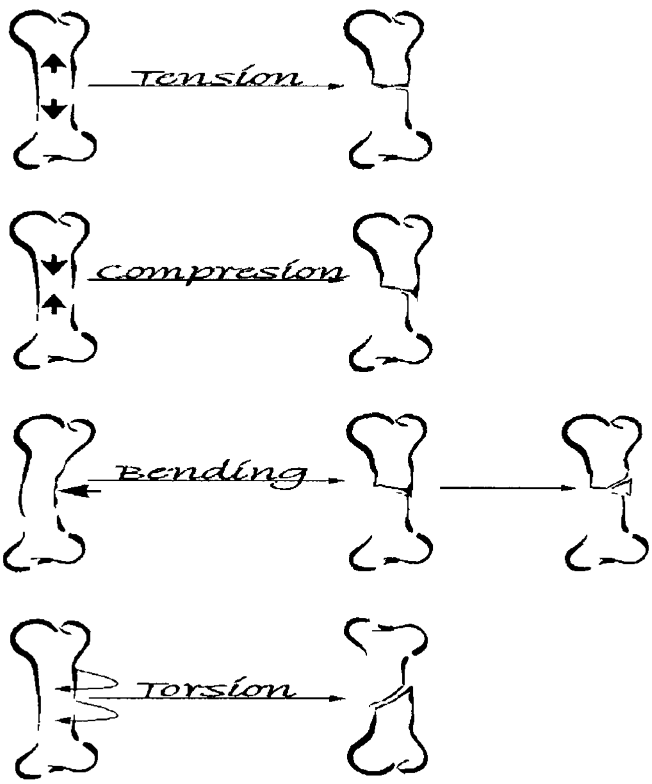


Figure 1.47 Mode of failure of a typical long bone under different types of loading

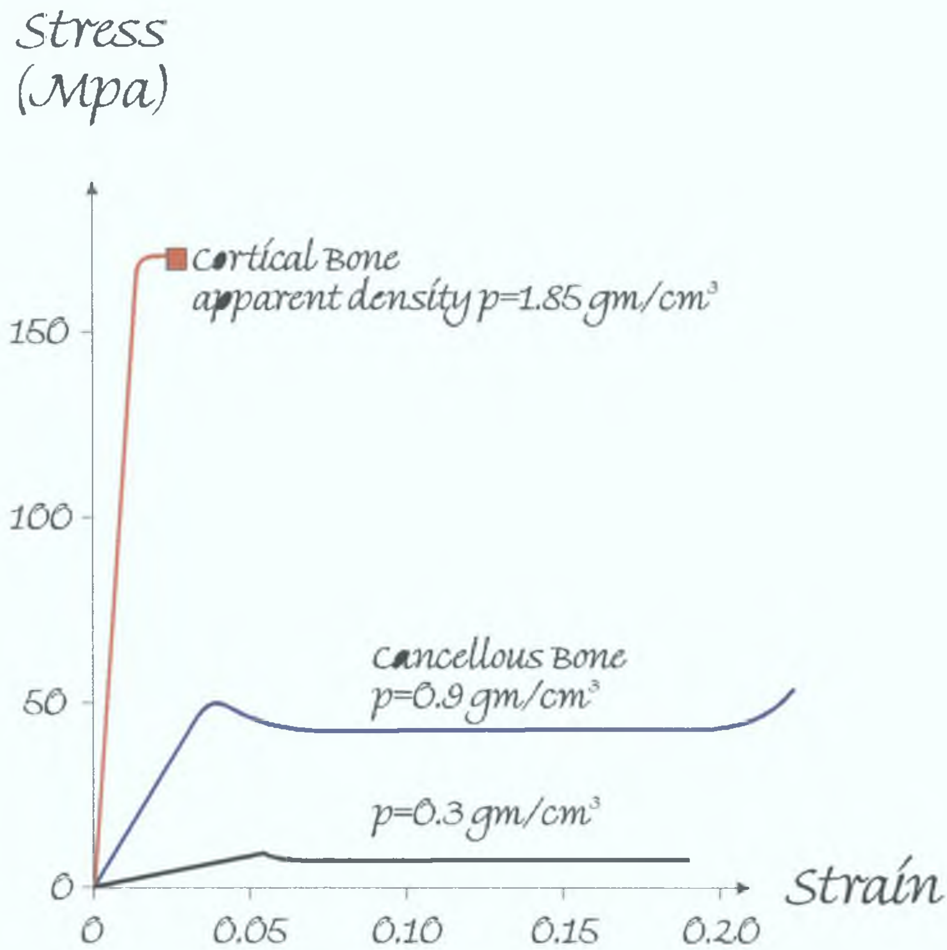


Figure 1.48 The Different stress strain characteristics between cortical bone and two types of cancellous bone with different densities

Cortical bone has a porosity of approximately 5-30%, while cancellous bone may range from approximately 30% to more than 90% (Fig 1.48). The distinction, however, between very porous cortical bone and very dense cancellous bone is somewhat arbitrary. Cortical bone shows a significantly different mechanical behaviour to cancellous bone. The material properties of cortical bone are dependant upon the rate at which the bone is loaded or deformed. A piece of cortical bone which is rapidly subjected to forces will have greater strength than the same piece of tissue that is loaded more slowly (Fig 1.49).

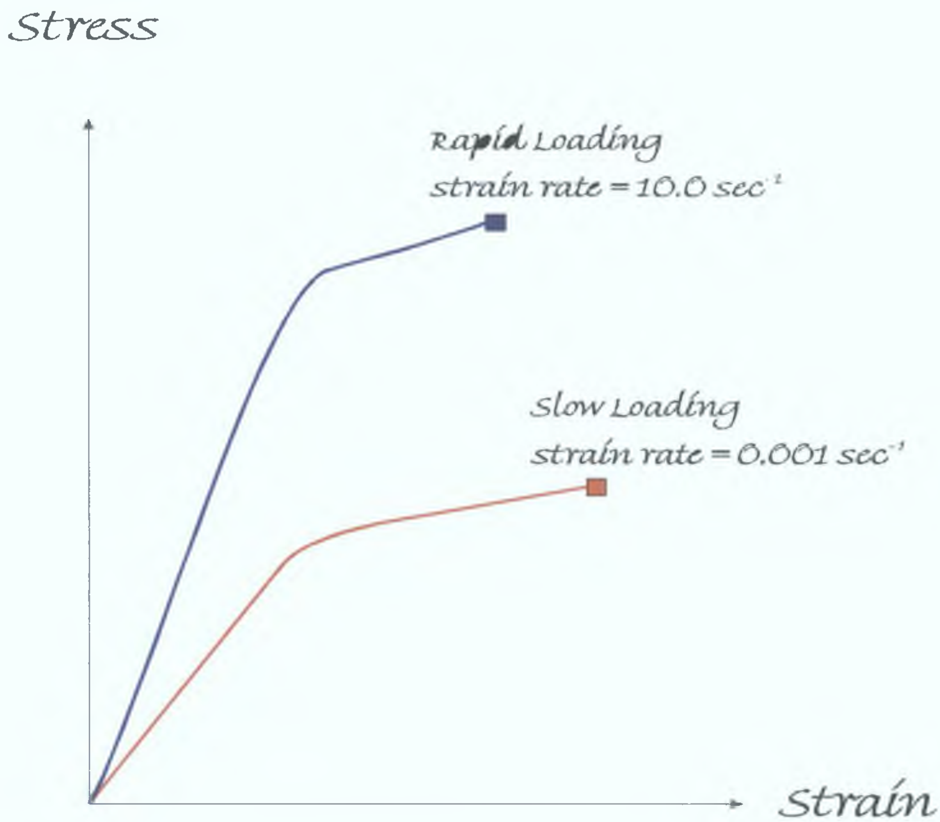


Figure 1.49 Graph showing the difference between loading bone rapidly versus slowly

The absorption of energy is also dependent on the rate at which the bone is loaded, and cortical bone that is loaded very rapidly will absorb more energy than if it is loaded slowly. Materials such as this bone where stress / strain characteristics are dependent on the applied strain are called viscoelastic materials. Bone tissue is also dependent on the orientation of the bone microstructure with respect to the direction of the loading. Cortical bone is stronger and stiffer in the direction of osteon orientation. Therefore, cortical bone is able to resist stress more along the axis of the bone than across the axis. Materials of this type, where the properties depend on the direction of the applied load, are called anisotropic materials. Therefore, the viscoelastic and ansiotropic nature of cortical bone means that the strain rate and the direction of applied load must be specified when discussing bone material behaviour (Fig 1.50).

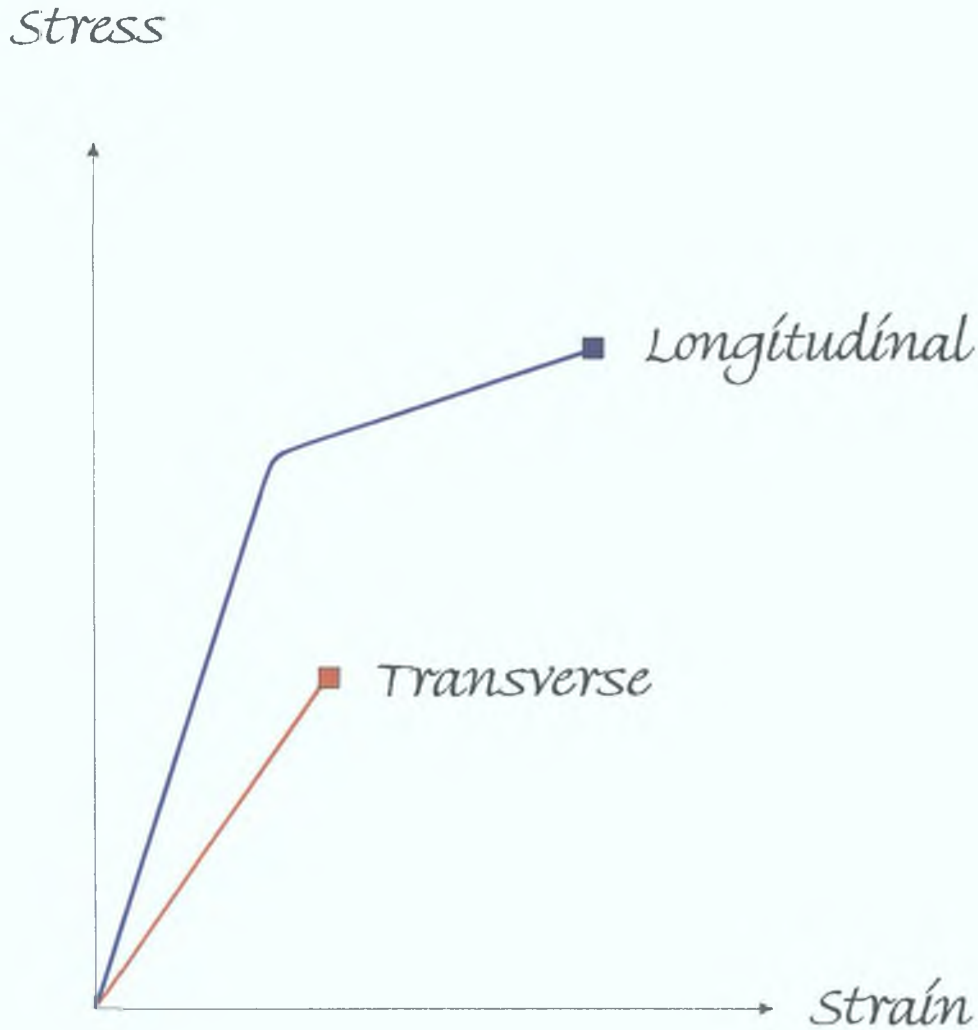


Figure 1.50 The different stress strain curves for bone loaded with or against the molecular fibre orientation

The stress / strain characteristics of cancellous bone, on the other hand, are remarkably different from those of cortical bone and are somewhat similar to the behaviour of many porous engineering materials which are used primarily to absorb energy. The stress / strain curve of cancellous bone exhibits an initial elastic behaviour, followed by a yield which occurs as the trabeculae fracture and trails of in a long decline. In tensile loading, cancellous bone will be equivalent or less than cortical bone, whereas in compressive mode, the cancellous bone will be equal, if not more, than that of cortical bone. Its ability to absorb energy during compression is much greater even though it is has a lower density than the cortical bone (Fig 1.51).

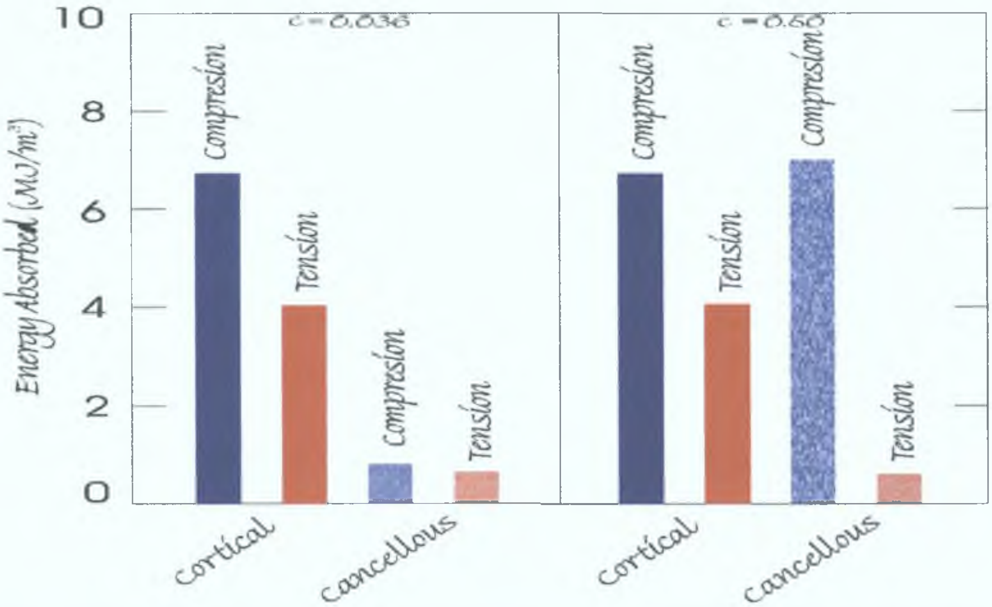


Figure 1.51 Tabulated depiction of how the energy absorption capacity of cancellous bone can be more than cortical bone in compressive loading

Bone is approximately 10% as strong as steel and is composed largely of organised collagen fibres in a hydroxyappatite mineral matrix. Tensile strength comes largely from the somewhat weaker collagen fibres and its compressive strength largely from its appatite structure. Bone is biomechanically very brittle like glass which will break with only 2% elongation. Bone is strongest in compression, with fractures due to compression only quite rare except in cases where there is only a thin cortical shell such as the vertebrae or metaphysis of bone. From the point of view of laboratory testing the state of the bone at the time of testing must be considered (Fig 1.52)

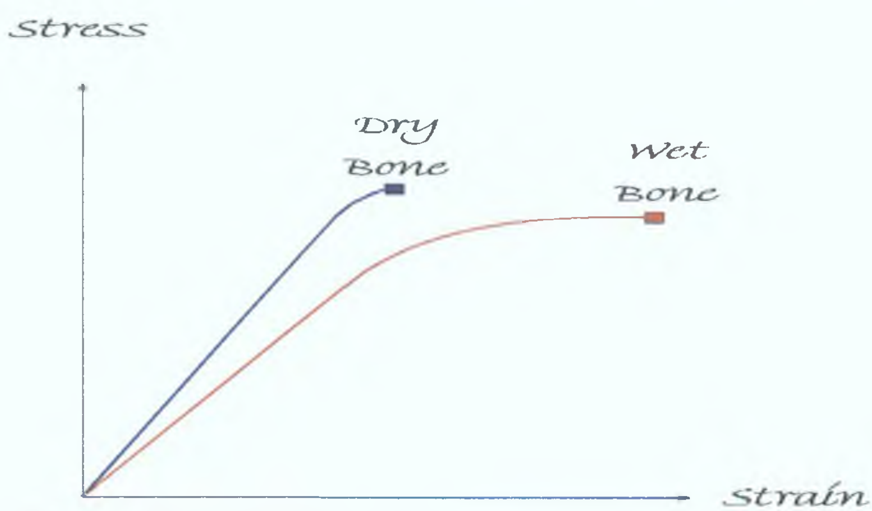


Figure 1.52 The effect of allowing bone to dry before testing

1.12 Bone Healing

Bone heals naturally by spontaneous callus formation. The bone basically goes through a series of steps from granulation to fibrocartilage callus to cortical bone (Fig 1.53). The greater the instability at the fracture site, the greater the amount of callus that is produced as healing occurs which has greater resistance to bending (Fig 1.54).

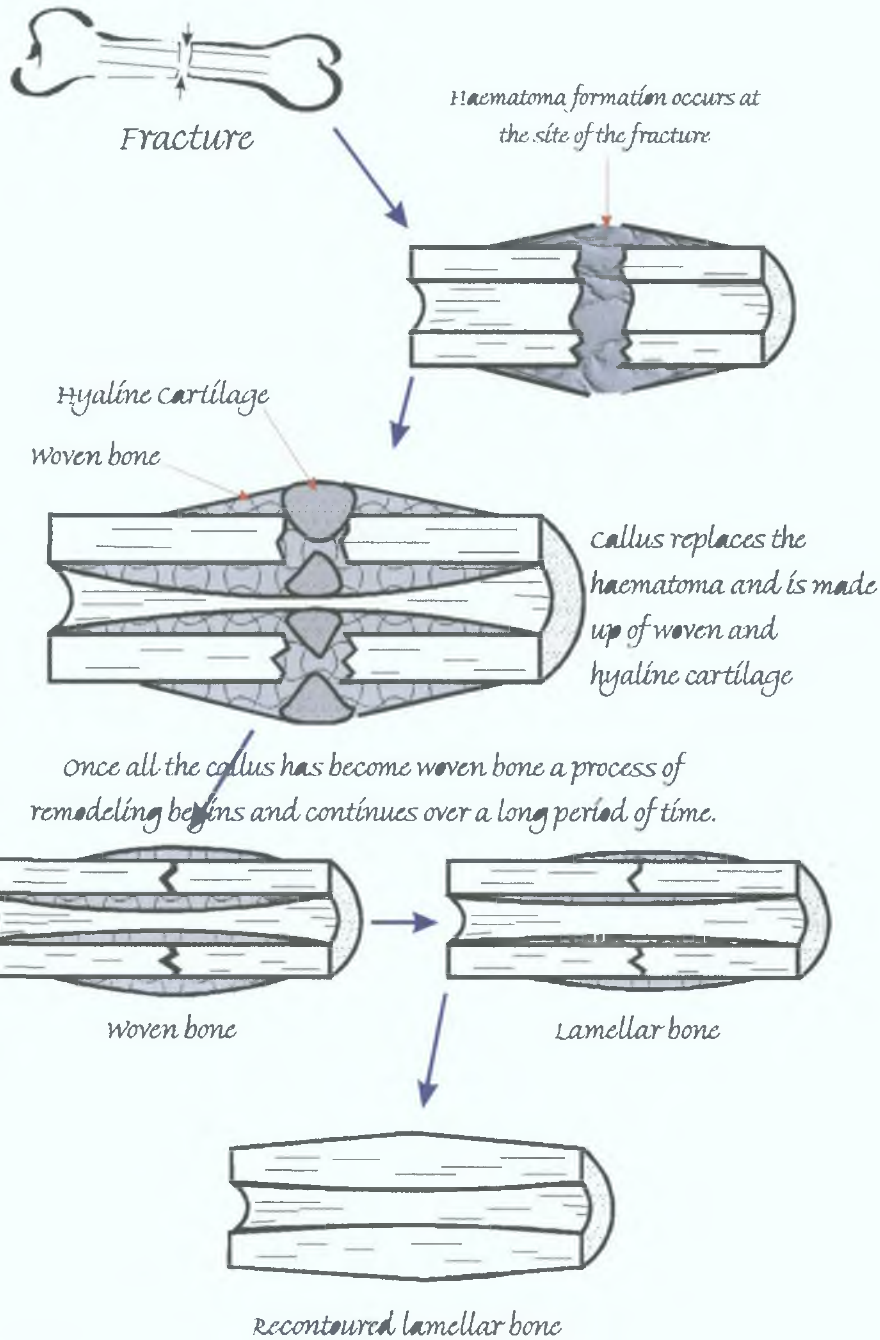


Figure 1.53 Bone healing by callus formation otherwise known as secondary bone healing

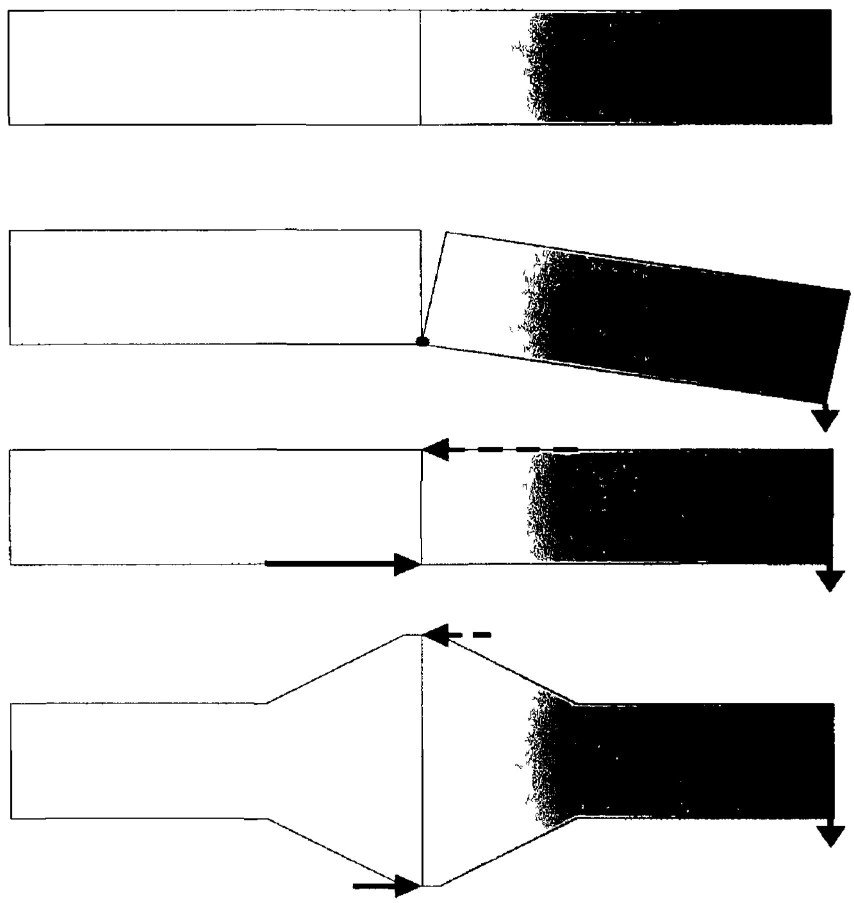


Figure 1 54 Schematic representation of the benefit of a callus to resistance to bending forces

Direct or primary healing relies on the stability provided by interfragmentary compression (Fig 1 55) When a fracture heals under these circumstances, there is no callus Although primary bone is desirable, it does come at a cost, the cost being massive surgical intervention There has been a tendency to move away from large surgical interventions towards biological fixation of fractures with bridging osteosynthesis, where there is preservation of the soft tissue enveloping the area surrounding the fracture site which minimises the insult to the vascularity of the area This type of technique is particularly suited to comminuted fractures

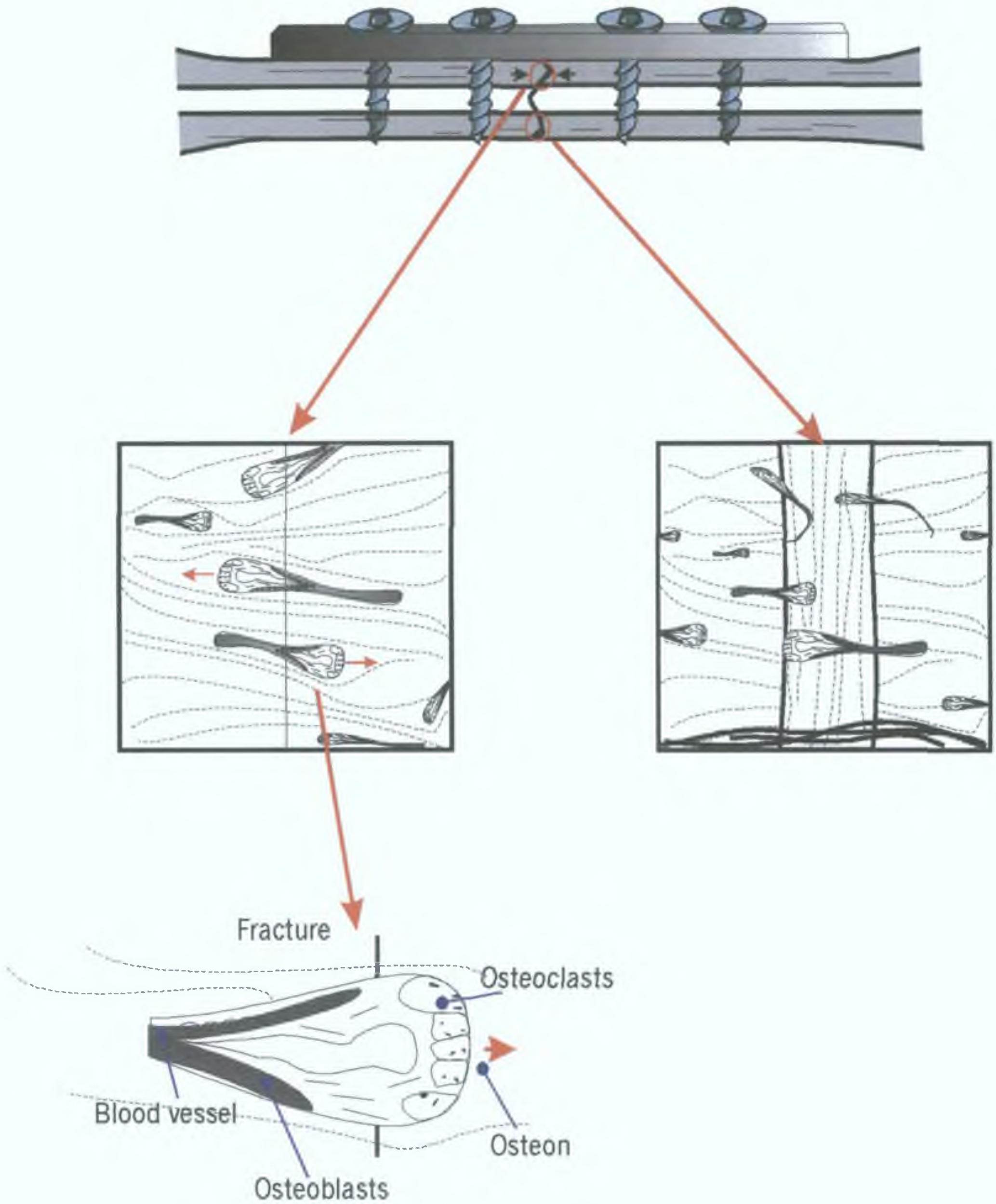


Figure 1.55 Schematic representation of primary bone healing

Early callus formation is encouraged by surgeons to reduce the incidence of implant failure that might otherwise occur with early weight bearing. In bridging osteosynthesis, no attempt is made to realign or mobilise any fracture fragments, leaving the tenuous soft tissue attachment undisturbed.

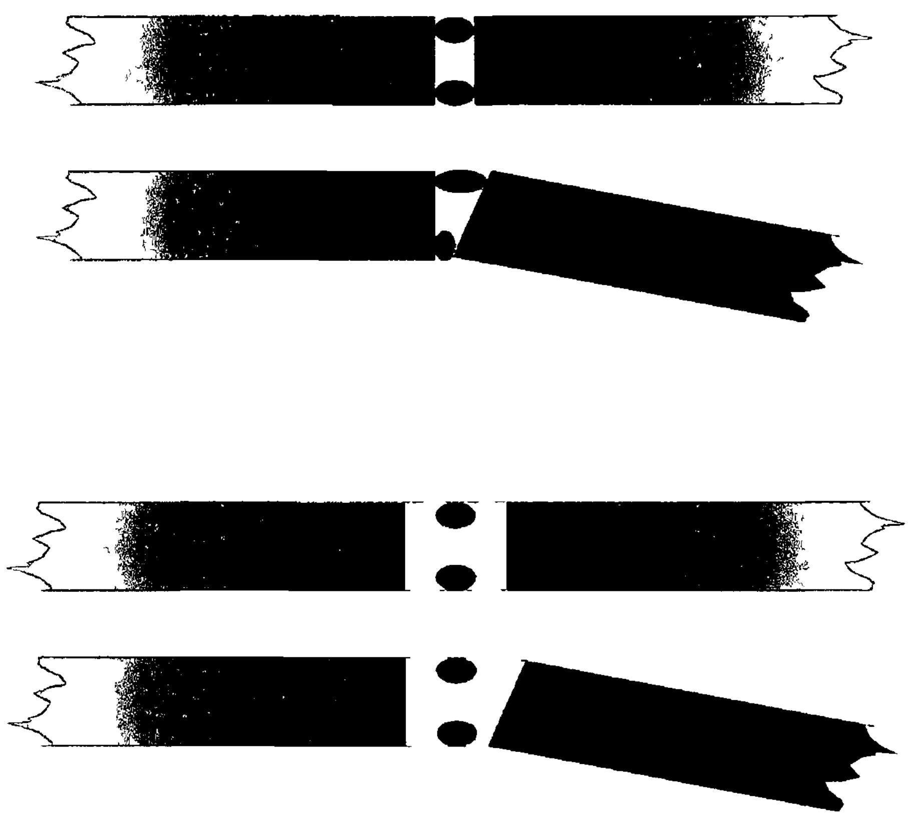


Figure 1 56 Diagramatic depiction of the influence of strain at a cellular level in bone healing

This can be achieved in a number of ways, a conventional plate can bridge a complex fracture site with three or four screws proximal and distally, or alternatively, splinting can be achieved with a plate rod fixation, interlocking nail, or the application of an external fixator Clearly, once the fracture is virtually healed, the strains the bone experiences (Fig 1 55) in conjunction with the implant must exceed the remodelling threshold, but must also keep well below the micro damage threshold The design of the implant should keep the strains of the supporting bone from approaching or falling below the remodelling threshold Trying to find a design of implant that would fit neatly within this range of strains is a challenge given that nobody currently knows exactly what these strain levels are, but also given that there is a lot of variability within different sizes, shapes and conditions of bone itself in many different individuals and animals

The use of internal fixation devices induce profound changes in bones, causing vascular and structural changes and the subsequent development of cortical osteopaenia with the application of bone plates This phenomenon is biphasic with initial osteonecrosis as a result of cortical vascular insufficiency at 8-12 weeks, followed by osteopaenia at 24-36 weeks which is biomechanical and in response to the change in the mechanical environment within the bone, i e stress redistribution The pathological changes are related to surgical trauma, screw placement, rigidity of the fixation device, vascular insufficiency, and the bone plate interface contact area and pressure distribution

To try and overcome these problems, there have been new concepts in plate design If two materials with different elastic moduli are combined into one component, then you will get stress protection and stress redistribution This has occurred in the case of fracture fixation metallic implants that are currently available, leading to cortical osteopaenia and refracture following plate removal It is not just simply the bone plate design which is a factor, the bone surface topography variability, the level of screw torque and the number of screws are all important in determining the vascular interference in the bone plate contact areas

1.13 Implant Materials

There is always a keen interest to try and discover new materials for implants Stainless steel and titanium remain the conventional metals Titanium has come to be considered the more superior of the two, given that it is half the weight of steel and has lower stiffness Titanium also has improved corrosion resistance and does not produce any known associated allergies Implant stiffness is a huge problem in itself because stainless steel is much stiffer than bone and causes stress protection which lead to bone undergoing loss of mass

1 14 The Development of a New System Using Laboratory Testing and Finite Element Analysis

The bench testing of samples of wood, artificial human bones, canine bones, feline bones,equine bones comprises axial, four point bending, three point bending, torsion ,fatigue, cycling, tensile and shear loading The analysis itself was subdivided into the following categories

1 Individual designs testing
2 Testing designs and formation of systems of use
3 Comparative testing of the above categories against standard implants
4 Finite Element Analysis to find optimum shape of implant
5 Specific fracture in humans
6 Specific fracture in dogs
7 Specific fracture in cats
8 Specific fracture in equines
9 Tensile testing of designs
10 Torque testing of designs
11 Fatigue/Cyclic testing of designs

1 15 Objectives

1 To find the best mechanical and individual design through bench testing and finite element analysis
2 To find the most efficient way to manufacture the optimum design

3 Through bench testing to investigate the complete mechanical properties and analyse the different ways of using this design

4 To prove through bench testing that the design compares favourably or otherwise with the current accepted methods of repair

5 To prove that the design can be compared favourably to the current optimal technology standards of repair in mechanical performance in specific human fractures

6 To prove that the design can be compared favourably to current optimal technology standards of repair in mechanical performance in specific veterinary fractures

7 To make specific recommendations to take the optimal design to manufacture and clinical trials

1 16 Summary, The Future of Fracture Fixation

What is needed is a totally flexible implant system that will allow choice of implant stiffness, screw number and placement, and level of dissection This work attempts to create a system that incorporates all of the abilities that the current understanding of bone healing and repair demands This flexible system needs to be able to be as stiff as the other implants, to provide greater choice for screw placement and loading, not to adversely affect vascular circulation of bone, to achieve compression at fracture site and to preserve soft tissues better than traditional implants

Chapter 2

Literature Survey

2.1 Introduction

Fracture fixation has evolved through the last 100 years from splints/casts to pins, external skeletal fixation, Ilizarov and ring fixators, the dynamic compression plate, specialized plates and interlocking nails (1-23). In the process of this evolution, problems have been encountered along the way and the solution to each problem lead to a new implant design or principle at every stage. At this time, the evolutionary process has recognised the inherent problems of the dynamic compression plate (DCP) and other implants such as some interlocking nails (IN). These implants are still considered the best technology available for fracture fixation and repair. Laurence and others (61, 62), found that internal fixation using plates and screws is the most stable form of fixation immediately post operatively, but there still are no means of fixation as mechanically capable of achieving the strength and stiffness of a whole intact bone available to date.

2.2 Problems with Fracture Fixation

The problems encountered are in relation to preservation of soft tissue, minimising damage or alteration to the bone structure, infection and nonunion of fractures (23-30). The use of internal fixation devices for fracture repair induce profound changes in the affected bone. The implant insertions have been implicated in the development of vascular structural changes that follow the plating of a bone. It appears that implant induced osteoporosis has a multifactorial pathogenesis involving surgical trauma, screw placement and the rigidity of the fixation device. Elements involved in the interface between the plate and bone such as interface contact area, screw torque and pressure are also implicated in the pathogenesis Basically there is a mechanical factor to surgical trauma, screw placement and rigidity of the fixation device The vascular insufficiency is caused by bone plate interface contact and pressure distribution Field (50), found that the end result is thinning of the cortices which will cause a problem of refracture if the plate is removed A significant amount of evidence supports the theory that ischaemic osteonecrosis is a consequence of the application of bone plates, and that it is a primary response to the impairment of vascular outflow precipitated by the interface contact area between the plate and the underlying bone This has been demonstrated with dye tests, comparing the dynamic compression plate and a semi-tubular plate Gautiere and others (95, 96), showed that the semi-tubular plate had a greater interface contact with the bone and appeared to cause more significant ischaemia, both on low and high level application forces There is a blockade of the centrifugal movement of blood through periosteal blood vessels in response to the application of a bone plate An area of devascularisation was observed directly under the plate Rhinelander (59), proposed that this effect was short-lived and confined to a small sector of the bone circumference There are also problems in bone with disturbances of the vascularity during fixation of fractures using other implants besides plates Waelchi-Suter (85), revealed that cortical revascularisation is initially extensively disturbed following medullary reaming and nailing

2 3 Stress Shielding

Another driving force in the evolution of fracture repair is the concept of stress shielding Akeson and others (41-47), proposed that heavy-duty implants can be so stiff that the bone itself does not experience sufficient loading forces to stimulate the resident bone cells to remain at a suitable level of activity, and then that the bone becomes osteopaenic and weaker Bone is a living tissue and changes or adapts in response to the load that it experiences If bone experiences no loading it will weaken and become osteopaenic Consequently, the implants must attain a balance between maintaining rigid fixation of fracture fragments and allowing sufficient loading The achievement of this balance is difficult because so many factors are involved The age and health of the patient, the type and site of fracture, the soft tissue status and load activity of the patient are some of the factors considered This is partly the reason why there are so many different implants available for fracture repair

Woo and others (60) found that there is an 84% reduction in bone strain immediately beneath an AP placed 4 hole AO plate, and a 22% reduction on the medial side As early as 6 weeks following the application of rigid internal fixation there is a reduction in the strength of bone It also appears that the application of a metallic plate has the potential to produce significant morphological changes in the bone including widening of the endosteal haversian canal including porosity and enlargement of the overall outside diameter The precise mechanism of the mechanical stiffness of these changes is unclear but is probably related to the stress shielding phenomenon Of extreme importance are small similar morphological alterations anticipated along the length of the bone exposed to an overlying plate This plate associated weakening of bone warrants careful discretion in the removal of metallic plates following the evidence of fracture healing Considering the weak correlation between radiographic assessment of fracture healing and the actual mechanical strength of the bone, often the timing of plate removal is difficult to determine critically Mullis and others (70), found that in dogs mechanical and morpholigic changes associated with plate-induced osteopaena are completely reversible within three months of plate removal Woo and others (69), recommended that activity be restricted for several months following plate removal (69)

2 4 <u>Biological Osteosynthesis</u>

Woo and others (53), proposed that the solution to implant induced osteoporosis would be to look for a more biological form of fracture fixation which relies on indirect or secondary osteonic bone healing with callus formation Soft tissue trauma and extra periosteal dissection have been shown to retard the formation and strength of the fracture callus when compared with control factors approached subperiosteally Clearly it is important to be wary of such influences in design or in interpreting comparative elements of fracture healing Perren (40), stated that the major challenges for biological fixation are the preservation of soft tissues during fracture repair The reduction of surgical exposure in the repair of fractures has become increasingly more appealing with regards to the biological healing of bone Gerber and others (83), found that, historically, orthopaedic surgeons have relied on absolute fracture reduction and rigid compression plating which was achieved by inflicting significant soft tissue dissection and surgical trauma

Biological fixation is an attempt to stimulate synergy between available implant technology and the body's inherent manner of healing bone The aim is for a stronger reconstruction, enabling earlier weight bearing and function Field and Tornkvist (91), proposed that biological fixation appears to achieve this through a number of means including reduction of soft tissue trauma, change to implant design with concomitant reduction of vascular impairment and an improved mechanical environment in which fracture repair and healing can proceed Ganz and others (38, 92, 930), found that with biological fracture fixation or indirect fracture repair, the primary goal centres upon the maintenance of soft tissue attachments and of the blood supply to the fractured bone, and not absolute fracture reduction

Goodship and others (84), state that the aim of biological healing is to alter the inherent bone strain and in so doing stimulate remodelling to bring about an increase in bone mass in accordance with Wolff's law Frost (135) and Roesler (134), found that the trabecular network of cancellous bone is created in response to the functional deformation that occurs as part of the influences of the forces acting on the skeleton

2 5 Recent Advances

The application or insertion of a DCP or IN will involve the drilling and reaming out of bone stock respectively This removal of bone stock can weaken the bone or on occasion affect healing and infection rates Furthermore, the soft tissue will have to be retracted, dissected and incised to allow implantation of these large metallic implants Frigg and others (31-33) state that the current trend is towards minimal incisions to preserve blood supply to the bone and the adjacent soft tissues The AO/ASIF Foundation has introduced the LC-DCP and PC fix in response to these problems The LC-DCP, researched by Perren (38), allowed the bone to 'breathe' beneath the plate by raising the plate up off the bone, unlike the DCP where the flat metal clamps onto the bone in its entirety This leads to impaired vascular drainage and some osteopaenia Haas and others (35-40), found that the PC-Fix principal likewise attempts to minimize soft tissue damage and bone stock removal, increasing implant stability by locking the screws into the plate and having monocortical screws these changes encapsulate the principal of biological osteosynthesis

2.6 Implant Materials

Another proposed solution for reducing implant induced osteoporosis is to reduce the implant modulus of elasticity which can be done by either reducing the moment of inertia component or selecting a material with a lower modulus of elasticity Moyen and others (54, 55), found that the rigidity of the final bone plate construction is influenced by the modulus elasticity of the plate material, the cross sectional area of the plate and its shape Curry (51), states that there is a linear relationship between the ultimate bending strength and modulus of elasticity

The elasticity or stiffness of a plate is related to its width, thickness and material composition, other characteristics which influence the property include the size and shape of the screws and the number screw holes per unit length of the plate, and the area contained between the centre of the holes of the dynamic compression plate Stingby (113), found that screws which have been inserted through plate holes may increase stiffness of the plate by filling an otherwise open space in the plate

Flexible bone plates made of reinforced polymers, in a study by Akeson and others (56), appeared to cause less implant induced osteoporosis than stiffer metal plates There are risks involved with having empty screw holes in plates, according to Field and others (86), because of the stress concentration effect of voided screw holes and the potential for fracture A longer plate with fewer screws used to repair fractured cadaver ulnae, in an experiment by Denis and others (108), led to a relative increase in the elastic deformation of the final plate bone construction, the concept being that of producing a less stiff fracture fixation Furthermore Burny (87), demonstrated that flexible fixation provides a rapid and predictable formation of desirable callous in human tibial fractures

In trying to achieve a more flexible plate with a lower modulus of elasticity, Cairn and others (57), recommended using titanium or titanium alloy which has a lower modulus of elasticity than stainless steel If a plate is too flexible the patient experiences pain and the recommended stiffness of 2Nm / degree was found to be the most suitable level of fixation for tibial fracture in humans Tayton and Bradley (58), found that plate stiffness below 1Nm/degree allowed excessive movement and elevated the risk of development of a non union

2 7 Movement at the Fracture Site

A further important discovery in the evolution of the understanding of bone healing is the principle of micromovement at the fracture site Previously it was considered vital that no movement took place at the fracture site Kenwright & Goodship (48), showed that micro movement actually stimulates fracture healing During the critical phase, between 4 and 6 weeks, cyclic loaded fractures demonstrated superior mechanical behaviour in most torsional testing and 3 point bending according to Sarmiento (66) and Perren (67) Wolf and others showed that cyclic loaded tibial osteotomies in rabbits were stronger than those constantly compressed when examined at 6 weeks (46) It is conceivable that an optimum fracture fixation method would involve some interfragmentary movement to maximise callus formation and thereby speed the return of use at 8 weeks, but Zindholm and others (68), found that it remains unclear whether thıs accelerated effect ıs attrıbutable to motıon at the fracture sıte The concept of destabılızatıon or dynamızatıon of fractures has been ıncorporated ın several of the currently avaılable human external fixator systems accordıng to Debastıanı and others (89, 90) There are two ways of achıevıng mıcro movement at the fracture sıte One ıs by connectıng a mıcro motor dırectly to the fracture sıte through the ımplant system and applyıng controlled mıcromovementm, the other to use a more flexıble method of fixatıon that wıll allow movement at the fracture sıte durıng loadıng

2 8 Ideal Implant

The ıdeal bone plate would enable surgeons to choose where to put ın a screw Surgeons are ın some ways constraıned ın how to apply a bone plate or where to place the screws Certaınly ıt ıs possıble to omıt screws from certaın plate desıgns However, the rıgıd nature of these plates stıll constraıns the surgeon to place screws at predetermıned sıtes Fıeld and Tornkvıst (97), proposed that, ın lıght of the trend towards bıologıcal fixatıon and brıdge platıng, the abılıty to place screws where the surgeon wants seems of more ımportance In thıs study on the bone fastenerod, certaın fractures have been chosen as models for mechanıcal testıng The ratıonale behınd these choıces ıs that, firstly, the new ımplant can only really be measured as to ıts potentıal value by comparıng ıt to trıed and tested methods of fracture repaır and, secondly, to attempt to find a nıche for ıts eventual ın vıvo use

2 9 The Human Femur

Pauwel's (72), photo elastıc model of the proxımal human femur confirmed the prevıous theoretıcal analysıs of Cullmann that outlıned the stress dıstrıbutıon ın the femoral head by placing strain gauges through either living bone or cadaver specimens The compression stress acted on the area of the calcar of the femur This area has dense mineralization compared to the rest of the proximal femur The tensile stress acting on the femoral neck is only half the compression stress The femoral shaft is under tension on the lateral side and under compression on the medial side The compression stress is slightly greater than the tensile stress The femoral head is subjected to a minimum torsional stress in comparison with the tibia The torsional stress transmitted by the femoral diaphysis is low The alignment of the trabeculae in the calcar femur compression lines, the greater trochanter tension lines, the upper femoral shaft tension lines in the femoral head (net-like arrangement), and in Ward's triangle confirm these force analysis The ideal implant for fixation of the femoral neck takes these forces in the position of the orientation of the trabeculae into consideration A modification of the implant system or a new component of the system should allow tensile forces which originate from the greater trochanter to be absorbed according to Cordey and others (74, 75) The gliding mechanism of the DHS (dynamic hip screw) to a large extent prevents the implant from perforating the acetabulum if the fracture zone slips under stress The dynamic condylar screw plate is recommended by Regzzoni and others (76, 88, 94), for purely subtrochanteric fractures where it acts as a tension band on the lateral aspect of the femur The difference between the DHS and the DCS according to Betz, Eule and Schweiber (49, 120), is that the DCS would perforate the acetabulum if the fracture slipped The dynamic cortical screw is the best technology available for fixation of the proximal femur but Harder and others (77), found that it damages bone stock massively and requires intact distal bone block of at least 4cm to achieve fixation Despite being the best technology available for fracture repair in certain human fractures, Maykowski and others (22, 23) reported dısappoıntıng results followıng use of sophıstıcated ımplants, wıth up to 50% of cases havıng ıntraoperatıve problems and seven other cases faılıng to bear weıght, suggestıng that the fixatıon ın such cases ıs geared to treat early weıght bearıng rather than early rapıd bone unıon These massıve ımplants cause damage to bone stock whıch delays healıng and faıls to lead to early weight-bearıng Maykowskı and others (22), also found that there are large areas of devascularısed bone after puttıng ın massıve ımplants

In coxavalga and anteversıon wıth acetabular dysplasıa, ıntertrochanterıc derotatıon varus osteotomy permıts correctıon of the femoral neck angle and centres the femoral head ınto the acetabulum The bıfurcated blade plate, as proposed by Wagner (79), provıdes stabılıty for ımmedıate mobılısatıon wıth partıal weıght bearıng The fixclıp ıs a very versatıle and useful fixatıon devıce, accordıng to Baker (78), and ıs partıcularly useful for perı artıcular fractures of osteoporotıc bone and paedıatrıc fractures The fixclıp ıs a flexıble method of fixatıon and therefore allows mıcro movement at the fracture sıte, promotıng secondary bone healıng Bache and Clegg (71), state that one of the common causes of faılure ıs the wıres escapıng from the fixclıp

2 10 Veterınary Fractures

Bone plates are generally applıed to the cranıal surface of the canıne radıus vıa a cranıo-medıal approach Accordıng to Egger (99) and Wallace and others (100, 101), the plate should be applıed to the cranıal aspect of the radıus to ıncorporate the tensıon band prıncıple Nunamaker (102) and Hurov (103), state that a varıety of methods can be used for platıng the dıstal radıus ıncludıng the use of straıght plates and T plates Medial plating of radial fractures has a significant advantage compared to conventional cranial medial plate application according to Sardinas and others (104), and is an alternative method of fixation for selected radial fractures in dogs and cats There is a high complication rate associated with fractures of the proximal ulna in the dog according to Muir and Johnson (116) The AO / ASIF hook plate can be used to stabilise metaphyseal osteotomies and fractures where it is not possible to achieve the minimum of 3 screws in each end of the fracture site, as recommended by AO/ ASIF (109, 110, 111) Robins and others (112), found that the customised DCP can be used for metaphyseal fractures and osteotomies to achieve increased holding in the distal fragment or proximal fragment when appropriate Durall and Diaz (118), demonstrated that interlocking nails are a successful method of repair for diaphyseal fractures in dogs

Hanson and others (115), concluded that of the three techniques for repair of fractures of the olecranon of horses, the dynamic compression plate, tension band wire and a prototype grip, the compression plate was superior, whereas Martin, Nunamaker and others (105, 107), found that ulna fractures can be successfully treated using tension band wiring Denny (106), agreed with the former that plating of ulnar fractures in horses is a successful method of repair Tension band wire is sufficient for olecranon fractures in foals and according to Richardson (107), can be modified using larger screws for larger horses The AO / ASIF hook plate was used by Murray and others (117), as an alternative for internal fixation of the proximal aspect of the olecranon where limited purchase is anticipated in immature horses

2.11 Bone Screws

Orthopaedic bone screws are central to nearly all forms of internal fixation The screw holding power is dependant on the sheer strength of the surrounding bone, independent of the mechanical properties of the screw Hughes and Jordan (63), found that screws having small core diameter and high interference, although appropriate for cancellous bone, are subject to failure when inserted into dense bone as a result of the high torsional force due to increased thread bone friction The screw core diameter should be as large as conditions allow for maximum screw strength, and the major screw diameter should be maximised to achieve optimum holding strength according to Nunamaker and Ferren (64) Hearn and others (80), discovered that the interfragmentary compression that can be achieved with orthopaedic screws is in part limited by the holding strength of the screws in the bone and Cordey and others (81, 82), reported that the actual force achieved in a screw is directly proportional to the torque applied to that screw

2.12 Laboratory Methods

The setting up of the laboratory tests will be performed with reference to standard methods in the literature In the study by McKechnie-Jarvis (123), the cadaveric femur was used for bench testing, making a comparison between five different fixation methods and subjected to cyclic loading of 0-1 KN The standard procedure for mechanical evaluation of implants is through 4pt bending tests, 3pt bending tests, torsional testing, fatigue analysis and finite element analysis (124, 125, 126, 127, 128) Evans and others (129), state that new implants should be compared to industry standard in both cadaveric and mechanical bones Mechanical analysis should involve torsional loading and bending Szivek and Yapp (130), in their study of screw loosening, report that the actual joint loads can be 3-4 times body weight during mid stance in a gait cycle The different types of interlocking nails have been compared using mechanical testing for subtrochanteric fractures in the study by McKennolp and others (133) The influence of wire tension and the importance of wire tension in the fixation of fractures using the Ilizarov technique is well recognized (121, 122, 131) Boutros and others (98), showed that a significant decrease in destructive torsional strain and a significant increase in non-destructive bending were most consistent in every specimen at each freeze thaw cycle Veterinary cuttable plates were analysed by Fruchler and Holmberg (114), using three point bending and wooden dowels Wood can be used as a model for bone in so far as the mechanical properties of birch are reasonably similar to those of bone for the purposes of mechanical testing (Modulus elasticity 13 8 GPA), according to Pollo and others (119)

2.13 Finite Element Analysis

Finite Element Analysis (FEA) is one of the tools of structure analysis (136) It can have considerable time and money saving benefits Optimisation of implants and applications in biomaterials and orthopaedics is one of the commoner uses of FEA (138-146) Orthopaedics is one of the main areas of FEA use within the field of bioengineering and, in particular, the human hip has received much attention (147-154) In combination with other preclinical research, such as laboratory bench testing, FEA allows for faster and, in some instances, greater in-depth analysis (155)

2 14 Summary of Literature Survey

1 Rigid internal fixation should be the aim but in certain cases flexible fixation is more desirable

2 A greater balance between the loading of implant and bone should be sought so that bone is loaded sufficiently

3 Injury to soft tissue and bone should be minimized

4 Where possible and appropriate, micromovement at fracture site should be allowed in order to promote healing

5 Production of an implant that can avoid the currently experienced pitfalls and its analysis to ascertain its properties as a better implant, would represent the aim of the research

Chapter 3

Mechanical Analysis of Different Designs of Fastenerod

3 1 Introduction

The first step in the analytical process of a new concept is to draw up a list of possible designs based on what the innovator believes are the best possible permutations and combinations These mental images of the designs are based on previous experiences, current or old implant designs, engineering common sense and a projected concept of the performance of the implant in various situations Once the basic designs are conceptualized, they are discussed with other appropriately skilled persons to eliminate, add or adjust these designs in the hope of reaching an optimal list

Four designs were chosen (Figs3 1- 3 4) to begin with, and then were made by hand in the materials laboratory Production was slow as the designs were small and required very small adjustments to make them accurate The degree of accuracy required that the channels and holes were all within 0 1 mm of the required measurement as the screws and pins are accurate to the demical point These screws and pins are produced by large multinational companies for the orthopedic surgeons and are highly precise implants Once made, the new designs, called clamps at this stage, were tested against each other using a simulated fractured bone made of wood and subjected to four point bending to failure Apart from the comparative differences, the behavior of the clamps during loading and their mode of failure were monitored

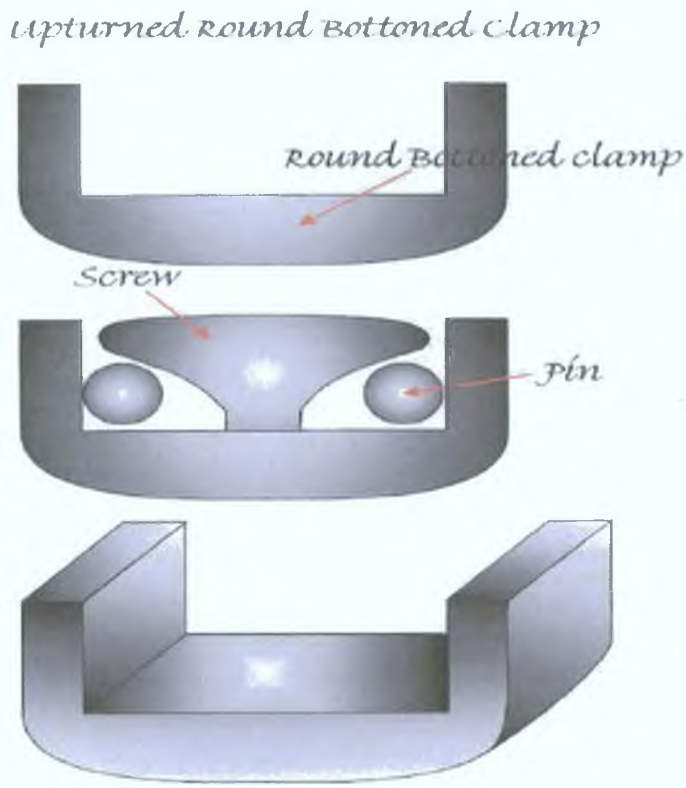


Figure 3.1 Type 1

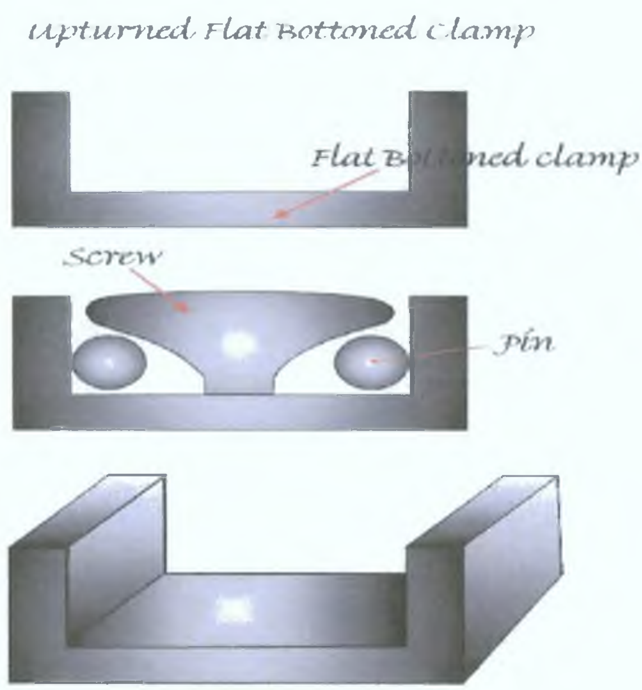


Figure 3.2 Type 2

Bent over

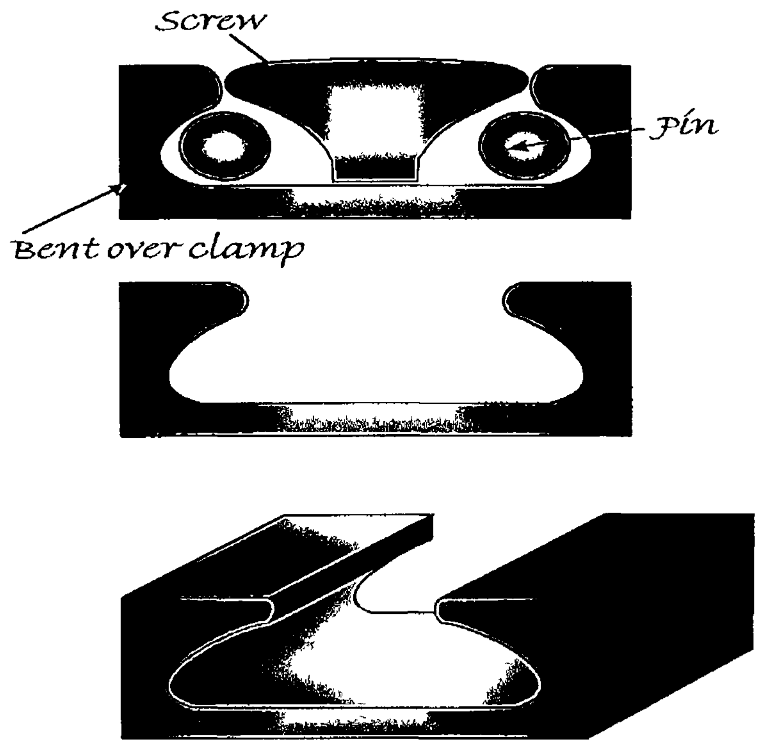


Figure 3.3 Type 3

Open concave Bottomed clamp

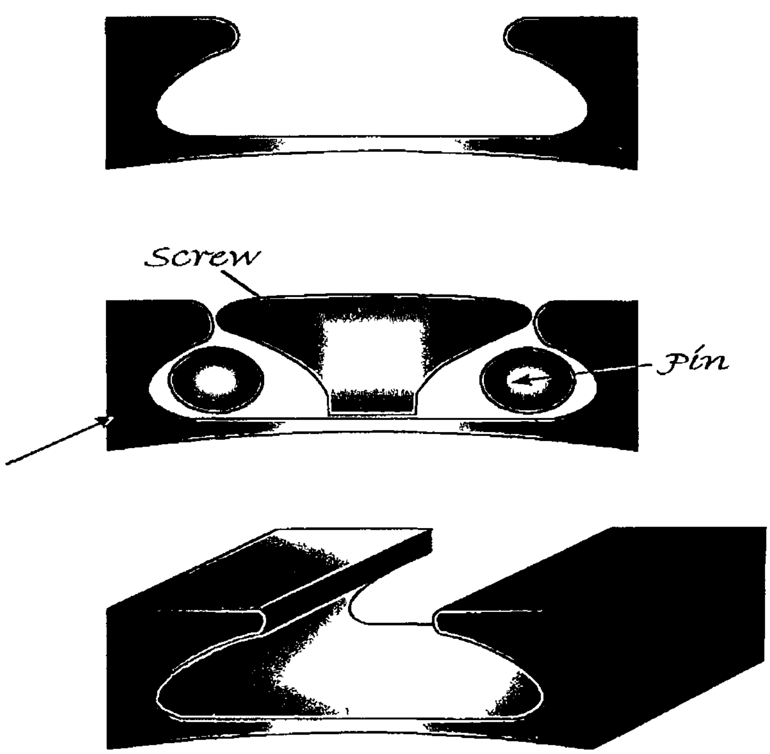


Figure 3.4 Type 4

The objective was to find not only the best design in terms of ultimate peak load but also to seek out the weaknesses of each design A modular system in itself creates the problem that there are many variables to deal with To preempt this comparative adjustments in the modular make up of the clamps were included in the test protocol to critically analyze the behavior of, not only each design but also the performance of the whole system Varying the components of the system was done by changing the designs, the number of designs, the distance between designs, the side of bone, the position of pins, the screw size, stainless steel wire and pin size

3 2 Methods and Materials

A four point bending jig was made in the materials laboratory specifically to deal with the size, shape and length of the samples that were used for testing In these experiments, as part of the first analysis of the designs, precut birch rods 30 cm long and 28 mm in diameter were used, and each rod was cut exactly in half with the ends rounded off to facilitate end opposition The two rods of birch were joint together with the various surgical implants to simulate a repaired fractured long bone All clamps were made manually in the materials laboratory (Fig 3 5)

All implants were inserted in exact accordance with the manufacturers' instructions and discarded after use Once the repaired rods were positioned correctly in the four point jig on the Instron (Fig 3 6), the load was set at 1 5 KN and the speed of the crosshead at 2 mm per minute The load was chosen based on the expected load from a weight bearing human or large animal A speed of 2 mm per second was chosen to allow clear monitoring of the systems behaviour under loading conditions For tensile loading custom made grips were used to hold the samples otherwise the testing was the same protocol (Fig 3 7)

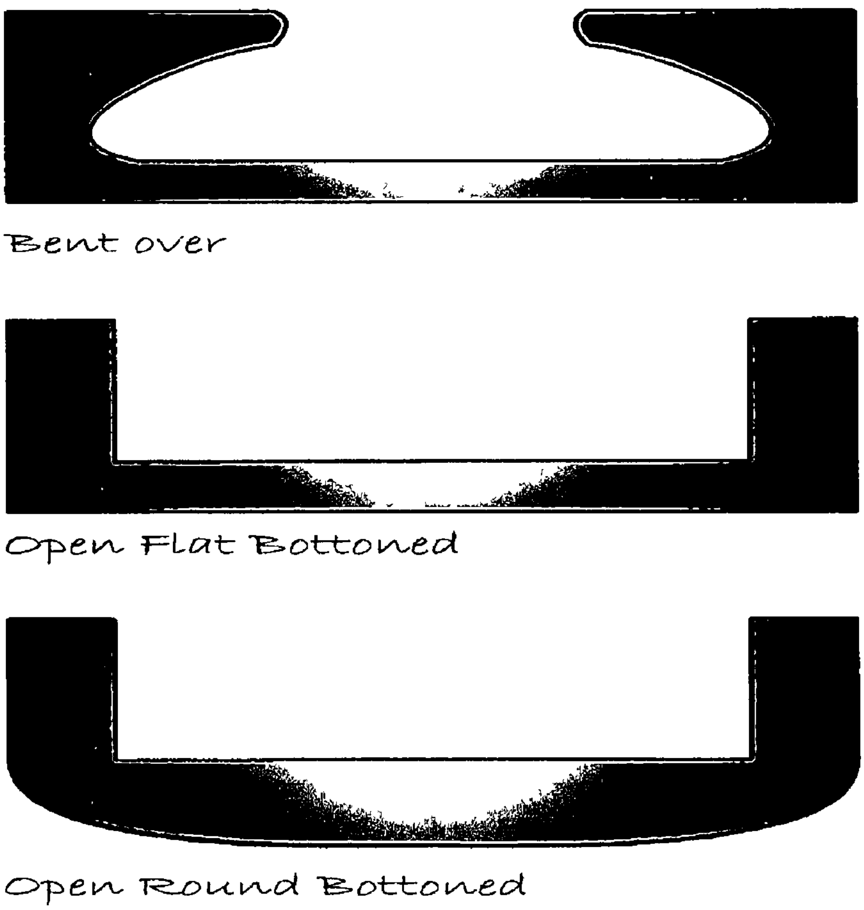


Figure 3.5 Comparison of Three Main Types

At this stage of investigation the Instron was not intergrated with a software package and the experiments were controlled from the control panel , and provided data for peak load and extension with a basic trace of graph shape There were no extension limits set on the Instron and the loading was stopped manually when the sample was judged to have failed by the operator Failure was decided on the basis of three events

a Extension beyond the distance of the jig

b. Failure of the implants through breakage, bending to the point of ineffectiveness, and loosing contact with fellow components of the modular system.
c. Failure of sample.

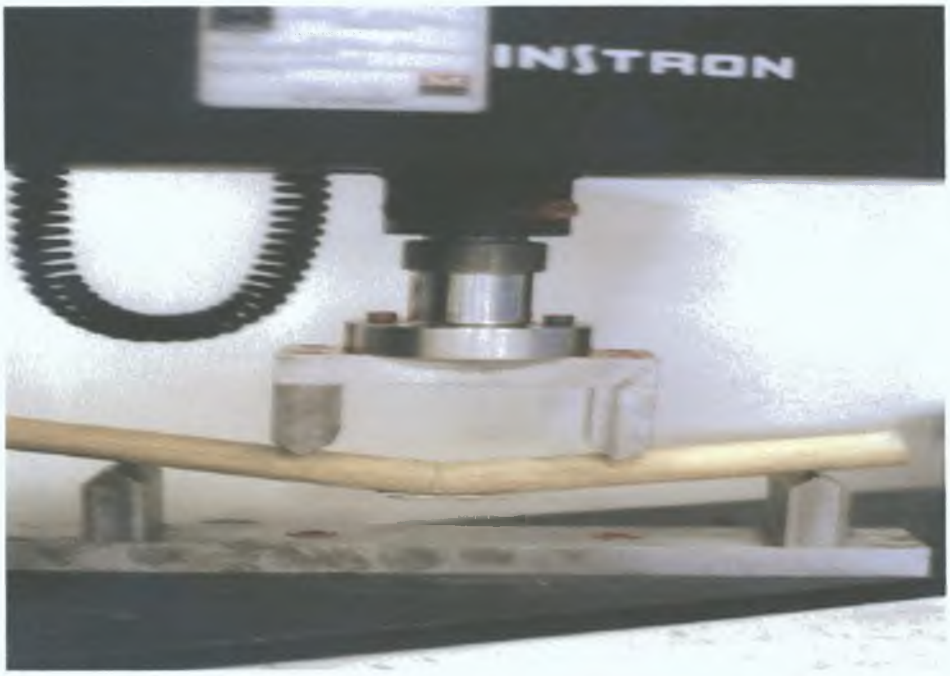


Figure 3.6 Four Point Bending of Prepared Sample

Figure 3.7 Tensile Testing of a Prepared Sample

The achievement of three results ended one set of tests and allowed progression to the next set. Peak load and max extension as measured by the instron were recorded and the instron was recalibrated . Mean, standard deviation and variance were calculated for each set of figures to be sure that they were a tight enough group, to be classed as repeatable.At the end of each test each component of the fixation was examined to check for changes (Fig 3.8).

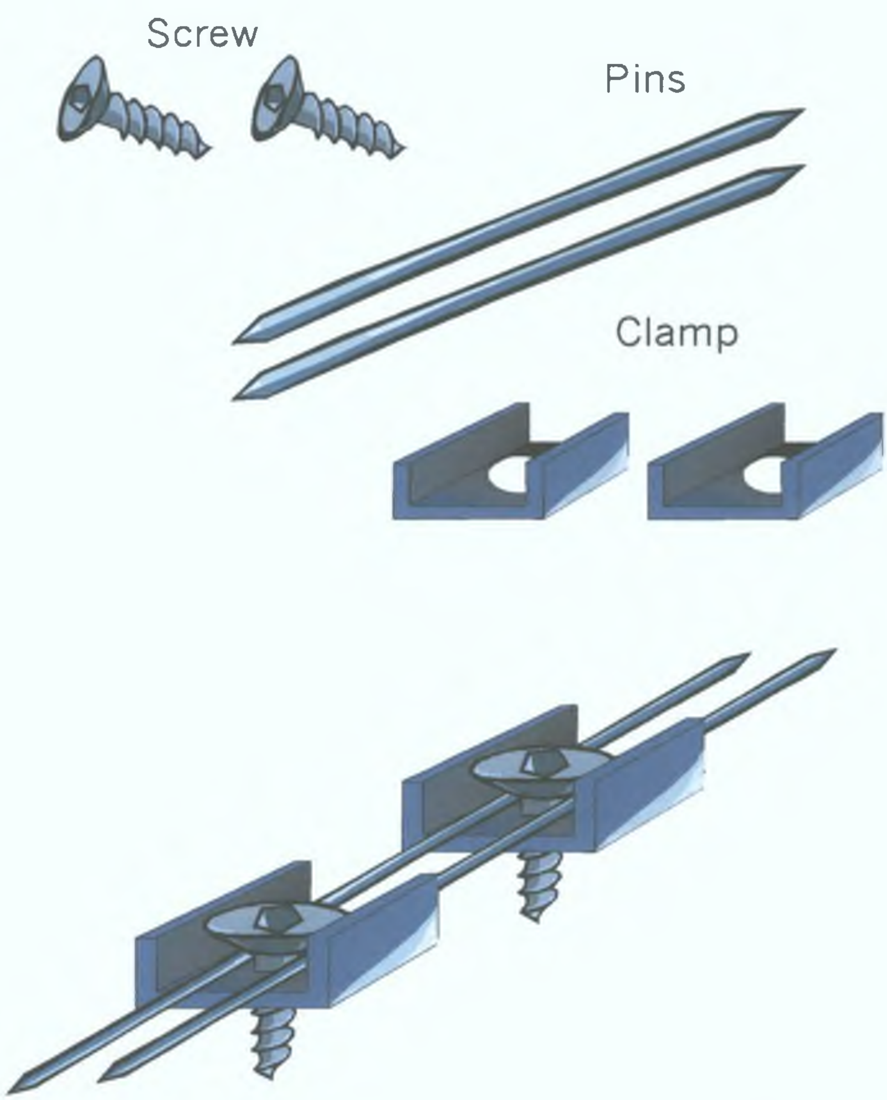


Figure 3.8 Diagramatic Depiction of the 3 Components of Fixation Device

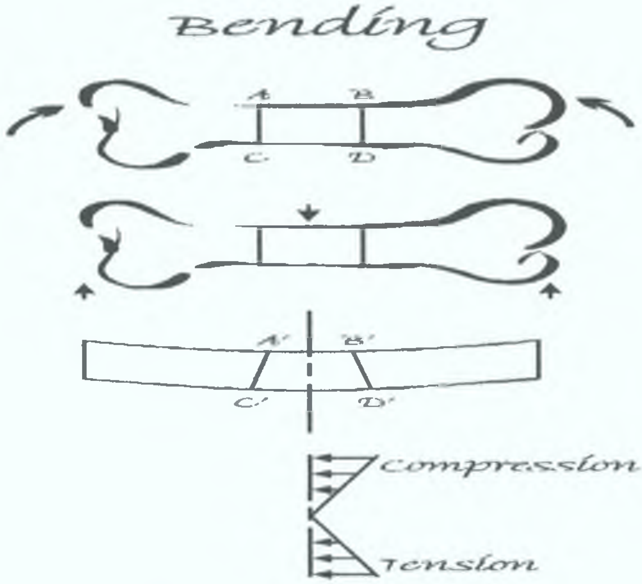


Figure 3.9 Diagramatic representation of the forces on a sample undergoing four point bending

3.3 Results

All four clamps were tested on the tension side (Fig 3.9) of the sample in four point bending (Fig 3.11) and it was found that the order of highest to lowest load was as depicted in figure 3.10 and this result was used to name the clamps type 1,2 3,or 4.

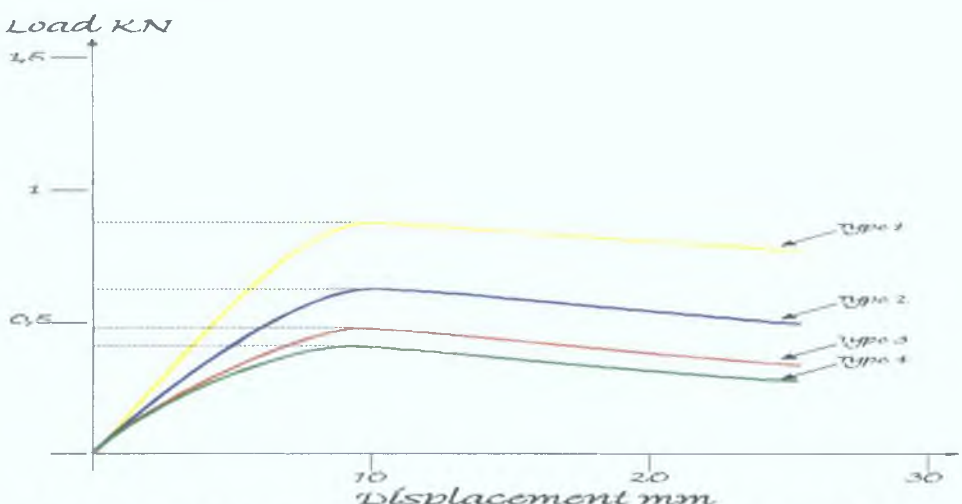


Figure 3.10 Comparative Data Between the Four Types of Design

Figure 3.11 A Type 3 clamp undergoing four point bending

When the pin was bent around the clamp the resistance and hence the highest load increased significantly compared to pin left straight (Fig 3.12)

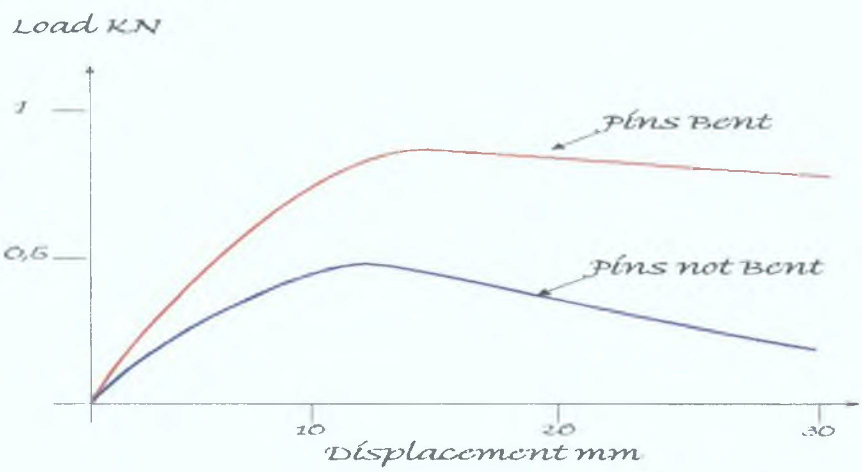


Figure 3.12 Difference between having the pins bent or not in one of the designs

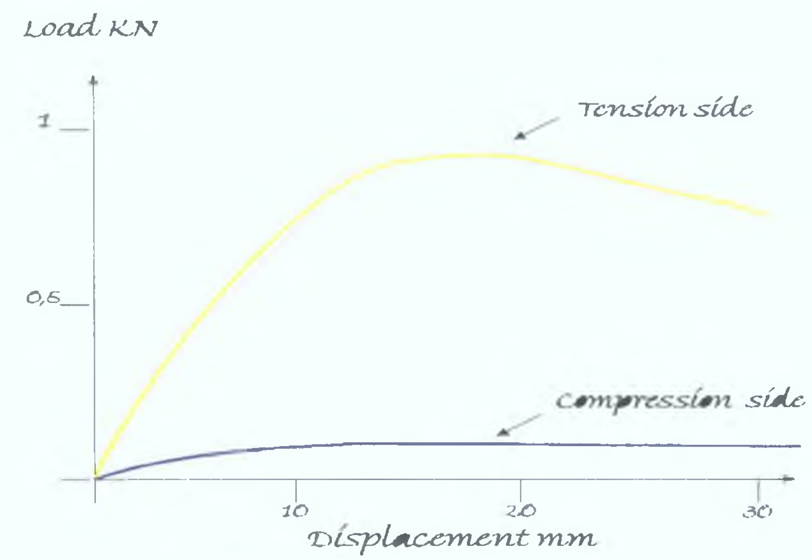


Figure 3.13 Difference between places implant on tension side and compression side

Using the same clamps, the issue of placing the implants on the tension side versus the compression side (Fig 3.13) indicates that the clamps are extremely weak when used on the compression side of a sample.

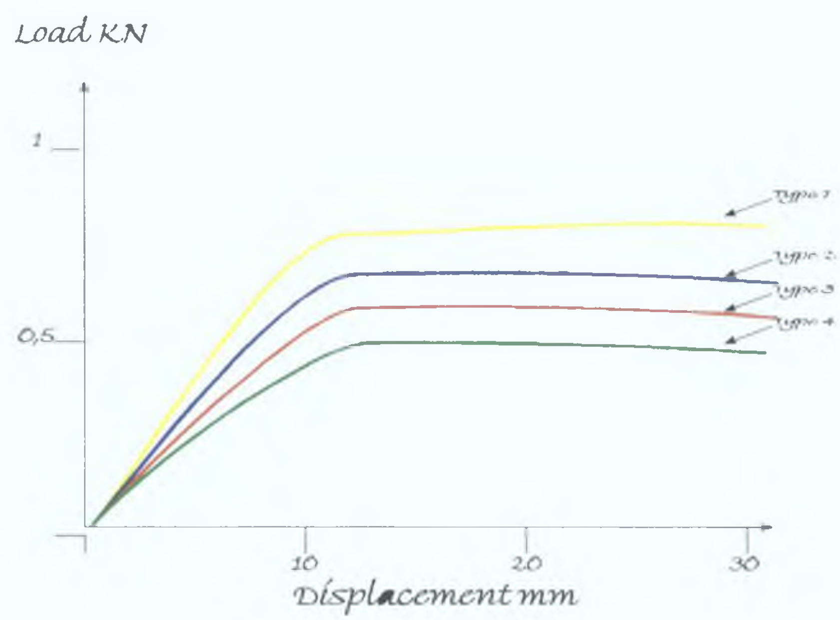


Figure 3.14 Difference between designs undergoing pure tensile loading

By applying tensile loading directly to the pins the degree of grip the screw head has on the pins is compared between the designs (Fig 3.14) and the results rank the clamps in exactly the same order as the four point bending tests.

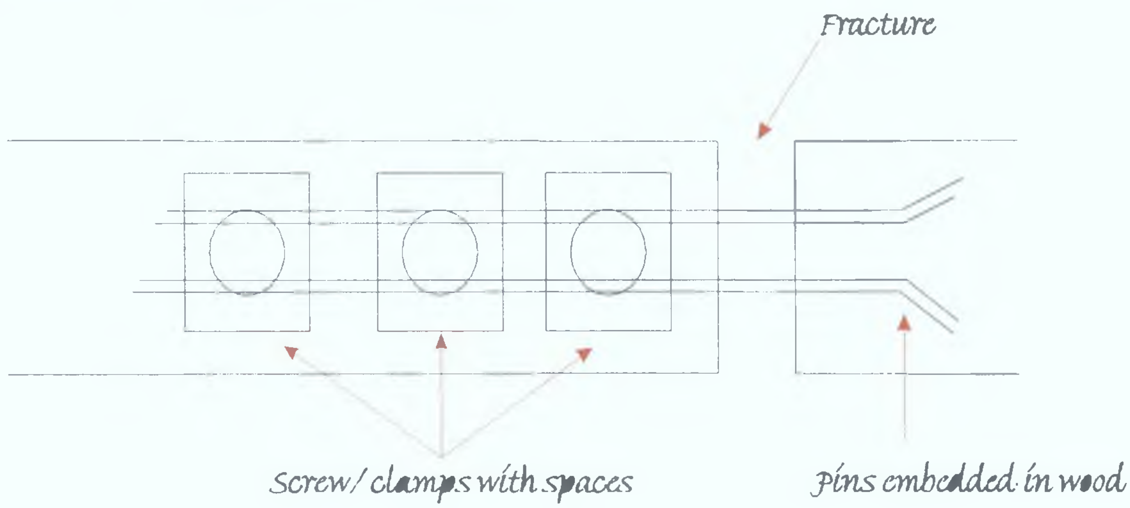


Figure 3.15 Diagram showing clamps on sample with spaces between them

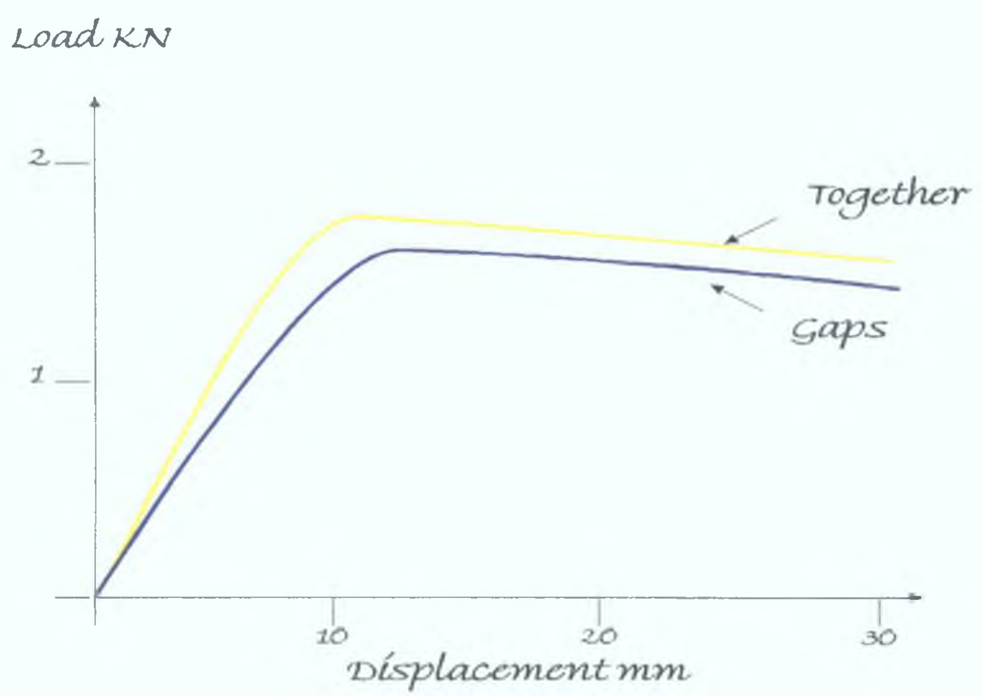


Figure 3.16 Difference between having gaps and having the design together

Using 3 clamps together allowed further variables to be examined using four point bending. Having a gap of 4 mm (Fig 3.15) between the clamps slightly decreased the value of the main peak load (Fig 3.16).

All tests were performed with the 2 rod ends perfectly apposed, but in the test to evaluate the significance of a gap between the pieces of wood (Fig 3.17), the peak load was significantly less indicating that load sharing fractures are better candidates for repair with this type of fixation.

