TIBIAL SHAFT FRACTURES
A BIOMECHANICAL AND CLINICAL APPROACH

BY

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DECLARATION OF WORK DONE

I hereby declare that this thesis has been composed by myself, that it has not been submitted in any previous application for a degree, that except as acknowledged the work has been carried out by myself, that the general matter of the thesis is my own general composition, and that I have distinguished all quotations and specifically acknowledged sources of information.

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SUMMARY

Among the problems associated with the use of tibial functional bracing for the management of tibial shaft fractures, are post-fracture ankle stiffness and the duration of immobilisation. This study was undertaken to investigate in detail these two problems. It involved the design and assessment of a new type of brace called the 2 in 1 functional brace.

The study was designed in 3 parts.

Part 1 deals with the problem of clarifying the biomechanical function of the brace. It led to the development of a method for estimating the three dimensional forces and moments carried by the limb-brace complex at the level of the fracture. For this five volunteer patients, treated with a 2 in 1 brace for tibial shaft fractures, were each tested on 3 separate occasions. This study led to the conclusion that the brace is neither an off-loading, nor an anti-buckling device, but functions with a combination of these two mechanisms. The data also highlighted the importance of the removable "foot-piece" in the design of the brace for optimum healing of tibial fractures. The information obtained allowed rationalisation of the new design.

Part 2 of the study concentrated on the problem of determining the optimum duration of immobilisation in the brace. A non-invasive method of assessing healing by measurement of fracture stiffness was developed. This method gave encouraging results and it was decided to computerise the system. The efficacy of the system was assessed clinically in a trial on 10 patients. The results were encouraging and it is recommended that the system be tested in a larger controlled trial, before its routine use.

Part 3 of the study tested the new design of brace in a clinical trial on 80 patients. The trial was conducted to test the efficacy of the design in a clinical environment and to assess its effect on the stiffness of the ankle and sub-talar joints following fracture healing. The brace gave good clinical results with a mean healing time of 97.5 days in the series. The ranges of lower limb joint motion were found to be near normal at a mean follow-up of 16 months, indicating the success of the design in decreasing the incidence of post-fracture ankle and sub-talar joint stiffness.

The conclusions from the study suggest that a controlled trial is justified to compare the efficacy of the "2 in 1 brace" against other methods of managing tibial shaft fractures. The data from this series showed that the nature (simple or open) of the fracture, axial stability of the fracture, fracture fragment apposition, treatment modality and time of brace application did affect the outcome of fracture healing.

LIST OF ABBREVIATIONS

Where not explained explicitly in the thesis, the following meanings apply:

GENERAL

A/P	Antero-posterior
Chp.	Chapter
DCPB	Department of Clinical Physics and Bioengineering
Hr.	Hours
Jt.	Joint
KAFO	Knee Ankle Foot Orthoses
M/L	Medio-lateral
OOEC	Oxford Orthopaedic Engineering Centre
p	Probability
Ref.	Reference
S.D	Standard Deviation
Syst.	System
Test	The experimental procedures in which kinematic and load data are acquired
Tib.	Tibia
Ver.	Version
2-D	Two Dimensional
%	Percent

INSTRUMENTATION

ADU	Angle Display Unit
ASCII	American Standard Code for Information Interchange
A/D	Analogue to digital
CCD	Charged couple device
DC	Direct current
D.S.O	Digital Storage Oscilloscope
D.V.M	Digital Volt-meter
FP1	Force-plate One
FP2	Force-plate Two
LED	Light emitting diode
MUX	Multiplexer
P.S.U	Power Supply Unit
R.M.S	Root Mean Square
S/N	Signal to Noise
TL	Lateral transducer
TM	Medial transducer
TR1	Transducer One
TR4	Transducer Four
TV	Television

UNITS

cm	Centimetre
deg.	Degrees
Hz	Hertz, unit of frequency
K	Stands for 1000
KPa	Kilo-Pascal, unit of pressure
lb.	Pounds
m	Metre
mm	Millimetre
mV	Milli-volts
N	Newton, unit of force
Nm	Newton-metre, unit of moment
V	Volt, unit of electrical voltage

KINEMATICS AND KINETICS

B.W	Body Weight
Fx,Fy,Fz	Forces in the X-,Y- and Z- directions respectively
g	Gravitational acceleration
Ground Origin	The origin of the ground reference system
GRS	The ground reference system
Mx,My,Mz	Moments in the X-,Y- and Z- directions respectively
Oa	The origin of system A
Og	The origin of the ground reference system
Xg,Yg,Zg	X-,Y- and Z- axes of the ground reference system

MATERIALS

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METHOD OF COMPILING THIS THESIS

This thesis was typed in Wordstar-2000 by the author on a portable IBM compatible micro-computer (Toshiba T1200). Data was analysed using the Minitab software program. Tables, bar graphs etc were drawn by the author using Freelance-plus graphics package. Printing was by laserprinter while diagrams and tables were pasted into the text. The original was photocopied and bound to produce the required number of copies. Full text and tables are available from the author on 3 1/2" floppy disc in IBM compatible format. The reference list is also available separately in IBM format. The software programs used in the study are lodged in the University Department of Orthopaedic Surgery, Western Infirmary Glasgow.

