INVESTIGATION OF A DEVICE FOR MEASUREMENT OF FRACTURE HEALING IN THE DISTAL RADIUS

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Declaration

I declare that this thesis has been composed by myself and is all my own work except where otherwise stated.

Lucia Cardone

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Abstract

The development of a measuring device and technique is presented to measure objectively the healing process in distal radial fractures treated with an external fixator.

External fixation is advocated in stabilization of unstable fractures of the distal radius to allow a rapid and better patient recovery. However, the safe removal time for these frames remains unclear and is based on subjective methods, such as X-ray examination and manual assessment. Removal of the external fixator too early can result in risk of refracture or late collapse of the fracture. Currently, the frame is usually left in place for six weeks, although this may be unnecessarily prolonged and lead to increased complication rate. The measuring device developed here is used to calculate the rigidity of the new callus; this quantitative parameter can contribute to the surgeon's decision to remove the frame.

Bone structure and bone fractures are examined from a mechanical and biological perspective. Fracture treatments and healing patterns are presented with particular attention to external fixators and the environmental fracture conditions imposed by these frames.

Previous studies on fracture healing (for tibial and femoral fractures) have been considered during the development of the measuring device. A fracture model has been created and used to verify the reliability of the device in laboratory testing. In-vivo testing has been performed to improve the performance of the device and protocol for using it; specifically, to produce an instrument that can be adapted to suit any external fixator geometry met on patients. A pilot study was subsequently organised and conducted to verify the usefulness and reliability of the device under clinical conditions.

In order to compare directly the results from different patients, the influence of various external fixator geometries has been investigated, by a finite element (FE) analysis. The FE analysis has been validated against laboratory testing with the fracture model.

Combining measurements from the device and data from the computational model (from the FE analysis), the callus rigidity is determined for patients involved in the pilot study. Callus rigidity increases significantly between the second and the sixth week of treatment. The rigidity values measured at the second week (i.e., when the healing process is at the initial stage) are below $12 kgf \cdot mm^{-1}$. This value of rigidity is exceeded by almost all the measurements taken at the sixth week (i.e., when the callus is believed to be satisfactorily strong enough to allow the external frame to be removed). At the fourth week, some patients present a rigidity value below $12 kgf \cdot mm^{-1}$; for other patients by week four the rigidity value of the callus is over $12 kgf \cdot mm^{-1}$.

The trend of the calculated callus rigidity is discussed and the results are compared with the conventional clinical methods to assess fracture healing. A good agreement was found between measurements and surgical opinions regarding removal time and it was noted that for some patients removal before the sixth week was possible.

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1 Introduction and hypothesis

The work described in this thesis was initiated in order to develop an instrument and methodology for monitoring the healing process of distal radial fractures treated with external fixation.

The aim of this research was to provide a quantitative and objective instrument to measure the healing of distal radial fractures in order to determine the correct time for the removal of external fixators.

External fixators are often used to stabilise complex and unstable fractures of the distal radius. At present, only subjective assessments (e.g., X-ray examination or manual assessment) are in regular use to assess fracture healing. For the distal radius, the duration of the treatment remains the most significant parameter to be respected in the decision of the surgeon to remove the external fixator.

Currently, following a conservative approach, external fixators are left in place for six weeks. This time for some patients may be too long with consequences of prolonged discomfort, or pin track infections (i.e., infection of the pin sites) - the main drawback of this technique and a problem that increases with time. Therefore, to reduce the complication rate, it is advocated that these frames should be removed earlier - as soon as the callus is strong enough to withstand the load condition (without risk of re-fracture) encountered during daily life.

A quantitative and objective method to assess the healing of the fracture could offer the opportunity to overcome the necessity for a six week treatment and introduces the possibility of being able to remove the external fixator as soon as the callus reaches a safe value of rigidity. This would reduce the morbidity for these patients.

The hypothesis to be tested is therefore:

Callus rigidity can be determined in patients with distal radial fractures treated with external fixator frames by combining mechanical measurements and finite element modelling; this rigidity value can be used to monitor the healing process of distal radial fractures.

2 Background

The engineering and medical background is introduced in this chapter. The aim of the chapter is to provide a basic knowledge and terminology to readers coming from different backgrounds. Specifically, to introduce engineers to medical terminology and to clarify understanding of mechanical concepts for medics.

Mechanical properties used in this thesis are presented (see §2.1). In order to provide a complete overview of the fracture healing process, biological aspects that regulate bone formation are described (see §2.2); causes and distribution of bone fractures are considered (see §2.3) and the main models of fracture healing are introduced (see §2.4).

Depending on the type of fracture and preference of the surgeon different treatments are used to stabilize a fracture (see §2.5).

The aim of this research was to develop a measuring device to assess the healing of distal radial fractures treated with an external fixator. Therefore, particular attention is given to external fixation treatment (see §2.6) and distal radial fractures (see §2.7).

Finally, an overview of the current mechanical techniques to assess fracture healing is presented (see §2.8).

2.1 Mechanical properties

Mechanics is the science that studies the effect of forces on bodies. Most mechanical laws have been derived using abstractions and ideal models. Applying these rules directly to a biological body, such as bone, can generate confusion and errors. Therefore, it is important to bear in mind the initial hypotheses and limitations of the rules applied.

Bone is a complex material. Several physical and biological rules are required to describe the global behaviour of this material. For the scope of this research, bone has been considered as an elastic material (see §2.1.1). An overview of viscoelastic and composite materials (see §2.1.2 and §2.1.3) is also presented since these models are also often used to model bone behaviour.

2.1.1 Elastic-plastic materials

Macroscopically, bone is considered as a continuous and deformable body. The three laws of motion, or Newton's laws, (principle of inertia, second law and the principle of action and reaction) together with the law of elasticity (i.e., Hooke's law) are the basis of the mechanical behaviour of bone.

Forces, displacements and all the other derived quantities are vectors in three-dimensional space. Therefore, three components (x, y and z) are required to define them. Unless otherwise stated, these quantities are considered vectors and when referring to single components the subscript option is used (i.e., F_x, F_y, F_z).

An external force (F) applied to a deformable body produces a deformation (δ). To represent internal forces the concept of stress (σ) has been introduced. Stress is calculated as the force divided by the area (A) where the force acts, and is measured in Nm^{-2} or Pa. Normal stress is produced when the force is perpendicular to the area, while shear stress is produced if the force is in the same plane as the area. Generally, a force produces normal and shear stresses. The physiological stress level in bone is usually at or below the MPa range.

Strain (ε) is defined as the ratio between the deformed and the original shape of the body. Strain is a dimensionless measure of a geometrical change. As for stress, there is normal strain (the measure of change in length with respect to original length) and shear strain (the measure of change in angle with respect to the original angle). It must be noted that these definitions of strain are valid only for small strain, for strain greater than 0.05-0.06 more complex geometric analysis is required.

The relationship between force (F) and displacement (δ) under axial loading can be illustrated (see figure 2-1a). This relationship is dependent on the size of the specimen being tested. If the same data are plotted as stress and strain (see figure 2-1b) the different curves converge into one. The elastic and the plastic region can be identified, representing two different behaviours of the material. In the elastic region the deformation is reversible - original shape is re-obtained when the force is removed. The sample shape is permanently changed if the material is in the plastic region. It is worth noting other definitions from the stress and strain graph since these terms have often created confusion, having been used with different meanings. The yield stress (or yield strain) is the point above which increasing stress (or strain) causes plastic deformation. The amount of strain that occurs in the material from the yield point to the break is a measure of the ductility of the material, a material with small ductility is brittle. The maximum stress sustained by the material is called ultimate stress and for some materials it coincides with the breaking stress that represents the stress at the break. The area under the stress and strain curve is a measure of the toughness - absorbed energy needed to cause the break. An extensive review regarding the behaviour of solid biomaterials analysed in term of toughness is presented by Zioupos [1998].

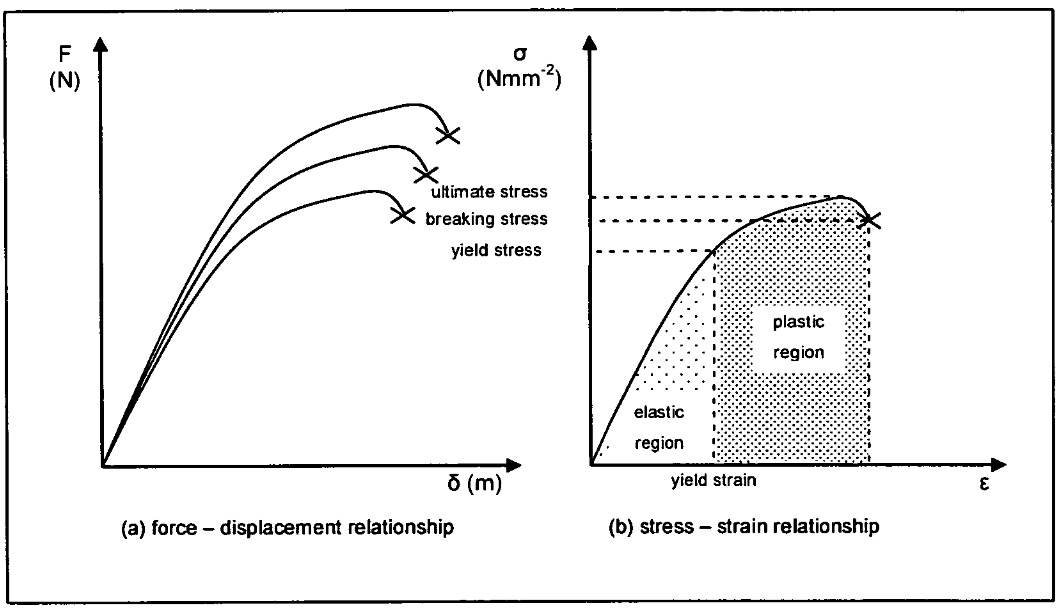


figure 2-1: Mechanical behaviour of the elastic-plastic material

In the elastic region stress and strain are regulated by Hooke's law:

$$\sigma = E \cdot \varepsilon \qquad [2\text{-}1]$$

where stress (σ) is proportional to strain (ε) with the constant of proportionality being equal to what is called Young's modulus (or modulus of elasticity - E), measured in Nm^{-2} or Pa.

The Young's modulus degrades over a period of time when a material is repetitively loaded. This phenomenon is called fatigue.

The application of a tensile (or compressive) force on a body usually produces an elongation (compressive:-reduction) in the direction of the force and reduction (compressive:-elongation) in the transverse direction. Respectively these are called axial and lateral strain. The absolute value of the ratio between the lateral over the axial strain is called Poisson's ratio (ν). Poisson's ratio is dimensionless and its range is between 0 and 0.5. For cortical bone a Poisson's ratio between 0.28 to 0.45 is used.

The properties above are called material (or intrinsic) properties since they are independent of the size and shape of the samples used. Anisotropic materials are those with properties that vary with direction. Anisotropic material with properties that vary in each of the three perpendicular axes (x, y and z) is called orthotropic. If the properties are the same in two of the three axes the material is called transversely isotropic. A material with the same properties in all three axes is called isotropic. A transversely isotropic behaviour is often associated with cortical bone (see § 2.2.2.1).

2.1.2 Viscoelastic materials

Hooke's law [2-1] is often used to describe the behaviour of solid materials subjected to small displacement conditions (i.e., the elastic behaviour). For some materials the relationship between stress and strain is also influenced by time and (or) load frequency. These materials are called viscous materials. Viscous materials do not recover instantaneously to their original shape when the load is removed, and may never return to their original shape.

Viscoelastic materials are those that respond to a load condition combining both elastic and viscous behaviour. Viscoelastic materials can exhibit one or more of the following phenomena:

1. Creep – the stress is held constant and the strain increases with time;
2. Relaxation – the strain is held constant and the stress decrease with time;
3. Hysteresis during cyclic loading;
4. The stiffness depends on the strain rate;
5. The attenuation of acoustic and ultrasonic waves is proportional to the phase angle between stress and strain.

Being a viscoelastic material, the elastic modulus of bone increases with the strain rate. Autefage [2000] reported that there is a power factor of 0.06 between the increasing of the value of Young's Modulus and the strain rate.

2.1.3 Composite models

Materials with different mechanical characteristics can be assembled together to form a unique body without loosing the identity of each of the materials. The resulting material has identifiable phases and it is called a composite material.

Depending on the shape of the particles present in the phases, composite materials can be classified as particulate, short or long fibre.

Long fibre composites are highly anisotropic since the fibres are often orientated in one unique direction. A composite material that includes long fibre phases orientated in different directions is called a cross-ply laminate.

The behaviour of the composite material is influenced by the material properties of each phase as well as by the volume fraction (v), the shape, orientation and interface properties between each phase.

If it can be accepted that the response of the composite is elastic and the bonding between each phase is ideal, two simple models can be adopted to simulate the composite behaviour: the Voigt and the Reuss model (see figure 2-2).