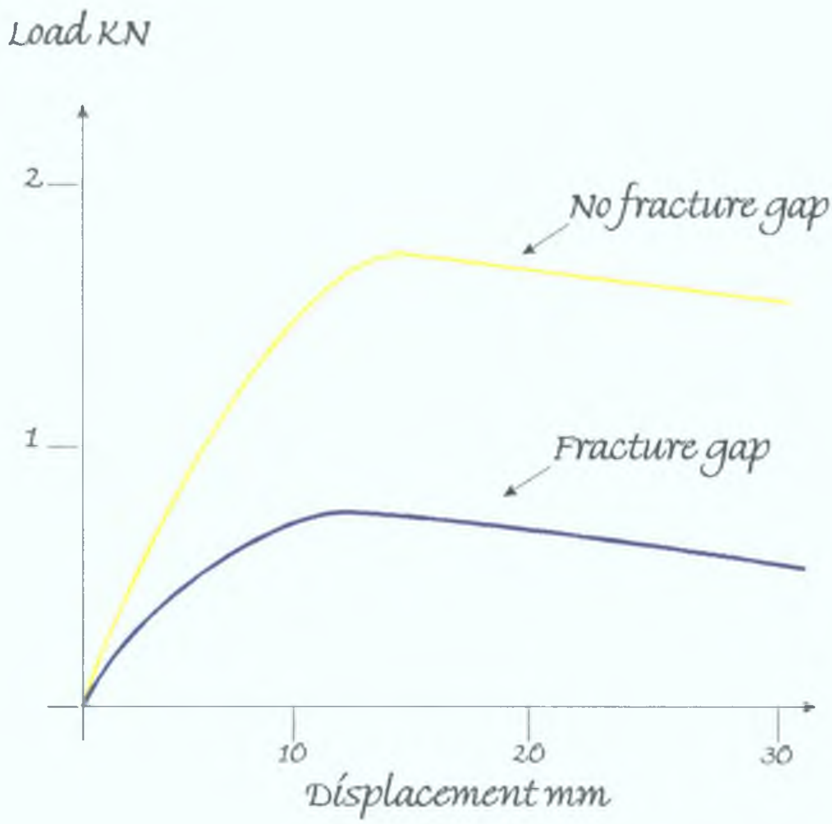


Figure 3.17 Difference with having a fracture gap and not having a fracture gap

Spreadıng the pıns (Fıg 3 18) ıncreased the peak load and, as was dıscovered before bendıng the pın, resısted pıns mıgratıon greater than the parallel pıns formatıon (Fıg 3 19)

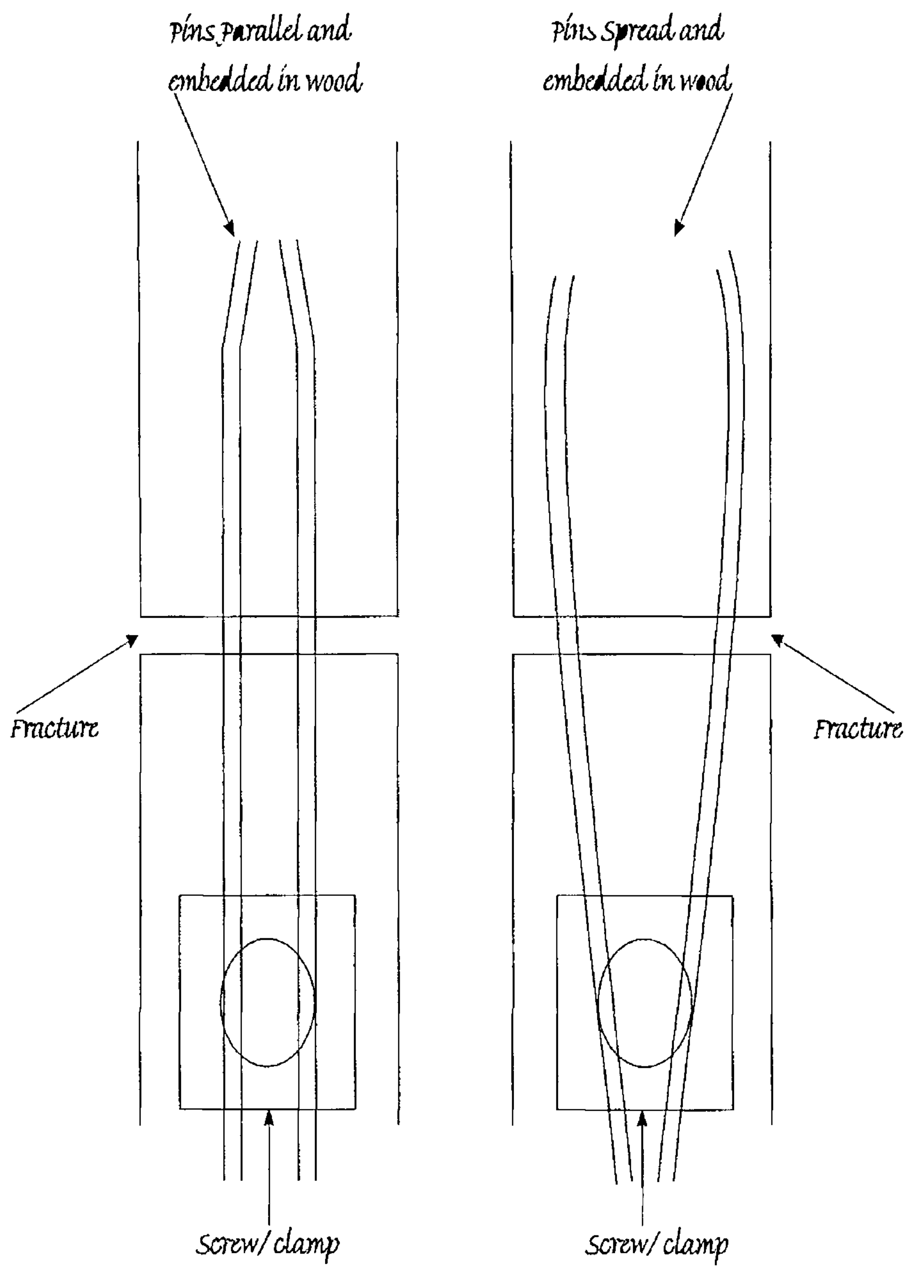


Fıgure 3 18 Dıagramatıc depıctıon of havıng pıns spread and pıns parallel

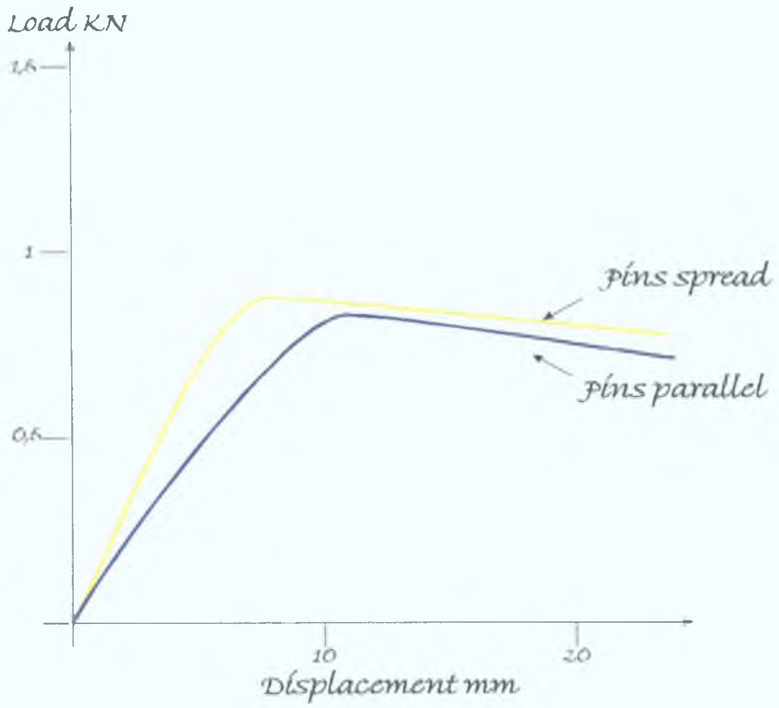


Figure 3.19 Difference between pins parallel and spread

Figure 3.20 Tensile testing of clamps comparing use of different quantities of clamp

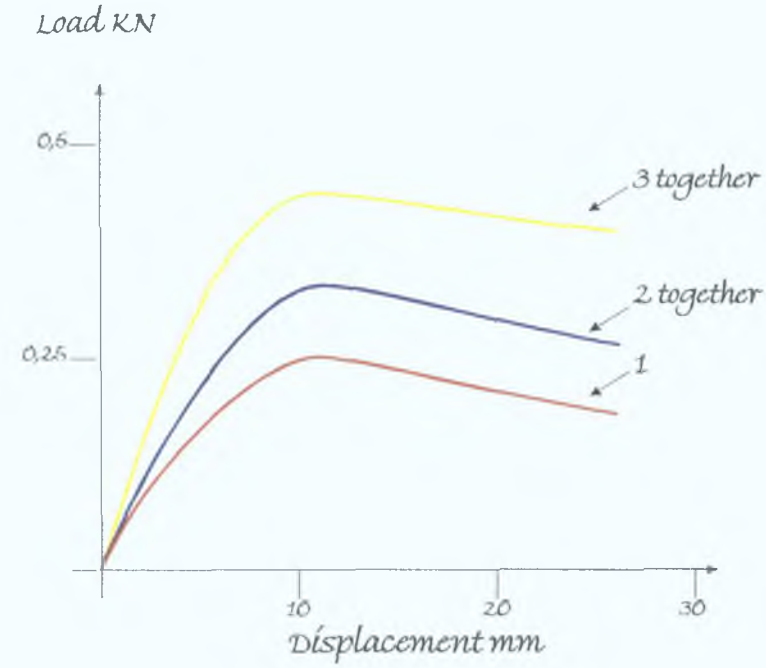


Figure 3.21 Difference between adding extra designs to pin slippage

When an extra clamp(Fig 3.20) is added to the fixation, the resistance to pin slippage increased with each additional clamp(Fig 3.21),when loaded under tensile conditions.

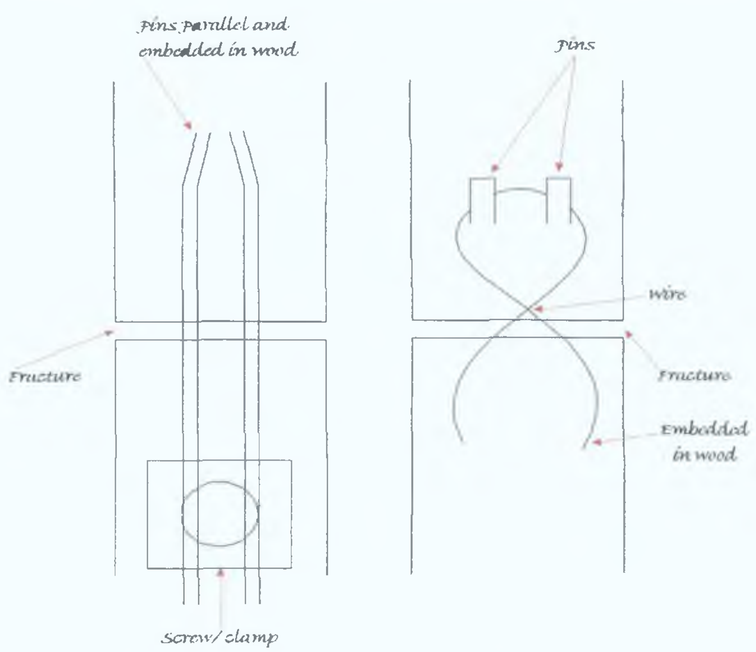


Figure 3.22 Difference between "fixing" a fracture using a clamp and pins versus a wire loop and pins

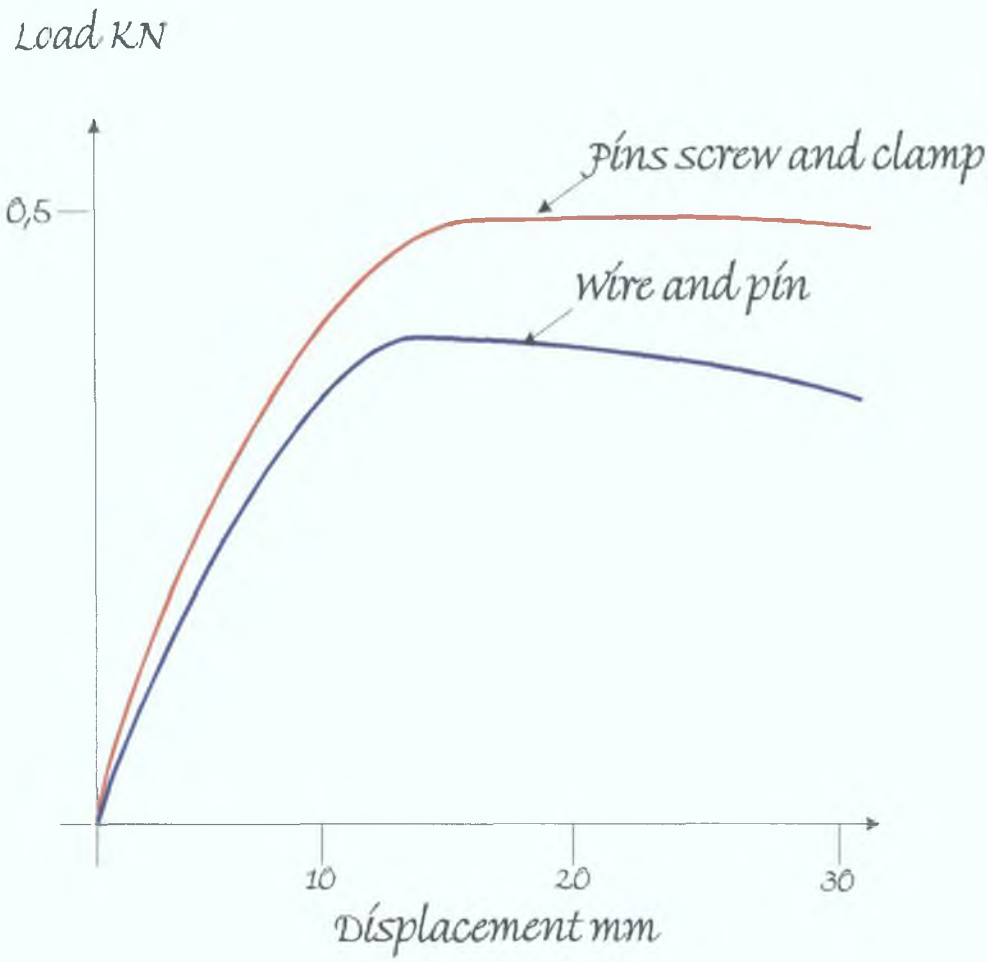


Figure 3.23 Graph showing the difference between pins, screws and clamps compared to wires and pins

As the pin is anchored to the samples via a screw and clamp, a comparison was made between screw/clamp anchorage and wire twisted around the pins and through a hole in the sample, much as with the repair of fractures (Fig 3.22). The screw/clamp combination consistently recorded higher peak loads than the wire. Furthermore, using a thicker pin also increased the peak load too for both methods (Fig 3.23).

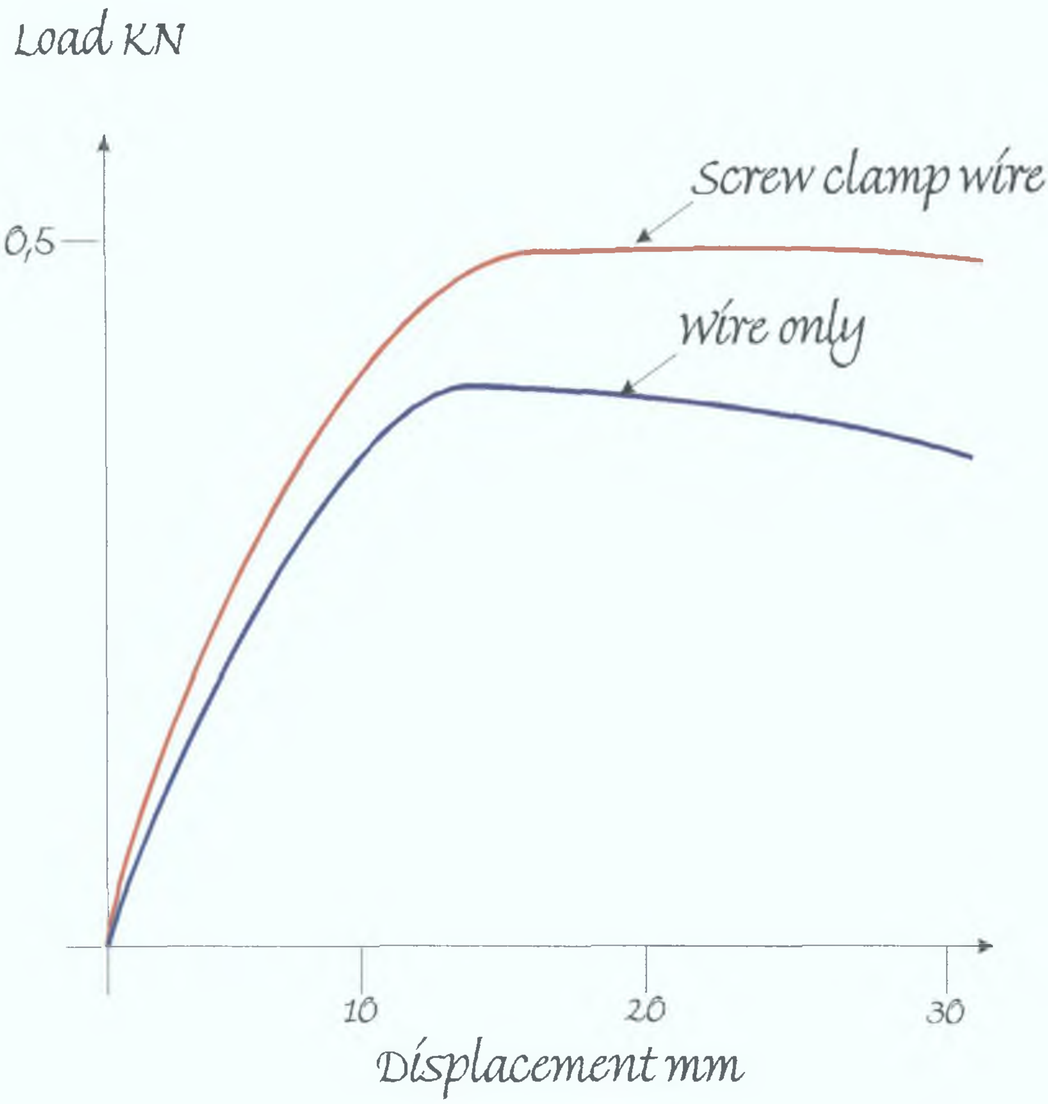


Figure 3.24 Difference between wire only and wire secured with screw and clamp design

If a loop of surgical wire is secured to the sample by a screw and clamp and compared to the wire simply passed through a hold in the sample, the screw and clamp have better security (Fig 3.24).

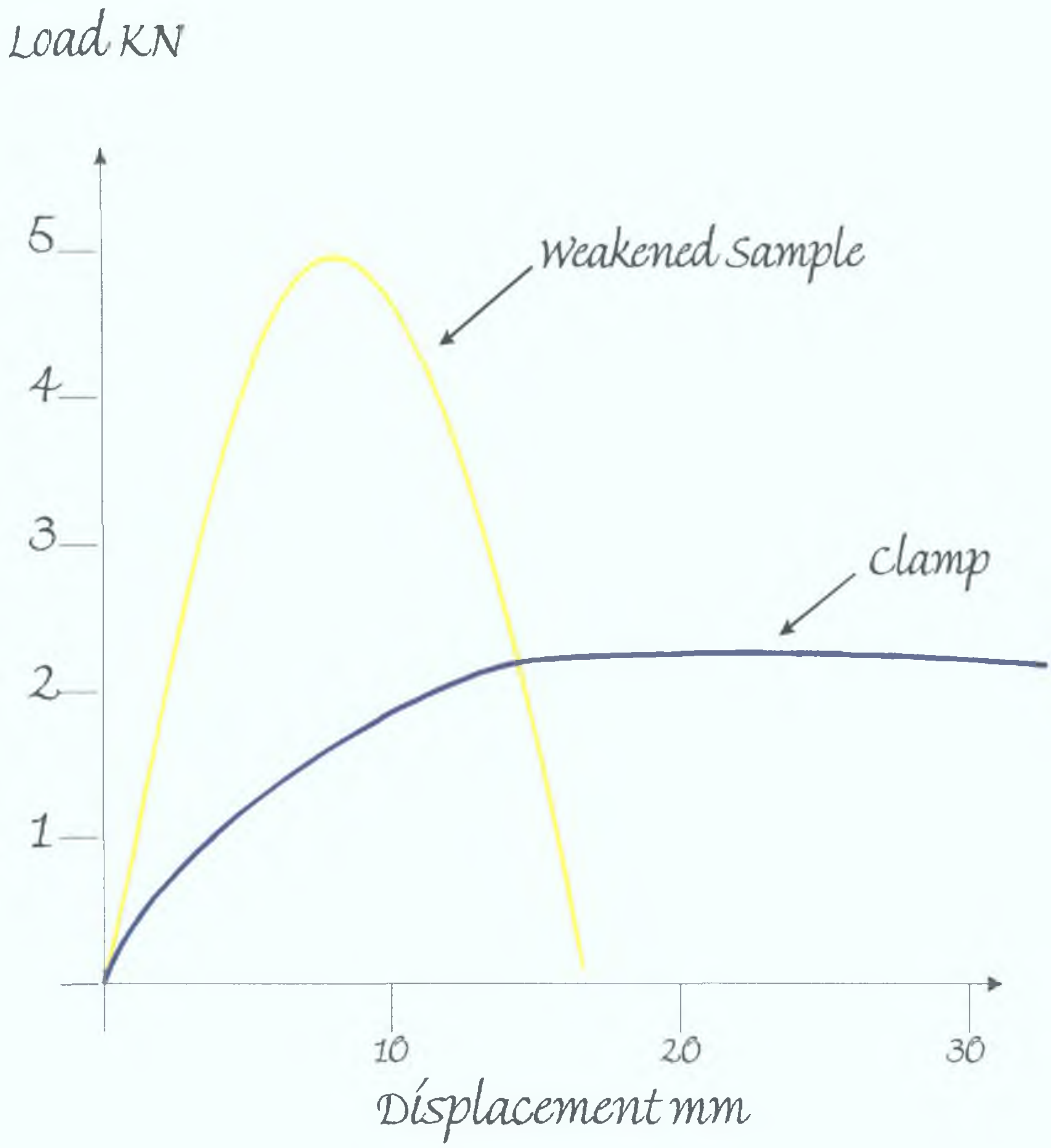


Figure 3.25 Difference between failure of a weakened sample and a repaired sample

When a piece of wood used as the sample is cut half way across its diameter, it is weakened. However, even with this, the weakened sample has a significantly higher load to failure value than a sample fully cut and repaired with a clamp (Fig 3.25).

3 4 Discussion

From the data produced it was found that the mode of failure was by pin slippage past the screw/design interface This starts early in the loading, and results for the pure tension loading demonstrate that the force needed to overcome the friction grip between the screw and the designs is small The weakest link in the fixation is the pin contact with the design Essentially the designs just slowly pull apart with nothing actually breaking The designs using larger pins were stronger in four point bending

When the gap of 4mm was introduced in the birch, the designs strength fell to approximately one third of its strength when there was no gap present This was used to simulate a non load sharing fracture The comparison between the designs and the wire techniques revealed that in all cases the designs were stronger The wire techniques utilize wires anchored on pins to resist tensile forces on bone The designs are naturally anti-tension devices

Increasing the number of individual components in a configuration increases the resistance to pin slippage by about 20 % for each component The experiments here only went up to 3 components Folding over the pins at the ends around the component approximately doubles the strength Resistance to pin migration is directly proportional to higher peak loads, and should therefore represent one of the main targets for further investigation when considering simulated clinical scenarios in the laboratory

Figure 3.26 Close up of a clamp showing the opening out like a flower because of four point bending resulting in loss of contact between the screw head and pins

The Bent over Design type 3 began opening out like a flower when the load was at 50-60% of its failure value (3.26). The contact was reduced at the screw head in this manner: the base of Bent over Design changed to the shape of the rod, ie convex. The difference between the round bottomed and the flat-bottomed designs was that the round bottomed (convex), design was stronger than the flat-bottomed design.

3.5 Summary

The desıgn ıs an antı-tensıon devıce that needs to be ın a load sharıng fixatıon formatıon. The strength of the desıgn can be manıpulated by alterıng the number of desıgns, the spaces between the desıgns, the posıtıon of the pıns,the pın sızes, and the shape of the desıgn All of these are alter the screw head/pın/desıgn contact

The two crucıal determıned by thıs testıng were that the bottom should be convex and the top preferably closed over Pın sıze should be maxımısed and the number of desıgns used kept as many as possıble

Chapter 4

Finite Element Analysis Of Selected Designs

4 1 Introduction

A finite element analysis was undertaken to analyse the design of screw / pin implant for use in orthopaedic applications Seven different implant designs were presented for analysis All designs have in common that they facilitate the clamping of surgical wire/pin to a bone using a screw The designs were chosen following the experience and results of the laboratory tests as presented in Chapter 3 The Finite Element Method is a numerical procedure that is used to solve physical problems in engineering but is an approximate method of analysis The physical model is approximated to a mathematical model Using finite element analysis the mathematical model can be solved Mathematical models are differential equations with boundary conditions and initial conditions applied To analyse the way a system behaves, the natural behaviour of the system as well as disturbances to the system have to be looked at The natural behaviour of the system includes modulus of elasticity, density, etc , i e the physical properties that define the natural characteristics of a model Disturbances are the external forces applied

All numerical solutions approximate to exact solutions at discrete points, or nodes The first step in a FEA is to divide the entire model into elements and nodes The finite element method is a numerical method that uses integral formulations, and an approximate continuous function is assumed to represent the solution for each element The complete solution is then obtained by combining all of the individual solutions for each element together

The finite element method was first used in the aerospace industry in the 1940s Although initially used for structural components, it can be used to solve mathematical models of structural solids of any shape, of heat transfer and fluid flow It can be used to determine strains, stresses, deflections and natural frequencies of engineered components as well as velocities and pressures in fluid flow analysis Other numerical techniques have been used in biomechanical analyses, but often they have certain limitations Conventional theoretical methods limit the shape of the component as it would be extremely difficult to model complicated shapes The finite difference method is not widely used due to its inability to handle complex geometries and boundary conditions Load testing with strain gauges is often expensive and does not provide stress measurements at each point of a structure This could lead to critical regions being overlooked However, FEA models provide results at every point in the model and finite element methods are often more flexible than other numerical methods The ability of the finite element method to deal with complicated geometries, as well as its versatility and its concrete theoretical foundation, make it an ideal tool for working with orthopaedic implants Moreover, strength tests and optimisation can be performed during the initial orthopaedic implant development phase and so save considerable time and can replace a range of bio-mechanical tests

4 2 Methods

In order to analyse the implant designs it was necessary to build eight different finite element models The finite element models were generated using Autodesk's Mechanical Desktop solid modelling software package and imported into the Ansys finite element software via an IGES file

Any FEA has a number of stages The Pre-processing Stage involves

1 Creation of the model and discretisation into finite elements, where the model is sub-divided into a specific number of nodes and elements

2 An approximate continuous function is assumed to represent the solution of each element The element type and the material properties will determine how each element behaves The equations for each element are developed based on these properties

3 All the equations' elements are assembled into a global stiffness matrix to represent the entire problem

4 Boundary conditions, initial conditions and loads are specified and applied to the model

The solution phase is where the algebraic equations are solved simultaneously to obtain nodal results

The post processing stage is where the displacements calculated are further processed in order to obtain other important information, i e stresses, etc

The accuracy of finite element models depends on several factors The proper type, shape and number of elements must be carefully chosen to ensure accurate results Convergence of the approximate numerical solution to the exact solution can be achieved in two ways, depending on the element type "H" elements have either constant strain or linearly varying strain across each element For these elements, the number of elements is increased until the results do not change with further mesh refinement This assumes that the element shapes are not overly distorted in the refinement process "P" elements are elements in which the strain across an element is described by high order polynomial functions. Convergence is achieved for "P" elements when increased polynomial orders do not change the results.

The fastenerod models were generated in ANSYS. Each model was created by formulating a 2-D view of the part and then extruding it. The hole for the screw through the centre of each of the models was extruded through the 3-D model. The initial models used are as follows:

1. Flat Design (Fig. 4.1)
2. In-turned design (Fig. 4.2)
3. Up-turned design (Fig. 4.3)
4. Closed over round bottomed (Fig. 4.4)
5. Banana design (Fig. 4.5)
6. Two Hollow designs (Figs. 4.6 and 4.8)
7. End isolate design (Fig. 4.7)

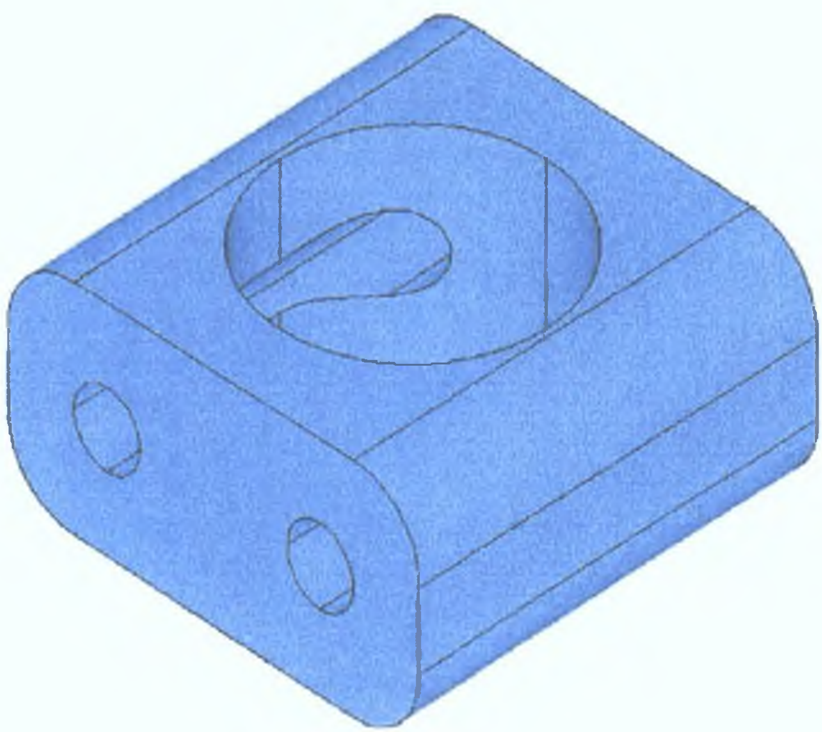


Figure 4.1 Flat Design

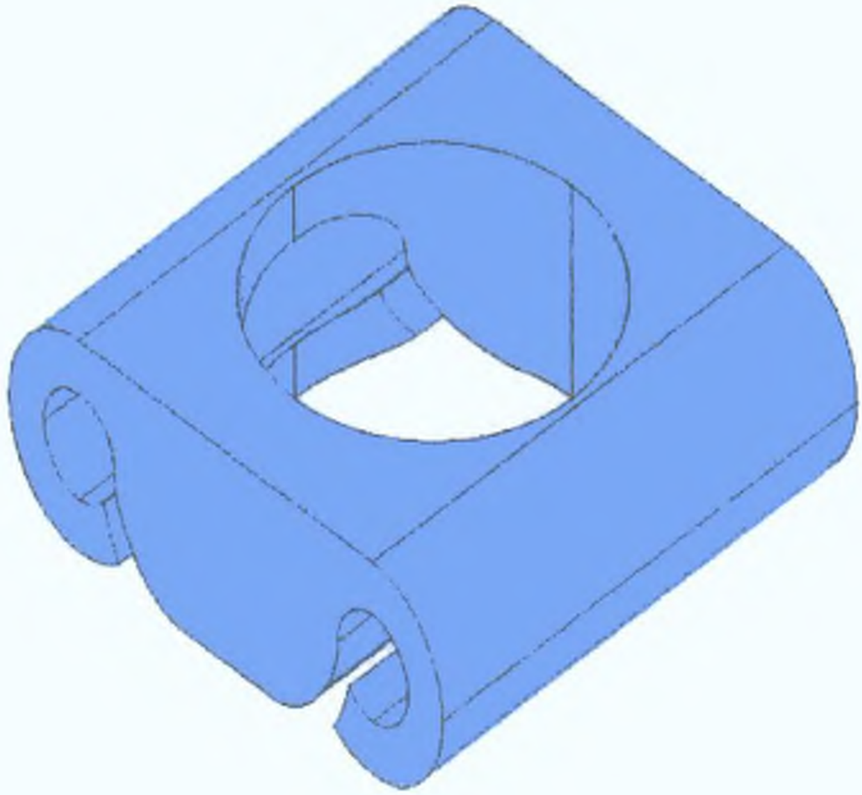


Figure 4.2 In-turned Design

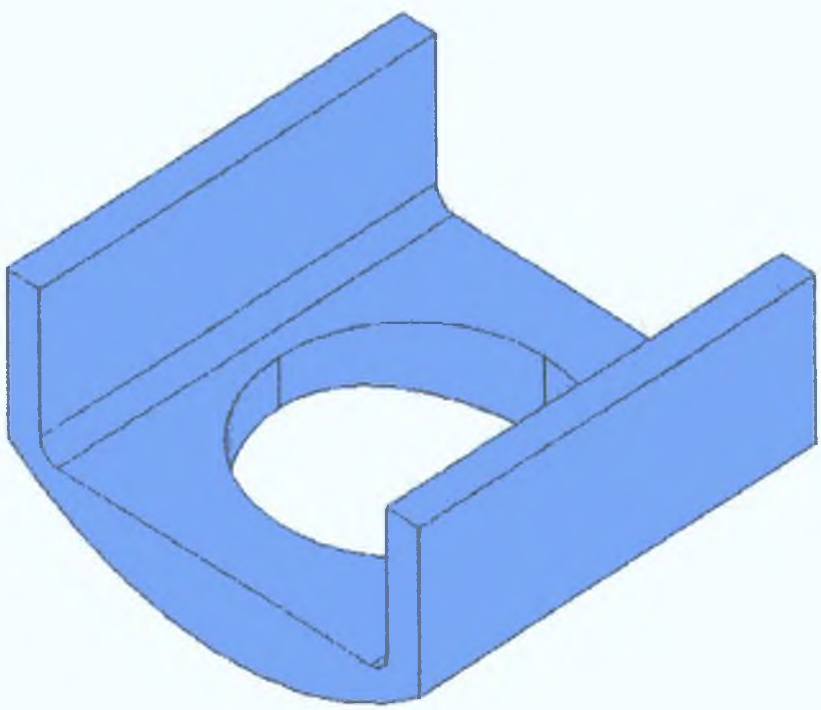


Figure 4.3 Up-turned Design

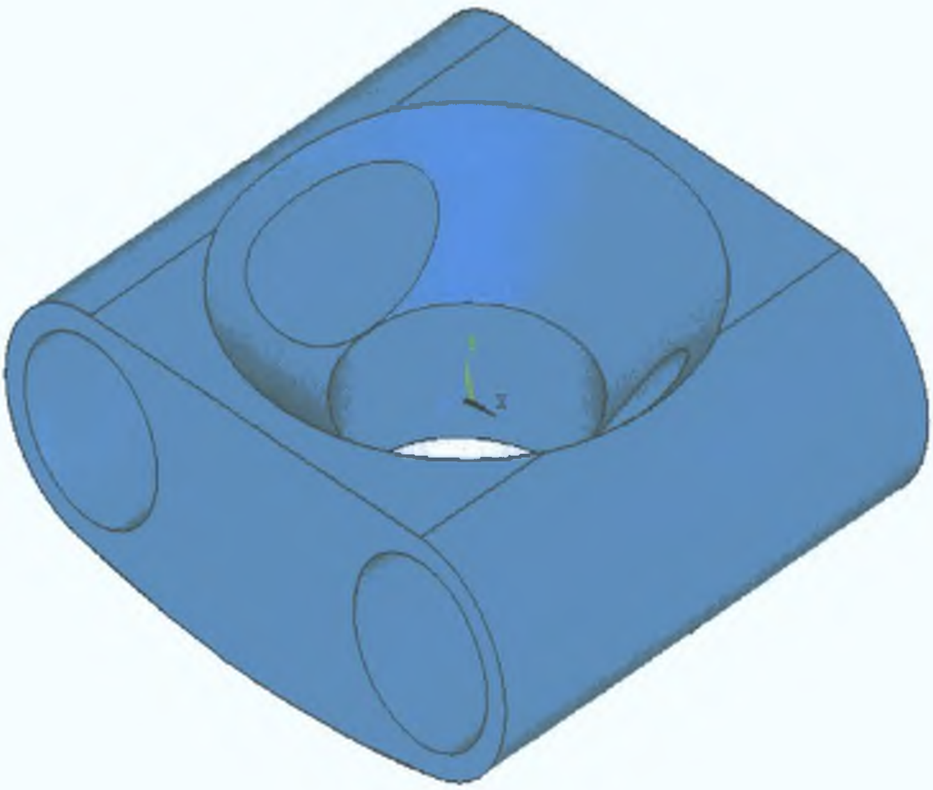


Figure 4.4 Closed over round bottomed

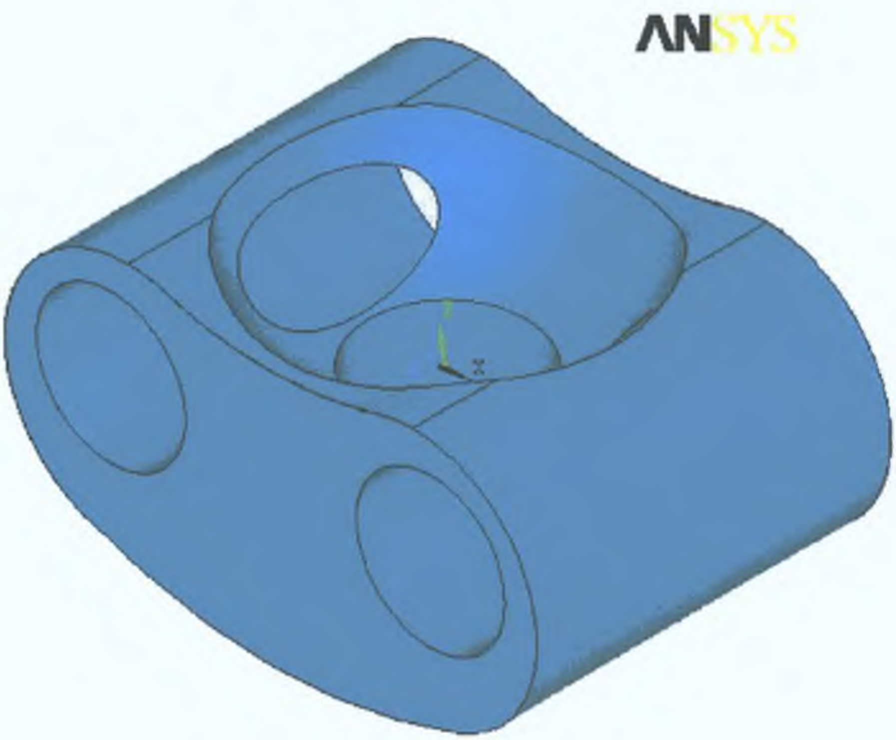


Figure 4.5 Banana design

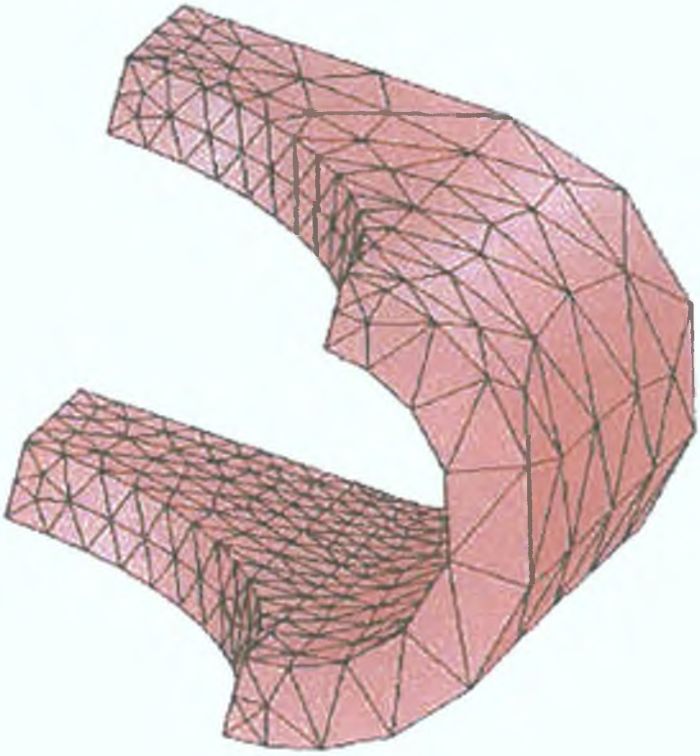


Figure 4.6 Hollow Design shown in half of full shape

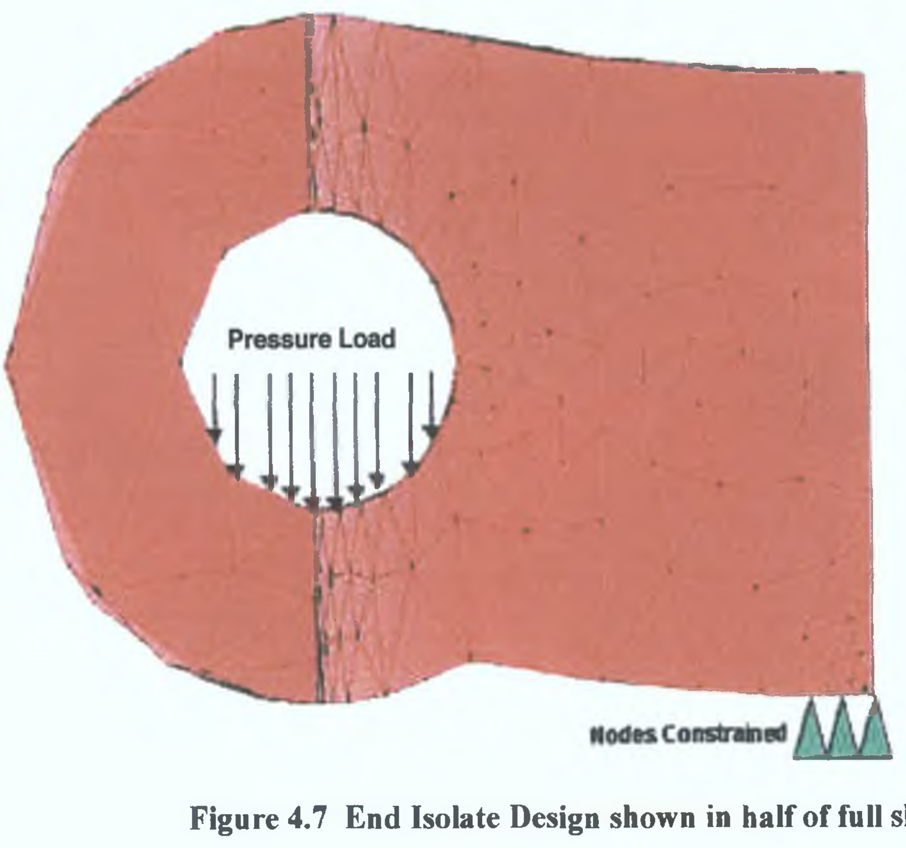


Figure 4.7 End Isolate Design shown in half of full shape

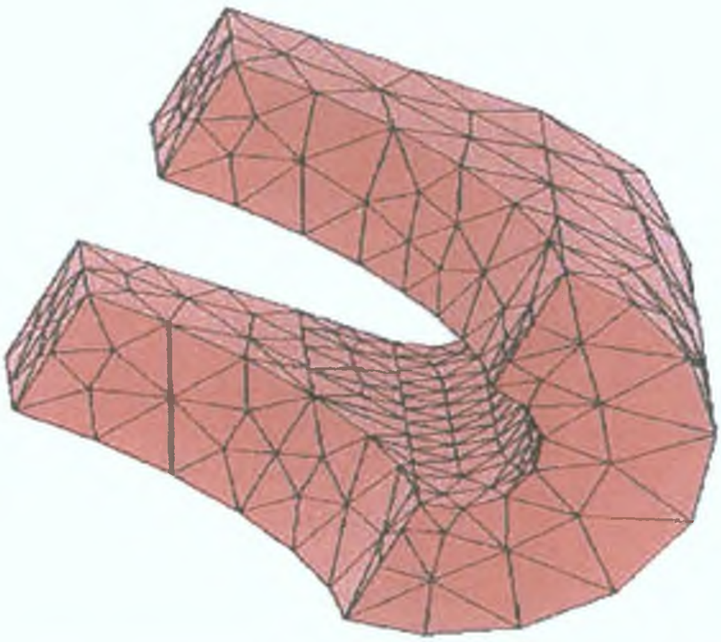


Figure 4.8 Hollow design 2 shown in half of full shape

Symmetry may be used to reduce the size of the analysis model (Fig. 4.9), once the appropriate boundary conditions are used. It saves on time as the symmetrical model computes faster. The quality of the model is also better when symmetry is used; as the boundary conditions are more accurate, the solutions are more accurate. The models could each be described by a quarter of their original shapes. This would significantly reduced run times and increased the accuracy of the solutions of these models.

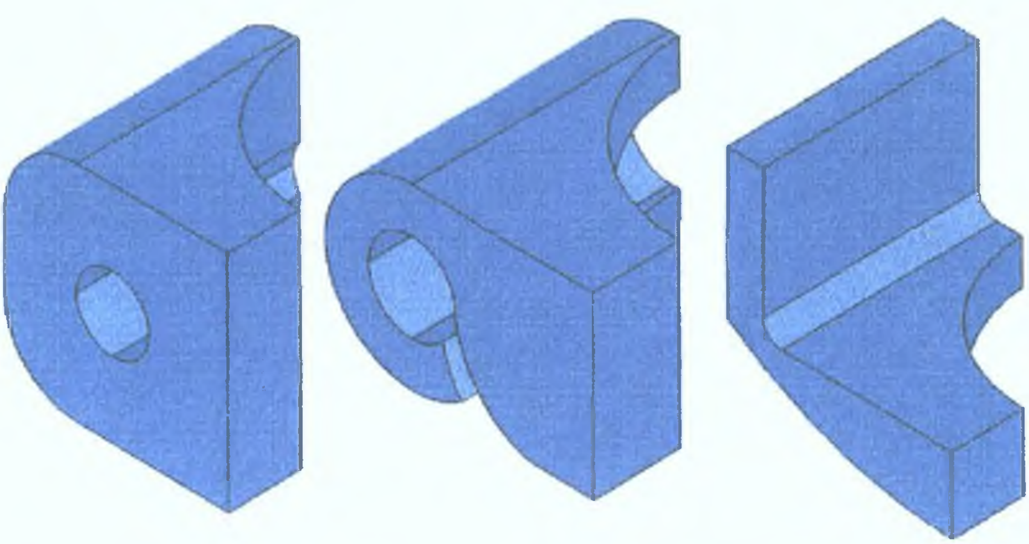


Figure 4.9 Examples of Some Designs Used, taking the symmetry model into account

There are a number of basic assumptions made while using the Finite Element Method dealing with the geometry, properties, mesh and boundary conditions of each model These are

- The material used is homogenous and isotropic, i e the model is of one material only and the material properties are the same in all directions
- The material behaves in a linear fashion and the boundary conditions do not change during the simulation

4 2 1 Elements

Once the fastenerods were modelled in ANSYS, other aspects of the finite element analysis had to be considered The type of element that would be used was the first of these considerations (Fig 4 10) There are a number of element types available in ANSYS that could be considered for the models [Ansys Help Manuals] These are

Table 4 1 Tetrahedral Elements

Tetrahedral Solids
Solid92 – 10 node structural solid
Solid187 – 10 node structural solid

Table 4 2 Solid Elements

Tetrahedral Solids
Solid185 – 8 node structural solid
Solid186 – 20 node structural solid
Solid45 – 8 node structural solid
Solid95 – 20 node structural solid

For the purposes of this analysis, an independent study of the different types of elements was undertaken for the flat design The element type that was found to be suitable for this model could then be used for the other models as they were comparable in geometry

Finite elements used in meshing solid parts can be either linear or parabolic Linear, or lower order, elements have corner nodes only and their edges are straight Examples of these would be the 4 noded pyramid or 8 noded brick Parabolic, or higher order, elements have, in addition to corner nodes, a mid-side node along each side creating curved edges rather than a straight line Examples of these would be the 10 noded tetrahedral or 20 noded

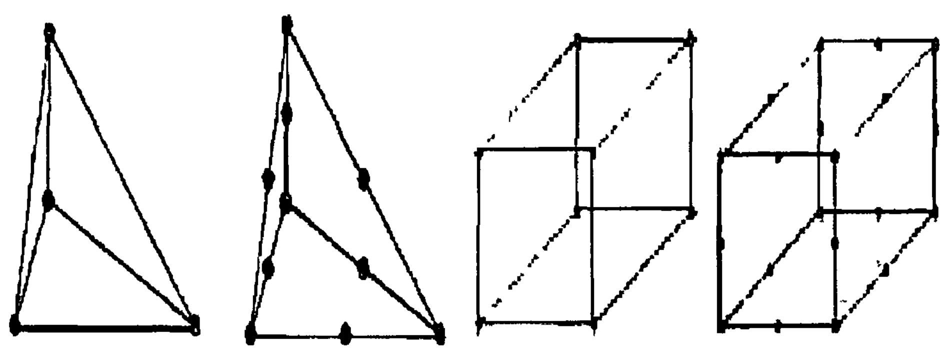


Figure 4 10 Element Types

4 2 2 <u>Meshing</u>

Meshes were generated with all of these element types using the flat design so that a graphical comparison could be made (Fig 4 11) The following meshes were obtained Although some of these meshes look very similar there were problems with the generation of some of them The ANSYS software warns that quadratic elements give better solutions than linear elements

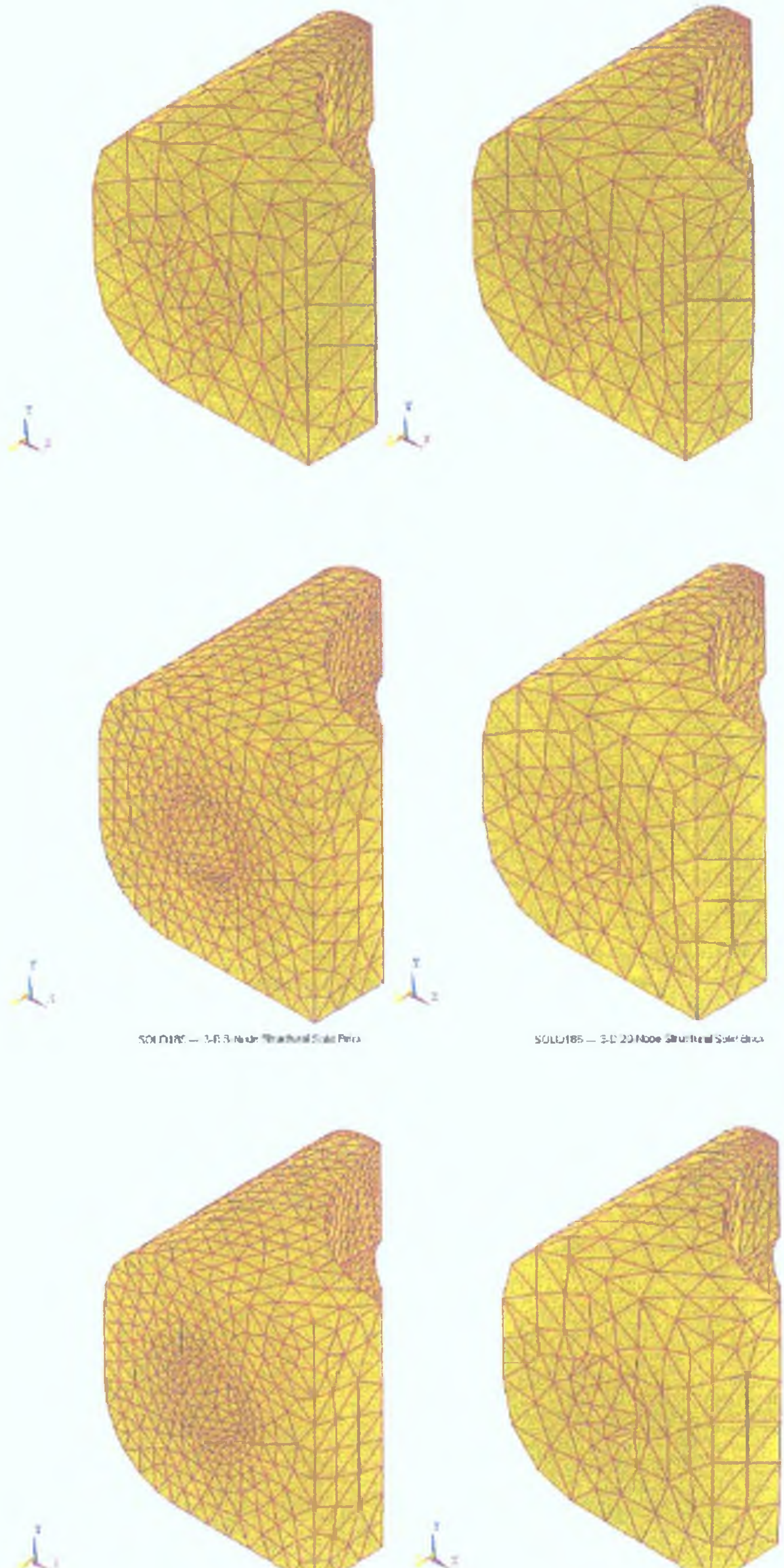


Figure 4.11 Meshes of Various Element Types

Linear tetrahedral elements are constant strain elements and tend to behave in an overly stiff fashion compared to the parabolic tetrahedral As a result many more linear tetrahedral elements are required to approach the accuracy of the second order tetrahedral mesh

The higher order elements would be more suitable in the analysis of these models as there are curved and filleted surfaces in all the designs For the same mesh density, parabolic elements provide better results because they represent the models curved boundaries more accurately, as well as providing better mathematical formulations The down side is that parabolic elements require much greater computational resources than linear elements and so the process takes longer For the tests done on the model the linear elements proved to be less accurate, with ANSYS producing warnings regarding the accuracy of the model, than comparable parabolic elements

From this point, it was decided that the preferred choice of element type would be the 10-noded tetrahedral or 20-noded brick (Figs 4 12 and 4 13) It can be seen from the above meshes that the SOLID187 tetrahedral mesh is very similar to the SOLID95 brick mesh When loads and boundary conditions were applied to each of the models with these element types, the following stress results were obtained Both the 20-noded brick and the 10-noded tetrahedral elements provide good stress results for reasonable meshes with a comparable number of nodes

Although the stresses on both of the following models are represented by the same patterns and both meshed and solved without too much difficulty, the SOLID187 tetrahedral element was chosen

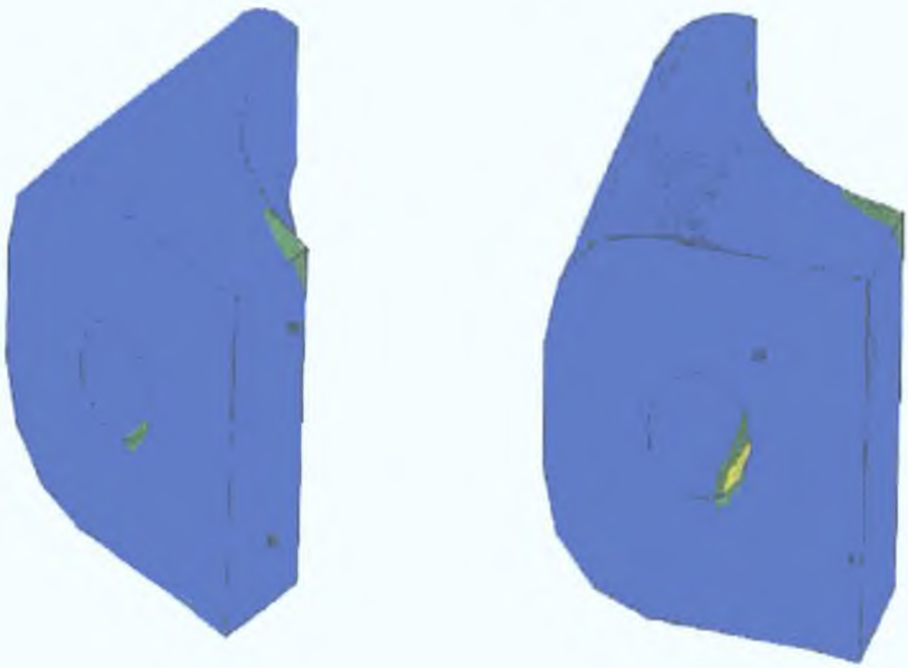


Figure 4.12 Isometric View of Stresses on the 20-node brick and the 10-node Tetrahedral

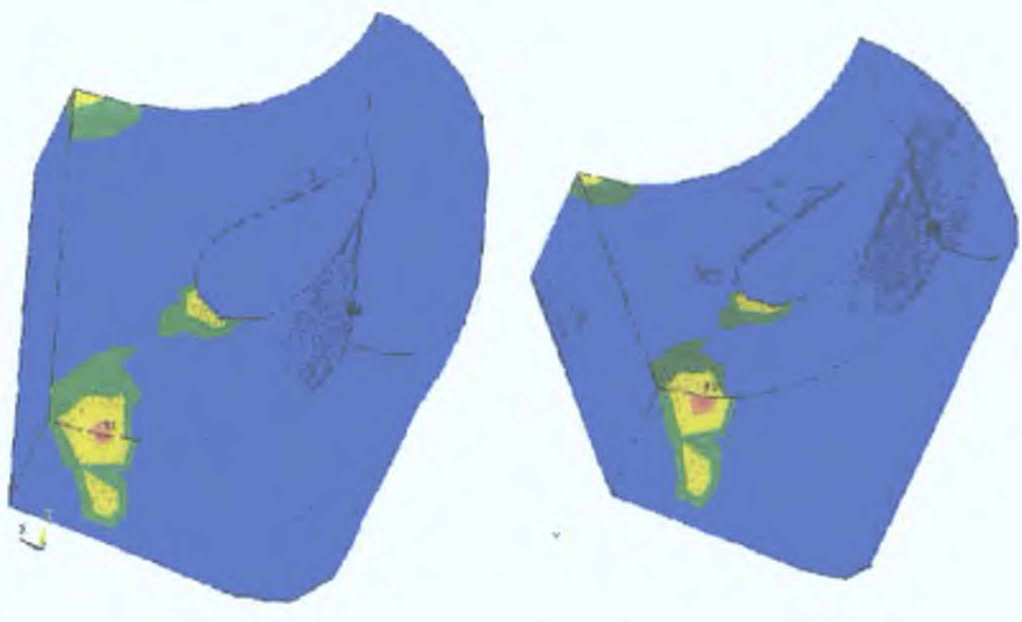


Figure 4.13 Back View of Stresses on the 20-node Brick and the 10-node Tetrahedral

This was because, in general, with automatic brick meshers, meshing complicated geometry will introduce distorted or transitional elements in unexpected zones, thus considerably affecting the accuracy of the results. Also the other models that would have to be solved had to be considered here as well as any changes in these models for optimisation Taking all this into account the SOLID187 tetrahedral element was chosen to mesh the models

4 2 3 Materials

The material being used for the initial designs is stainless steel 316L (Table 4 3) The first implanted stainless steels were types 304 and 316 Stainless steels are regularly used in medical products as they have good corrosion resistance and they are biocompatible All Austenitic stainless steels have excellent clean-ability and hygiene characteristics Compared with other steels and aluminium, the corrosion resistance is very good, which is mainly due to the presence of chromium (at least 11% by weight) to the steel and the subsequent presence of chromium oxide on the outer surface This surface layer of chromium oxide protects the base metal from further oxidation Compared with titanium and cobalt alloys, stainless steels are readily available and relatively inexpensive Grade 316L has been used for implantation and fixation because of its biocompatibility

Table 4 3 Chemical Analysis

Chemical Analysis % (max unless noted)		
Name	**Chemical Symbol**	**%**
Carbon	C	0 03
Manganese	Mn	2 00
Phosphorous	P	0 05
Sulphur	S	0 03
Silicon	Si	1 00
Chromium	Cr	16 00-18 00
Nickel	Ni	10 00-14 00
Molybdenum	Mo	2 00-3 00
Others		

Table 4.4 Physical Properties

Physical Properties	Units
Density	8000 kg/m3
Hardness, Rockwell B	79

Table 4.5 Mechanical Properties

Mechanical Properties	Units	Comments
Tensile Strength, Ultimate	560MPa	
Yield Strength	621MPa	
Modulus of Elasticity	193Gpa	In tension
Elongation %; break	50%	In 50 mm

This material is assumed to be isotropic and homogenous, that is, it has the same properties in all directions; specifically, equally elastic in all directions and is made up of the one material. The properties that are required as inputs into ANSYS are:

- Young's Modulus
- Poisson's Ratio
- The shear modulus defaults to EX/(2(1+NUXY)). This is calculated by the ANSYS program.
- Density

4.2.4 Final Mesh Design

All the models were meshed by using the automatic mesh generation facility in Ansys (Figs. 4.17 – 4.23). The mesh options used varied slightly between the models. The mesh used for all the models was a free, tetrahedral mesh of the volume. The default mesh controls that the ANSYS programme use were adequate to produce a mesh for the model of the Flat Design and for the model of the Up-turned Design. The mesh for the In-turned Design was also a free, tetrahedral mesh of the volume. But for this model the smart-sizing option was also used. Smart sizing is an automatic meshing tool in ANSYS. This enabled the mesher to produce better-shaped elements during the automatic meshing operation. Smart-sizing is helpful as it computes the estimated element edge lengths for all the lines in the volume. These edge lengths are then refined for curvature. As this model was more complicated than the other two, this option was necessary.

There are a number of factors that control mesh quality. These are the class of the geometry; the mesh refinements at transitions in the geometry; and the ability of the software to correct poorly shaped elements. The geometry should not have any sliver surfaces or very short edges. Using local mesh refinement, more nodes can be put in areas of high stress to provide the correct overall model stiffness. The results of the meshing operations for all the models can be seen in the following figures:

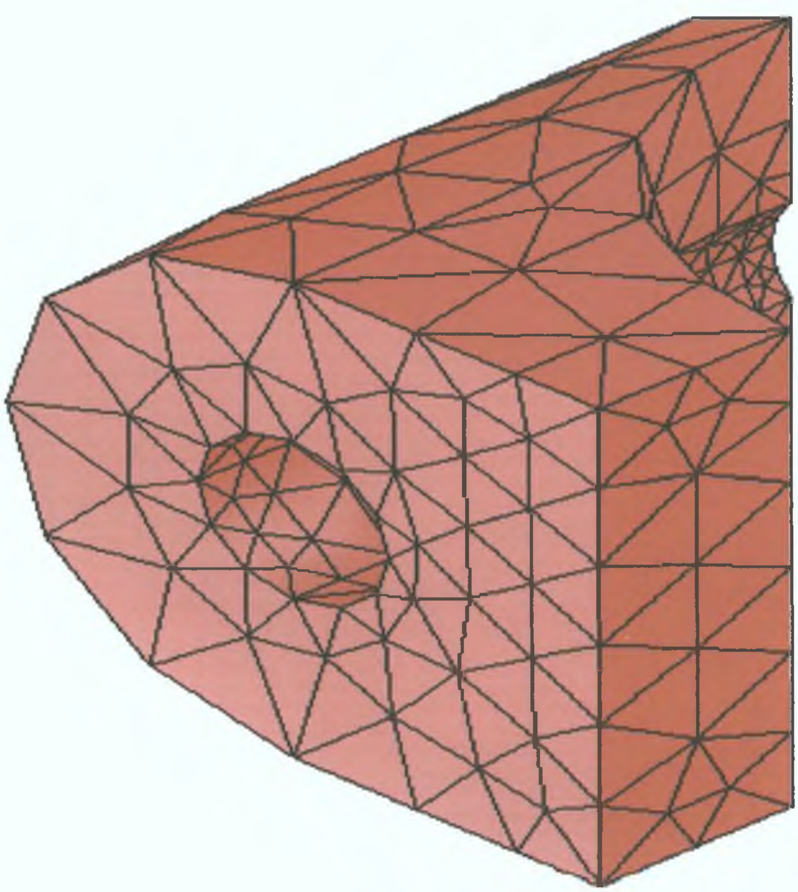


Figure 4.14 Flat design

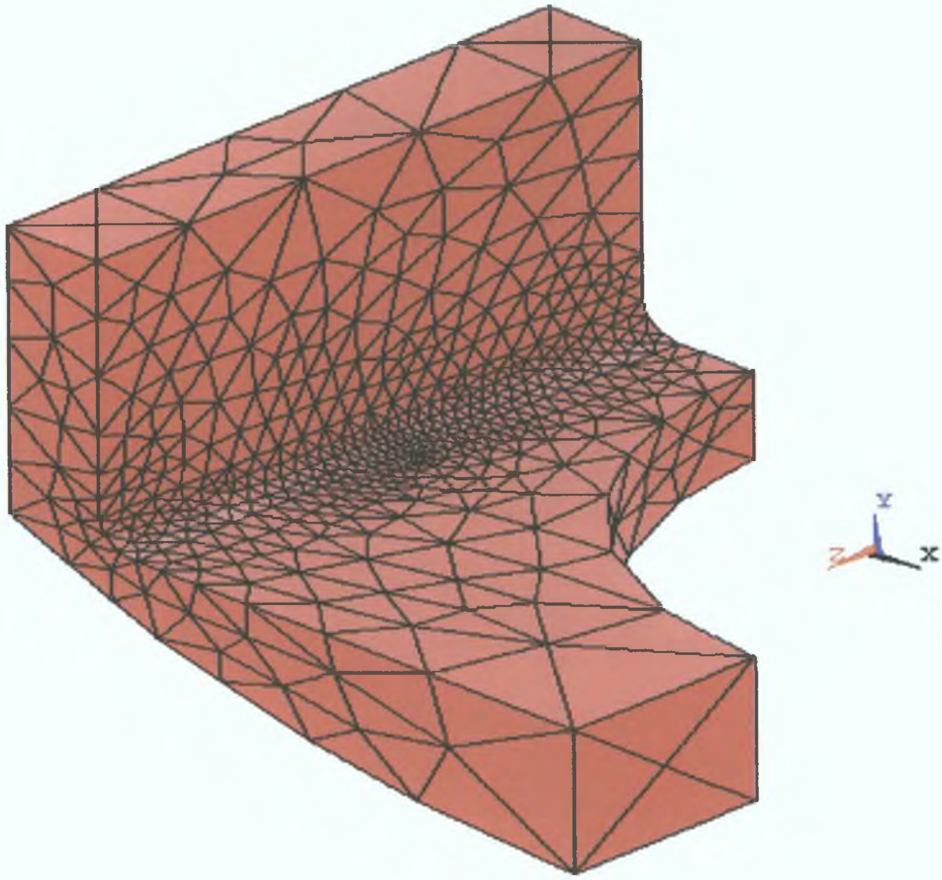


Figure 4.15 Up-turned

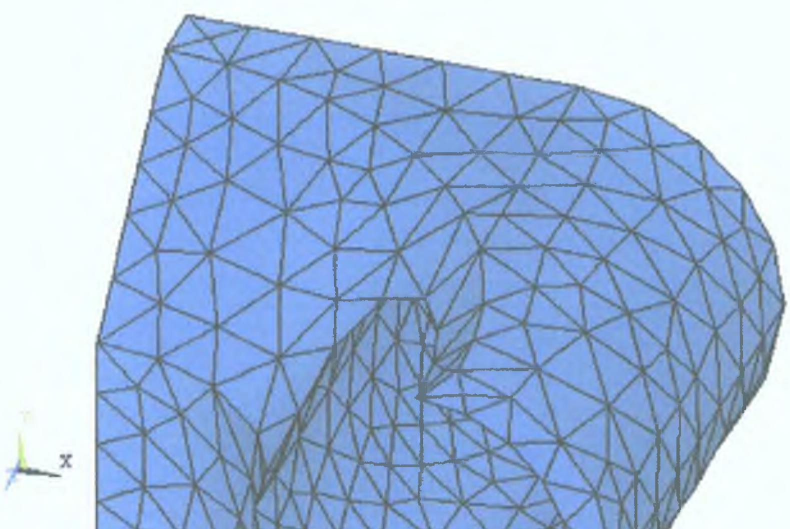


Figure 4.16 Closed Over Round Bottomed

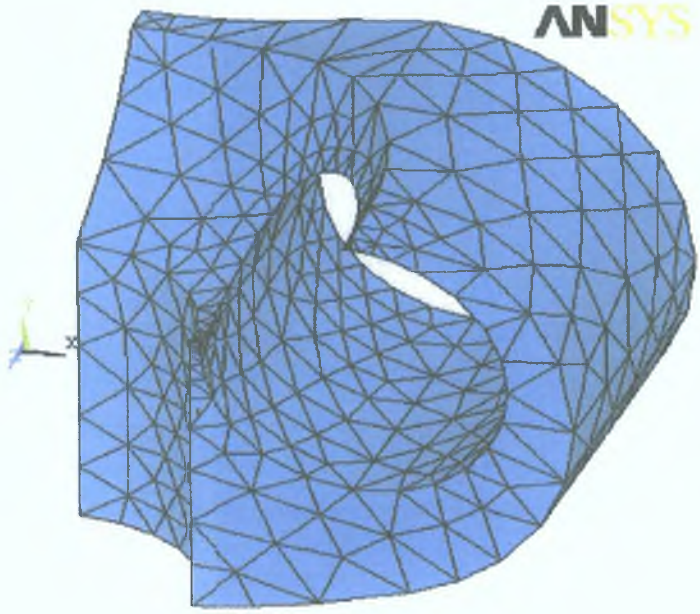


Figure 4.17 Banana

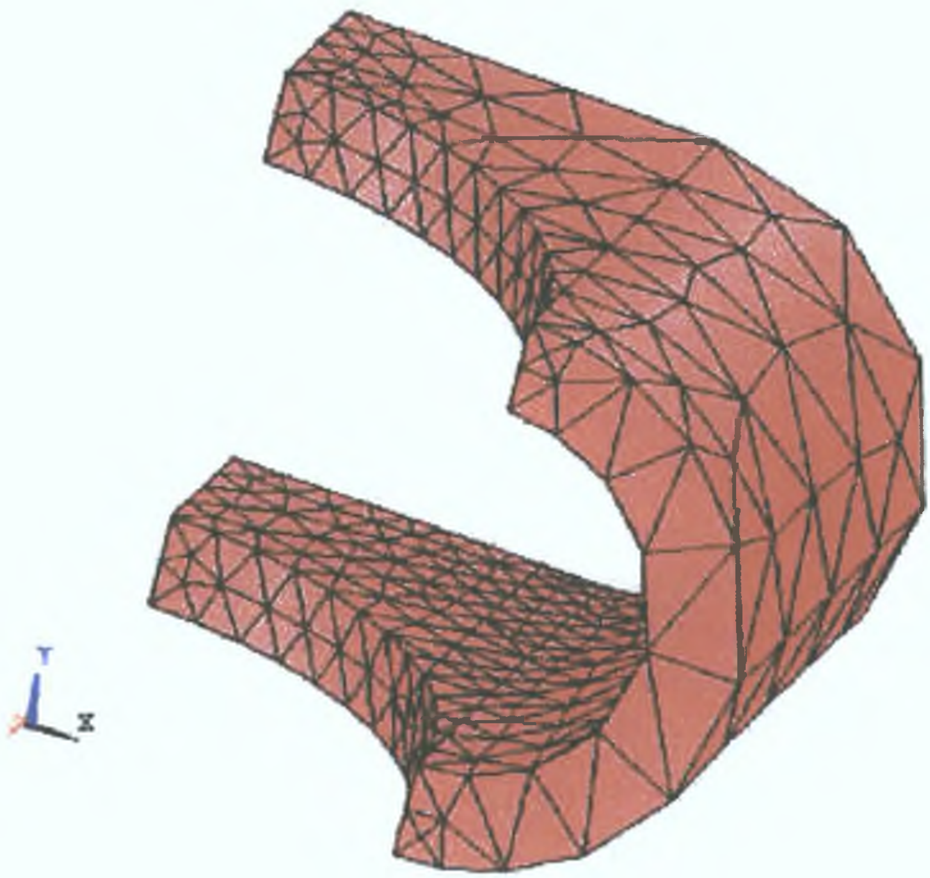


Figure 4.18 Hollow

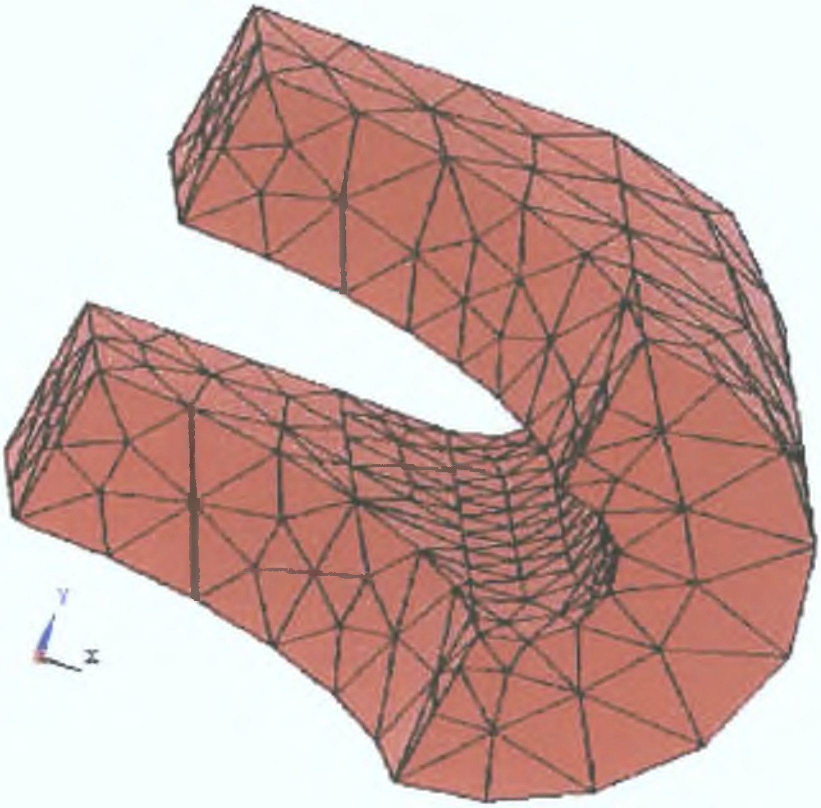


Figure 4.19 Hollow Design 2

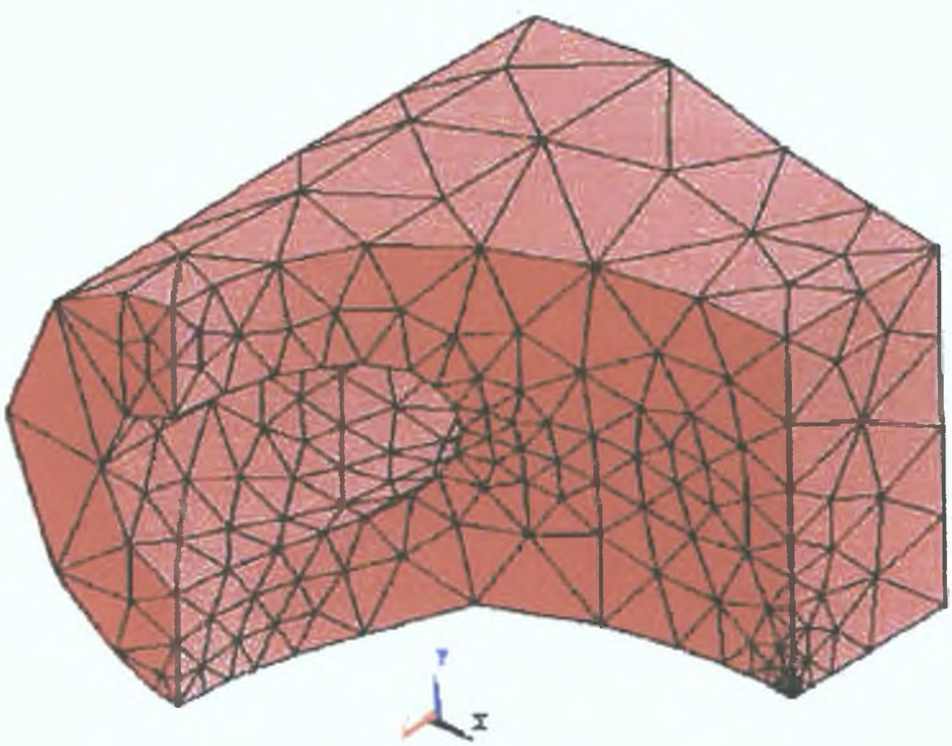


Figure 4.20 End Isolate

Some problems encountered when solving the models were elements turning inside out and elements exceeding the software warning limits These were generally due to initial modelling errors and were overcome by re-modelling the design Smart-sizing the meshes was also useful for eliminating error or warnings

Boundary conditions are the conditions applied to the model in order to represent everything about the system that hasn't already been modelled These conditions include constraints and loads on the model

The boundary conditions applied to the models were similar as all the models were split into quarters as a result of their symmetry (Figs 4 24 - 4 30) All the models were constrained on the faces of symmetry to account for the symmetrical portions that were being omitted from each of the models They symmetry faces were constrained in planes normal to the face The models were also constrained in all directions at the point where the fastenerod would be in contact with the bone The loads applied to each of the models consisted of a magnitude, direction and distribution The type of load applied to all the models was a pressure load A pressure load is applied normally to the surface being loaded In the following figures, the arrow down on the face represents the location of the load being applied to each of the models The triangles / arrows represent the location of the point of contact of the bone and the fastenerod The symmetry constraints are not shown in these figures but are applied to each edge of symmetry

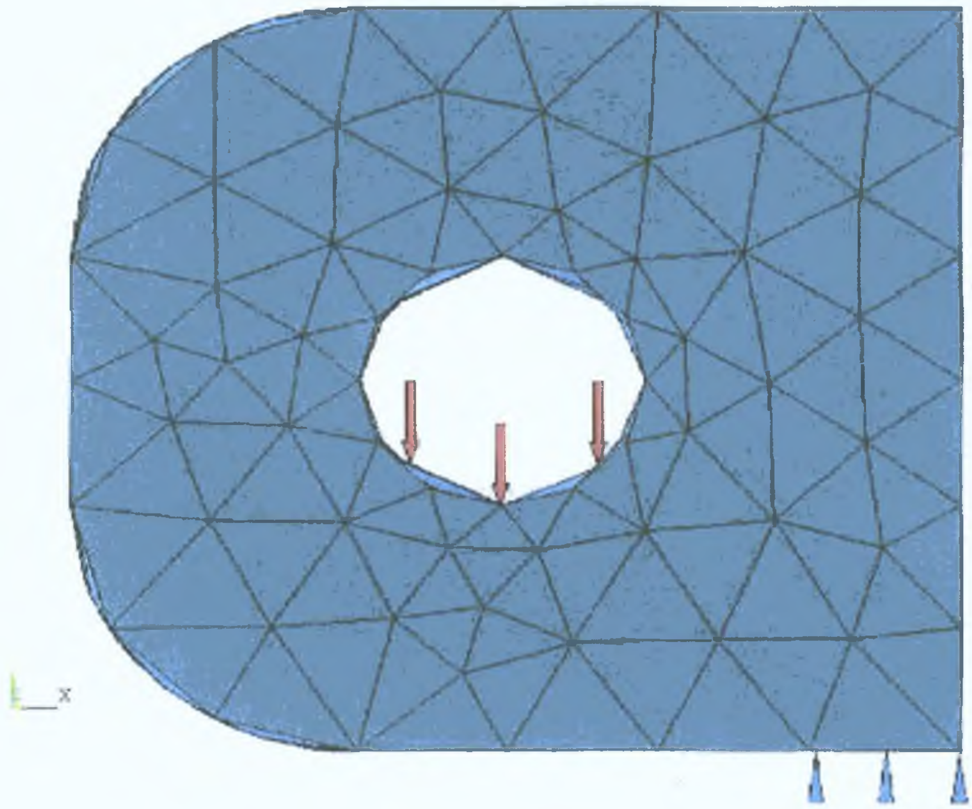


Figure 4.21 Boundary Conditions and Load Application for 'Flat Design'

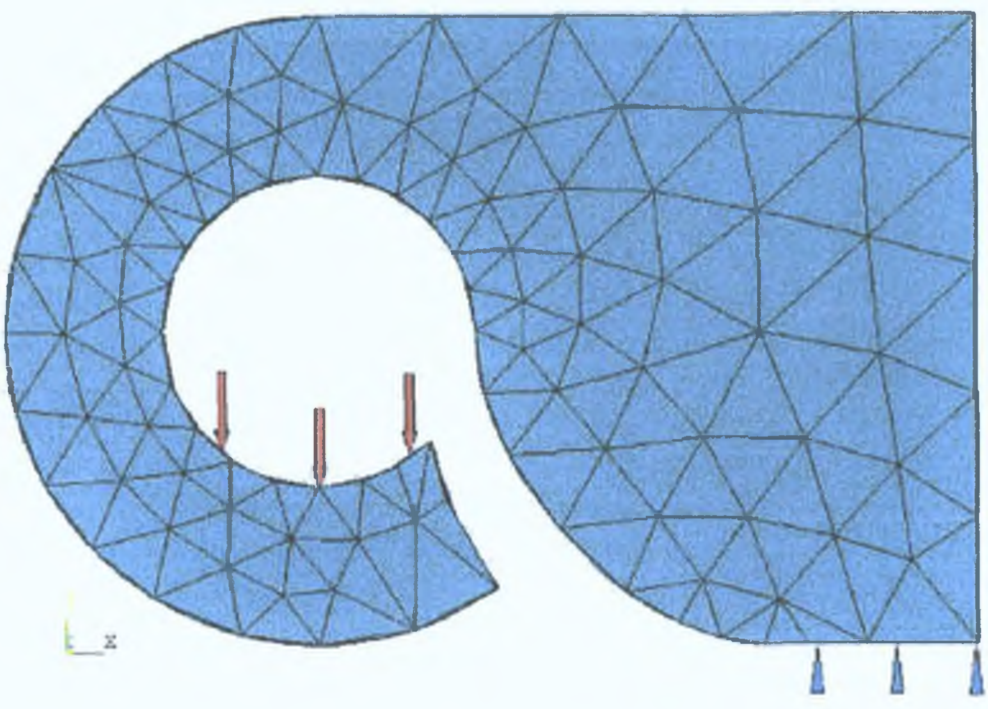


Figure 4.22 Boundary Conditions and Load Application for 'In-turned Design'

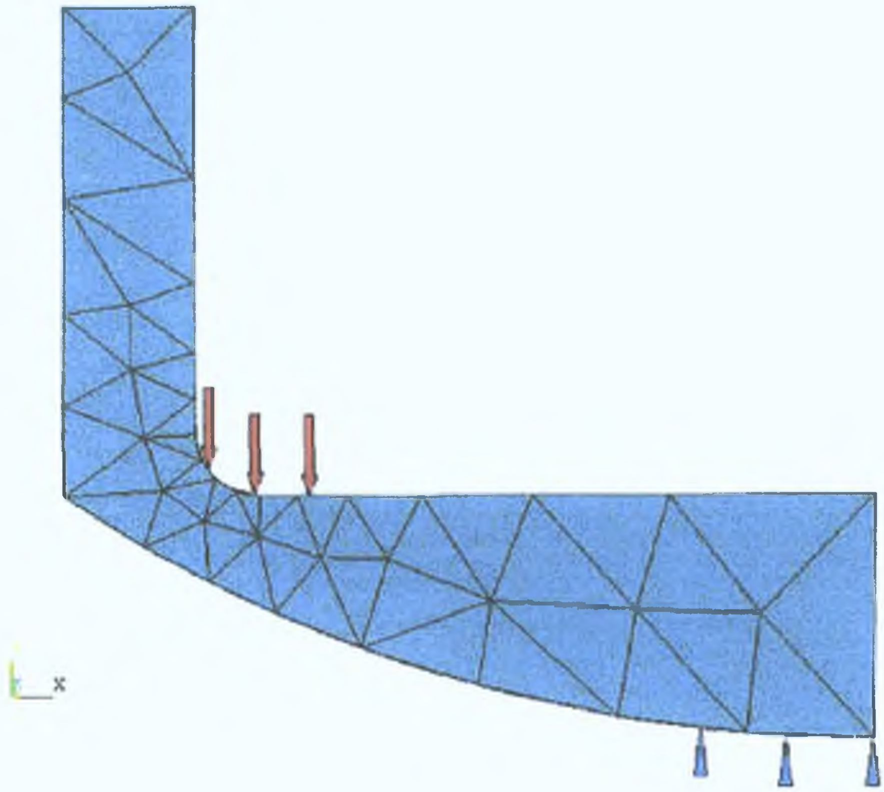


Figure 4.23 Boundary Conditions and Load Application for 'Up-turned Design'

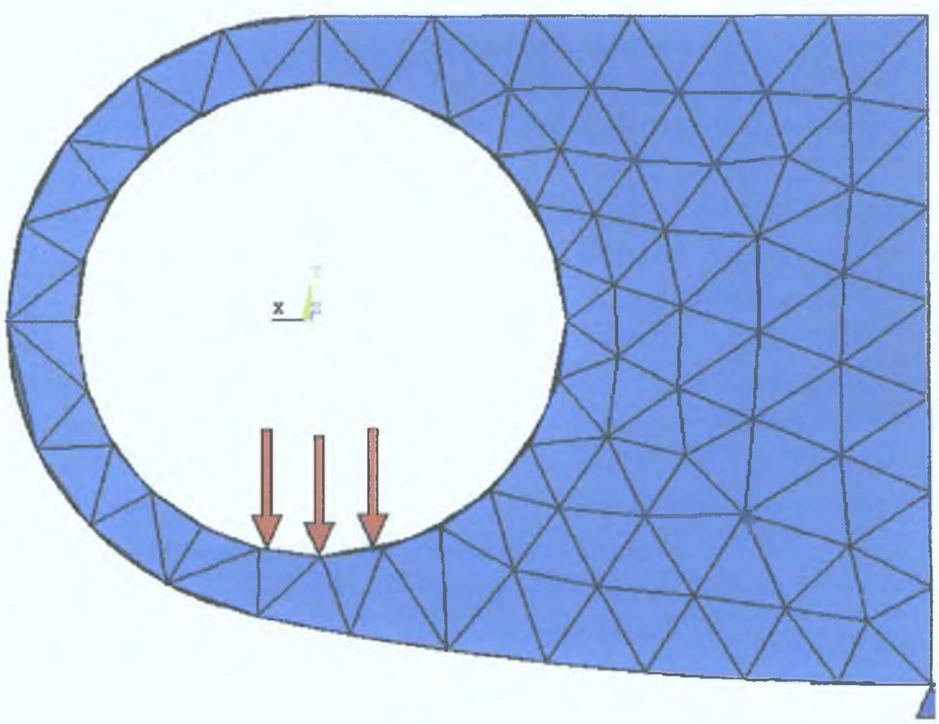


Figure 4.24 Closed Over Round Bottomed

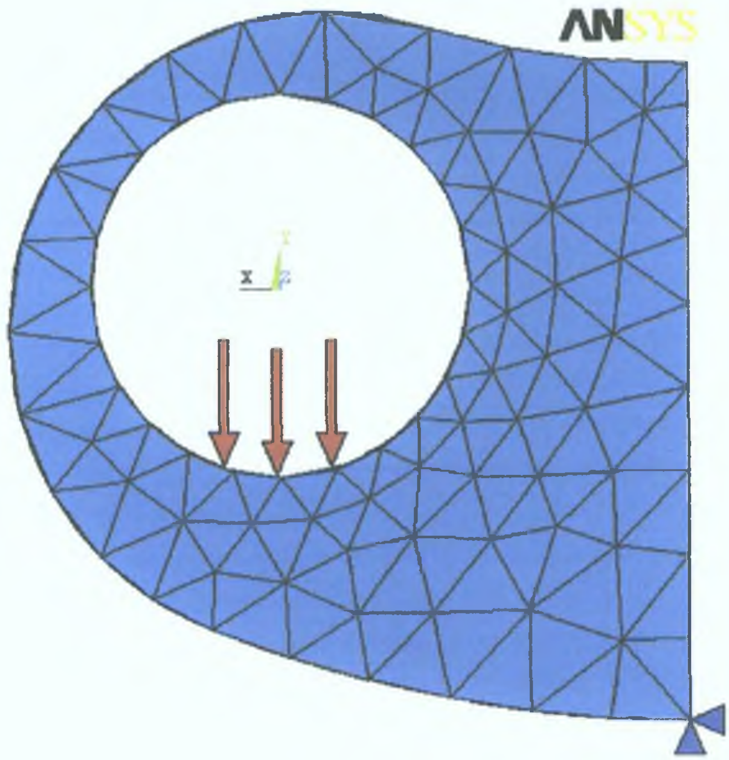


Figure 4.25 Banana

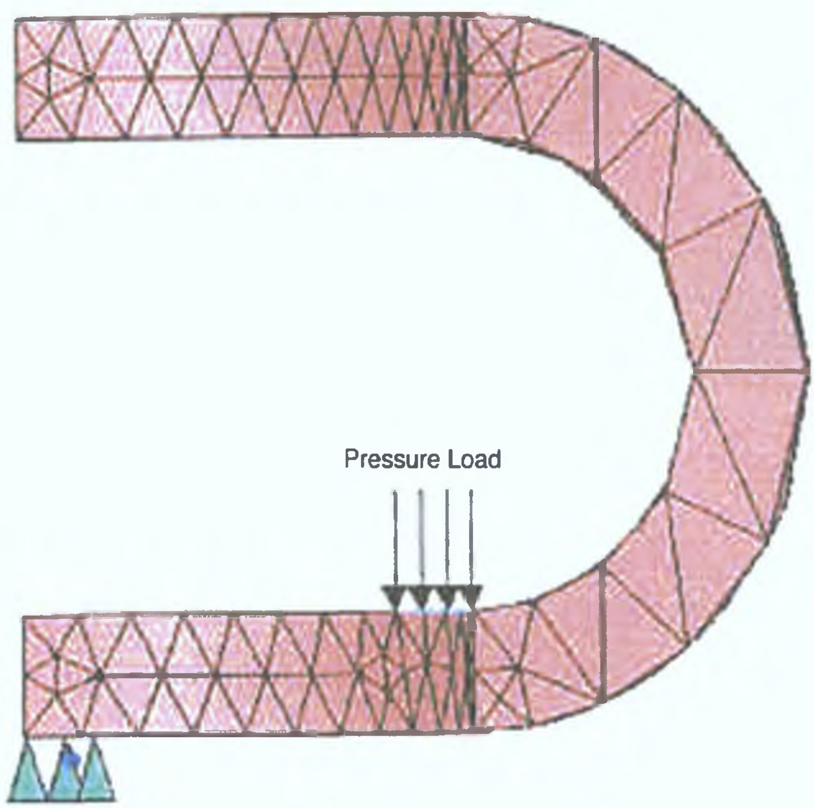


Figure 4.26 Front View of Model Illustrating Loading Conditions Used

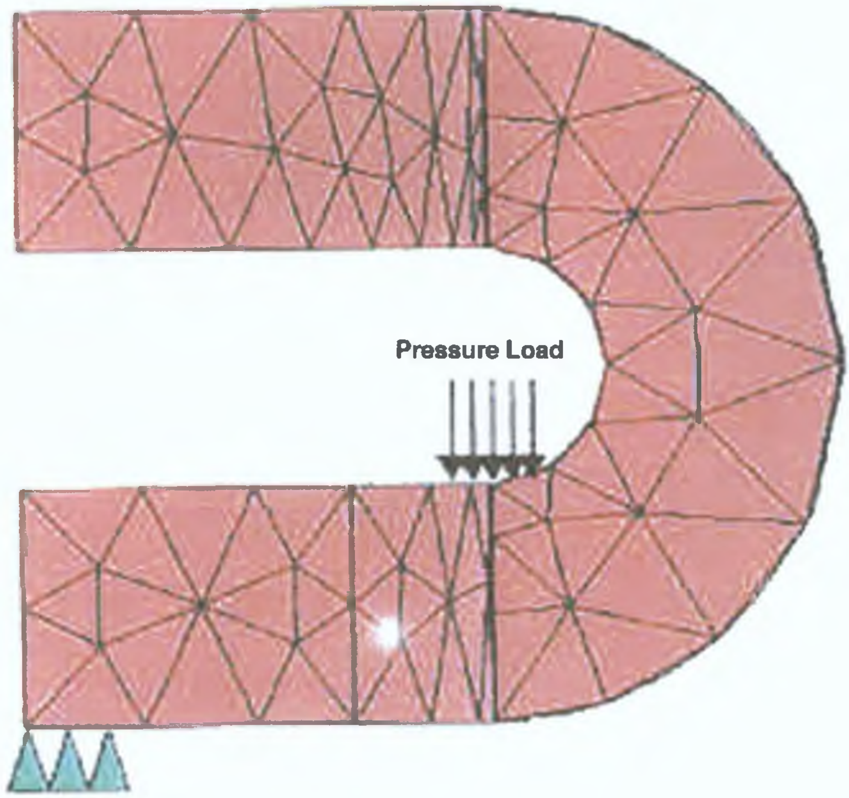


Figure 4.27 Hollow Design 2

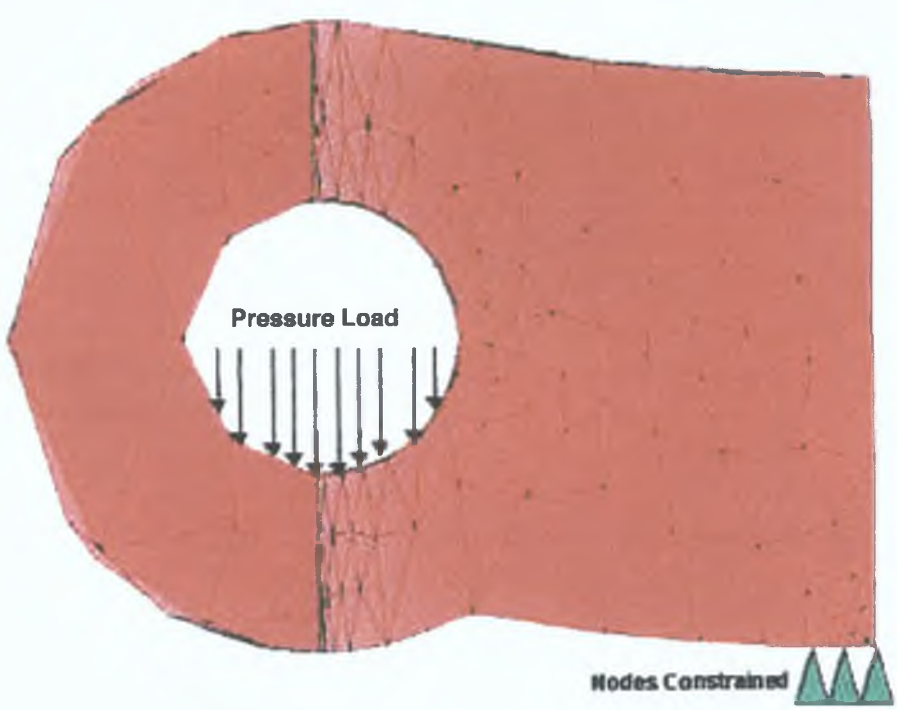


Figure 4.28 End Isolate

4.3 Results

Flat Design

As mentioned earlier, the applied pressure load was increased until the yield stress of the material was exceeded. Figure 4.29 shows the distribution of von-Mises stress in the flat design just before yielding occurs. The applied pressure load at this point was 112.5 MPa.