CHAPTER 1

GENERAL INTRODUCTION AND LITERATURE REVIEW

"The Ancients discovered much, and yet left much more still to be discovered".
(Johannes Scultetus 1595-1645)

The treatment of tibial shaft fractures is controversial. There is a spectrum of methods ranging from immediate internal fixation to long term cast immobilisation (Leach 1984). The author's interest in the subject began during his Orthopaedic training in Pakistan. Trauma cases accounted for 70% of the bed occupancy, with the majority due to long bone fractures in young people. The need for a cheap, effective out-patient method of management for these fractures was obvious. In 1985 a project was set up at Jinnah Post-Graduate Medical Centre Karachi, to investigate the possibility of using functional cast bracing for the treatment of femoral and tibial shaft fractures.

One of the limiting factors in the introduction of a new method of treatment in a developing country is the cost of the necessary equipment and raw materials. In the case of femoral braces this proved to be the knee hinges (commercially available for approximately 25 Pounds Sterling). The author's design of knee hinges, a thin strip of the material "Teflon" reinforced with stainless steel curtain railings, was finally chosen (figure 1.A). The low unit cost (less than 50 pence) and their multiple use made the project economically as well as clinically viable.

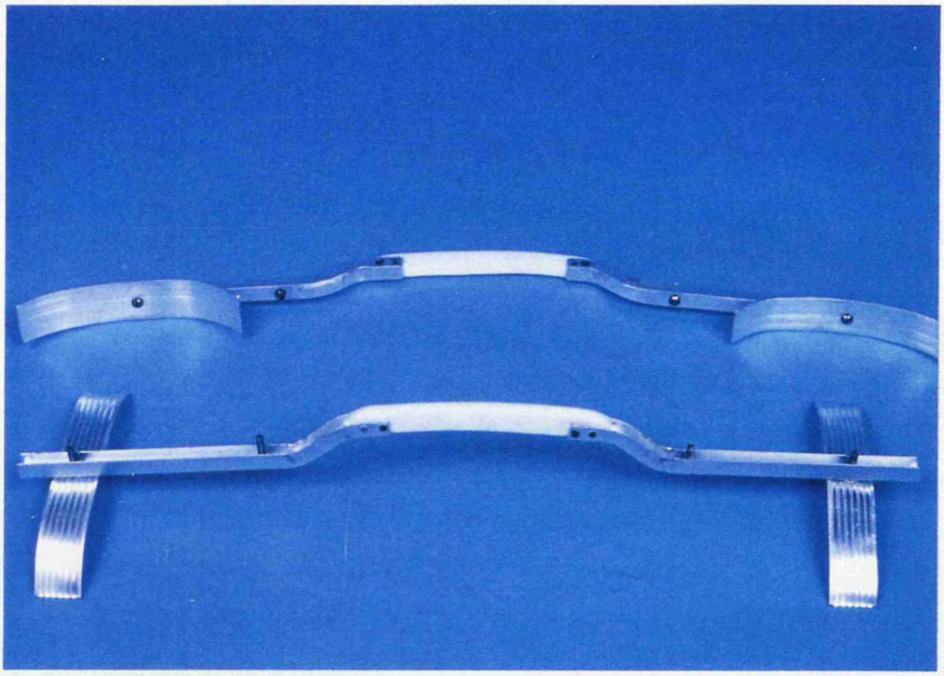


FIGURE 1.A: Low cost knee hinge design made from available materials in Pakistan.

Tibial functional bracing was a clinical success but post fracture ankle stiffness and the duration of immobilisation were identified as problems in the population treated. The large distances involved in patient travel resulted in limited access to physiotherapy.

The author's period of post-graduate study in the United Kingdom provided an opportunity to study the design, function and duration of application of the tibial braces scientifically in order to make them applicable to a developing country.

A new design of tibial functional brace was developed and gait analysis studies provided biomechanical information on its mode of action. The concurrent development of a non-invasive method of measuring fracture stiffness, as a guide to fracture healing, allowed a more objective measure of the duration of bracing. A clinical trial was initiated at the Western Infirmary Glasgow to test the effect of the brace on fracture healing, ankle stiffness, its cost and ease of application.

It is believed that with improvements in design and a better understanding of its mode of action, together with objective methods of assessing fracture healing, the role of functional bracing will increase in both the developed and developing worlds.