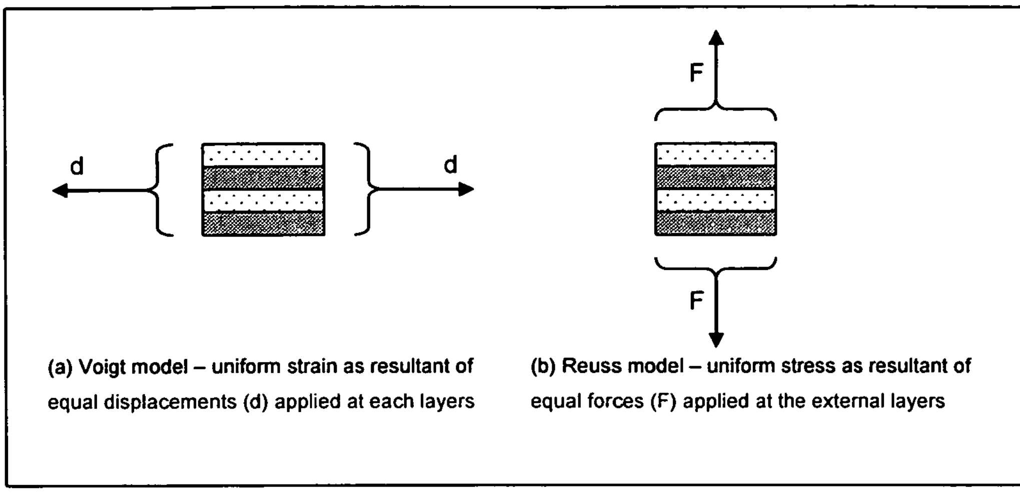


figure 2-2: Behaviour of composite models

The Voigt model (see figure 2-2 a) reproduces a composite material in which the layers have been equally strained (i.e., same displacement across each phase) and it is described by the following equation:

$$E_{comp} = \sum_{i=1}^{n} v_i \cdot E_i \qquad [2\text{-}2]$$

where E_{comp} is the elastic modulus of the composite material. E_i and v_i are respectively the elastic modulus and the volume fraction of each layer, n is the number of layers.

The Reuss model (see figure 2-2 b) is adopted to simulate a composite material with layers that have been equally stressed and is described by the equation:

$$\frac{1}{E_{comp}} = \sum_{i=1}^{n} \frac{v_i}{E_i} \qquad [2\text{-}3]$$

The composite elastic modulus obtained using the above equations represents the two extreme values (upper using Voigt and lower using Reuss) of the real elastic modulus of composite materials. Both models have been widely applied to describe bone behaviour [Lucchinetti, 2000].

A different approach is used in the unit-cell-based method. This model has been based on the assumption that the overall composite material has a periodic character. Therefore it is possible to analyse the behaviour of the material considering a representative volume element (RVE) that is statistically homogeneous (i.e., the average of the properties of the RVE reflects satisfactorily the behaviour of the composite material).

The above method represents a simple and approximate technique for analysis of composite materials, to obtain an idea of the macroscopic behaviour of the composite.

2.2 Bone biology

Bone is considered as a self-repairing structural material, able to adapt its mass, shape and properties to external environmental changes.
Bone macro structure and the cells that regulate the bone activities are introduced (see §2.2.1) and chemical composition and bone tissue differences are described (see §2.2.2). The genesis of the bone adaptation theories and discussion is dealt with (see §2.2.3) and the ageing effect on bone is considered (see §2.2.4).

2.2.1 Morphology and structure

The main constituent of the skeletal system is bone. Bone gives rigidity and structure to the body and enables the skeleton to maintain the shape, to protect the soft tissue and organs, and to transmit the forces throughout the body.

Macroscopically, a typical long bone (see figure 2-3) comprises of a central shaft called the diaphysis and two rounded ends called the epiphyses. The region between the diaphysis and an epiphysis is called metaphysis.

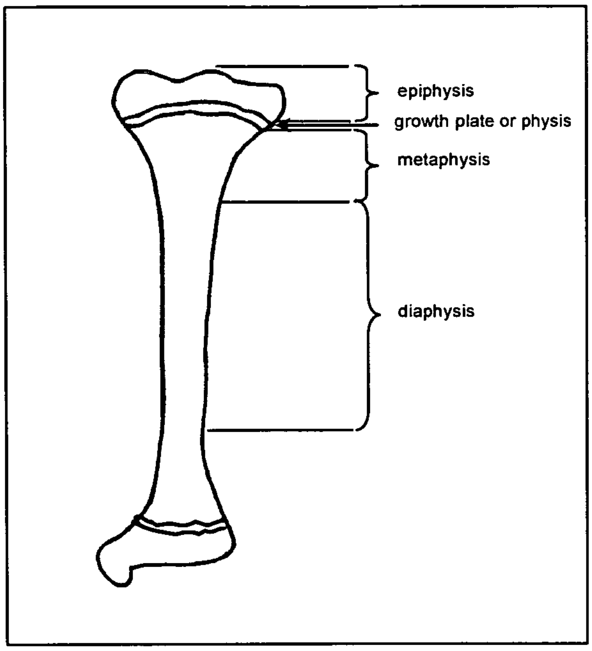


figure 2-3: Bone regions

Bones are connected at joints and to facilitate the contact and the transmission of forces the epiphysis is covered with articular cartilage. Being less rigid than bone, the articular cartilage requires a wider area to sustain the same amount of force that goes through the bone, therefore the epiphysis that supports the cartilage is larger than the diaphysis [Jee, 2000].

During growth there is a plate of hyaline cartilage known as the growth plate or physis (see figure 2-3) between the epiphysis and the metaphysis. In adults this plate is replaced by cancellous bone. The exterior of all bones, except at the articular surface, is covered by a membrane of fibrous connective tissue called the periosteum. Similarly, the marrow cavity and the cavity of cancellous bone are covered by a vascular connective tissue called the endosteum. Both layers, periosteum and endosteum, act during the growth and the fracture healing forming the base for the new callus.

At any specific time the bone surface may be in one of three functional stages: forming, resorbing or quiescent. These stages are activated by different bone cells and are discussed here. Osteoblasts are bone forming cells that synthesize and secrete a bone matrix. Bone formation occurs in two stages: the matrix formation, with the deposit of collagen and other proteins, and then the mineralization that confers rigidity to the collagen framework. During the bone formation some osteoblasts are left behind during the production of the bone matrix. These embedded cells become osteocytes. These cells are believed to sense the magnitude and distribution of strains and to respond to changes in mechanical strain.

The osteoclasts are bone resorbing cells that dissolve both the mineral and organic component of the bone. The signal for the selection of sites to be resorbed is still unclear as is the mechanism of attachment of osteoclasts to the bone surface. The cessation of bone absorption is associated with the migration of the osteoclasts into the marrow space.

2.2.2 Bone composition

Bone is composed of a 65% mineral and 35% organic matrix including water. The main mineral is impure hydroxyapatite, $Ca_{10}(PO_4)_6(OH)_2$ with traces of carbonate, citrate, magnesium, fluoride and strontium. The organic matrix consists 90% collagen and the remaining 10% comprising several noncollagenous proteins. The roles of these noncollagenous proteins are unclear, however the urinary excretion and plasma or serum levels of some of the noncollagenous proteins, unique in the bone, are used clinically to assess the bone turnover.

The diaphysis of long bone and the outer shell of the metaphyses are mainly constituted by cortical bone while the cancellous (trabecular) bone is the main constituent of the epiphysis and methaphysis. The distribution between cortical and cancellous bone varies between different bones. The main differences of these two types of bone are summarized (see table 2-1).

	Cortical	Cancellous
skeletal mass	80%	20%
bone surface	33%	67%
porosity	5-10%	50-95%
turnover	slow	rapid

table 2-1: Main differences between cortical and cancellous based on information in Jee [2000]

2.2.2.1 Cortical bone

Cortical bone or compact bone has porosity range between 5% and 10%. It is generally homogeneous but anisotropic with the cortical material being stronger along the bone axis than in the radial direction, mainly due to its structure. The main units of the cortical bone (secondary osteons) have a cylindrical shape with a diameter between 100μm and 300μm. Secondary osteons are orientated along the longitudinal direction of the bone and they are embedded in interstitial tissue, which is the remnant of old osteons. A thin layer of amorphous substance (cement line, 1μm to 5μm thick) glues the secondary osteons to the interstitial bone tissue. An orthotropic or transverse isotropic constitutive relation can be used to describe the elastic properties of cortical bone.

Mechanical properties of cortical bone have been well investigated in the past with traditional mechanical testing (i.e., uniaxial tensile or compressive test, three-point or four-point bending tests) and innovative techniques (e.g., ultrasound and micro-indentation tests). A large amount of work has been done on secondary osteons material, while the knowledge of the mechanical properties of interstitial bone tissue in cortical bone are still limited.

The main function of cortical bone is to give rigidity and support to the skeletal system.

2.2.2.2 Cancellous bone

Cancellous bone is a porous structure with a porosity range between 50% and 95%. The structure of cancellous bone comprises an interconnected network of rods or plates (trabeculae) that results in a highly anisotropic behaviour. The cancellous framework is a combination of number of trabecular subunits joined by cement lines.

Mechanical testing of cancellous bone is more complex than cortical bone due mainly to the small and irregular shape of cancellous bone. All techniques used to measure cortical properties have been adapted for cancellous measurements, (i.e., uniaxial tensile or compressive test, three-point or four-point bending tests – on a representative volume sample of cancellous bone) in particular introducing finite element correction and machined sampling, in addition to new techniques, that have been developed (e.g., back calculation using a finite element model). An exhaustive review of these techniques has been reported by Jee [2000]. It remains unanswered as to whether cancellous bone has similar values of elasticity to those for cortical bone, where the macro-difference in behaviour is only attributed to differences in density. However since the values of cancellous bone reported [Jee, 2000] vary from 0.76GPa to 20GPa, a definitive answer is still not clear and it seems to be accepted that cancellous bone is 20% to 30% less stiff than cortical bone. In the same review, it has been reported that cancellous bone tissue has significantly lower fatigue resistance than cortical bone, with the implications in terms of mechanical behaviour and implant failure. Again, the different behaviour has been associated with the difference in the tissue microstructure.

Cancellous bone is believed to distribute and dissipate energy of contact loads and to be the mineral homeostasis for bone. It is mainly the reduction of cancellous bone that causes osteoporosis.

2.2.3 Bone functional adaptation

More than a century of research has increased understanding of the rules which regulate bone genesis and differentiation. Mechanical rules have been adapted to model these processes.

The first modern collaboration between an engineer (Culmann) and an anatomist (von Meyer) is presented in drawings by Culmann and von Meyer [1867], where the principal stress trajectories of a new design for a crane were compared to the lines of cancellous bone observed in the proximal femur. This supported the idea that bone formation may be regulated, in some manner, by external loading conditions. However, the same authors had doubts concerning the relationship between stress and bone formation and the role of dynamic loads was queried.

A few years later Wolff resumed the work presented by Culmann and von Meyer [Roesler, 1987]. Wolff stated that the shape and the structure of bone adapts itself to the physiological loads applied. This assertion has become the starting point for any bone-mechanics research.

Wolff also gave a mathematical formulation (Wolff's law) to the trabecular architecture based on the hypothesis that there is a one-to-one correspondence between the trabecular lines in the bone and the stress trajectories for a body with the same shape and load condition of the bone. To support his hypothesis Wolff modified the drawings presented by von Meyer changing the cross angle between the trabeculae lines from oblique to orthogonal.

Wolff's law does not justify how the bone structure can be compared with a continuous, linear elastic, homogeneous and isotropic body (i.e., the hypotheses of the stress trajectories theory). Therefore, the mathematical formulation has always been considered the weakness of this theory.

The reliability of Wolff's law has always been debated. This thesis will not cover this argument but will adopt Wolff's law as a philosophical statement for functional adaptation of bones.

2.2.4 Influence of age

Ageing of the population is a phenomenon that engenders worldwide concerns. Many studies have investigated the change in bone properties and the risk of fractures in relation to age. In the review by Jee [2000], preliminary results on human vertebra show that the elastic modulus of both cortical and cancellous bone decreases with age.

2.3 Bone fractures

Materials break when the induced stress exceeds the breaking stress and bone is not an exception. Fracture of bone can be a consequence of a simple fall, although there are many other situations that produce sufficient force to fracture bone. Causes of fractures and the distribution of fractures with age and gender, are discussed (see §2.3.1). Fracture classifications are presented (see §2.3.2) referring to those used in clinical practice and those based on the mechanical quantities (e.g., the type of force or the amount of energy) involved in the fracture.

2.3.1 Epidemiology of long bone fractures

Several studies have investigated the relationship between gender, age, type and causes of fractures. A comparison between each of these studies can be complex, bearing in mind that different hospitals use different coding systems and the typology of patients can be different between hospitals. However, it seems to be agreed that particular fractures are more likely to occur at a specific age for a specific gender [e.g. Court-Brown et al., 1998; Cordey et al., 2000] due to the degradation of the bone properties with age and to the level of activity sustained.

Court-Brown et al. [1998] present data for open long bone fractures, collected over a period of six years at the Edinburgh Trauma Unit. This unit served a population of 700,000. The patients treated were 66% male (average age 37 years old) and 34% female (average age 61). The fracture distribution between genders changes significantly for patients in their 50s, when the number of fractures for females becomes two to three times the number of fractures in males (which is initially four to five times higher) mainly due to the increased number of osteoporotic females at this age.. A similar distribution has been reported by Singer et al. [1998], Cordey et al. [2000] and Martinet et al. [2000] for specific bone fractures. The causes of fracture are summarised (see table 2-2).

Most fractures present a bimodal distribution with a first peak representing young males with high energy injuries and a second peak being due to elderly females with low energy injury.

Percentage of fractures	Cause
57.7	road traffic
19.0	simple fall *
9.7	fall from height
6.2	direct blow
4.5	sport accidents *
1.9	fall down stairs
1.0	caused by sharp object

(* injuries most commonly associated with distal radial fractures)

table 2-2: Percentage of fracture by cause based on information in Court-Brown et al. [1998]

2.3.2 Fracture classifications

Classification of fractures has always been in dispute; they are used to help to determine the best choice the treatment and for the evaluation of the treatment outcome. The importance of using a uniform code is clearly recognised, however the realisation of an unique code that considers all parameters related to a fracture has not yet been agreed.