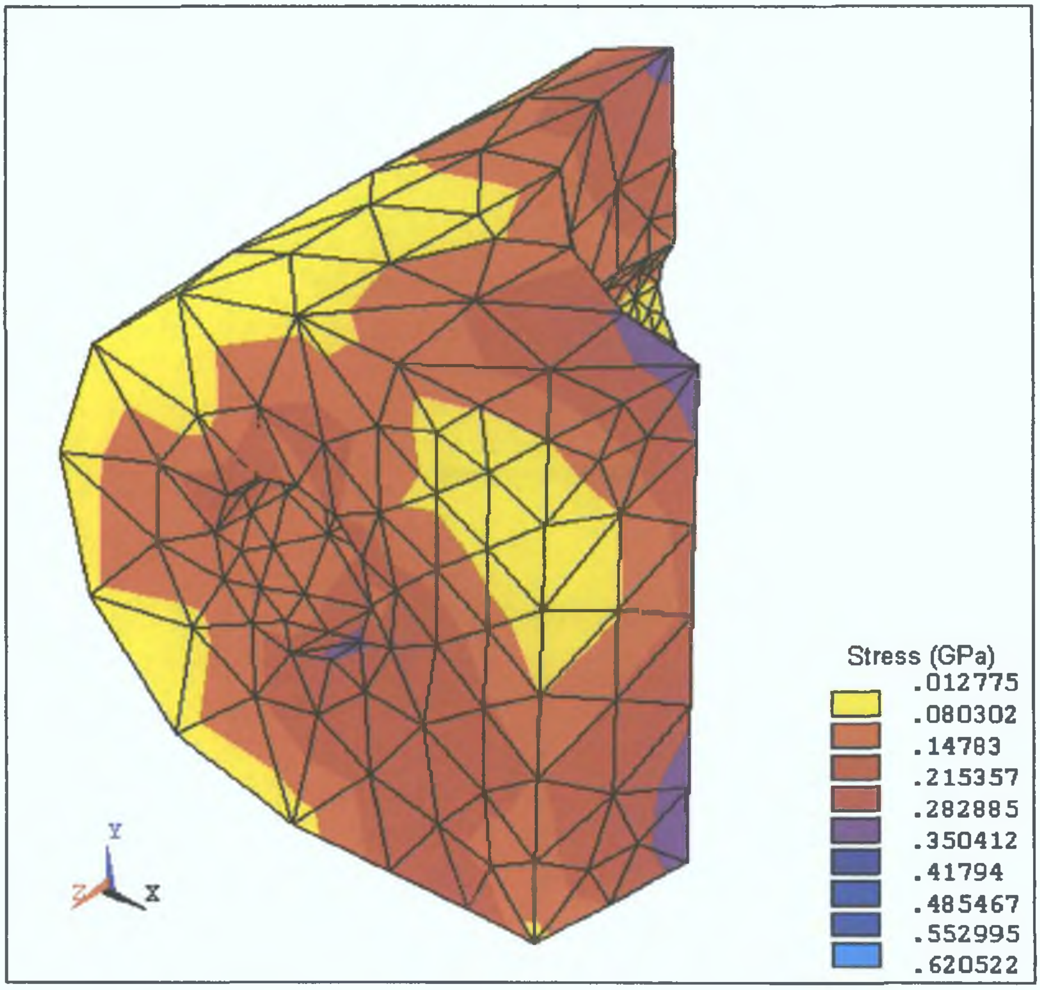


Figure 4.29 Distribution of Von-Mises Stress in the Flat design Just Before Yielding Occurs

von-Mises stress in a widely used method of determining when yielding will occur in three dimensional problems. The von-Mises stress in 3-D, σ_{vm}, is given by:

$$2\sigma_{vm}^2 = (\sigma_1 - \sigma_2)^2 + (\sigma_2 - \sigma_3)^2 + (\sigma_3 - \sigma_1)^2$$

Where: σ_1 = First principal stress
σ_2 = Second principal stress
σ_3 = Third principal stress

Figure 4.30 shows an alternative view of the model, clearly showing the area of maximum stress. It is in this region that yielding would be expected to occur. It is possible that the stress concentration here may have been influenced by the manner in which the boundary conditions were applied, specifically the fact that the nodes in this region were constrained in all directions. It should be mentioned, however, that this result agrees well with experimental investigations. During experimental tests it was in this region that yielding and subsequently failure occurred with the application of high load.

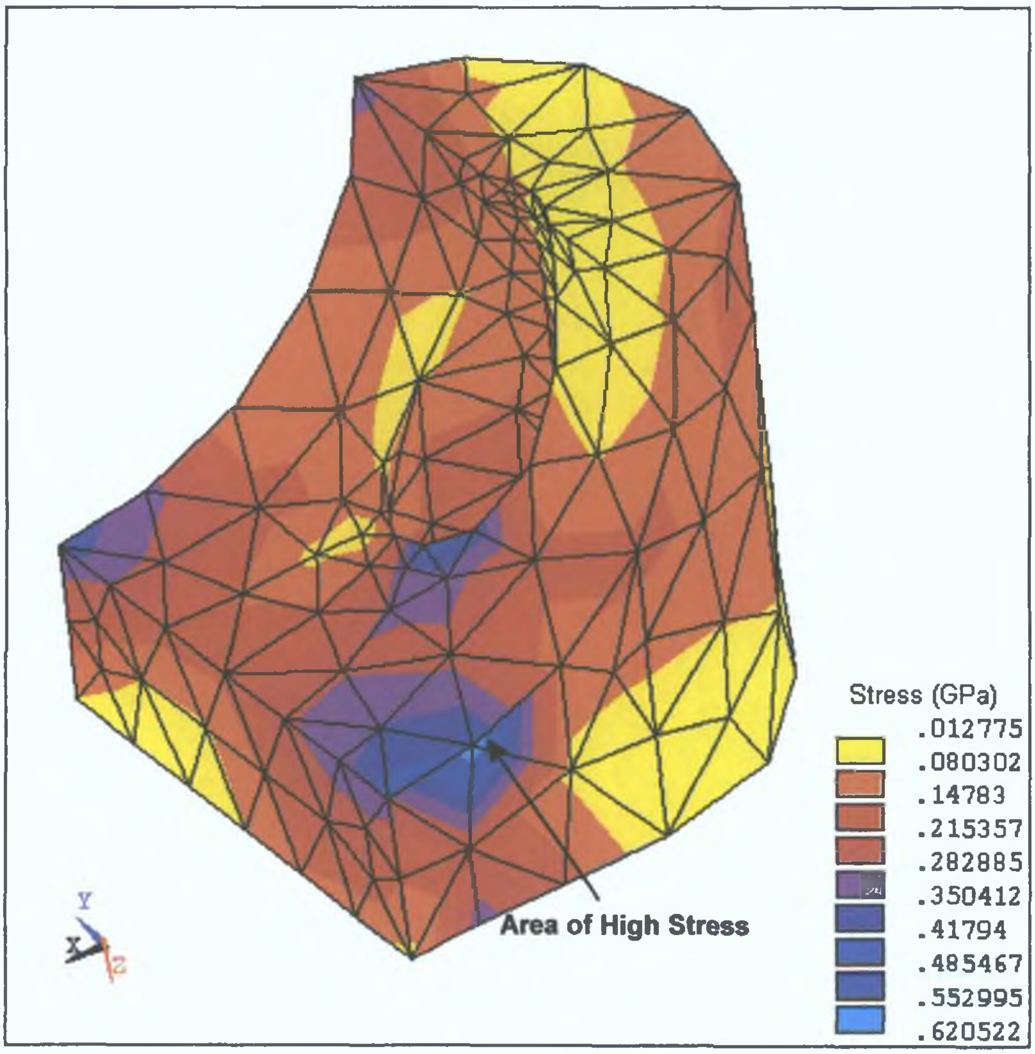


Figure 4.30 Alternative View of Flat design clearly showing area of High Stress

Upturned Design

Figure 4.31 shows the distribution of von-Mises stress in the upturned design just before yielding occurs. The applied pressure load at this point was 64.5 MPa. An alternative view of the model is shown in Figure 4.32 which clearly shows the area of maximum stress. It is in this region that yielding and subsequently failure would be expected to occur.

It can be seen that the area of maximum stress occurs in a similar area as was experienced in the previous analysis. Again, it is in this region that failure occurred during experimental investigations. The applied load in this case is much smaller than in the previous simulation, thus indicating that this design is not as successful in resisting load when compared to the previous simulation. The maximum load before yielding occurs for the upturned design was approximately 30% of the load allowed by using the flat design.

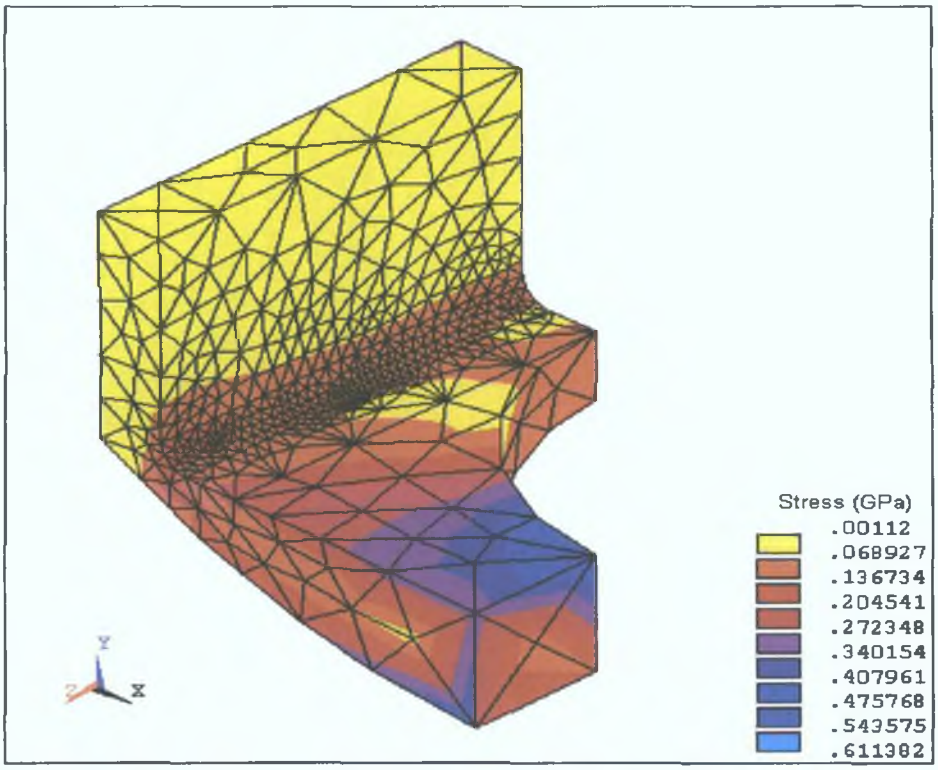


Figure 4.31 Distribution of Von-Mises Stress in the Up-turned Just Before Yielding Occurs

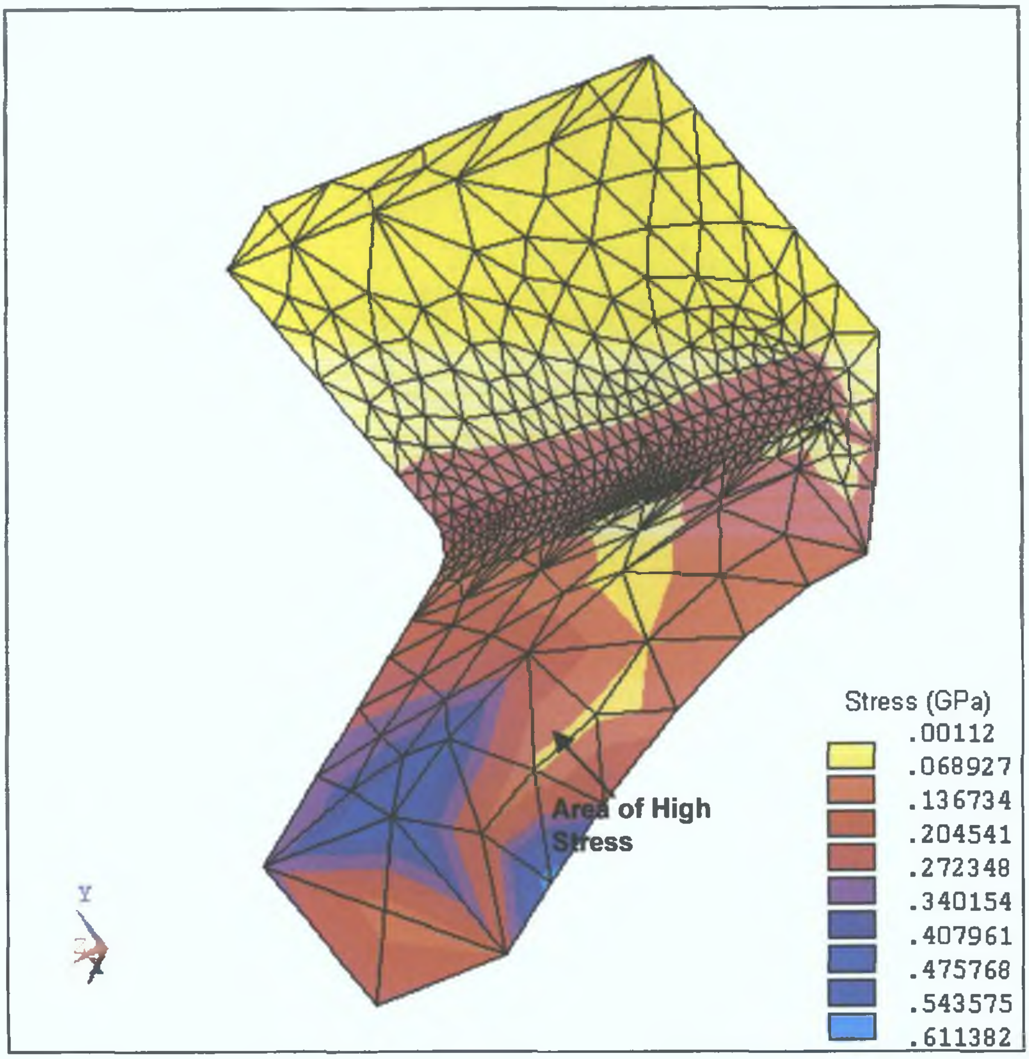


Figure 4.32 Alternative View of Upturned Design clearly showing area of High Stress

In-turned Design

Figure 4.33 shows the distribution of von-Mises stress in the In-turned design just before yielding occurs. The applied pressure load at this point was 17.2 MPa. This was approximately 50% of the load allowed by using the upturned design and 15% of that allowed by using the flat design. The maximum stress was experienced in a different location to the previous two analyses. The location of maximum stress is detailed in Figure 4.33. It can be seen that the maximum stress occurs in the bent over channels. This result is not surprising considering the thickness of the clip at this point. The results seem to indicate that further loading would bend the channels back and allow the wires to become free, thus rendering the screw grip redundant.

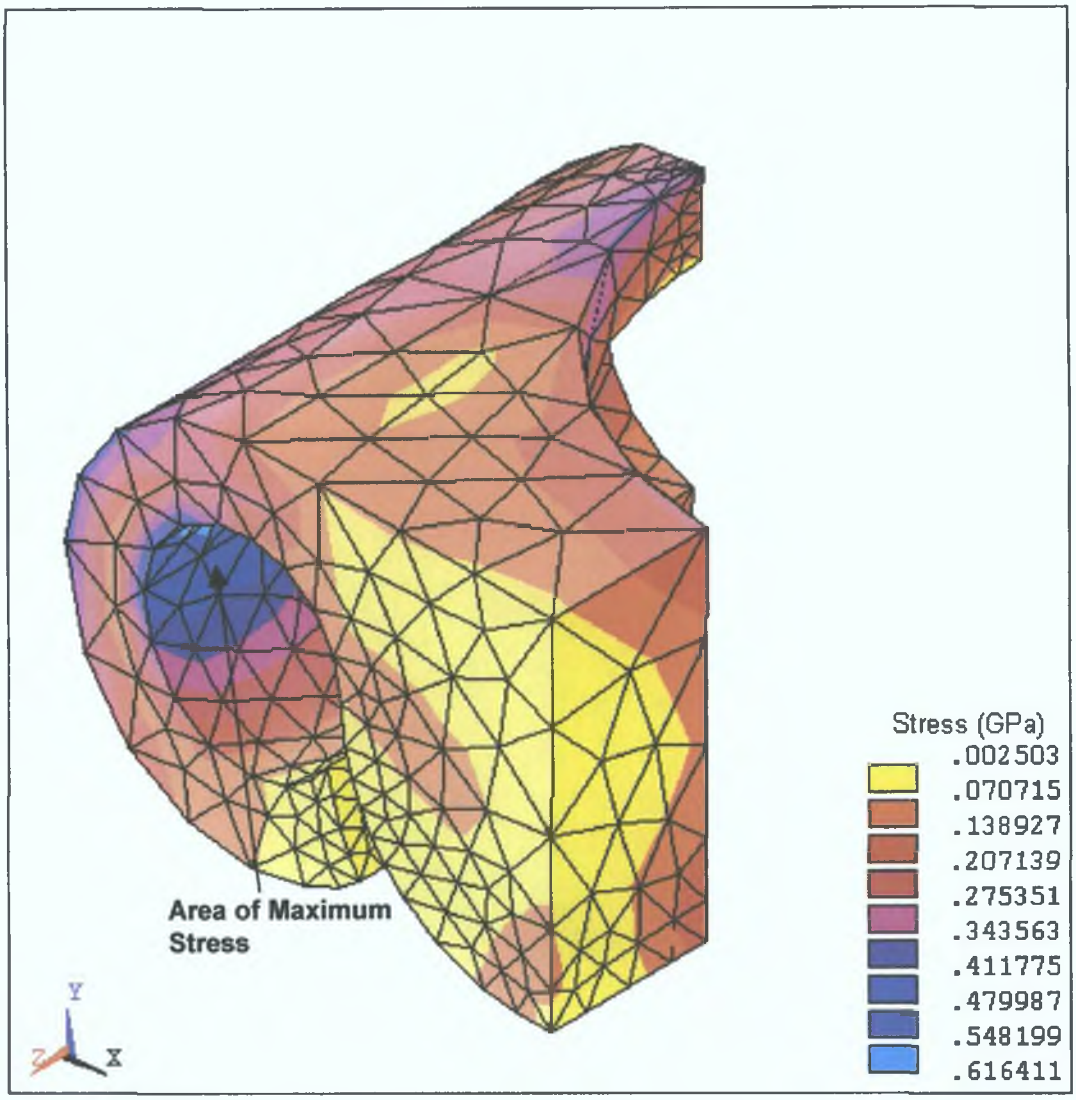


Figure 4.33 Distribution of Von-Mises Stress in the In-turned Just Before Yielding Occurs

Hollow Design 1

As mentioned earlier, the applied pressure load was increased until the yield stress of the material was exceeded. Figure 4.34 shows the distribution of von-Mises stress in the hollow fastenerod just after yielding had occurred. The applied pressure load at this point was 23MPa.

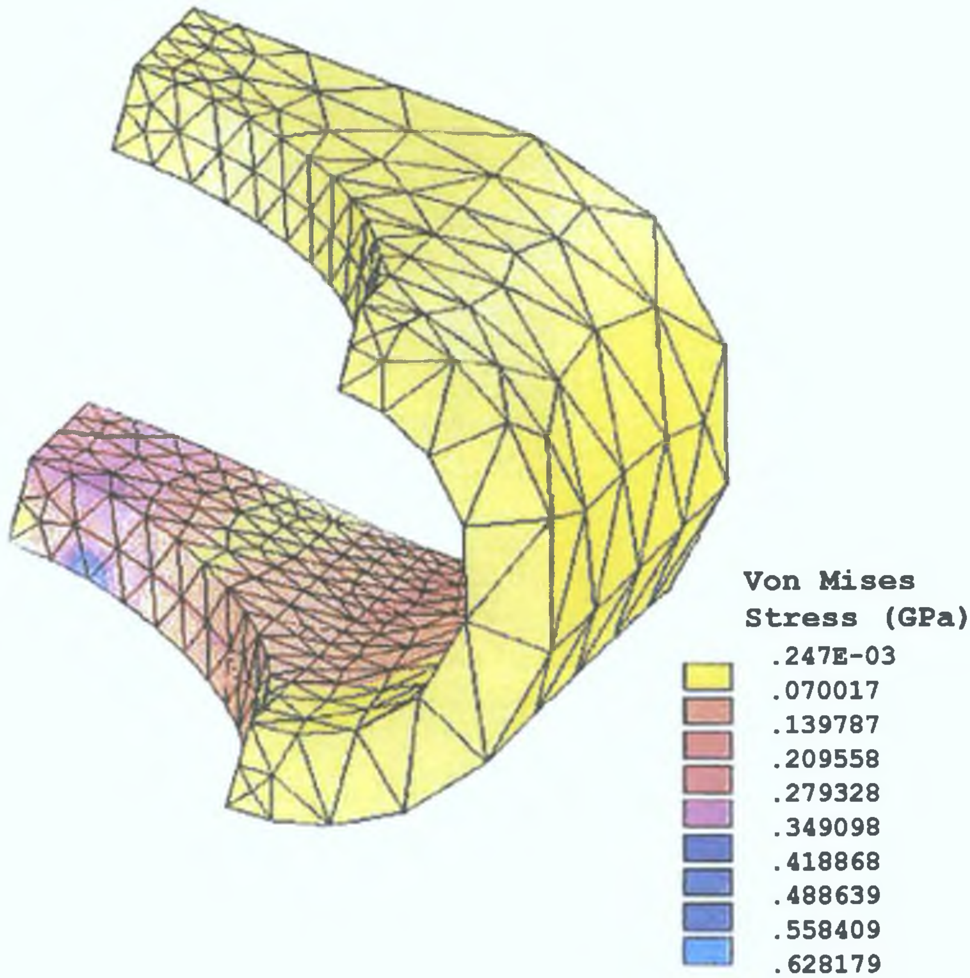


Figure 4.34 Distribution of Von-Mises Stress in the Hollow Design Just Before Yielding Occurs

The figure clearly shows the area of maximum stress. It is in this region that yielding would be expected to occur. It is possible that the stress concentration here may be influenced by the manner in which the boundary conditions were applied, specifically the fact that the nodes in this region were constrained in all directions.

Hollow Design 2

As mentioned earlier, the applied pressure load was increased until the yield stress of the material was exceeded. Figure 4.35 shows the distribution of von-Mises stress in the flat fastenerod just after yielding had occurred. The applied pressure load at this point was 60MPa.

The figure clearly shows the area of maximum stress. It is in this region that yielding would be expected to occur. It is possible that the stress concentration here may be influenced by the manner in which the boundary conditions were applied, specifically the fact that the nodes in this region were constrained in all directions.

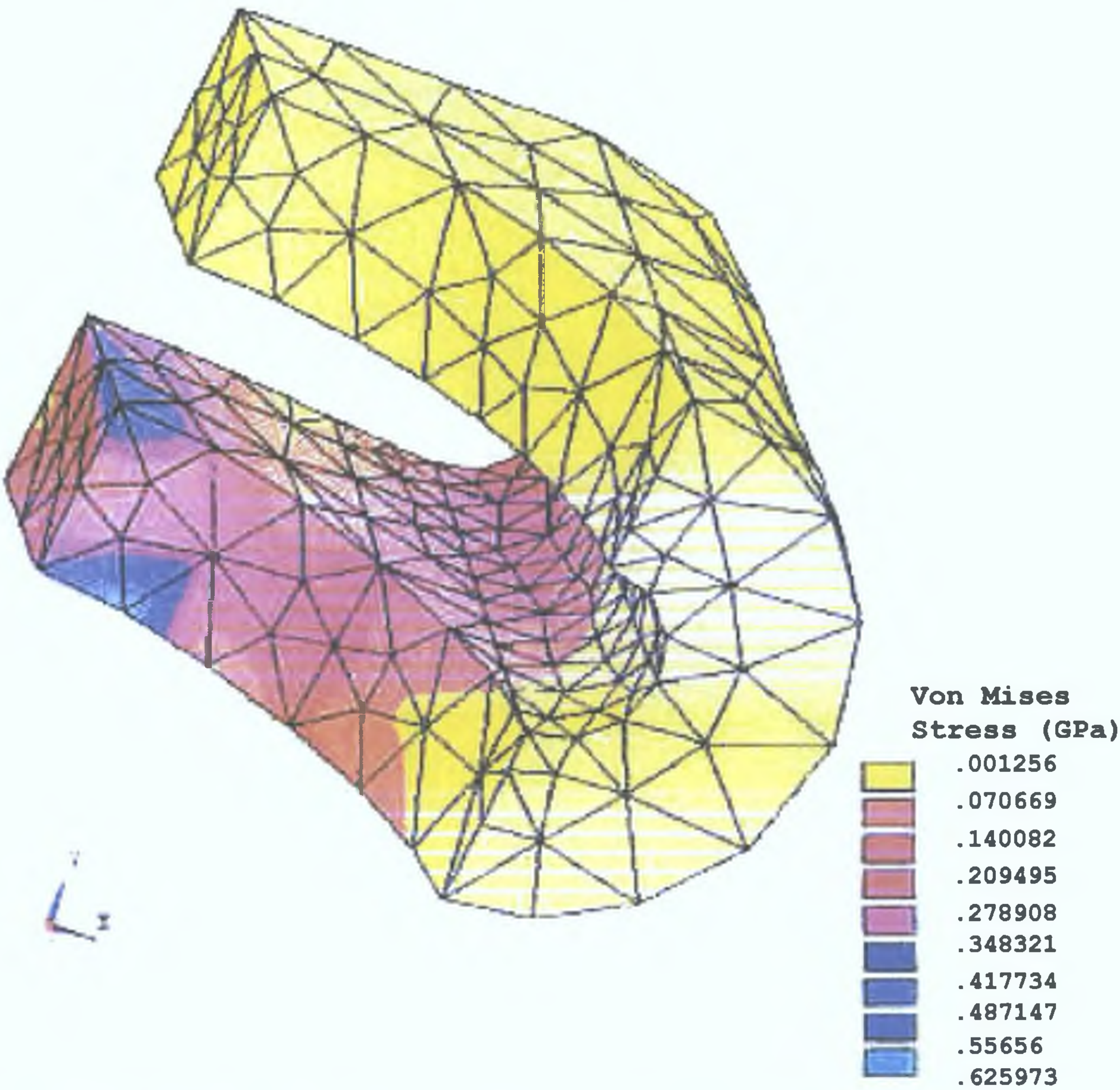


Figure 4.35 Distribution of Von-Mises Stress in the Hollow Design 2 Just Before Yielding Occurs

End Isolate Design

As mentioned earlier, the applied pressure load was increased until the yield stress of the material was exceeded. Figure 4.36 shows the distribution of Von-Mises stress in the End Isolate just after yielding had occurred. The applied pressure load at this point was 20 MPa. An alternative view of the model is shown in Figure 4.37, which clearly shows the area of maximum stress. It is in this region that yielding and subsequently failure would be expected to occur.

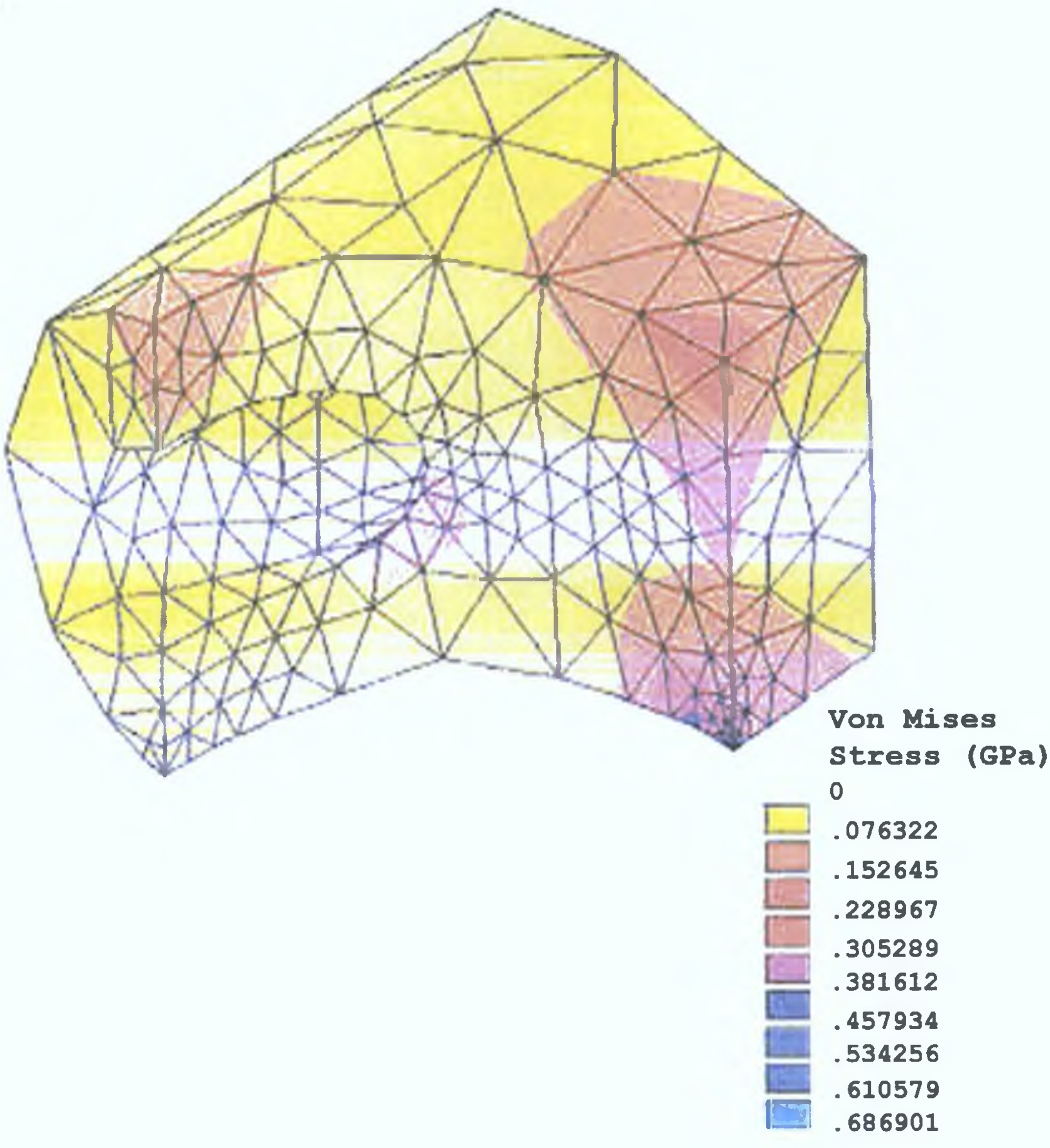


Figure 4.36 Distribution of Von-Mises Stress in the End Isolate Just After Yielding Occurs

It can be seen that the area of maximum stress occurs in a similar area as was experienced in the previous analysis.

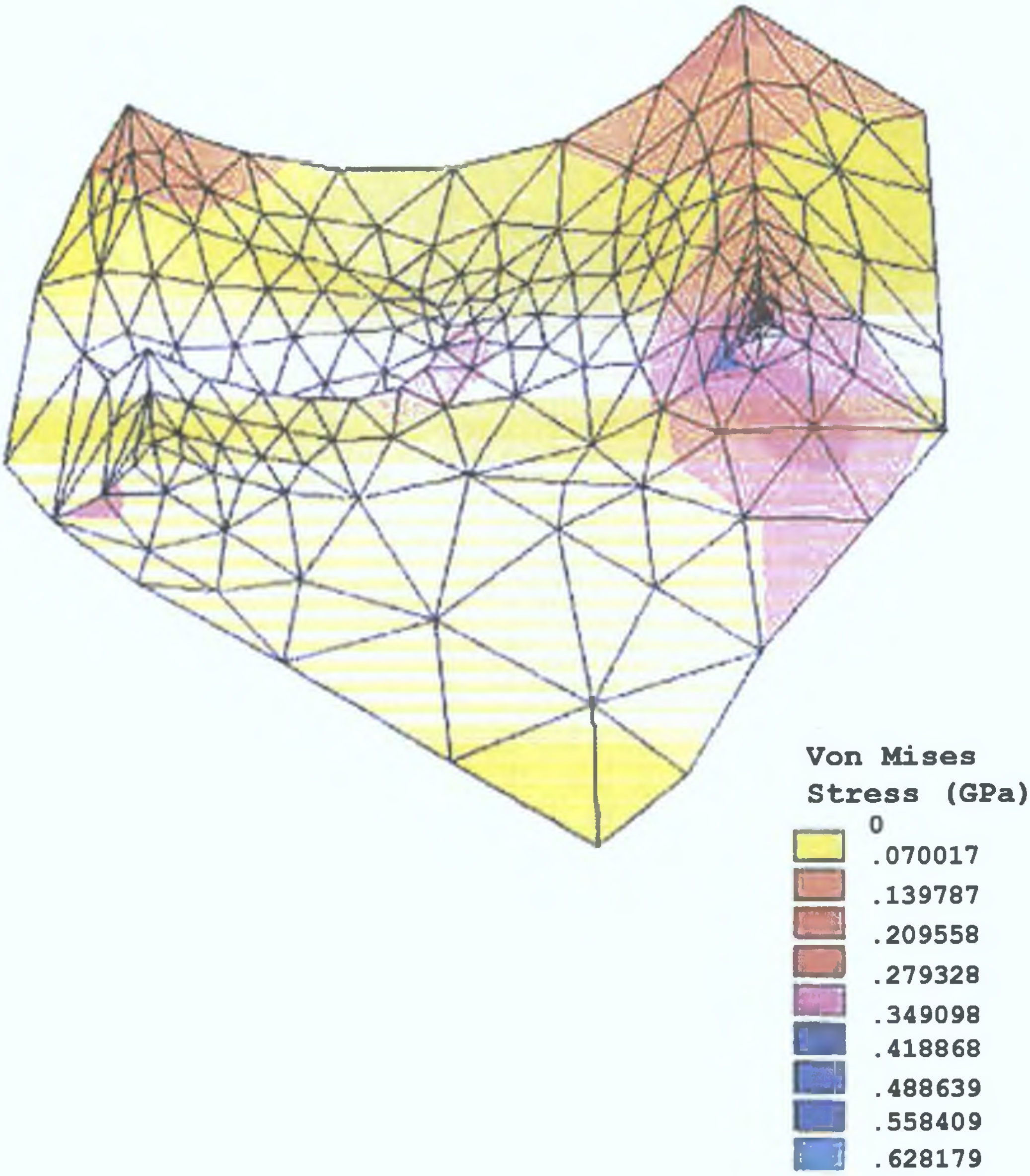


Figure 4.37 Alternative View of Figure 4.36 Clearly Showing Area of High Stress

The point of maximum stress was on the underside of the End Isolate design. This was the point where the design would be touching the bone as well as experiencing pressure from the wire. This was very similar to the stress experienced by the flat design.

Closed Over Round Bottom Design

In the case of the Closed Over Round Bottomed design, the point of maximum stress is similar to the flat design. The load needed to reach 621MPa was 120MPa. Figure 4.38 clearly shows the area of highest stress.

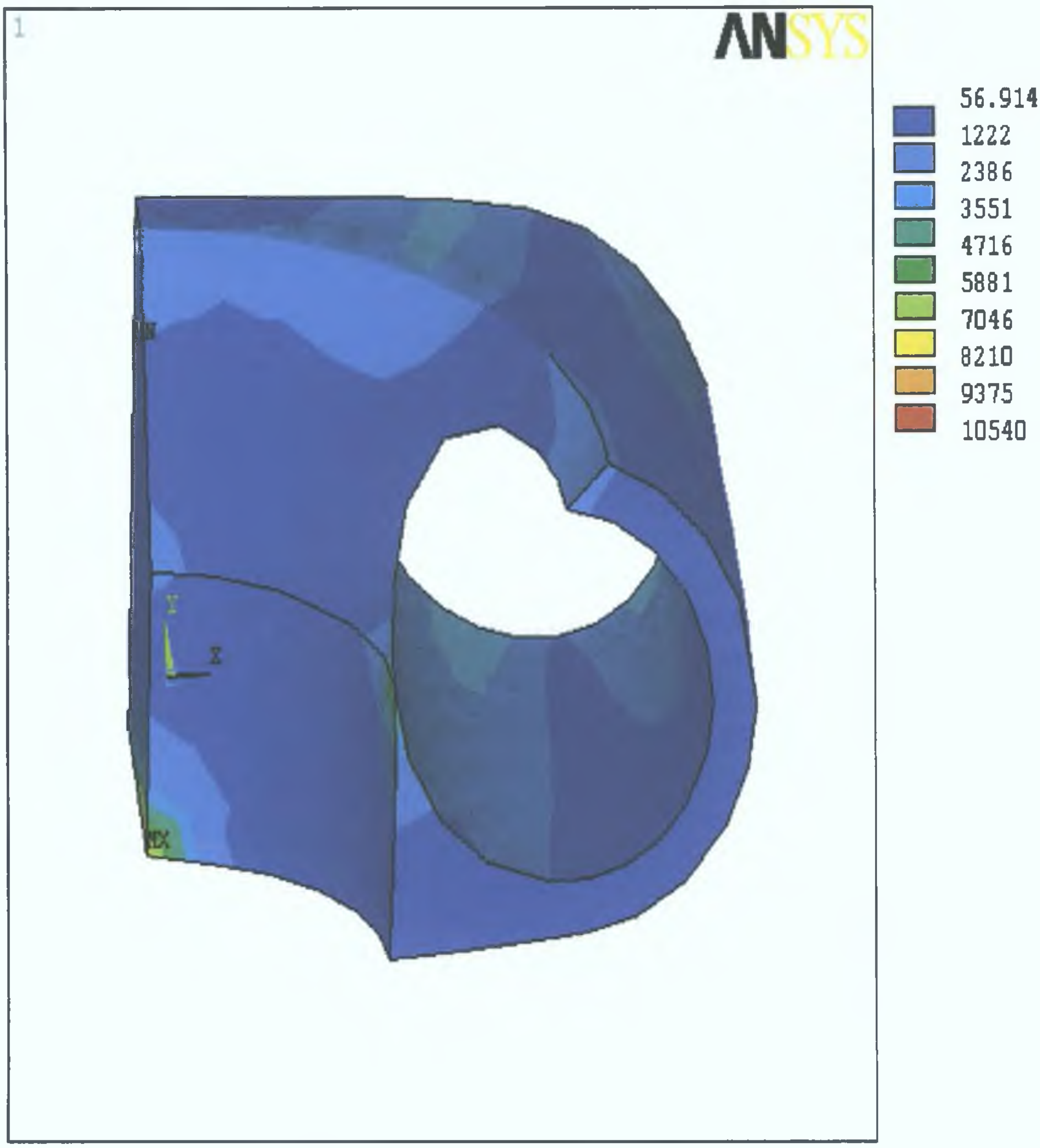


Figure 4.38 Closed Over Round Bottom

Banana Design

The Banana design was the strongest of all the designs, with a maximum load of 180MPa. Figure 4.39 shows the area or point of failure which was found to be at a similar location as other designs. This location would represent the point of contact between bone and fastenerod.

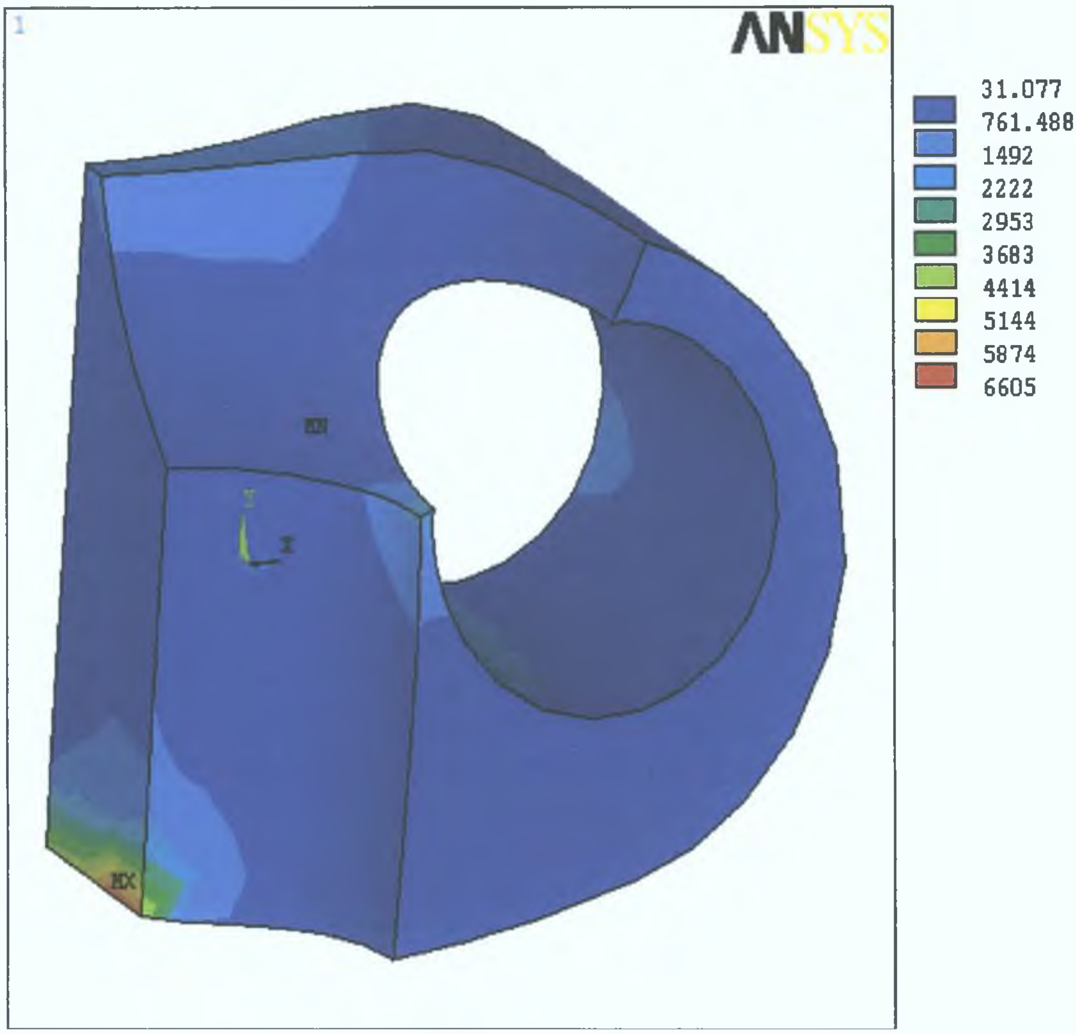


Figure 4.39 Banana

4.4 Discussion

4.4.1 Assumptions

Finite Element Analysis is an approximate method. The underlying mathematical model is an approximation of the real physical system, and this means that a number of assumptions have to be made to approximate the model. These assumptions are that the ANSYS program only understands nodes and elements. It was assumed that the material used is homogenous and isotropic, and the mesh used is of good quality. The boundary conditions represent the actual environment of the model and symmetry used Many of these can introduce sources of error into the solution of the model

4 4 2 Sources of Error

Various sources of error affect the results from the finite element method solution These sources of error include errors in the input information such as material properties, dimensional errors, poor meshes, the application of boundary conditions and loads, flaws in the model and simplification and approximations in ANSYS Material properties are assumed to be homogenous and isotropic, but this might not be the case in an actual model The model could contain more than one material type, even particles introduced in manufacturing stages, as a result, this could introduce varying properties in the model

Furthermore, the mesh quality has to be good to ensure that a good approximation to the solution is calculated The mesh has to be continuous to ensure that the FEM approximation is continuous as badly shaped elements can give inaccurate results The elements approximate the shape of the model and so, in curved areas, piecewise polynomials approximate the shape To reduce the error from the FEM discretisation significantly it was necessary to refine the finite element mesh in these areas

Additionally, most finite elements are stiffer than the real structure For these elements, a coarse mesh generally results in a structure that under-predicts deflection A coarse mesh is less sensitive to stress concentrations A fine mesh generally gives an answer closer to the exact solution However, a fine mesh also results in larger models, more data storage and longer model solution and display times The application of boundary conditions and loads is also an area typically causing problems in the accurate solution of the model The loads and boundary conditions have to be estimated based on previous studies and by trial and error The loading of the model is an approximation of what happens in reality and the boundary conditions approximate how the bone supports the structure As the bone is rounded, these boundary conditions are likely to be of low accuracy This is in the area most likely to have the greatest effect on the solution accuracy

Other causes of inaccuracies in the solution could arise because the material properties assumed are approximate Additionally, the overall dimensions of the model approximate the model that has to be manufactured within a tolerance level Many details are idealised, simplified, or ignored Stress results are based on the derivatives of the displacement solution, amplifying the errors

4 5 Summary

The objective of this section was to analyse a number of fastenerod designs using the ANSYS finite element package and hence, to produce an optimal design for the fastenerod The best design was found to be the Banana design as it withstood the highest applied load before yielding occurred (Fig 4 40) However, the closed over round bottom design resisted the highest load with the lowest profile and would therefore be the best practical choice

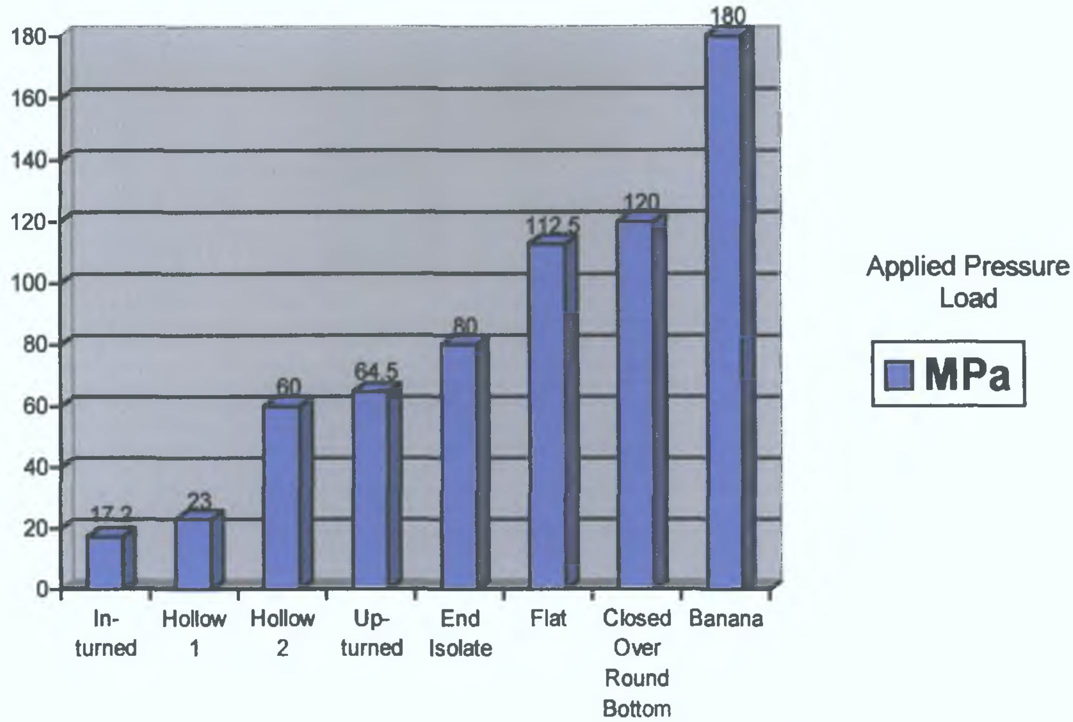


Figure 4.40 Summary of highest applied load for each design before yielding occurred

Chapter 5

Manufacturing Process of the Fastenerod

5 1 Introduction

Manufacture of the optimal designs presented difficulties due to the small size of the implant Manual production was possible but was labour intensive and time consuming and furthermore, as each implant had to be identical to ensure that the results of the tests were reliable, human error had to avoided At the same time, a fully automated manufacturing process was too costly as the number of implants needed for laboratory testing could not justify mass production The process of manufacture was chosen on the balance between these factors, and only through use of Computer Aided Design (CAD) and Computer Aided Manufacture (CAM) could a reasonable compromise be reached

5 2 Methods and Materials

The fastenerods required are manufactured from AISI 316 L Stainless Steel (EN 1 4404) Due to the high chromium content and toughness of the material, it is recommended to use high quality Tungsten carbide tooling during the production process

Operation 1

Firstly, the raw Stainless Steel material is cut to a required length to enable 10 of the fastenerods to be machined in sequence during the milling operation The required length of material will vary according to the type of fastenerod required

Operation 2

The component fastenerod is draughted from a hard copy to DXF standard drawing format using a computer aided design (CAD) / computer aided manufacture (CAM) interface Tool paths were generated from the drawing and a machining programme produced, the numerical code (NC) code was then outputted to computer numerical controlled (CNC) Machining center (Fig 5 1)

Fig. 5 1 CNC machining centre

Operation 3

Due to the required outer profile and blend arcs of the fastenerod, it is necessary to CNC Mill this section (Figs 5 2 and 5 3)

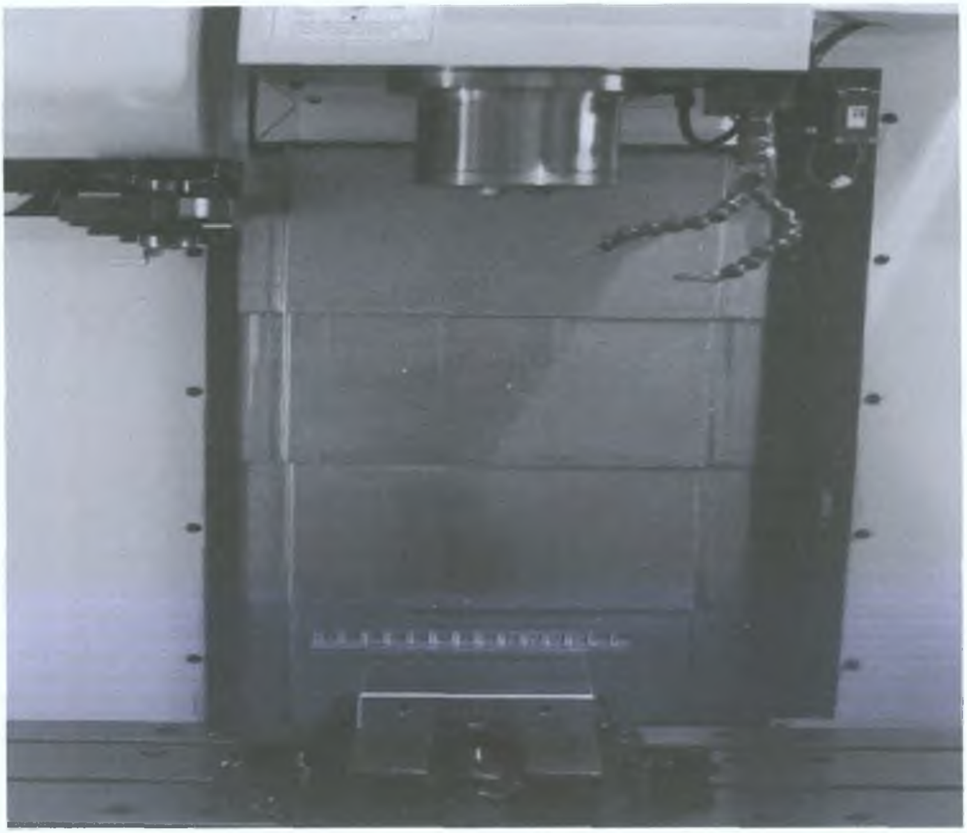


Fig 5.2 Close up of the spindle and vice

The raw material is securely clamped using a hydraulic machine vice, making sure to leave adequate material proud of vice jaws.

Tool 1 requires the top surface of the material to be machined flat (16 mm End milling cutter solid carbide 4 flute). Tool 2 centre drills shaft holes in required position (carbide spot face drill 3 mm diameter). Tool 3 drills for required hole diameter (solid carbide 2 flute drill). Tool 4 rough cuts to generate profile of fastenerod (8 mm 3 flute solid carbide slot drill). Tool 5 finish cuts to generate profile of fastenerod. (8 mm 3 flute solid carbide slot drill).

Approximate machining time to produced 10 off fastenerods is 3 hours (Figs. 5.3 and 5.4). It is important to note that during the machining process the work piece should remain in a stable condition. To avoid any dimensional variation and poor surface finish, soluble oil based cutting lubricant must be used and continuous monitoring of cutting tools is required.

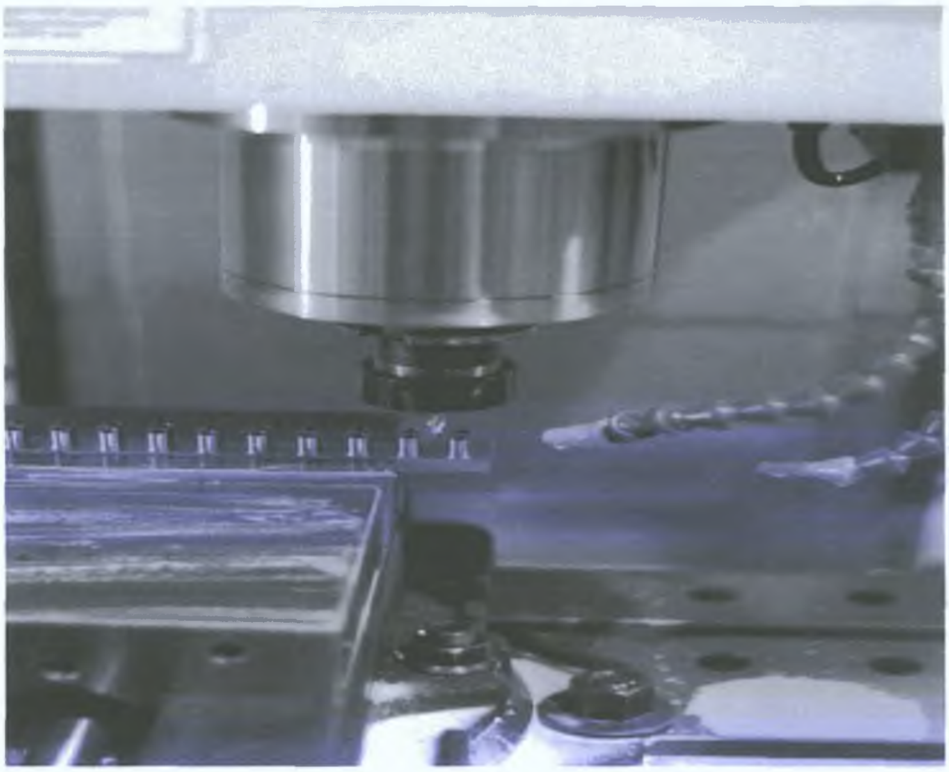


Fig. 5.3 Machining outside profile and creating holes

Operation 4

Once the fastenerod's profile is completed, it is now necessary to machine the component to the desired length. Again, to avoid any distortion it is advisable to wire-erode the fastenerod in the electrical discharge machine (EDM) (Fig. 5.5). The billet of material is clamped directly into the bed of the wire machine and positioned parallel to the cutting axis of the machine head.

Some distortion of the work piece may occur during the milling operation so the fastenerods are wire-eroded, leaving approximately 0.2 mm stock allowance on the overall length.

Operation 5

It is now required to remove the stock allowance after the wire erosion process. A fixture manufactured from a soft material, preferably aluminium, is produced to locate the fastenerod. The fixture is comprised of two plates 10 mm thick. When clamped together the exact profile of the fastenerod is machined along the split line of the plates. This fixture plate now enables the fastenerod to be housed accurately without any distortion. The fixture plate is then placed in a precision grinding vice, the fastenerod is inserted and clamped. Stock allowance can now be surface ground with ease.

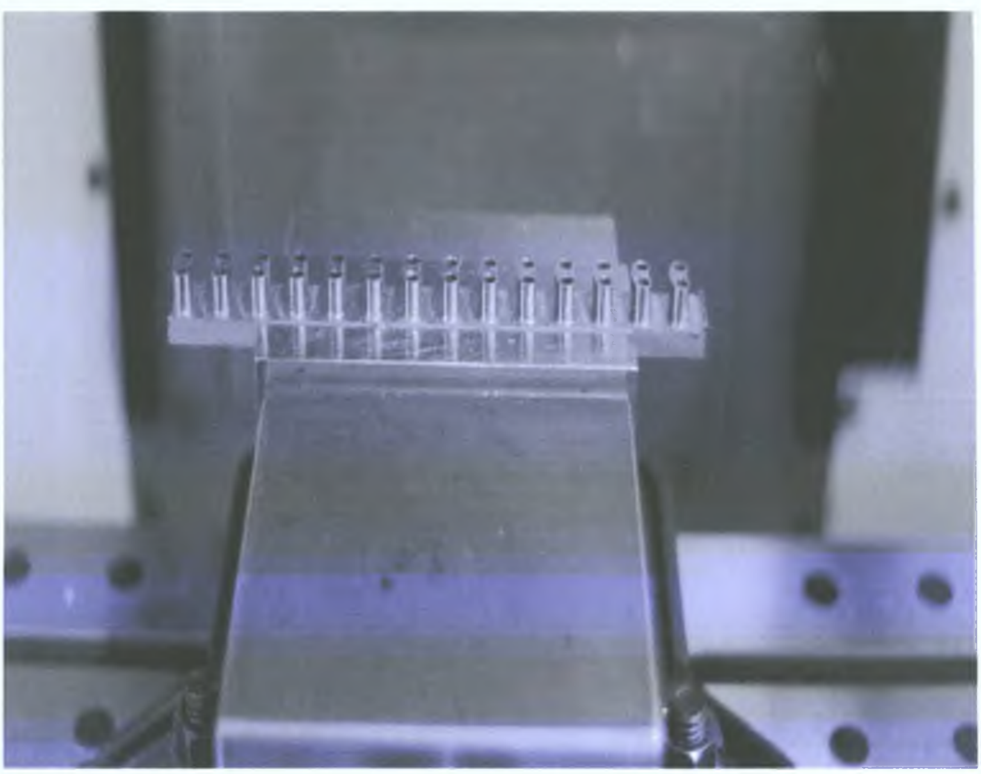


Fig. 5.4 Close up of components

Operation 6

The final operation is to produce the profile for screw location. Again, to avoid any cutting forces during machining, which would distort the fastenerod, it is advisable to spark-erode this section. A copper electrode is machined on a C.N.C lathe to the exact profile of the screw. The electrode is then mounted in the spindle of the spark-eroder and set at right angles to the bed of the machine using a dial indicator. A precision ground vice is clamped on the bed of the machine and set parallel to the spindle head again using a dial indicator. To ensure the fastenerod is level, two precision pin gauges are inserted through the previously drilled holes. The pin gauges sit on the jaw faces and locate the fastenerod parallel and at right angles to the electrode. The jaws are not clamped and pin gauges removed.

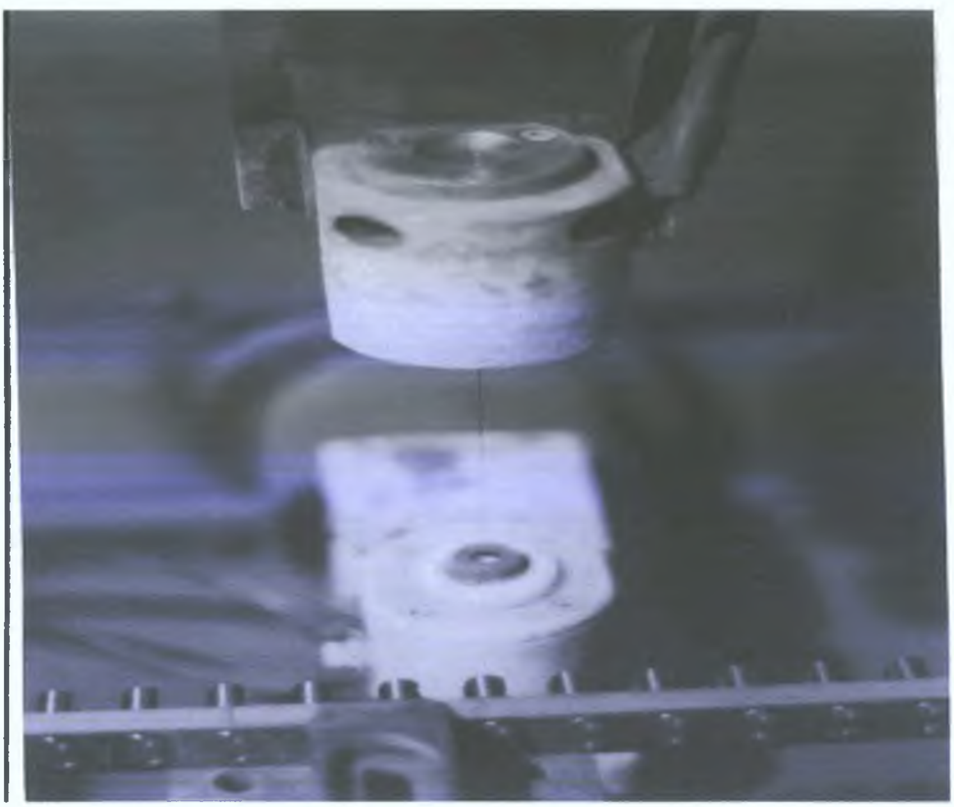


Fig. 5.5 EDM cuts off fastenerod from stainless steel block

It is important that the electrode is set up centrally in relation to the drill holes so as to provide equal pressure on both shafts when the screw is inserted. A pre-set depth is set in the machine and gradually increased until the radius profile on the electrode breaks through the two drill holes. This depth is then set and will remain constant for all the fastenerods.

Fig. 5.6 Checking accuracy of height

When the required shafts are inserted through the fastenerod, they should be visible and central in relation to the eroded screw profile.

5 3 Results

Usıng the combınatıon of the CNC machıne and wıre erosıon even the smallest fastenerod (1 1mm) could be successfully produced Beıng able to run off ten or more at a tıme also made the productıon relatıvely effıcıent Once the system was set up, the productıon could contınue untıl such tıme as ıt was decıded to stop The larger fastenerod (4 5mm) took sıgnıficantly longer to run off due to greater proportıon of steel to contour and used more toolıng materıals The method of manufacture chosen was flexıble enough to allow whatever quantıty were requıred, and thıs was useful durıng testıng and would be useful for productıon for clınıcal use later on

5 4 Dıscussıon

Beıng able to brıng together the dıfferent facets of manufacture to produce a new ımplant ınvolves more tıme dedıcated to plannıng than actual productıon Economıcs, materıal propertıes, component geometry and the fınısh requıred were explored ın each ınstance The cost of productıon was a crucıal factor gıven that there were only fınıte resources avaılable for research and, for eventual clınıcal sales to progress successfully, the prıce cannot be prohıbıtıve Implants for orthopedıcs are by theır nature expensıve whıch ıs partly due to the materıals ınvolved, productıon methods and, most ımportantly, standards of precısıon It ıs a legal requırement under European Law that all ımplants must comply wıth the regulatory standards and these are naturally enough very hıgh So much so that when thıs law was enacted many companıes could not maıntaın competıtıveness and moved out of the market Consequently, the prıce to the surgeon or hospıtal has ın the last decade nsen exponentially On the other hand there are no legal requirements for implant production use in veterinary patients

However, veterinary orthopaedics is a fully commercial market place with no subsidies and clients/vets exact the highest standards of their implants Many of the implants used in veterinary patients are actually human implants in the first place In fact, in the case of orthopedic screws, the human 4 5 mm screws are cheaper than the most commonly used veterinary 3 5 mm screw So, manufacturers for the veterinary orthopedic industry solely always claim to have similar standards the manufacturers of human implants, even though they are not obliged to attain them But the point is that money during production can be saved by not having to attain all of the high legal implant requirements for humans, as long as the geometry is precise and the material is not m any way corrosive or reactive to other metal implants or instruments

Stainless steel is the standard material for the vast majority of all implants, 316 L stainless steel being the basic foundation Resistance to corrosion whilst immersed in active biological fluids and tissues with no reaction with these that would lead to rejection is the key to its success Early use of other metals showed that the material had to be inert for the implant to achieve its end result If the tissues react inappropriately the bone will never heal, the healing process will be disrupted by a foreign body reaction However, a slightly different version is now used in implants, namely stainless steel 316 LV For the purposes of laboratory testing 316 L stainless steel was chosen to make the prototype fastenerods It has very similar material properties to 316 LV but is significantly cheaper to buy as a raw material and is more readily available

The component geometry of the fastenerod is crucial as the optimization process that had already been performed had shown Keeping to this geometry was the goal of manufacture but there was another aspect that had to be considered as well and that was the end clinical use A fastenerod that had the absolute optimum but was unusable misses the whole point In particular, the overall height and the convexity at the bottom needed to be married accurately Too high an implant would have rendered it too irritant and unwieldy for intra operative use but, conversely, too low a degree of convexity would not be in keeping with the optimization process However, in the optimization process these two aspects were always kept hand in hand and the final manufacture was as near as one could get to the original optimum design

All orthopedic implants are electropolished to produce an inert smooth surface that has a film on it which provides it with extra anticorrosive properties impossible to achieve without polishing The polishing itself does not affect the mechanical performance of the implant and therefore was not performed in the fastenerods produced for laboratory testing However, for clinical trials the fastenerods would be electropolished, 316LV finished implants

5 5 Summary

A method of manufacture that allowed the main factors of production number, size, and shape was successfully achieved ,using computer aided design

Chapter 6

Comparative Mechanical Testing of Implant Formations

6 1 Introduction

Using a composite system that involves three individual components (pins, screws, and fastenerods) creates a system with many possible permutations and combinations Some of these have been addressed in Chapter 3 To be able to analyse the performance of a system such as this a clear set of data must be produced The variables have to be controlled and a set formation adhered to All testing was performed so that each sample was identical where possible and also that the comparative implant was used as a template to ensure that there was uniformity and comparative equality A further variable in this analysis is that bone size can be from ten millimeters to 40 millimeters in diameter when including cats, dogs, humans and equines For this reason a fastenerod was produced for each possible size (Fig 6 1 and 6 2)

1 A fastenerod with 1 2mm holes which takes 1 1 pins and a 2mm screw It is denoted by the abbreviation 1 1/2 Fd

2 A fastenerod with 1 7mm holes which takes 1 6pmm pins and a 2 7mm or 3 5mm screw They are denoted as 1 6/2 7 Fd or 1 6/3 5 Fd respectively

3 A fastenerod with 2 5 mm holes which takes 2 4 mm pins and a 3 5 mm screw It is denoted as 2 4 / 3 5 Fd

4 A fastenerod with 4 2mm holes which takes 4mm pins and a 4 5 mm screw It is denoted as 4/4 5 Fd

With the fastenerod system classified the comparative industry standard implant is chosen as follows

1 1/2 Fd	Vs	2 0 plate
1 6/2 7 Fd	Vs	2 7 DCP
1 6/3 5 Fd	Vs	various implants
2 4/3 5 Fd	Vs	3 5 DCP
4 /4 5 Fd	Vs	4 5 DCP

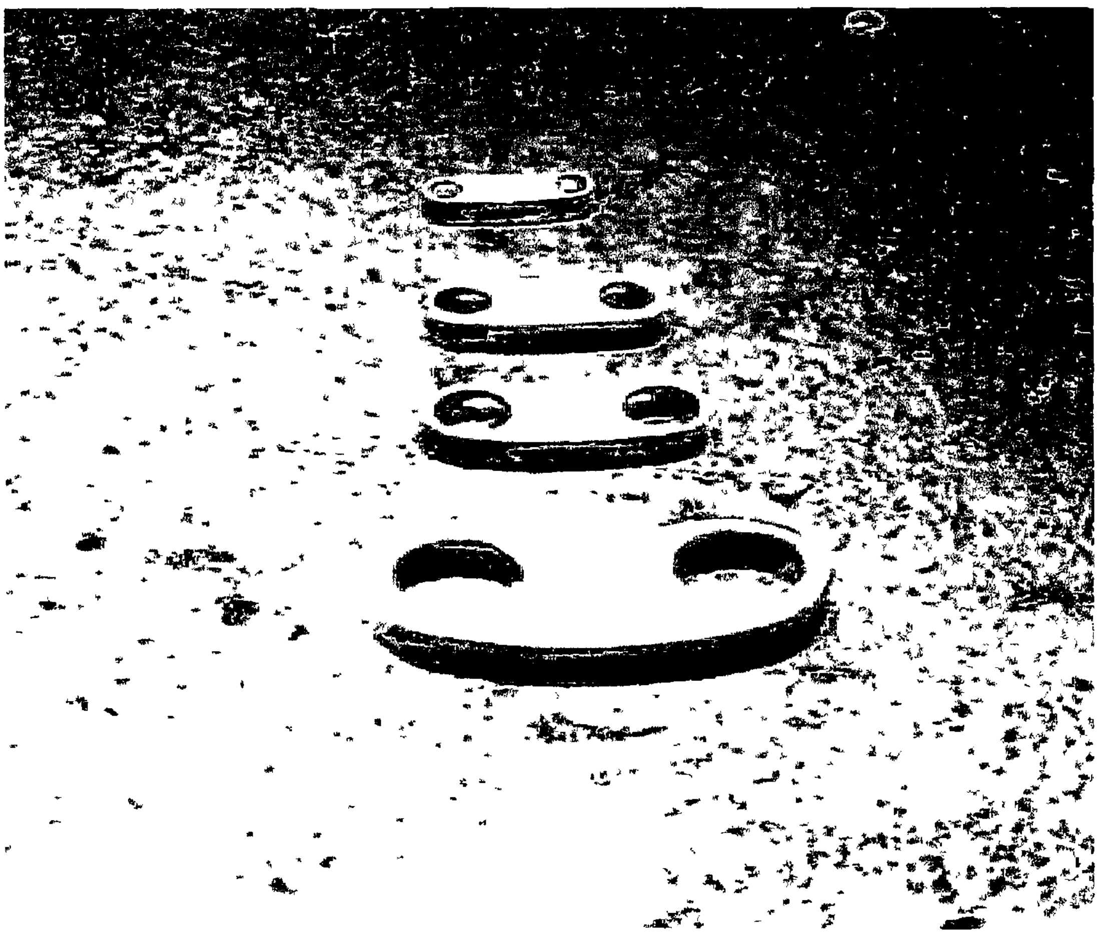


Fig. 6.1 1 1/2Fd at top to 4/4 5Fd at bottom

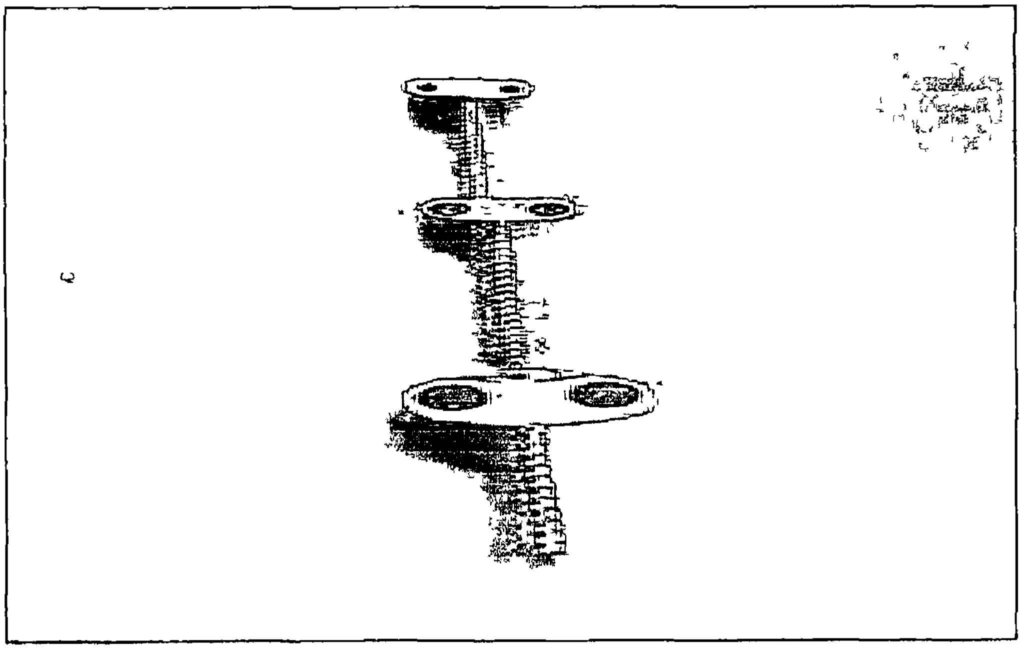


Fig 6.2 Last 3 sizes fastenerod with screws in place

By doing a comparative test to industry standards, the data is much more meaningful than creating data in isolation

6 2 Methods and Materials

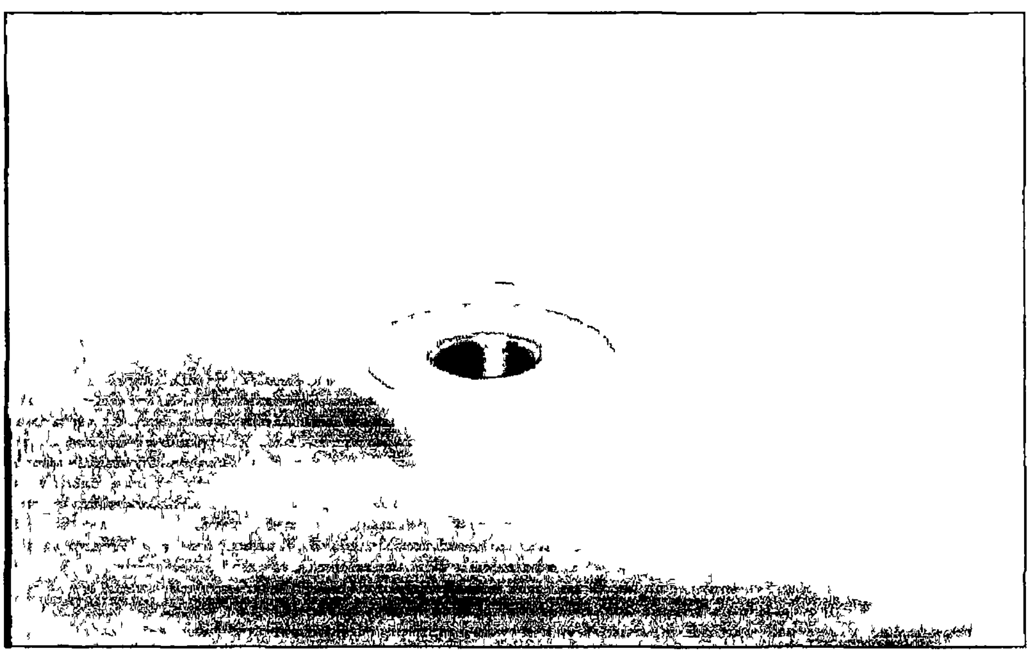


Fig 6 3 End view of wood prepared sample

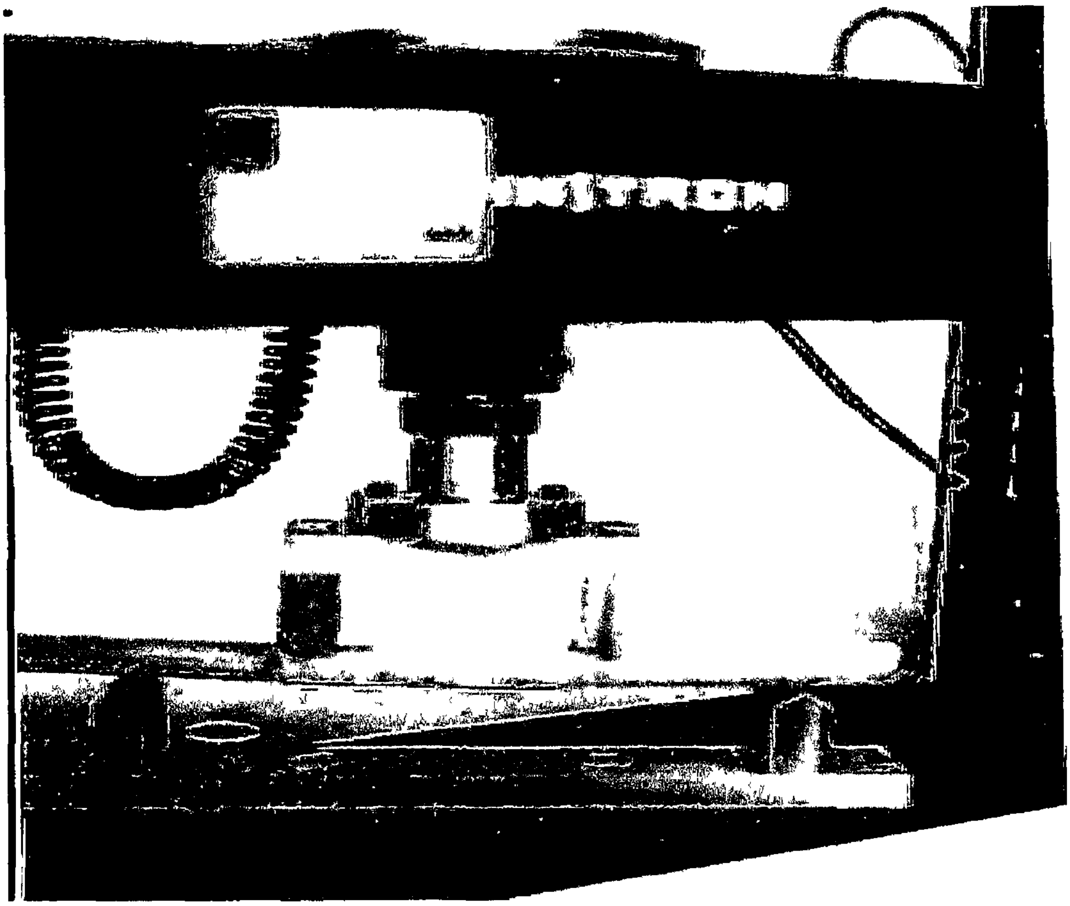


Fig 6 4 Wood sample in place for 4 point bending

Wooden (birch) dowels of diameters ranging from 10mm to 38mm were cut to lengths of 35cm Each dowel was then labeled and cut in half to simulate a complete fracture The central cores of the dowels were drilled out creating hollow diameters ranging from 6mm to 26mm to simulate the medullary cavity of a bone (Fig 6 3) Using a bench vice grip the two matching pieces were lined up to create a fracture gap ranging from 2mm to 10mm to simulate a non load sharing fracture The corresponding plate was placed on the samples and the screw holes marked on the samples The screw holes were marked in exactly the same place for the corresponding fastenerod After the screw holes had been drilled and tapped with the appropriate size of instrument, the plate and fastenerod were applied In the case of the fastenerod, pin holes were generally drilled into the sample at points ranging from 3mm to 20mm from the last screwhole The pin ends were gently tapped into the holes with a mallet This required the operator to preplace the fastenerods before bending over the pin ends In this way each set of samples for each size category were prepared to be sure of uniformity and comparative equality In the case of the controls used during the testing, there was no fracture "gap" The industry standard for loading implants is to leave a gap between so that it is only the implant that is being tested

Following preparation of the samples, the Instron was set up for each experiment At the start of each set of experiments the Instron was completely recalibrated The prepared sample was placed in the jig and the crosshead moved slowly to position ready for loading Using the Instron computer software the chosen method of testing was selected (compression, tensile, cyclic) and the speed of the crosshead was set at 2-4 mm per second The parameters for gauge length and surface area were put into the software, having been measured beforehand The gauge length was different for each set of experiments and was recorded in millimeters, whilst the surface area was measured and was uniform as all samples had the same surface area There was no load limit set and the test stopped only after automatic recognition of a break as recorded by the Instron software in most cases Six sets of tests were performed

1 Four point bending test (Fig 6 4)
2 Side four point bending test
3 Compressive axial loading test

4 Fatigue / Cyclic Analysis

5 Torque Tests (Fig 6 5)

6 Tensile tests (Figs 6 18 and 6 19)

The samples were tested using a four point bending jig, except for the torque test and axial test where custom made grips were used All sets of samples were subjected to a minimum of three separate tests until three repeatable results occurred Torque samples were tested using a separate machine and system All tests were performed until failure occurred Failure of the implant was defined as being when the sample fractured the screws pulled out, or the sample reached maximum extension possible on the machine and jig In the vast majority of cases the software automatically detected a break and stopped the test In the few cases were the sample continued to the maximum possible extension, the test was manually stopped

In the case of the fatigue / cyclic testing the four point bending jig was used and the parameters used ranged from speed 2 mm/second to 10 mm/second and the load from 0 5 KN to 2 KN The samples were left to cycle until failure which was always by fracture The torque testing was carried on a Torque/tension machine The samples were held using custom made grips and each sample was subjected to a quasi static strain rate of $1x15^3$ per second The torque transducer produced a variation of 2 NM due to disturbance All these samples were also tested to failure which ended with fracture or maximum extension Maximum extension was decided to be a 180° or more turn (Fig 26)

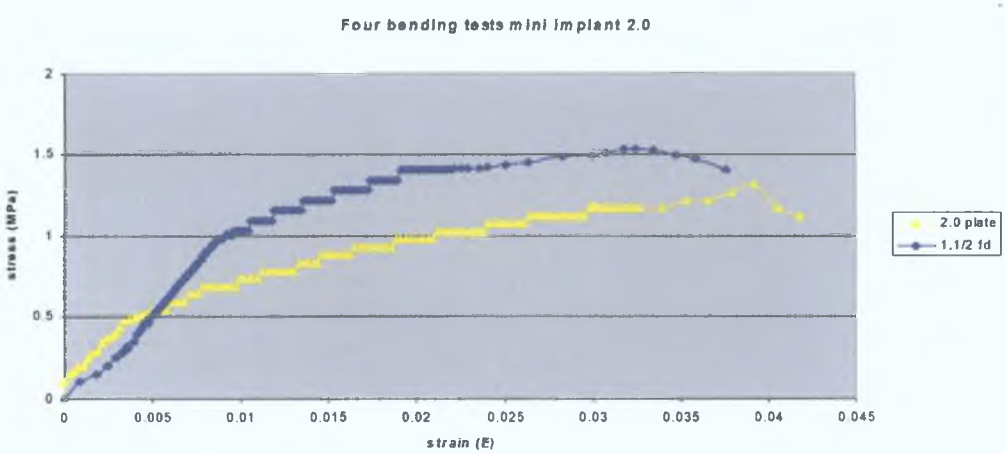
Fig. 6.5 Torque testing

Pin migration was evaluated by anchoring the sample to the base of the Instron and attaching the pins to one of the standard Instron grips available.