1.1 DEFINING THE PROBLEM

Among the conservative methods of treatment for tibial fractures, functional bracing has been accepted as the best option based on the concept of "controlled motion" which is physiologically induced and is perhaps the single most important factor in promoting osteogenesis (Sarmiento 1967, Dehne 1980, Rowley and Lee 1989, Leach 1984). Although researchers have contributed to the understanding of functional fracture bracing and its application in the clinical context, there are still some unanswered questions. In particular the following problems require further elucidation:-

MECHANISM OF TIBIAL BRACING: The clinical results of functional bracing have shown its effectiveness in the treatment of tibial shaft fractures. Evolution in brace design has followed better understanding of its mechanism of action. Biomechanical studies of functional braces have helped to improve the design and effectiveness of this method of treatment (Sarmiento and Latta 1981, Pratt et al 1982). Despite this, there has been some controversy on the mechanism of functional bracing.

Opinion is divided between those who believe it is primarily an "off loading" device (Hardy 1981, Wardlaw et al 1981, Pratt et al 1982, Scott 1989) and those who believe it functions primarily as an "anti buckling" device (Mooney 1974, Meggitt et al 1981, Kwong 1988).

Hardy (1981) estimated the distribution of load between the skeleton and the brace in five patients, with femoral shaft fractures treated by cast bracing. He used a set of standing scales to measure ground reaction forces, while strain gauges applied to knee hinges measured the axial forces passing across the cast brace. He estimated that the force transmitted across the knee hinges varied between 35 - 67 per cent of body weight. These figures were based on a simple set of instruments. The strain gauges were capable of measuring only axial forces and had to be calibrated in a complex manner introducing an element of error. The study was a "static" one and could not be used to reflect the situation in a dynamic environment. The application of strain gauges at the knee could not give a true estimation of the force acting across the femoral fracture, which is situated more proximally. The study therefore cannot be taken as evidence that the brace primarily acts as an off-loading device.

Wardlaw et al (1981) conducted a similar study but used more sensitive instrumentation. They measured the forces off-loaded by the femoral cast brace in 30 patients by applying strain gauge transducers at the level of the fracture, after splitting the cast circumferentially at that level. Again these strain gauges were only capable of measuring axial forces, but the ground reaction force was measured using a force-plate. The study was again a static one as the patient was asked to stand on the force-plate while bearing as much weight as possible on the injured leg. They concluded that the maximum off-loading capability of the brace varied from 20 - 50 per cent of the body weight. This study though improving on the methodology of measuring forces and confirming the results of Hardy (1981), cannot be considered proof in favour of the primarily axially off-loading concept for the brace. The shortcomings were similar in the static nature of the study and the inability of the transducers to measure the "moments" occurring at the level of the fracture.

Pratt et al (1982) investigated 25 femoral fractures during the stance phase of the gait and found the brace to off-load 20 - 40 per cent of the body weight axially. A subsequent two dimensional analysis was performed to include inertial effects and to estimate the net muscle action allowing calculation of the forces acting on the femur. However, in a detailed description of the system Pratt (1981) stated that the multi-component transducers employed to measure the loads at the fracture level were only capable of measuring forces. This was confirmed by one of his co-authors, J M Scott (1989). The analysis was restricted to an analysis of the forces and moments calculated from these two dimensional forces. The values of the moments transmitted by the transducers could not be measured. Thus the inference that the brace is primarily an off loading device (Scott 1989) was influenced by the limitations of the measuring system.

In contrast to these studies, Mooney (1974) believed that 10-20 per cent of off loading occurs at the knee in a well contoured brace. Meggitt et al (1981) presented a study of 32 patients treated with a femoral cast brace and estimated the loads carried by incorporating strain gauges into the knee hinges. These were capable of measuring axial forces only and the ground reaction forces were measured using a portable force-plate. They disagreed with the concept that the cast brace was primarily an off-loading device and concluded that it carried loads of only 10 - 20 per cent of body weight and thus functioned mainly as an anti-buckling hinged tube. They believed that the three-point fixation principle applied to the cast brace. The upper thigh cast proximally and the shin cast distally provided medial supports, while the lower thigh cast and hinges gave lateral support. This study also had its limitations, as Meggitt and his co-workers were reaching their conclusions without estimating or considering the moments involved at the level of the fracture. The strain gauges used were not capable of measuring the orthogonal moments, nor did they conduct a dynamic study to estimate the variations in forces and moments that occur during gait.