Descriptive fracture classifications are most used in clinical practice today; while some of them provide an accurate representation of the fracture, others are more helpful for predicting outcome. Mechanical studies considering the amount of energy or the load condition have resulted in the establishment of two more methods of classifying a fracture.

2.3.2.1 Clinical classification

Several different descriptive fracture classifications are used nowadays. Although it is not the aim of this work to define these classifications, the general approach that is the basis of all classifications is presented.

A fracture is open (i.e., compound) or closed, depending on presence of soft tissue injury extending through the skin to the fracture site. Subsequently, a fracture is classified as simple or comminuted (i.e., multifragmented) depending on the number of breaks.

A more detailed categorization, specific to each bone, is represented by classifications such as Older, Frykman, Melone in the case of the distal radius. A universal and more comprehensive classification is represented by the AO classification. Each bone has a number. Then each part of the bone has a letter (i.e., A, B or C) and a subscript number (i.e., $_1$, $_2$, $_3$) is associated to respectively identify the morphological type of fracture and the fracture zone; fracture severity is indicated with an increasing number (i.e, 1, 2, 3).

It is not only bone damage that needs to be considered in identifying the most suitable treatment for each patient. Open fractures are often associated with severe soft tissue injury. A classification such as the Gustilo classification is used to describe these types of injury.

The overall severity of the injuries can be assessed using different global scores, such as the Injury Severity Score (ISS).

2.3.2.2 Energy absorbed

Due to the viscoelastic nature of bone, both strain and stress at fracture increase with the strain rate. In the physiological condition the strain rate value is smaller than $0.001 s^{-1}$, while during a fracture the strain rate value can reach $10 s^{-1}$ [Autefage, 2000]. Therefore, the amount of energy accumulated during a fracture increases significantly with strain rate. If the energy cannot be dissipated by a single fracture, several fractures occur, with possible soft tissue damage. The number and the shape of the fracture fragments are influenced by the amount of energy released. Based on the amount of energy liberated Autefege [2000] proposes classification of fractures into four groups (see table 2-3).

Energy of trauma	Description of fracture
low energy	spiral or short oblique fracture displacement smaller than diaphyseal diameter
moderate energy	fracture with small comminution displacement equal to diaphyseal diameter
high energy	fracture with severe comminution fracture with loss of fragments
very high energy	gunshot or crush fracture

table 2-3: Fracture classification based on the amount of energy (produced with reference to Autefege [2000])

At the Fifth Combined Meeting of the Orthopaedic Research Society (ORS) a new technique was presented [Anderson et al., 2004] to quantify the amount of energy from a CT-scan images in order to classify the fracture gravity on an energy scale. The basic principle is that the amount of energy is proportional to the fracture surface area and bone density. The technique has been validated, by comparing data taken from 11 patients with the response given by a clinician after radiographic assessment.

2.3.2.3 Load classification

It is possible to associate the type of load with the bone fracture geometry. Chao and Aro [1989] reported five load conditions (i.e., axial tension or compression, torsion, bending and shear load) that may overlap and combine. For each of these loads a particular fracture shape is identified (see figure 2-4). The basic hypothesis is that bone is stronger in compression than in tension and shear, and it is modelled as a transverse isotropic material (the properties along the transverse and radial directions are the same and weaker than the properties in the longitudinal direction).

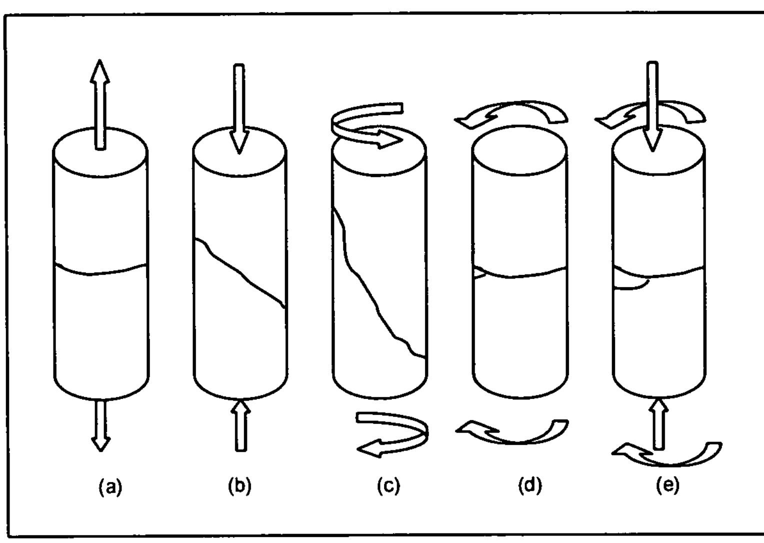


figure 2-4: Relationship between fracture pattern and load condition

A tensile force applied longitudinally produces a fracture line in the transverse direction (see figure 2-4 a), while a line at 45° to the load axis is produced by a compressive force (due to the combination of axial and shear breaking stresses - see figure 2-4 b). Torque produces a spiral fracture line around the bone (see figure 2-4 c), while bending produces a transverse fracture on the tension side and one or two oblique lines on the compression side (butterfly fragments - see figure 2-4 d). A large size of the butterfly fragment is associated with combined bending and compression loading (see figure 2-4 e).

2.4 Fracture healing process

The healing of fractures is a complex process that begins immediately following the bone fracture and ends completely months later. It is necessary to have a good knowledge of this process to provide better treatment; however, the process is still not fully understood. The two main healing patterns are considered (see §2.4.1). Several theories have been developed to simulate different stages of the healing (see §2.4.2) and experimental studies have been conducted to determine external factors that enhance the healing process (see §2.4.3).

2.4.1 Patterns of bone healing

Conventionally bone healing has been divided into two patterns: direct (or primary) and indirect (or secondary) processes (see §2.4.1.1 and §2.4.1.2). The first phase immediately following the bone fracture is the formation of the haematoma and this is common to both processes. The haematoma provides two important factors for the healing process [Prendergast and van der Meulen, 2000]; it guarantees a small amount of mechanical stability to the fracture site (in case of close fracture) and it brings all necessary agents for the repair process. At this stage the mechanical environment strongly influences the healing process [e.g., Carter et al., 1998; Lacroix and Prendergast, 2002]. The amount of movement at the fracture site distinguishes direct and indirect healing process [e.g., Goodship et al., 1998; Prendergast and van der Meulen, 2000].

2.4.1.1 Direct healing process

Direct healing occurs when there is little or no interfragmentary motion. Clinically this condition is achieved using internal fixation techniques (i.e., conventional plates), when the bone matrix of one fragment is compressed against that of the opposite fragment [e.g. Goodship et al., 1998; Prendergast and van der Meulen, 2000].

The mechanisms that induce this process are poorly understood [e.g., Chao and Aro, 1989; Goodship et al., 1998]. It is believed that the osteoclasts (bone reabsorbing cells) are activated along the longitudinal axis of the bone across the fracture line, forming what is called the cutting cone. Immediately following the osteoclasts, the osteoblasts and vascular buds are activated to form secondary osteons. Gradually the fracture line is obliterated by the formation of several secondary osteons.

During the direct healing process there is no formation of external or internal callus, small gaps, less than 1mm [Chao and Aro, 1989], are initially filled with woven bone, which is subsequently replaced by lamellar bone. The process is slow, the growth of secondary osteons starts months after the fracture and takes years to complete [Chao and Aro, 1989].

2.4.1.2 Indirect healing process

The indirect fracture repair process involves the formation of callus bone to minimise the relative movement between the fracture ends. This type of repair is faster, with bone union achieved in weeks or months [Goodship et al., 1998].

The indirect healing process is a sequence of biological stages, where cartilage is formed, calcified and replaced by bone tissue [Prendergast and van der Meulen, 2000]. However, the cellular and biological mechanisms that control the processes are still poorly understood [Goodship et al., 1998].

The bridging callus is compounded by a hard callus, produced by the periosteum and endosteum through intramembranous ossification, and a soft callus located under the hard bridging callus. It is within the soft callus that the tissue differentiation takes place (i.e., haematoma – granulation tissue – fibro tissue – cartilage – woven bone – lamellar bone).

Following the new bone formation, the anatomical shape of the bone at the fracture site is restructured over a long phase (i.e., months to years), referred to as callus remodelling [Goodship et al., 1998].

2.4.2 Healing models

During the first phase of fracture healing (i.e., the haematoma), in the fracture callus, there is a rapid proliferation of pluripotential tissue that will become bone, cartilage or fibrous tissue [Carter et al., 1998]. These processes are regulated by both biological and mechanical factors. However, the interaction between these factors is unclear [Carter et al., 1998].

Several models have been developed to investigate the influence of the stress state in the differentiation process and are examined subsequently (see §2.4.2.1, §2.4.2.2, §2.4.2.3and §2.4.2.4).

2.4.2.1 Pauwels' theory

As reported by Carter et al. [1998], Pauwels developed his theory of tissue differentiation based on many in-vivo experiments, recalling the ideas of Roux and Benninghoff in the early 1900s. Assuming that the tissue is a continuous elastic and isotropic material, Pauwels based his theory on the fact that a mechanical stimulus can generate a hydrostatic and a shear stress.

Pauwels noted how shearing forces produce a change in the shape of the tissue sample, while a hydrostatic pressure results in a change in volume [Prendergast and van der Meulen, 2000].

Comparing tissue samples with the assumption of the mechanical loading at the sample site, Pauwels concluded that hydrostatic compression is a specific stimulus for cartilage formation, while shear stress is the load condition for the development of connective tissue and a combination of both stresses generates fibrocartilage.

2.4.2.2 Interfragmentary strain theory

In a study conducted by Perren [1979] the author identified the amount of strain that a biological tissue is able to tolerate before break occurs.

Interfragmentary strain (IFS) has been defined by Perren as

$$\mathrm{IFS} = \frac{\Delta\ell}{\mathrm{L}} \qquad [2\text{-}4]$$

where $\Delta\ell$ is the deformation at the fracture gap under loading, and L is the original width of the fracture gap.

Perren theorized that the magnitude of the interfragmentary strain determines the sequence of the tissue differentiation in the fracture gap. New tissue can be generated in the fracture gap only if it can tolerate the current interfragmentary strain.

Based on experiments by Perren [1979], interfragmentary strain between 100% and 10% leads to initial fibrous tissue formation. Strain between 10% and 2% leads to cartilage formation, while interfragmentary strains below 2% lead to direct bone formation.

It should be noted that Perrens's hypothesis only includes the influence of longitudinal strains, without considering the strains in all three orthogonal directions and shear strains. These additional strains may reach the break limit before the longitudinal strain [Gardner and Mishra, 2003].

2.4.2.3 Osteogenic index and pressure model

Considering the stress state advocated in work by Pauwels, Carter et al. [1988] proposed classifying the mechanical stress into two conditions: hydrostatic and octahedral shear stress.

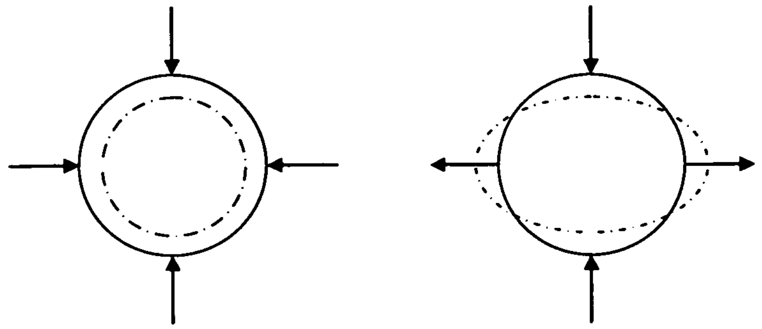
Hydrostatic stress is given by

$$D = \frac{1}{3}\left(\sigma_x + \sigma_y + \sigma_z\right) \qquad [2\text{-}5]$$

and the octahedral shear stress is given by

$$S = \frac{1}{3}\sqrt{\left(\sigma_x - \sigma_y\right)^2 + \left(\sigma_x - \sigma_z\right)^2 + \left(\sigma_y - \sigma_z\right)^2 + 6\left(\tau_{xy}^2 + \tau_{yz}^2 + \tau_{xz}^2\right)} \qquad [2\text{-}6]$$

where, σ_x, σ_y and σ_z are the normal stresses and τ_{xy}, τ_{yz} and τ_{xz} are the shear stresses. A pure hydrostatic stress consists of equal normal stress in all directions, while a pure shear stress is given by stresses which are equal, converging in one direction and diverging in the perpendicular direction (see figure 2-5).



(a) compression hydrostatic stress

(b) shear stress

figure 2-5: Deformations under hydrostatic and shear stress

A differentiation model characterised by the stress state and by the vascular supply was proposed by Carter et al. [1988]. In the case of good vascular supply to tissue, bone is believed to form directly if minimal hydrostatic stress is present. Meanwhile fibrocartilage would form if high compressive hydrostatic stress is present. In the latter case, a subsequent shear stress would lead the fibrocartilage to differentiate in bone (see figure 2-6 a). Fibrous tissue is instead generated when high tensile hydrostatic and shear stress are present. If the fracture gap has poor vascularity, cartilage would form in place of bone (see figure 2-6 b).

To examine the tissue differentiation in the fracture callus, Carter et al. [1988] and Blenman et al. [1989] (respectively, for an early and later healing stage) associated an osteogenic index with computer simulation (finite element models). To consider the entire loading history (e.g., an "average" day) in terms of the number of loading cases (c). The osteogenic index (I) has been calculated as

$$I = \sum_{i=1}^{c} n_i \left(S_i + kD_i\right) \qquad [2\text{-}7]$$

where, S_i and D_i are respectively the octahedral shear and hydrostatic stress (as defined in [2-5] and [2-6]), n_i is the number of loading cycles (from 1 to c) and k is an empirical constant, weighing the relative contribution of the two types of stress.