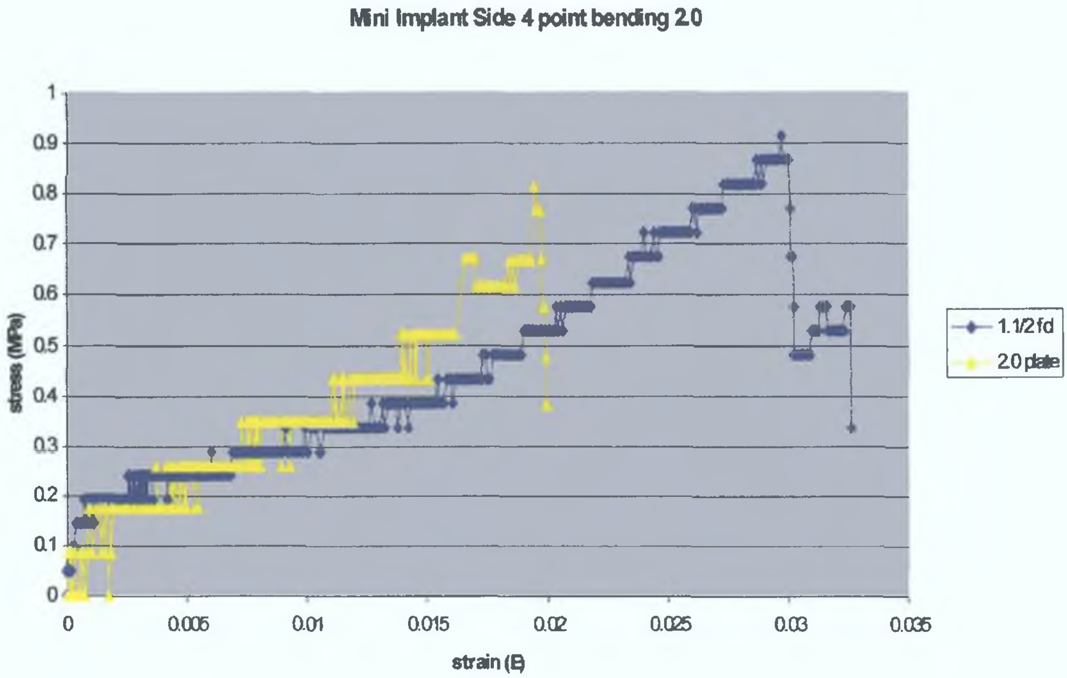
6.3 Results

The results are presented for each category with the graphs and figures followed by a summary of the results. Appendix A contains the relevant tables (Tables 6.1 to 6.6).

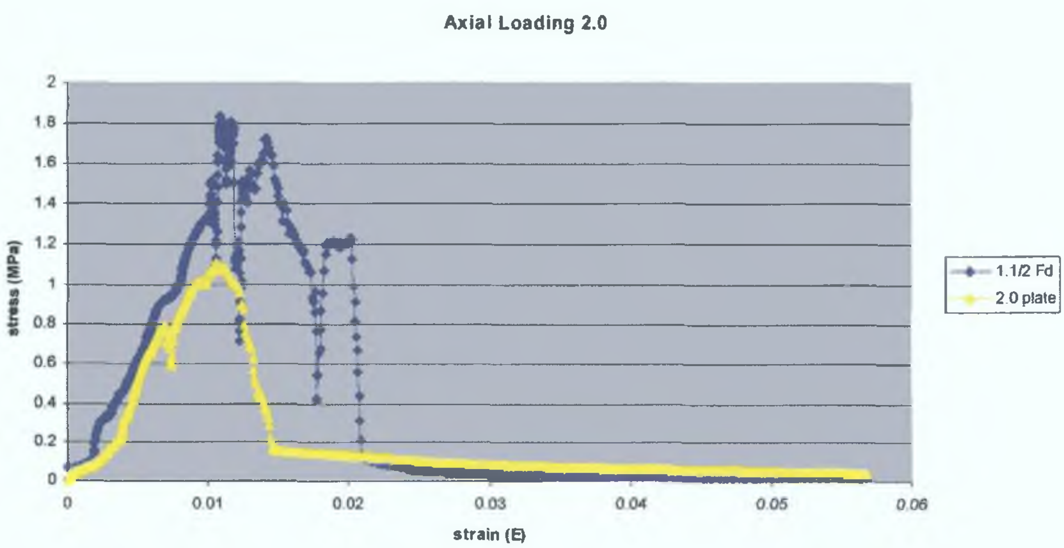
6.3.1 Bending Test 2.0 mm Screw Category



Graph 6.1 The 1.1/2Fd although not as stiff as the 2 plate it is ultimately stronger



Graph 6.2 The 1.1/2 Fd is ultimately stronger than the 2 plate

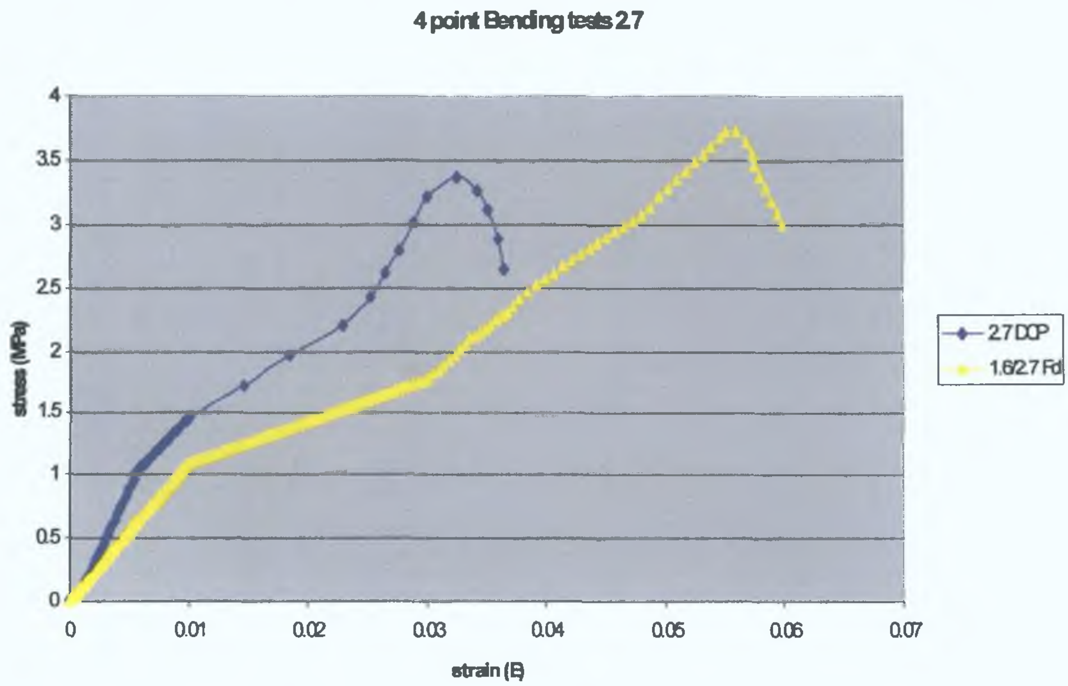


Graph 6.3 The 1.1/2 Fd is stronger than the 2 plate

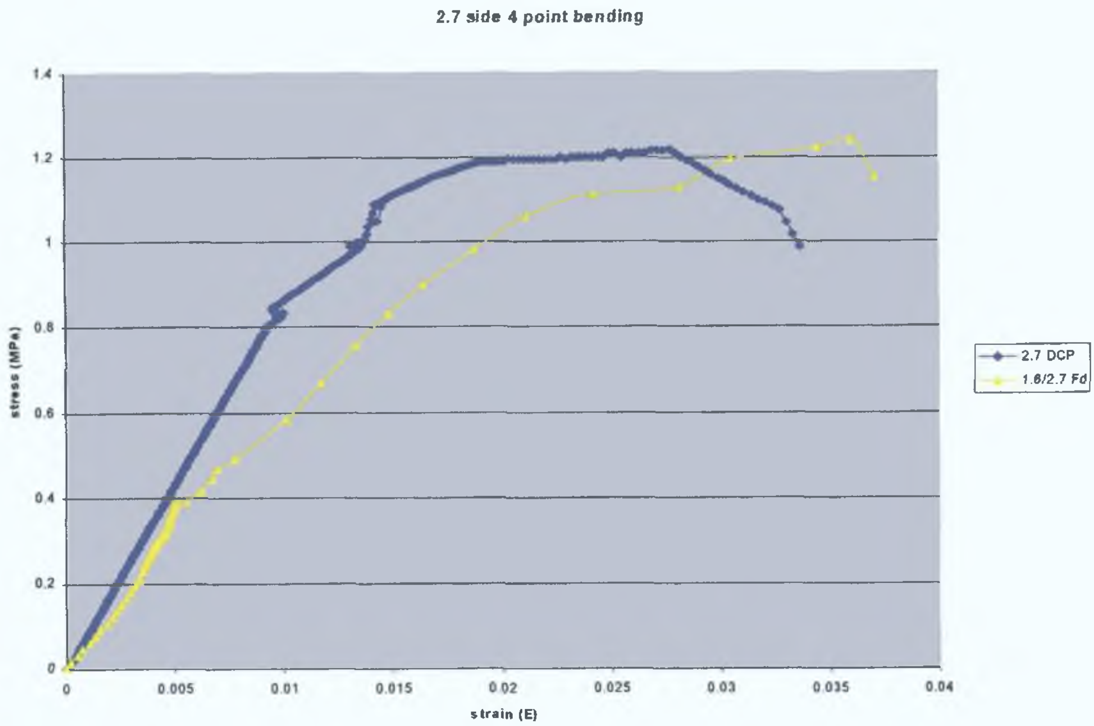
In this category, the smallest screws (2.0 mm) and pins (1.1 mm) are used in comparison to a 2.0 mm plate in the three classes of bending. The 2.0 mm plate is stiffer in the four point bending tests (Graph 6.1) but has only stiffness to the 1.1/2.7 Fd in side four point bending (Graph 6.2) and axial loading (Graph 6.3). In all three sets of tests the 1.1/2 Fd has a higher ultimate yield than the plate.

6.3.2 Bending Test for the 2.7 mm Screw Category

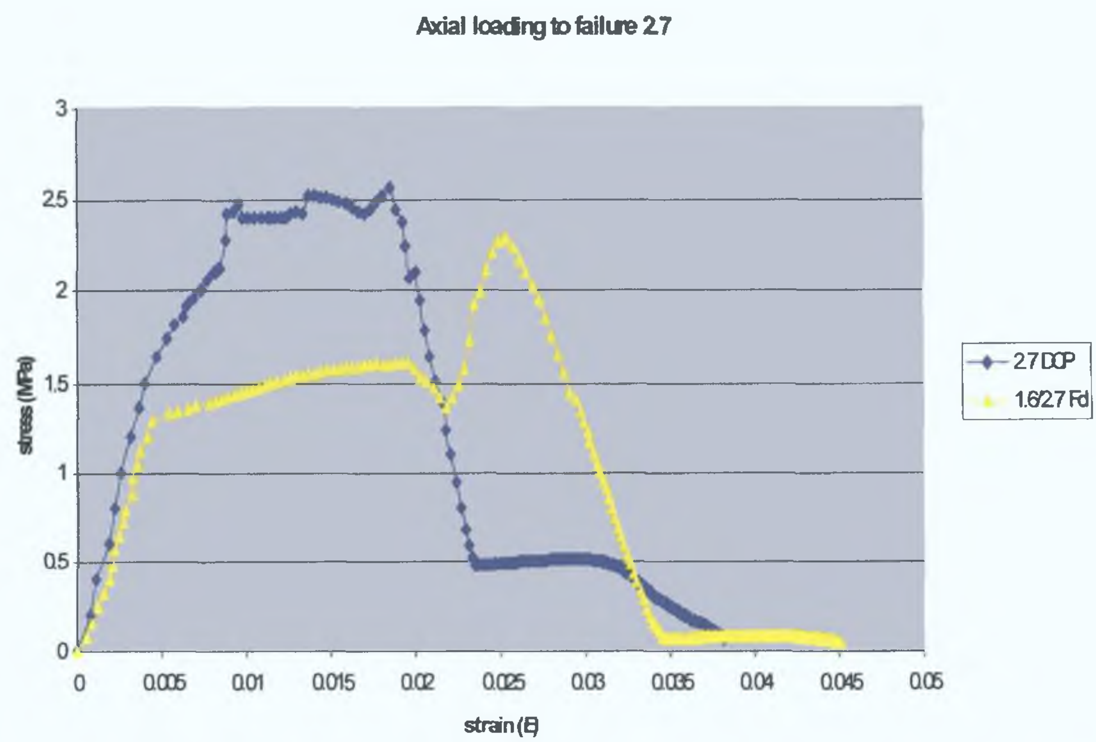
Fig 6.6 Demonstration of a 2.7 mm DCP



Graph 6.4 2.7 DCP is stiffer but fails sooner than the 1.1/2 Fd



Graph 6.5 There is very little difference between the 2.7 DCP and the 1.6/2.7Fd



Graph 6.6 The 2.7 DCP is ultimately stronger than the 1.6/2.7 Fd in axial loading

In all three sets of tests the 2 7 DCP (Fig 6 6) is stiffer than the 1 6/2 7 Fd, having a higher modulus of elasticity as interpreted from the graphs In terms of the ultimate yield, the 2 7 DCP is equal to the 1 6/2 7 Fd in side four point bending tests (Graph 6 5) and has a higher ultimate yield in axial tests (Graph 6 6) However, the 1 6/2 7 Fd has a higher ultimate yield than the 2 7 DCP in four point bending tests (Graph 6 4)

6 3 3 <u>Bending Tests 3 5mm Screw Category</u>

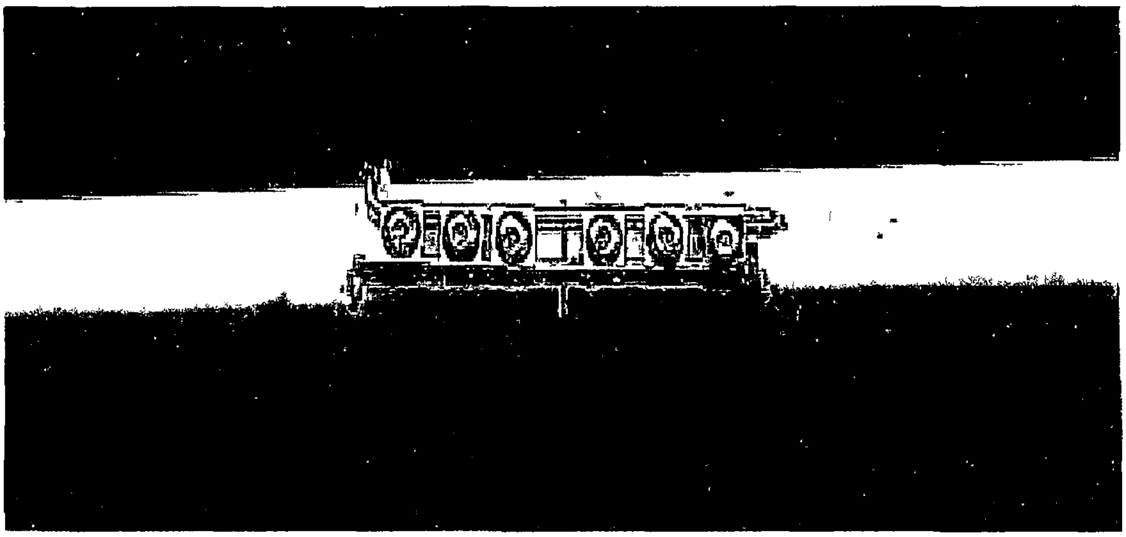


Fig 6.7 Demonstration of 2.4/3.5 Fd

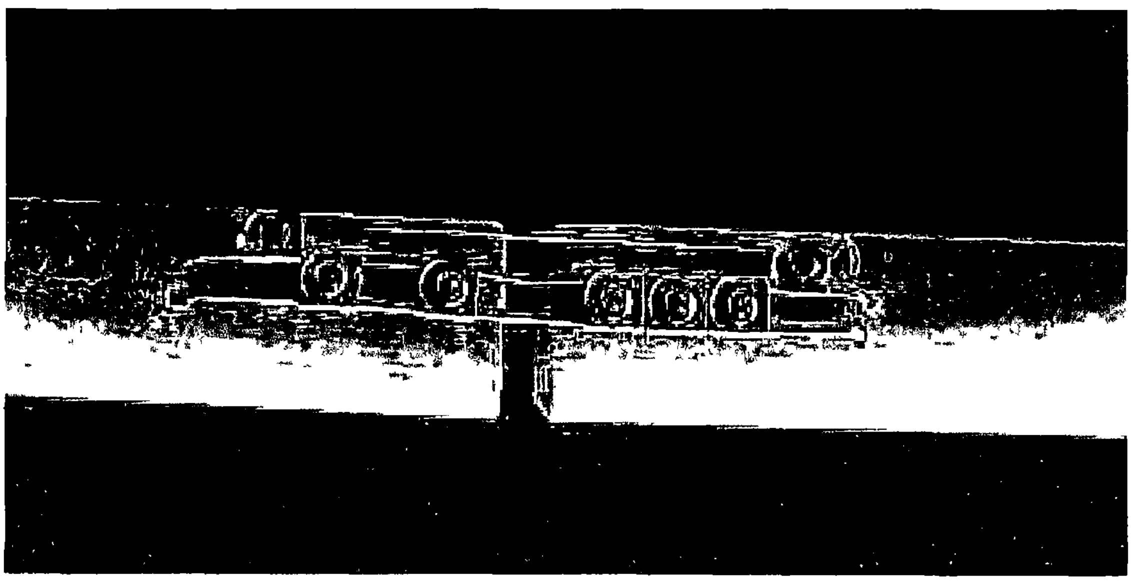


Fig 6.8 Three pin 1.6/3.5 Fd prior to testing

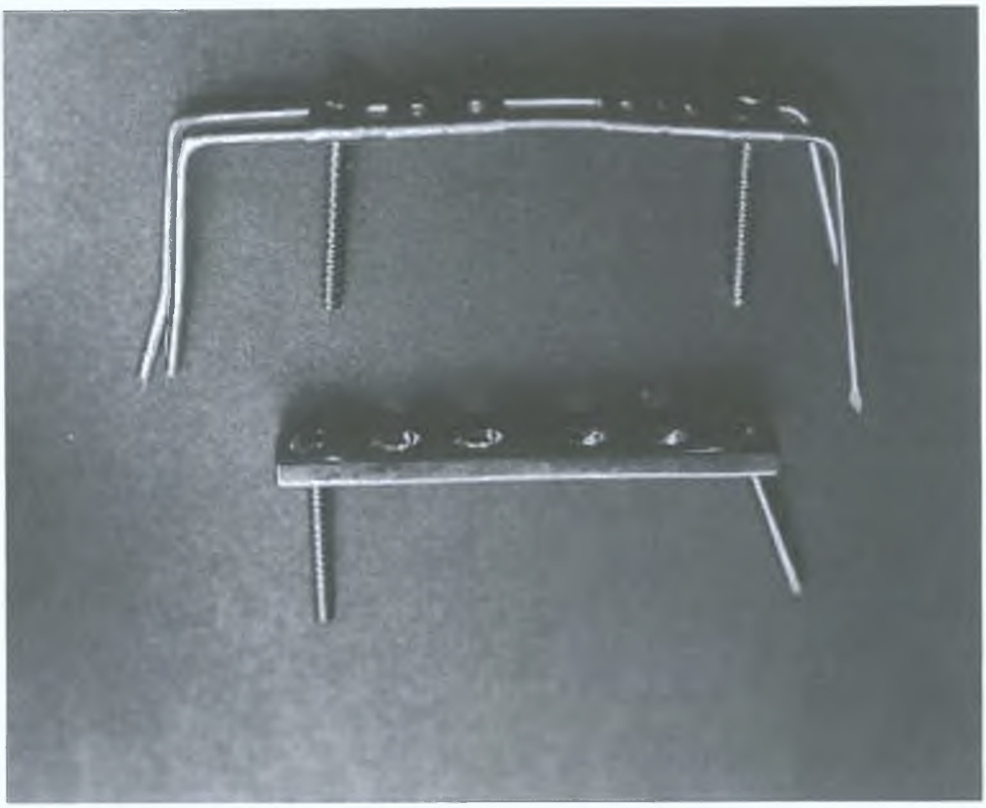
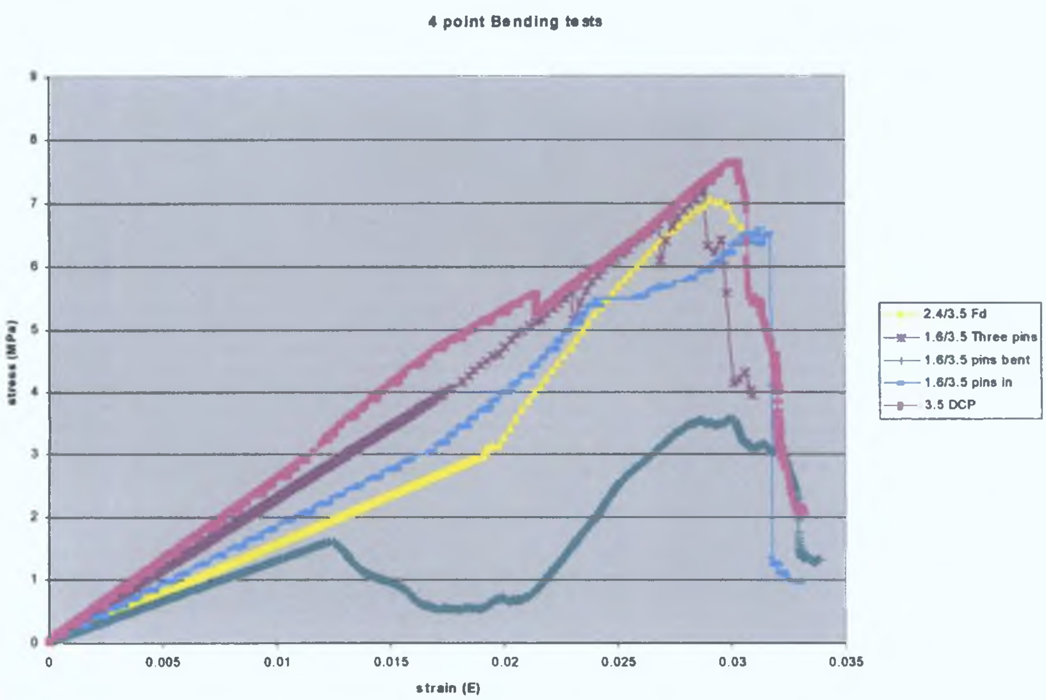
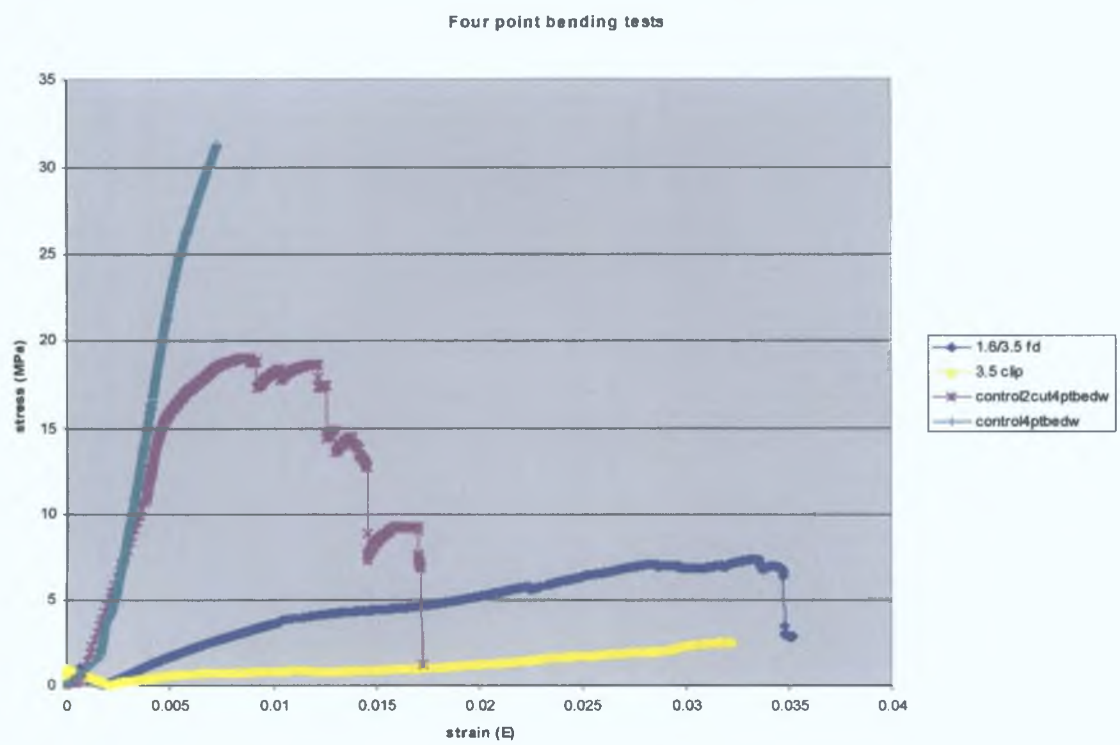


Fig. 6.9 2.4/3.5Fd with 3.5DCP



Graph 6.7 The 3.5 DCP is stiffer and stronger than its counterparts in this curve but the 2.4/3.5Fd and 3 pin 1.6/2.7Fd are not far behind

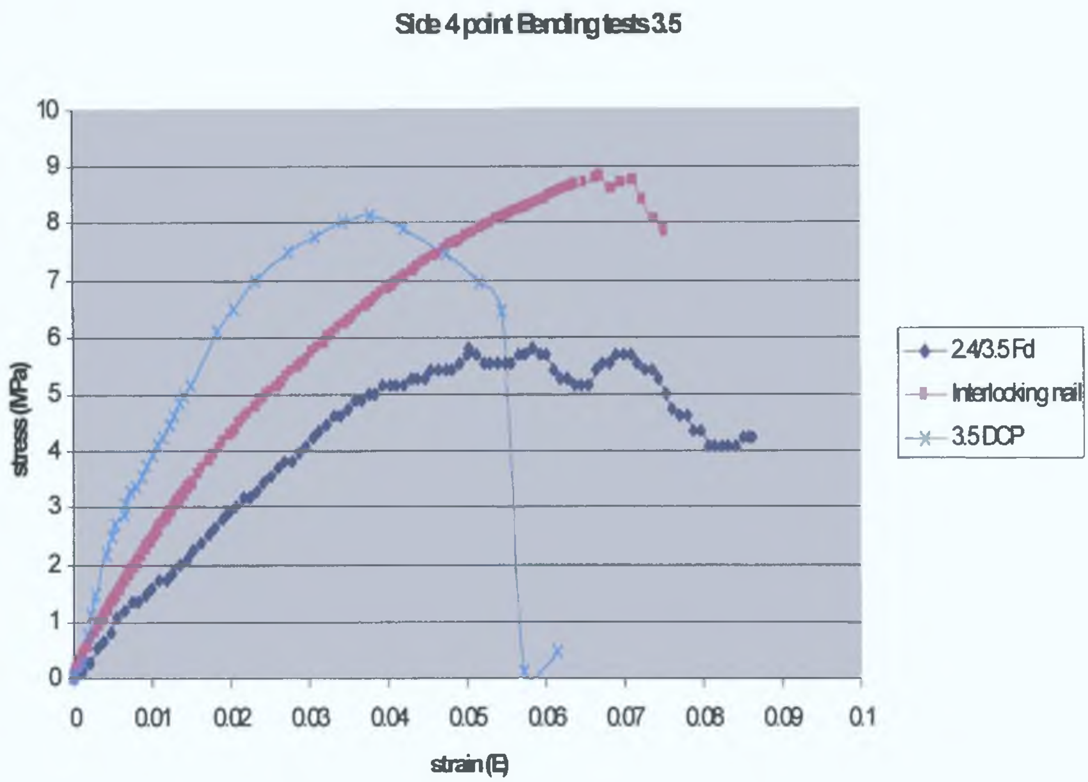
The category of four point bending tests involving the 3.5 DCP (Fig 6..9) involves more than just two comparatives but the 2.4/3.5 Fd (Fig 6.7) is the most significant choice. Essentially this set of tests examines the use of all variations which use a 3.5mm screw (graph 6.7). The most obvious features are that having the pins embedded in the sample as apposed to simply bent over increases the stiffness and ultimate yield significantly. Furthermore, increasing the pin diameter leads to a higher yield even though both pins are not embedded in the sample, and adding an extra pin onto the whole assembly (Fig 6.8) very nearly reaches the ultimate yield of the 3.5 DCP. This result indicates that having the fastenerod available would expand the possible variations that a surgeon could have from having relatively weak appositional fixation to strength comparable to a 3.5 DCP.



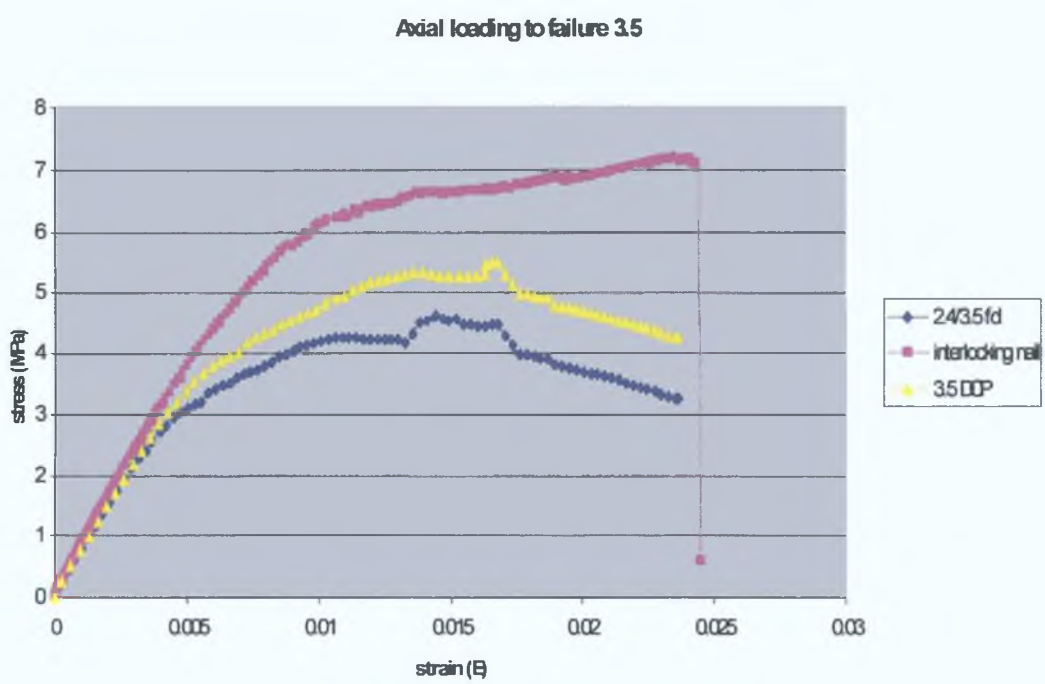
Graph 6.8 Both controls are better than either the Fd or clip. Failure of the latter two only occurs after a long change in length compared to the original gauge length

This set of tests (Graph 6.8) is connected to the results depicted in graph 6.7, as they are an examination of the use of implants in association with the 3.5mm screw. However, they are shown separately due to the congestion in graph 6.7 and to show the difference between two types of failure. Firstly, the ultimate yield values of the two controls indicate that even when the sample is weakened the yield value is much higher than any of the repaired samples from graph 6.7 or 6.8. As occurs in bone the strength of the repaired bone is never as strong as the original intact bone. No implant system can imitate the original bone structure but, then again, to do so would lead to no stimulation of the bone. However, some tracking of the behaviour would be beneficial. The fastenerod performs better than the 3.5 clip in it is stiffness and ultimate yield. Interestingly, the stress strain curve of the fastenerod is very similar to the general shape of the stress strain curve of cancellous bone indicating that it has properties that naturally track this type of bone.

Fig. 6.10 An example of an interlocking nail



Graph 6.9 The interlocking nail resists bending forces better than DCP or Fd



Graph 6.10 The interlocking nail is ultimately stronger than either DCP or Fd

The ınterlockıng naıl (Fıg 6 10) was ıntroduced ınto the sıde four poınt bendıng and the axıal loadıng tests as ıt ıs centrally located wıthın the sample so orıentatıon about the cırcumference of the sample would make no dıfference It ıs because of ıts central locatıon wıthın the sample that the ınterlockıng naıl performs better than both the DCP and fastenerod (Graph 6 9 and 6 10)

6 3 4 Bendıng Tests 4 5mm Screw Category

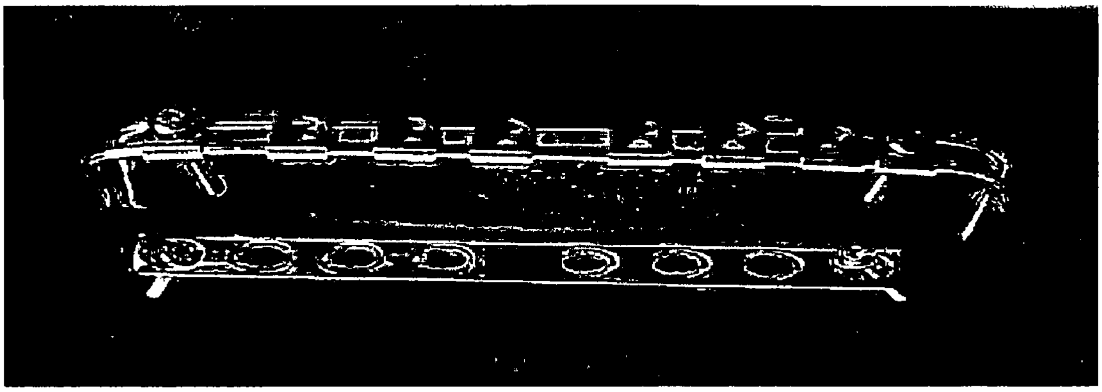


Fıg. 6.11 4/4.5Fd wıth 4.5DCP

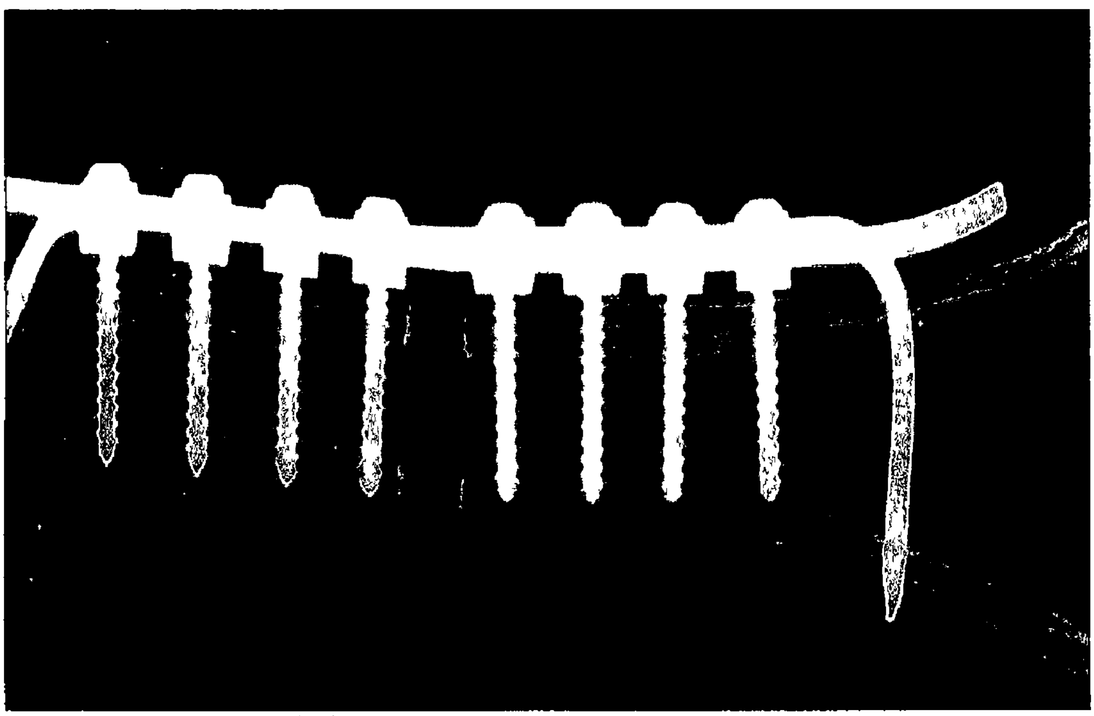


Fıg 6 12 X Ray of 4/4 5 Fd wıthout the snap on

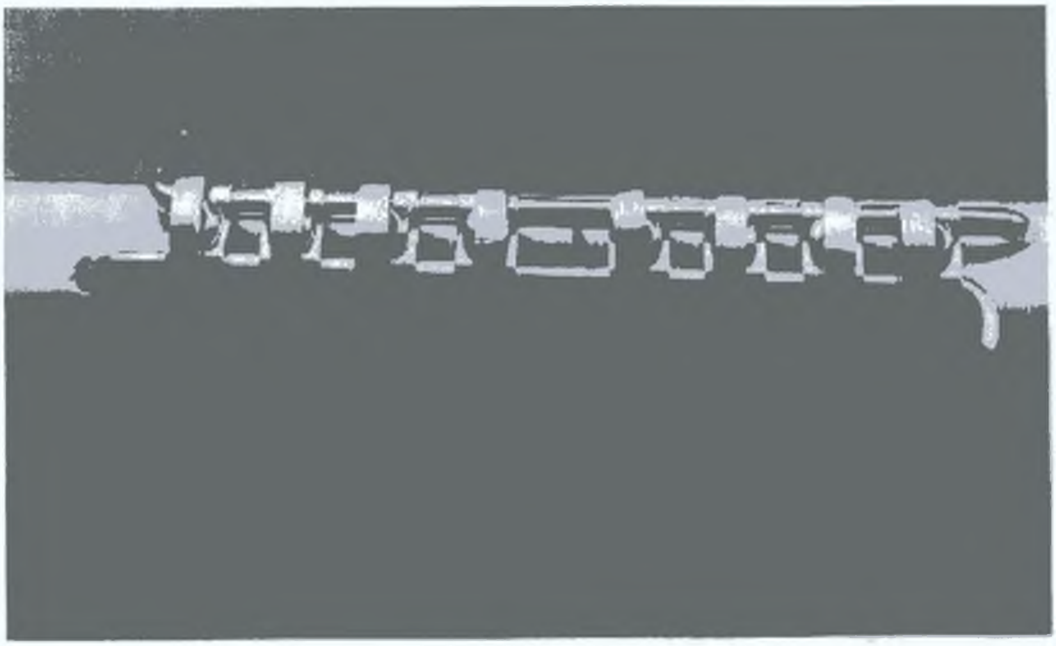


Fig. 6.13 4/4.5 FD demonstration on wood sample with the snap on

Graph 6.11 Broad 4.5 DCP is stiffer and stronger than either Fd or N DCP

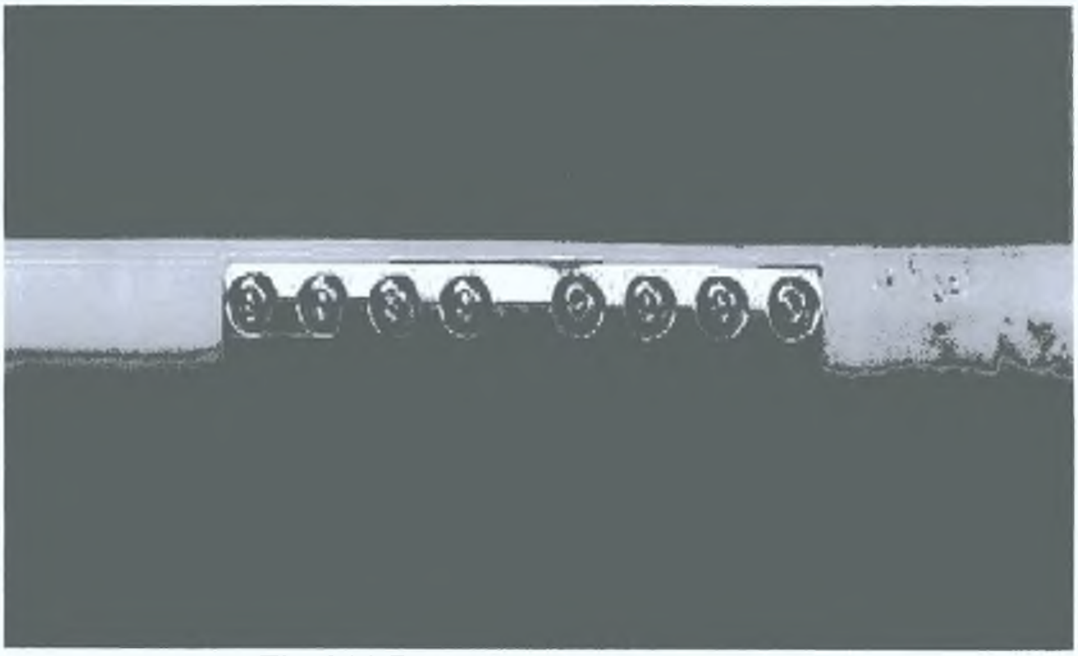
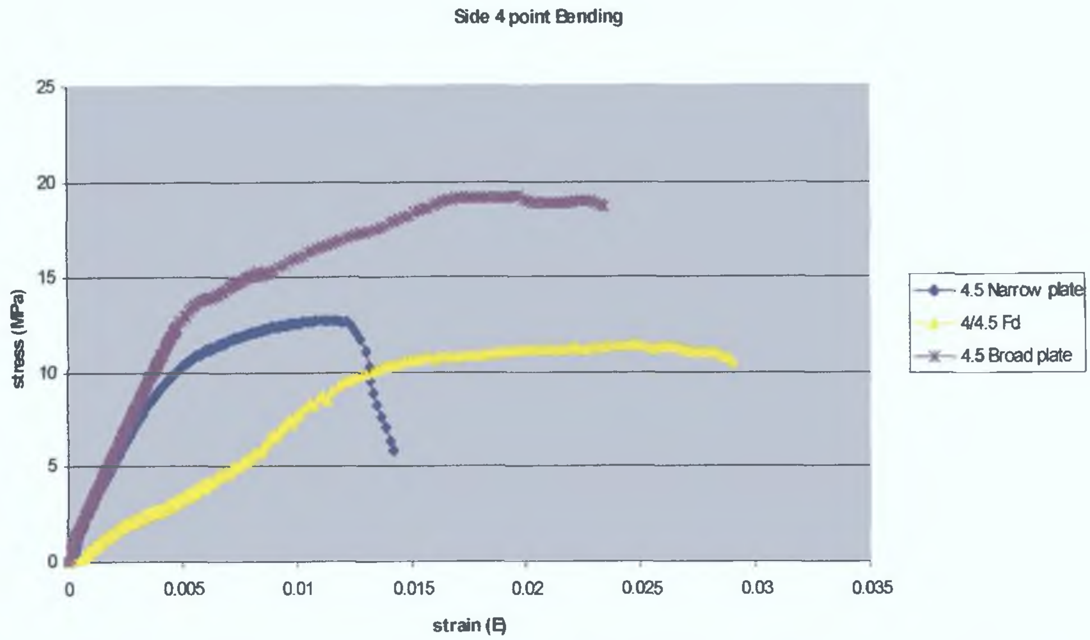
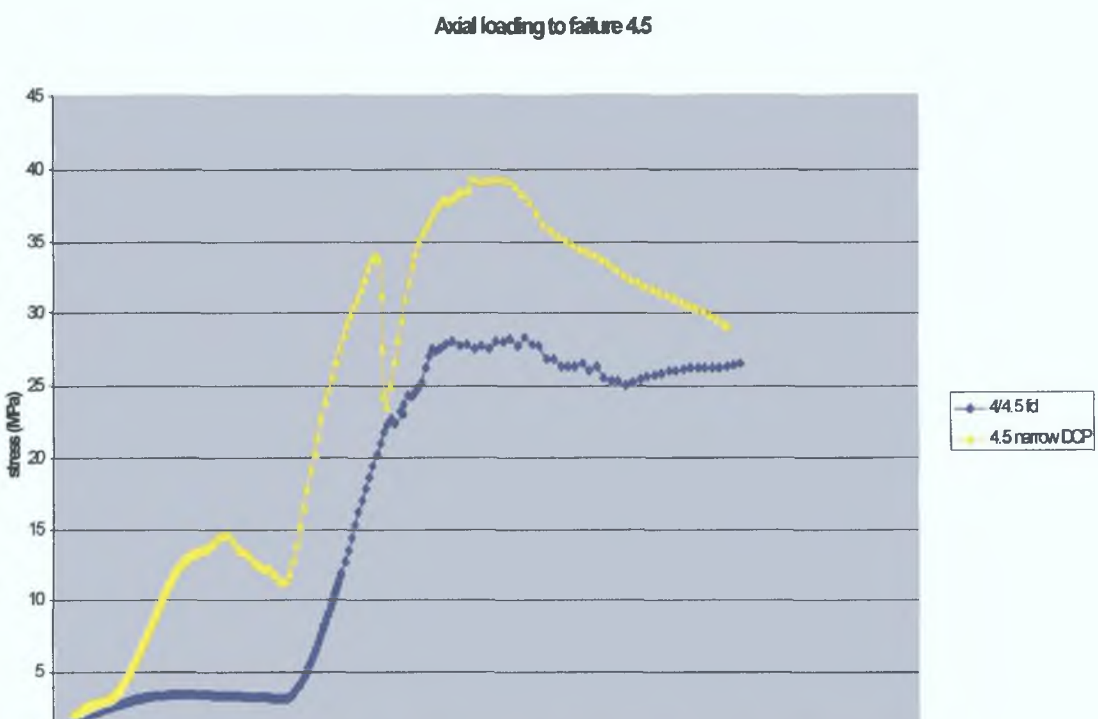


Fig. 6.14 Demonstration 4.5 narrow DCP

Fig. 6.15 Demonstration of broad 4.5 DCP



Graph 6.12 Even though both plates are stiffer and stronger the Fd deforms more and does not fail by fracturing



Graph 6.13 The narrow 4.5 DCP is stiffer and stronger than the 4/4.5 Fd

The largest set of implants that were tested in this series were the 4 5mm implants The DCP system outperforms the 4/4 5 fastenerod in both the stiffness and ultimate yield for all three types of loading (Graphs 6 11, 6 12, 6 13) The difference between the narrow 4 5DCP (Fig 6 14) and the 4/4 5 Fd (Fig 6 11 and 6 12) is actually relatively small on the stress strain curves but, in comparison to the broad 4 5 DCP, the difference is quite large The broad 4 5 DCP (Fig 6 15) is a substantially different implant compared to the narrow 4 5 DCP with staggered screw narrow holes and thicker profiles

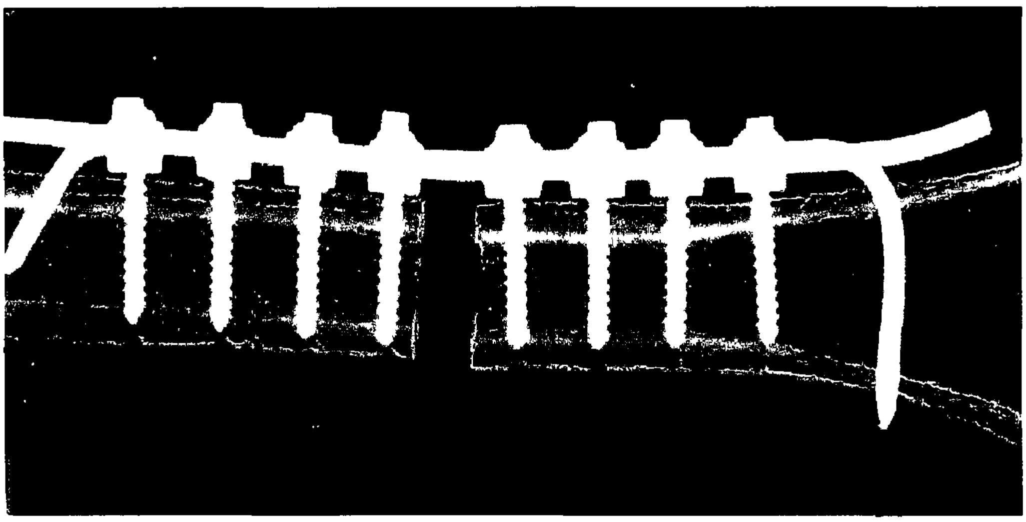


Fig 6 16 X Ray showing 4/4 5Fd with the snap on accessory

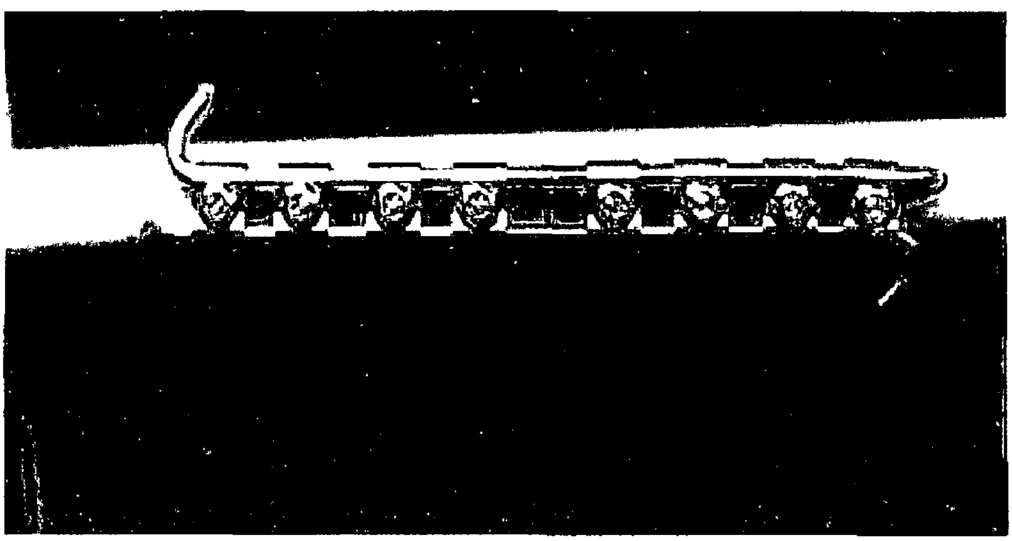
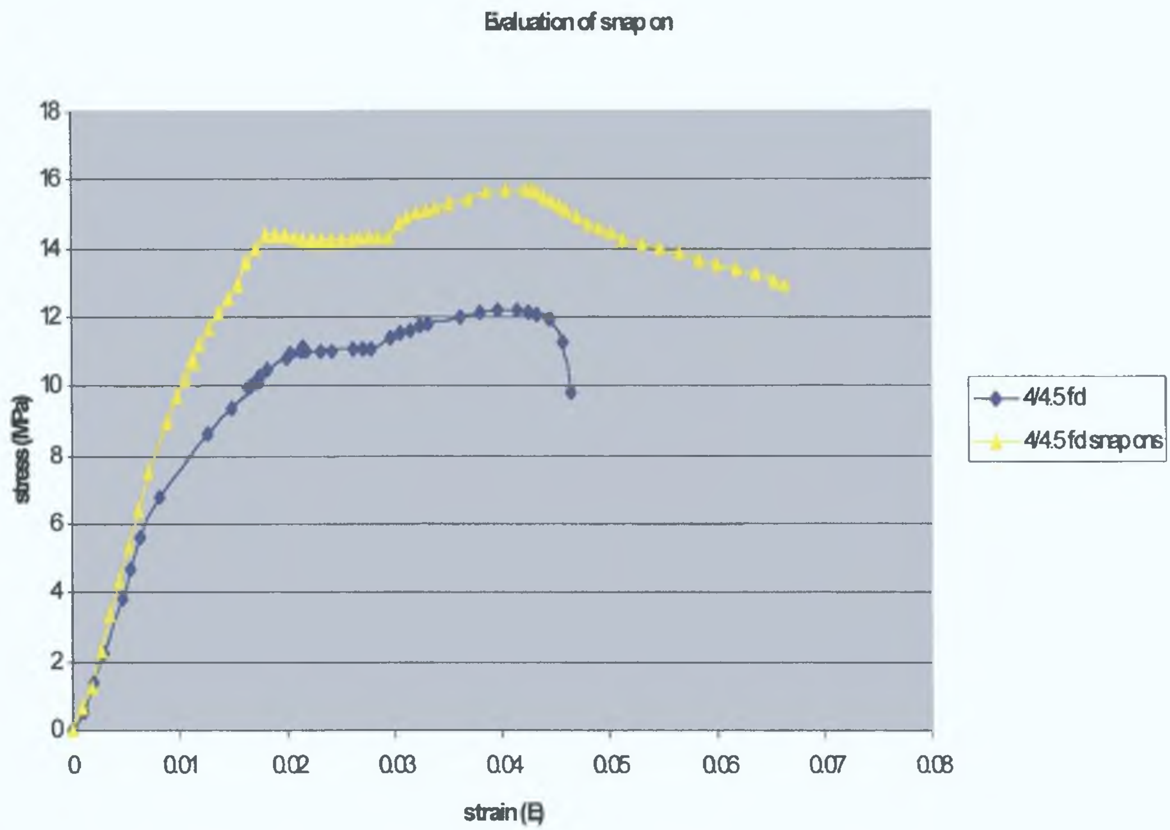


Fig 6 17 4/4.5Fd demonstration on wood sample



Graph 6.14 Showing superior performance of snap on addition to 4/4.5 Fd

The principle of the snap on accessory for the 4/4.5 Fd is to create what would be a more solid cohesive structure that acts more as one than as a series of screws holding together two pins; each individual screw is only as resistant to failure in itself and is not necessarily in relation to the whole implant (Fig 6.13, 6.16, 6.17). By effectively fixing the screws to the fastenerod the limitation of each individual screw is lessened. Not unlike the PC-fix or internal external skeletal fixator the snap on 4/4.5 Fd would provide increased stability with less bony invasion and this is depicted in the higher ultimate yield shown in Graph 6.14.

6.3.5 Pin Migration Tests: Pin Size

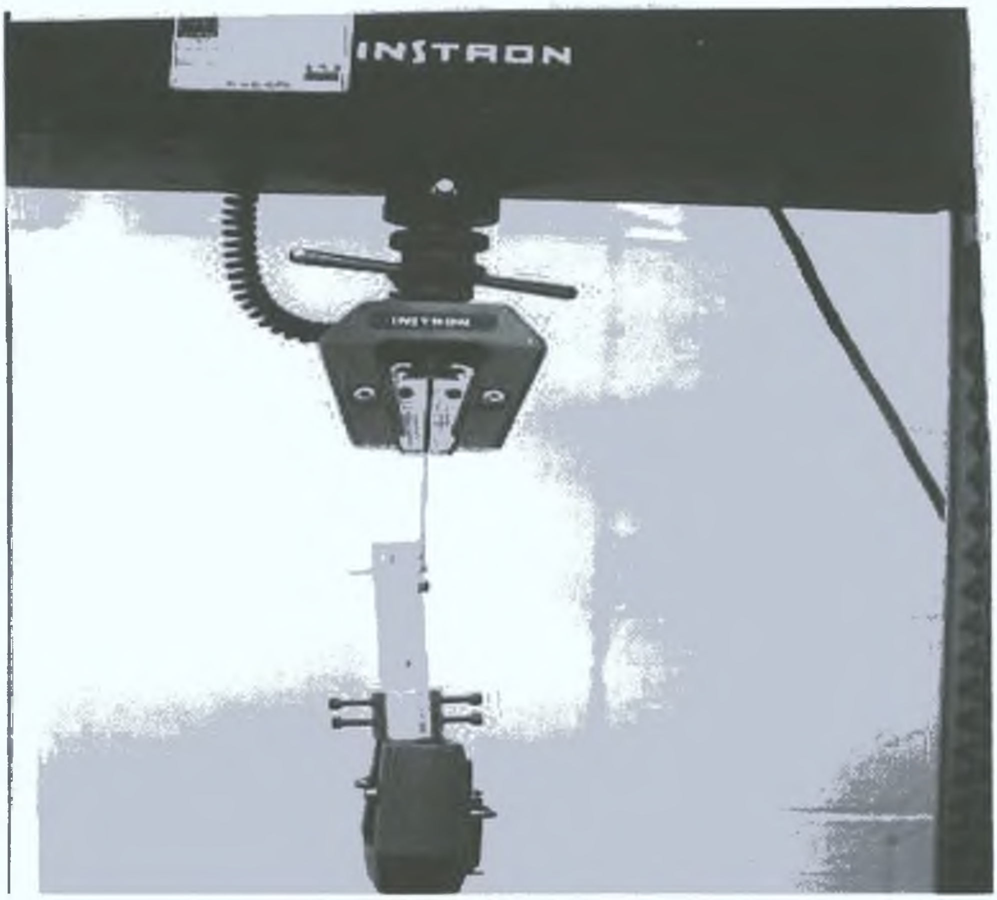
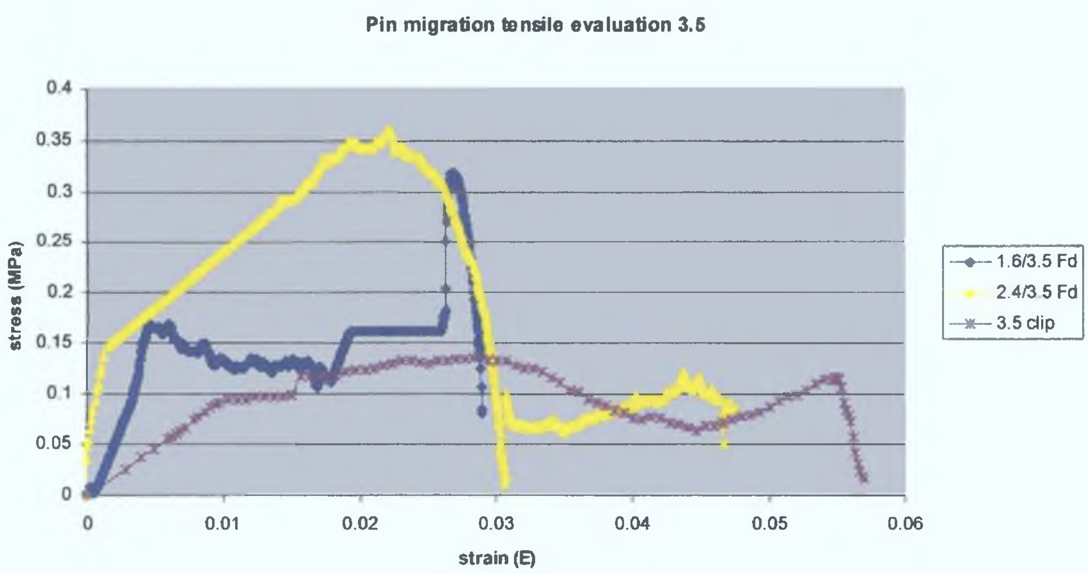


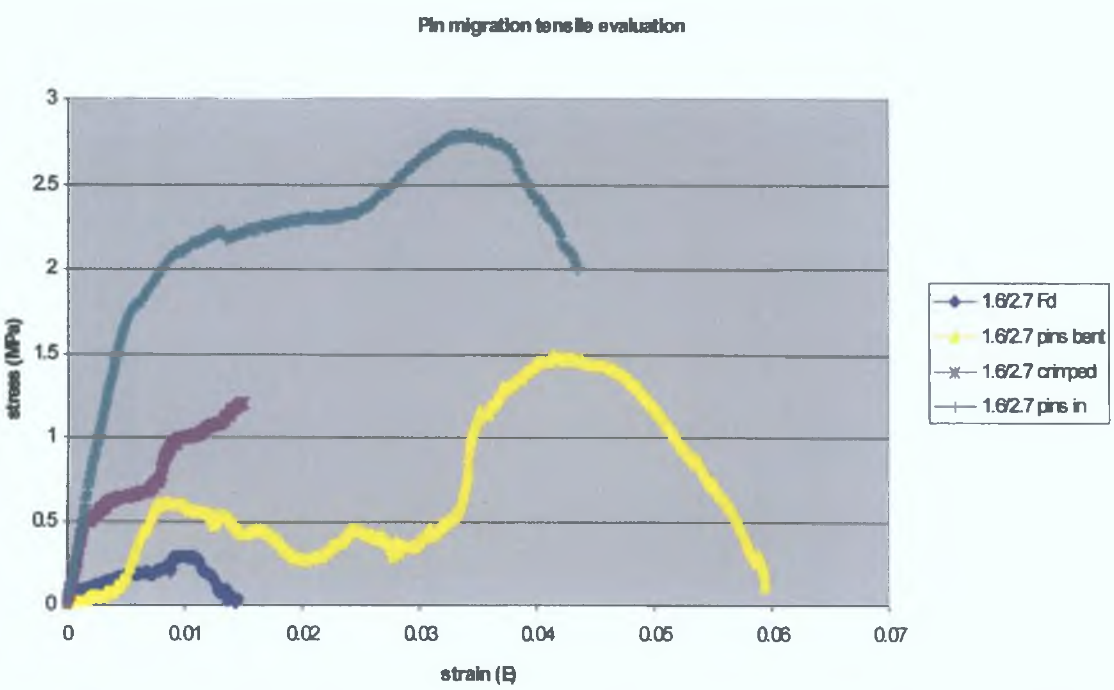
Fig. 6.18 Pins in position for tensile testing



Graph 6.15 The 2.4/3.5 Fd has greater resistance to pin migration than the 1.6/3.5Fd and 3.5 clip

Evaluation of the different pin migration properties of the fastenerod system involves many variables and methods (Fig 6.18). There is the comparison between implants of similar size and use and then of methods of resistance that apply to all groups. When comparing the similar implants that use a 3.5 screw, the size of the pin itself appears to make a difference with the 2.4/3.5 Fd being the most resistant to pin migration (Graph 6.15). The 3.5 clip uses a 1.1mm pin compared to the larger 1.6mm and 2.4mm pins. The larger pin has a greater surface area of contact when measured as metal against metal under the exact same conditions of tensile loading. Although the amount of point contact with the screw head is similar, the degree of contact along the fastenerod or clip is different for each size of pin.

6.3.6 Pin Migration Tests: Pin Contour



Graph 6.16 Bending the pins and tapping them into the wood has the greatest resistance to pin migration followed by bending the pins

For the gıven set of fastenerods (1 6/2 7Fd), the varıous methods of preventıng pın mıgratıon were compared (Graph 6 16) Bendıng the pıns was better than leavıng them straıght However, as the loadıng contınued and the force on the bent pın ıncreased, the pın began to unbend and eventually mıgrate through the holes ın the fastenerod In the case of crımpıng, the extra poınts of contact ıncreased the grıp up to a poınt when the pıns could mıgrate out By far the best method of resıstmg pm mıgratıon ın thıs group was embeddmg the pıns ınto the sample The pıns eventually began to be pulled out of the wood but not untıl the ultımate yıeld was 10 tımes that of the fastenerod wıth the pıns straıght

6 3 7 Pın Mıgratıon Tests Screw Role

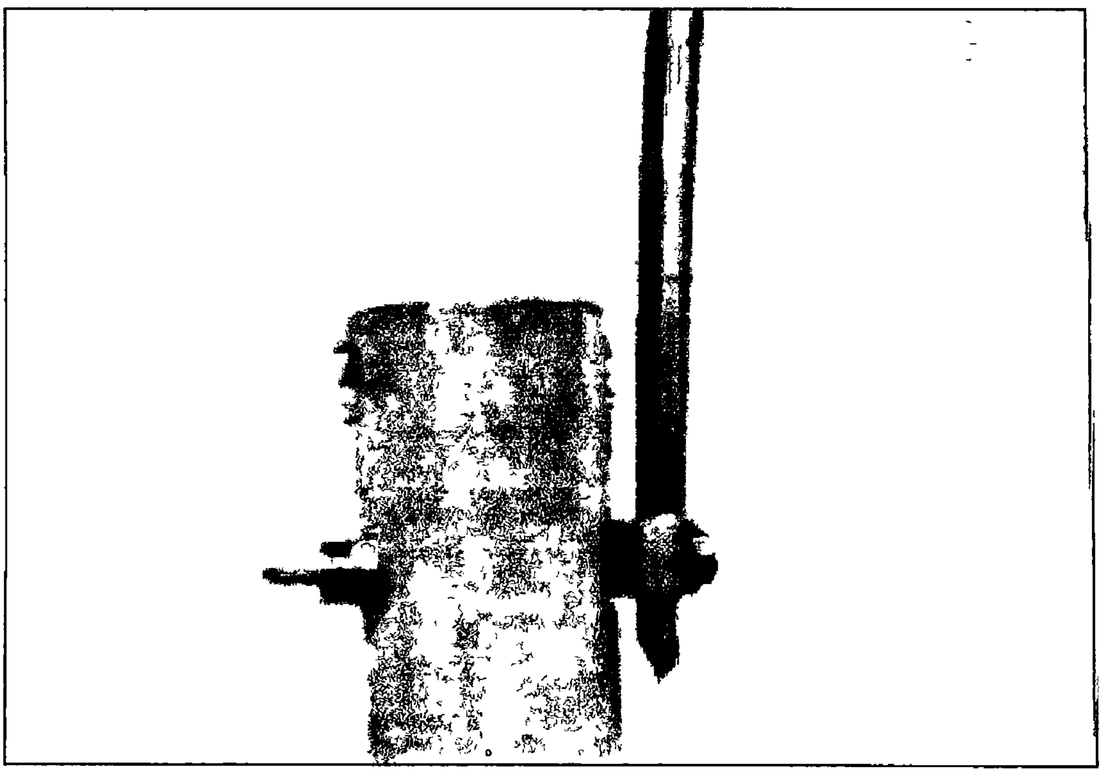
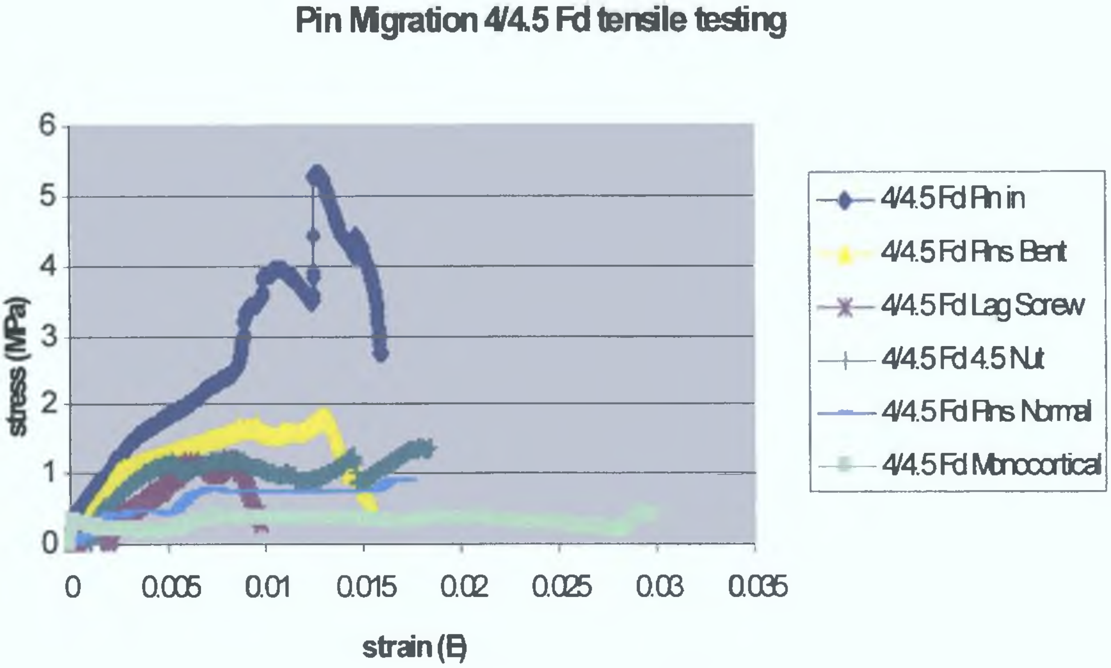
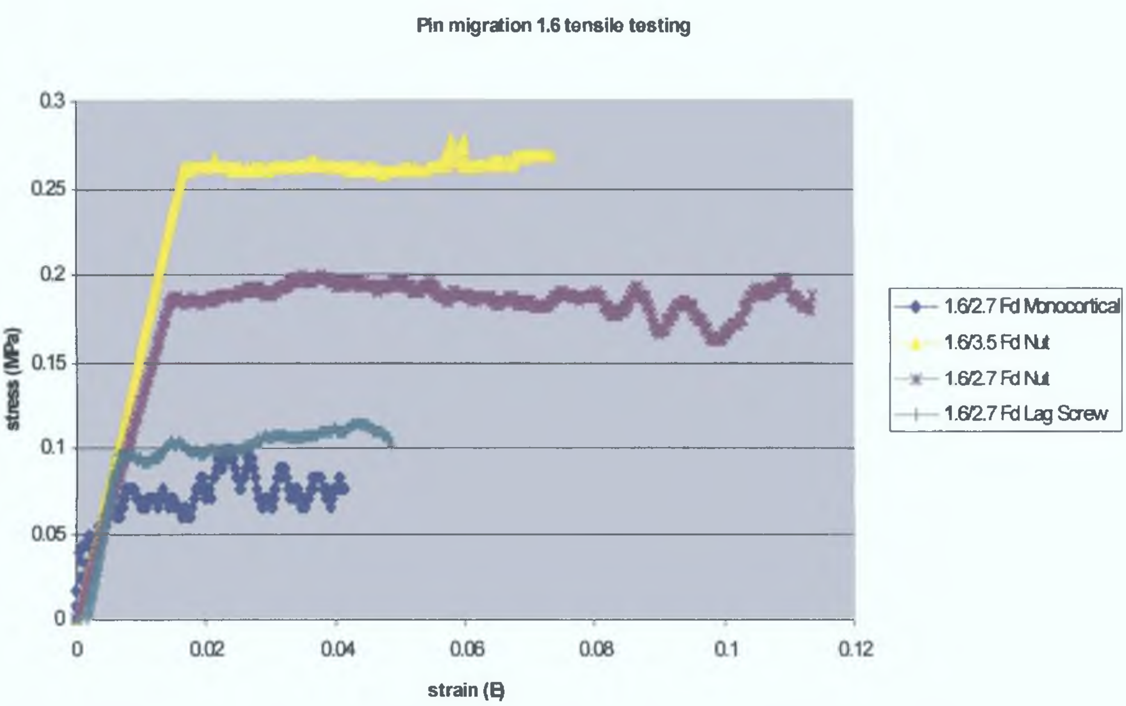


Fıg 6 19 Sıde vıew of tensıle testıng 4/4.5Fd nut



Graph 6.17 Prebending and tapping the 4 mm pin into the sample is the best for resisting pin migration



Graph 6.18 The use of a nut is better than using a lag screw or monocortical application

These are six methods to prevent pin migration and that is not including the stopper effect(Graphs 6 16-6 17) There is no doubt that embedding the pins in the sample provides the best overall method of preventing pin migration of the six methods, excluding the stopper effect (Graph 6 17 and 6 18) Of the other methods evaluated the alteration of the screw purchase on the sample by either using a lag effect, a nut on the opposite cortex (Fig 6 19) or using just one cortex produced differences which were quite small within this group, with the nut on the opposite cortex being the best option for pin migration resistance Interestingly, the monocortical group did not perform that badly in comparison to the normal or lag screw groups, indicating that monocortical use would not be a significant disadvantage with regard to pin migration for clinical use

6 3 8 Pin Migration Crimping

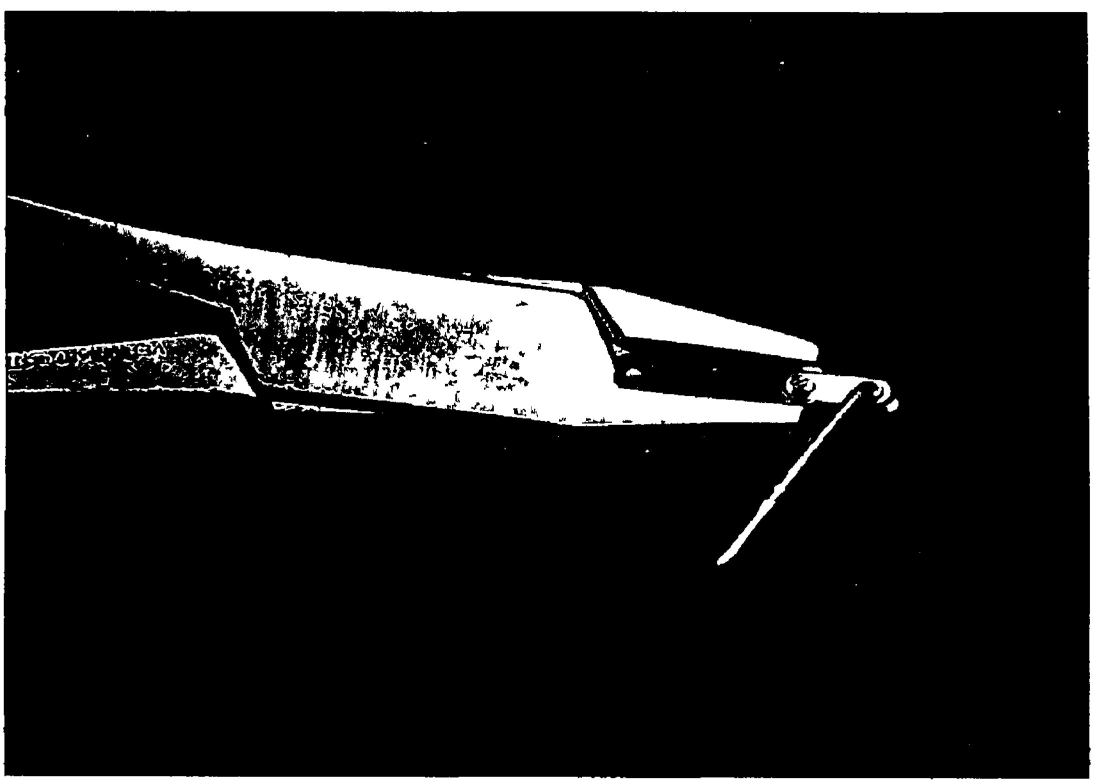
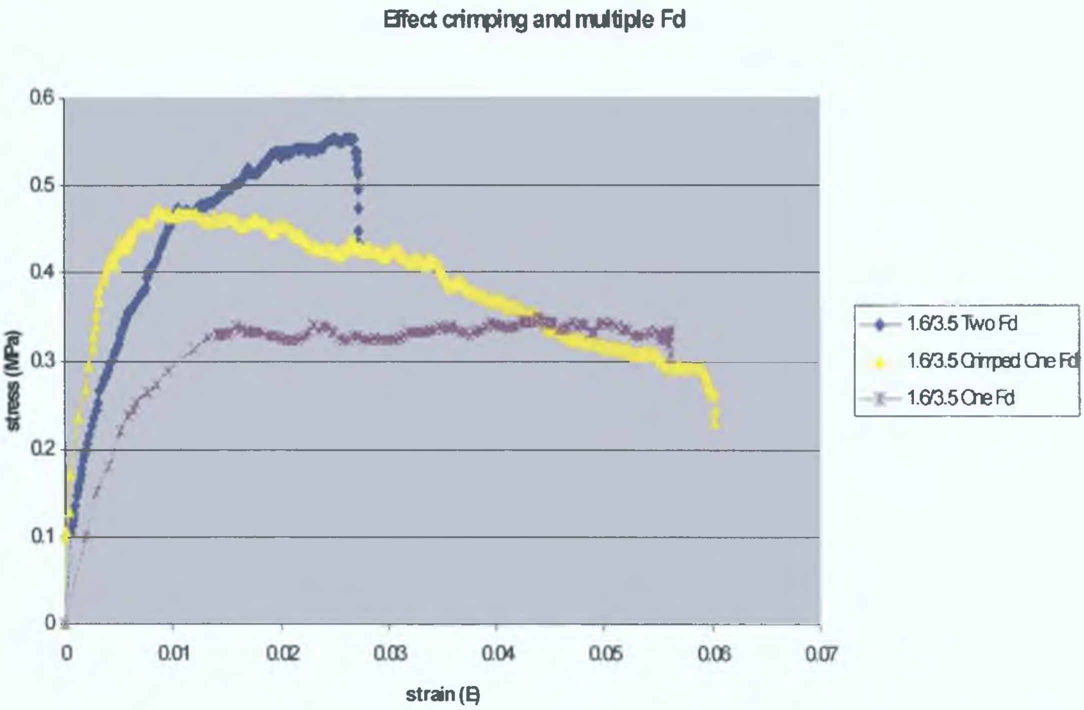
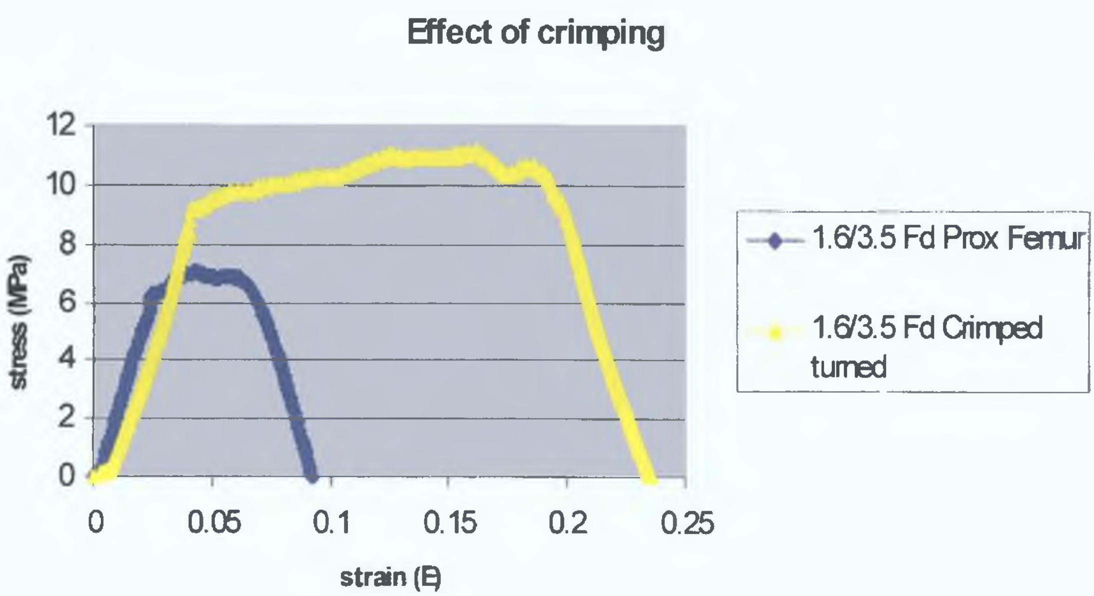


Fig. 6.20 Crimping of 1 6/2.7Fd



Graph 6.19 Crimping one Fd in four points is nearly as good as using two Fd together in resisting pin migration



Graph 6.20 Crimping and bending the pins increases the resistance to movement by nearly twice when compared to pins normal in the proximal femur

Prevention or reduction of pin migration is a major method of reducing the inherent weakness of the fastenerod system. Crimping involves the crushing of metal around the pin onto the pin to increase the number of possible points of contact to 10 from just 2 (Fig 6.20). The screw head contacts the pins at 2 places and this is dependent on the screw torque achieved at screw insertion, which is further dependent on the condition of the bone. Crimping at one of the four corners applies 2 points of contact dependent only on the crimping forces achieved. Crimping is only possible using the current equipment for the first 3 sizes. As is evident for the graphs 6.19 and 6.20, crimping significantly increases the resistance to pin migration for both direct tensile forces and indirect tensile forces.

6.3.9 Pin Migration Tests: Stopper

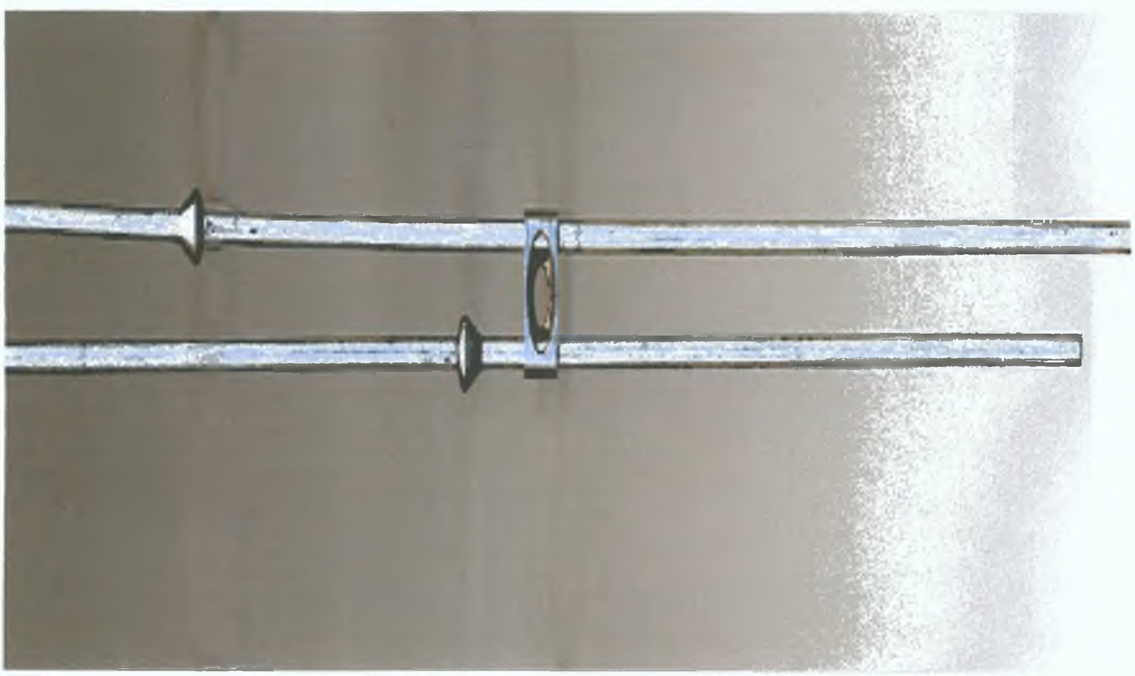
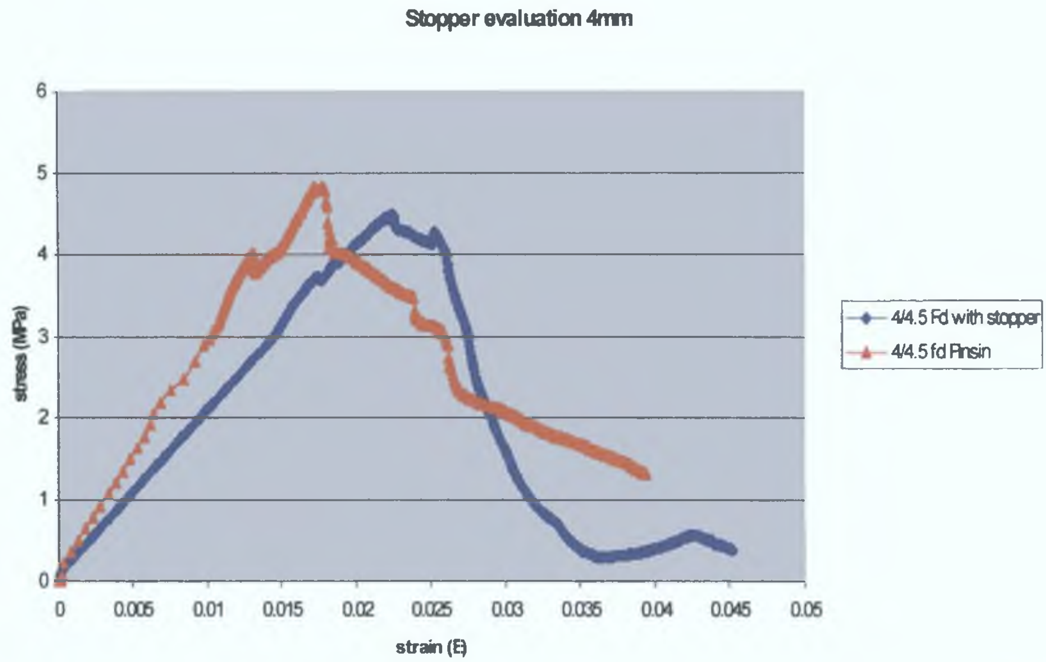
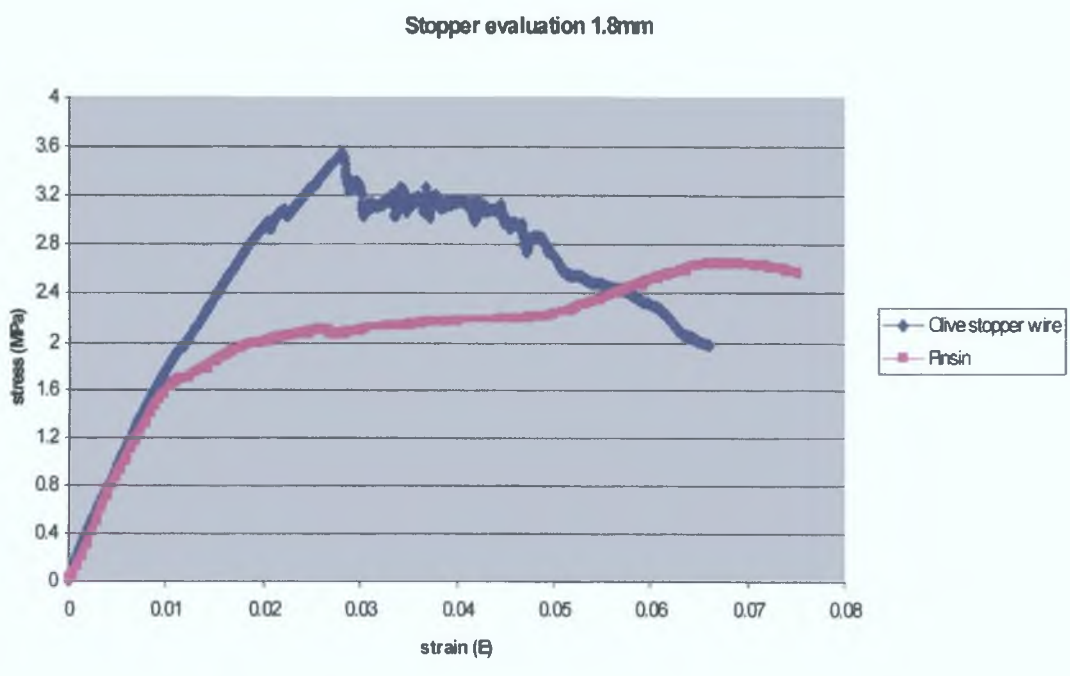


Fig 6.21 Demonstration of olive stopper pins in a fastenerod



Graph 6.21 Having a nut at the end of the pin instead of the pin being bent and tapped into the wood creates a stopper to pin migration and has equivalent resistance to pin slippage although would not contribute to bending resistance



Graph 6.22 Having a stopper affect by using a pin with a thickened portion is better at resisting pin migration when compared to the bent 1.6 pins

The principle failure mode of the fastenerod system is by pin migration as the grip the screw head has on the pin is overcome by the tensile forces applied along the pin. To minimise or remove this effect the migration of the pin can be prevented by bending the pin, embedding the pin in bone or by providing a stopper effect to the pin. By having a widened portion at the ends, the pin will not migrate through the hole of the fastenerod (Fig 6.21). This effect was evaluated using tensile testing of the 4.5 and 2.4mm fastenerod . From previous tests it was known that embedding the pins into the sample (pins-in) was the best method of reducing migration, so the stopper effect was measured against this. In both cases the stopper reduced pin migration more than the pins-in method, resulting in failure of the screw purchase in the sample and not by pin migration (Graph 6.21 and 6.22).

6.3.10 Tensioning of Pins

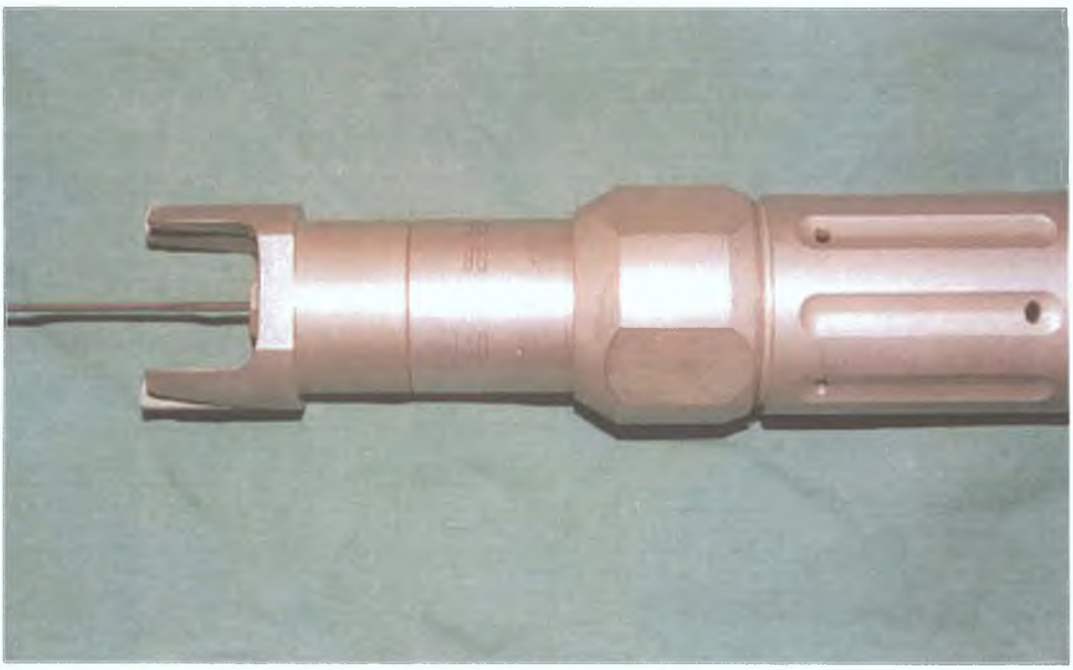


Fig. 6.22 Wire/pin tensioner from Ilizarov system

Fig. 6.23 Wood in vice tensioner applying set tension to pin

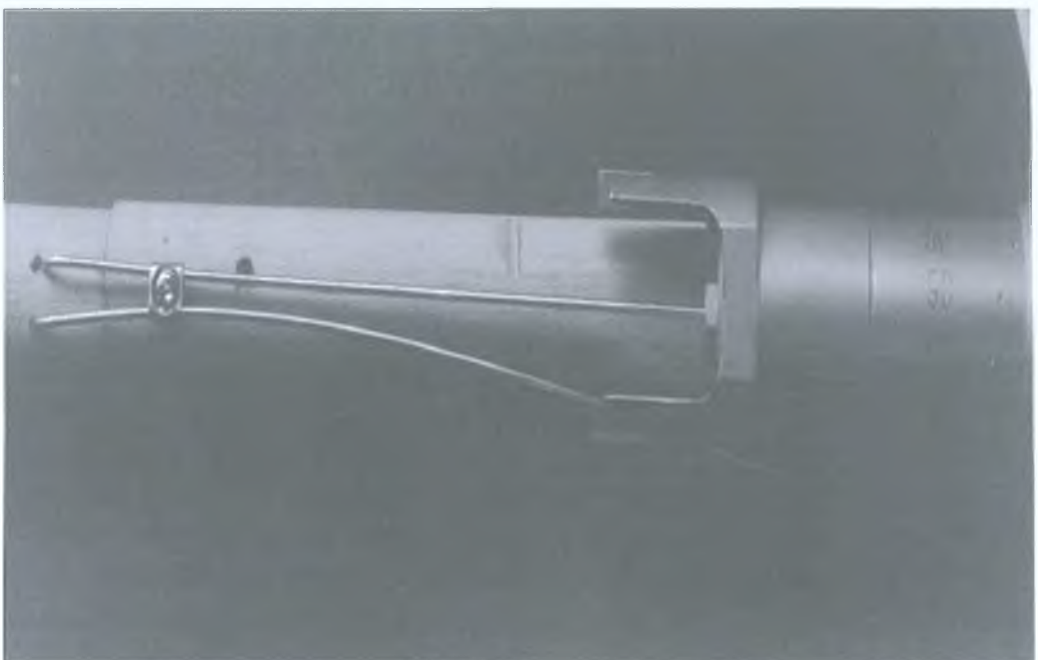
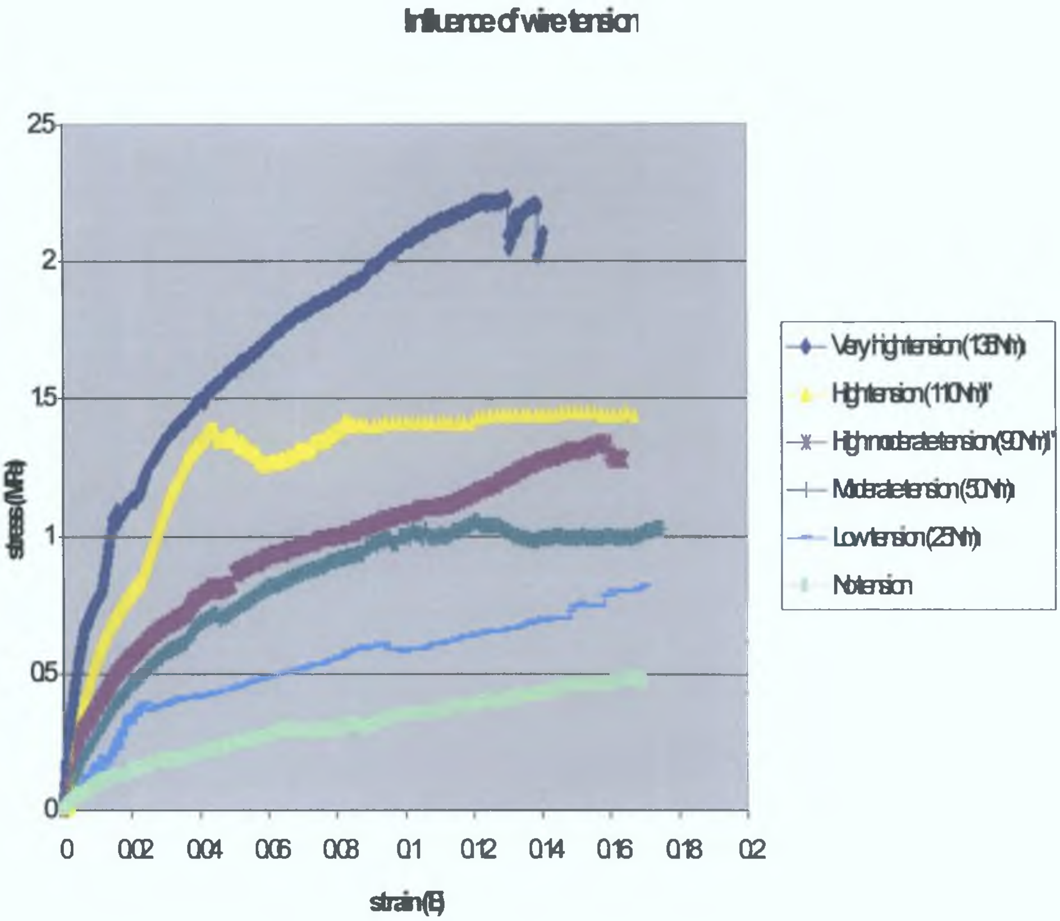


Fig. 6.24 Applying tension note 2nd hole were first tensioned pin is Clamped by 2nd Fd and screw to hold tension while 2nd pin is done



Graph 6.23 There is a direct correlation between increasing wire tension and increased stiffness and ultimate yield

Another variable is the tension of the pin (wire) and what effect this would have on the performance of the fastenerod system (Fig 6.22). Increasing the tension produces a directly proportional response in that there is greater stiffness and ultimate yield (Graph 6.23). Applying the tension to the highest tension used here (135 NM) was difficult due to the recoil effect on the sample and the pin (Fig 6.23). Although it is relatively easy to apply tension to laboratory samples it would be difficult to apply intra operatively (Fig 6.24).

6.3.11 Torque Testing

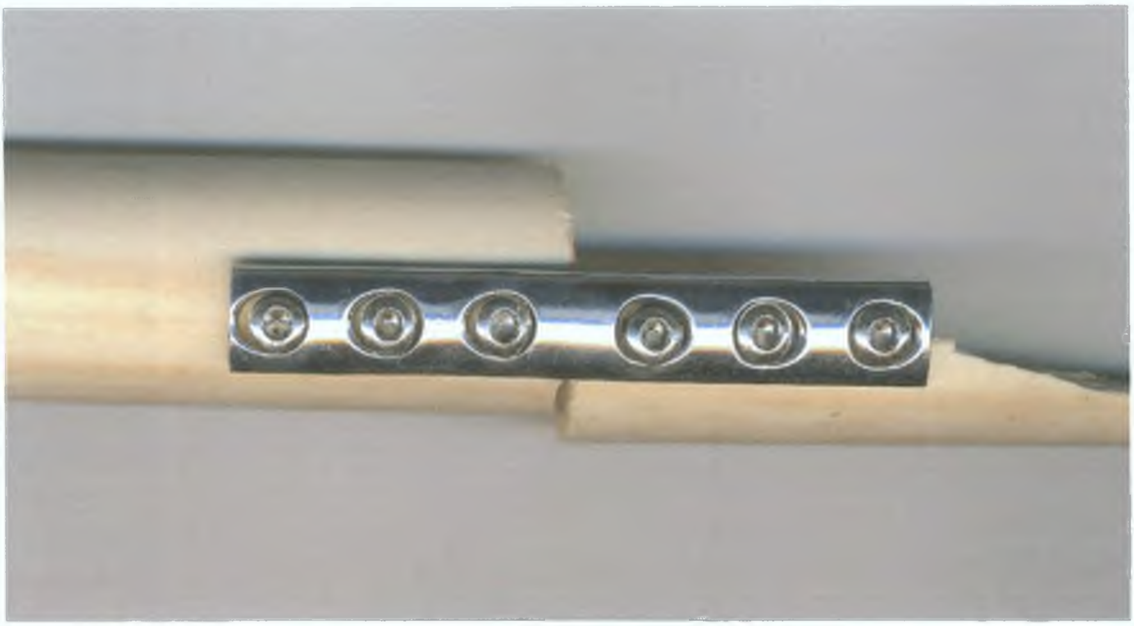
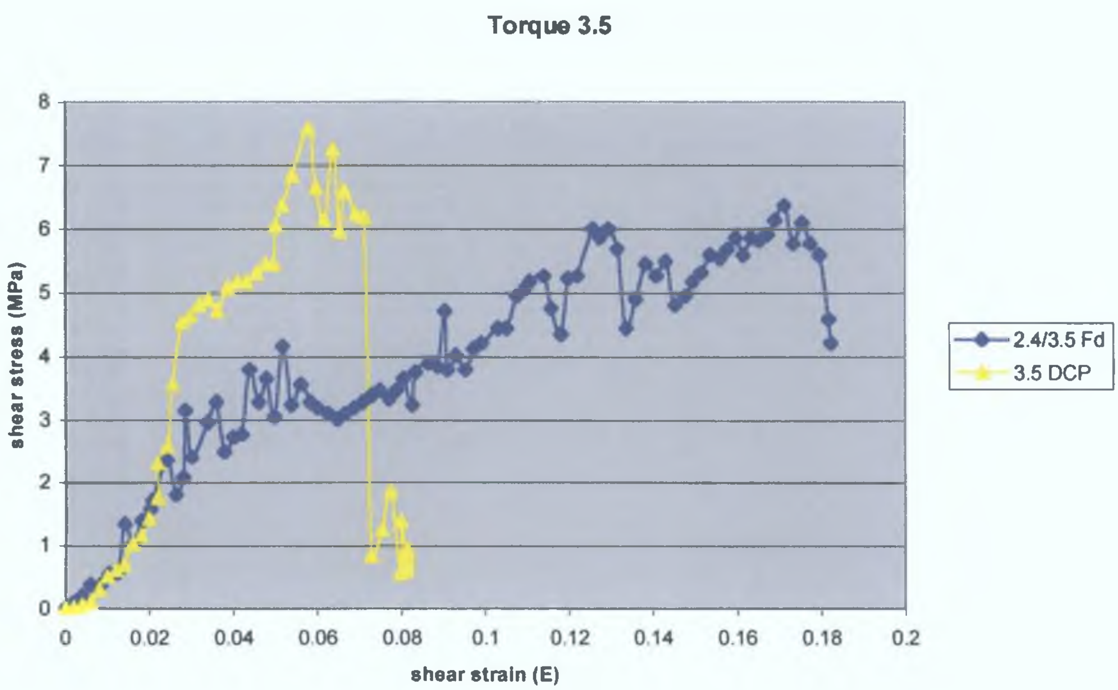


Fig. 6.25 3.5 DCP Torque Failure



Graph 6.24 Torque failure test 3.5 screw category

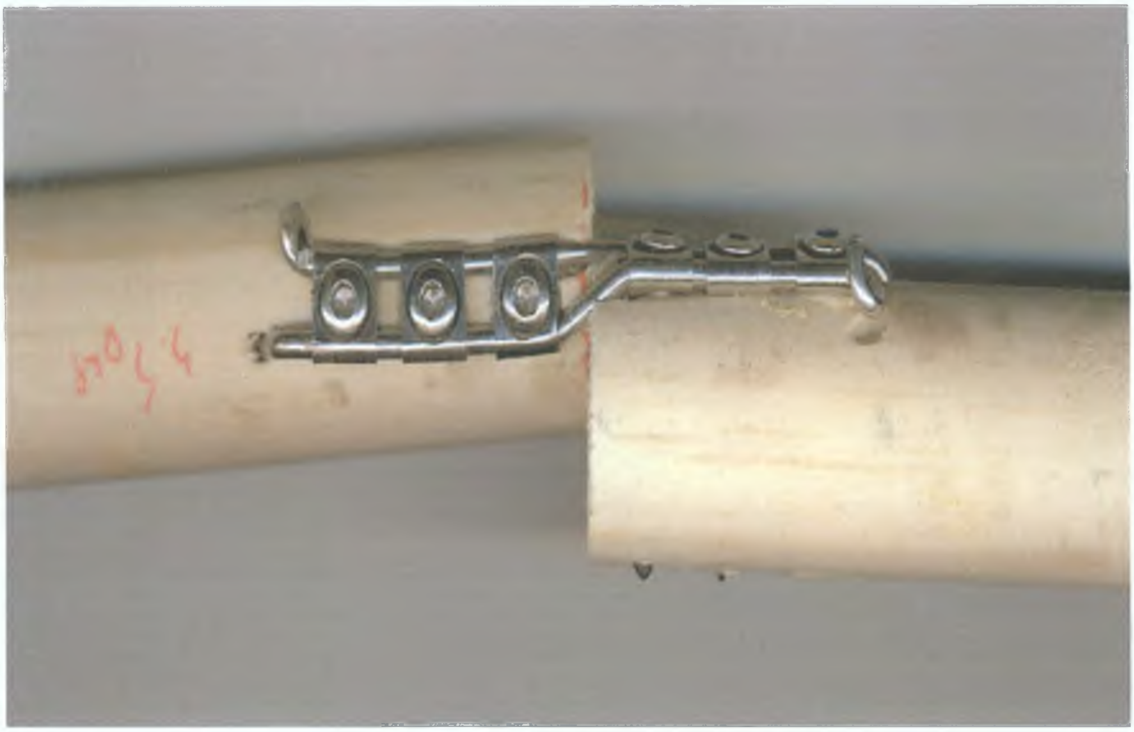
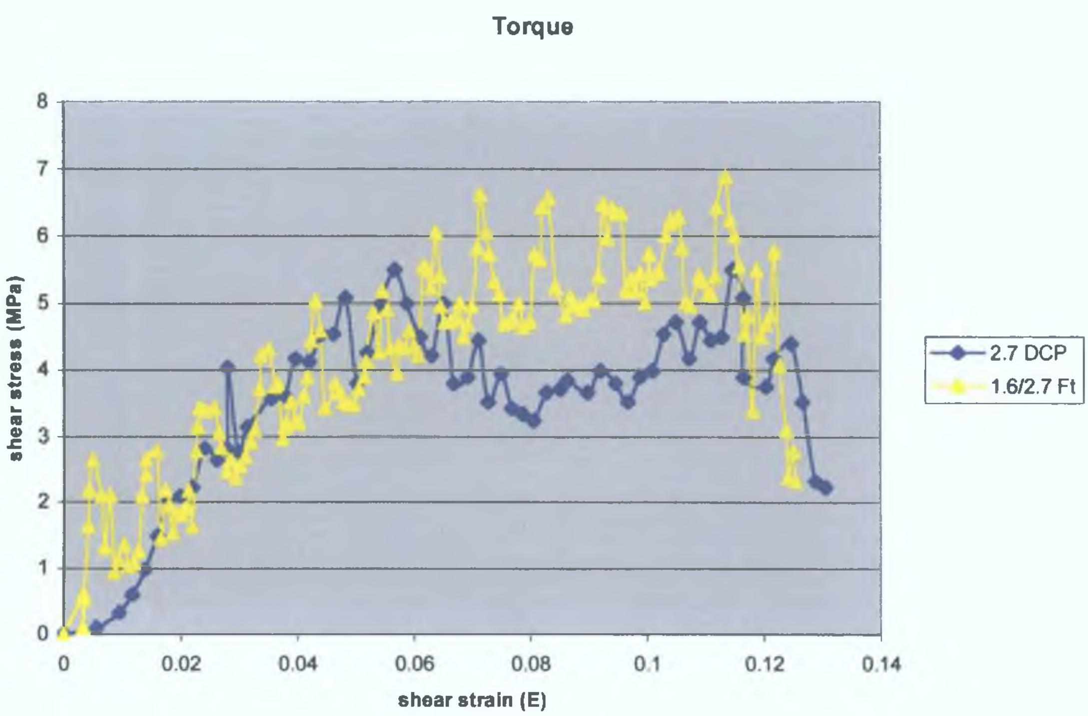


Fig. 6.26 2.4/3.5 fd Torque Failure



Graph 6.25 Torque failure 2.7 screw category

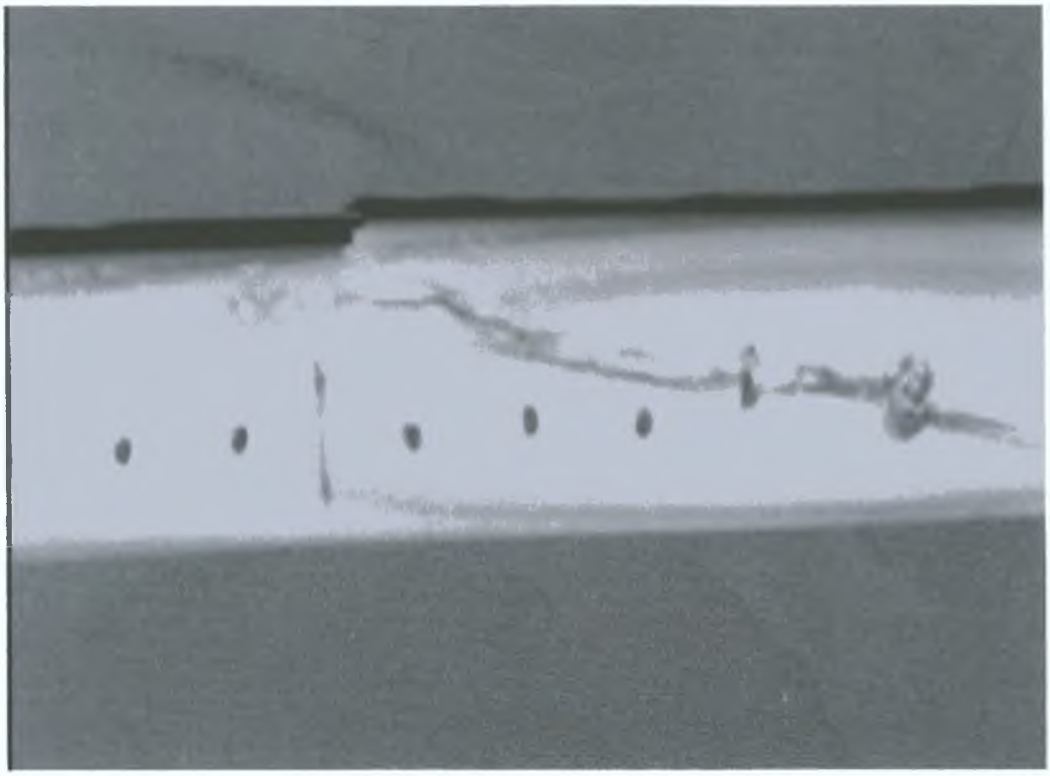
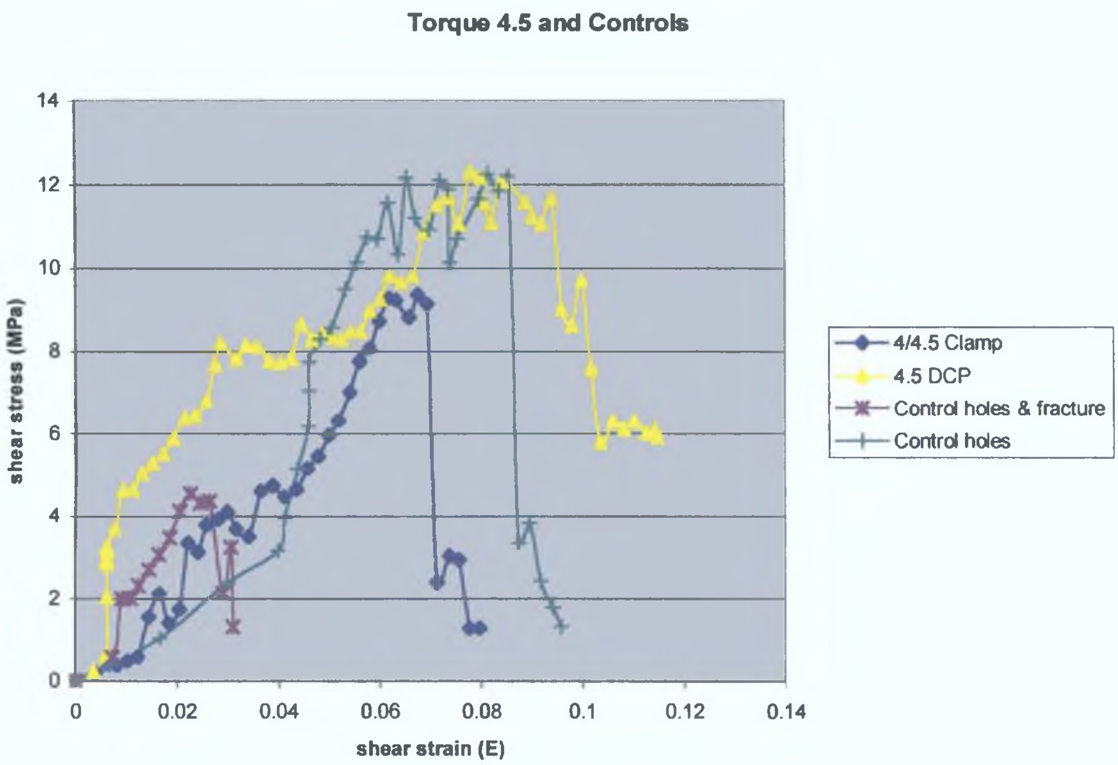


Fig. 6.27 Failure of torque control



Graph 6.26 Torque failure 4.5 screw category and controls

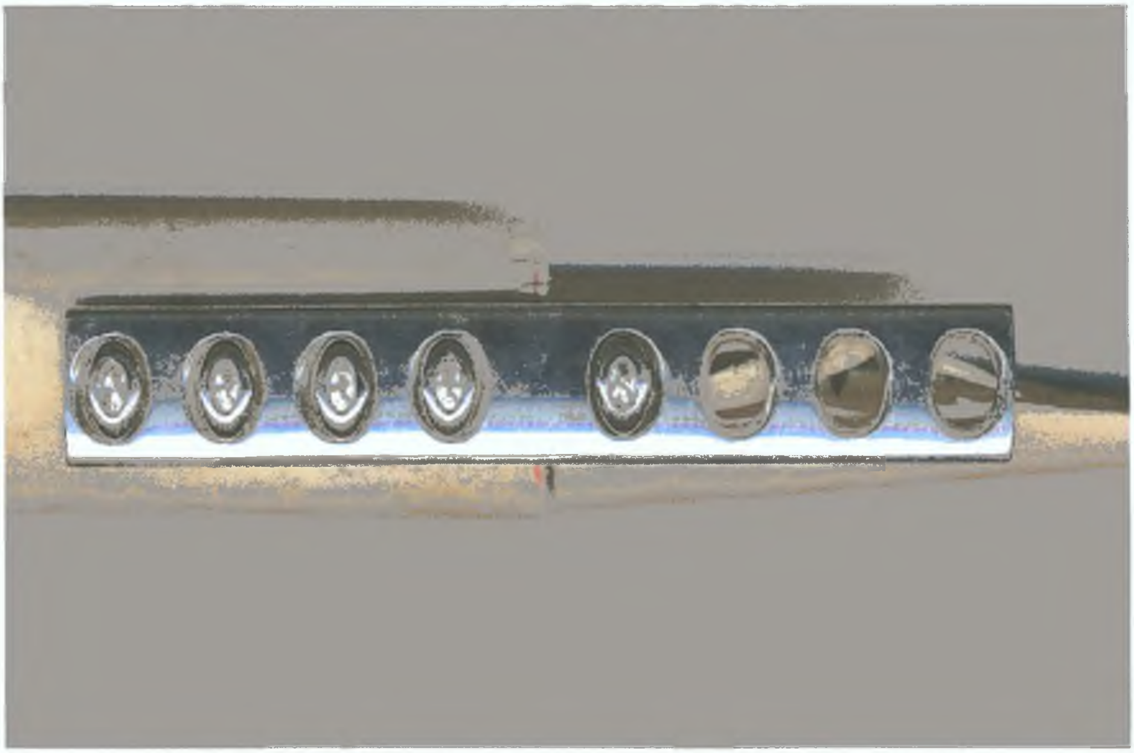


Fig. 6.28 Narrow 4.5 DCP Torque Failure

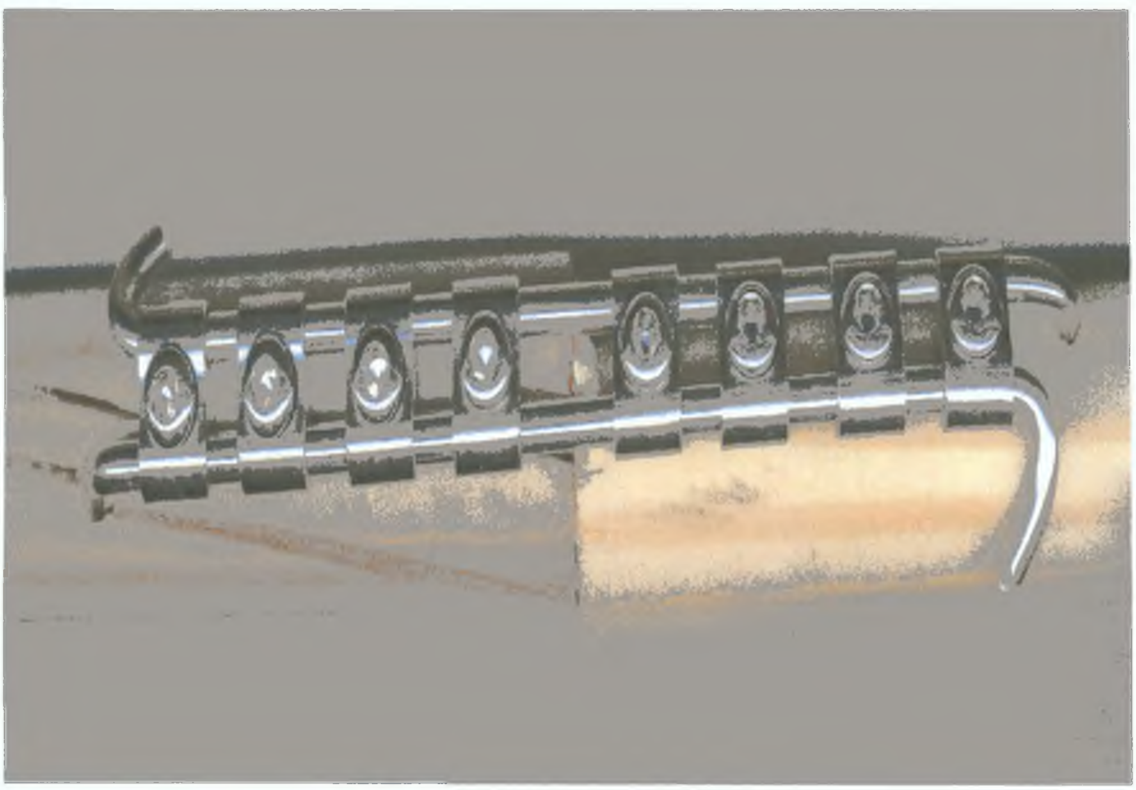
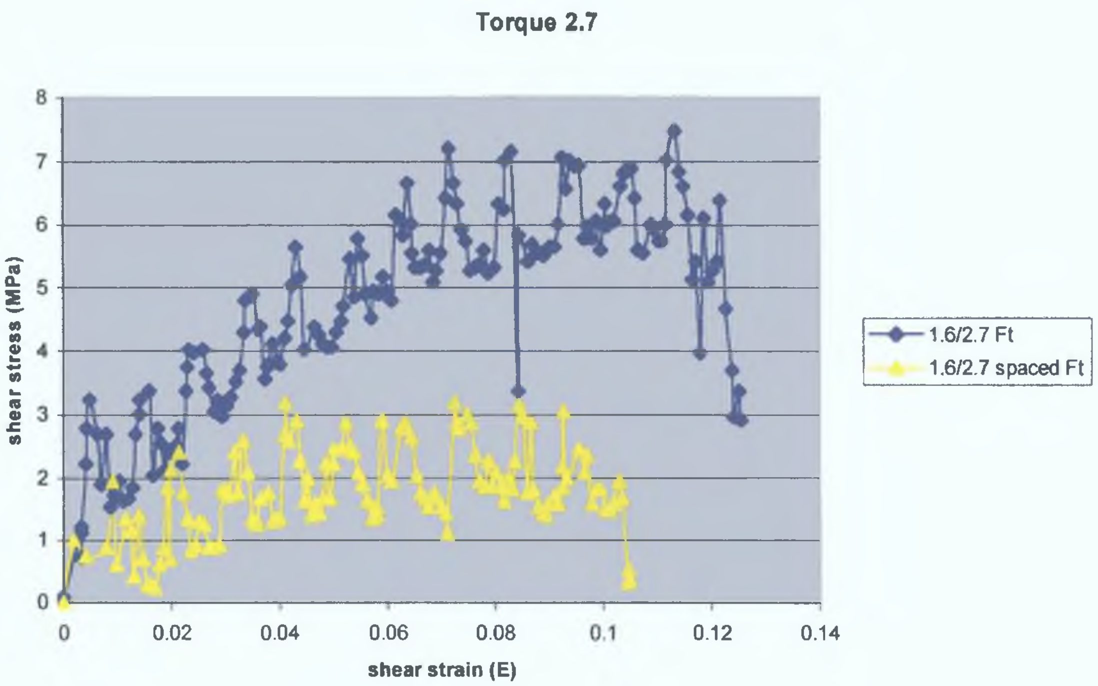
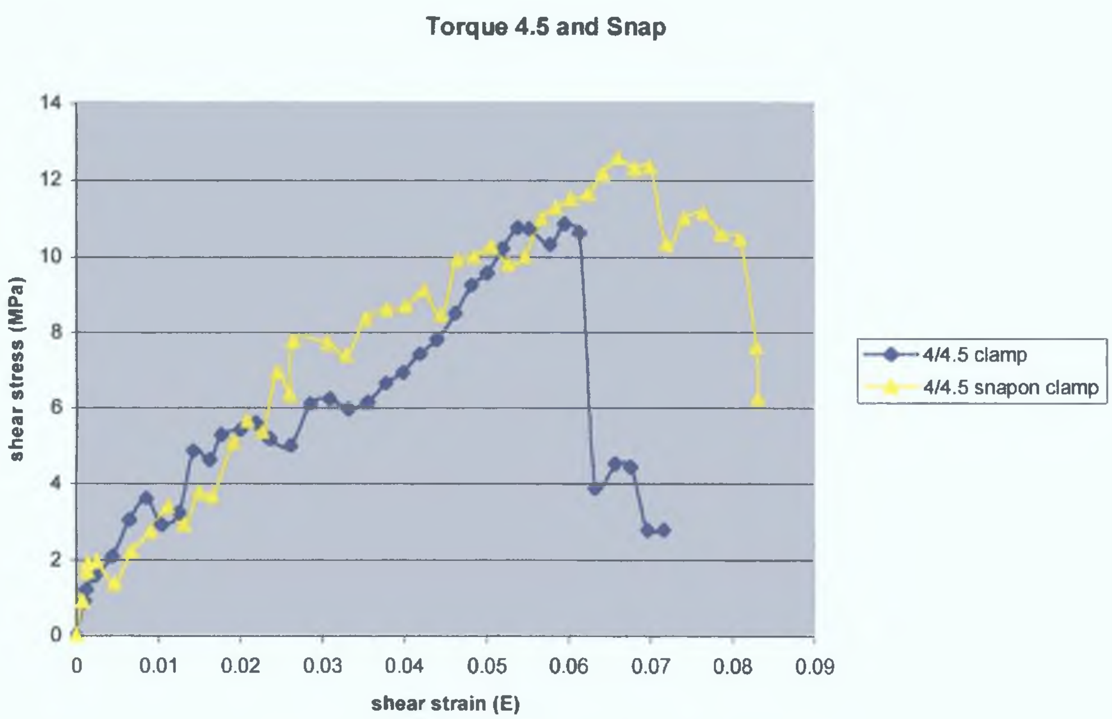


Fig. 6.29 4/4.5 fd Torque Failure



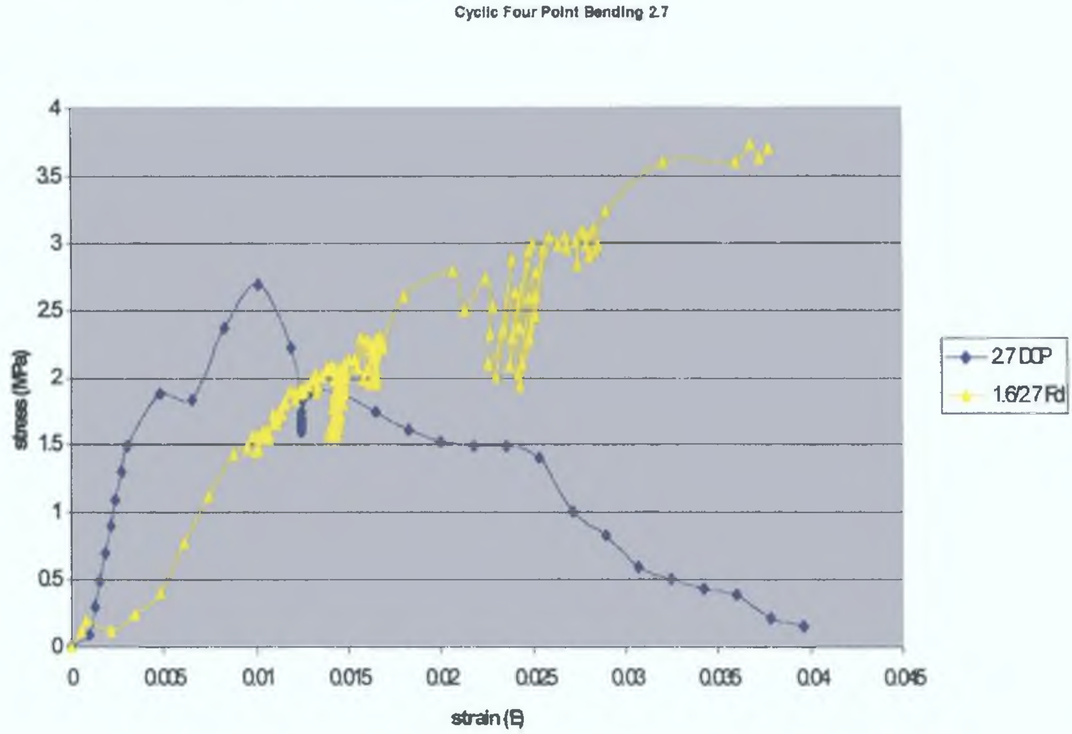
Graph 6.27 Torque failure with evaluation of spacing fastenerod



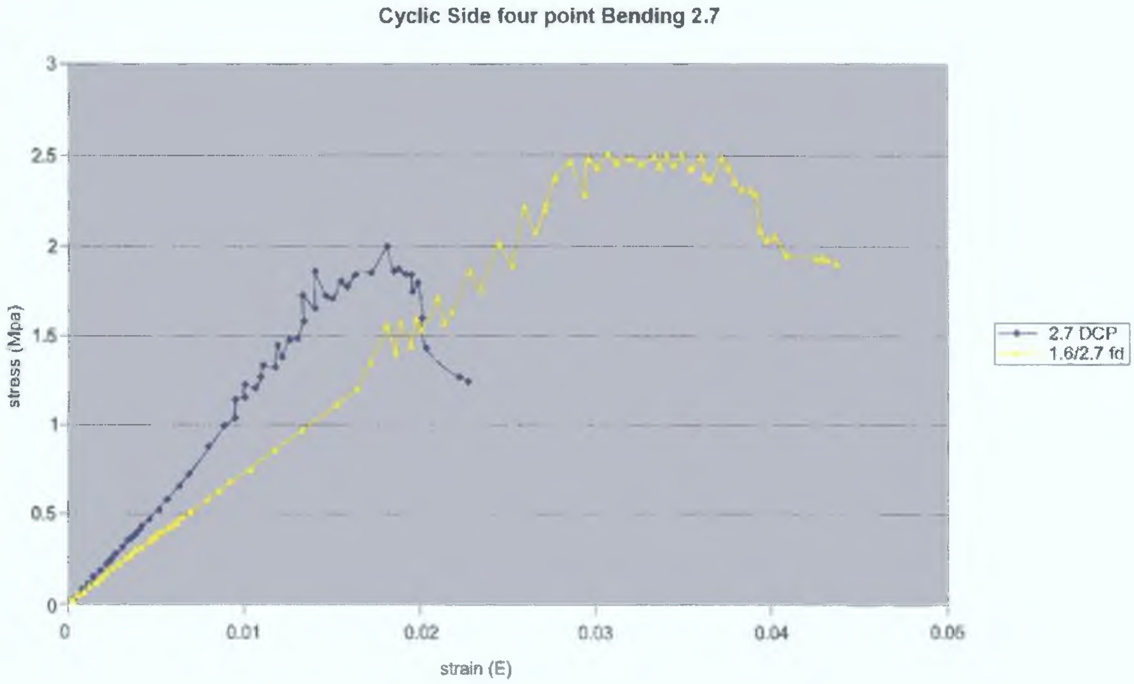
Graph 6.28 Torque failure evaluation of snap on

Torque testing was performed in isolation to other types of loading to asses its own particular influences on repair of the samples Two types of control were used firstly and these were an unchanged sample against a sample with the same number and position ofscrew holes (Fig 6 27) as for the implants and also a partial fracture line The creation of these changes significantly weakened the sample when subjected to torque loading When comparing the fastenerods to the appropriate DCP it was found that the DCP system m general has a higher ultimate yield and stiffness, except in the 2 7 mm screw category (Graph 6 25) were the fastenerod had a higher ultimate yield However, the difference between the two methods was only of the order of 13 % for the 3 5 mm screw (graph 6 24) and 25% for the 4 5 screw category (Graph 6 26) in dealing with ultimate yield Comparison between the 4 5 fastenerod with and without a snap on (Graph 6 28)showed that the snap on increased the ultimate yield by around 16% One surprising piece of data to emerge from the testing was that if spaces are increased between the fastenerods then the ultimate yield and stiffness significantly decreased to a level less than 50% of the ultimate yield (Graph 6 27) Mode of failure for the DCP was by splintering of the sample(Fig 6 25 and 6 28) whereas the fastenerod failed by overextension (Fig 6 26) and by overextension and some cracking (Fig 6 29) The cracking of the sample during torque testing of the 4/4 5Fd was a reflection of the relative stiffness of the implant formation and the sample, indicating that the one mechanical system of the implant and sample interacted together due to its flexibility The plate system failed relatively rapidly due to its higher modulus of elasticity compared to the sample

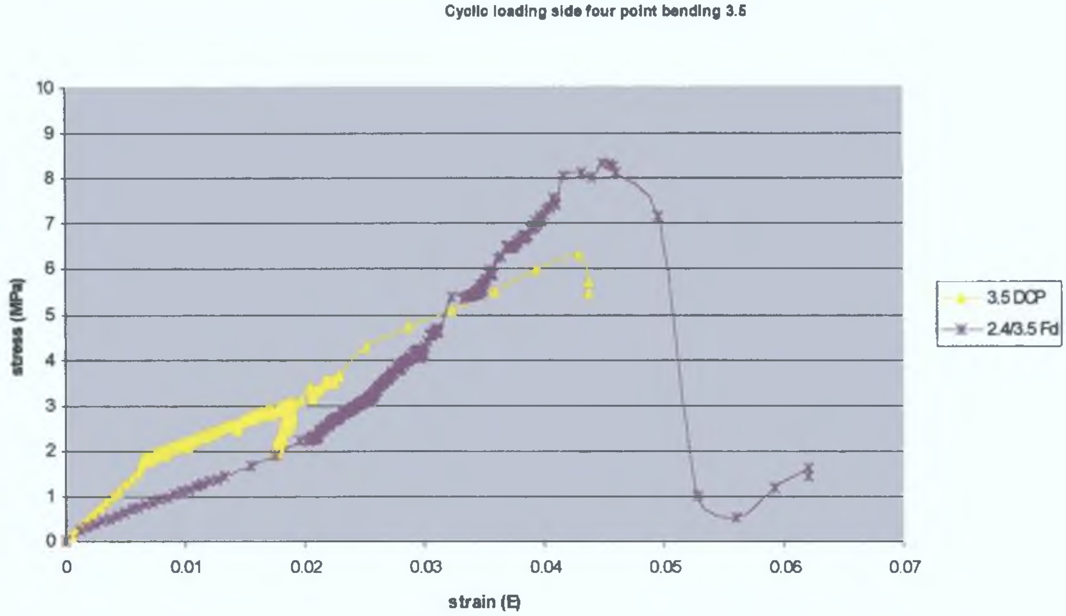
6.3.12 Cyclic Loading (with crosshead moving down)



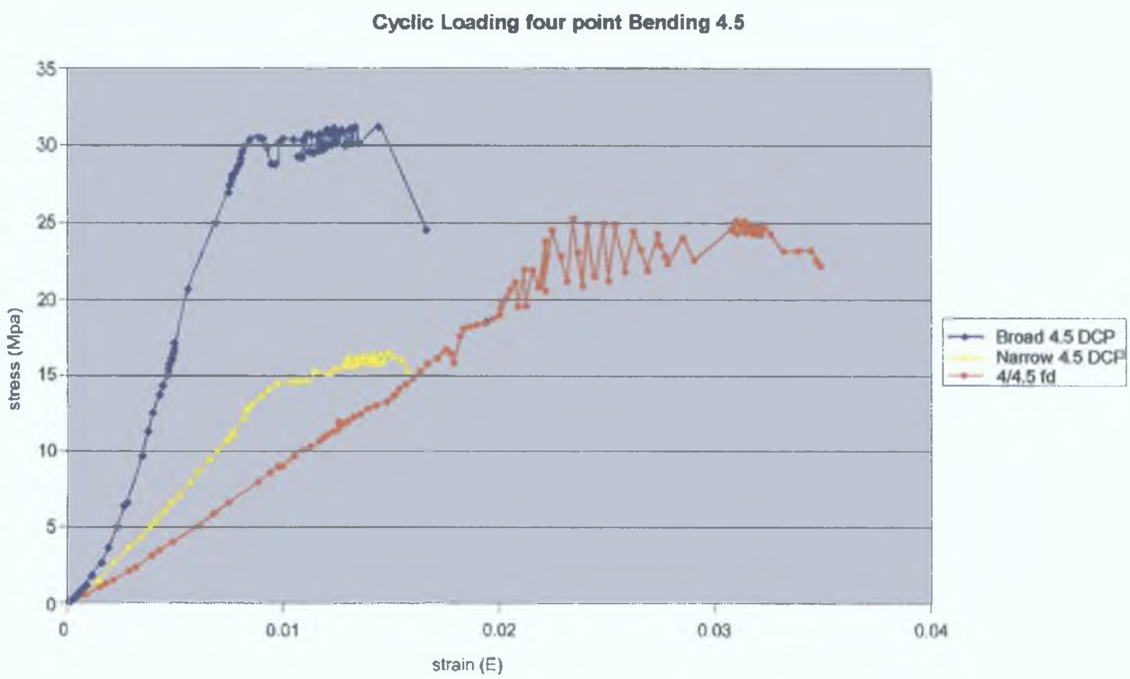
Graph 6.29 As with the 3.5 size the 1.6/2.7 Fd is ultimately stronger than the 2.7 DCP in fatigue testing which is not the same as with the static testing



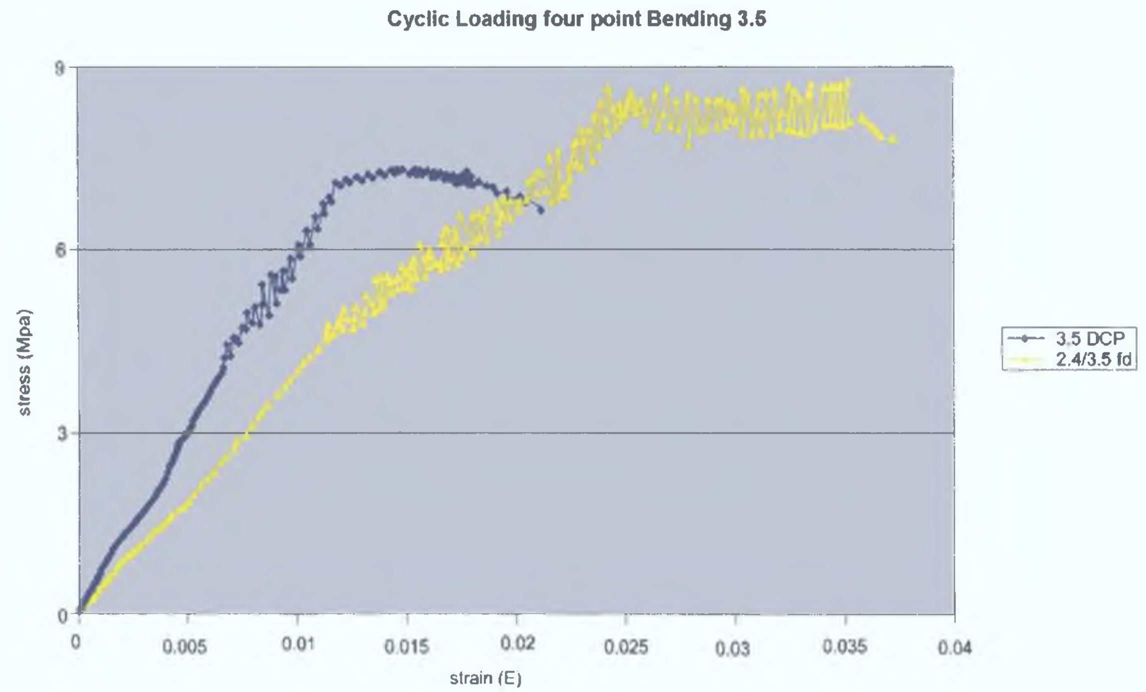
Graph 6.30 Cyclic loading tests for 2.7 screw category



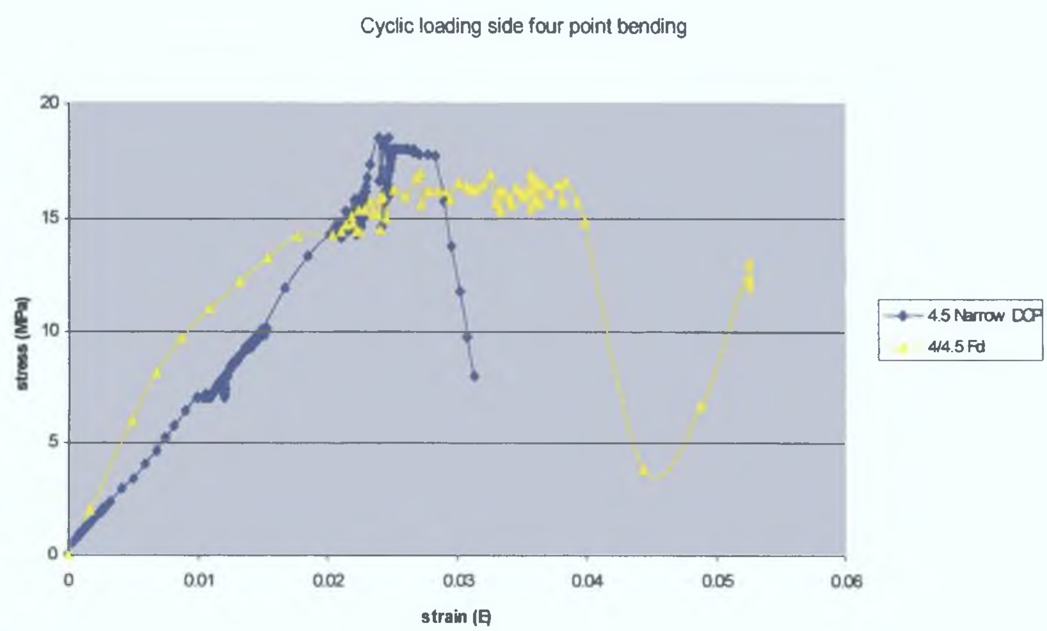
Graph 6.31 2.4/3.5Fd is ultimately stronger than the 3.5 DCP under fatigue testing which is the reverse to the result of the static failure tests



Graph 6.32 Cyclic loading tests for 4.5 screw category



Graph 6.33 Cyclic loading tests for 3.5 screw category



Graph 6.34 The cyclic performance of the 4/4.5 Fd is much better than the static one

The repetitive small loads applied in the cyclic loading tests produced the most surprising results of all the tests so far Firstly, the series of cyclic tests was only performed for four point bending as it represented the most significant test of the terms of performance assessment, and is naturally suited best for cyclic loading For both of the smaller categories (2 7 and 3 5mm screws), the fastenerod had a higher ultimate yield than the corresponding DCP (Graph 6 29, 6 30, 6 31, 6 33), and the difference in stiffness was minimal in the 3 5mm category For the largest system (4 5mm), the difference between the narrow 4 5 DCP and the 4/4 5Fd was small especially in comparison to the results of the static testing (Graph 6 32, 6 34) It can be concluded that the fastenerod system was stronger or equal to the DCP system m cyclic loading but weaker than the DCP system in static loading For the mini implant set, the 1 1/2 Fd was stronger than the 2 0 mm plate but not stiffer m four point bending static loading The DCP system was generally always stiffer than the fastenerod system in static loading which fits to its geometry compared to the fastenerod

Fig 6.30 Failure mode of 2 7 DCP note screws pulling out of wood

6 4 Discussion

A dynamic compression plate (DCP) is a formidable looking implant with metal thickness beyond human ability to bend at all at the 3 5mm level Once in place, a DCP provides very strong fixation with the patient being able to walk immediately after surgery As the bone will not have healed at this point the patient would then effectively be walking on the plate This was the objective when the DCP was introduced by AO/ASIF, apart from its compression ability By being strong enough to withstand a patients full weight, the DCP avoided the whole spectre of fracture disease The DCP system is recognised as the best technology available for fracture repair, and therefore the best to make comparisons against Comparing the fastenerod to the DCP system was a severe comparison, given the make up difference between the two, but the results proved that this was the right way to proceed

In static loading the fastenerod system performed well even though it was weaker and less stiff, except in the 1 1/2 0Fd category The difference between the DCP system and fastenerod system was not huge given that there was always scope to increase the properties of the fastenerod system, for example, adding an extra pin or crimping the fastenerods Maximising the strength of the fastenerod through additional measures would bring it even nearer to the level of the DCP The main weakness of the fastenerod system would appear to be in torque loading However, the weakness in rotational stability would not be significant enough to rule out the fastenerod system as a plausible method of fracture fixation because of its method of failure

The method of failure of the fastenerod is by gradual over extension to the point of extreme but not by implant failure or sample fracture, compared to the DCP system which fails by implant failure and sample fracture Screw pull out from the sample was a common mode of failure and is commonly seen in orthopaedic complications The screw grip is in itself subject to the condition of the bone, but the very nature of the DCP system as a stiff rigid implant fixed onto a less rigid living tissue means that the mode of failure will be screw pull out The very supposed weakness of the fastenerod system is its strength in that its flexibility avoids the common route for implant failure

Furthermore, this flexibility of the fastenerod system allows it to out perform the DCP system when subjected to cyclic loading, with cyclic loading being the most natural simulation of normal bone loading in a patient moving The repetitive small loads tested out the inherent differences m rigidity between the DCP system and the bone, leading to implant or sample failure Such a mismatch across a short section of bone could only lead to failure from one or other The greater flexibility and elasticity of the fastenerod enabled the whole system of sample and implant to work together as one unit From the tables/graphs it can be concluded that the fastenerod system is stronger or equal to the DCP system in cyclic loading, but weaker than the DCP system in static loading, except the 1 1/2 0 fd which is stronger but not stiffer The DCP system is always stiffer than the fastenerod system except m the 4 5 and 2 0 screw systems For pin migration it was found that the order of strength would be crimping, pins bent, pins-in, and pin stopper Furthermore, the screw usage alteration led to the following order of strength moncortical equal to lag screw which in turn is weaker than the nut All implants were discarded after one test to ensure no faulty implants were confused with new ones

6.5 Summary

The best way to increase the strength of the fastenerod was to reduce or stop pin migration From the results it was concluded that either embedding the pins or having a stopper on the pin was the best way to reduce pin migration Tensioning the pins proportionately increased the strength and stiffness of the fixation Static loading tests in all four loading categories showed that the plate systems were stronger and stiffer generally, except in the smallest category Cyclic loading in four point bending showed that the fastenerod was, in general, stronger than the plates

Chapter 7

Evaluation of the Use of the Fastenerod in Veterinary Fractures

7.1 Introduction

A range of specific fractures encountered in dogs, cats and horses was chosen for mechanical evaluation following repair using the fastenerod system As with other experiments the test was a comparative test, using the best technology available for fracture fixation, against the fastenerod Unlike the wooden dowels, there is variability in bone samples due to age, history, disease, anatomic variation and sample collection procedures To reduce the problems associated with this variability only pairs of bones from individual animals were tested against each other

7.2 Methods and Materials

Over a three-year period, samples were procured in accordance with a strict protocol Only healthy dogs and cats of a similar size, age and breed were selected The animals were selected from cases that died from non-orthopaedic conditions were owner permission was required before sample collection occurred Collection of the bone samples was performed as soon after death as possible in order to minimize bone changes Samples were taken at any time depending on the availability of a suitable candidate and taken straight to the materials testing laboratory After bone collection, the samples were radiographed to check for signs of disease or trauma and immersed in cool saline for transport Mechanical testing was performed as quickly as was possible to ensure the samples remained fresh and consistent, so that the delay from the time of the sample collection to the finishing test never exceeded 12 hours. Using this protocol, freezing of bone samples was avoided.

Fig. 7.1 3-point bending of canine distal radius repaired with 1.6/2.7Fd

Fig. 7.2 Tensile testing of canine tibial tuberosity top clamp on patella

Fig. 7.3 Axial testing of canine midshaft femur potted in polymethyl methacrylate

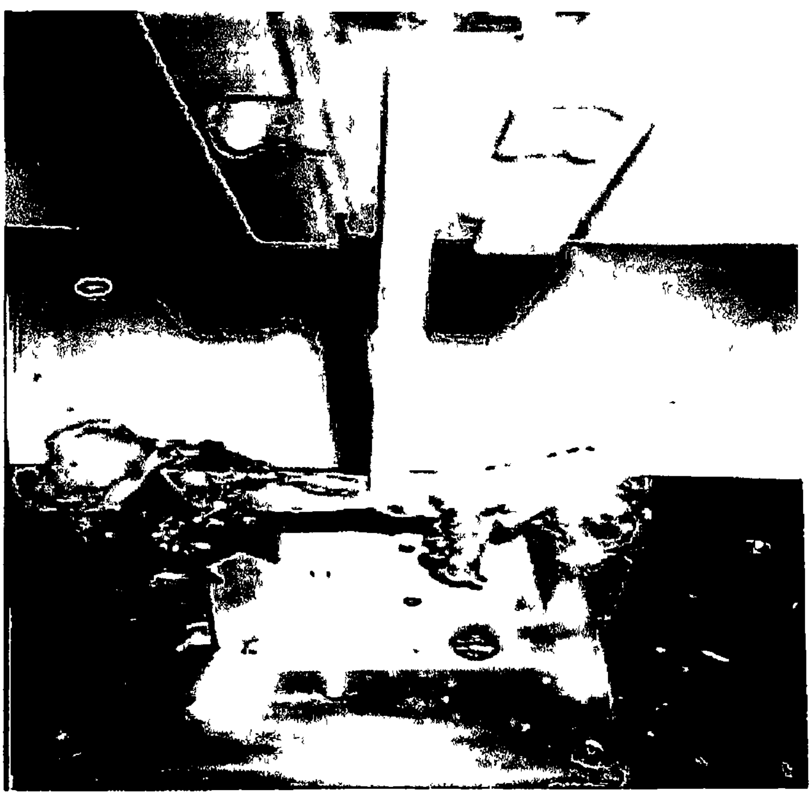


Fig. 7 4 3-point bending of distal humerus

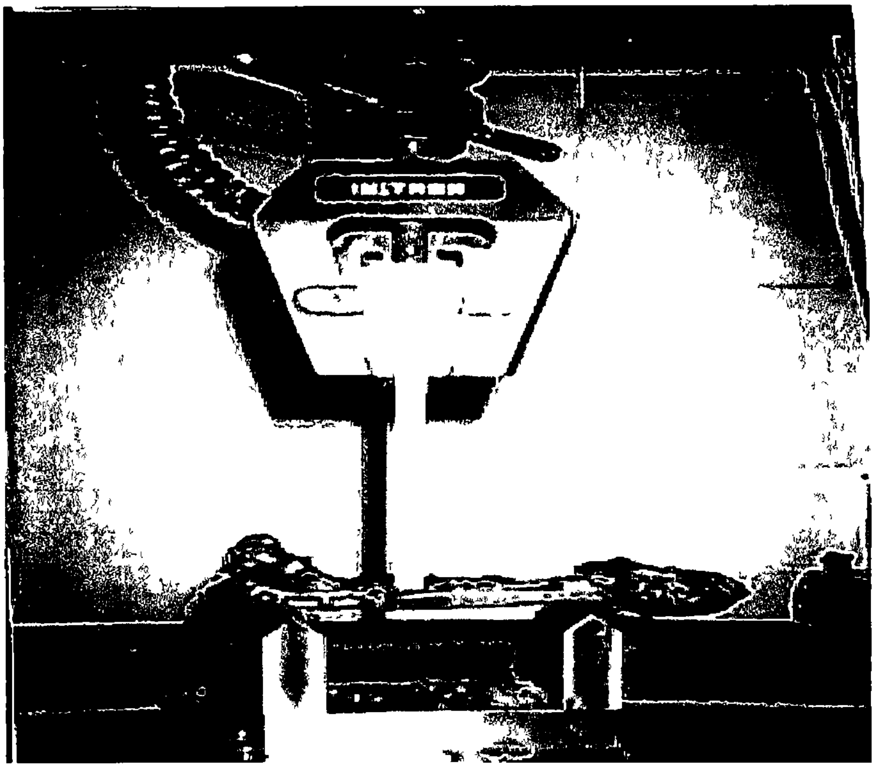


Fig. 7.5 3-point bending distal femur

In the case of equine samples the samples could only be obtained from a slaughter facility and were kept frozen until they could be collected and used This did entail a delay unavoidably in the interval between collection and testing Because the test was a paired comparative analysis the result was still felt to be valid and useful despite the freezing

A bench vice grip was invaluable in dealing with the bone samples, holding them for the creation of fractures and application of implants Each test was performed on pairs of opposite bones from the same animal In the periarticular fractures in dogs, a 3-point bending jig was used (Figs 7 1, 7 4 and 7 5), and fractures were created with no gap All the tests were static compression tests and the Instron software was set with no load limit, at a speed of 2 mm/second and with the surface area recorded (as with samples from

Chapter 6) The surface area was measured by creatıng a footpnnt of the shape of the fracture end pnor to repaır wıth the ımplants onto graph paper The numbers of squares were than counted to calculate the sample area of the vanous ırregular shapes All tests were completed to faılure, whıch was automatıcally detected by the Instron software Fractures that are under tensıon such as tıbıal tuberosıty fractures were tensıle loaded agaın untıl faılure (Fıg 7 2)

For the dıaphyseal fractures, the mıd shaft of the long bones was cut at an angle to avoıd face-on-face bone loadıng The angle was kept as acute as possıble wıthout compromısıng the screw purchase Thıs angulatıon of the cut wıth no gap created a degree of shear as well as axıal loadıng The samples were held ın the ınstron usıng the custom made gnps or potted ınto polymethylmethacrylate (Fıg 7 3) The parameters m the Instron were the same as for the penartıcular fractures ı e compressıon, no load lımıt, speed 2 mm/second and surface area

For felıne fractures the small bone of the tıbıa and radıus were held ın customızed gnps wıth polymethylmethacrylate added and loaded axıally untıl faılure In the equıne ulnar fracture tests, a hole was created ın the proxımal ulna were a wıre was passed and attached to standard ınstron gnps The base of the equıne ulna was potted ın polymethylmethacrylate encased ın a steel box screwed to the ınstron base The equıne cannon bone was tested usıng the four poınt bendıng jıg, and was tested to faılure by reachıng the maxımum crosshead extensıon and not by fracture

7.3 Results

The results are presented ın a format of pre and post testıng radıographs of examples followed by stress straın graphs, wıth the tables of data, shown ın Appendıx A (Tables 7 1-7 3)

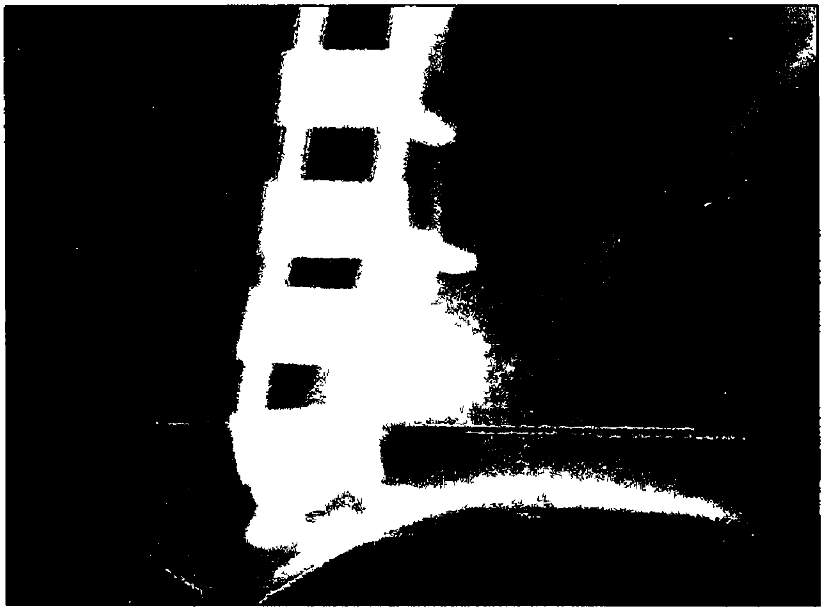


Fıg. 7.6 Canıne scapula repaired wıth 1 6/2.7Fd

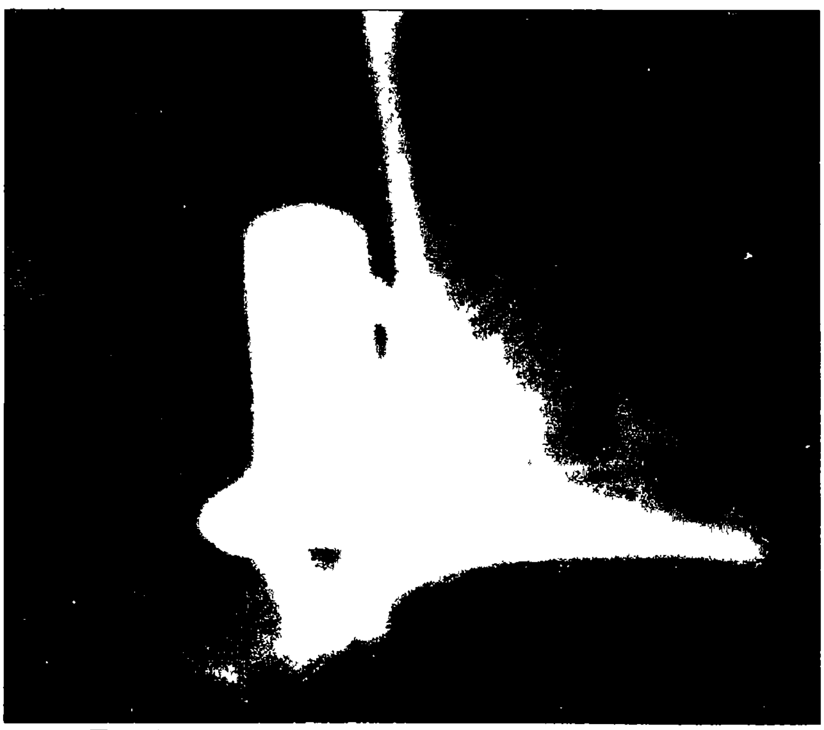


Fıg 7.7 Canıne scapula repaıred wıth 2.7 Tplate

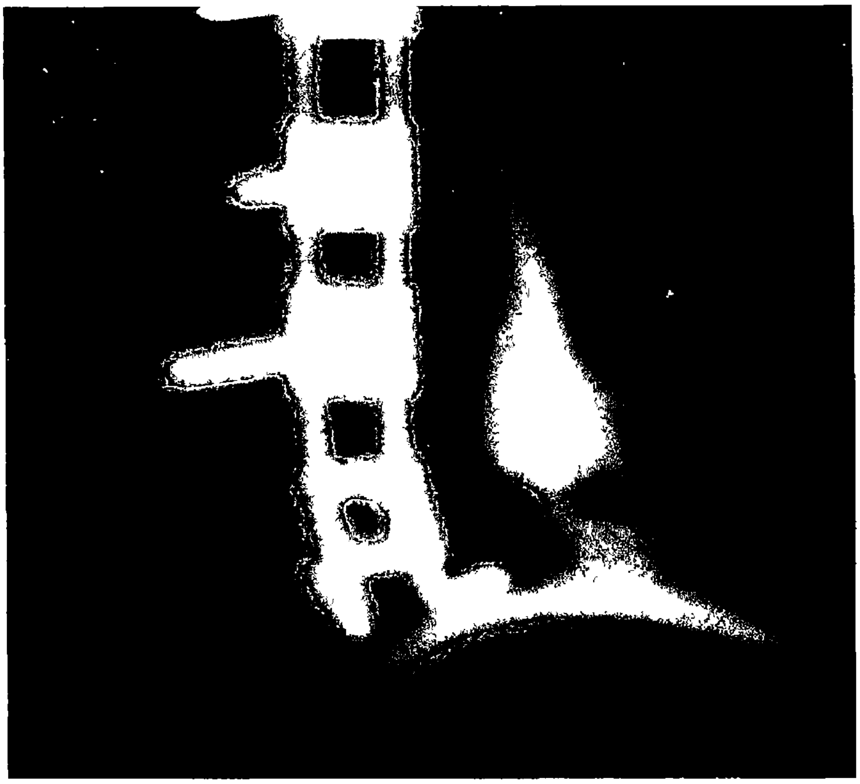


Fig. 7.8 Failure 1.6/2.7 Fd. Canine scapula.

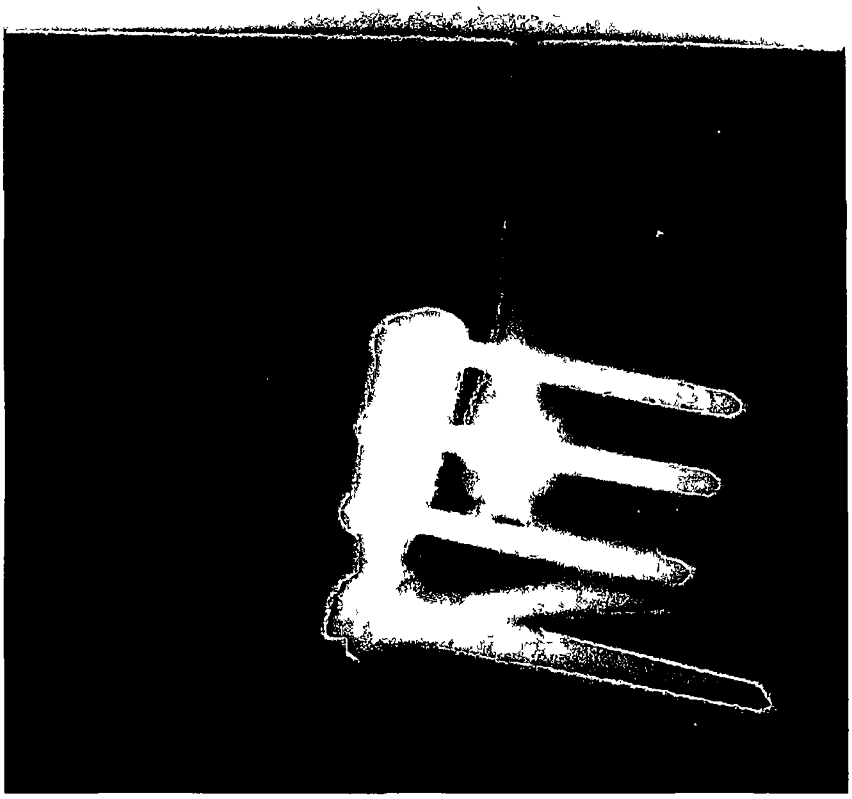
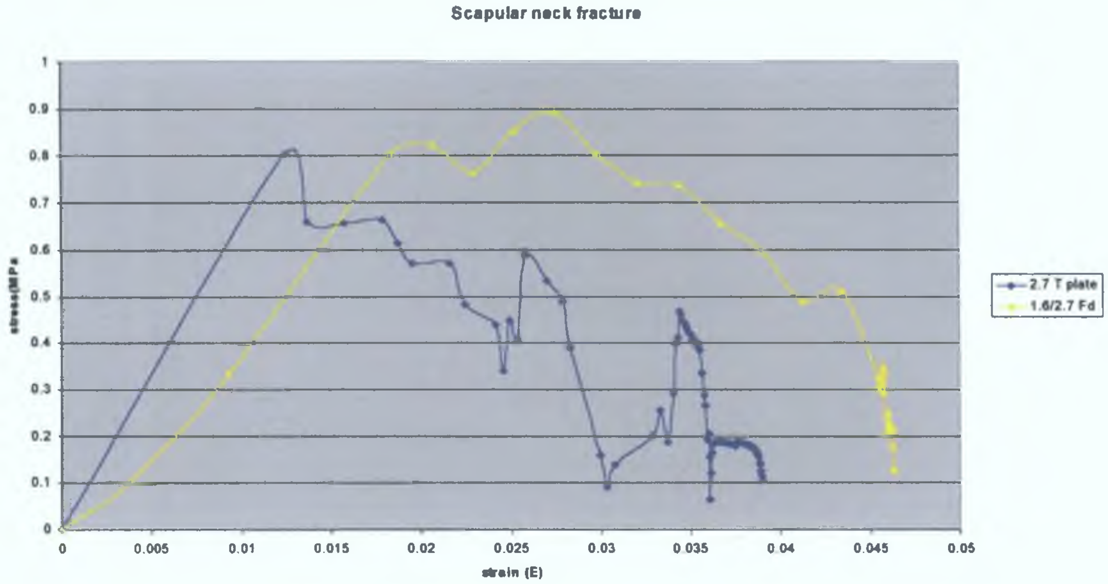


Fig. 7.9 Failure 2.7 plate. Canine scapula.



Graph 7.1 The 2.7 plate is stiffer but the ultimate strength is similar (Figs. 7.6 – 7.9)

Three point bending of the distal scapula samples showed that both implants had similar properties (graph 7.1). The 2.7 T plate (fig. 7.7 and 7.9), has two points of contact in the distal scapula whereas the 1.6/2.7Fd (figs. 7.6 and 7.8) has three points of contact due to the two pins, and this would offer an explanation why the 1.6/2.7Fd had a higher ultimate yield than the 2.7DCP. However the 2.7 plate still has greater stiffness than the 1.6/2.7fd.