A high value of I is believed to predict osteogenesis or fibrogenesis, while a low I value is associated with cartilage. Comparing the computational results with experimental findings from previous investigations the value of k was determined; a k value greater or equal to 2.0 appears to match best previous experimental studies. This result suggests that hydrostatic stress has more influence on tissue differentiation during fracture healing. The ossification pattern has also been investigated and it is reported that there is an initial tendency to ossify starting from a wedge-shaped region in the outer callus.

An attempt to give quantitative boundary values to tissue differentiation has been made by Claes et al. [1998]. As with the theory advocated in Carter et al. [1988] and Blenman et al. [1989], the theory presented by Claes et al. is still based on the Pauwels' assumption of tissue differentiation. In contrast to the work of the previous authors Claes et al. believe that new bone formation (either intramembranous or endochondral) occurs only on existing bone surfaces or calcified cartilage, under a defined range of strain and pressure. Comparing animal experiments with finite element models and cell culture studies, Claes et al. report that for strain less than 5% and compressive hydrostatic pressure smaller than 0.15MPa, intramembranous ossification occurs. Endochondral ossification occurs for compressive hydrostatic pressure greater than 0.15MPa and strain less than 15%. All other load conditions lead to connective tissue or fibrous cartilage.

The predictive performance of the Claes et al. theory based on measured and calculated data from a human, diaphyseal tibial fracture, has been tested by Gardner and Mishra [2003]. Claes et al. successfully predicted the healing pattern at the interfragmentary gap and at the periphery of the periosteal callus during the healing process. Although, the pattern predicted for the main periosteal callus was incorrect for the early healing stage, it was correct for the late healing process.

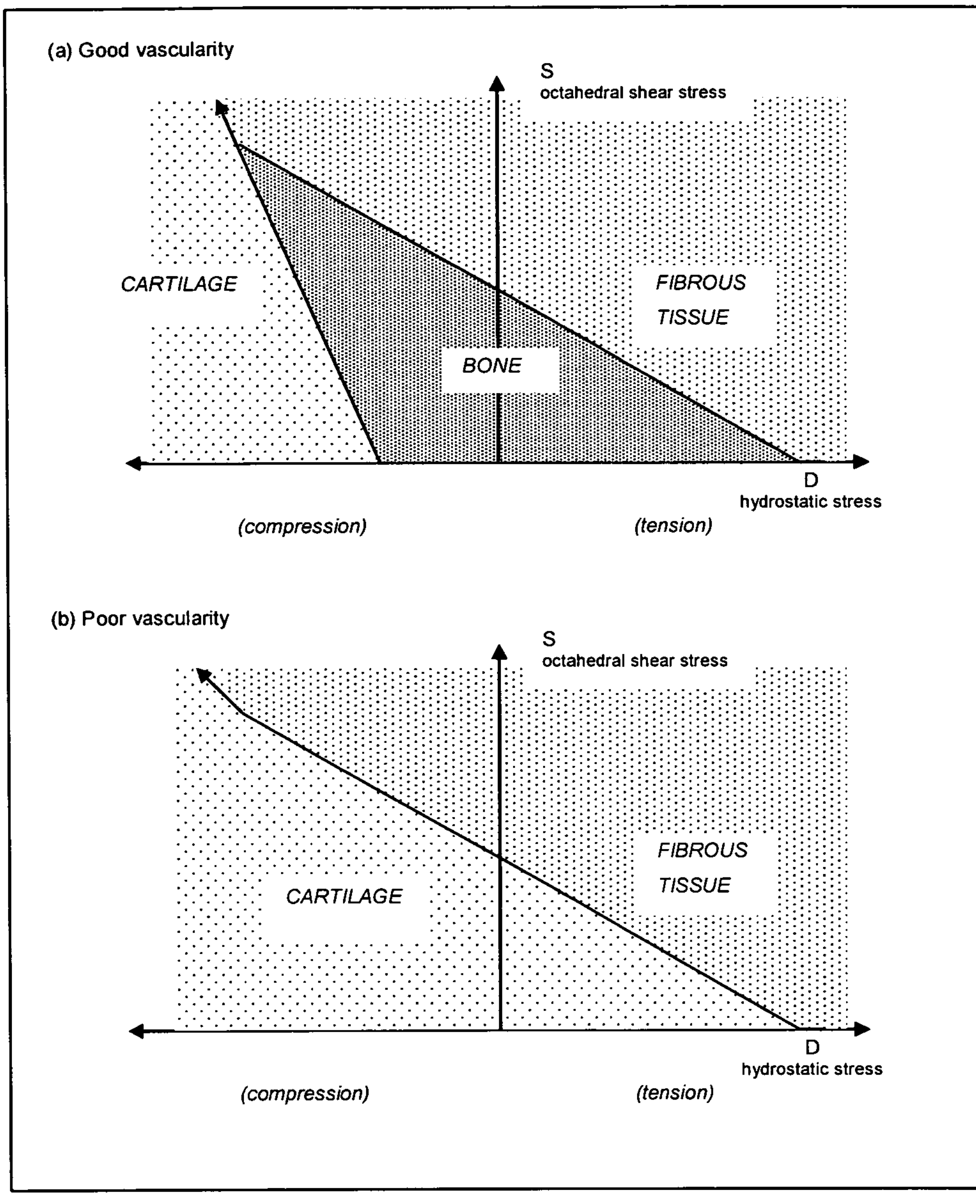


figure 2-6: Bone differentiation model proposed by Carter et al. [1998]

2.4.2.4 Fluid flow considerations

Bone is a multiphase material consisting of a solid and a fluid phase. The above models (§2.4.2.1, §2.4.2.2, §2.4.2.3) have considered bone as a solid elastic material and in these models the bone differentiation is based on the macroscopic load-deformation response of the solid phase. However, when the bone tissue is loaded the fluid component may flow and cause a complex mechanical condition (i.e., due to pressure), potentially greater than that developed by the solid matrix [Lacroix and Prendergast, 2002]. Prendergast and van der Meulen [2000] have reported several in-vitro studies that consider the stimulus of the fluid flow on the bone cells. Following Pauwels and the interfragmentary theories, high fluid flow increases the mechanical stresses and decreases the potential for tissue differentiation in the case of each tissue type. If the fluid flow, becomes low the cells may begin to differentiate (see figure 2-7).

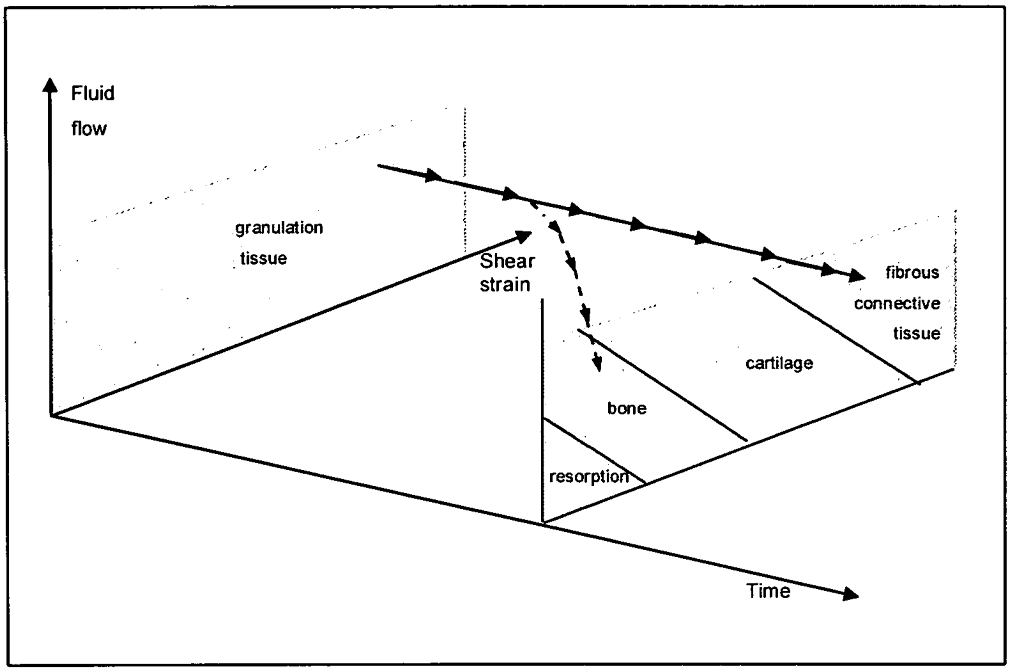


figure 2-7: Bone tissue differentiation due to fluid flow

2.4.3 Proposals for enhanced fracture healing

Various techniques have been proposed for achieving enhanced fracture healing and quantifying the optimum mechanical environment at the fracture site for the different stages of the healing process. The type of fixation device and the musculoskeletal loading determine the mechanical environment at the fracture gap [Prendergast and van der Meulen, 2000].

In a comparative experimental study on sheep, Goodship and Kenwright [1985] established that cyclic axial motion induced an early ossification and more rapid healing, based on an increase in bone stiffness. Similar findings have been obtained by Kenwright et al. [1987] in a study of human tibial fractures, suggesting that a range of 0.5mm-1.0mm displacement, applied at 0.5Hz for 30min per day, accelerated fracture healing process in adult tibial shaft fractures by 24% (based on bone stiffness). This is with respect to fracture healing where there was no motion applied. A bigger displacement range (i.e., 0.5–2.0mm) has been investigated by Kelly et al. [1987] at the same frequency (i.e., 0.5Hz) for a shorter application period (i.e., 17min). The results underlined that while small displacements (i.e., 0.5mm) enhanced the healing process, bigger displacements (i.e., 2.0mm) were harmful. A frequency of 0.5Hz was choosen as it is considered [Kenwright and Goodship, 1989] to represent the frequency of normal walking.

The optimal amount of displacement within a 1mm range has been investigated by Wolf et al. [1998] in a comparative experimental animal (i.e., sheep) study. Although the callus formation increases with increased displacement, the higher bending rigidity and bone mineral density were obtained in the group subjected to 0.4mm displacement. However the difference between groups was not significant, and this led the authors to believe that the amount of movement during normal weight bearing (due to the flexibility of the fixator) has greater influence than the applied stimulus.

Reproducing the same experimental condition of Goodship and Kenwright [1985] (e.g. with the same type of sheep, osteotomy size, fixator configuration, duration and frequency of displacement application), Gardner et al. [1998a] investigated the effect of reducing displacement across the fracture gap during healing. The reduced displacement amplitude was proportional to the increased rigidity of the fracture gap and this produced a more rapid healing.

However, the amount of displacement is not the only factor to consider. Frequency of the displacement applied, time to commence the application, stiffness (or rigidity) of the fixation system, gap size, may also have a considerable influence [e.g., Goodship et al., 1985; Gardner et al., 1996; Chao et al., 1998; Kenwright and Gardner, 1998; Cunningham 2001].

Some of these variables have been investigated by Kenwright and Goodship [1989] and Goodship at al. [1993] in an experimental study on sheep, this was followed by a clinical study. In the animal testing, the same experimental conditions reported in Kelly et al. [1987] were used and the influence of the fixator rigidity was investigated. The results confirm the outcome of Kelly et al. [1987] regarding the influence of the displacement range and they show that a greater callus volume was obtained with less rigid fixators. From the ovine and clinical results (where 1mm displacement is applied at 0.5Hz for 30min per day) it was deduced that an early application of displacement (during the first week after operation) was important in enhancing the fracture healing process.

The influence of the frequency of the applied displacement has been examined by Goodship et al [1998] in an experimental study on sheep using three different displacement rates ($2mms^{-1}$, $40mms^{-1}$ and $400mms^{-1}$ for a 0.5mm displacement across a 3mm gap). A greater formation of periosteal callus (examined from radiography) and a higher value of in-vivo stiffness was obtained with the highest displacement rate ($400mms^{-1}$). However, it was interesting to note that the application of the moderately high displacement rate ($40mms^{-1}$) produces a significantly higher value for torsional stiffness and strength (examined post-mortem), and bone mineral content. This discrepancy may be explained by considering the more complex pattern of loading involved in the in-vivo measurements, compared with the pure torsion loading, that was used in the post-mortem tests. However, the results show that the healing process was enhanced by a moderately high displacement rate. This study has also confirmed that an early application of the displacement (i.e., one week after operation) improved the healing process. Delaying the mechanical stimulation until after the initiation of ossification eliminated the positive influence of cyclic loads.

The influence of the gap size has been investigated by Claes et al. [1997] and Augat et al. [1998] with respect to the bending stiffness and tensile strength during a comparative experimental study on animals (i.e., sheep). Their results indicated that increasing the gap size reduces the mechanical properties of the callus. Comparing the influence of the gap size with that of the initial interfragmentary strain, Claes et al. [1997] and Augat et al. [1998] also indicated that the gap size had a dominant effect on the healing process. In the same study the authors also investigated the influence of the callus area and found that a larger callus does not necessarily lead to greater mechanical stability. In a histological investigation

Augat et al. [1998] found that the percentage of bone tissue decreased with increasing gap size and the amount of calcified cartilage and bone tissue also decreased with increased interfragmentary strain.

Lack of correlation between callus size and bending stiffness has also been noted in a comparative, human study conducted by Marsh [1998] on tibial shaft fractures. Furthermore, Marsh [1998] indicated that stiffness measurements correlated better than callus size with injury severity and functional outcome.