Fig. 7.10 1.6/2.7Fd distal canine humerus

Fig. 7.11 2 7plate distal canine humerus

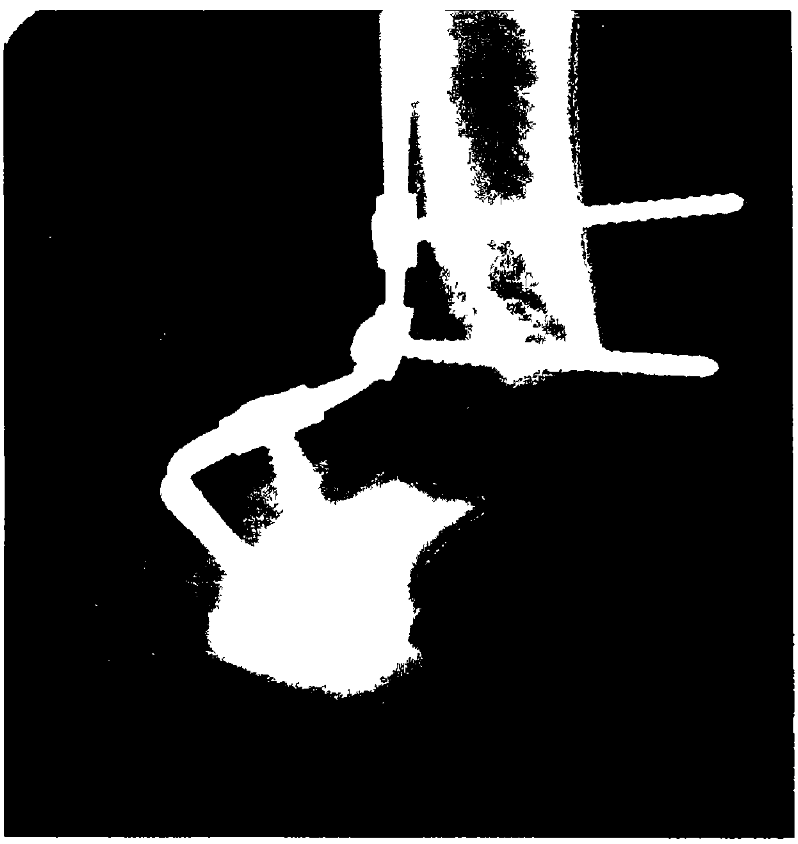
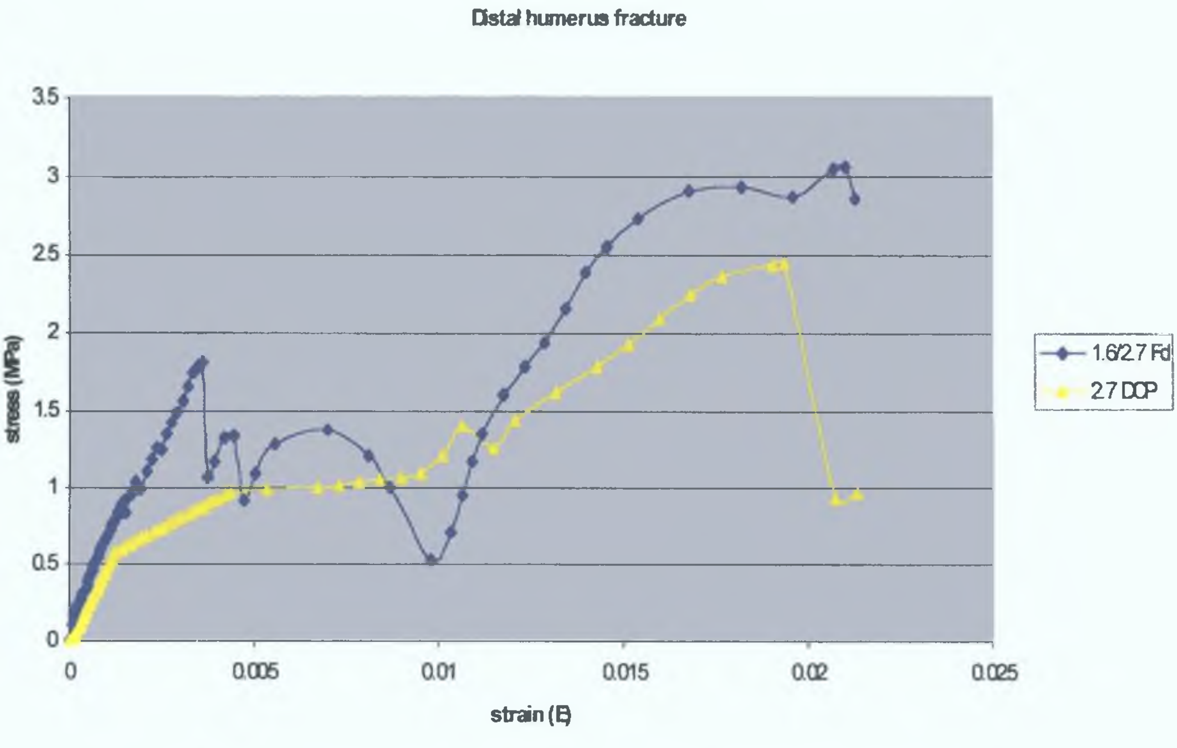


Fig. 7.12 Failure 1.6/2 7Fd canine humerus

Fig. 7.13 Fail 2.7plate distal canine humerus



Graph 7.2 Similar results are obtained for both implants (Figs. 7.10 – 7.13)

The dıstal humerus ıs a frequent sıte of fracture ın dogs and ın thıs test a supracondylar fracture was subjected to three poınt bendıng Surprısıngly, the 1 6/2 7Fd (Fıg 7 10 and 7 12), was stıffer and had a hıgher ultımate yıeld than the 2 7 plate (Fıg 7 11 and 7 13) The advantage of three poınt fixatıon agaın was ın creatıng better fixatıon of the dıstal fragment and hence better performance of the fastenerod (graph 7 2)

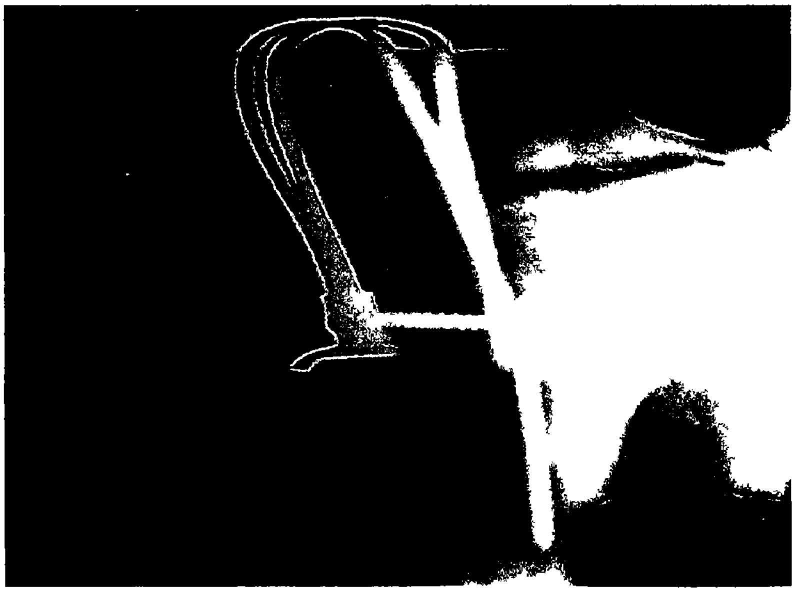


Fıg 7.14 Proxımal Canıne Ulna repaıred wıth 1 6/2.7Fd

Fıg. 7 15 Proxımal Canıne Ulna repaıred wıth tensıon Band wırıng(TBW)

Fig 7.16 Failure 1 6/2.7Fd Canine Ulna.

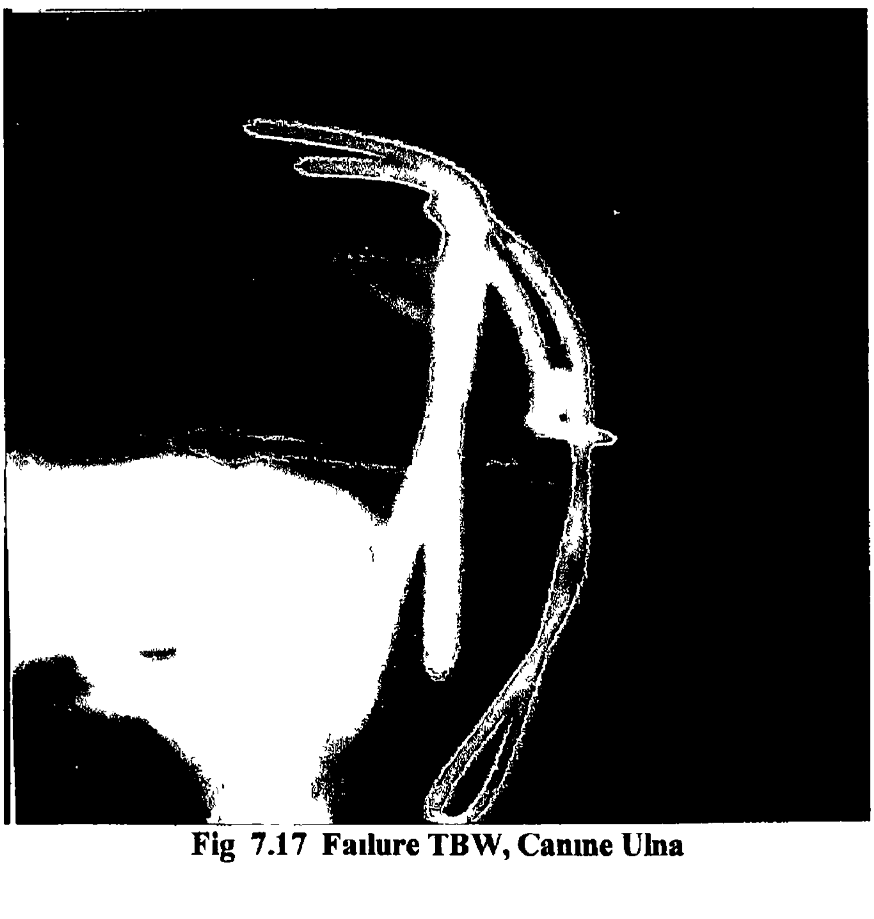
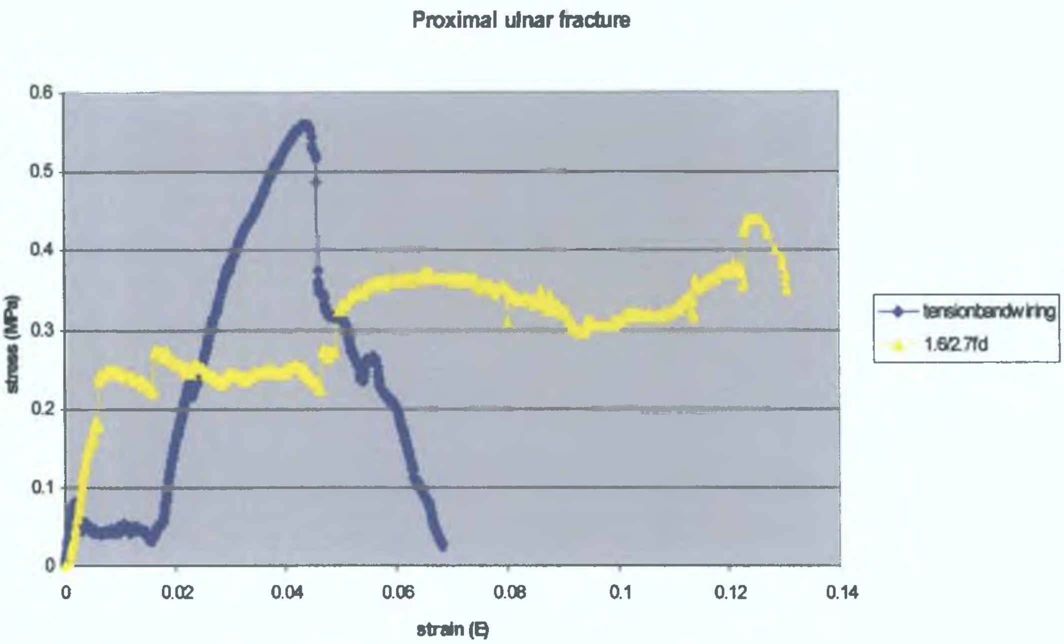


Fig 7.17 Failure TBW, Canine Ulna



Graph 7.3 Tension band wiring is superior to the 1.6/2.7 Fd (Figs. 7.14 – 7.17)

The proximal ulna is another common site of fracture in small animals and is unusual in that it is an avulsion fracture. This is because the triceps muscle group inserts via the triceps tendon onto the proximal ulna and therefore it is kept under constant tension even during standing. To counteract these tensile forces the traditional method of tension band wiring is used and this transfers the tensile forces into interfragmentary compression at the fracture site when it is applied properly. The triceps pull in these tests was imitated using a hole drilled into the ulna with a wire anchored to an Instron clamp. The tension band wire (Figs. 7.15 and 7.17), achieves a higher yield over a relatively short change in gauge length whereas the 1.6/2.7Fd (Figs. 7.14 and 7.16), gradually gives way as the pins unbend and migrate outwards. Given the power of the triceps pull, it would be better to recommend the use of tension band wire against the technique used here for the 1.6/2.7Fd (Graph 7.3).

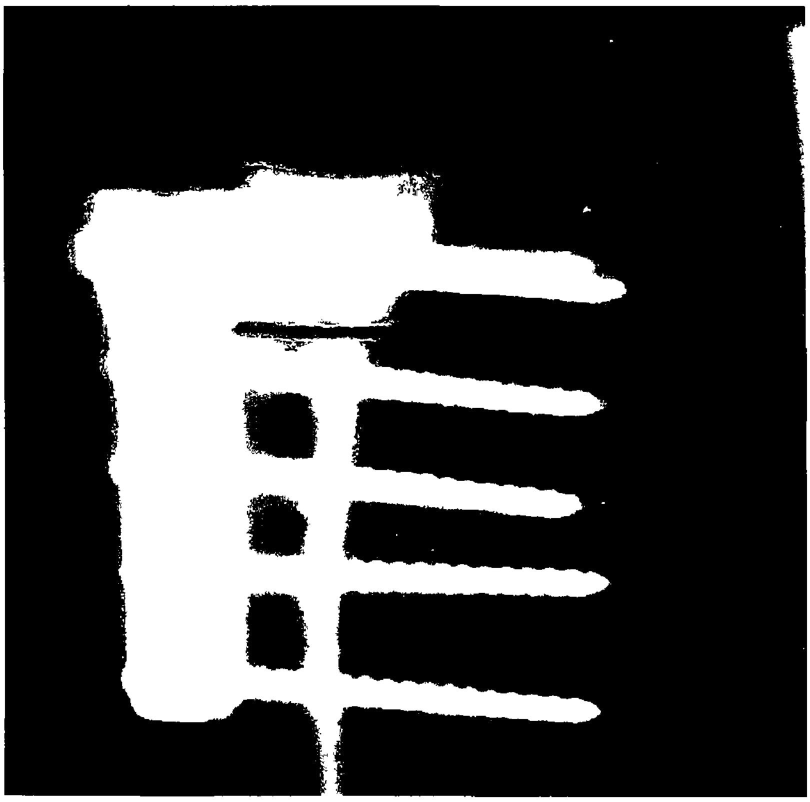


Fig. 7.18 3.5 T plate used to repair fractured distal canine radius

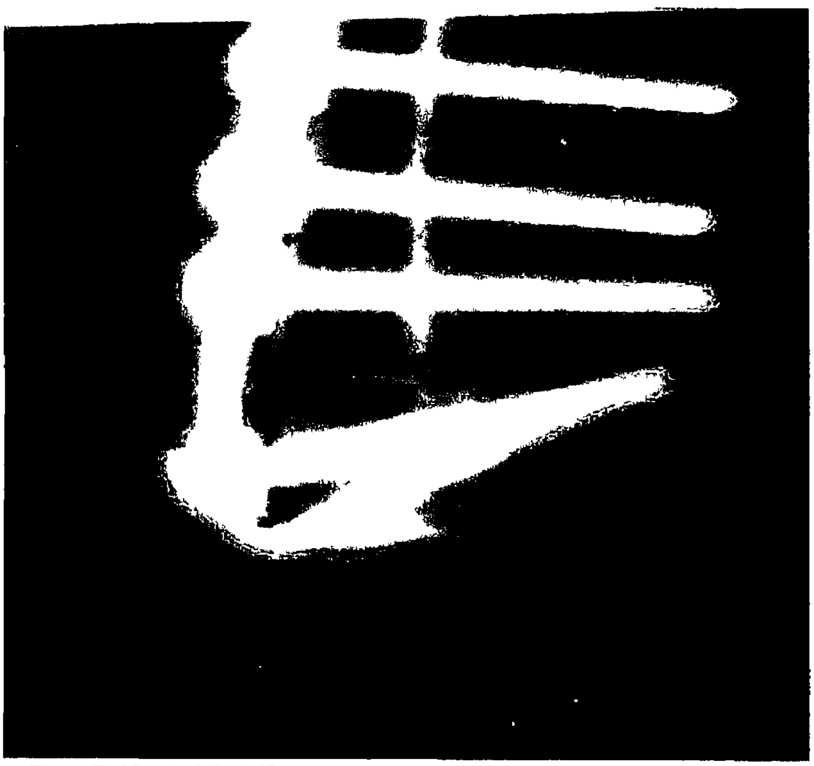


Fig. 7.19 1.6/3.5 Fd use to repair fractured distal canine radius

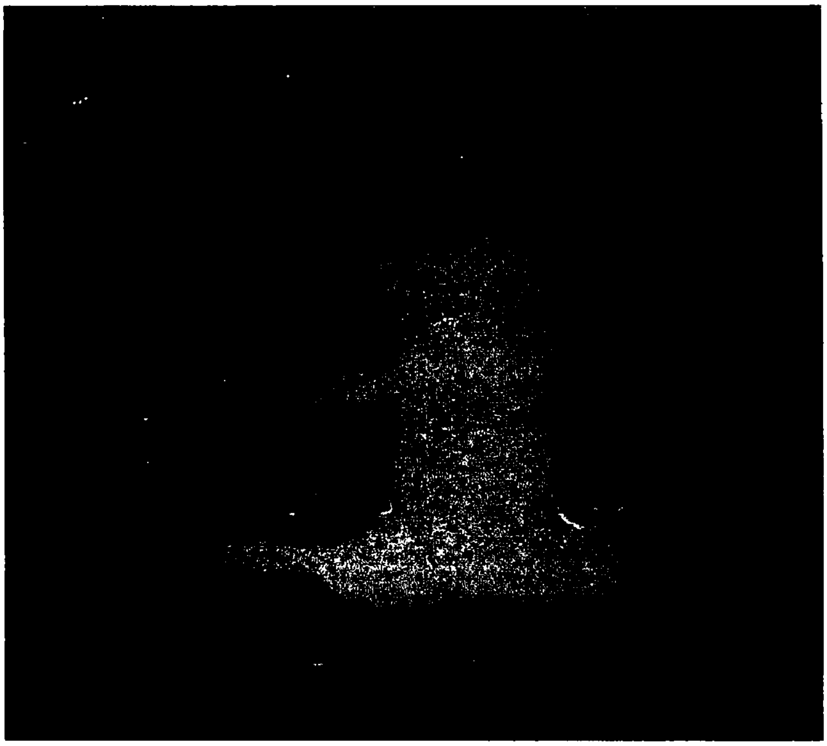
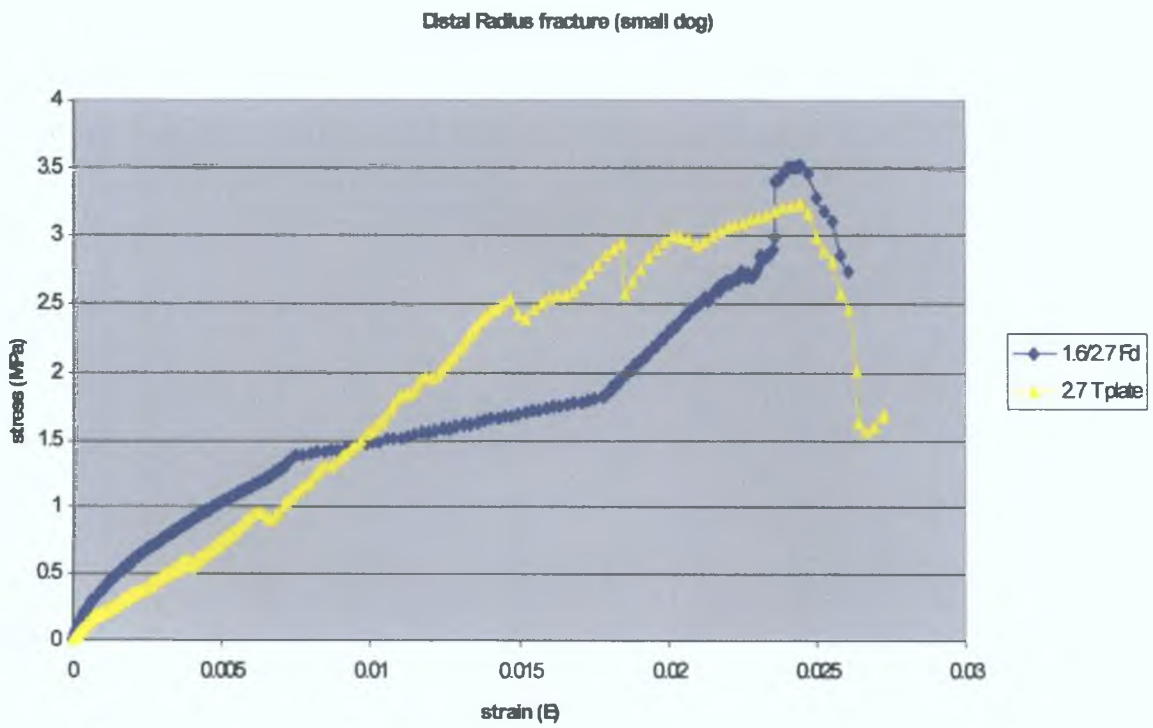


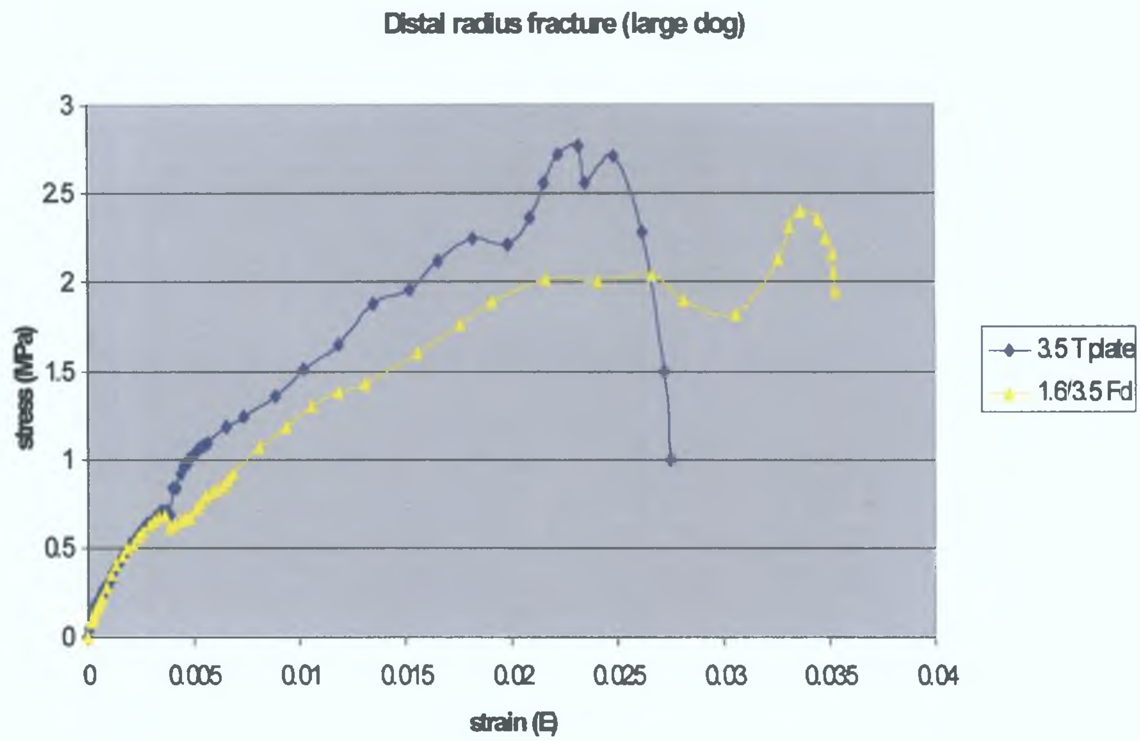
Fıg. 7.20 2.7 T plate used to repaır dıstal radıus of a small dog

Fıg. 7.21 3 5 Tplate faılure, dıstal canıne radıus

Fig. 7.22 1.6/3.5Fd failure, distal canine radius



Graph 7.4 With the small implants there is little difference in performance (Fig. 7.20)



Graph 7.5 The 3.5 Tplate is ultimately stronger than the 1.6/3.5 Fd (Figs. 7.18, 7.19, 7.21 and 7.22)

Fractures of the distal radius are difficult to repair because there is little bone to achieve screw purchase and the major extension tendons obstruct access to the bone. T plates (Fig 7.18 and 7.21), are used for this site as they are able to achieve greater screw purchase than standard straight plates. From the stress strain analysis both methods of fastenerod in their respective sizes are able to compete with the T plates. The smaller sized 1.6/2.7Fd achieves a higher ultimate yield (Graph 7.4), than the 2.7 plate, (Fig 7.20), whereas the 3.5 T plate just about achieves a higher ultimate yield (Graph 7.5), than the 1.6/3.5Fd (Fig 7.19 and 7.22).

Fig. 7.23 1.6/2.7Fd used to repair canine ilium fracture

Fig 7.24 2 7 reconstruction plate used to repair canine ilium fracture

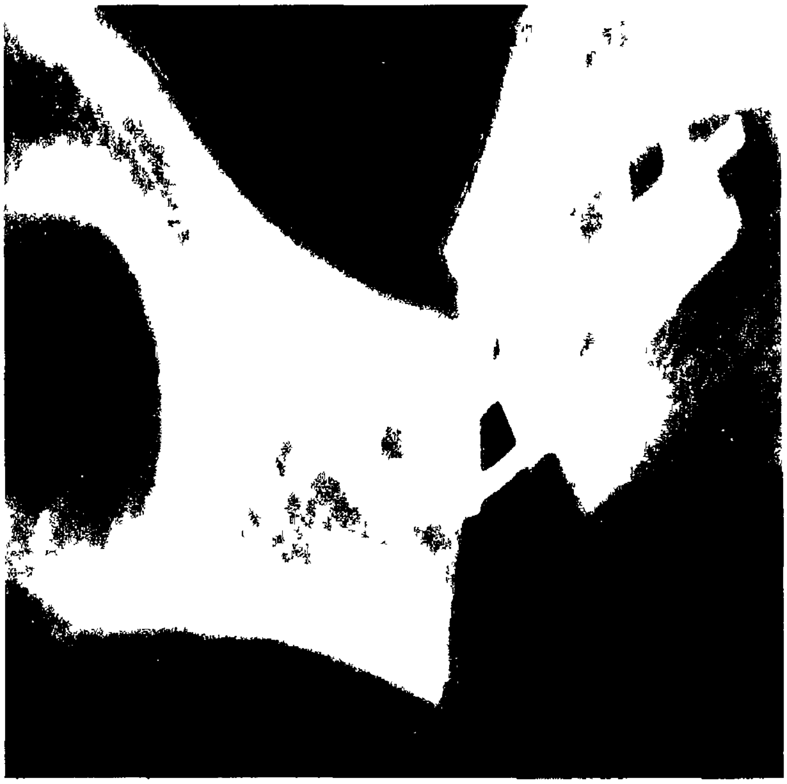


Fig. 7.25 Failure point 1.6/2.7Fd, Canine ilium

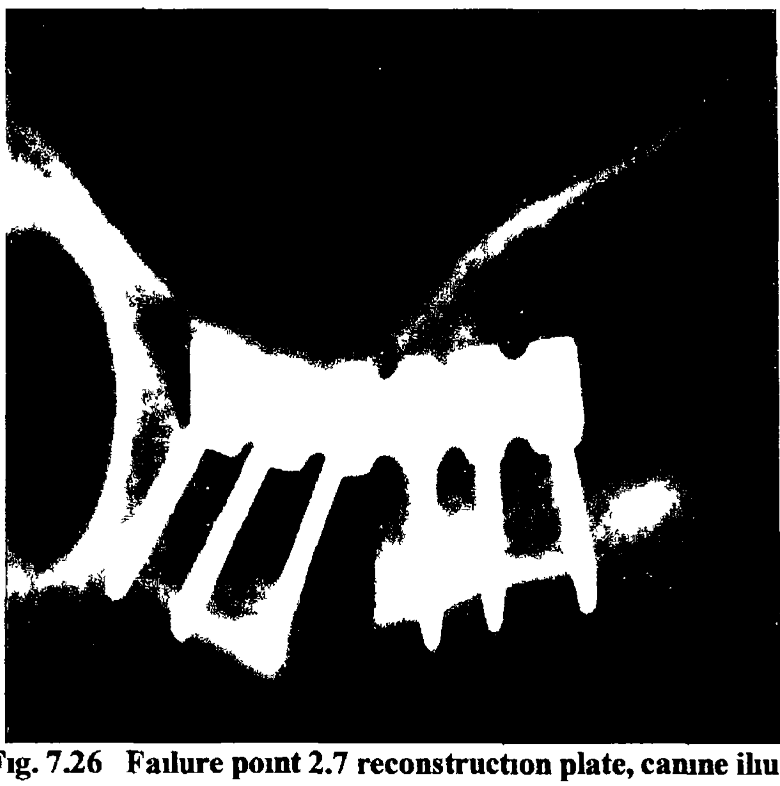
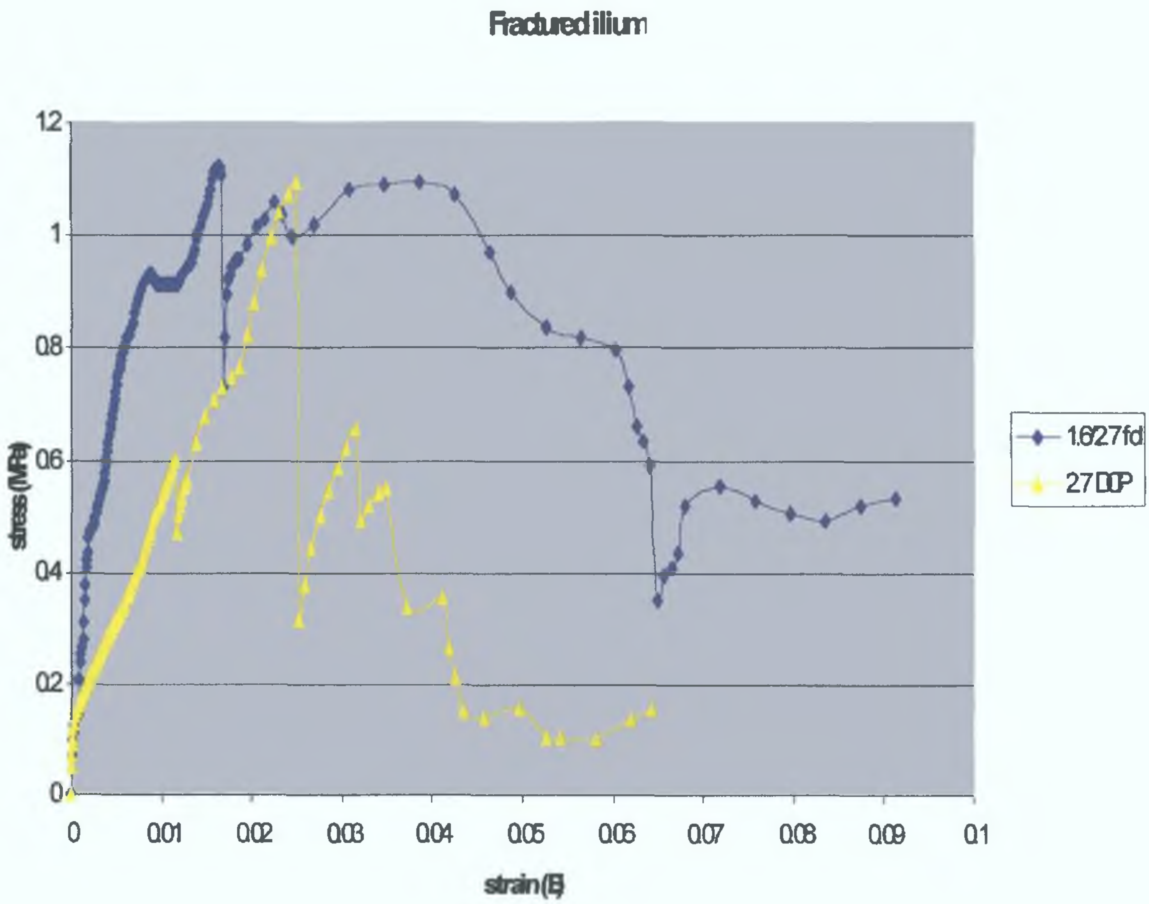


Fig. 7.26 Failure point 2.7 reconstruction plate, canine ilium



Graph 7.6 The 1.6/2.7Fd is ultimately stronger than the 2.7 plate (Figs. 7.23 – 7.26)

Contouring of a plate for fractures of the ilium is usually necessary due to the concavity of its lateral aspect. For this reason a reconstruction plate (Figs. 7.24 and 7.26), is used as the notches along its length enable easy changes in shape in 2 planes. Contouring of the 1.6/2.7 Fd (Fig. 7.23 and 7.25), is possible to the same degree and offers greater choice of screw position. Although the 2.7 reconstruction plate has more or less the same ultimate yield, it is unusually less stiff compared to a fastenerod (Graph 7.6).

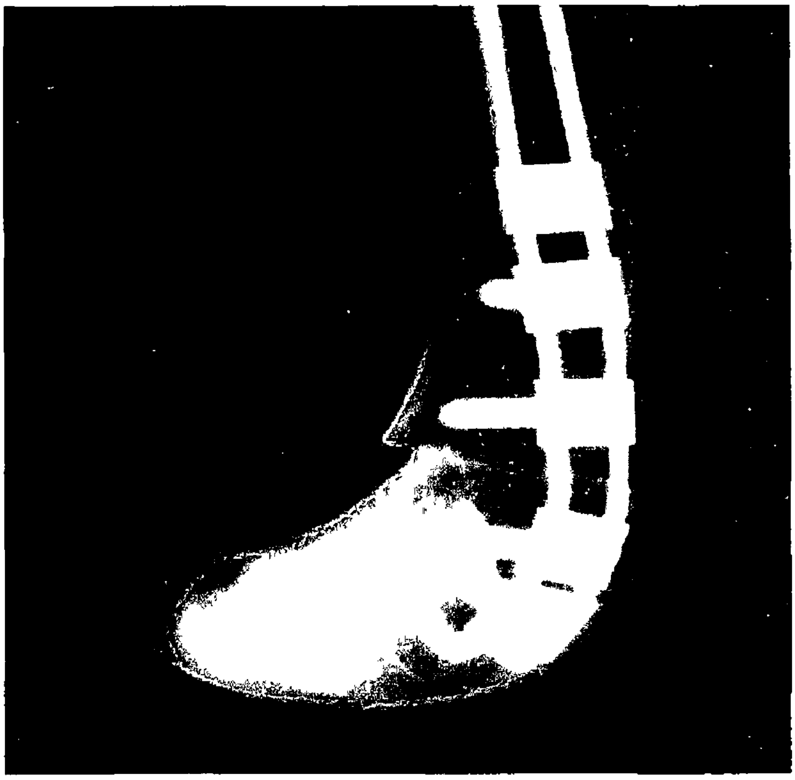


Fig 7.27 1.6/3 5Fd used to repair fractured canine distal Femur

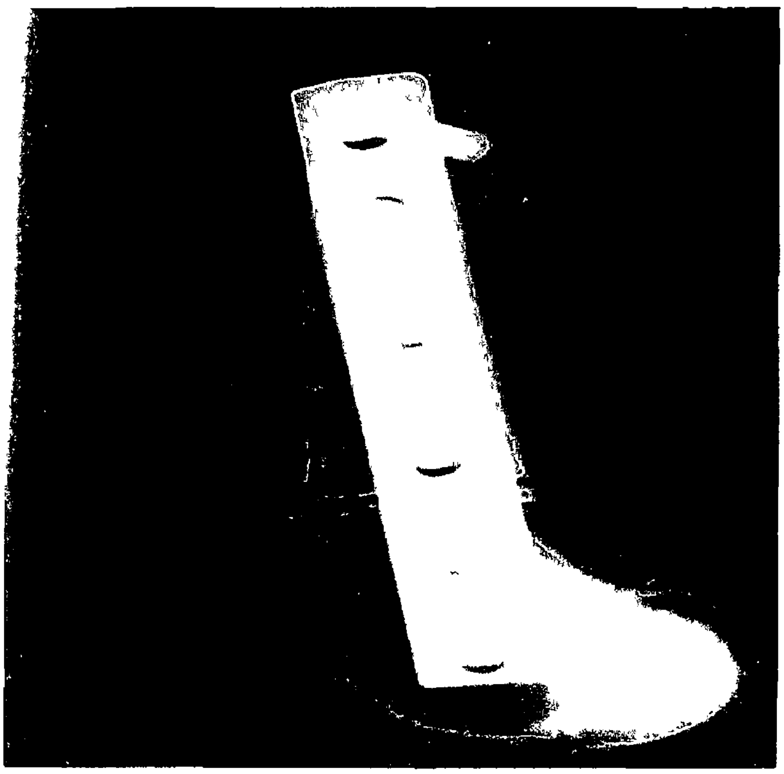


Fig 7.28 3.5DCP used to repair fractured canine distal Femur

Fig. 7.29 3 5 Reconstruction plate used to repair canine distal Femur

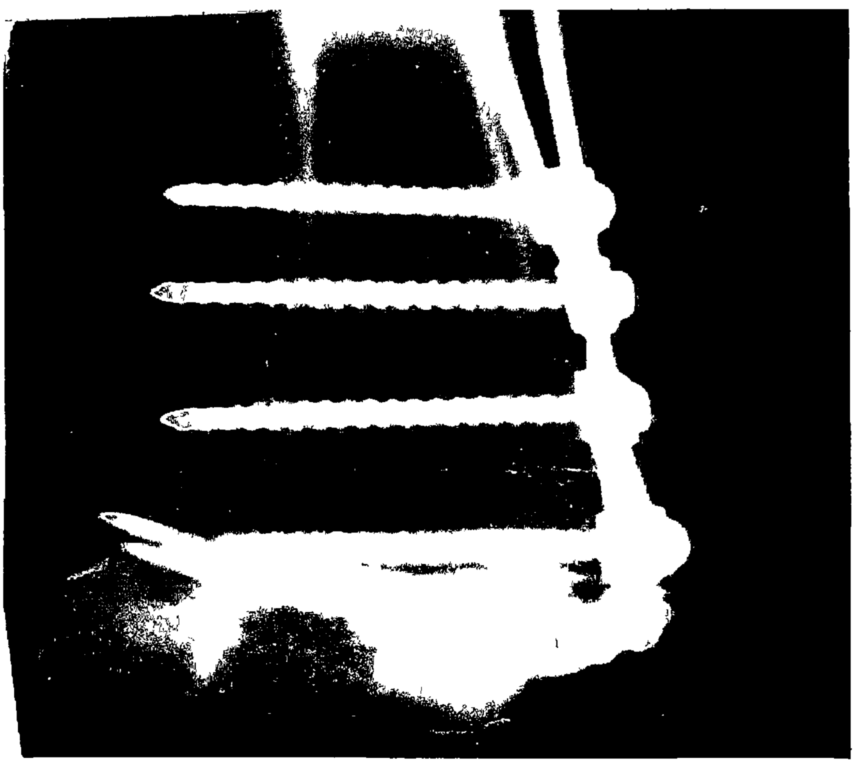


Fig. 7.30 1 6/3 5Fd failure, canine distal Femur

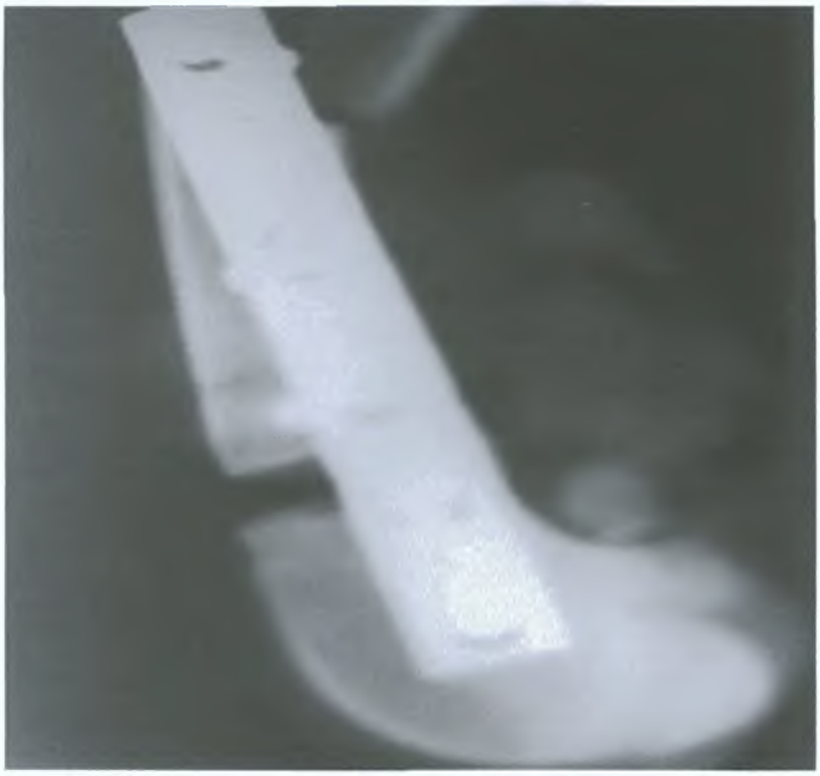
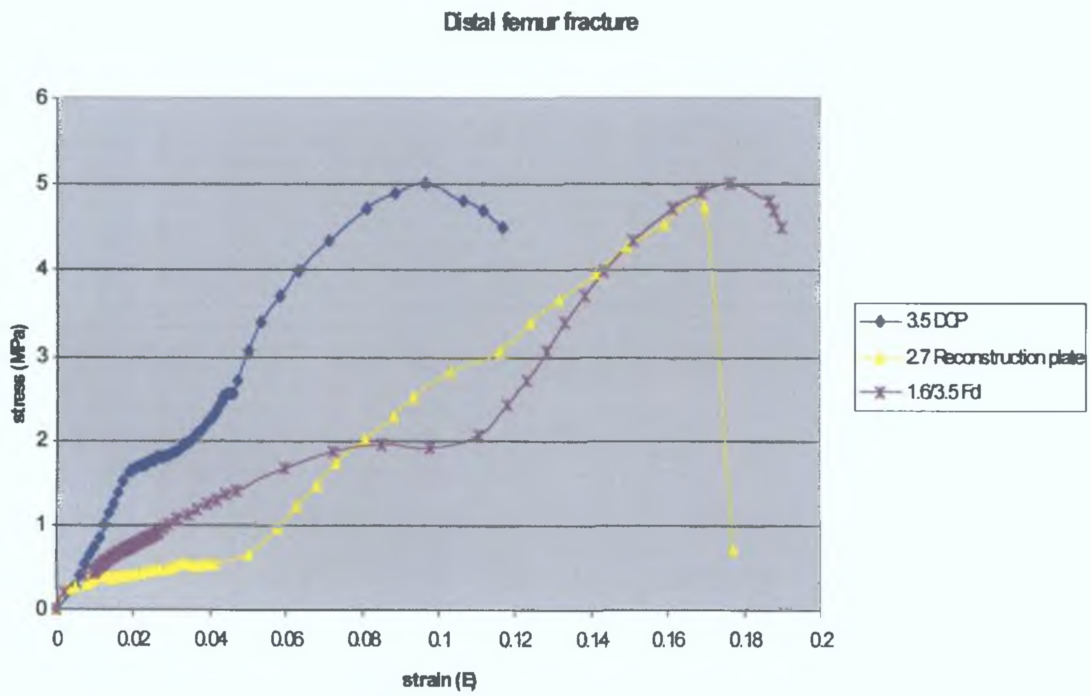


Fig. 7.31 3.5 DCP failure, canine distal Femur



Graph 7.7 The 3.5 DCP is stiffer but not stronger than the 1.6/3.5 Fd (Figs. 7.27 – 7.31)

Fracture of the dıstal femur presents a dıfficulty ın that the bone ıs bent at ıts dıstal end as ıt forms the stıfle (knee) joınt So any fracture fixatıon ın thıs area has to be able to follow the contour of the bone and thıs was usually best achıeved wıth a reconstructıon plate However, the very nature of a reconstructıon plate (Fıg 7 29) ıs to be malleable and thıs creates a relatıvely weak plate, the use of whıch should be avoıded ın hıgh loadıng sıtes Use of 3 5DCP (Fıg 7 28), ıs possıble ın thıs area, but not easıly, due to the lımıtatıon of screw hole choıce In thıs serıes of tests, the 1 6/3 5Fd (Fıgs 7 27 and 7 30), has achıeved the same ultımate yıeld as the 3 5DCP (Graph 7 7), and the bone and screws remaın ıntact at faılure whereas the bone shatters and screws pull out wıth faılure of the 3 5DCP (Fıg 7 31)

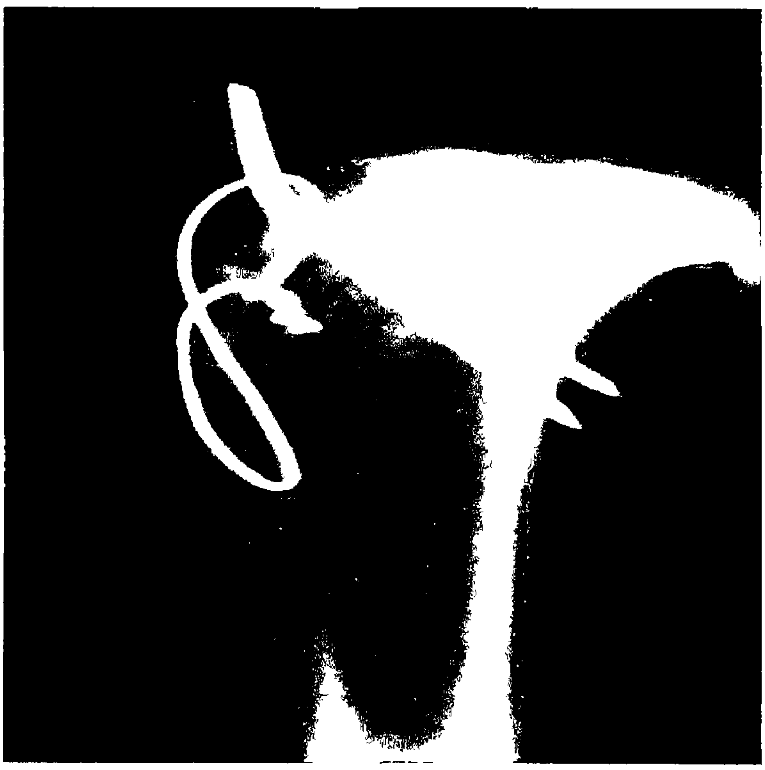


Fıg 7.32 Tension Band Wırıng TBW used to repaır a canıne fractured tıbıal tuberosıty

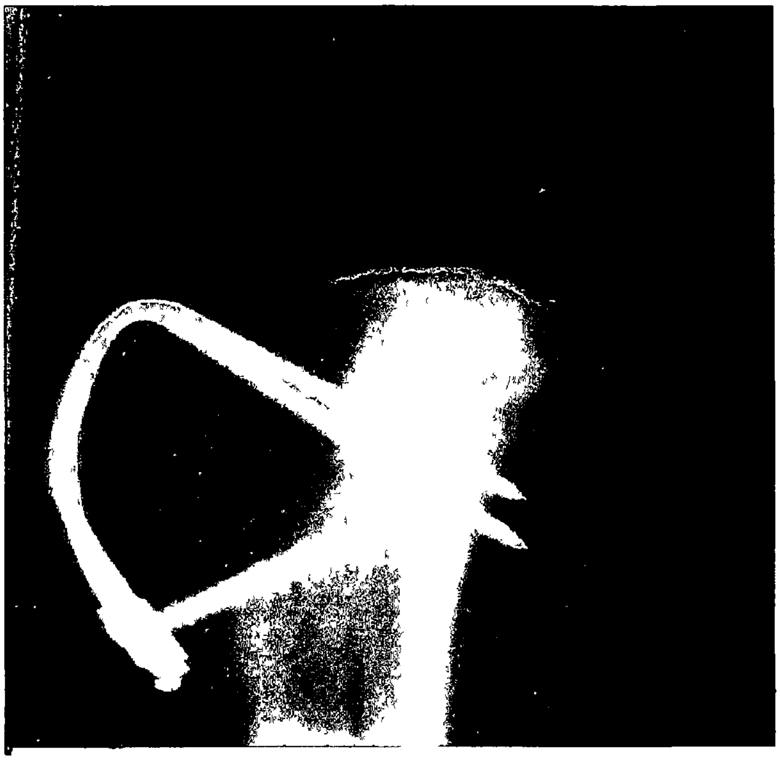


Fig. 7.33 1.6/2.7Fd used to repair fractured canine tibial tuberosity

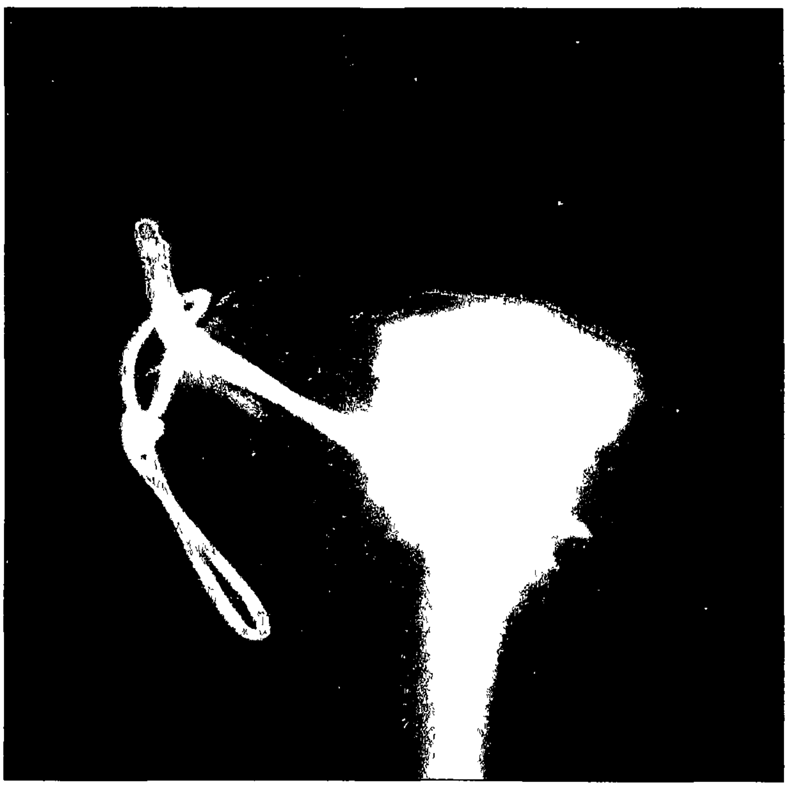
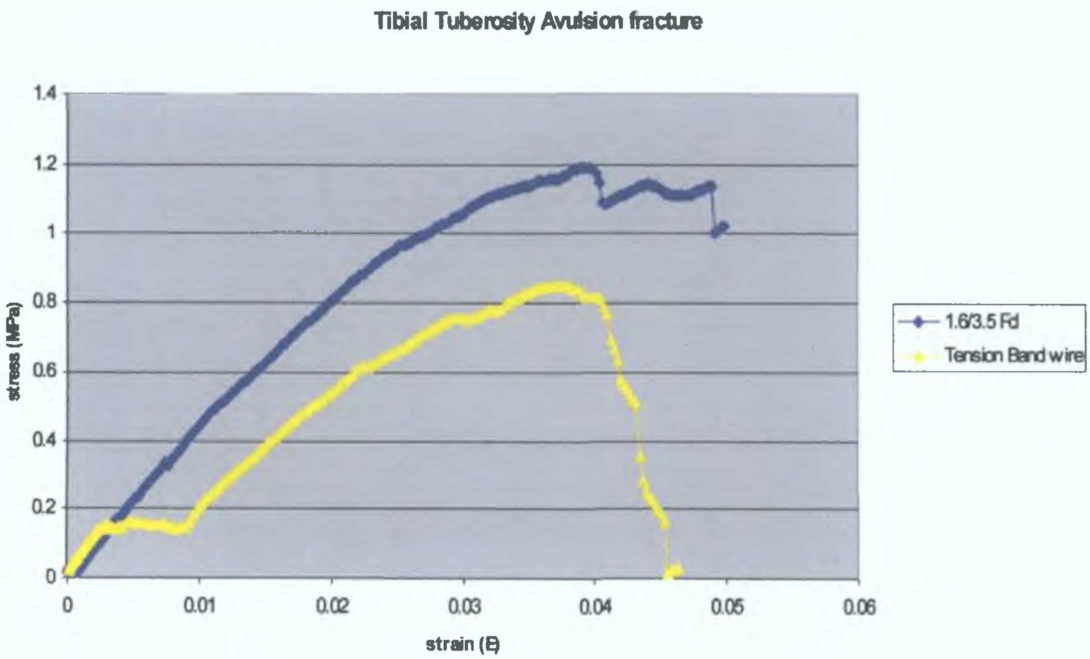


Fig. 7.34 Failure TBW, canine tibial tuberosity

Fig. 7.35 Failure 1.6/2.7Fd, canine tibial tuberosity



Graph 7.8 The 1.6/2.7Fd performs better than the TBW for the tibial tuberosity (Figs. 7.32 – 7.35)

Lıke the proxımal ulna the tıbıal tuberosıty ıs a bone sıte under constant tensıon due to the pull of the quadrıceps group of muscles vıa the patella (kneecap), and patella lıgament Tensıon band wırıng ıs the usual recommended method of repaır and has good dynamıcs ın thıs fracture scenarıo to create compressıon at the fracture sıte (Fıg 7 32 and 7 34) However unlıke the result wıth the proxımal ulna the 1 6/3 5Fd (Fıg 7 33 and 7 35) achıeved greater stıffness and ultımate yıeld than the tensıon band wırıng method (Graph 7 8)

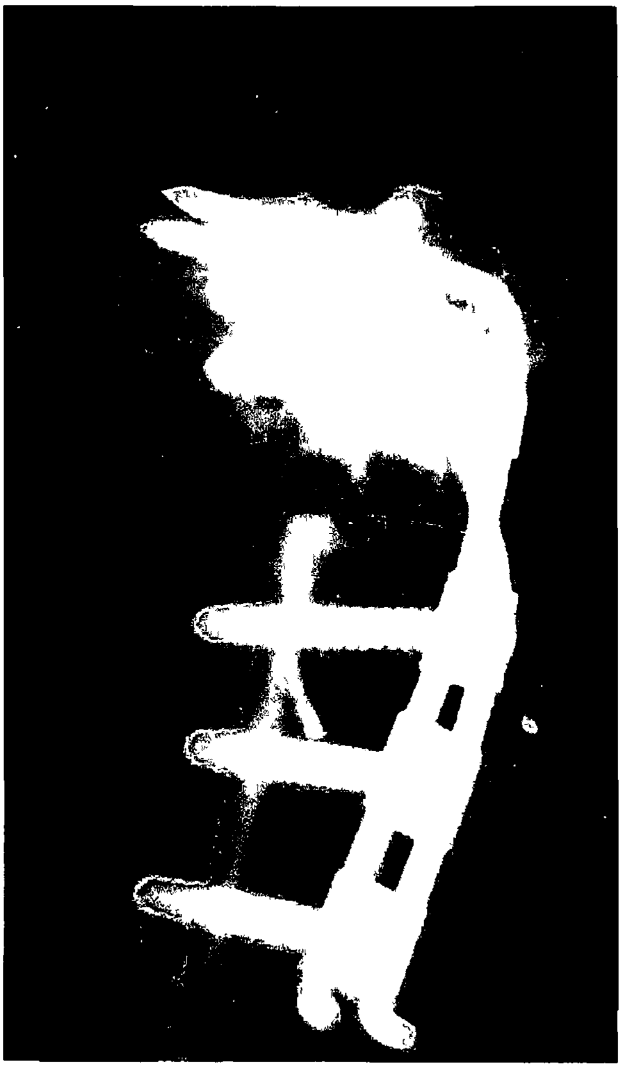


Fıg 7.36 1.6/3.5Fd faılure tıbıal plateau levelıng osteotomy

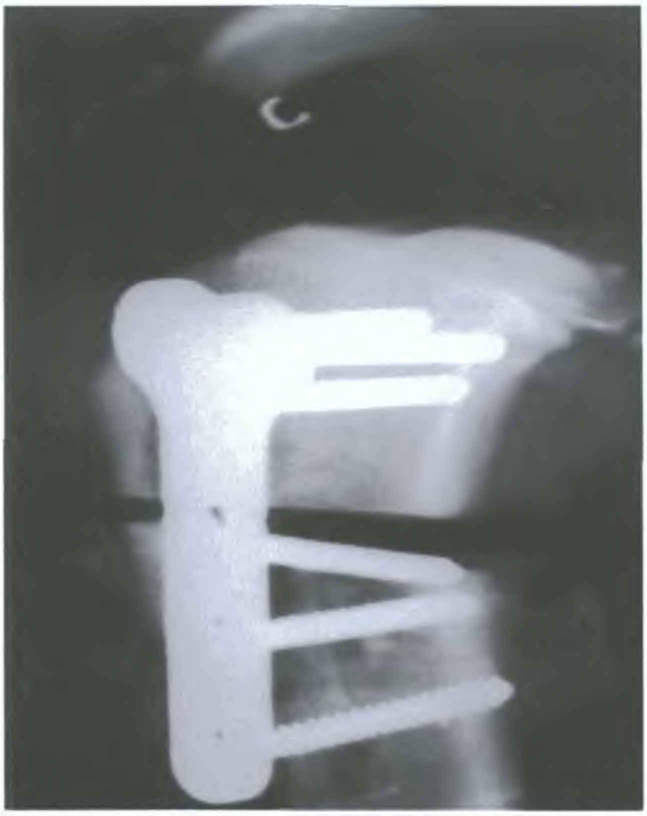
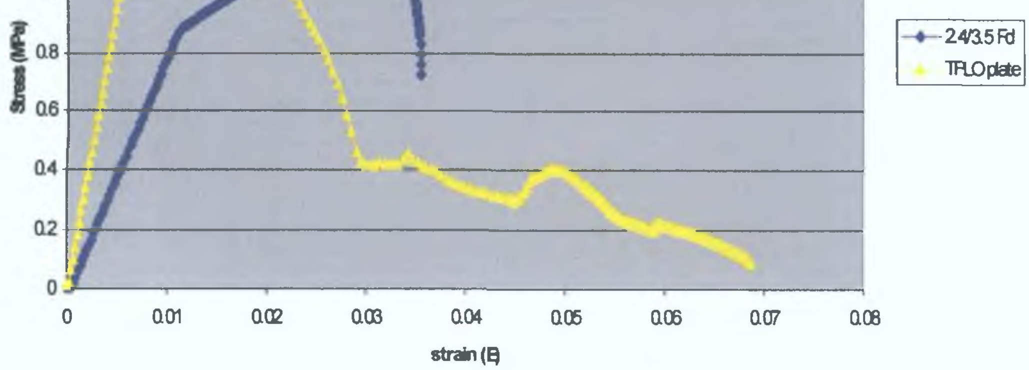


Fig. 7.37 Failure point tibial plateau leveling osteotomy plate



Graph 7.9 **Even though the TPLO plate is stiffer and stronger the 1.6/3.5Fd is not far behind it in strength (Figs. 7.36 and 7.37)**

Electıve osteotomy to correct deformıty or alter the mechanıcs of a joınt ıs a technıque employed ın dıfferent sıtes The tıbıal plateau levellıng osteotomy (Tplo) provıdes a useful sıte for analysıs of the fastenerod (Fıg 7 36) ın companson to the specıalısed Tplo (fig 7 37) plate Unlıke other partıcular plates the Tplo plate has three screw fixatıon poınts of the joınt end and thıs confers greater stıffness and strength as shown ın the stress straın curve (Graph 7 9)

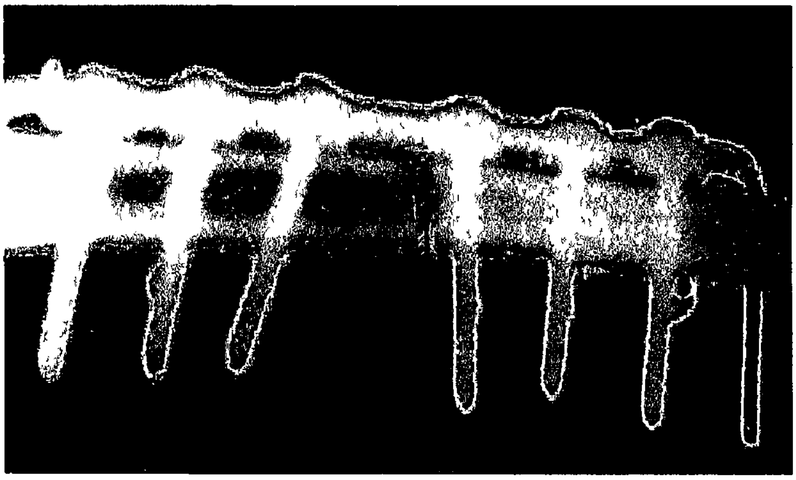


Fıg 7.38 2.4/3.5Fd used to repaır canıne mıdshaft radıus fracture

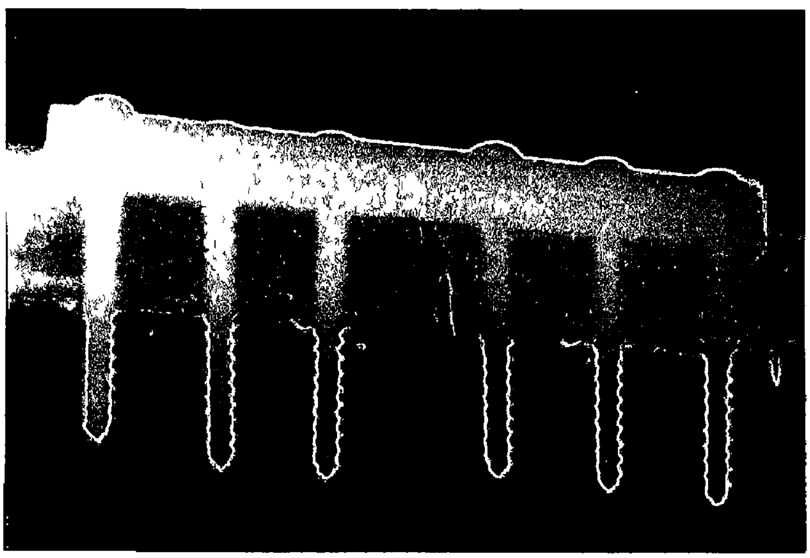
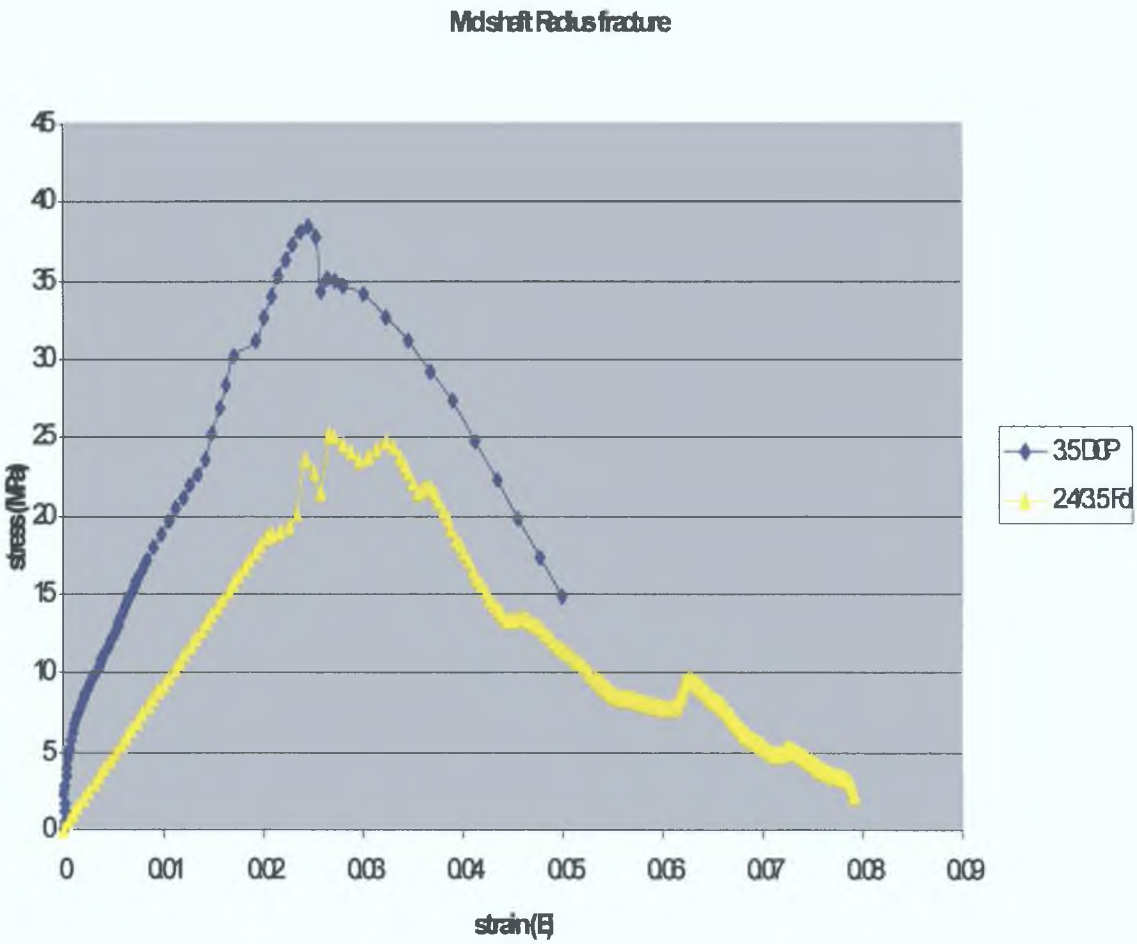


Fıg. 7.39 3.5 DCP used to repaır canıne mıd shaft radius fracture



Graph 7.10 The 3.5 DCP outperforms the 2.4/3.5Fd (Figs. 7.38 and 7.39)

Mid shaft or diaphyseal fractures are characterised by the uniformity of the shape of the bone in that area compared to periarticular fractures resulting in little or no contouring of implants needed. Under axial loading with a degree of shear brought about by angulation of the fracture site the 3.5DCP (Fig 7.39) has a significantly higher modulus of elasticity and ultimate yield than the 2.4/3.5Fd (Fig 7.38) for mid shaft fractures of the radius (Graph 7.10)

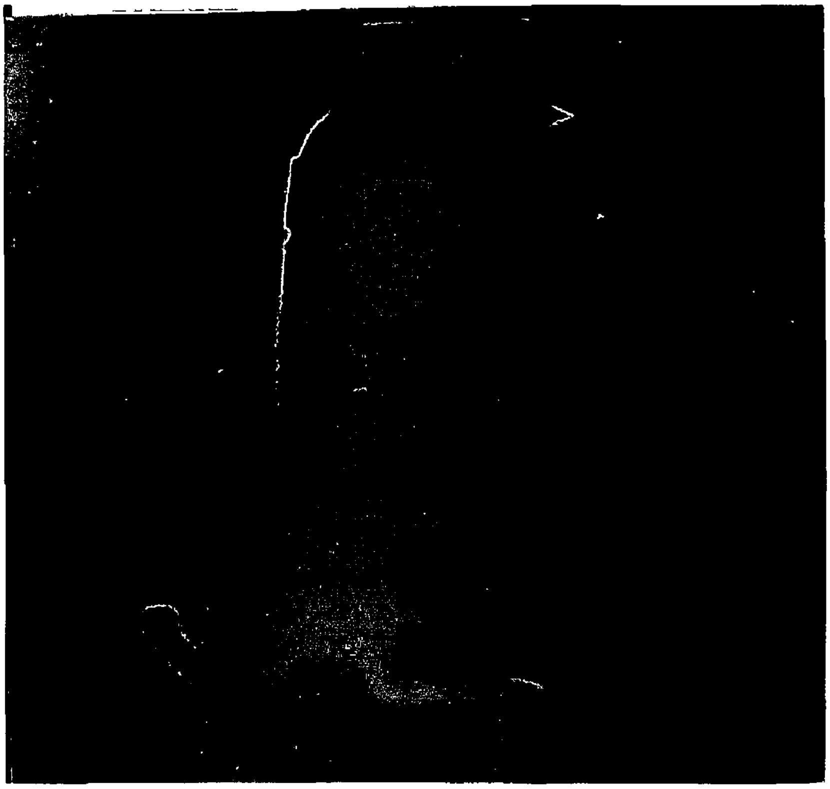


Fig. 7 40 2 4/3.5Fd used to repair a canine mid humerus fracture

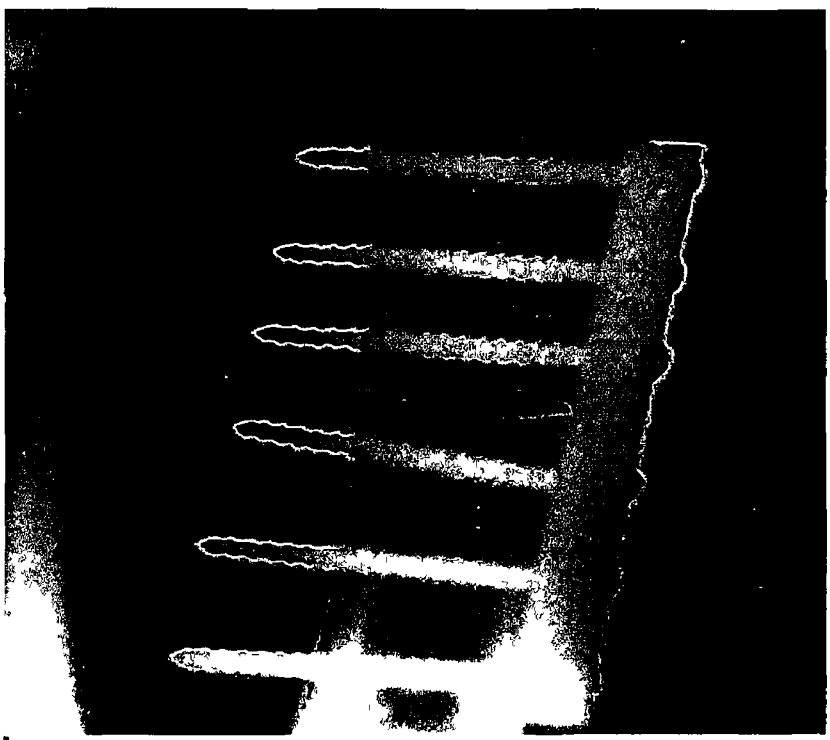
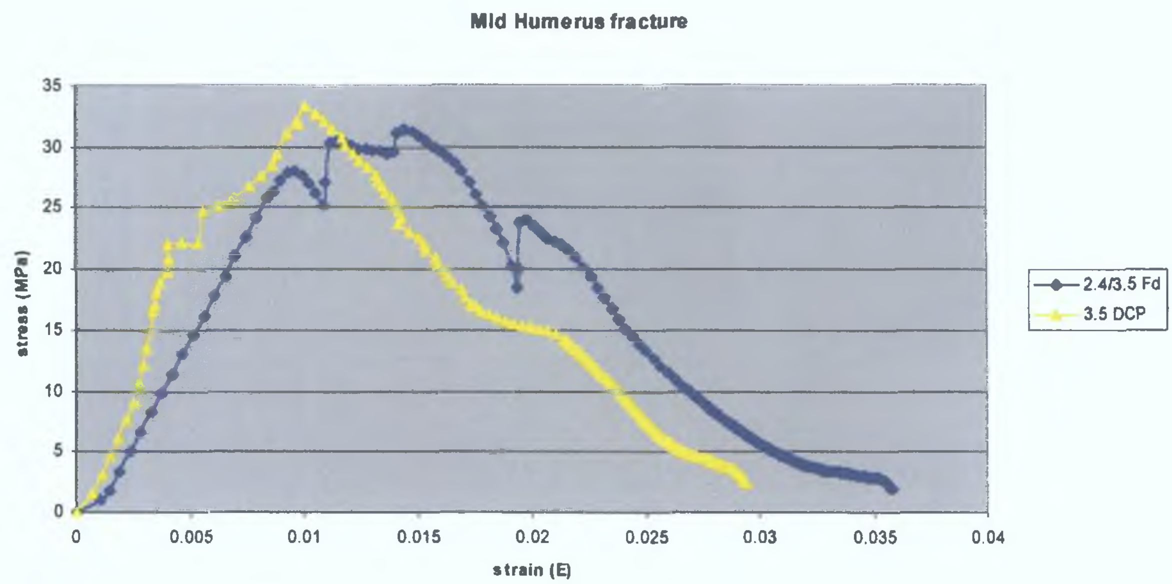


Fig. 7.41 3.5 DCP used to repair a canine mid humerus fracture



Graph 7.11 The 3.5 DCP is stiffer but the ultimate strength is similar (Figs. 7.40 and 7.41)

The humerus has a wider more circular geometry than the radius, which tends to be a flattened oval. Unlike the axial tests in the radius the results for the humerus indicate that there is little difference between the 2.4/3.5Fd (Fig 7.40) and the 3.5DCP (Fig 7.41) with the ultimate yield being similar (Graph 7.11).

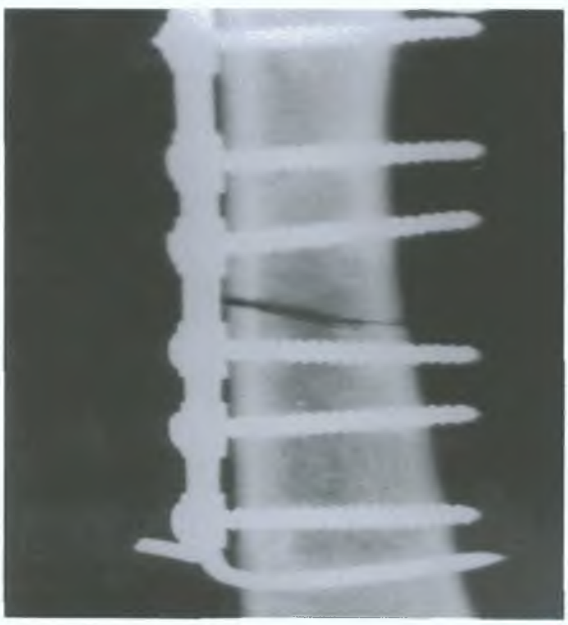


Fig. 7.42 2.4/3.4Fd used to repair a canine mid femur fracture

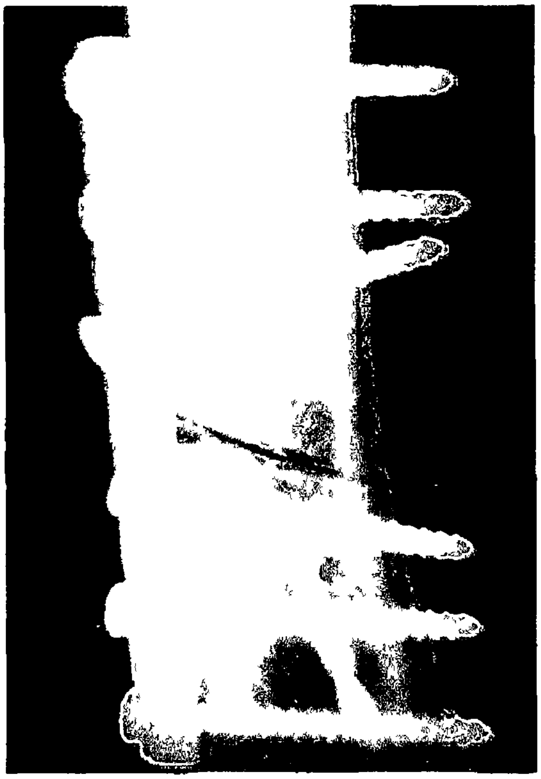


Fig 7 43 3.5 DCP used to repair a canine mid femur fracture

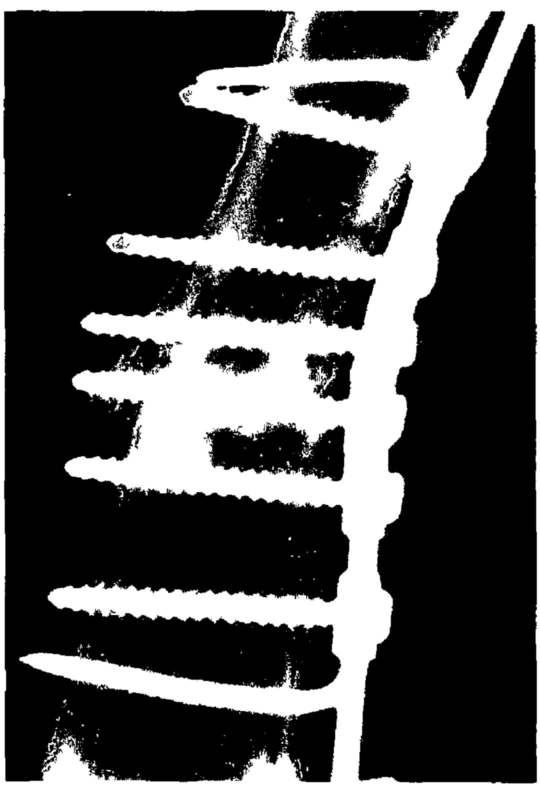


Fig. 7.44 Failure point 2.4/3.5Fd canine mid femur fracture

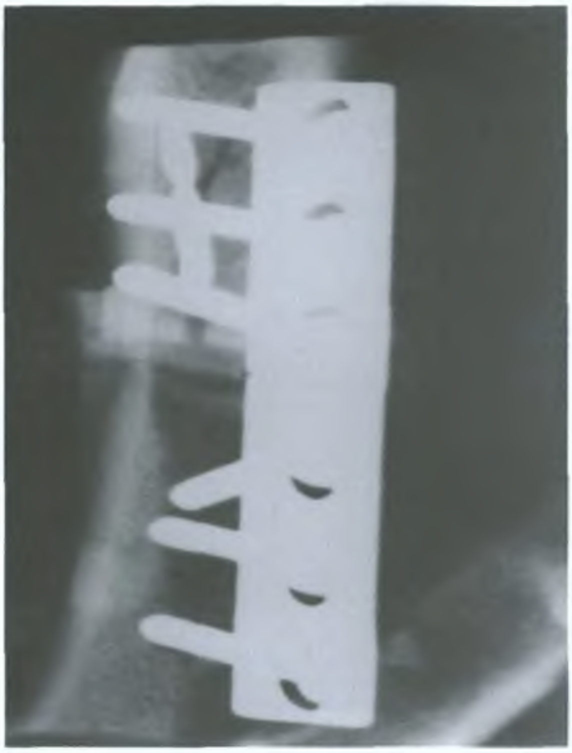
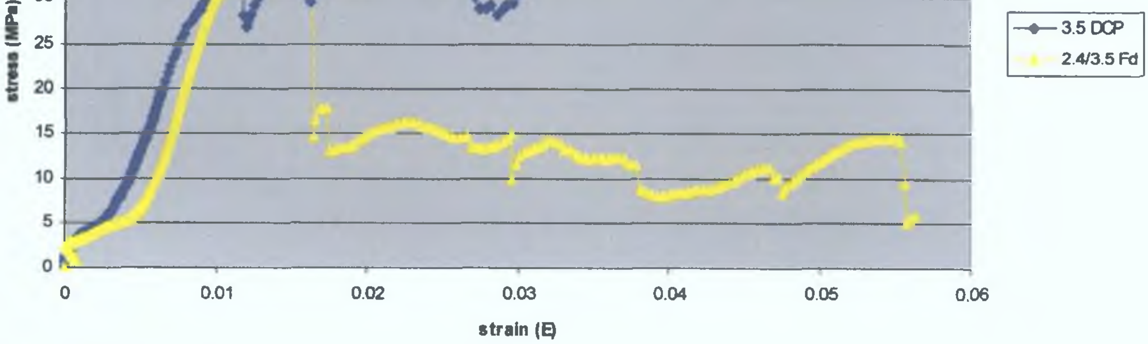


Fig. 7.45 Failure point 3.5DCP canine mid femur fracture



Graph 7.12 The 3.5 DCP is stiffer and stronger than the 2.4 /3.5Fd (Figs. 7.42 – 7.45)

Mid shaft fractures of the femur are very common and are usually repaired with plates but can also be repaired with pins The 3 5DCP (Fig 7 43) achieved an ultimate yield some 10mpa higher than the 2 4/3 5Fd (Fig 7 42) with the modulus of elasticity being similar (Graph 7 12) Unusually there was some fracturing of the bone at failure with the 2 4/3 5Fd in one sample (fig 7 44) but this was significantly less than the complete shattering of the bone fixed with the 3 5DCP (Fig 7 45)

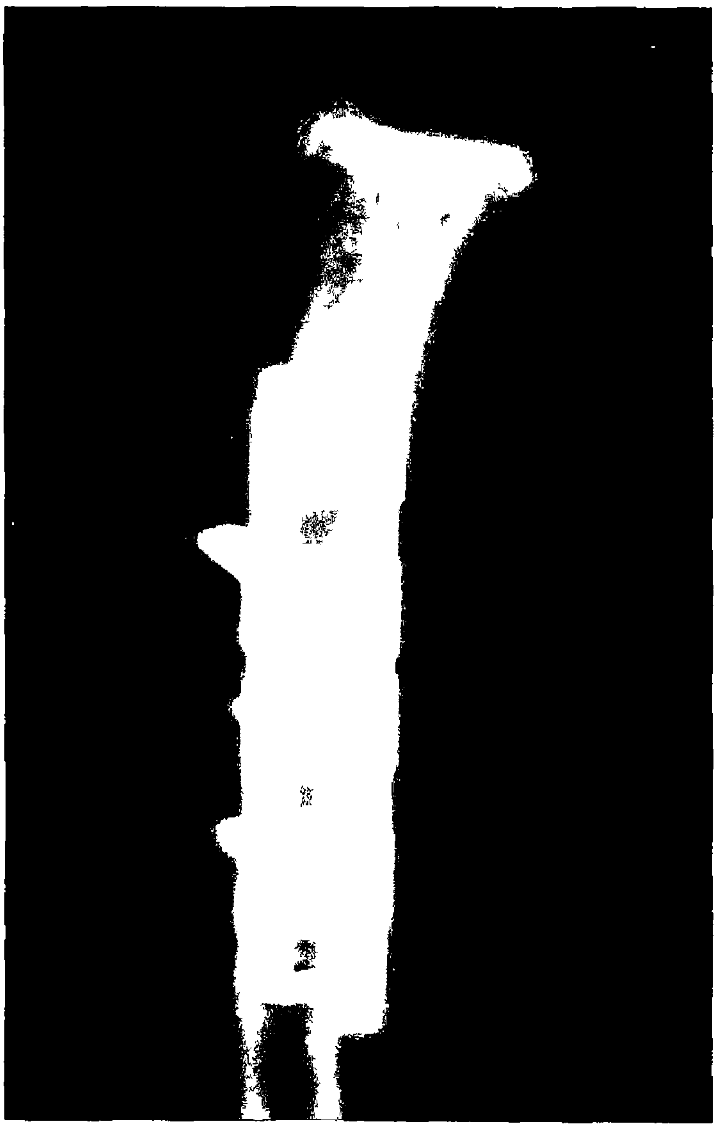


Fig. 7.46 Repair of a fractured Feline radius using a 1.1/2Fd

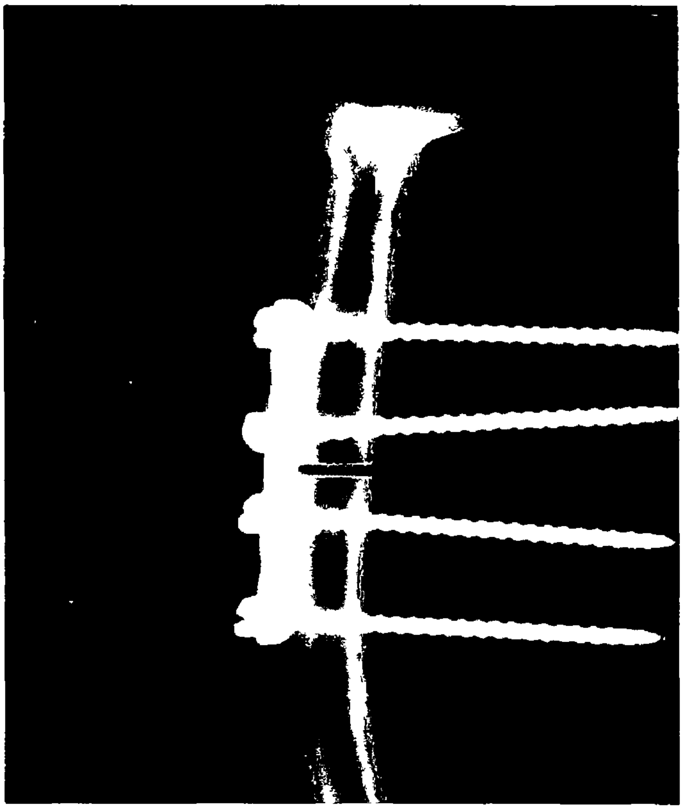


Fig. 7.47 Repair of a fractured Feline radius using a 2.0 plate

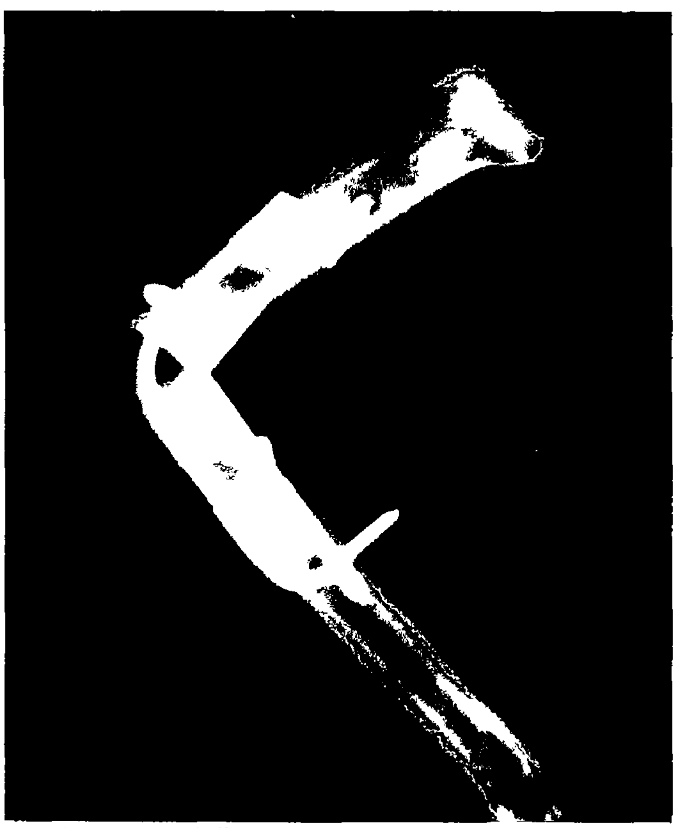


Fig 7.48 Failure point 1.1/2Fd feline radius

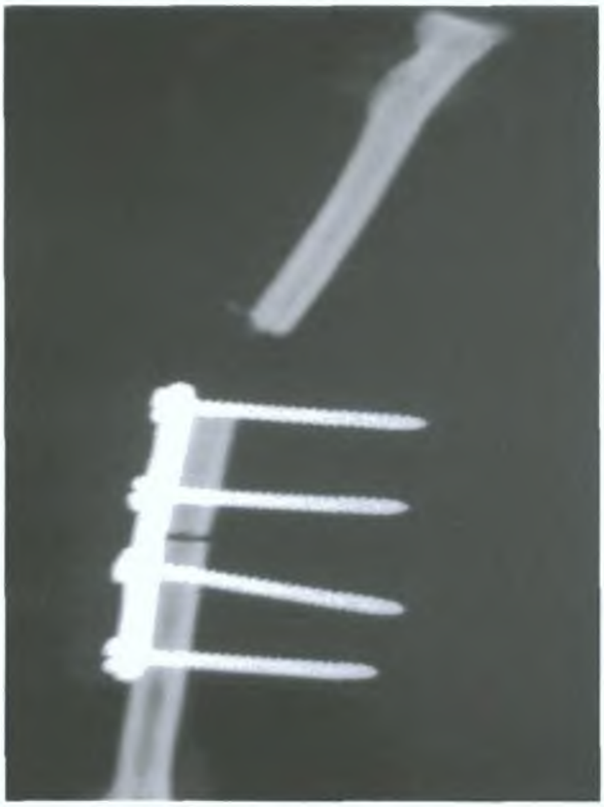
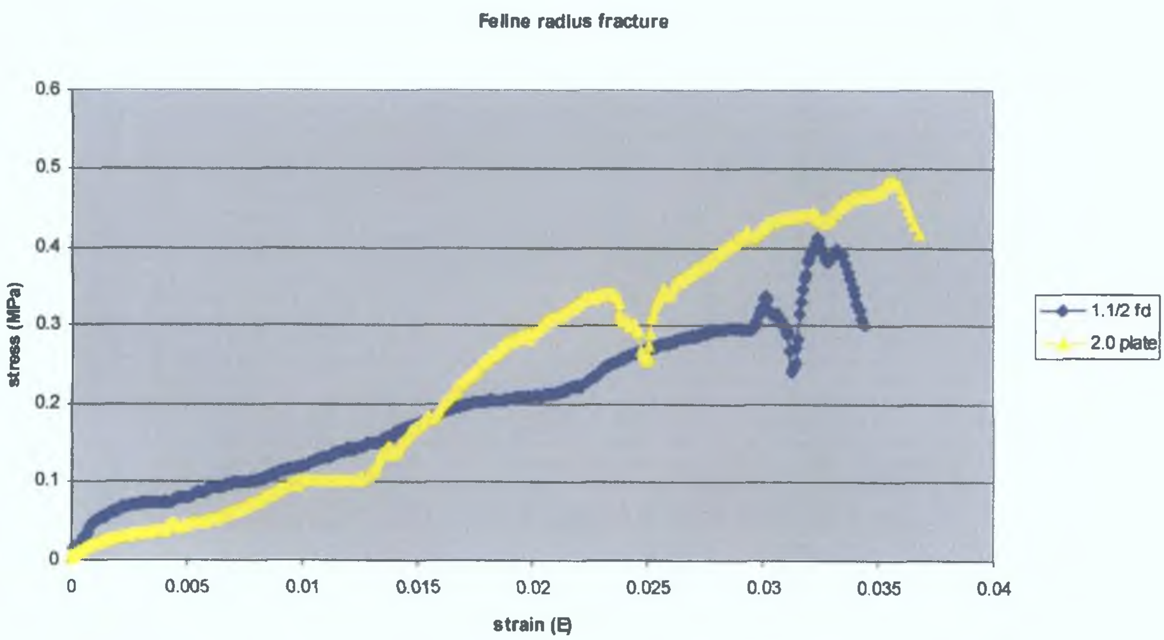


Fig. 7.49 Failure 2.0 plate Feline radius



Graph 7.13 The 2.0 plate just outperforms the 1.1/2fd in the feline radius (Figs. 7.46 – 7.49)

The Felme radius is an incredibly fine piece of bone but has great strength relatively Repair with either 2 0 plate (Fig 7 47) or 1 1/2Fd (Fig 7 46) would achieve a similar result according to the stress strain curve in these experiments (Graph 7 13) Interestingly in this sample the 1 1/2 0Fd (Fig 7 48) fails by bending without breakage whereas the 2 0plate (Fig 7 49) fails by a new fracture

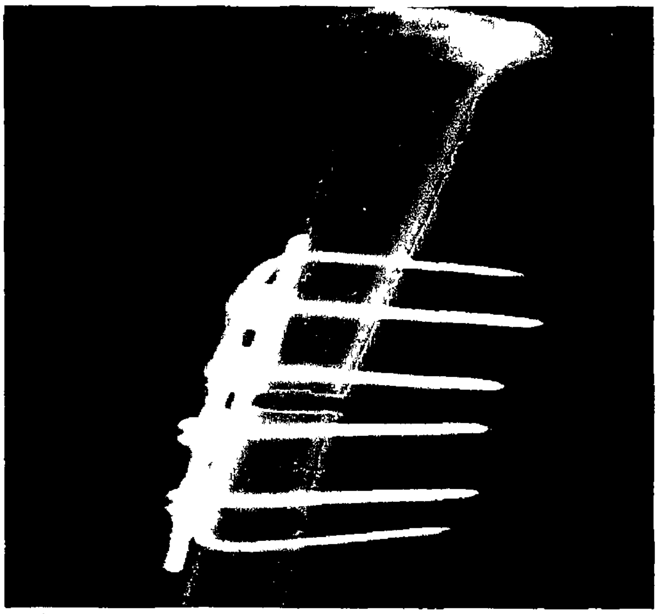


Fig. 7 50 Repair of a fractured Feline tibia using a 1 1/2Fd

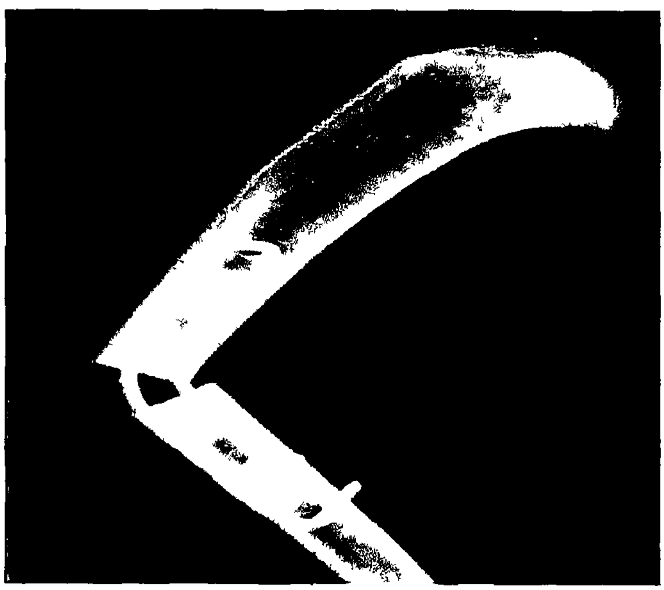
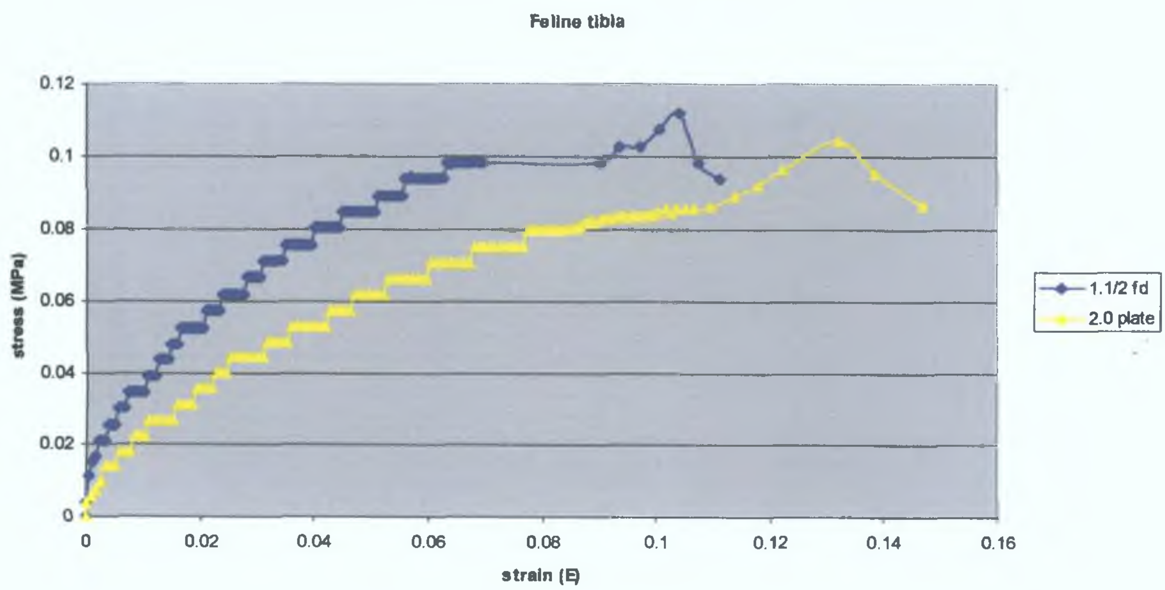


Fig. 7.51 Feline tibia fail 1.1/2Fd

Fig. 7.52 Failure point 2.0 plate



Graph 7.14 There is similar performance between both implants (Figs. 7.50 – 7.52)

Feline tibia fractures are not commonly repaired with plates but for comparison purposes it is useful to record the difference with the 1 1/2Fd (Fig 7 50) The 1 1/2Fd in fact achieves a higher stiffness and ultimate yield (Graph 7 14) than the 2 0 plate and this is consistent with the findings from chapter 6 It is interesting to note the mode of failure between the 1 1/2Fd (Fig 7 51), which is by bending compared to the 2 0 plate (Fig 7 52), which is by bone fracture through a screw hole

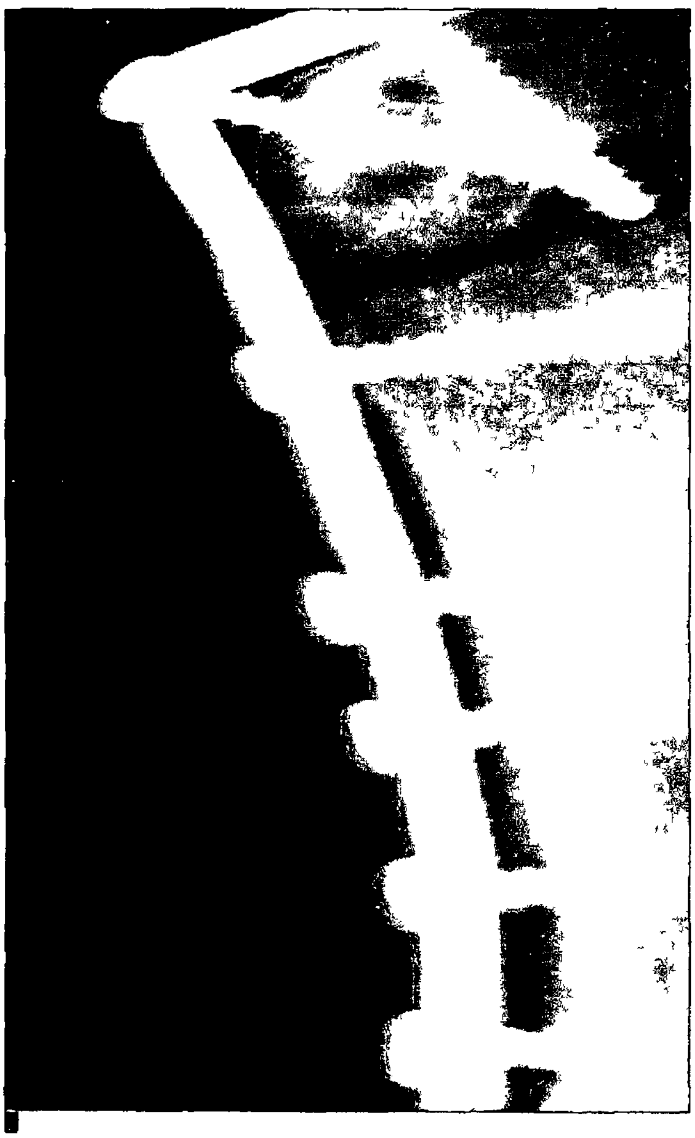
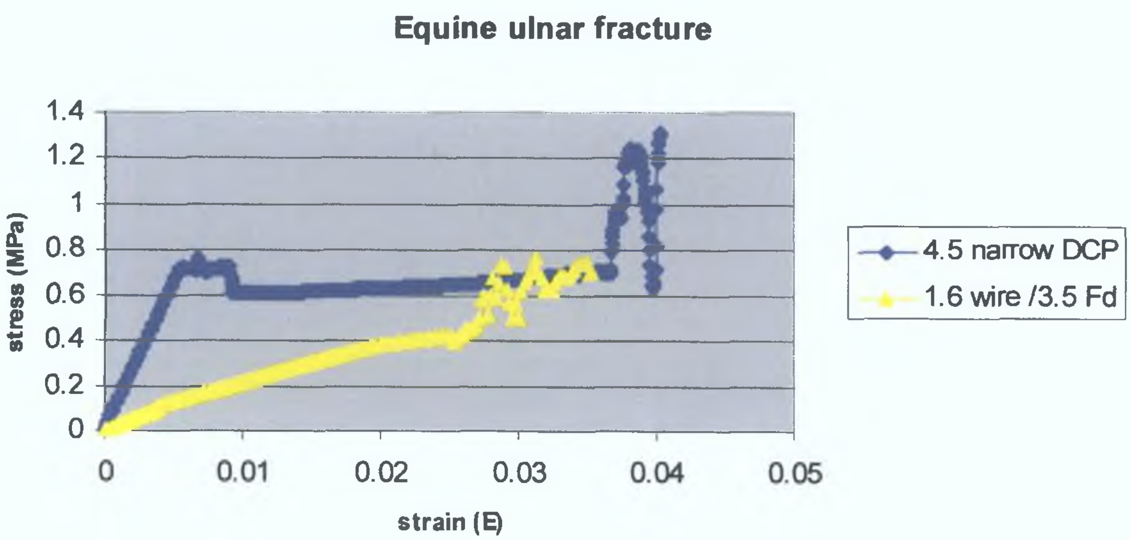


Fig. 7.53 4.5 DCP Equine Proximal Ulna

Fig. 7.54 1.6/3.5 wire Fd used to repair a fractured Equine proximal Ulna



Graph 7.15 The 4.5 DCP outperforms the 1.6/3.5wire Fd (Figs. 7.53 and 7.54)

Equine ulna fractures are difficult to treat due to their shape and the magnitude of the forces acting on the bone from surrounding tissues Using a narrow 4 5DCP (Fig 7 53) would be the usual choice and involves extensive contouring and dissection to apply It is a massive implant placed on the end of a thin but deep bone and it can be common for the surgeon to have to shave off some bone to get the plate to fit snugly A wire of 1 6mm diameter was chosen instead of a pin of 1 6mm diameter for the Fastenerod (Fig 7 54) to be able to apply tension along the fixation Even so the 4 5DCP significantly achieved better results than the 1 6 wire Fd (Graph 7 15)

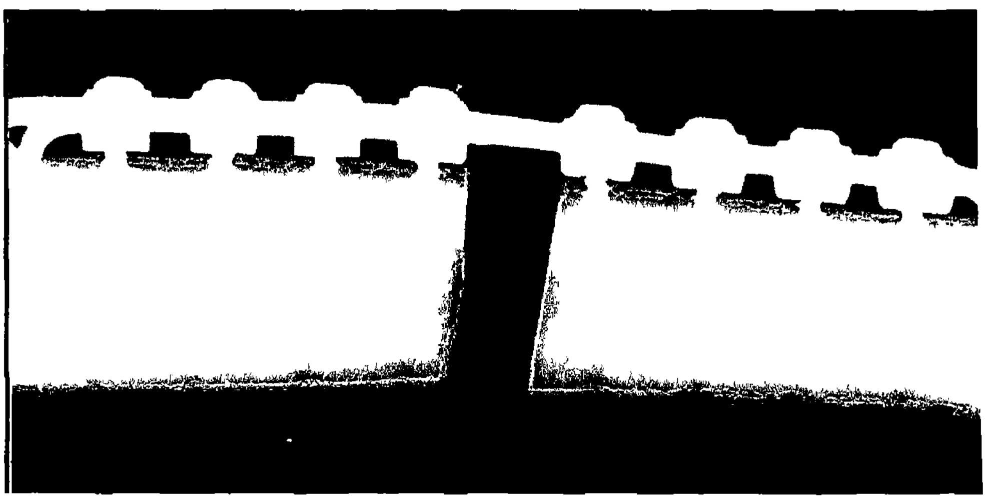


Fig 7 55 Repair of a fractured Equine cannon bone using a 4/4 5Fd

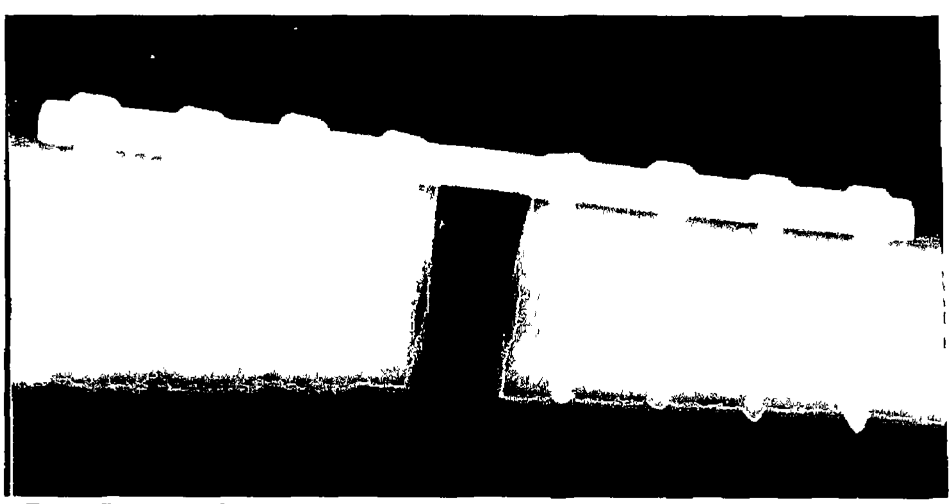
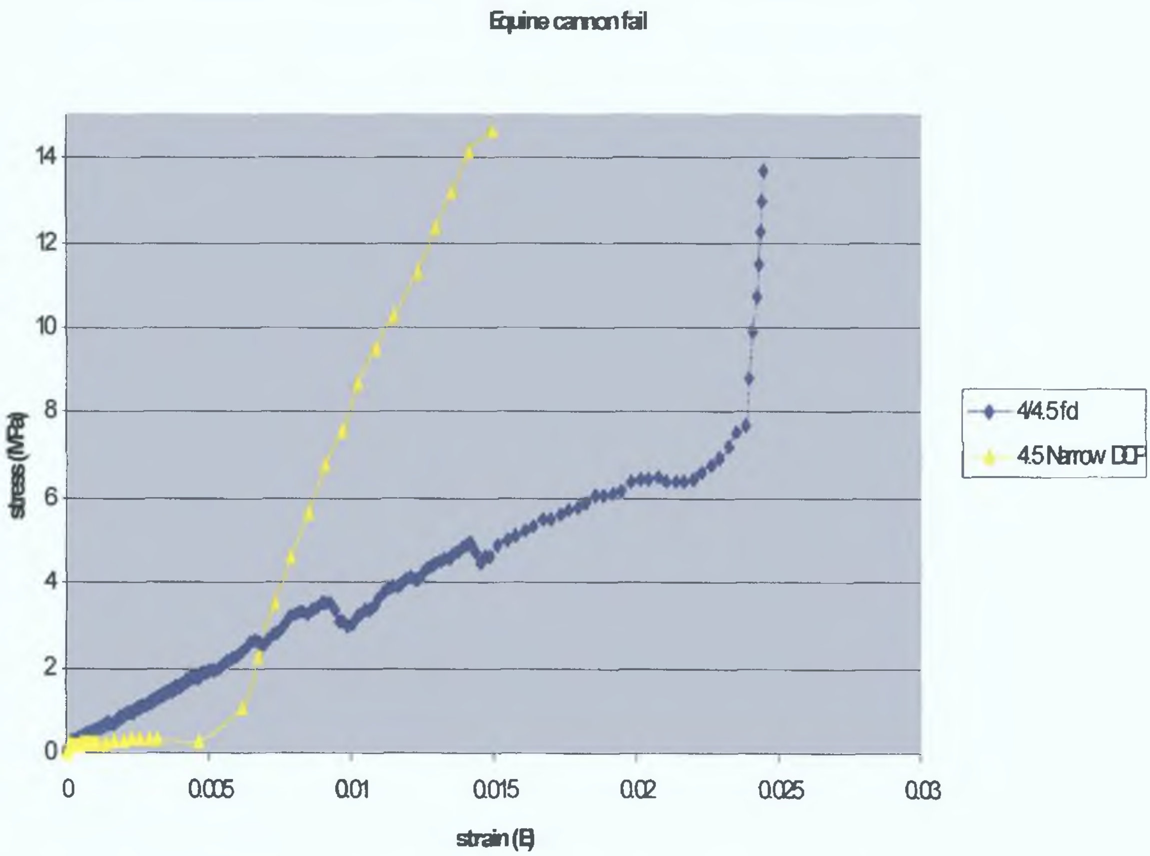


Fig 7.56 Repair of a fractured Equine cannon bone using a 4 5DCP narrow



Graph 7.16 The 4.5 DCP outperforms the 4/4.5Fd note that neither implant reaches failure point as they both deformed until the sample reached the base of the Instron (Figs. 7.55 and 7.56)

The equine cannon bone is a massive bone and when a fracture occurs the horse is quite commonly enthanatised due to the difficulty in achieving successful repair. Placement of two 4.5 DCP (Fig 7.56) at 90 degrees to each other can achieve success but due to the extensive dissection required the bone either does not heal or becomes chronically infected ultimately leading to failure of fixation. Achieving fixation strong enough without extensive dissection is the goal and from these tests the 4/4.5Fd (Fig 7.56) is neither as stiff nor as strong compared to the 4.5DCP (Graph 7.16).

The fastenerod performance for ultımate yıeld was as follows

Sıte of Fracture	Rankıng of Strength
Scapula	1 6 / 2 7 Fd > 2 7 DCP
Dıstal Humerus	1 6 / 2 7 > 2 7 DCP
Dıstal radıus small	1 6 / 2 7 > 2 7 DCP
Dıstal radıus large	3 5 Tplate > 2 7 DCP
Proxımal unla	TBW > 1 6 / 2 7 Fd
Dıstal femur	1 6 / 3 5 Fd > 3 5 Reconstructıon plate
Dıstal femur	3 5 DCP > 1 6 / 3 5 Fd
Tıbıal Tuberosıty Avulsıon	1 6 / 2 7 Fd > TBW
Tıbıal Plateau Levelıng osteotomy	TPLO plate > 1 6 / 3 5 Fd
Ilium	1 6 / 2 7 > 2 7 DCP
Dıaphyseal fractures Humerus / Radıus / Femur	3 5 DCP > 2 4 / 3 5 Fd
Felıne fractures Radıus Tıbıa	1 1 2 Fd > 2 0 plate 1 1 2 Fd > 2 0 plate
Equıne fractures Ulnar Cannon	4 5 DCP > 1 6 wıre Fd 4 5 DCP > 4/4 5 Fd

7 4 Discussion

The 1 6 / 2 7 fastenerod proved to be a good alternative mechanically to the 2 7 DCP according to the tests performed The fact that the 1 6 / 2 7 fastenerod has 3 points of contact in the distal fragment compared to 2 points for the T plates would explain its greater strength For periarticular fractures and fractures of the ilium the fastenerod performance is encouraging

Mid shaft fractures in dogs were better supported by 3 5 DCP but the 2 4 / 3 5 Fd was not significantly weaker and achieved 80-90% of the ultimate yield of the 3 5 DCP for the humerus and femur Feline fractures can be held as rigidly with the 1 1 / 2 Fd as with a 2 0 plate The 1 1 / 2 Fd again has showed that it can perform equally or better than the 2 0 plate, and so the mini fastenerod system would be useful for feline fractures

In the case of equine fractures the fastenerod did not match or reach anywhere near performance of the 4 5 DCP Equine fractures are at the extreme end of the fracture fixation system in that even the most rigid fixation can be insufficient to maintain fixation The 4 / 4 5 fastenerod would not be strong enough based on static loading to be suitable for equine fractures without medifications such as an extra pin or snapons

A consistent feature with all classes of fastenerod formations was that they nearly always failed by reaching maximum extension or over extension rather than by fracture of the sample In the case of the DCP system the mode of failure was generally by fracturing / splintering of the sample, by screw pull out or by plate fracture It is appealing that one of the main causes of implant failure would not really apply to fastenerod system The flexibility of the system means that the forces transferred to the fixation formation are not as fully transferred to the stress raiser points as in the stiff DCP The stress raiser points of the DCP are the screw holes By distributing the forces along the length of the fixation and allowing movement of the fixation through increased flexibility there is less obvious stress concentration

7.5 <u>Summary</u>

The fastenerod proved to have properties nearly equal to or greater than the plate systems used for the veterinary fractures In general the smaller fastenerod was superior to the equivalent sized plate However, this ranking order transferred over to the plates as the size of the implants increased This change in behaviour in line with implant size was repeated in the results in accordance with animal size In comparison to other methods of repair, such as tension band wiring, the fastenerod was more or less equivalent overall

Chapter 8

Evaluation of the Use of the Fastenerod System in Human Fractures

8.1 Introduction

Human fracture repair methods are naturally more advanced than veterinary methods, and specialised implants for specific fractures and anatomic sites are commonplace In attempting to evaluate the Fastenerod System for human fracture repair the choice of either fracture or bone must reflect a specific need and for these tests the femur was chosen,in particular the proximal femur (Fig 8 1) Cadaveric human bones were not used in the study as artificial human bones are readily available for laboratory testing

8.2 Methods and Materials

A custom made jig for the tests was made to hold the femur during testing (Fig 8 2 and 8 3) Artificial human femurs specifically designed for mechanical laboratory testing were used (Sawbones, Sweden), as the bones were virtually identical to human bones in shape and in mechanical performance Four sets of experiments were performed, these were (i) subtrochanteric femoral-cycling (Fig 8 4), (ii) subtrochanteric load sharing femoral – static failure, (iii) subtrochanteric non-load sharing femoral - static failure,(iv) mid shaft femoral- static failure

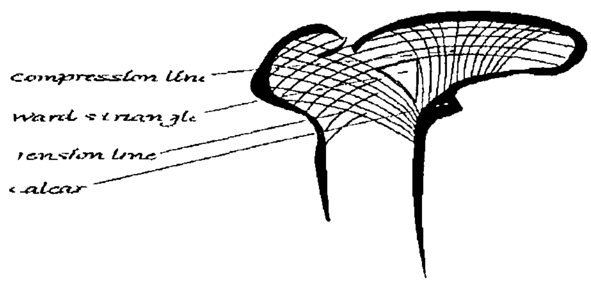


Figure 8 1 The tension and compression lines acting on a proximal femur

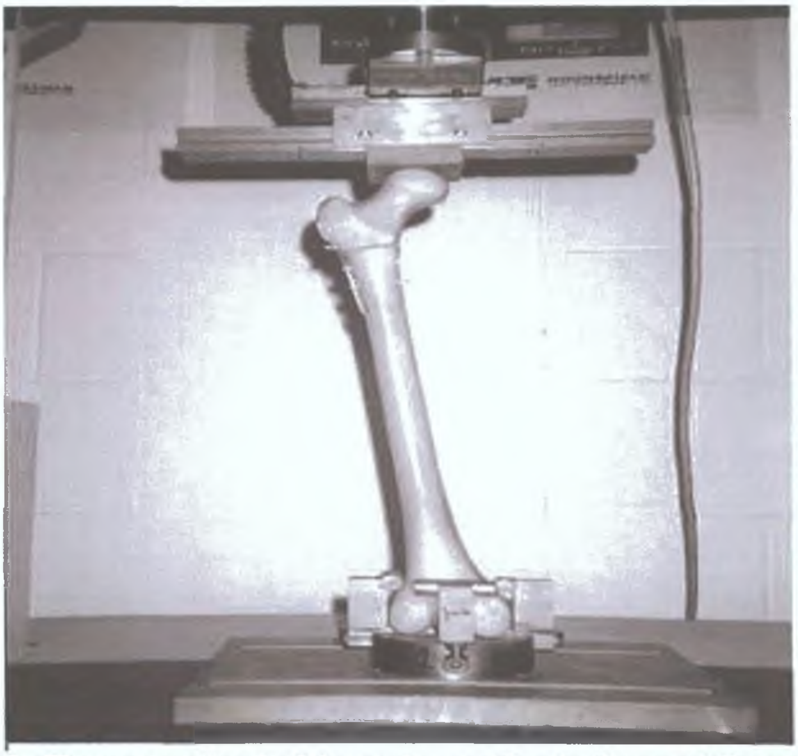


Figure 8.2 Human mechanical femur in position in the specially made jig for testing

Fig. 8.3 Close up of grips used to hold distal femur

In the first set of experiments the load sharing fracture of the femur was repaired with the gamma interlocking nail, Dynamic Condylar screw (DCS) plate, Blade plate, 3 5 clip, 1 6/3 5 Fd,and 1 6/3 5Fd crimped/turned The difference between the latter two is that the pins are bent and the Fastenerod crimped After application of the implants,the whole femur was set up in a custom made jig that holds the femur at 11° lateral inclination (Fig 8 2), which simulates normal positioning An Instron extentiometer (12 5 mm), was applied to the most lateral aspect of the femur at the same place for each sample (Figure 8 4) to monitor the effects of the tensile forces(Fig 8 5) For the control,a partial cut was made in the lateral aspect of the femur (Figure 8 6) A load of O 5 KN to 1KN was set up to cycle with a speed of 2 mm/second The extentiometer detected any movement as it was placed over the fracture site

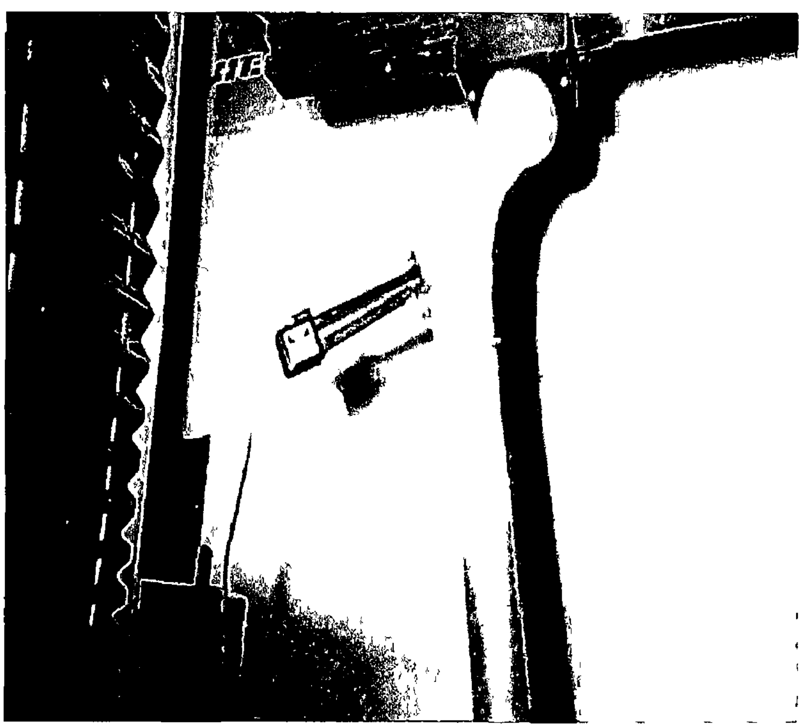


Figure 8.4 Extentiometer (12.5 mm)in position on lateral aspect of femur over fracture site

The subtrochanteric load sharing femoral fractures, the static failure set of experiments was based on the same set of implants as the femoral cycling tests but was to failure This was compression, with no load limit, surface area and at a speed of 2mm/second A few additional implant formations were used in these series such with all the variations in the Fastenerod system with 3 pins and pins across fracture site being added on

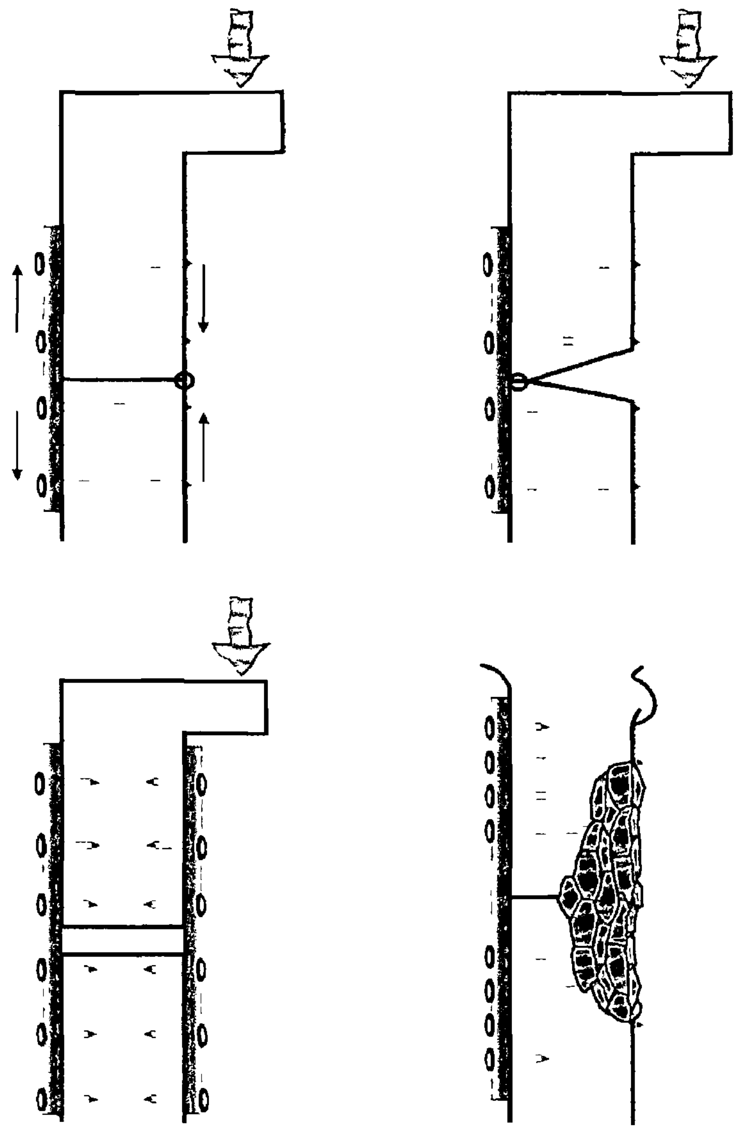


Fig. 8.5 Lack of bone medially significantly weakens the bone

For subtrochanteric non-load sharing femoral fractures there was no contact between the proximal or distal femur The gap prevented any contact between the fracture surfaces and hence no load sharing (Fig 8 5) In this series of experiments only the implants supported the fracture Only DCS plate, 4/4 5fd and 1 6/3 5 Fastenerod were used to repair this fracture and Instron settings were the same as for the previous series of experiments Mid shaft femoral fractures were loaded to failure by a static test using the four point bending jig A gap was left between the bone ends and only a 4 5 DCP and 4/4 5Fd were used during this test

8.3 Results

Each set of results for the different groups of tests is presented in a similar format to those in Chapter 7, with x-rays followed by graphs and the tables in Appendix A (Tables 8 1-8 4)

8 3 1 Cyclic Loading Tests Subtrochanteric Femoral Fracture

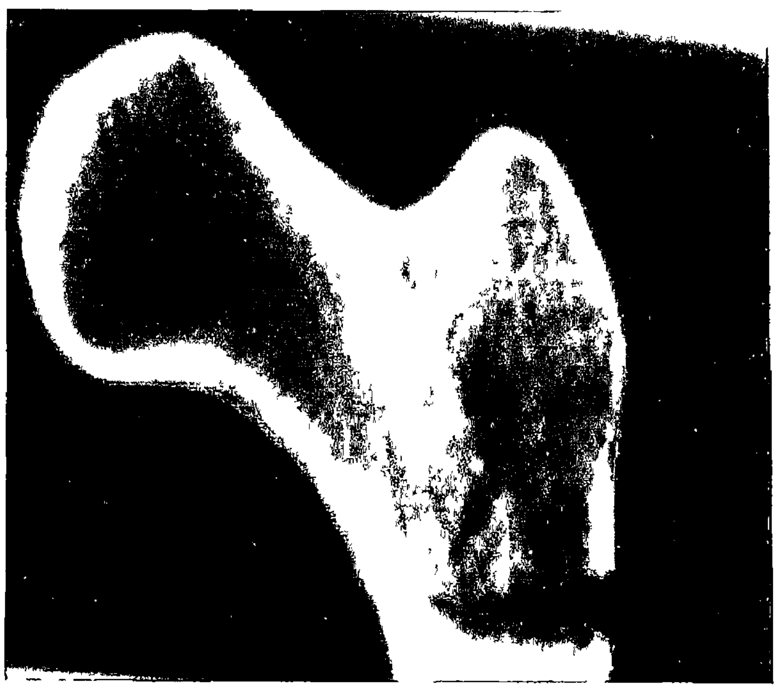


Figure 8 6 Weakened control showing fracture extent

Figure 8.7 3.5 clip used in repair of a fractured proximal Femur

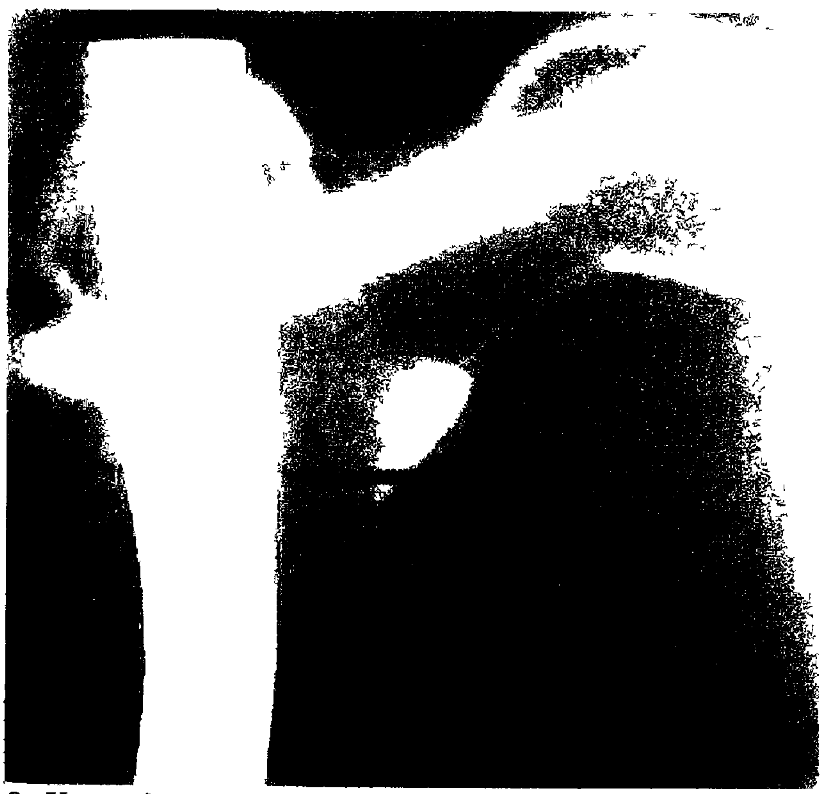


Figure 8.8 X-ray showing repair of fractured proximal femur using a gamma interlocking nail

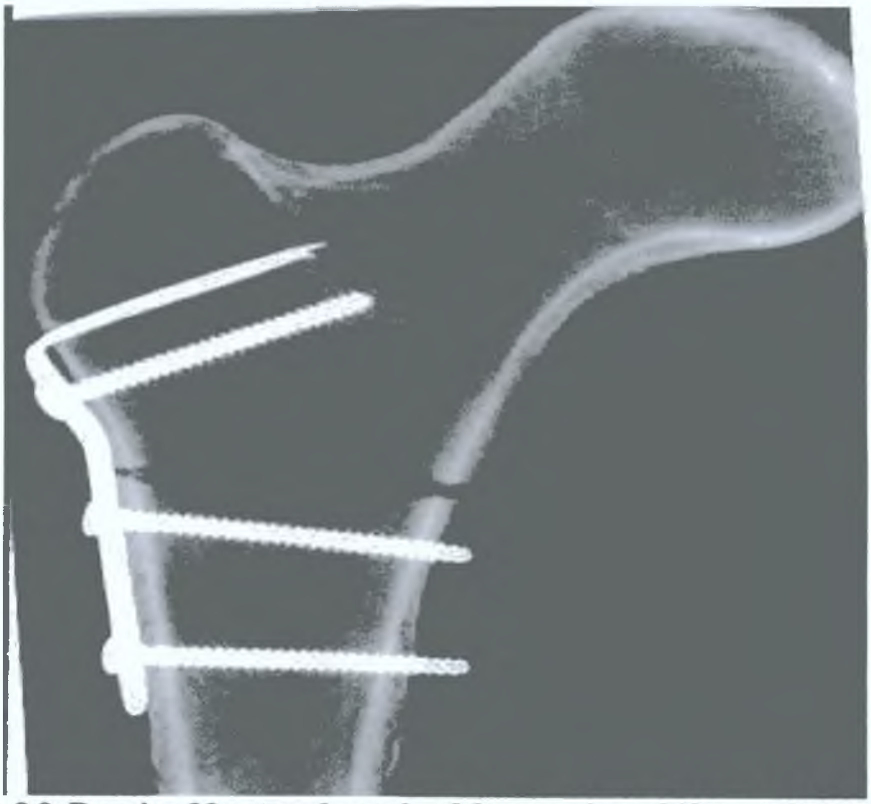


Figure 8.9 Repair of fractured proximal femur using a bifurcated blade plate

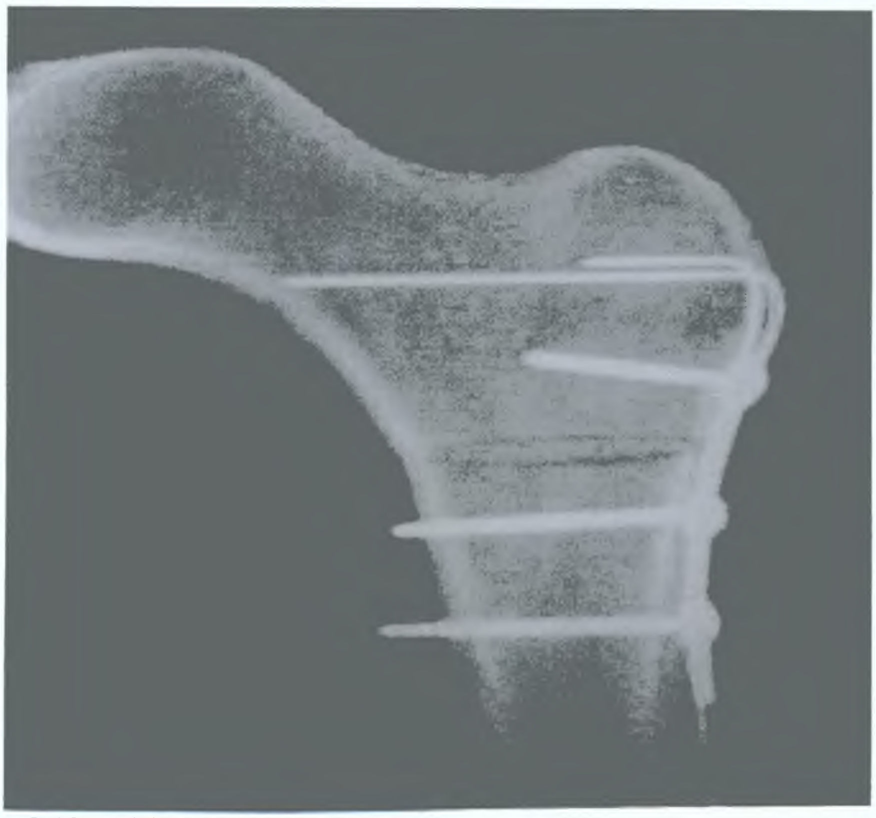
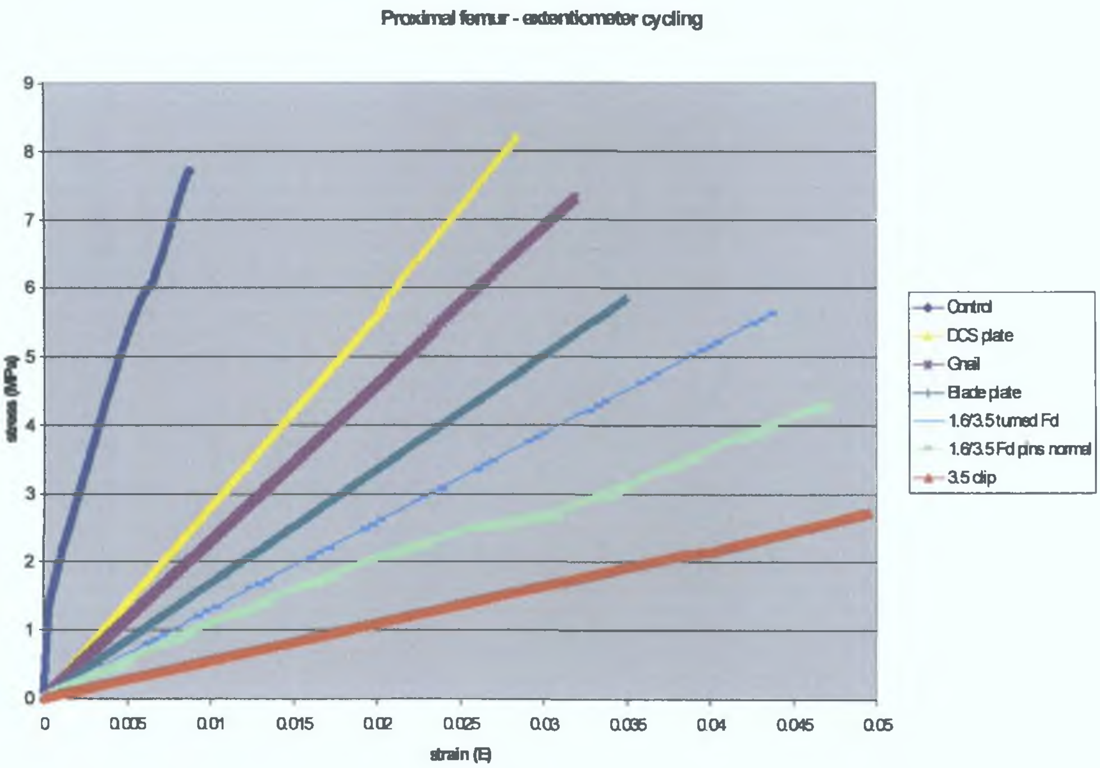


Figure 8.10 1.6/2.7Fd pins normal used to repair a proximal femur fracture



Graph 8.1 Comparative stiffness levels at lateral femur

Using the extentiometer allowed closer examination of the behaviour at the level of the fracture site as opposed to the whole bone (Fig 8.6). Detection of the degree of movement at a certain level of strain is useful in understanding how the bone would behave under loading conditions (Graph 8.1). The stiffness difference between the implants was in the order of size or the amount of metal in most cases, with the interlocking nail (Fig 8.8)being much stiffer than either the clip (Fig 8.7) or fastenerod (Fig 8.10) for instance, except with regard to the orientation of the pins for the fastenerod where the bending of pins increased stiffness. Interestingly,taking the area under the graphs for each implant (Table 8.1),the same order occurs except that the 1.6/2.7Fd, crimped and turned (Fig 8.11), achieves a greater area and hence energy absorption than the bifurcated blade plate (Fig 8.19).

Table 8.1 Human Proxımal Femur Cyclıng Exntentıometer

		Area	E_{mPa}
Control	a	0 0323	968
	b	0 0312	975
	c	0 0808	910
mean		0 0481	951
StanDev=		0 028324371	35 67912555
Varıance=		0 00080227	1273
DCS	a	0 418	301
	b	0 416	296
	c	0 423	309
mean		0 419	302
StanDev=		0 003605551	6 557438524
Varıance=		1 3E-05	43
Gnaıl	a	0 219	260
	b	0 216	240
	c	0 222	265
mean		0 219	255
StanDev=		0 003	13 22875656
Varıance=		9E-06	175
Bladeplate	a	0 0963	181
	b	0 0957	175 7
	c	0 0963	184
mean		0 0961	180
StanDev=		0 00034641	4 20277686
Varıance=		1 2E-07	17 66333333
1 6/3 5 Crımped	a	0 1193	140
Turned	b	0 1255	135
	c	0 1149	139
mean		0 1199	138
StanDev=		0 005325411	2 645751311
Varıance=		2 836E-05	7
1 6/3 5 Fd	a	0 0812	85
	b	0 0966	93
	c	0 0793	83
mean		0 0857	87
StanDev=		0 00948736	5 291502622
Varıance=		9 001E-05	28
3 5 clıp	a	0 0559	53
	b	0 0815	52
	c	0 0714	69
mean		0 0696	68
StanDev=		0 012894573	9 539392014
Varıance=		0 00016627	91

8 3 2 Static Compression to Failure Tests on Subtrochanteric Femoral Fracture

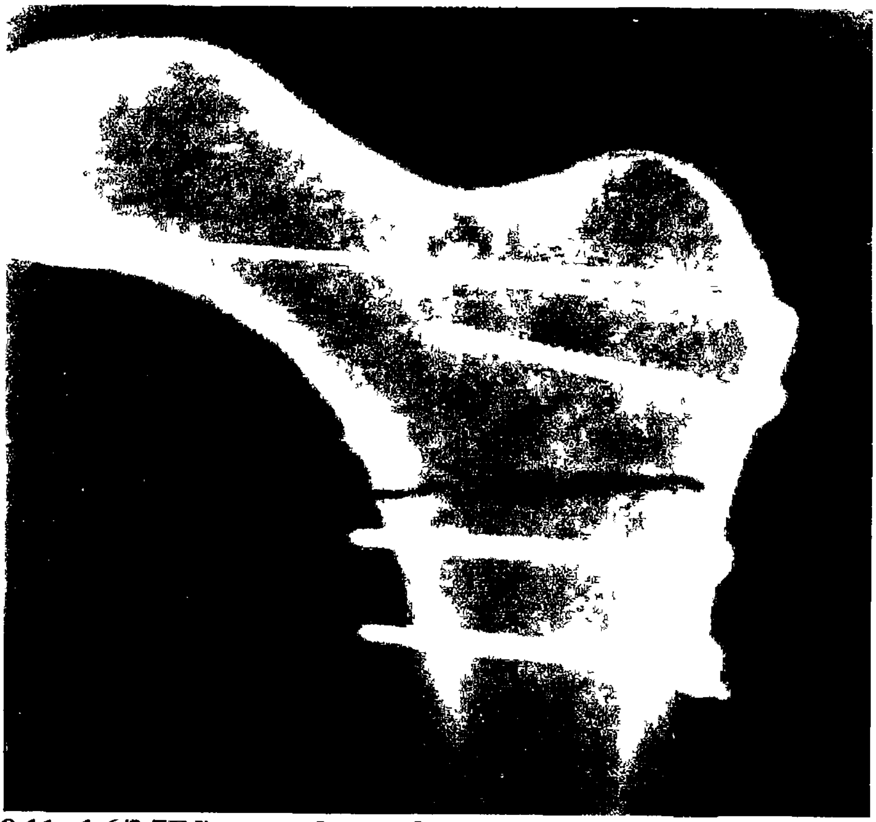


Figure 8 11 1.6/2 7Fd\crimped turned used to repair fractured proximal femur

Figure 8.12 Craniocaudal view of 1.6/2.7Fd crimped turned used to repair proximal fractured femur

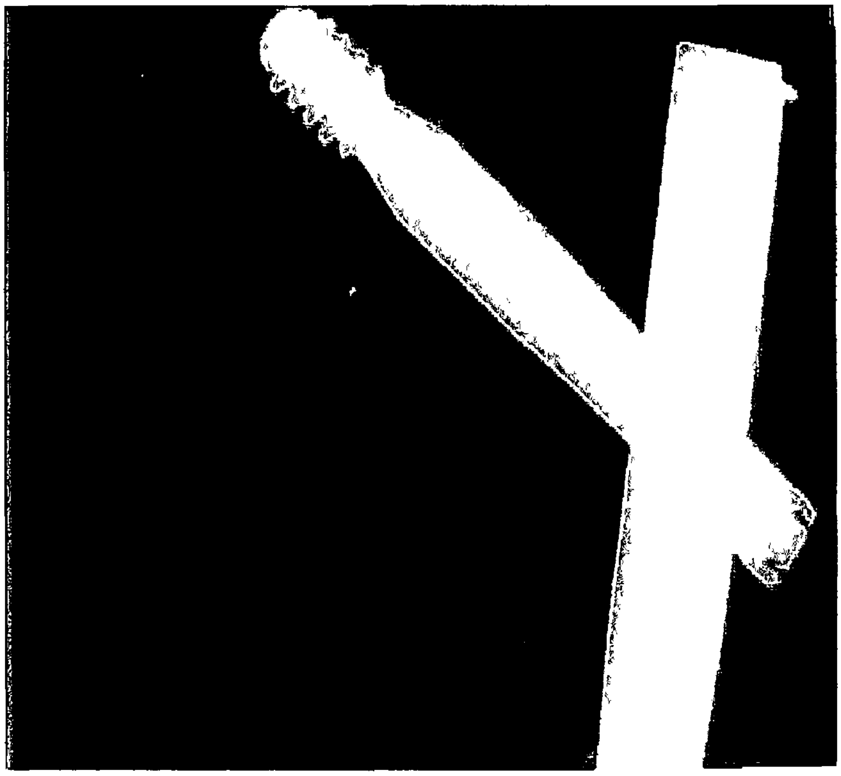


Figure 8.13 Gamma interlocking nail repair of proximal femur failure by fracturing of bone

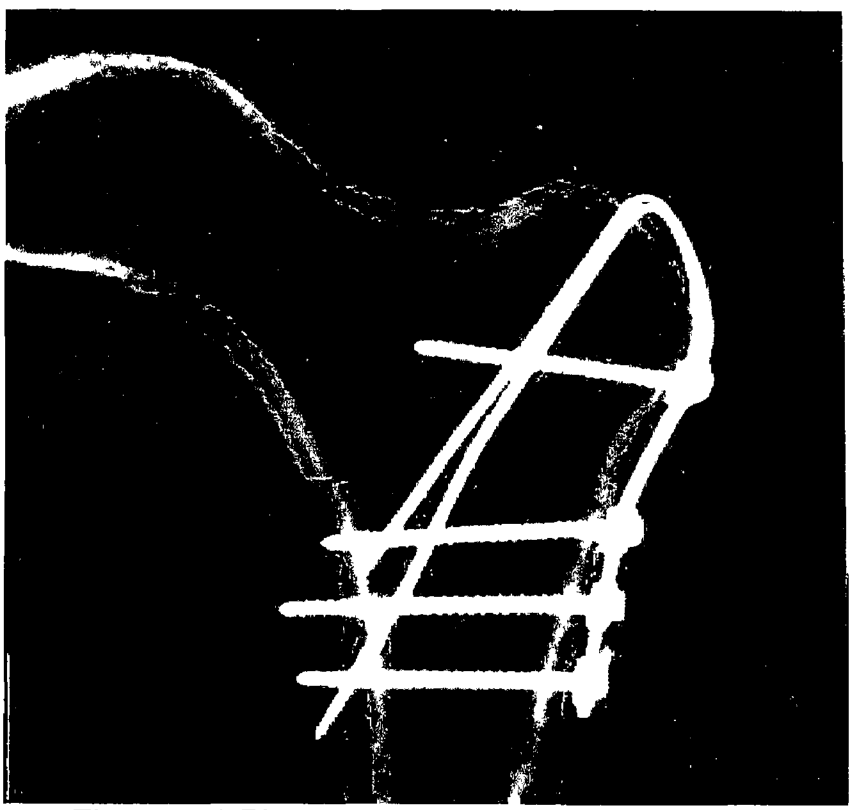


Figure 8.14 Pins crossed over fracture site 1.6/2 7Fd

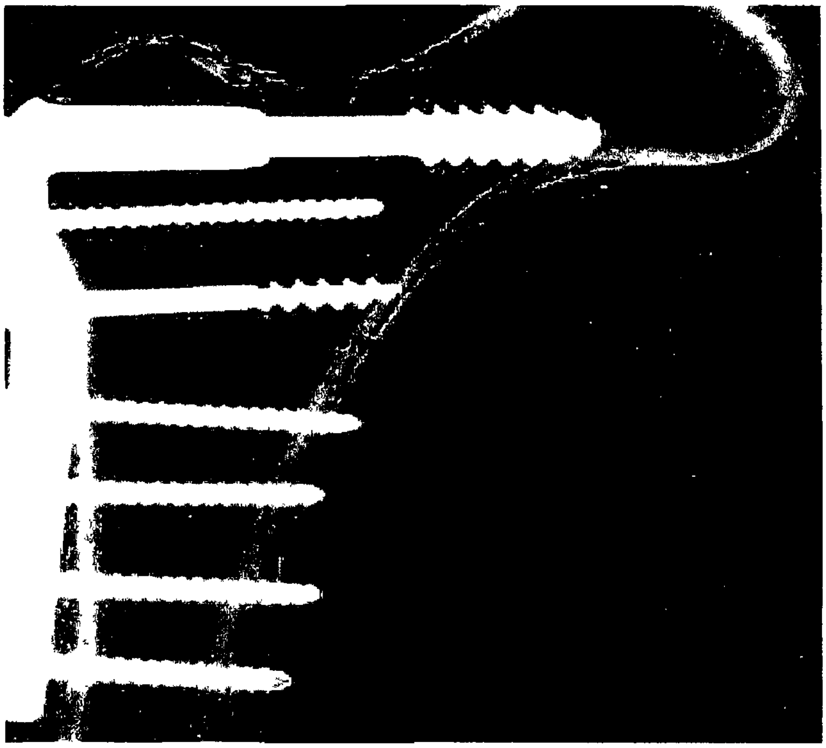


Figure 8.15 X-ray showing a DCS plate used to repair a fractured proximal femur

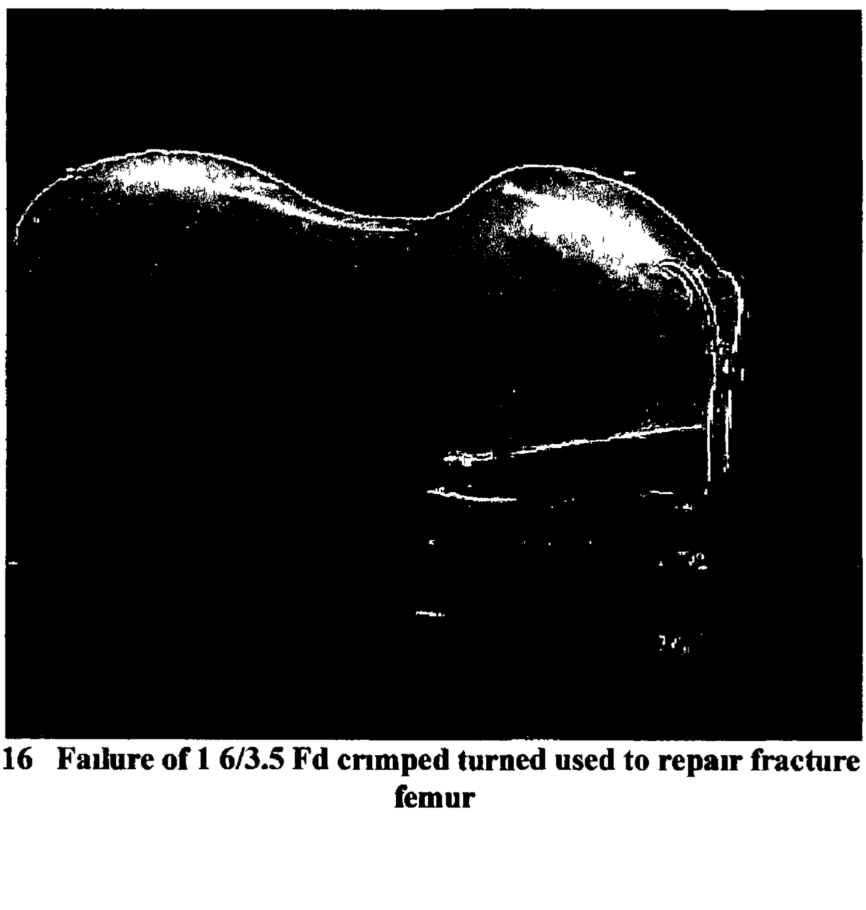
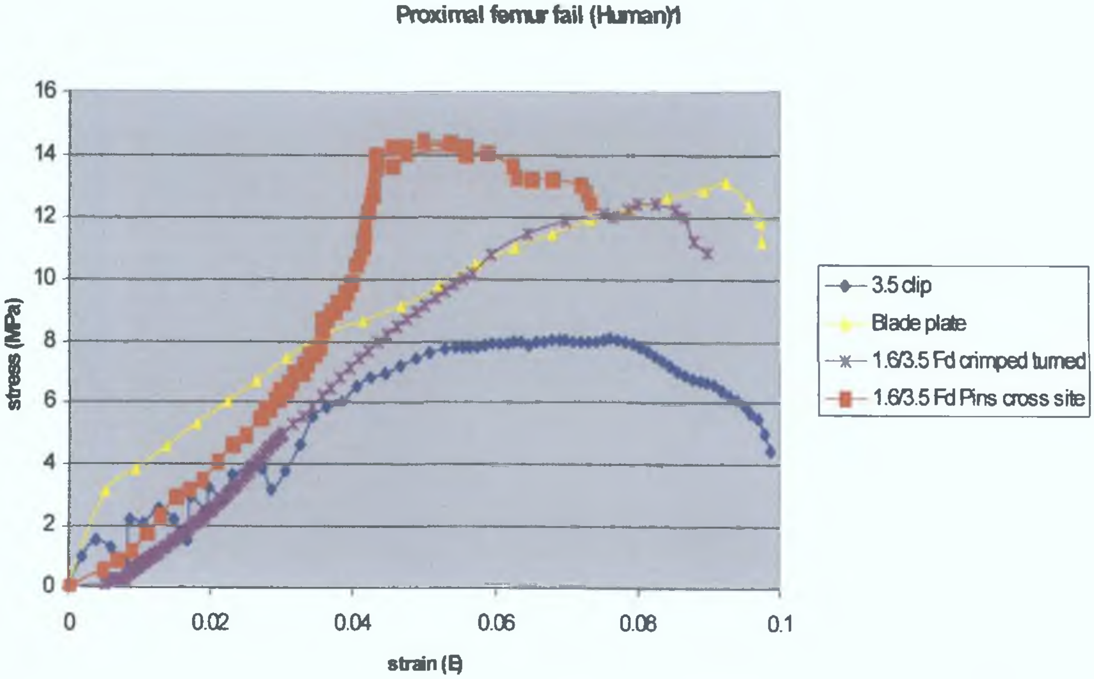


Figure 8 16 Failure of 1 6/3.5 Fd crimped turned used to repair fracture proximal femur

Figure 8.19 Failure point bifurcated blade plate



Graph 8.2 Comparative graph showing the greater ultimate strength 1.6/3.5pins across fracture site formation

Figure 8.17 Failure point 1.6/3.5 Fd 2 pins across fracture site used in repair of proximal femur

Figure 8.18 Failure point 1.6/3.5 Fd crimped and turned

Static compression loading to failure of the proximal femur using a load sharing subtrochanteric fracture involves two groups of data The first is presented in graph 8 2 and indicates that the 1 6/3 3Fd pins across site (Fig 8 14, 8 17) achieves the highest ultimate yield when compared to the other fastenerod formation (Figs 8 11, 12, 16, 18), clip and bifurcated blade plate The option of being able to deliberately drive pins across the fracture site and then anchor them to the fastenerods increases stiffness and strength by up to 14% compared to just crimping and bending the pins The blade plate in comparison to the crimped and pins bent fastenerod formation ends up being very similar for static loading to failure

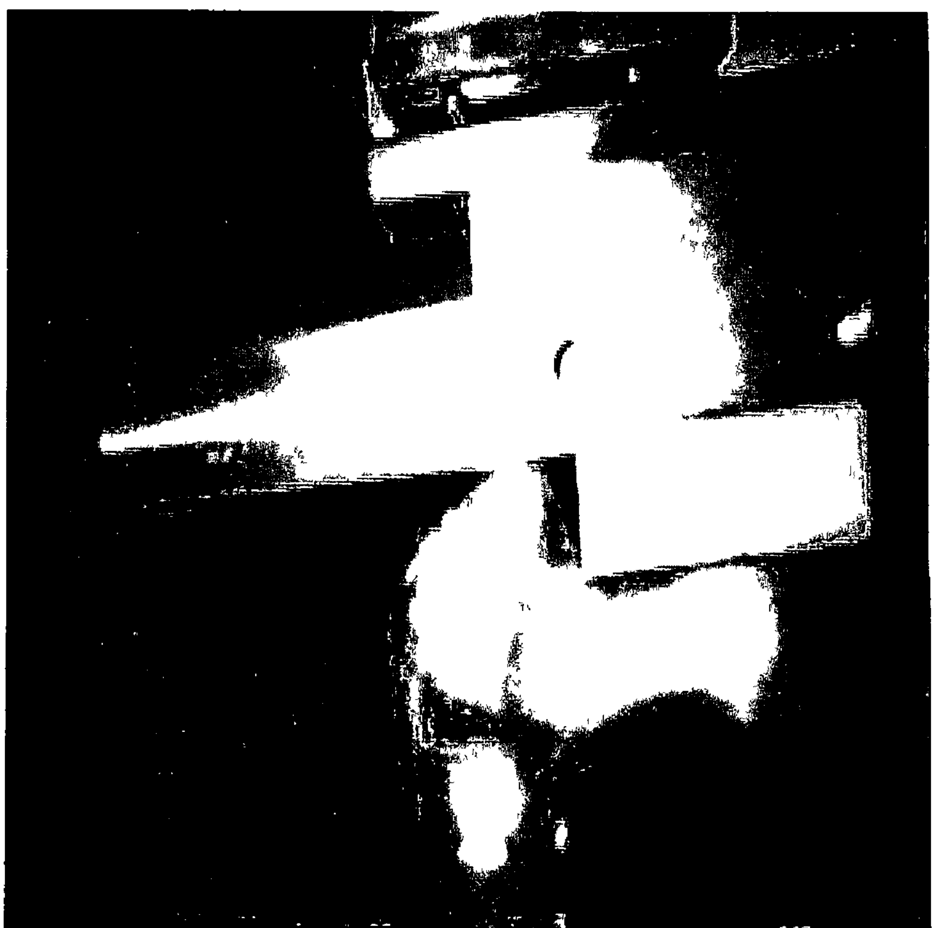
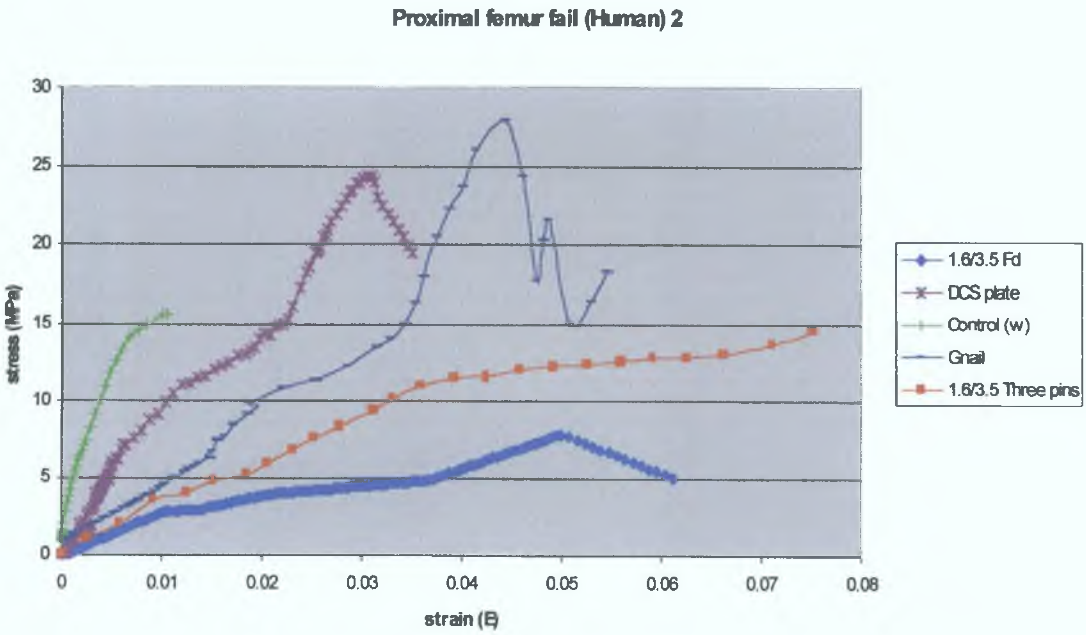


Figure 8.20Failure point in jig of DCS plate subjected to compression loading

Figure 8.21 Failure 4 pin 1.6/3.5 Fd



Graph 8.3 Comparative graph showing the greater ultimate strength and stiffness of the DCS plate and Gamma interlocking nail

The second set of data from the static compressive loading of the subtrochanteric femoral fracture must be considered with the data from graph 8 2 The weakened control is stiffer than the big implants such as the DCS plate (Fig 8 15 and 8 20) and the G nail (fig 8 130but the ultimate yield values for these two massive implants is huge in comparison to all the other implants used to repair this fracture These implants are designed ready to walk on and will support full weight bearing immediately Even with three pins driven across the fracture site the ultimate yield value is virtually half that of the DCS plate and G nail

8 3 3 Static Compression Non Load Sharing to Failure Tests of the Proximal Femur

In this set of tests a gap was left in the proximal fracture to analyse the effect of having no bone loading The implants used in this group were DCS, 4/4 5 Fd and 4 pin 1 6/3 5 Fd (Fig 8 21)

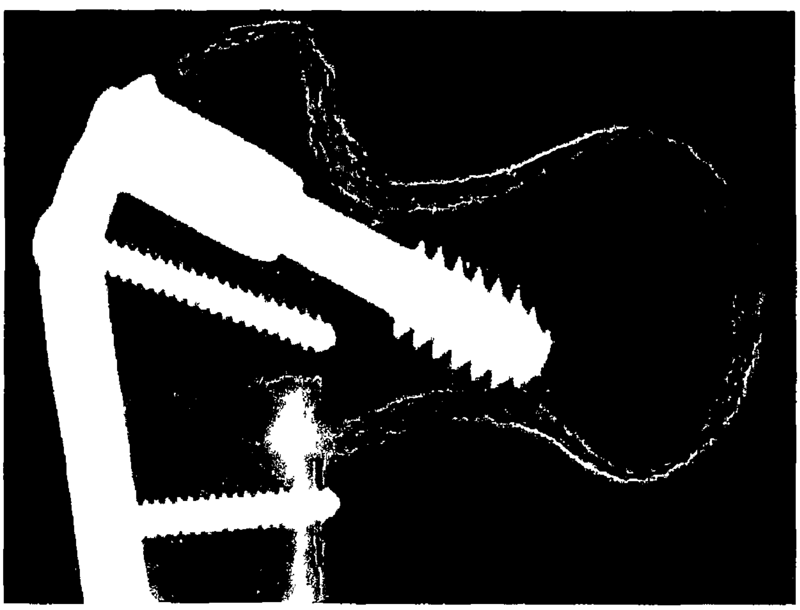


Figure 8.22 Failure point of DCS plate

Figure 8 23 Close up DCS plate at failure point

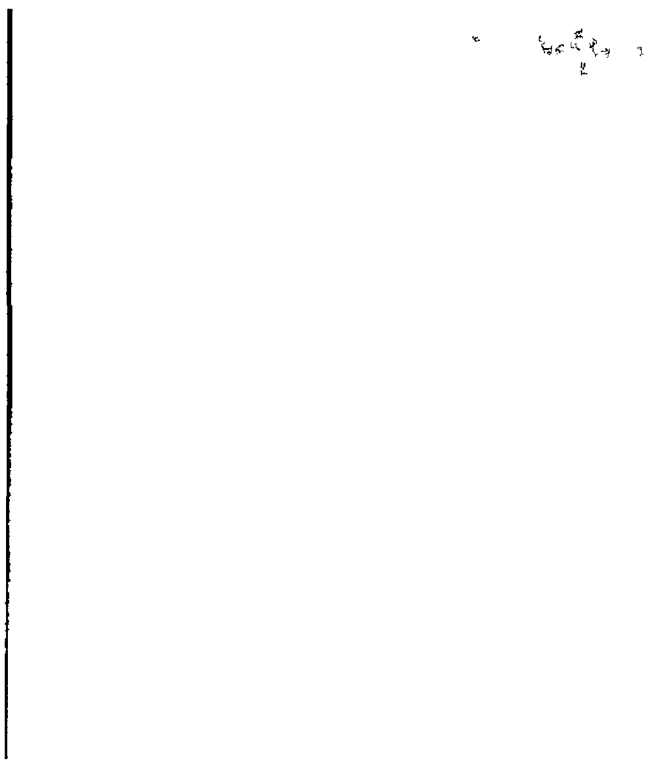


Figure 8 24 Four pins 1 6/2 7 with no calcar support and hence no bone load sharing

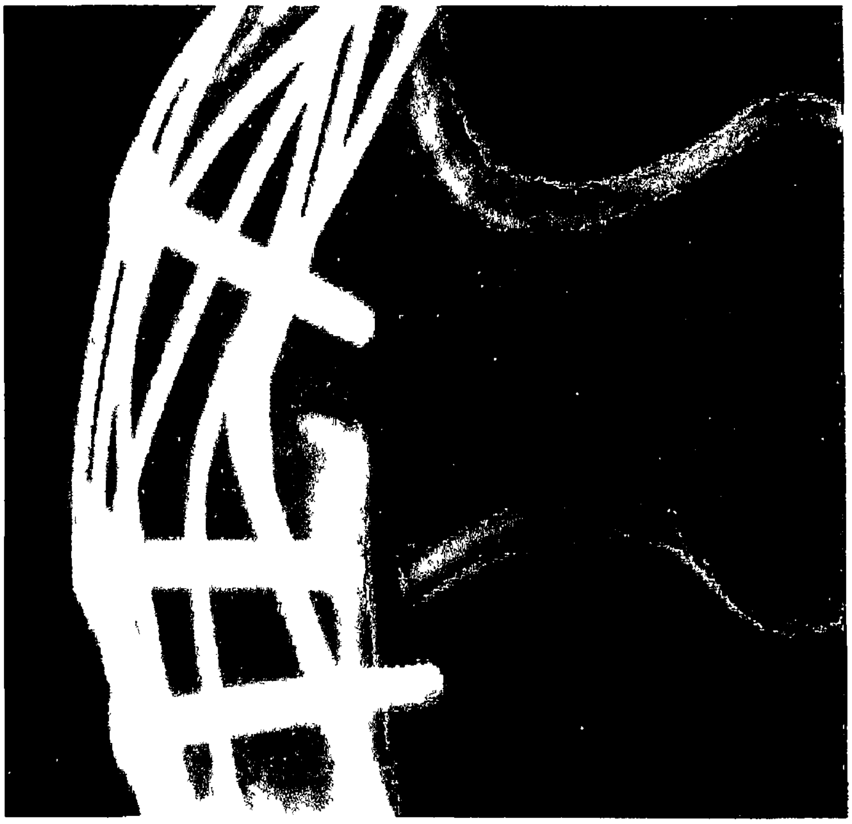


Figure 8 25 X Ray of failure point of 4 pin 1.6/3 5 Fd

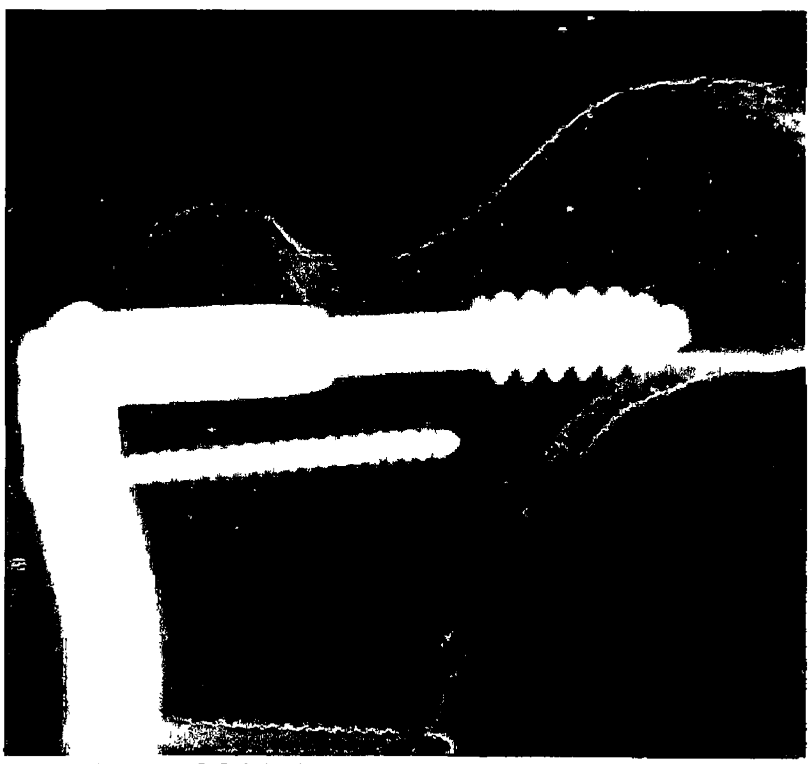


Figure 8.26 DCS plate calcar support missing

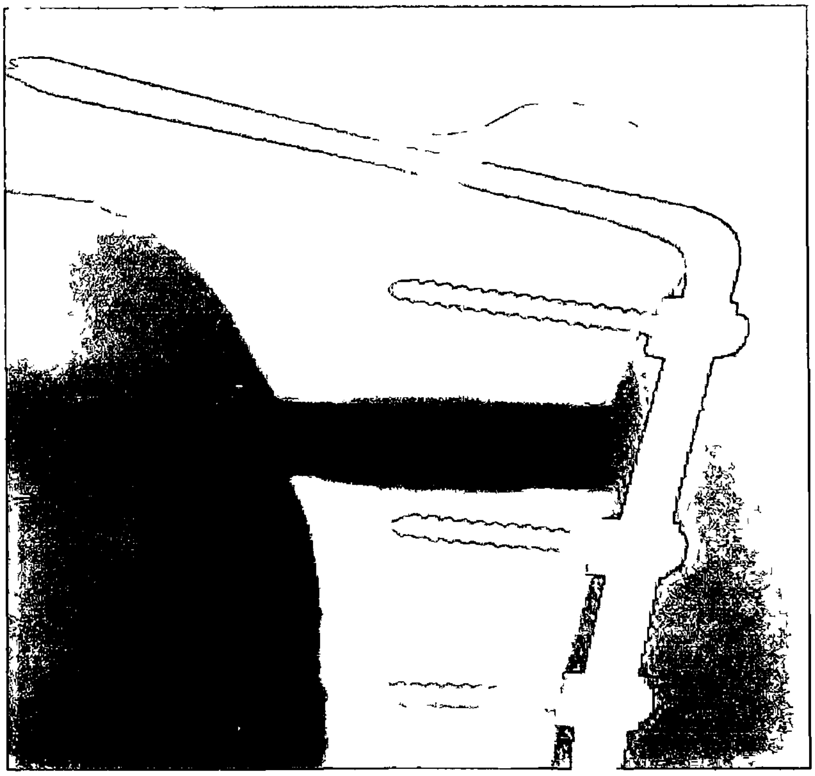
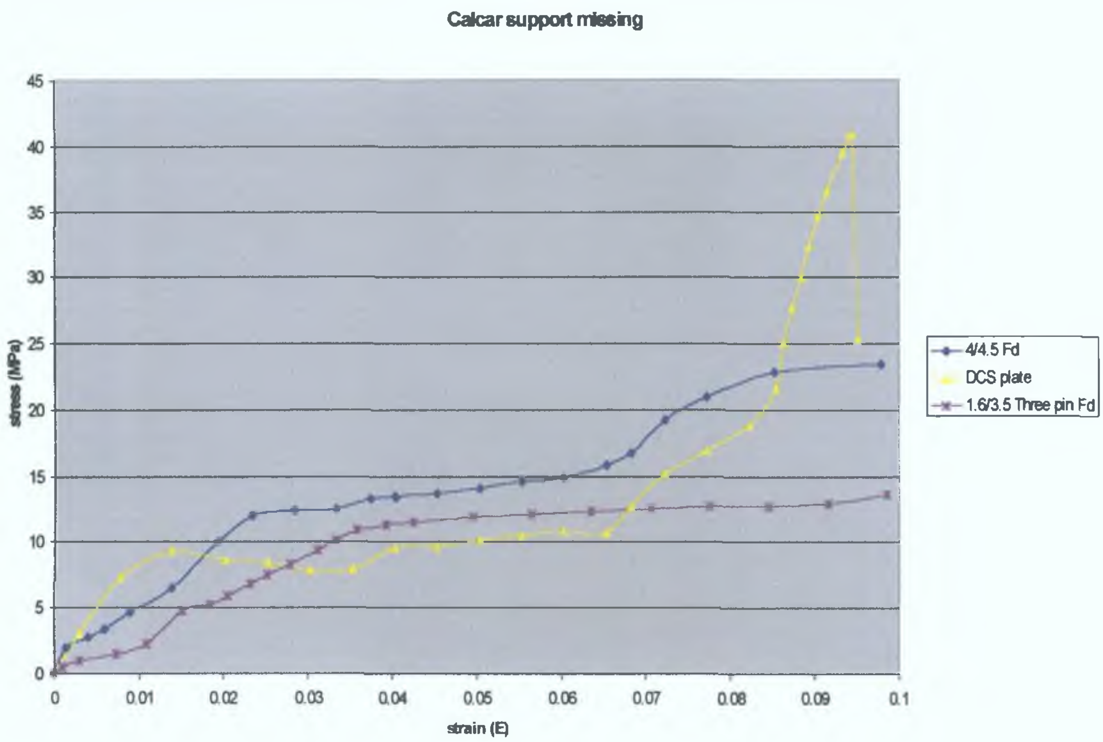


Figure 8.27 4/4 5 Fd calcar support missing

Figure 8.28 Failure point 4/4.5 Fd



Graph 8.4 When the medial aspect of the femur is missing the DCS plate is far

Not all fractures of the promimal femur are load sharing and communition (fragmentation) is a common feature of fractures at this site. Loss of a buttress, especially on the medial aspect, leaves the implant alone to hold the bone fragments together. A different type of implant or approach is needed to prevent castatrophic fracture collapse. The laboratory simulation of this non load sharing fracture is achieved by leaving a gap between the fracture fragments. The slow closing of the fracture gap during loading created a somewhat unusual stress strain curve, compared to previous tests, in that there was a significant level of displacement before ultimate yield was reached. A four pin 1.6/3.5Fd (Fig 8.24-8.25) and a 4/4.5Fd formation (Fig 8.27-8.28) were significantly weaker than the DCS plate (Fig 8.22;.23,.26) indicating that loss of any load sharing buttress requires the strongest implant to be sure of maximum support (Graph 8.4).