In a review conducted by Kenwright and Gardner [1998] the authors investigated the mechanical conditions presented during the healing of tibial diaphyseal fractures. The review compares the in-vivo mechanical condition with the ideal conditions recommended in the previous experimental studies. A finite element model predicted the stress-strain state during the healing process based on interfragmentary movements under weight bearing conditions. The authors found that at the initial healing stage, due to the high rigidity of the external frames, interfragmentary movements can be much lower than those considered ideal. A late callus and bone formation was a consequence of this condition. Increasing patient activity produced a greater movement amplitude. However in the late phase of healing, the computational model predicted high stress and strain that may damage the tissue differentiation. Therefore, the authors suggested that the rigidity of the external fixation should be increased until the fracture has healed and the frame can be removed.

2.5 Fracture treatment

The previous section (see §2.4) has underlined how the technique of stabilization influences the healing process. The aim of this section is to review the main methods used to treat fractures. In particular considering the biomechanical aspect associated with each treatment, such as location of fracture site; loading which needs to be withstood; and type of injury.

The main objectives during fracture stabilization are to maintain reduction, to allow an early function of the limb and to create favourable mechanical and biological conditions to assure that the healing takes place. All these conditions are important for a successful healing but

the early motion of the limb is essential to avoid the loss of function of adjacent joints, muscles and soft tissues, which are the most disabling complication [Cunningham, 2001].
This section introduces cast treatment (see §2.5.1) and internal fixation (see §2.5.2). External fixation (see §2.6) is reviewed separately as it is the treatment used to stabilize distal radial fractures in this study.

2.5.1 Cast treatment

The use of casts has been the most common form of fracture treatment for hundreds if not thousand of years. It is only recently that more invasive techniques have been developed to treat injuries associated with the modern and industrialised society [Cunningham, 2001].

Casts act as a rigid shell to restrict the displacement of soft tissue and consequently the movement of the bone fragments, when a load is applied [Cunningham, 2001]. However, due to the deformability of the tissue between plaster and bone, movements may still be possible, primarily in the axial direction [Perren, 1979].

Casts are suitable for simple and stable fractures. Angular alignment is controlled using the principle of three-point fixation, however, in order to control rotation it is necessary to include the joint above and below the fracture [Cunningham, 2001]. It has been shown [Sarmiento et al., 1974] that the cast is only able to carry a small percentage (15%) of the load applied. Therefore, the majority of the load applied is supported by the bone with possible negative consequences (e.g., inhibition of the healing process, or non union).

2.5.2 Internal fixation

Internal fixation treatments include screws (see §2.5.2.1), plates (see §2.5.2.2) and intramedullary nails (see §2.5.2.3). In comparison with the cast treatment internal fixation techniques allow the earlier use of the fractured limb without loss of reduction due to the higher rigid stabilization achieved.

2.5.2.1 Screws

Screws are used to compress two (or more) fragments of bone together, to allow direct healing to take place. The ideal screw should produce a high level of compression between fragments (interfragmentary compression), relatively low values of tensile stress within the screw and low values of shear stress in the adjacent bone, to avoid a fracture of the screw or a pull out of the screw from the bone [Cunningham 2001].

Designs of screws are specified to maximise the holding power considering different outer and inner diameter size, the thread form and the pitch of the thread. However, the properties of the bone into which the screw is inserted as well as the depth of the thread into the bone have the greater influence on the holding power. As reported by Cunningham [2001], it has been shown that pre-tapping into cancellous bone reduces the holding power while in cortical bone this increases the holding power. To increase the holding power in cancellous bone a fine thread with a small inner diameter and large outer diameter is required.

Care should be taken when creating the pilot holes for the screw. Too small a pilot hole leads to a high level of torque to insert the screw and possible radial cracking of the bone, while too large a pilot hole diameter reduces the holding power of the screw. In the Cunningham [2001] review a pilot diameter between 85% and 90% of the outer screw diameter has been suggested.

2.5.2.2 Plate fixation

Plate fixation is based on the same principle of interfragmentary compression as for screws. In addition a rigid plate and its position close to the bone increases the rigidity of this technique. Direct healing is therefore achieved using this type of fixation and if callus formation is detected this should indicate some instability or failure of this technique [Cunningham, 2001].

In an experimental in-vivo animal study conducted by Perren [1979] the author indicates that although the interfragmentary compression is reduced within the first week of treatment, a significant level of compression remains until the end of the treatment.

Different materials have been proposed for the plate with increasing interest in bioresorbable polymers. However, the lower strength compared to metals and the loss of stiffness in too short time are the primary limitations to the use of these materials, as reported in Cunningham [2001].

2.5.2.3 Intramedullary nails

Intramedullary nails have been indicated as one of the most effective treatment for diaphyseal tibial and femur fractures [e.g., Cunningham, 2001; Court-Brown et al., 2003]. Intramedullary nails reduce, but do not eliminate the interfragmentary motion, in particular they resist the bending load but allow some axial movements. Indirect healing, with callus formation is therefore achieved using this technique.

The rigidity of this type of fixation is influenced by the contact area between the nail and the bone, as well as the rigidity of the nails. Reaming the bone before inserting the nail increases the bone-nail contact surface. The material and the cross section area of the nails influence its rigidity. Thin walled tubular nails are the most often used, although open section is also common [Cunningham, 2001]. Bending resistance is proportional to the fourth power of the diameter of the nail, and this should be considered when choosing between hollow and solid nails (which are usually thinner). Comparing nails with the same diameter, open and closed sections offer a similar bending stiffness, although open sections are weaker in torsion.

2.6 External fixation

In this research the healing of distal radial fractures treated with external fixation is investigated. This section introduces the reader to the external fixation treatment, starting with a brief outline of the history and development of this technique (see §2.6.1), an overview of different configurations of external fixators used today (see §2.6.2), the mechanical behaviour and synopsis of the literature review (see §2.6.3). It is not the aim of this research to consider the insertion procedure for external fixation.

2.6.1 History of external fixation

Almost 2400 years ago Hippocrates [Peltier, 1989] described a method of external fixation. Although there were no pins placed through the bone, the fixator addressed the two main characteristics of external fixation: to immobilise a fracture and, at the same time, to allow a soft tissue injury to be treated.

In 1847 the concept of external fixation was revisited [Green, 1989]: Malgaigne developed a semicircular metal arc with a screw passing through a slot. The fixator was specifically designed to reduce fractures of the patella, however, the device simply punctured the surface of the bone. It was around 1900 that "modern configurations" of external fixators were developed. Parkhill (Colorado, USA) and Lambotte (Belgium, Europe) developed devices that comprised threaded pins implanted in bone fragments, externally connected with plates [Green, 1989].

Initially (circa 1900) external fixation was mainly applied for treatment of animals (dogs). It was not until World War II that external fixation techniques were extensively used for treatment of humans. It was at this time that Hoffmann (1938) developed his innovative external fixator using universal ball joints in pin-gripping clamps. This fixator became one of the most popular models in the west [Green, 1989], while in the USSR the circular fixation introduced by Ilizarov was predominant.

In the last two decades external fixation has become one of the most effective and versatile methods for stabilizing complex injuries of soft tissue and bone [Behrens, 1989]. This is due to new techniques of pin care and, to an increased understanding of the mechanical behaviour and concepts that regulate a safe and effective application of these frames.

2.6.2 External fixation configurations

Various designs of external fixation have been developed since their first appearance. In all configurations the bone fragments are secured to the external frame to provide support to the fractured bone.

Bone fragments are fixed to the external frame using pins or wires which are generally made of stainless steel. The diameter should not be bigger than one third of the bone diameter to avoid pin hole fracture [Behrens, 1989]. Wires are mainly used for circular frames. Longitudinal rods are used to provide support to the frame and they are made of metal or composite materials. Some rods may have telescopic elements to fix different bone lengths and, or, allow axial dynamization. Articulations or joints are used to connect pin to pin, pin to rod, rod to rod, pin to ring and ring to rod. Clamps are used to connect two or more parallel pins to a rod, usually through a joint.

Fixator configurations are divided in two main groups: pin and ring fixator. In this research, distal radial fractures are treated with pin fixation. Therefore the term fixator will be used to refer to this type of frame. To refer to circular fixation the term ring fixator will be used.

Pin fixators are assembled using different configurations (see figure 2-8) in respect to the geometry of fracture and the level of stability to be achieved. In this research, distal radial fractures were treated using the unilateral configuration.

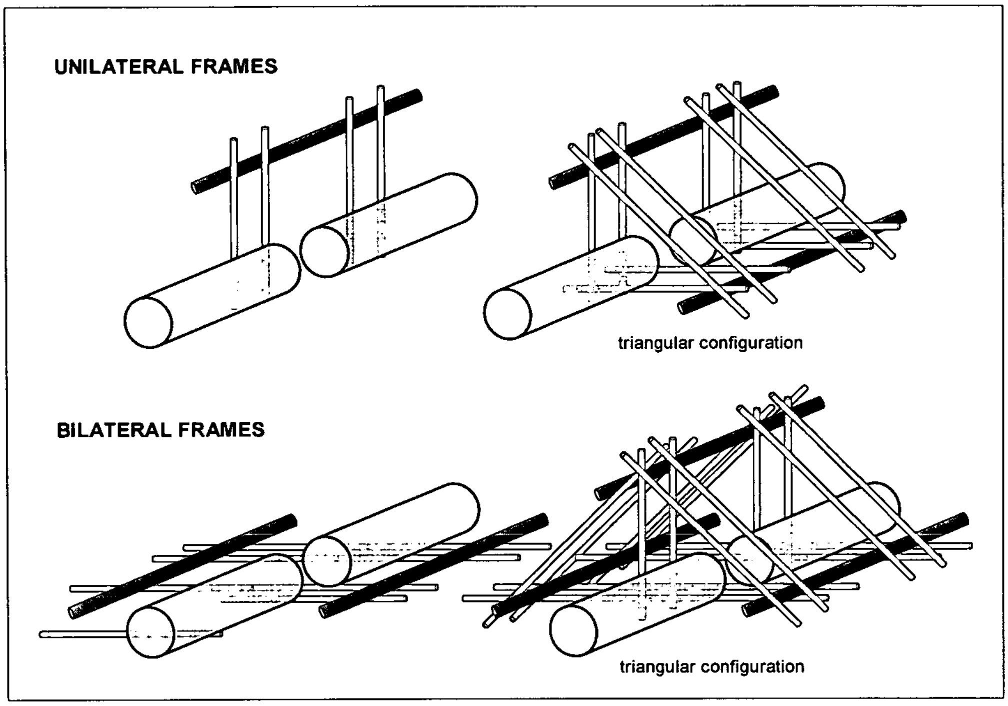


figure 2-8: Pin fixator configurations

2.6.3 External fixator behaviour

Load-displacement data for each configuration of external fixator follows the elastic-plastic behaviour seen in §2.1.1. A loss of reduction at the fracture site is produced when the load on the fixator exceeds the yield load and the fixator reaches the plastic zone [Cunningham, 2001]. The rigidity of the fixator depends on the components used, on the geometrical configuration and on the level of stability created at the fracture site. The main factors that influence the fixator rigidity have been examined by Chao and Aro [1989] and Cunningham

[2001] and are summarised (see table 2-4). The slight difference in the order of importance between factors can be due to the different conditions used during the tests.

Chao and Aro [1989]	Cunningham [2001]
Screw diameter	Number of screws
Bone-fixator column distance	Screw diameter
Number of screws	Bone-fixator column distance
Screw separation distance	Screw separation distance
Pin group separation	Rigidity of the fixator column

table 2-4: Factors influencing frame rigidity, in decreasing importance order

Bilateral frames are generally more rigid than unilateral frames and using a triangular configuration increases the fixator stability up to seven times [Behrens, 1989].

For the ring fixator the rigidity depends on the tension in the wires, the separation distance of the rings on either side of the fracture and the size of the ring used [Chao and Aro, 1989; Cunningham, 2001].

The knowledge of the mechanical properties of each external fixator is essential for the choice of the treatment and frame configuration to be used. A significant amount of work has been done to investigate the mechanical behaviour of these devices under in-vitro and in-vivo conditions and they are summarised below.

The aim of this research is to measure the rigidity of the new callus for distal radial fractures treated with external fixation. The measurement device should be able to work immediately post operation (i.e., within one-two weeks post operation) when it is not advisable to remove the frame to carry out the test. Therefore it is important to understand how the external frame acts during the healing process if a rigidity value of the new callus has to be calculated. Adapting the interfragmentary strain theory (e.g. Perren, 1979), it is accepted (e.g., Evans et al. [1985]; Chao and Aro [1989]) that, at the early stage of fracture repair, the external frame carries most of the load since it is much stiffer than the initial tissue in the fracture gap. As the fracture callus becomes stiffer, it starts to share load with the external fixator. Since the fixator stiffness is the same during the treatment (if it has not been modified by the surgeon), and the callus stiffness increases, the overall stiffness of the compound system (i.e., the. bone and external fixator) increase reducing the strain at the fractured gap, allowing bone differentiation to take place.

Several studies reported by Chao and Aro [1989] on different frame configurations indicate an axial rigidity value between 20N/mm and 40N/mm. However, the frames considered were mainly those used for lower limb (e.g. tibia) and therefore, the axial rigidity of the fixator used to treat distal radial fractures in this research has been calculated for different frame geometries (see §4).

In clinical practice, mechanical failure for modern external fixation is rare and the most common weakness is represented by the interface between the bone and the screws. Pin infection is a common cause of this failure and cyclical loading of the screw has been reported [Cunningham, 2001] to increase the incidence of screw loosening over unloaded or statically loaded screws. Dynamization of the external fixator reduces the pin bending load and, consequently, the risk of failure at the screw-bone interface [Chao and Aro, 1989].