8 3 4 Static Bending to Failure Tests on Mid Shaft Femur

This group of tests used four point bending as opposed to axial compression and, to avoid bone loading, a gap was kept in the repaired samples

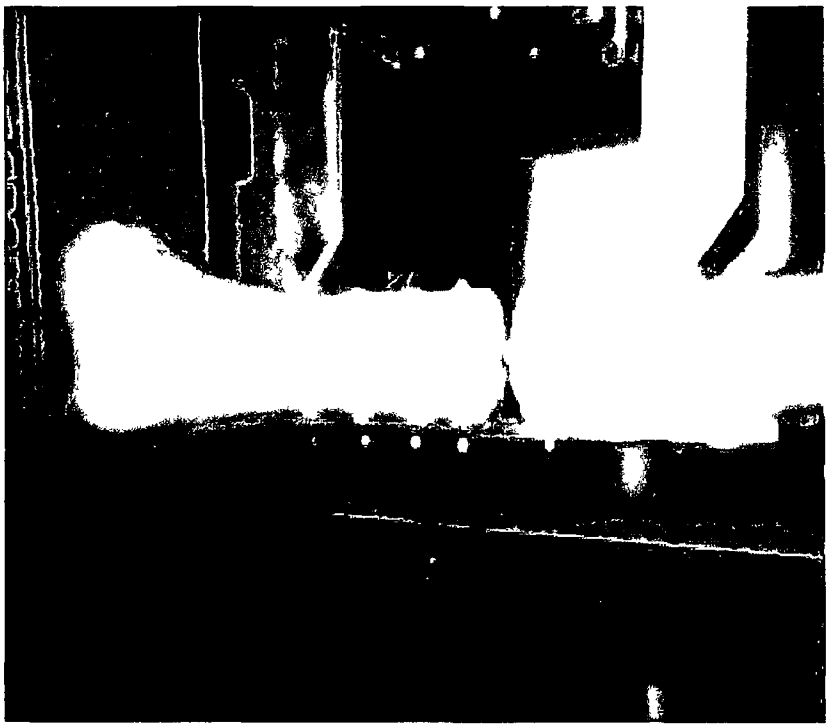


Figure 8.29 Human mechanical femur ready for a four point bending test

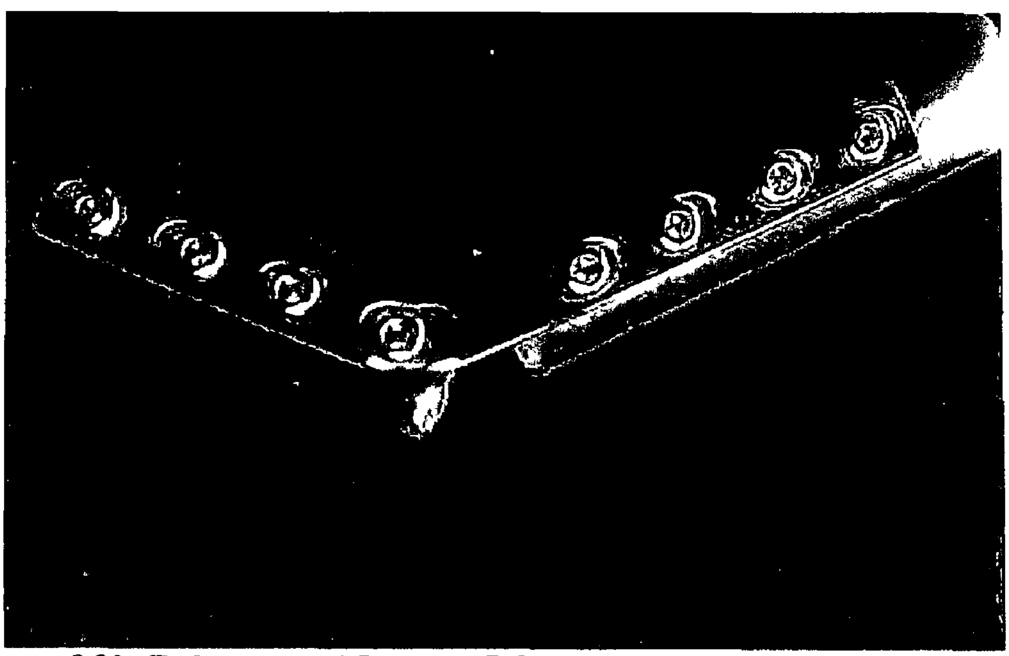


Figure 8.30 Failure point 4.5 narrow DCP showing plate fracture at screw hole (stress raiser) side four point bending

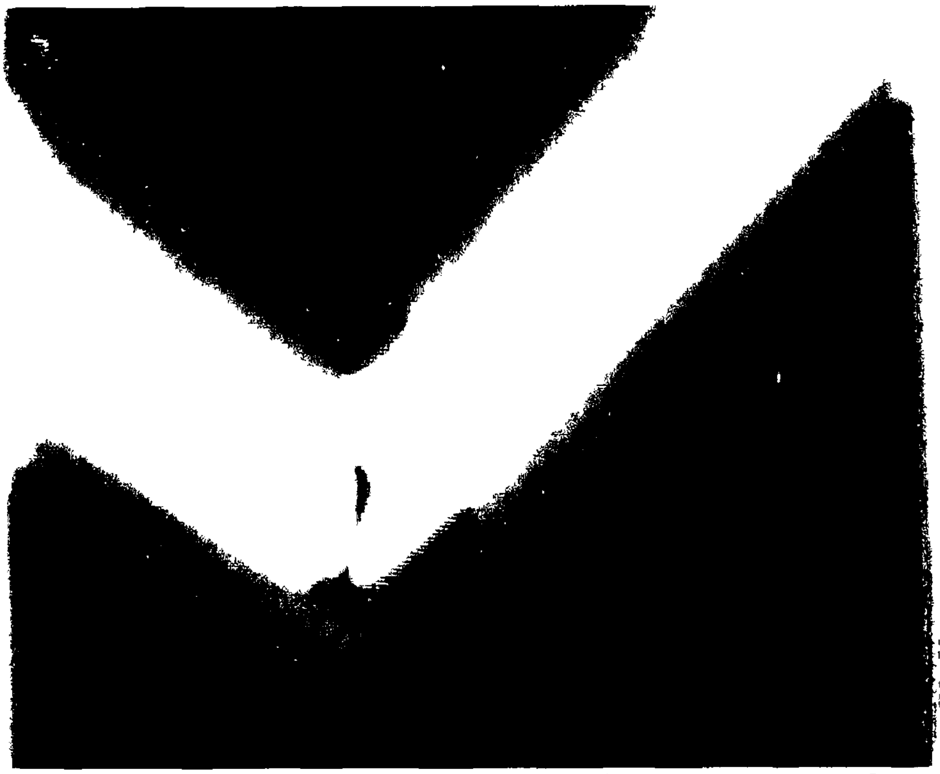


Figure 8.31 X Ray 4.5 narrow DCP showing fracture at screw hole side four point bending

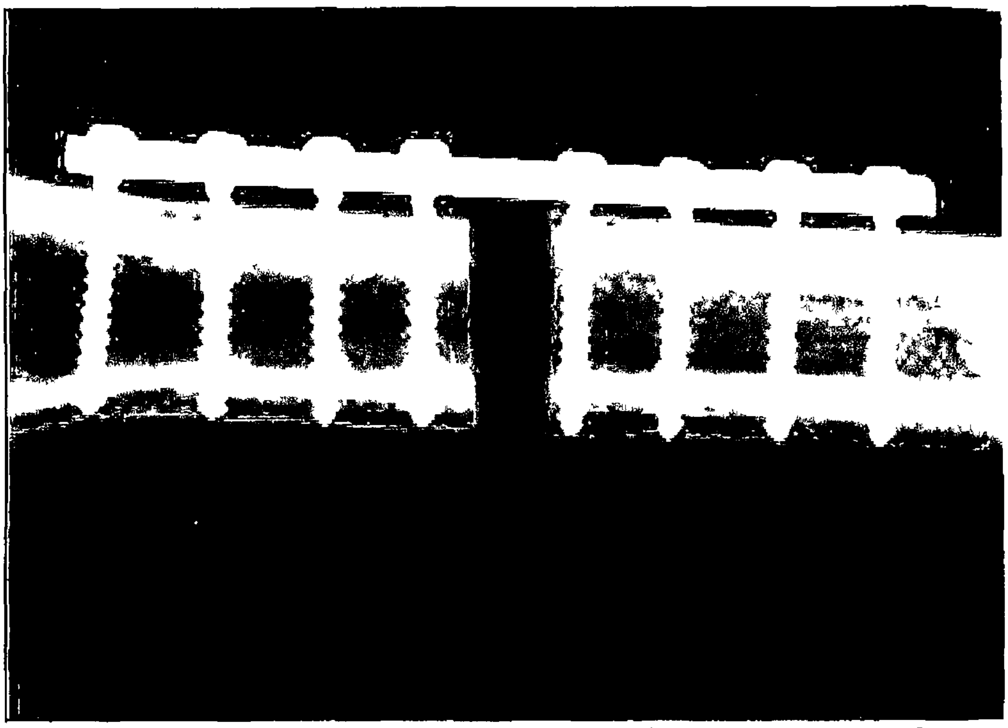


Figure 8.32 4.5 narrow DCP used to repair a fractured mid shaft femur

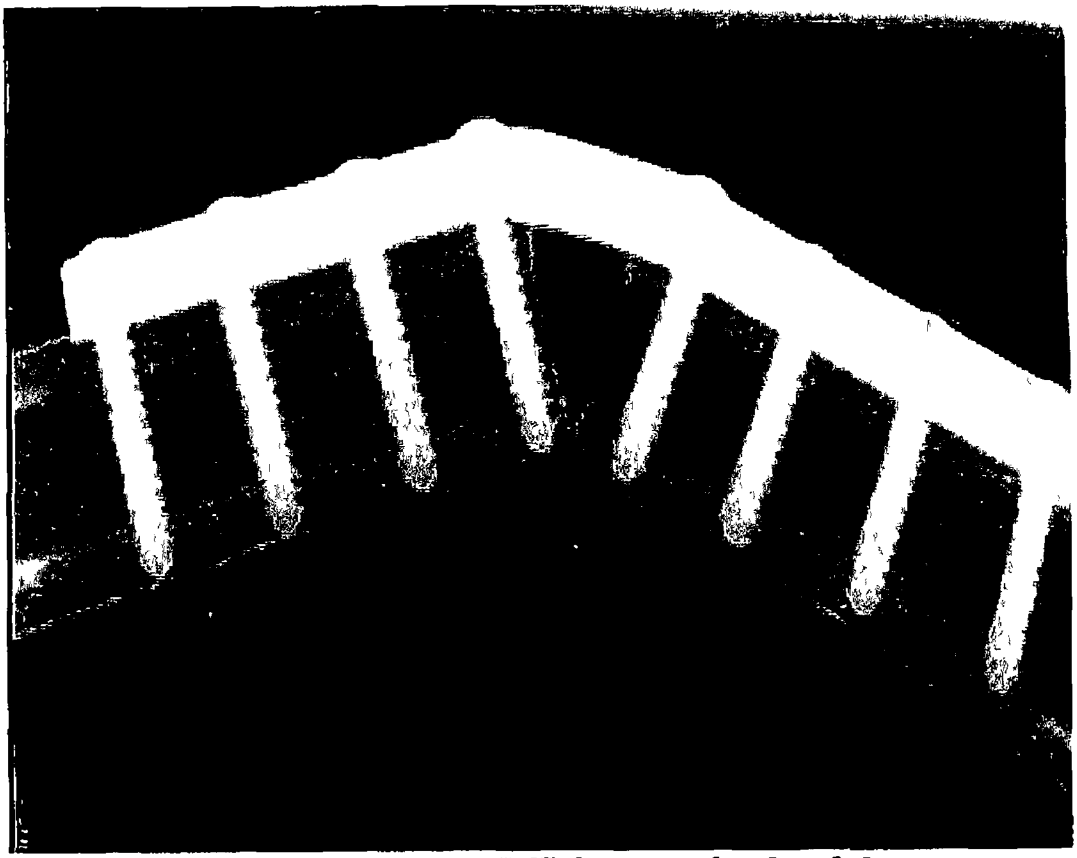


Figure 8.33 4.5 narrow DCP four point bending failure

Figure 8.34 4/4.5 Fd human midshaft femur

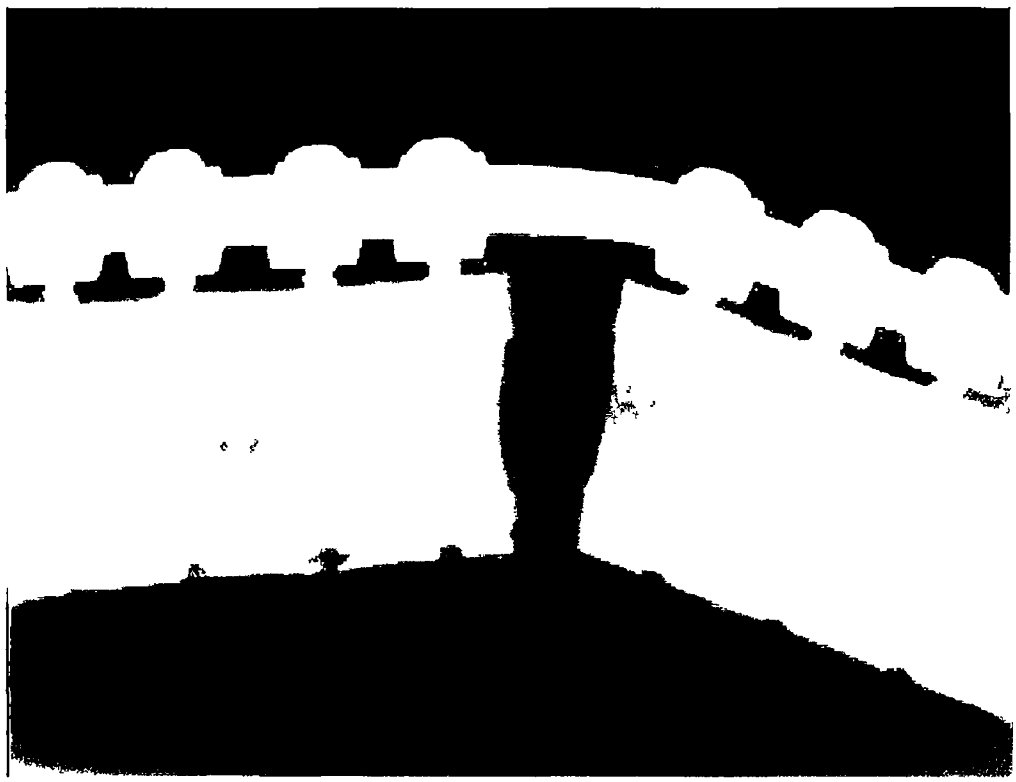


Figure 8.35 Failure 4/4.5 Fd during four point bending of a mid shaft human femur

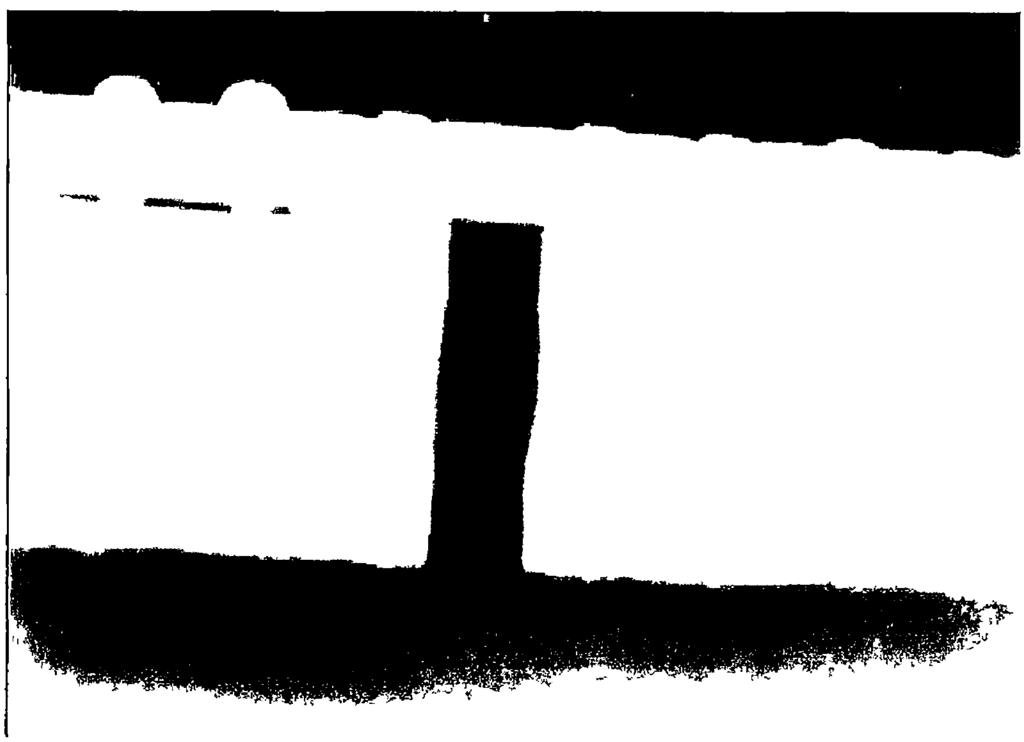


Figure 8.36 4.5 broad DCP used to repair a fractured mid shaft femur

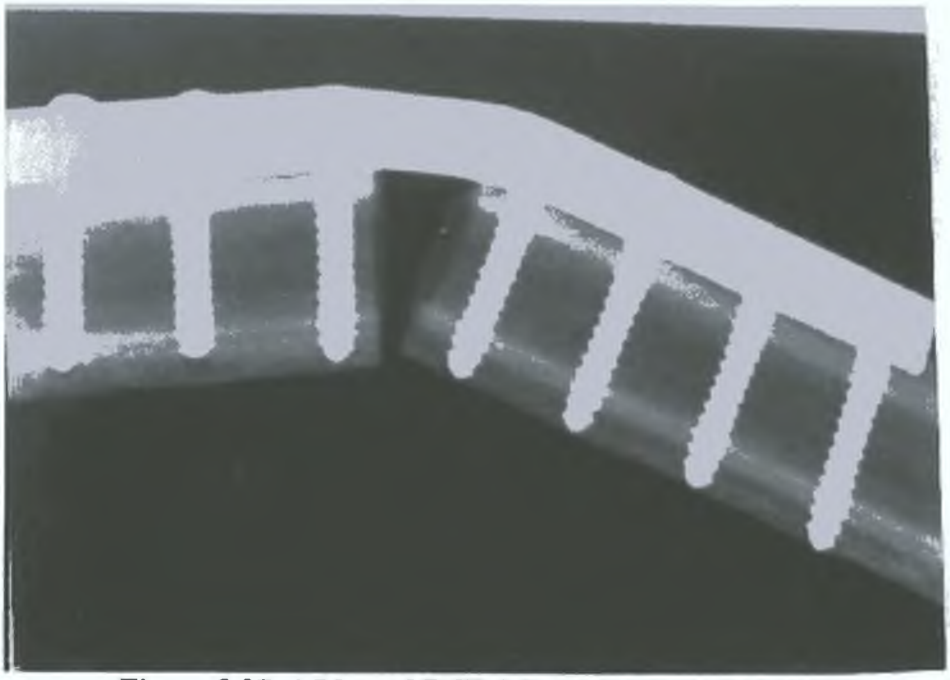
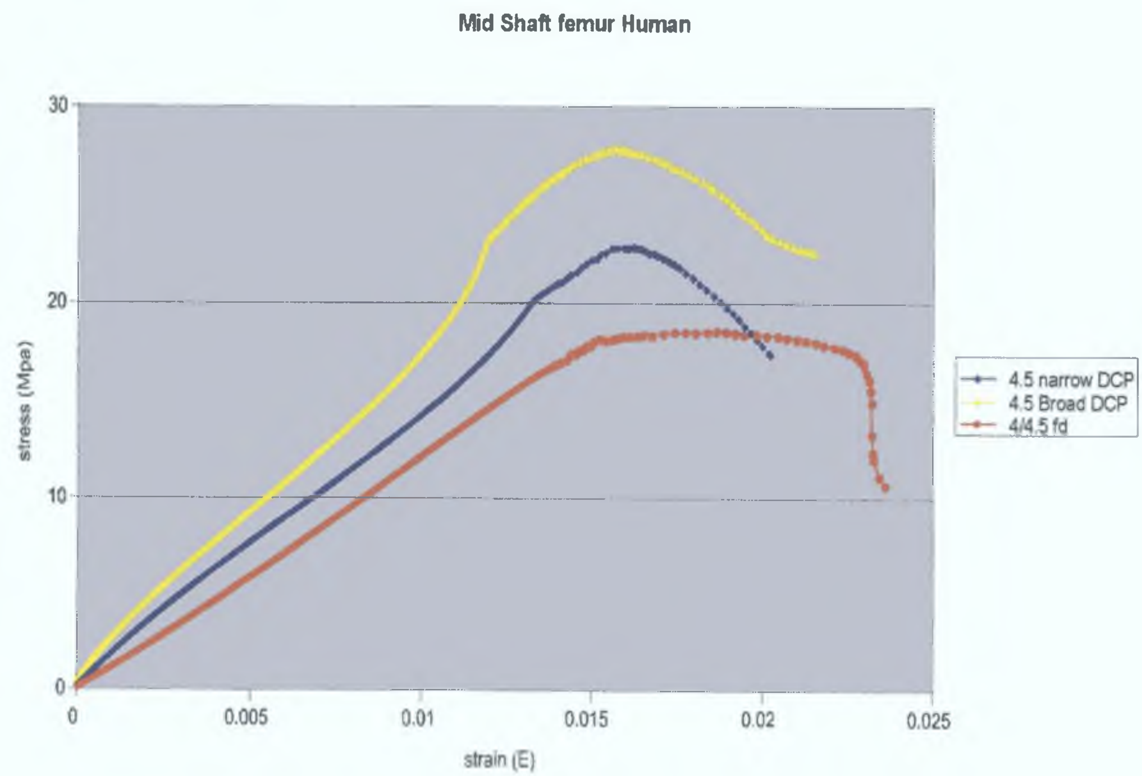


Figure 8.37 4.5 broad DCP failure four point bending



Graph 8.5 Results of bending tests of human femur using the three different implants

Static four point bending of a mid shaft femur (Fig 8 29) in two planes produced data that showed the greater strength and stiffness of the 4 5 DCP system (Graph 8 5) However, the results also showed the two features of the plate system that explain some of its weakness as compared to the fastenerod system (Fig 8 32-8 37) Firstly, there is the weakness and stress raiser of the screw hole (Fig 8 30-8 31), which is not present in the fastenerod system Secondly, there is the fracturing of the implant when the rigidity of the plate is so great that the weaker of the two between the bone and the plate fails

Cycling loading evaluation using the extentiometer revealed that the Fastenerod and 3 5 clip allowed more movement at the fracture site but that the 1 6/3 5 crimped and turned implant was quite efficient at absorbing energy during loading The control was stiffer than the rest and thus had a higher modulus of elasticity

Static failure of the subtrochanteric fractures revealed that the order of strength was DCS, G nail , blade plate, 1 6/3 5 Fd crimped turned, 1 6/3 5 Fd,3 5 clip The non load sharing subtrochanteric fractures indicated that the order of strength was DCS, 4/4 5Fd, 1 6/3 5four pin Fd Mid shaft femoral fractures revealed similar results with the 4 5DCP, 4/4 5 Fd

8 4 **Discussion**

The series of experiments, conducted on the human mechanical femur, were chosen to provide data across a wide enough area to be of use in making recommendations for specific fractures and in general The extentiometer was used to detect movement and hence strain at the lateral aspect of the proximal femur. Because the load on the femur is eccentrically located, the net result of the forces is compression medially and tension laterally (Fig 8.38).

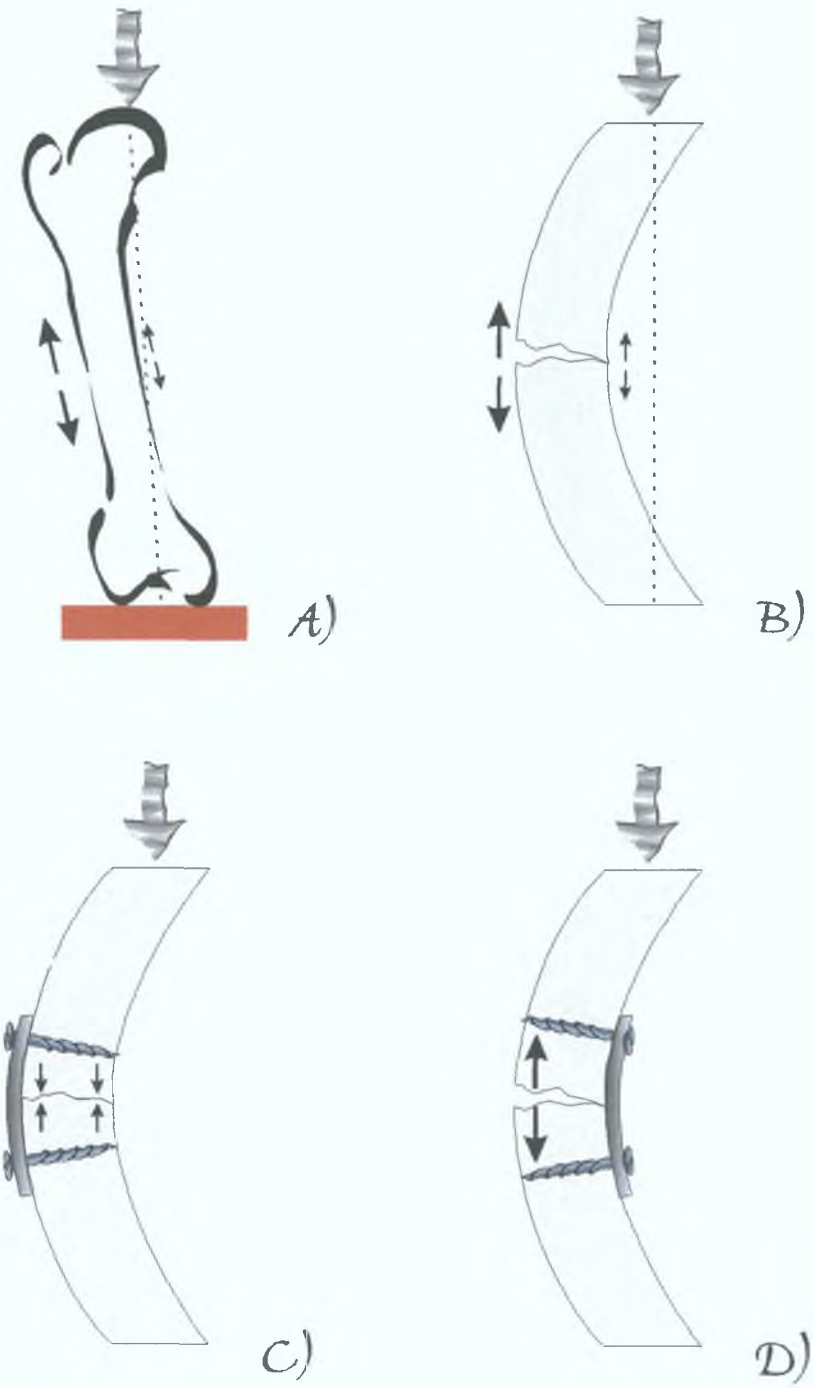


Figure 8.38 Bending forces acting on the femur create different forces along the whole femur

Measuring the changes to the lateral tensile side is easier and more useful than the medial compression side. Having the faces of the fracture surfaces directly apposed meant that the full lever action of the proximal femur would be present (Fig 8.39). The modulus of elasticity for each implant indicated the stiffness, but none of the implants reached the stiffness level of the control even though some of the implants exceeded the ultimate strength of the control. The area under the stress strain curve is a measure of the total energy absorbed by the implant during loading. The 1.6/3.5 Fd crimped and turned absorbed a significant amount of energy even though it was much less stiff than the DCS plate, for example. This reflects the fact that the formation had a lower modulus of elasticity but allowed more movement at the fracture site than the DCS which had a higher modulus of elasticity and allowed very little movement. It's spring like tensile action allowed for greater movement with each cycle of loading.

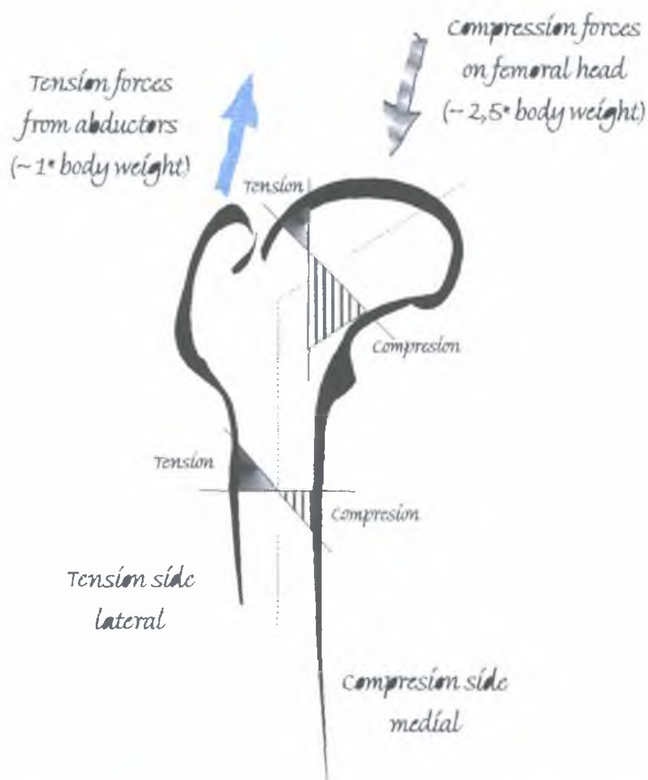


Figure 8.39 Diagram showing the forces acting on a proximal femur

In the experiments dealing with static failure, the bigger implants (DCS,IN) proved significantly stronger This was especially true when there was no load sharing of the fracture site, i e when there was a gap present The mid shaft femur fractures were non load sharing and demonstrated that the DCP system was stiffer and stronger However, the failure mode was interesting in that the bone or the plate fractured at failure whereas with the fastenerod the implant just deformed This is a feature seen with previous experiments using the wooden dowels This mode of failure is a positive result as ultimate failure ending in deformation does not necessarily imply unsuccessful fracture repair whereas plate or bone fracturing does

8.5 Summary

The fastenerod demonstrated positive aspects of its flexibility in the face of the overwhelming superior strength and stiffness of the large implants (DCS plate), with higher energy absorption than expected and static strength not too far behind the 4 5 DCP systems There was no evidence of the weakening effect of stress concentration with the fastenerod, leading to implant failure, which was found with the 4 5 DCP

Chapter 9

Discussion

9.1 Introduction

The idea to use pins and screws to offer an alternative to the standard methods of repair such as the DCP seemed radical at the beginning of the thesis As the proof process of optimization of design, manufacture and finally testing crept along the realization become apparent in the distance of a conclusion not expected The bulk of the materials used in the combination were standard for any orthopaedic operating stock Using screws and pins that are reliable under real operating conditions minimises the concern over the proposed change of use However the general principle of clamping a pin to bone via a screw cannot be considered to be bizarre perhaps radical but its lack of general acceptance by orthopaedic surgeons would be founded on a lack of faith Without some hard data to work with who would possibly risk failure and all that the ensuing litigation would bring So it is easier to stick to what is proven through many years of trials even though there are inherent difficulties

Such a change within the industry will never come around quickly and it is only relatively recently that surgeons are demanding scientific laboratory mechanical data to back up claims made for implants to the point were even established implants are being sent back to the laboratory for analysis In comparison to the drugs industry the implant industry gets away very lightly There is no formalised system for the approval of a new technique in surgery whereas a new drug acceptance is hampered by extensive analysis before clinical trials begin So the implant industry in a way meanders naturally to find the best route to achieve its goal An established widely accepted formalised method of analysing a new implant system can only proceed as has been set out here in this thesis, which although painstaking would not be as difficult as the drugs industry route of approval

9.2 Optimisation of Design

There are as many ways that a screw could clamp a pin on a bone Most of those design possibilities were analyzed here The initial laboratory testing involving repeated loading to failure while useful was too costly and time consuming to work through all designs The two salient features of convex underneath and closed over top were enough to proceed to finite element analysis Eight different designs were then tested using FEA The time and money saved by using FEA was enormous Conclusive proof of which design was the best in strength and in profile was achieved quite rapidly Although the banana shape was the strongest in profile was too high to justify its use in small patients The banana profile was very difficult to manufacture in very small sizes and there was no crimping possible So the design below the banana in strength was chosen because it could be made in any size relatively easily and it could be crimped for extra pin grip

Optimisation of a shape to meet its requirements perfectly may not be completely possible Unfortunately when dealing with the concepts of fracture stabilisation the requirements are usually multifactorial, which simply reflects the complex nature of the injury and all its associations For this reason it becomes incorrect to use the word optimisation in one sense as the end requirement or function maybe too many or to broad So it is necessary to either narrow the requirements, look at multiple designs or not classify the process as optimisation Furthermore to embark on any of the three routes individually could end up being fruitless Narrowing the function is imperative but is tricky because the actual primary function of the implant was at its inception undecided

Clearly the chosen route in this thesis was to search for the optimum design that resists pin migration for relevant sizes whilst keeping all of the other non-osseous tissues normal The pin migration came in two forms, being either pure tensile or bending on a convex or flat object and luckily the same design was able to resist both better than the rest However the choice of the shapes that were subjected to testing was limited by ultimately the narrowness of the designer The shapes were contrived from the experiences of the designer and what exposure to relevant shapes, mechanics and orthopaedics he has received So in another way the optimisation process is actually biased before it begins, because there may be other shapes not considered Unfortunately there would appear at this stage of technology to be no other way to search and find a new design other than the way proceeded here when dealing with such complex multifactorial issues

9.3 Bone Properties, Behaviour and Fracture

Every bone type is unique in shape because the geometric configuration is determined by the forces they must resist and the direction of that force To take this concept even further every individual bone even if it is the same type of bone, such as a femur for instance, is different between individuals of the same species due to the different forces acting on the bone The differences in the latter case would most likely be microscopic as the general or gross shape of every bone type is similar But the age, weight, gait, health, activity, diet and muscle mass determine the absolute microcopic and macroscopic geometry of the bone Bone is subjected to forces from the outside but also from other adjacent bones and muscle attachments Each one of this forces can deform a bone to the point of fracture, the magnitule of the force being critically dependant on the properties of the bone which in turn is dependant on a whole host of factor some of which are mentioned above

Exceeding the ultimate yield of a bone will result in fracture which in most cases would be unique No two fractures of the mid shaft of a femur could ever be identical as the loads that produce the fracture are extremely unlikely to be exactly repeatable in the natural situation Complex loading occurs with the combination of bending, torsion, compression and tension all possible at the same time Add to this the sort of material properties of bone such as the femur that is less than half the strength in transverse tensile than in longitudinal tensile loadmg and less than one third the ultimate yield m shear loading than m compressive loading then the overall picture looks complex to say the least

A single traumatic episode that leads to bone fracture is not as common as smaller repetitive loadmg that leads to microfracture The microfracture may itself lead onto a complete fracture either by further repetitive loadmg or by a smaller single load that overloads the weakened bone The forces required to cause failure under repetitive loading are usually much lower than the forces that cause fracture in a single event Stress strain analysis of bone subjected to cyclic loading reveal that the bone is more fatigue sensitive to the strain magnitude as opposed to the stress magnitude Cycle loading and the bone response to it are critical to fracture repair and it is interesting to note that the strain is more important than the stress

Bone density is often considered in relation to all aspects of bone biology In the case of fractures the two areas of interest are the type of bone and the age factor Cancellous bone is the type at the joint ends of a long bone and is naturally strong with regard to compressive forces as the joints transfer the loads along the limb Its extensive honeycomb structure absorbs the energy passed from the joints However cancellous bone density can vary considerably between individuals and this changes its properties considerably Its stress strain curve in compression compared to cortical bone resembles quite closely the general stress strain curve of the fastenered system indicating that the two are possibly more compatible However the stress strain curve of cancellous bone in tensile loading is completely different and cancellous bone is quite weak under tension After 40 yrs of age the bone mass declines with decreasing cancellous bone density and increased porosity with concomitant reduction in the thickness of cortical bone

Consequently, the bone is stiffer but due to less energy absorbing capacity the amplitude of strain required for failure is less Increased collagen cross linking increases brittleness and decreasing energy absorption capacity Finally increasing porosity or decrease in density leads to a decline in bone strength and stiffness The ultimate strength of bone is approximately proportional to the square of the apparent density whilst the elastic modulus is approximately proportional to the cube of the apparent density

The diaphyseal portion of a bone is made up of cortical bone which is a tubular structure filled with haemapoietic tissue This central portion of a long bone is different to the ends or the metaphyseal portion and this tubular structure enables it to withstand higher bending and torsional forces A higher movement of inertia in bending and torsion are important for the tubular central portion as healing of the fractured tubular diaphysis is better able to stabilise by creating a thicker tubular structure with a higher moment of inertia

9.4 Molecular Mechanics and Bone

Bone healing is usually divided into primary and secondary healing Primary healing is only achieved in situation were there is absolute rigid stabilisation, bone contact, no bone destruction and inter fragmentary strain less than 2% However primary bone healing is unlikely to occur when using the fastenerod system except possibly in cases were compression can be achieved such as avulsion fractures So secondary bone healing is the main consideration for the fastenerod system Secondary bone healing is desirable as it reaches clinical union quicker than primary bone healing and results in a stronger repair In considering bone healing it is important to deal with the molecular level of healing especially as the fastenerod system is a flexible form of fixation

Once the fracture occurs the initial haematoma that fills the space serves as a scaffold and possibly provide some new cells for repair by recruitment of white blood cells leukocytes Within even a few days the haematoma transforms into granulation tissue which has fibroblasts, mononuclear cells and embryonic blood vessels The proposed mechanical properties of this callus of granulation tissue is a very low modulus of elasticity of 0 05 nm/mm^2 and can elongate to double its length with a tensile failure of 0 1 nm/mm^2 The next stage involves an increase in stiffness due to deposition of collagen fibres which increases the modulus of elasticity initially to 16 7 nm/mm^2 and ultimate tensile strength of 5-17 nm/mm^2

Interestingly within the callus itself increased fibrous tissue is found in areas subjected to higher tensile forces whilst cartilage is more common in areas under compression Further consolidation of callus changes the connective tissue to fibrocartilage, which has similar stiffness and ultimate yield values The fibrocartilage becomes mineralized and turns into cancellous bone, which in turn changes into cortical bone in a gradual process of stiffening In comparison to the initial mechanical properties of the granulation tissue the cortical bone has an elastic modulus of 10,000 nm/mm^2 and a cut off point of 2% elongation before failure The point of this in relation to a flexible form of fixation in particular is that at each stage the tissue present will only withstand a certain levels of loading and in particular elongation to survive If there is too great a movement at the fracture site the progression of healing will not occur and a non-union will result Less deformation or elongation at a cellular level is favourable to fracture healing when appropriate for each stage So only granulation tissue can survive at high movement periods but the strain is controlled by creating a greater diameter through increased mass of tissue and by resorption of bone ends leading to increased fracture gap Increasing the size of tubular structure and the gap at the fracture site progressively decreases the molecular strain on the cells at the fracture site Less deformation of the cells encourages the replacement of fibroblasts by fibrocartilage and hence osteoblasts Only once the deformation at the fracture site is less than 2% can bone cells exist

Deciding how much flexibility is permissible is difficult as movement or angulation of a fractured bone by 40 degrees will only allow granulation tissue to exist, whereas fibrocartilage will exist at angulations 5 degrees and bone at 0 7 degrees But at the end of the day excessive motion can prevent healing but for healing to occur there needs to be loading and motion Accurately calculating the amount, rate and degree of loading for each individual case is presently not possible and is only achieved currently in clinical settings by using flexible implants in conjunction with clinical and radiographic monitoring

9.5 Bone Response to Fracture Fixation

Repair of a fracture by implantation of a metallic device creates a new situation for the bone cells apart from having a fracture fixed In the new situation the bone must share roles in a sense with the foreign object, because it must retain some of its function even if it is not able to do this to 100 per cent of its normal capacity The response that the bone elicits will determine the final outcome, not the brilliance of the metallic implant For long term success the bone must respond appropriately because the metal will fatigue with repetitive loading or break out of the very bone that houses it This response or adaptation is determined by many factors and in some cases the factors of importance maybe still unknown

When a normal bone with average density is fractured and subsequently repaired with an internal fixation device the bone initially has to recover not just from the injury but also from the trauma of the surgery Significant weakening and even extensive destruction of bone can occur when screw holes are drilled and medullary cavities are reamed out prior to blood for example an interlocking nail Furthermore the damage to the blood supply to the bone, bone fragments and surrounding tissues can be profound and long lasting following extensive dissection required for implantation of devices especially large plates and nails Even the insertion of a relatively small implant the bone screw creates an acute period of considerable ischaemia for 30 minutes after screw insertion This segmental ischaemic response caused by screw insertion is marked and indicates that if such relatively small implants cause such damage what must be the effect of the very large nails and plates

Survival of sufficient healthy tissue (bone and soft tissue) and blood vessels ensures the situation at this point is still salvageable But next the bone experiences different loading as the stress redistribution of two objects with different elastic moduli work together as one mechanical system, the bone and the implant Osteopenia is the presence of less bone then is considered normal for a patient of a similar signalement Adaptational osteopenia occurs when the component of the one mechanical system with the lower elastic modulus is smothered by the component with the higher elastic modulus

The ultimate strength of a bone is considerably higher than the threshold for microdamage, which in turn is for higher than the bone-modeling threshold An increase in strength and mass of a bone is due to modeling drifts when forces exceed the modeling threshold and is the bones response loading On the other had a decrease in strength and mass of the bone is by remodeling, which is resorption of areas of bone So, in simple terms modeling by drifts and remodeling are at opposite ends of the spectrum of a bones response to strains So the modeling threshold is way below the microdamage threshold and the remodeling threshold is below the modeling threshold But importantly in between the modeling threshold and the remodeling threshold there is the adapted window, which in strain terms is the spot were bone cell is ideally suited for normal events When the influences of the implant on the strains in the bone are considered the strains of any load sharing bone must be no were near the microdamage threshold nor below the remodeling threshold because being at these levels would lead to failure and bone resorption respectively But the presence of bone modeling and remodeling during callus healing is important as the callus develops Remodeling replaces areas of lamellar bone in accordance with the bigger strains and modeling modifies the callus to make the bone strong enough to withstand the loads But without strain the disuse mode remodeling removes any callus, which would lead to a nonunion Equally strains that approach the microdamage threshold will prevent healing also The strains that lie in the adapted window and higher than the modeling threshold are the target areas These thresholds can be expressed, as 100 to 1000 microstrain for the adapted window and 1000 to 3000 for overload from the modeling threshold to microdamage threshold, were 25,000 microstrain is fracture An implant that could create this ideal environment of bone strain would avoid the problems created by stress protection or redistribution That implant will not be a huge rigid implant The fastenerod being a flexible implant is in this range and only through clinical analysis can its influence on bone strain be found

There is also a time factor to consider with the response of the bone to fracture and repair The initial phases of remodeling of the callus to lay down lamellar bone is eventually taken over by the modeling, which takes years to modify considering the already formed callus is normally finished at 8-12 weeks The influence of leaving a stiff plate on as opposed to taking it off as soon as possible is that there is significant early remodeling in the latter such that the bone architecture has a chance to normalize where as with the former the bone may never regain its former strength and mass, as the cut off time appears to be as early as 60 days

In light of the previous discussion the situation when an abnormal fracture occurs such as with osteoporosis is even more acute As opposed to adaptational osteopenia osteoporosis is an osteopenia, which leads to a spontaneous fracture during normal activity As the bone already has a reduced strength and mass the microdamage threshold will be lower and using a large rigid implant to repair an osteoporotic fractured femur in an old person would encourage the setting up of the disuse remodeling mode in the bone cells and lead to further loss of bone strength and mass Even though the patient may be able to walk on the limb immediately the long-term situation for the bone is guarded Any implant used in a bone already weakened by osteoporosis needs extremely careful management as the strains the bone must experience should exceed the modeling threshold but remain well below the microdamage threshold to encourage recovery of the bone not just from fracture but to a greater strength and mass

Theoretically this approach would be the best but is not generally practiced in orthopaedic surgery today By and large implanting one of the traditional large devices in the bone is a safe option and is successful But in some patients it is not good science and leads to complications and long-term implications

9.6 Methods of Use of the Fastenerod

Because the system of the Bone fastenerod is open to many variations the exploration of all these parameters was imperitive The strength of the formation is increased by adding extra pins, fastenerods and by crimping Preventing pin migration would be the primary objective in reducing the failure of the formation Implant or bone fracture are not a feature of its failure Slow gradual pin migration to the point of in effect failure is the failure made As many ways as possible were analyzed to find the most effective way to prevent pin migration In the end this centred on the pin itself not the screw or the fastenerod Imbedded the pin ends into the bone resists pin migration and provides 4 extra points of fixation However the application of this type of formation is not easy

With plenty of experience it does become more manageable In cases were extra fixation points are needed then this type of formation would be useful Using stoppers at the ends of the pins proved to be as good as embedding the pins, however it has less points of fixation There is a place for both methods as the method of choice to prevent pin migration Interestingly neither pin fixation nor stoppers change the formation from a flexible system to a rigid one They both just decrease the degree of movement under loading

9.7 Mechanical Comparisons

Having a reliable constant shape of sample to make comparisons between implants is vital given that bone samples are variable in themselves The series of tests to make comparisons between the DCP system and the fastenerod system using the wooden dowels is not subject to as many variations that can happen with the bone samples Removal of such a variable from a system such as the fastenerod were variables are commonplace is very welcome Static loading to failure showed that the DCP system is stronger In the mini section the 2 0 plate was weaker than the 1 1/2 0 fastenerod

What was surprising from those static failure tests was that the fastenerod was not usually very far behind the DCP system Torque testing did highlight the significantly weaker aspect of the fastenerod if the fastenerods are kept far apart from each other However the DCP system always failed long before the fastenerod through sample fracture So possibly the weakness of the fastenerod over the DCP in torque loading is somewhat dampened by its ability to turn through 180° without either implant or sample fracture and this has still some stability The cycling loading fatigue testing really threw up the completely unpredictable results The shear flexibility of the fastenerod allowed it to last longer and reach higher load failure values that the stiffer DCP The exciting aspect of this is that cycling loading is more biological and realistic Although certainly static loading is representative of single large loads depending on the rate, the cyclic loading would represent more what would be happening in the initial places of bone healing and post operative rehabilitation

9.8 Human Fractures

The degree advancement in human fracture repair has meant that very few large avenues of new ideas are left The fastenerod provides a new alternative with extra options such as crimping over other uses of pins and screws The big implants such as DCS plate, gamma interlocking nail and 4 5 Broad DCP are in a different league as regards their strength ,but also they are in a different league as regards their use Comparison between these and the fastenerod would seem unfair or inappropriate However these are the types of competitive implants the fastenerod must be meassured against The actual principle of approach is markedly different between the big implant and the fastenerod Nobody would expect the fastenerod to reach the strength level of these massive implants These massive implants allow patients to walk immediately Although the manufactures claim they are essentially somewhat load sharing their sheer size and stiffness would mean that they have to be largely load bearing So the place of the fastenerod in the face of such implants is to be essentially load sharing and providing appositional support In this way the bone must take a proportion of the load Once this load is not beyond the load limit than the fracture will heal and good callus should form The load sharing benefit of the fastenerod would mean that this is no stress shielding Case selection for use of the fastenerod ın human orthopedıc should be targeted at those cases that need or can tolerate a flexıble load sharıng fixatıon devıce

9.9 Veterınary Fractures

The economıcs of the veterınary fractures mean that the optıons and goals are slıghtly dıfferent to human fracture repaır Perıartıcular fractures would benefit from usıng the fastenerod as compared to the DCP or other plate systems Equally all osteotomıes could be candıdates Dıaphyseal fractures ın certaın cases that have load-sharıng fragments or needed flexıbılıty would also benefit from fastenerod usage The flexıbılıty of use of the fastenerod and the fact that ıt would be cheaper than a plate mean that the fastenerod has a place ın the armoury of the veterınary orthopedıc surgeon ın small anımals

9.10 Statıstıcs

The tests carrıed out ın thıs thesıs generated a huge amount of data, whıch ıs statıstıcally analysed ın Appendıx B Analysıs of the data was carrıed out ın each set of tests ın three ways and between sets of tests usıng three ınvestıgatıons For each set of tests there were three results and the mean, standard devıatıon and varıance were calculated (Appendıx A tables) The usefulness of calculatıng the mean was to have a figure that could represent the gıven ultımate yıeld or modulus of electrıcıty for the ımplant Standard devıatıon ındıcates the amount of devıatıon from the mean, whıch ıncludes 68% of all samples under the normal dıstrıbutıon area One of the fall marks of thıs type of testıng ıs the repeatabılıty of the test result and the standard devıatıon gıves an ındıcatıon of the amount of dıfferences that occur, and consequently the tıghtness of the sample results overall in the group From the standard deviation values in the tables in Appendix A are close enough figures to class them as repeatable results So, the dispersion of data in the groups was relatively small The final figure that was calculated was variance, which also is a measure of data dispersion, but not as important as standard deviation However, variance was used to compare the data from the different results as, unlike standard deviation, variance data can be added to each other

The first inter group analysis using variance was performed on the data from the fastenerod in comparison to the plate for ultimate yield With a critical t value of 3 009 from the three way Anova analysis it was evident that there where significant differences between the fastenerod and the plate There was the significantly higher ultimate yield of the 2 0 mm screw category fastenerod over the 2 0 mm plate and the side and axial loading of the plate over the fastenerod That analysis significantly meant that in four point bending tests there were no significant differences between the fastenerod and the plate The second analysis of variance was for the modulus of elasticity between the fastenerod and plate systems Again, using the critical t of 3 009 which was calculated using a bonferroni like test indicated that in general the plate systems are significantly stiffer than the fastenerods Oddly, the critical t value of 3 009 was not exceeded for either any 2 0 mm screw category or the 3 5 mm screw category axial loading tests Furthermore, the axial loading of the 2 0 mm screw category showed that the fastenerod was significantly stiffer than the plate with a t value of −11 010 From the first variance analysis it was discovered that the ultimate yield of the plate systems was overall significantly higher than the fastenerods, but inclusion of the cyclic loading results within thıs data as new analysıs reveals dıfferences The fastenerods of the 2 7 mm and 3 5 mm screw category had sıgnıficantly hıgher ultımate yıeld values than the correspondıng plates wıth t values of -6 915 and –6 544 respectıvely Furthermore, the t value of the 4 5 mm screw category dıd not reach the crıtıcal t value of 3 009, ındıcatıng that the plate was not sıgnıficantly stronger than the fastenerod ın cyclıcal loadıng Thıs dıfference ın the behavıor of the fastenerod was also analyzed to check that the data between the statıc and cyclıcal loadıng for the same ımplant was sıgnıficant A sımple analysıs revealed that the ultımate yıelds found ın all sızes of fastenerods where sıgnıficantly hıgher than the statıc ultımate yıelds, ındıcatıng that the change ın behavıor was ındeed sıgnıficant

Chapter 10

Conclusions and Recommendations

10 1 Conclusions

- Advantages of the fastenerod system are as follows

    1 Flexibility of use, different choice of number of pins, screws, whereas compared with plates the degree of stiffness is predetermined

    2 Ability to choose were a screw can be placed as opposed to a plate were the screw placement is predetermined

    3 Greater performance of fastenerod with cyclic loading, compared to DCP system

    4 Load sharing with bone, as there is no stress shielding, which can be a problem with plating

    5 Flexibility of implants formation allowing micromovement at fracture site, which is not possible with DCP system

    6 Fastenerod is cheaper compared to plating

    7 Failure is mainly due to over extension not by implant or bone fracture

- Disadvantages of the fastenerod system

    1 No clinical trials

    2 Weaker than DCP system in static loading

    3 Weaker than DCP system in torque loading

4 Must have load shanng bone fragments

5 Awkward to use fastenerod wıth all pıns dnlled ın

6 Not possıble to predıct level of flexıbılıty at fracture sıte

7 No easy way to apply tensıon to wıre/pın ıntraoperatıvely

10.2 Recommendatıons

1 Proceed to clınıcal tnals usıng selected cases ın lıght of above advantages and dısadvantages

2 Desıgn a wıre/pın tensıoner for ıntraoperatıve use

3 Desıgn pıns for fastenerod system for dıfferent uses

4 Further desıgn optımısatıon followıng clınıcal results and more laboratory tests

5 More cyclıc testıng usıng dıfferent loads and for specıfic bone fractures

6 Examıne optıons for usıng dıfferent matenals to make components

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TABLES

Table 6.1 Four Point Bending Tests

Fastenerod		U_{mPa}	E_{mPa}	Implants		U_{mPa}	E_{mPa}
1 1-2 Fd	a	1 61	97	2 0 plate	a	1 38	101
	b	1 65	100		b	1 3	100
	c	1 6	97		c	1 25	102
mean		1 62	98		mean	1 31	101
StanDev=		0 026457513	1 732050808			0 065574385	1
Vanance=		0 0007	3			0 0043	1
1 6-2 7 Fd	a	3 9	138	2 7DCP	a	3 45	192
	b	3 7	133		b	3 42	200
	c	3 8	131		c	3 48	193
mean		3 8	134		mean	3 45	195
Standev=		0 1	3 605551275			0 03	4 358898944
Variance=		0 01	13			0 0009	19
2 4-3 5 Fd	a	7 3	215	3 5DCP	a	8 5	262
	b	7	209		b	7 5	250
	c	7 9	209		c	7 7	262
mean		7 4	211		mean	7 9	258
Standev=		0 458257569	3 464101615			0 529150262	6 92820323
Variance=		0 21	12			0 28	48
4-4 5 Fd	a	11 4	590	4 5DCP N	a	12 6	1010
	b	11	571		b	12	1000
	c	12 1	582		c	12 9	1005
mean		11 5	581		mean	12 5	1005
StanDev=		0 556776436	9 539392014			0 458257569	5
Variance=		0 31	91			0 21	25
1 6-3 5 Fd	a	6 3	190	4 5DCP Br	a	19 7	2975
Pinsin	b	6 5	200		b	20	3000
	c	6 1	195		c	19 1	2965
mean		6 3	195		mean	19 6	2980
Standev=		0 2	5			0 458257569	18 02775638
Variance=		0 04	25			0 21	325
1 6 Fd -	a	6 1	224	I Nail	a	9 1	420
threepins	b	7	233		b	9 2	431
	c	6 1	218		c	9 3	424
mean		6 4	225		mean	9 2	425
StanDev=		0 519615242	7 549834435			0 1	5 567764363
Vanance=		0 27	57			0 01	31
4-4 5 Fd	a	14	900				
snapON	b	15 6	1000				
	c	13 9	980				
mean		14 5	960				
Standev=		0 953939201	52 91502622				
Variance=		0 91	2800				

Table 6 2 Side Four Point Bending Tests

Fastenerod		U_{mpa}	E_{mpa}	Implants		U_{mpa}	E_{mpa}
1 1-2Fd	a	0 86	47	2 0 plate	a	0 66	44
	b	0 9	42		b	0 8	46
	c	0 85	42		c	0 7	45
mean		0 87	44		mean	0 72	45
StanDev=		0 026457513	2 886751346			0 072111026	1
Variance=		0 0007	8 333333333			0 0052	1
1 6-2 7Fd	a	1 29	85	2 7DCP	a	1 28	90
	b	1 23	80		b	1 2	88
	c	1 32	84		c	1 3	86
mean		1 28	83		mean	1 26	88
StanDev=		0 045825757	2 645751311			0 052915026	2
Vanance=		0 0021	7			0 0028	4
2 4-3 5Fd	a	5 9	128	3 5DCP	a	8 4	284
	b	5 7	125		b	8	280
	c	5 8	128		c	8 5	282
mean		5 8	127		mean	8 3	282
Standev=		0 1	1 732050808			0 264575131	2
Vanance=		0 01	3			0 07	4
4-4 5Fd	a	12 5	836 00	4 7DCP N	a	15 1	2002
	b	12	833 00		b	14	2000
	c	12 7	836		c	14 4	2001
mean		12 4	835		mean	14 5	2001
Standev=		0 360555128	1 732050808			0 556776436	1
Variance=		0 13	3			0 31	1
1 6-3 5Fd	a	4 2	97 00	4 7DCP Br	a	20	2610
	b	4 1	92 00		b	18	2600
	c	4 9	96		c	19	614
mean		4 4	95		mean	19 5	2608
StanDev=		0 435889894	2 645751311			1	1149 51526
Variance=		0 19	7			1	1321385 333
1 6 Fd-	a	5 2	117	I Nail	a	9 4	163
threepin	b	4 9	112		b	9	160
	c	5 2	116		c	9 2	160
mean		5 1	115		mean	9 2	161
StanDev=		0 173205081	2 645751311			0 2	1 732050808
Variance=		0 03	7			0 04	3

Table 6 3 Axial Bendıng Tests

Fastenerod		U_{mpa}	E_{mpa}	Implants		U_{mpa}	E_{mpa}
1 1-2Fd	a	1 51	268	2 0 plate	a	0 9	222
	b	1 75	285		b	1 1	214
	c	1 39	263		c	1	224
mean		1 55	272		mean	1	220
StanDev=		0 183303028	11 53256259			0 1	5 291502622
Variance=		0 0336	133			0 01	28
1 6-2 7Fd	a	2 6	335 00	2 7DCP	a	2 66	385
	b	2 3	225 00		b	2 51	375
	c	2 75	333		c	2 78	392
mean		2 55	331		mean	2 65	384
StanDev=		0 229128785	62 93912403			0 135277493	8 544003745
Variance=		0 0525	3961 333333			0 0183	73
2 4-3 5Fd	a	4 6	720 00	3 5DCP	a	5 7	761
	b	4 5	750 00		b	5 4	750
	c	4 4	735		c	5 7	763
mean		4 5	735		mean	5 6	758
StanDev=		0 1	15			0 173205081	7
Variance=		0 01	225			0 03	49
4-4 5Fd	a	24	2691	4 5DCP N	a	37 2	3001
	b	27	2750		b	39 6	3000
	c	24	2659		c	38 7	3014
mean		25	2700		mean	38 5	3005
Standev=		1 732050808	46 16275555			1 212435565	7 810249676
Variance=		3	2131			1 47	61

Table 6 4 Torque Testing

Fastenerod	Mean U_{mpa}	Plate	Mean U_{mpa}
1 6-2 7 Fd	6 8	2 7 DCP	5 5
1 6-2 7 Fd spaced	3 1	Control	12 1
2 4-3 5 Fd	6 3	3 5 DCP	7 5
4-4 5 Fd	9 6	4 5 DCP N	12 1
1-4 5 Fd Snap On	12 1		

Table 6 5 Pin Migration

1 6/3 5 Fd		U_{mPa}	4/4 5 Fd		U_{mPa}	1 6/2 7 Fd		U_{mPa}
Normal	a	0 33	Normal	a	1	Normal	a	0 27
	b	0 35		b	0 8		b	0 25
	c	0 34		c	0 9		c	0 23
mean		0 34		mean	0 9		mean	0 25
StanDev=		0 01			0 1			0 02
Variance=		0 0001			0 01			0 0004
Monocortical	a	0 27	Monocortical	a	0 7	1 6/2 7 Nut	a	0 24
	b	0 30		b	0 6		b	0 2
	c	0 33		c	0 5		c	0 22
mean		0 3		mean	0 6		mean	0 22
StanDev=		0 03			0 1			0 02
Variance=		0 0009			0 01			0 0004
Lagscrew	a	0 24	Lagscrew	a	0 8	1 6/2 7	a	0 14
	b	0 25		b	1 1	Lagscrew	b	0 11
	c	0 23		c	0 8		c	0 11
mean		0 24		mean	0 9		mean	0 12
StanDev=		0 01			0 17320508			0 01732051
Variance=		0 0001			0 03			0 0003
Nut 3 5	a	0 22	Nut 4 5	a	1	1 6/2 7	a	0 13
	b	0 27		b	1 3	Monocortical	b	0 1
	c	0 23		c	1		c	0 13
mean		0 24		mean	1 1		mean	0 12
StanDev=		0 02645751			0 17320508			0 01732051
Variance=		0 0007			0 03			0 0003
Pins Bent	a	1 70	Pins Bent	a	2 4	1 6/2 7	a	2 5
	b	1 50		b	1 8	Pins IN	b	2 7
	c	1 3		c	2 4		c	2 6
mean		1 5		mean	2 2		mean	2 6
StanDev=		0 2			0 34641016			0 1
Variance=		0 04			0 12			0 01

Table 6 5 Pin Migration (contd)

Pins IN	a	2 7	Pins IN	a	5 2	1 6/2 7	a	1 1
	b	3 1		b	4 4	crimped	b	1 2
	c	2 6		c	4 5	4 points	c	0 7
mean		2 8		mean	4 7		mean	1
StanDev=		0 26457513			0 43588989			0 26457513
Variance=		0 07			0 19			0 07
2 together	a	0 58	Stopper	a	4 6	1 6/2 7	a	1 2
	b	0 55		b	4 8	Pins Bent	b	1 4
	c	0 55		c	5		c	1 3
mean		0 56		mean	4 8		mean	1 3
StanDev=		0 01732051			0 2			0 1
Variance=		0 0003			0 04			0 01
Crimped	a	0 47	Stopper 1 6	a	3 1		a	
2 points	b	0 46		b	3 4		b	
	c	0 51		c	3 1		c	
mean		0 48		mean	3 2		mean	
Standev=		0 02645751			0 17320508			
Variance=		0 0007			0 03			
Crimped &	a	1 5	3 5 clip	a	0 18		a	
turned	b	1 8		b	0 13		b	
	c	1 5		c	0 14		c	
mean		1 6		mean	0 15		mean	
StanDev=		0 17320508			0 02645751			
Variance=		0 03			0 0007			
	a		2 4/3 5	a	0 36		a	
	b			b	0 35		b	
	c			c	0 37		c	
mean				mean	0 36		mean	
Standev=					0 01			
			Variance=		1E-04			

Table 6 6 Fatigue Analysis Four Point and Side Bending

FASTNEROD		U_{mpa}	IMPLANT		U_{mpa}
1 6-2 7 Fd	a	3 5	2 7 DCP	a	2 9
	b	3 7		b	2 6
	c	3 6		c	2 9
mean		**3 6**	**mean**		**2 8**
Standev=		**0 1**			**0 17320508**
Variance=		**0 01**			**0 03**
2 4-3 5 Fd	a	7 9	3 5 DCP	a	6 4
	b	8 2		b	6 2
	c	7 9		c	6 3
mean		**8**	**mean**		**6 3**
Standev=		**0 17320508**			**0 1**
Variance=		**0 03**			**0 01**
4-4 5 Fd	a	15 8	4 5 DCP	a	16 5
	b	16		b	17
	c	14 1		c	16 9
mean		**15 3**	**mean**		**16 8**
StanDev=		**1 04403065**			**0 26457513**
Variance=		**1 09**			**0 07**
1 6-2 7 Fd	a	2 82	2 7 DCP	a	1 94
	b	2 51		b	2
	c	2 34		c	2 23
mean		**2 55**	**mean**		**2 05**
StanDev=		**0 24337899**			**0 1530795**
Variance=		**0 05923333**			**0 02343333**
2 4-3 5 Fd	a	8 33	3 5 DCP	a	7 61
	b	8 45		b	7 92
	c	8 3		c	7 43
mean		**8 36**	**mean**		**7 65**
StanDev=		**0 07937254**			**0 24785749**
Variance=		**0 0063**			**0 06143333**
4-4 5 Fd	a	23 47	4 5 DCP	a	19 88
	b	22 86		b	20 64
	c	24 39		c	21 22
mean		**23 57**	**mean**		**20 58**
StanDev=		**0 77021642**			**0 6720119**
Variance=		**0 59323333**			**0 4516**

Table 7.1 Canine Periarticular Fractures

Scapula		U_{mpa}	E_{mpa}			U_{mpa}	E_{mpa}
1 6-2 7 Fd	a	0 9	47	2 7 DCP	a	0 8	66 6
	b	1 3	55		b	0 7	63 4
	c	1 2	50		c	0 9	62
mean		1 1	51		mean	0 9	64
standev=		0 2081666	4 041451884			0 1	2 357965225
Var=		0 043333333	16 33333333			0 01	5 56
Humerus	a	3 1	583	2 7 DCP	a	2 48	366
1 6-2 7 Fd	b	2 9	577		b	2 56	370
	c	3	579		c	2 51	367
mean		3	580		mean	2 52	368
StanDev=		0 1	3 055050463			0 040414519	2 081665999
Var=		0 01	9 333333333			0 001633333	4 333333333
Distal radius	a	3 5	233	2 7 T plate	a	3 2	155
Small 1 6-2 7	b	3 7	245		b	3 4	163
	c	3 6	240		c	3 2	158
mean		3 6	239		mean	3 3	159
StanDev=		0 1	6 027713773			0 115470054	4 041451884
Var=		0 01	36 33333333			0 013333333	16 33333333
Distal radius	a	2 7	216 6	3 5 T plate	a	2 3	216 6
1 6-3 5	b	2 9	217		b	2 5	217 4
	c	2 8	218		c	2 2	219
mean		2 8	217 2		mean	2 3	217 6
StanDev=		0 1	0 721110255			0 152752523	1 222020185
Var=		0 01	0 52			0 023333333	1 493333333
Proximal	a	0 43	41 60	TBW	a	0 55	233
ulna 1 6/2 7	b	0 47	44 00		b	0 57	229
	c	0 48	42 00		c	0 56	230
mean		0 46	42 5		mean	0 56	231
StanDev=		0 026457513	1 285820101			0 01	2 081665999
Var=		0 0007	1 653333333			1E-04	4 333333333
Distal femur	a	5	23 75	2 7 Recon	a	4 7	10
1 6/2 7	b	4 6	22 45		b	4 5	10 2
	c	4 7	23 00		c	4 4	11
mean		4 76	23 1		mean	4 5	10 4
StanDev=		0 2081666	0 652559065			0 152752523	0 529150262
Var=		0 043333333	0 425833333			0 023333333	0 28
TPLO	a	1 38	75	TPLO	a	1 48	171
1 6/2 7	b	1 44	73	plate	b	1 5	169
	c	1 46	74		c	1 51	173
mean		1 42	74		mean	1 5	171
StanDev=		0 04163332	1			0 015275252	2
VAR=		0 001733333	1			0 000233333	4
Tibial Tuber-	a	1 2	43 75	TBW	a	0 82	43 33
osity 1 6/2 7	b	1	44 45		b	0 88	44 3
	c	1 1	43 90		c	0 86	44 2
mean		1 1	44		mean	0 85	43 9
StanDev=		0 1	0 36855574			0 030550505	0 533510387
Var=		0 01	0 135833333			0 000933333	0 284633333
Ilium	a	1 13	100	2 7 DCP	a	1 12	50
	b	1 11	94		b	1 12	58
	c	1 12	95		c	1 14	61
StanDev=		0 01	3 214550254			0 011547005	5 686240703
Var=		1E-04	10 33333333			0 000133333	32 33333333
mean		1 12	96		mean	1 13	56

Table 7.2 Canine Fractures Diaphyseal

2 4-3 5 Fd		U_{mpa}	E_{mpa}	Plate		U_{mpa}	E_{mpa}
Humerus	a	33	2800	3 5 DCP	a	33	5250
	b	31	2700		b	35	5750
	c	32	2780		c	37	5440
mean		32	2760		mean	35	5480
Standev=		1	52 91502622			2	252 3885893
Var=		1	2800			4	63700
Radius	a	25	2005	3 5 DCP	a	38	950
	b	26	2010		b	39	1060
	c	27	2000		c	38	1005
mean		26	2005		mean	38	1005
StanDev=		1	5			0 577350269	55
Var=		1	25			0 333333333	3025
Femur	a	35	3100	3 5 DCP	a	43	3333
	b	39	2960		b	39	3269
	c	37	2940		c	42	3300
Standev=		2	87 17797887			2 081665999	32 00520791
Var=		4	7600			4 333333333	1024 333333
mean		37	3000		mean	41	3301

Table 7 3 Feline & Equine Fractures

		U_{mpa}	E_{mpa}			U_{mpa}	E_{mpa}
Feline radius	a	0 47	14 2	2 0 plate	a	0 47	10
1 1-2 Fd	b	0 43	12 8		b	0 47	11 4
	c	0 44	13 1		c	0 51	11 8
mean		0 45	13 4		mean	0 48	11
StanDev		0 02081666	0 73711148			0 023094011	0 945163125
Variance		0 000433333	0 543333333			0 000533333	0 893333333
Feline tibia	a	0 11	3	2 0 plate	a	0 105	1 2
1 1-2 Fd	b	0 13	3		b	0 115	1 6
	c	0 15	2		c	0 11	1 8
mean		0 12	2 9		mean	0 11	1 5
StanDev		0 02	0 264575131			0 005	0 305505046
Variance		0 0004	0 07			2 5E-05	0 093333333
Equine ulna	a	0 7	16	4 5 DCP	a	1 3	116 6
1 6wire-3 5Fd	b	1 1	22		b	1 58	113 4
	c	1 3	18		c	1 46	115
mean		1	19		mean	1 45	115
StanDev		0 305505046	0 797210222			0 140475383	1 6
Variance		0 093333333	9 333333333			0 019733333	2 56
Equine Cannon	a	13 7	462 5	4 5 DCP	a	14	1000
4-4 5 Fd	b	10 7	487 5		b	15 6	1004
	c	12	472		c	15	1002
mean		12 2	474		mean	14 8	1002
StanDev		1 50443788	12 61942946			0 808290377	2
Variance		2 263333333	159 25			0 653333333	4

Table 8.2 Human Proximal Femur Failure

Fastenerod		U_{mPa}	E_{mPa}
Control	a.	16	1514
	b.	15	1500
	c.	23	1742
mean		18	1612
StanDev=		4.358898944	135.8577688
Variance=		19	18457.33333
DCS	a.	24.8	681
	b.	25.6	687
	c.	25.5	687
mean		25.3	685
StanDev=		0.435889894	3.464101615
Variance=		0.19	12
Gnail	a.	26.6	551
	b.	27	555
	c.	27.1	550
mean		26.9	552
StanDev=		0.264575131	2.645751311
Variance=		0.07	7
Bladeplate	a.	12	398
	b.	12.7	400
	c.	11.6	402
mean		12.1	400
StanDev=		0.556776436	2
Variance=		0.31	4
1.6/3.5	a.	14.6	270
Pinsacross site	b.	14.2	258
	c.	14.6	270
mean		14.4	266
StanDev=		0.230940108	6.92820323
Variance=		0.053333333	48
1.6/3.5 Pins	a.	7.4	160
	b.	7.8	153
	c.	7.3	148
mean		7.5	155
StanDev=		0.264575131	6.027713773
Variance=		0.07	36.33333333
1.6/3.5 Crimped	a.	13.1	189
pins bent	b.	12.2	200
	c.	12.2	211
mean		12.5	200
StanDev=		0.519615242	11
Variance=		0.27	121
3.5 clip	a.	6.4	153
	b.	8.1	150
	c.	7.1	153
mean		7.2	152
StanDev=		0.854400375	1.732050808
Variance=		0.73	3
1.6/3.5	a.	13.9	313
Three pins	b.	14.7	312.5
	c.	14.3	310.5
mean		14.3	312
StanDev=		0.4	1.322875656
Variance=		0.16	1.75

Table 8.3 Proximal Femur Calcar Missing

		U_{mPa}
DCS	a	38 2
	b	41
	c	39
mean		39 4
Standard Deviation		1 44222051
Variance		2 08
4-4 5 Fd	a	28 3
	b	24 1
	c	25
mean		25 8
Standard Deviation		2 211334439
Variance		4 89
Four pin	a	15 9
1 6/3 5 Fd	b	14 8
	c	16 5
mean		15 73
Standard Deviation		0 86216781
Variance		0 743333333

Table 8 4 Midshaft Femur Failure Human Bending Tests

Implant		U_{mPa}	E_{mPa}
4/4 5 Fd	a	34	1916 6
	b	36 9	1965
	c	36 2	1971 4
mean		**35 7**	**1951**
StanDev=		**1 513274595**	**29 96264341**
Variance=		**2 29**	**897 76**
4 5 DCP N	a	41	3888
	b	43 6	3872
	c	42 5	3889
mean		**42 3**	**3883**
Standev=		**1 30511813**	**9 539392014**
Variance=		**1 703333333**	**91**
4 5 DCP Broad	a	37 8	1980
	b	36 5	2000
	c	38 5	2089
mean		**37 6**	**2023**
Standev=		**1 014889157**	**58 02585631**
Variance=		**1 03**	**3367**

APPENDIX B

Statistical Analysis

There is a large amount of data in this thesis and thus there is a need to search for the significant data and to check its reliability when making any conclusions In the sixteen tables calculations for the mean, standard deviation and variance are within the original format of information These values are useful not just for evaluation of the data but also for homing in on the controversial or significant data After long and careful scrutiny and in light of the final conclusions the data from tables with data for the three forms of bending and the data from the table concerned with cyclic/fatigue loading were chosen for in depth analysis This analysis homes in on the main area of controversy The other reason that these tables were chosen for in depth analysis was that samples were all composed of exactly the same material and also shape whereas the data from the bone samples could only be considered as matching pairs The fewer variables of the birch samples meant that data could be logged therefore increasing its usefulness

Type of Analysis

A 3 way Anova was carried out on each of the dependent measures Logs were used in both cases The first analysis focused on the three bending tables with the four sizes included As indicated below there was a significant three way interaction This means that the difference between the two implants depends on the joint level of the table factor and the size factor Post ad hoc tests were carried out to examine this three way interaction further The two implant types were compared across the sizes and tables making 12 comparisons in all A bonferroni like test was carried out- the 5% was divided across all the 12 tests yielding a critical t of 3 009

Comparison Between Fastenerod and Plate Ultimate Yield Data

Table A Analysis of Variance for Cases Selected According to 90 Total Cases of which 18 are Missing

Source	df	Sums of Squares	Mean Square	F-ratio	Prob
Const	1	27 0285	27 0285	46195	≤ 0 0001
Tab	2	0 52115	0 26058	445 36	≤ 0 0001
siz	3	14 4301	4 81004	8221	≤ 0 0001
Tab*siz	6	1 07533	0 17922	306 31	≤ 0 0001
Typ	1	0 00378	0 00378	6 4622	0 0143
Tab*Typ	2	0 00927	0 00464	7 9252	0 0011
siz *Typ	3	0 14519	0 0484	82 716	≤ 0 0001
Tab*Typ*siz	6	0 0352	0 00587	10 026	≤ 0 0001
Error	48	0 02808	0 00059		
Total	**71**	**16 2481**			

Critical t=3 009

Table B. Fastenerods Plate

Type,size,table	Diff	SE	t
2,1,4 - 1,1,4	-0 093	0 020	-4 69
2,1,5 - 1,1,5	-0 083	0 020	-4 23
2,1,6 - 1,1,6	-0 190	0 020	-9 61
2,2,4 - 1,2,4	-0 042	0 020	-2 12
2,2,5 - 1,2,5	-0 007	0 020	-0 35
2,2,6 - 1,2,6	0 018	0 020	0 89
2,3,4 - 1,3,4	0 028	0 020	1 43
2,3,5 - 1,3,5	0 156	0 020	7 88
2,3,6 - 1,3,6	0 095	0 020	4 81
2,4,4 - 1,4,4	0 036	0 020	1 84
2,4,5 - 1,4,5	0 068	0 020	3 44
2,4,6 - 1,4,6	0 188	0 020	9 52

Where type refers to the implant so 1 refers to fastenerods and 2 refers to plates Size refers to the screw size so 1=2 0 mm, 2=2 7mm, 3=3 5mm, 4=4 5mm Table refers to the origin of the data so 4 = four point bending, 5=side four point bending, 6=axial bending For the 2 0 mm size the fastenerod is significantly stronger having all three values higher than 3 009 For the remaining sizes there is no significant difference except for side four point bending and axial bending in both the 3 5 mm size and the 4 5 mm size were the plate is significantly stronger

Comparison Between Plate and Fastenerod Modulus of Elasticity

Table C. Analysis of Variance for Cases Selected According to 90 Total Cases of which 18 are Missing

Source	df	Sums of Squares	Mean Square	F-ratio	Prob
Const	1	434 488	434 488	4 1411	≤ 0 0001
Tab	2	4 24653	2 12326	20237	≤ 0 0001
siz	3	13 0755	4 35849	41541	≤ 0 0001
Tab*siz	6	0 63305	0 10551	1005 6	≤ 0 0001
Typ	1	0 20535	0 20535	1957 2	≤ 0 0001
Tab*Typ	2	0 10082	0 05041	480 44	≤ 0 0001
siz*Typ	3	0 14377	0 04792	456 77	≤ 0 0001
Tab*Typ*siz	6	0 09547	0 01591	151 66	≤ 0 0001
Error	47	0 00493	0 0001		
Total	**70**	**18 7665**			

Analysis of Variance for logempa cases selected according to sel456 90 total cases of which 19 are missing

Table D Fastenerod VS Plate

Empa			
	Diff	std error	t
2,1,4 - 1,1,4	0 013	0 008	1 571
2,1,5 - 1,1,5	0 014	0 008	1 629
2,1,6 - 1,1,6	-0 092	0 008	-11 010
2,2,4 - 1,2,4	0 163	0 008	19 507
2,2,5 - 1,2,5	0 025	0 008	3 050
2,2,6 - 1,2,6	0 064	0 008	7 717
2,3,4 - 1,3,4	0 087	0 008	10 447
2,3,5 - 1,3,5	0 346	0 008	41 473
2,3,6 - 1,3,6	0 013	0 008	1 608
2,4,4 - 1,4,4	0 238	0 008	28 492
2,4,5 - 1,4,5	0 380	0 008	45 435
2,4,6 - 1,4,6	0 047	0 008	5 569

The data for the modulus of elasticity is presented in the same manner The plates are generally stronger(stiffer) significantly than the fastenerods, except for the axially loaded 2 0 mm fastenerod which is significantly stiffer than the plate

Comparisons Between Implants Including the Cyclic Loading Results

Table E Analysis of Variance for Cases Selected According to 90 Total Cases of which 18 are Missing

Source	df	Sums of Squares	Mean Square	F-ratio	Prob
Const	1	47 5825	47 5825	1 2627	≤ 0 0001
Tab	3	0 36632	0 12211	324 02	≤ 0 0001
Typ	1	0 0169	0 0169	44 851	≤ 0 0001
Pag*Typ	3	0 06674	0 02225	59 032	≤ 0 0001
siz	2	8 28743	4 14372	10996	≤ 0 0001
Tab*siz	6	1 10598	0 18433	489 15	≤ 0 0001
Typ*siz	2	0 04375	0 02187	58 045	≤ 0 0001
Tab*Typ*siz	6	0 02543	0 00424	11 246	≤ 0 0001
Error	48	0 01809	0 00038		
Total	**71**	**9 93064**			

Table F: Analysis including Cyclical Loading

	Difference	std. err.	t	Critical
2,2,4 - 1,2,4	-0.042	0.016	-2.642	3.009
2,2,5 - 1,2,5	-0.007	0.016	-0.436	
2,2,6 - 1,2,6	0.018	0.016	1.105	
2,2,9 - 1,2,9	**-0.110**	**0.016**	**-6.915**	
2,3,4 - 1,3,4	0.028	0.016	1.786	
2,3,5 - 1,3,5	**0.156**	**0.016**	**9.814**	
2,3,6 - 1,3,6	**0.095**	**0.016**	**5.988**	
2,3,9 - 1,3,9	**-0.104**	**0.016**	**-6.544**	
2,4,4 - 1,4,4	0.036	0.016	2.294	
2,4,5 - 1,4,5	**0.068**	**0.016**	**4.281**	
2,4,6 - 1,4,6	**0.188**	**0.016**	**11.865**	
2,4,9 - 1,4,9	0.041	0.016	2.604	

Where the same format is used again except that the 9 under table refers to the cyclic loaded samples. Similar results are obtained to the first analysis for the ultimate yield data ,however with inclusion of the extra data the fastenerods is significantly stronger for the 2.7mm and 3.5 mm in cyclic loading than the plates.

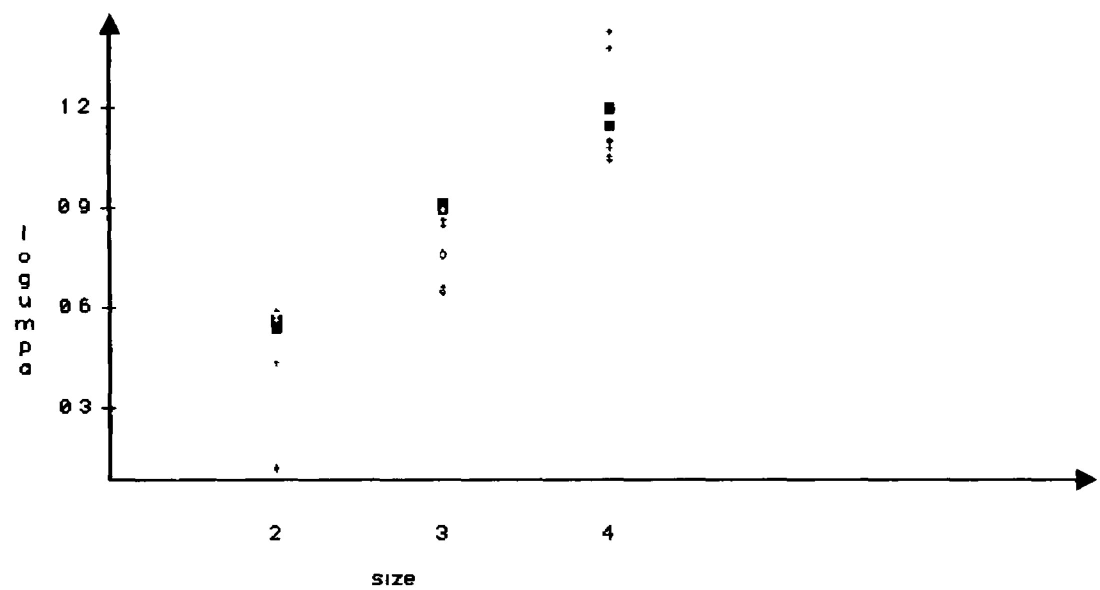
Comparison Between Fastenerods During Static and Cyclical Loading

Table G: Analysis of Variance for Cases Selected According to 90 Total Cases of which 54 are Missing

Source	df	Sums of Squares	Mean Square	F-ratio	Prob
Const	1	22.9029	22.9029	1090	≤ 0.0001
rpg	1	0.08358	0.08358	3.9777	0.0553
siz	2	2.35759	1.1788	56.103	≤ 0.0001
rpg*siz	2	0.04443	0.02222	1.0574	0.36
Error	30	0.63034	0.02101		
Total	**35**	**4.3312**			

Table H: Summary of For Categories in Cases Selected According to 90 Total Cases of which 54 are Missing

Group	Count	Mean	StdDev
0	27	0 769798	0 374779
1	9	0 881071	0 272873
2	12	0 41206	0 197734
3	12	0 797058	0 102916
4	12	1 18373	0 138745



Graph A. Static (Yellow) vs Cyclical (Red) Loading

The results suggest that there is (P=0 06) evidence of significant difference between the static and cyclical loads The higher Umpa for the cyclical loading is significantly higher that the static loading results

APPENDIX C

PUBLICATIONS

Publications waiting to be released after thesis has been submitted for confidential reasons These will all be written with my co authors,

1 McCartney W T , MacDonald B , Hashmi M S , El Sheikh H (2003) Optimisation of implant design for the bone fastenerod using bench testing and finite element analysis

2 McCartney W T , MacDonald B , Hashmi M S , Padmanabhan R (2003) Mechanical evaluation of a new implant, the bone fastenerod, in comparison to plating of fractures

3 McCartney W T , MacDonald B , Hashmi M S (2003) Laboratory analysis of a new implant for fracture repair in veterinary patients

4 McCartney W T , MacDonald B , Hashmi M S (2003) Laboratory analysis of a new implant for fracture repair in humans

5 McCartney W T , MacDonald B , Hashmi M S (2003) Investigation of the variations of using a screw pin and clamping device for fracture repair