The influence of dynamization on the healing process has also been investigated in an animal (i.e., sheep) study conducted by Claes et al. [1995]. A custom made external fixator was developed to allow only axial displacement in the osteotomy gap. Histological and mechanical testing were performed after nine weeks. Greater mechanical quality of the new callus and a larger cross sectional area of the callus led the authors to believe that dynamization of external fixation enhances the healing process.

The performance of five unilateral tibial external fixators were investigated in a comparative in-vitro study [Gardner et al., 1996a] during five virtual stages of healing (simulated with the introduction of materials with different rigidity in the fracture gap). The fixators were tested in both locked and unlocked (e.g. axial dynamization) mode, for the simulation of the well-supported (e.g. stable) fracture, and only the lock mode for the unsupported (e.g. unstable) model. A combination of an eccentric axial load (220N at 16mm from the longitudinal axis) with torsion (2Nm), applied by pneumatic drivers at 1Hz for 10000 cycles, was adopted to simulate the walking action. The results show that during the early stage of fracture repair (≈ 2-4 weeks) the mechanical proprieties of the fixator are important since, at this stage, it is mainly the frame rigidity that resists the load. When the rigidity of the fracture gap increases the external fixator contribution becomes negligible and the degree of weight bearing has a dominant influence on the fracture motion.

The failure behaviour of the five unilateral tibial external fixators was examined in a later study [Gardner et al., 1997]. The frame failure was investigated using an axial constant rate (i.e., $50\text{mm}\cdot\text{min}^{-1}$) and only the unstable fracture with locked fixators was considered. For fatigue failure the walking action has been simulated adopting the same arrangements outlined by Gardner et al. [1996], the fixators are tested in both locked and unlocked condition, for the simulation of the unstable fracture and only in the unlocked condition for the stable fracture. The results showed that for these fixator models the frame failure occured with a load value much smaller than the average human weight (i.e., 650N). Therefore, full weight bearing was not recommended during the early stage of the fracture healing. The fatigue test did not show a marked loss of stability, although the result did not deny the possibility.

During in-vitro testing Gardner et al. [2001] compared the mechanical properties of two external fixators mainly designed for a rapid application against the mechanical behaviour of three more conventional external fixators. External fixators for a rapid application require less instruments (i.e., power drill, image detector) and they may be used in a field hospital, in a disaster or battlefield scenario. The load used to simulate walking conditions was similar to that used in previous studies (i.e., Gardner et al., 1996; Gardner et al., 1997). The rigidity of both external fixators was significantly lower than the conventional fixators and therefore, they were not recommended for weight bearing.

In-vitro and animal testing gives a preliminary understanding of the behaviour and influence of these frames on fracture healing. However, the load and boundary conditions applied were unlikely to recreate the real environment for the human fracture healing process. In-vivo testing on humans avoids the difficulties arising from laboratory testing. However, different problems such as sample size and fracture geometry may compromise these tests. In an in-vivo comparative test, Gardner et al. [1998b] investigated the influence of two different configurations of external fixators. Although the sample size was not large enough to support any statistical difference between the two frames, the results suggest the type of fixator used does not influence the patient weight bearing and the interfragmentary displacement compared to the influence of the patient gait and type of fractures.

The influence of dynamization of external fixators has been examined in an in-vivo study [Gardner et al. 1996b] at the sixth week, during walking on ten patients with diaphyseal tibial fracture. Data show that there was no significant difference in the interfragmentary motion before and after dynamization although monitoring some patients for an hour after dynamization, the authors found a significant gap shortening. However, these results are relevant for dynamization of the external fixator at the sixth week of treatment and different findings may be obtained if unlocking the frame earlier or later than six weeks.

2.7 Distal radial fractures

Fractures of distal radius represent one of the most common fractures. The bone geometry and the more usual fracture patterns are described (see § 2.7.1). The majority of fractures of the distal radius are considered to be classic osteoporotic fractures, although a significant number of children also incur these fractures. The epidemiology of distal radial fracture is introduced (see §2.7.2). Treatments for distal radial fracture, in particular external fixation, are examined (see §2.7.3).

2.7.1 Location of distal radial fractures

The radius is one of two bones (i.e., radius and ulna) present in the forearm. In respect to the distance from the trunk, distal refers to the end for fractures away from the trunk, thus distal radius is the end closest to the wrist joint, while, the proximal radius is the end closest to the elbow joint. Being at the end of a long bone, the distal radius is mainly made up of cancellous bone, with consequently lower mechanical properties and better vascularization compared to the diaphysis of the radius.

The radius is part of a complex anatomical structure that requires coordination between muscles, tendons, bone and joints to enable movements of the wrist and hand. The wrist mobility and capacity to support loads depend on both osseous and ligamentous integrity.

X-Rays are the main examination method used to diagnose a distal radial fracture. Palmar tilt, radial angulation, radial length and radial shift are common measurements made on the X-ray and are used to describe the fracture (these are illustrated in figure 2-9). Distal radial fractures can be classified using the AO classification. However, it is still quite common to use the name of the people who described the fracture (e.g., Colles fracture – for fracture fragments displaced dorsally, Smith's fracture – for fracture fragments displaced palmarly, Barton's fracture – intra-articular fracture with dislocation of the radiocarpal joint).

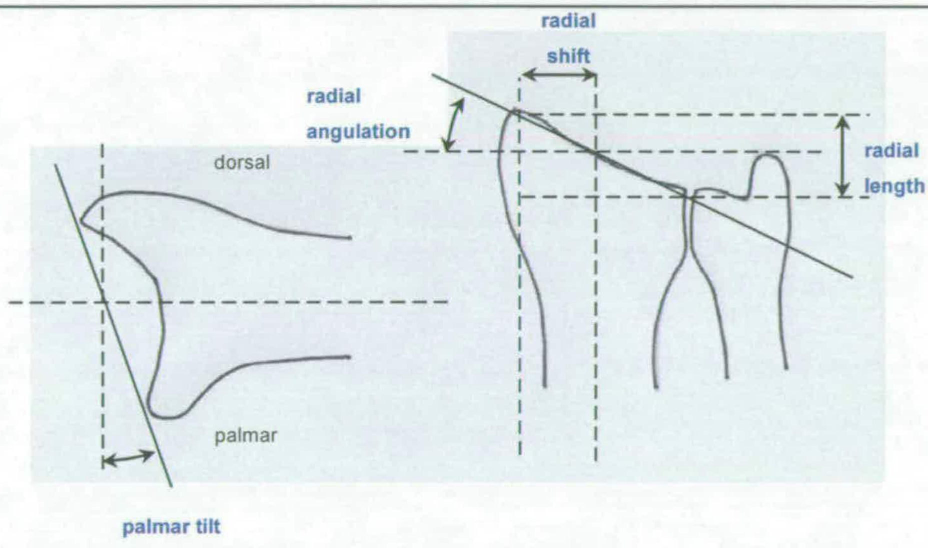


figure 2-9: X-ray measurement to describe distal radial fractures

2.7.2 Epidemiology of distal radial fractures

The distribution in the occurrence of distal radial fractures with age and gender is similar to that seen for long bone fractures (§ 2.3.1), with a bimodal distribution representing the elderly and young population. In a long term (24 year) retrospective study reported by Oskam et al. [1998] the highest peak was in the age group above 79 years old (with a male-female ratio of 1 : 4) and the second peak was in the age group below 9 years old (with a male-female ratio of 1 : 1). A similar class of age for the highest peak was reported in the studies conducted by Singer et al. [1998] and Thompson et al. [2004].

The variation in the incidence of distal radial fractures related at different time of the year is examined by Wareham et al. [2003] and the frequency of these fractures is related to seasons and shows a different pattern for different age groups. In children (i.e., below 15 years old) distal radial fractures occurred predominately in the summer months when better weather encourages outdoor activities. While in the group above 75 years of age the peak of fracture incidence was in the winter, when ice and bad weather increase the chance of falling. January and August peaks in incidence of distal radial fractures are also reported in the study conducted by Thompson et al. [2004].

The bigger number of distal radial fractures in the elderly female population suggests that there is a strong relationship between these types of fractures and osteoporosis [Hegeman et al. 2004]. However, previous studies reported by Graff and Jupiter [1994] indicate that women with distal radial fractures have similar bone mineral content of an age-matched control group and suggest that the distribution of distal radial fractures follows the pattern of falling in the ageing population. Owen et al. [1982] and Mallmin et al. [1993] have examined the relation between these kinds of fractures and the occurrence of hip fractures and found a positive correlation.

2.7.3 Distal radial treatments

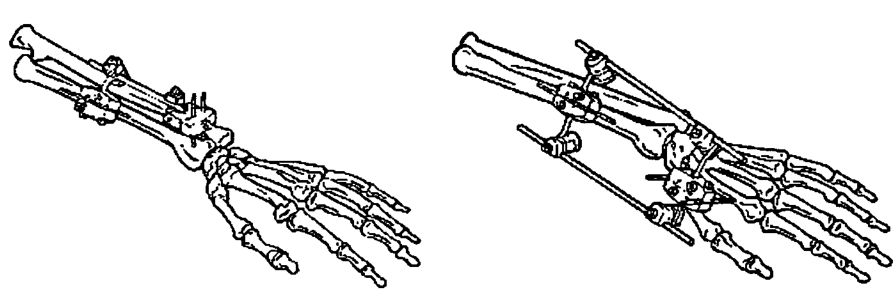
Fracture type is not the only factor considered in the choice of the stabilisation device; bone quality, soft tissue injuries, patient lifestyle and medical conditions also have significant influence. Increased life expectations and quality have contributed to the development of several techniques aimed at restoring the wrist anatomy and functionality.

Plaster cast immobilization is used for simple stable fractures, however, redisplacement of the fracture and residual stiffness of the joint are common [e.g., Clyburn, 1989; Graff and Jupiter, 1994; McQueen et al., 1996 and 1998]. To maintain the reduction a combination of wires or pins and plaster has been developed [Graff and Jupiter, 1994]. However, pin track infections are common since pins under plaster cannot be inspected and cleaned.

For complex, unstable fractures internal (e.g., screw and plates) and external fixations are adopted. As for all the other bone fractures, there is not a fixed algorithm to be used to identify the most suitable treatment and surgical experience and preference remains the significant factor in the choice of the treatment. However, when the fracture is too comminuted, or the distal radial bone is too soft to allow interfragmentary compression through the screws, external fixation may be preferred [Clyburn, 1989].

It is not the aim of this research to discuss the choice of the fixation technique. External fixation is examined since this is the main treatment used to hold distal radial fractures at the Royal Infirmary of Edinburgh, where this research has been conducted.

According to the position of the pins, external fixation for distal radial fractures can be classified as non-bridging and bridging fixators. Non-bridging external fixators are characterized by one set of pins inserted in the diaphysis of the radius and a second set of pins in the distal radius (see figure 2-10 a). Bridging external fixators act as a bridge on the wrist, with one set of pins inserted in the distal radius and the second set attached to the second metacarpal bone of the hand (see figure 2-10 b). Non-bridging external fixation does not restrict the motion of the wrist, and it is preferred as it reduces joint stiffness. However, depending upon the location of fracture, the space at the distal end of the radius can be limited and may not allow the insertion of the pin set. Dynamic bridging external fixators have been developed with the aim of allowing wrist motion while maintaining the reduction using a locking ball joint system; however, there is a debate as to whether these fixators achieve this.



(a) non bridging external fixator (b) bridging external fixator

figure 2-10: External fixation configuration for distal radial fractures
(produced with reference to www.stryker.com)

In a prospective randomised study conducted by McQueen et al. [1996] four different fixation techniques (plaster (1), open reduction and bone grafting (2), bridging external fixation with (3) and without (4) dynamization of the wrist at three weeks) have been compared. The four techniques have been assessed with reference to the anatomical and functional outcomes. The best dorsal angulation was obtained with the open reduction, followed by external fixation (with and without dynamization). Palmar tilt and carpal alignment were not restored with any of the four treatments, although they were indicated as the most important factors for a good functional outcome. In fact, functional outcome was not satisfactory for any of the four methods and, regarding external fixation, mobilization of the wrist did not improve the range of movements or hand functions.

Following the previous study [McQueen et al. 1996], the palmar tilt and carpal alignment together with the functional outcomes have been investigated to compare bridging (without dynamization) with non-bridging external fixation [McQueen, 1998]. Significant improvement for the non-bridging group was found in all stages of the assessment (six weeks, three months, six months and one year) and therefore non-bridging external fixation has been suggested as the best treatment for unstable fractures of the distal radius.

Non significant differences between dynamic bridging and non-bridging external fixation were described by Krishnan et al. [2003] following a prospective randomised study using functional outcomes and radiological measurements.

Whatever the type of external fixation device that has been decided for use, the challenging question is the safe removal time [Richardson et al., 1994]. That is, the time when the fractured bone is strong enough to withstand the load conditions encountered during the daily life without risk of re-fracture. As result of the lack of specific studies on the healing of cancellous bone, the decision to remove the external fixator is based on x-ray assessment and the experience of surgeon. The reliability of both methods are the subject of debate in several studies [e.g., Kenwright, 1985; Wade and Richardson, 2001]. At present, a conservative approach tends to leave these frames in place for six weeks. Without any objective measurement of the healing process, this may lead to these frames being left longer than necessary with an increased risk of pin-track problems [Richardson et al., 1994].

Alternatively, this time could be too short for some patients resulting in a delay of callus maturation.

2.8 Mechanical measurements

An overview of different methods to measure fracture healing is given (see §2.8.1). Fracture healing follows different patterns depending on the reduction technique used, in this work only fractures treated with external fixation have been considered. Previous measurement devices and studies have also been considered (see §2.8.2and §2.8.3).

2.8.1 Fracture healing assessment

In clinical practice, the assessment of fracture healing is usually made based on a combination of x-ray examination and manual assessment. X-rays may provide an image of the callus (although, specifically for distal radial fracture, the callus formation is minimal), but does not provide any information regarding the quality of the callus; manual assessment is used to estimate the strength of the new bone but on its own has been shown to be inaccurate [Webb et al., 1986]. In addition the presence of tenderness or pain on activity or stressing the fracture site are also used to assess the degree of healing. Although individually these measures have a low accuracy to define fracture union, their combination is usually enough to give a satisfactory interpretation of the fracture healing. However, conventional clinical methods to assess fracture healing are inadequate in difficult diagnostic cases, particularly in the quantification of healing rate, or assessment of sequential healing stages and it is likely that clinicians keep the external frames in place longer than may be necessary [e.g., Evans et al., 1985; Kenwright, 1985; Baker et al., 1989; Webb et al., 1996; Wade and Richardson, 2001a; Hente et al., 2003]. More objective methods have been researched, but not many of these are used regularly as clinical tools for assessment of fracture healing.

Different techniques have been developed to quantify the fracture union and they are based mainly on vibrational (see §2.8.1.1) and mechanical testing (see §2.8.1.2).

2.8.1.1 Vibrational technique

In simple terms, in vibrational testing, the mode of a wave passing through the fractured bone is compared with that obtained from the unfractured contralateral limb. A compression wave can be generated by simple impact on the bone or by using a transmitter. Piezo crystal can be used both to produce and to detect waves, and these operate at frequency from the lowest a few Hz to several MHz. – well above the normal hearing. Waves with frequencies above 20kHz are in the ultrasonic range.

In impact testing, the input and the output waves in the time domain can be transformed into the frequency domain and the frequency response function (FRF) obtained as the ratio of the two waves. The FRF is used to calculate the resonant frequency of the fractured bone. The difference between this frequency and that of the contralateral unfractured bone can be used as an indication of the healing process.

In other tests the stiffness of the new callus is related to the wave velocity across the fractured bone.
Soft tissue interference is one of the major problems of the method of wave analysis. Many studies have used a vibrational technique to monitor the healing process [e.g., Lowet and Con der Perre, 1996; Akkus et al., 1998; Njeh et al., 1998; Nokes, 1999; Kawchuk et al., 2000; Njeh et al., 2000], however they are not investigated in this thesis which is more focused on mechanical techniques.

2.8.1.2 Mechanical technique

Since the main function of bone is to resist load, it is natural to use the rigidity of the new callus as an index for the fracture union. Fractures stabilised with external fixators offer a good opportunity to perform in-vivo mechanical testing. The frame is in direct contact with the fractured bone and it can be used to apply load and to measure displacement at the fracture site.

The behaviour of the external fixator during fracture healing has been discussed (see §2.6.3). Mechanical testing of the callus rigidity can be divided into direct and indirect measurements, respectively if the fixator column is disconnected or left in place.

Direct measurements are independent from the influence of the external fixator geometry, allowing a quick estimation of the callus rigidity and comparison between different patients. However, because the fixator column (which gives stability to the system) is removed, this type of measurements cannot be carried out during the initial weeks of treatment.

During indirect measurements, the external fixator bar is left in situ, therefore there is no risk of loss of reduction and measurements can be made soon after operation. This system is suitable for engineering analysis and it is represented as two springs in parallel [Evans et al., 1988; Cunningham et al., 1989a; Tanner and Churches, 1989]. The overall rigidity of the system (k_{sys}) is then given by:

$$k_{sys} = k_c + k_{fix} \qquad [2\text{-}8]$$

where (k_c) the rigidity of the callus and (k_{fix}) is the rigidity of the fixator. Therefore, the rigidity of the callus can be calculated knowing the rigidity of the frame and measuring the rigidity of the system.

2.8.2 Previous measurement devices

The ideal in-vivo device should be non invasive, easy and rapid to use with no discomfort for the patient.

No measurement devices for distal radial fractures have been developed to the level of having been trialled and published. Most of the devices reported have been designed for tibial fractures. Due to their specific dimensions, the devices for tibial fracture measurement are not suitable for monitoring movements of distal radial fractures.

When the device is used for indirect measurements, to translate the data from the sensors to the fracture gap, knowledge of the geometry of the situation is necessary (e.g., the distance from the device to the fixator column and from the pins to the fracture, the angle between the pins and the fixator column). Additional assumptions of the rigidity of the bone and device components are required to calculate fracture movement.

Multiple photo detectors have been used by Tanner [1985] to investigate the three-dimensional movement of tibial fractures. Three p-i-n diode detectors were mounted orthogonally at the end of a rod which is rigidly clamped to one pin of the external fixator. Three infra-red light emitting diodes are orthogonally mounted to another rod clamped to another pin on the other side of the fracture. The two parts of the transducer are free to move relative to each other and the displacement of each detector from its spot of light is used to calculate the relative movement between the two components. The reduction of axial displacement while the fracture is subjected to bending has been shown for six patients. The results show that using these measurements an increase in stiffness can be detected before it becomes evident from radiographs. However, this device has been criticised in a later study conducted by Gardner et al. [1996] for the low resolution (i.e., 0.2mm) obtained during clinical testing.

Strain gauges have been widely used in civil engineering to monitor mechanical changes in many constructions, including bridges. External fixators can be considered to be a bridge over the fracture gap. Therefore, it seems reasonable to use strain gauges to monitor changes in the fixator behaviour during the fracture healing. However, it is not practical to bond strain gauges directly to the frame. Evans et al. [1988] described a monitoring device based on strain gauges, which can be fitted to the fixator column without requiring any modification to the fixator system. The load was applied manually just above the knee when the patient was sitting and the leg supported at the heel (i.e., inducing a bending load), or when the patient was sitting and the foot rested on a force plate (i.e., measuring axial loading) This device has been used in experimental trials to investigate the influence of micromovement [Goodship and Kenwright, 1985] and bone graft [Evans et al., 1985] on fracture healing.

A different use of strain gauges has been proposed by Cunningham et al. [1989b] where the sensors are used to measure the deflection of the fixator pins. The deflection at the bone screw is translated at the fracture site using the elasticity theory of the beam. This application is supported by the study conducted by Evans et al. [1979], showing that almost all deformation of the fixator-bone system (97%) is due to the bending of the pins.

In research conducted by Baker et al. [1989], fracture healing has been related to the load carried by the callus. A force plate was used to measure the ground force reaction during weight bearing and a permanent transducer, based on strain gauges, was attached to the fixator to quantify the amount of load sustained by the fixator. The authors claimed that the loads were than translated to the tibial fracture site and the difference between these two loads represented the load carried by the callus. The assumption at the basis of this technique is that the muscle force can be ignored. This is not supported by a later study conducted by Gardner et al. [1994], where the muscle response produces movements five to six times greater than those arising from the transfer force through the tibia during weight bearing.

The need to characterise the type of movement in tibial fractures drove Gardner et al. [1996] to develop a new device to measure three-dimensional movements based on electro-magnetic sensors. The performance of the device was checked against the thermal instability and magnetic cross channel interference of the sensors. Positional errors due to friction were tested in laboratory experiments and a high accuracy (i.e., 0.025mm over a range between 5mm to 8mm and 0.025 degrees for 8 degrees of rotation) was achieved. This device has been used in clinical investigations and it is known as the Oxford micromovement transducer (OMT). The device is clamped between the inner pair of screws of the external fixator across the fracture at a fixed distance from the skin.

Linear variable displacement transformers (LVDT) are used by Ogrodnik [2001]. Five LVDTs are used to detect relative motion between two reference blocks clamped to the bone pins of the external fixator. The motion at the tibial fracture is calculated from the LVDT reading using trigonometrical relations, the accuracy of the measurements was however, dependent on the position of the device. It is important that the fixator pins are perfectly aligned with the same position and orientation, therefore it is necessary that the fixators are inserted using a specially designed reduction device. This system has been used in a clinical trial, the initial stiffness measurement was performed at seven weeks from the date of the operation, because the use of this device requires that the column of the fixator is removed before measurements are made.

Pin loosening is a common complication and source of errors for measurement devices. Hente et al [2003] developed a new device to measure bending stiffness in tibial fractures with less error due to pin loosening. The authors state that the lower error is due to the different way of applying load which, in their device, simulates the four point bending condition. In this scenario the forces act mainly along the pin axes instead of perpendicular to the pin axes. This load state results from a load cell placed at the upper part of the measuring device between the pin clamps of the fixator. The angular displacement is measured by strain gauges attached to flexible blades, which connect two rigid U shape frames attached to the fixator pins on both side of the fracture. The fixator column is removed after this device is attached to the fixator and the authors state that the stability of the fracture is guaranteed by the device rigidity. This apparatus has been tested in the laboratory and in animal experiments, however, until now no human studies have adopted this device.

2.8.3 Previous studies

Using the above devices (see §2.8.2) several studies investigated the type of movements and healing in tibial diaphyseal fractures. To date, no study on healing of distal radial fractures treated with external fixation has been published. Therefore, the review of tibial studies is the main source of useful background information for this investigation. However, due to the differences in bone type, size, location and physiologic load conditions, it is not possible to directly transfer the findings of the tibial studies directly to other fracture sites [Richardson et al., 1994; Simpson et al., 2000; Wade and Richardson, 2001a].

Three-dimensional movement of tibial fractures has been examined by Gardner et al. [1994] using the Oxford micromovement transducer (OMT). This research focused more on the investigation of the type of movement in the fracture gap, following normal patient activities (e.g., load bearing, walking with and without crutches). It does not analyse the time for safe removal of the fixator. Therefore, only a small number of patients have been considered and data from different patients have not been compared. This study stresses that compressive rigidity can indicate the development of interfragmentary tissue during healing, but it does not indicate the restoration of the mechanical integrity in the fracture. Tensile rigidity is suggested as a better estimate of the mechanical properties of the callus. Muscular activities are also indicated as having a significant influence on fracture movement of the tibia.

The effectiveness of the stiffness level in determining the time to remove the fixator safely was the aim of the study conducted by Richardson et al. [1994]. Following their previous work [Richardson et al., 1992] the authors suggested a value of 15Nm/degree as a safe criteria for frame removal for tibial fractures. In a clinical study on 219 patients they tested this criteria against radiological and clinical assessments. Bending rigidity was calculated applying a manual load proximal to the fracture and measuring the angulation at the fracture site. Direct (removing the fixator column) and indirect (without removing the fixator column) measures of the rigidity were taken using respectively an electrogoniometer attached to the fixator pins (direct measure) or removable strain gauges attached to the fixator column (indirect measure). Patients with different types and geometries of external fixator were included in this study. However since the authors used predominantly the direct method to measure the rigidity, the influence of different fixators was not considered. The authors found that the rigidity measure was superior to the radiological and clinical assessment. This statement was supported by a reduction of refracture in the group of the patients where the decision to remove the external fixator was based on the mechanical measurement. Although only one value of bending rigidity (15Nm/degree) has been considered in this study, the authors were conscious that there were many variables that could influence this value, such as the weight of patient, the distribution of the callus across the fracture site and the anatomy of the site. Therefore further investigation was advised for different applications of the rigidity measurements.

The healing endpoint value (15Nm/degree) suggested by Richardson et al. [1994] has been further investigated by Wade et al. [2001]. In their clinical study the authors showed that the measurement of fracture bending rigidity in one plane was not reliable and suggested that it was only safe to remove the external frame when bending rigidity of the fracture had achieved the healing endpoint value in at least two orthogonal planes.

3 Measuring fracture healing

As stated in the last chapter, the lack of studies focusing on distal radial fracture means that at present external fixators are left in place for six weeks to ensure that the removal does not compromise the alignment the mechanical properties of the new callus. In this chapter, a device has been developed (see §3.1) to provide quantitative measurements of healing at the distal radial fracture site. A simplified fracture model (see §3.2) has been used to verify the reliability of the measuring device with laboratory testing (see §3.3). Measurements from the device have been translated at the fracture site (see §3.4). A technique and a protocol has been established (see §3.5) in order to investigate the mechanical properties of the new callus in distal radial fractures and examine whether the rigidity of the new callus can be used to monitor the healing process. Laboratory testing (see §3.6) has been used to verify the technique. Finally, the device has been tested on patients in clinic (see §3.7)

3.1 Measurement device

The rigidity of the new callus has been identified from previous studies as a reliable index of fracture healing. Therefore, the initial stage of this research was to create a device to be used on distal radial fractures to measure the rigidity of the new callus, during the healing process.

Rigidity can be calculated in three different ways to obtain respectively bending, axial and torsional rigidity (see figure 3-1). For tibial fractures, bending rigidity has mainly been used to monitor fracture healing [Richardson et al., 1992 and 1994]. In this research, a handgrip was used to generate the load condition at the distal radius. The use of the handgrip mainly generates an axial load through the distal radius [Pfaeffle et al., 1999 and 2000]. Therefore, the device was developed to measure the axial loading and the relative axial deformation of the callus, in order to determine the axial rigidity.

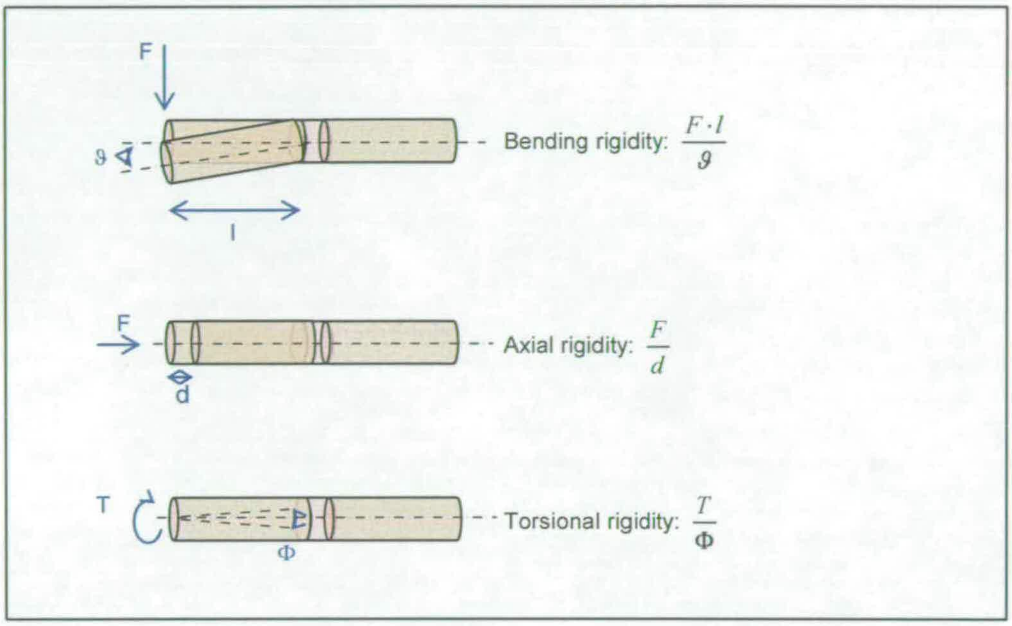


figure 3-1: Rigidity measurements (i.e., bending, axial and torsional rigidity)

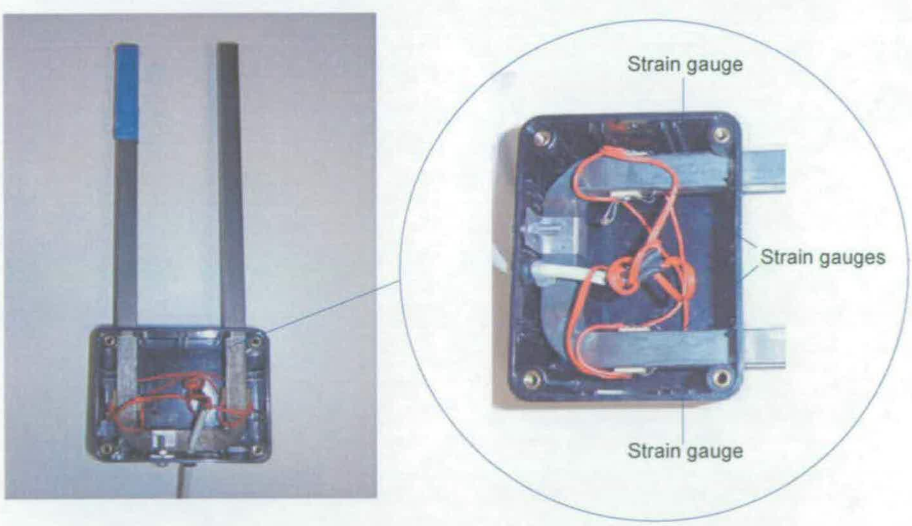
The ultimate aim of this work is to use the device for human in-vivo measurements. Therefore, in addition to the requisites necessary for a measurement instrument (e.g., accuracy, reproducibility of the measurements), this device must respect some elementary requirements for use in clinical practice. Particular attention was given to create an instrument that was easy to clean (to avoid any risk of infection between patients), easy and rapid to use with no discomfort for the patient. In addition, it was necessary to be wary of financial constraints during the development of the device.

An instrumented handgrip was developed to measure the load (see §3.1.1), a linear variable displacement transformer (LVDT) was chosen to measure the axial displacement (see §3.1.2). The data acquisition capability and the development process for the device are presented (see respectively §3.1.3 and §3.1.4).

3.1.1 Instrumented handgrip

It was decided, with respect to patient safety, that rather than applying an external load on the fractured limb, the patients would decide the amount of load that they were comfortable sustaining (i.e., the patients subject their fracture to loading). Therefore, by not applying an external load at the fracture, the requirement is removed for tests to be performed by specialist clinicians with full understanding of fracture site manipulation.

To allow the patient to generate the load, physiotherapy exercises were evaluated. A handgrip was considered to be a good and simple method to apply load at the fracture site. However, the handgrip used in physiotherapy measures the grip strength. The forces that the patient is able to apply directly in tension and compression are the quantities of interest in this research, so that the rigidity of the callus can be calculated. The handgrip was therefore designed as a U-shape metal beam (see figure 3-2 a), enabling it to be used to record the grip strength (i.e., from squeezing the handgrip) and the compressive force (i.e., from pushing and pulling one of the parallel bars while the other is maintained fixed). The analysis of the load generated using the handgrip is described further (see §3.4.1).



(a) Handgrip: U-shape metal beam

(b) Handgrip: strain gauge set-up

figure 3-2: Handgrip used to measure the load applied by the patients

The handgrip (i.e., the U-shape metal beam) has been instrumented with four foil resistive strain gauges (see figure 3-132 b) arranged to form a full Wheatstone bridge circuit (i.e., two active gauges for each parallel bar, one on the internal and one on the external side). Change in strain on the structure is proportional to change in strain gauge resistance. Passing a constant current across the full bridge circuit enables a change in strain, detected by the strain gauges, to be measured as a change in voltage (i.e., applying Ohm's law, where the change in resistance of a circuit is proportional to the output voltage). The output voltage is amplified to increase the signal to a suitable level for the data acquisition system.

The handgrip has been calibrated in compression and tension (i.e., the output voltage has been correlated to an input force) using a Zwick/Roell Z005 test machine (Zwick Roell Group Ltd). As expected, a linear relationship was obtained between the force and the voltage for the load range of interest (see Appendix A-1), confirming the ability of the strain gauges to measure the force. The ratio between the force and the voltage changes in respect to the position of the application of the force on the handgrip. Patients were asked to apply the force in a specific position marked on the handgrip. This allowed the use of the calibration constant to calculate the force applied by the patients.

Continuous recording of the load was necessary to be able to correlate the force applied to the displacement produced. This condition required the handgrip to be linked to a data acquisition system (see §3.1.3), with data being stored on a laptop computer.

3.1.2 Linear variable displacement transformer

The reduction of a fracture (i.e., the manoeuvre to restore the anatomical position of a fractured bone) often leaves a gap between the two bone components. The width of this gap depends on the complexity of the fracture. For distal radial fractures, it is frequently in the millimetres range. It is around and between this gap that the fracture callus grows. Applying an axial force on one bone component produces a displacement that is proportional to the overall rigidity of the callus and external fixator.

In fractures stabilised using an external fixation technique, sets of pins of the external fixator are secured in the bone on both sides of the callus fracture. Therefore, the movement at the fracture gap is transmitted to the fixator pins. The direction of this displacement depends mainly on the fracture geometry, but it is the component parallel to the axis of the radius that is needed to calculate the axial stiffness of the new callus.

A linear variable displacement transformer (LVDT) is a sensor designed to detect and to measure displacement along the direction of its main axis. Therefore, the displacement component of interest (i.e., the component parallel to the axis of the radius) is measured by arranging the LVDT to be parallel to the radius.

The LVDT comprises a primary central coil that establishes a magnetic flux, coupled by two secondary coils (see figure 3-3). The secondary coils are symmetrically placed at both sides of the primary coil - in series, but coiled in opposite directions. There is a mobile armature between the primary and secondary coils. In the balance position (i.e., the moving armature is centred between the two secondary coils), there is equal magnetic flux between the two secondary coils with the voltage induced in one secondary coil being balanced by the opposite voltage produced in the other secondary coil: therefore there is zero voltage output. When the moveable armature is displaced from the balance position, more magnetic flux is coupled by one of the secondary coils than the other, producing a voltage imbalance that results in an output voltage at the sensor. The displacement value is calculated from the voltage output using a calibration curve.

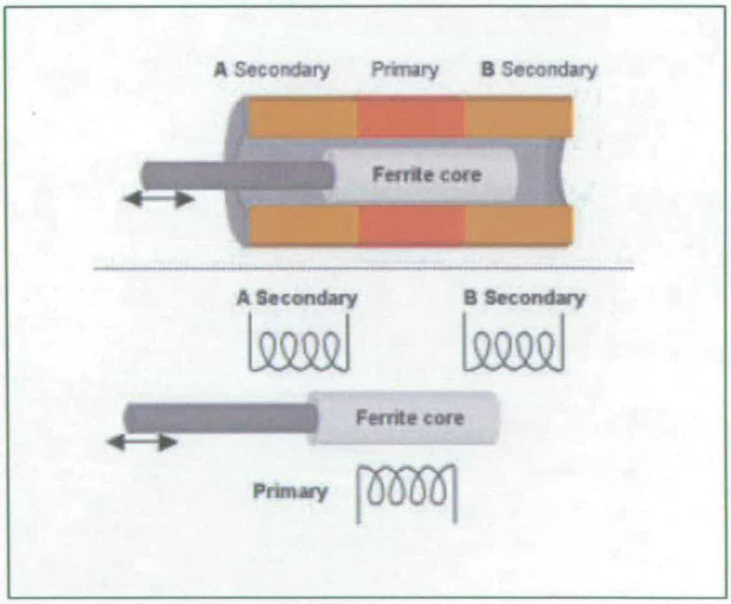
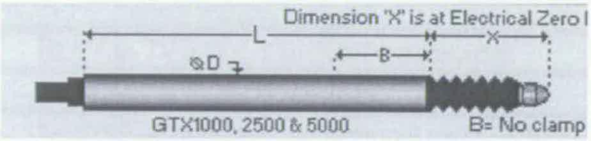


figure 3-3: LVDT frame draft (with reference to www.euclidres.com)

There is a wide variety of LVDTs available with different specifications to suit different applications. In this research dimension and weight are restricting factors in the choice of LVDT. A low spring constant (i.e., the spring inside the LVDT, which restores the armature to the balance position) is also considered a positive feature (see §3.1.4). A GTX2500 (RDP Electronics Ltd) has been used in this research and a summary of its specification is presented in table 3-1.

The LVDT has been calibrated (i.e., the output voltage has been correlated to the displacement) using Vernier callipers. A linear relationship was obtained between the voltage and the displacement for the range of interest (see Appendix A-2), confirming the reliability of the sensor.



Range	L	B	X	D	Spring constant	error of full range
±2.5mm	57mm	18mm	20mm	8mm	9.6gmm^{-1}	0.1%

table 3-1: LVDT (GTX2500) specification (reproduced with reference to RDP Electronics Ltd datasheet)

Continuous recording of the displacement is necessary to be able to correlate it with the force applied by the patient on the handgrip. This condition requires the LVDT to be linked to a data acquisition system (see §3.1.3), with displacement-force data being stored simultaneously on a laptop computer.

3.1.3 Data acquisition system

Data from the handgrip and the LVDT need to be collected and post-processed (i.e., logged and then processed) to obtain the callus rigidity. Data are recorded continuously however, a relatively low acquisition frequency (i.e., sampling rate of 40 Hz) is used since the load and displacement values do not change rapidly.

A low cost PC based data acquisition system (i.e., a Pico ADC-11/10) was used. This analogical to digital converter (ADC) is plugged into the parallel port of the PC, and PicoLog data acquisition software allows storage and manipulation of data. The converter is capable of multiplexing up to 11 channels with a 10 bit resolution. The input range of the system is between 0V and 2.5 V therefore, it requires a power supply to offset the zero and enable negative values to be recorded.

3.1.4 Device developing

External fixator geometry (i.e., specifically the distance between the two pin sets, pin set position, and column offset) changes for different patients. The design of a device able to be adapted to diverse fixator geometries has been one of the challenges of this research.

To measure the displacement between the proximal and distal set of pins, the LVDT needs to be fixed between both sets. The distance between these two sets of pins is influenced by the forearm length and fracture position (in this research the pin distance has varied between 55mm and 100mm). Mounting the LVDT on an additional support shaft allows the sensor to be moved to accommodate different distances (see figure 3-4).

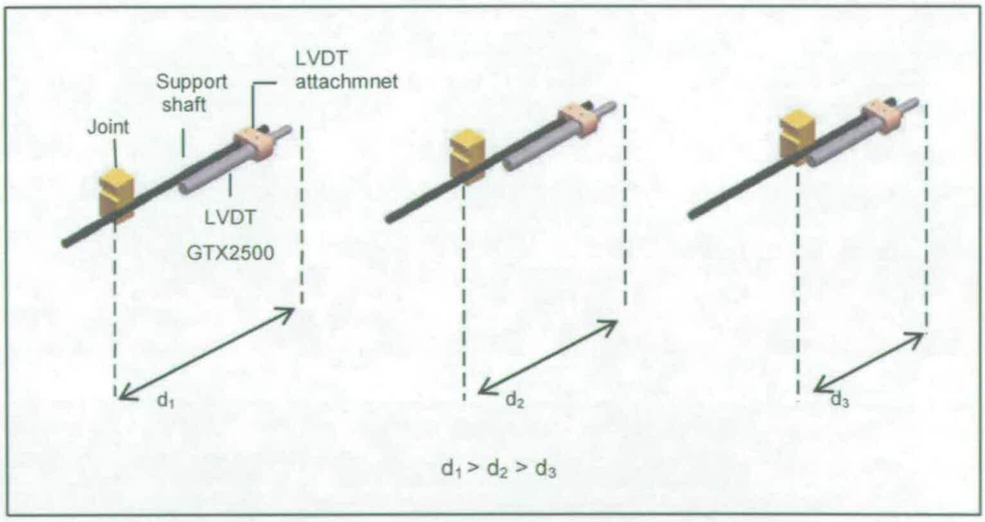


figure 3-4: LVDT attached to a support shaft to cover different distances (d_i)