Kwong (1988) conducted a dynamic study using multi-component strain gauged transducers capable of measuring the three forces and moments at the level of the fracture in a femoral cast brace. He agreed in general with the conclusions of Meggitt et al (1981) that the brace was primarily an anti-buckling device. He showed that the component of axial off-loading by the brace was small and did not exceed more than 10 per cent of body weight at any time during the stance phase of gait. The medio-lateral moment (Mx) off-loaded was comparatively higher than expected, supporting the anti-buckling concept. The limitation of this study was in the shortcoming of the "software" used for collecting data from the strain gauge transducers, force-plate and the TV cameras. The data was not collected simultaneously and had to be merged at a later stage, introducing an element of error in the calculations.

To resolve the controversy as to the primary function of the brace, measurement of the three dimensional dynamic moments as well as the axial forces is essential. It is only from such comprehensive data and analysis that any definitive conclusions can be drawn. All the biomechanical studies conducted to elucidate the functions of a cast brace have been carried out on femoral braces. The conclusions drawn were then extrapolated to tibial braces, on the assumption that the functions of the two orthoses would be essentially the same. It is important to carry out independent studies on tibial functional braces because the nature of the forces and moments experienced by the tibia, as well as its anatomy, is different from the femur and may require a different approach.

A resolution of the biomechanical role of the tibial functional brace may well give designers scope for improvement on the present design of functional braces through a clearer understanding of the requirements for their component parts.

DURATION OF BRACING: Functional fracture bracing has been successful in the clinical management of the tibial fractures, but the clinician still lacks an objective method on which to base his decision to discontinue treatment. Fracture healing prediction is unreliable. Clinicians rely on clinical assessment and radiological evidence to assess how far the fracture has healed, these evaluations tend to be conservative thus resulting in over-treatment. The clinical and radiological evidence is subjective and unreliable

(Burns and Young 1942). Nicholls et al (1979) concluded that a physician, whether an orthopaedist or radiologist, is not very reliable at determining early osseous union, using x-rays alone.

Clinical methods combined with radiological examination, however, are satisfactory for defining the end-point of fracture union in approximately 90 per cent of patients, though with an accuracy of +/- 3 weeks for an average long bone fracture (Kenwright 1985). This implies that some of the fractures are over-treated by as much as 3 weeks.

The following could be considered as the problem areas where normal clinical and radiological methods are inadequate.

a) THE DIFFICULT DIAGNOSTIC PROBLEM: Those patients who are returning to strenuous work or professional sport require an accurate assessment, of the mechanical integrity of the healed fracture. These patients who have sustained tibial diaphysial fractures may be at risk of re-fracture. Kenwright (1985) stated that "in our present state of knowledge these patients may either be placed at risk of re-fracture, or be prevented from taking part in normal activities for many months longer than is necessary".

Non-union can be difficult to assess clinically and radiologically. This could lead to non-recognition and late intervention.

b) COMPARING TREATMENT REGIMENS: In order to compare different treatment methods for tibial fractures, it is essential to have an objective, accurate and repeatable method of recording biomechanical end points for fracture healing.

c) INVESTIGATIONS OF STAGES OF FRACTURE HEALING: There is a considerable literature describing research into the histological, microvascular and biochemical events that occur during fracture healing. But very little information is available about the sequence of biomechanical events. It is essential that further investigation is carried out into:

1 The biomechanical changes occurring during healing.
2 The influence of different mechanical environments upon the stages of fracture healing process.

Researchers have suggested different methods of assessment of fracture healing. Radio-isotopes (Johannsen 1973, Hughes 1980), ultrasound (Abendschein and Hyatt 1972), radio opaque dye injection (Puranen and Kaski 1974), bone percussion (Sekiguchi and Hirayama 1979) and mechanical stress testing methods (Burny 1979a, Jorgensen 1979, Hammer et al 1984, Rymaszewski 1984) have all been used. Most of these methods have their limitations. They are either invasive techniques or are not "quantitative" enough to give a reliable assessment of fracture healing. Some of the above techniques do not assess mechanical integrity of the skeleton and thus are not representative of the mechanical strength of the skeleton.

Before the advent of radiographic techniques, surgeons relied on evidence of manual stressing of fractures before removal of the support. Radiographic technology diverted the clinicians attention to what was "appearing" on the x-rays from what was actually happening to the fracture.

The strength of a bone is largely due to its collagen and not its minerals (Sevitt 1981, Dee and Sanders 1989). Radiographic techniques demonstrate the process of mineralisation during fracture healing because mineral is radio-opaque, it cannot identify the presence of collagen which is radio-lucent. On appearance of mineralised callus during healing, the clinician assumes that formation of collagen or osteoid matrix must have occurred already, because mineralisation always follows osteoid matrix (Sevitt 1981). If a large amount of mineralised callus is seen on x-rays in conjunction with stiffness of bone on manual stressing then the decision to remove cast support from the tibial fracture is usually taken. The problem with the radiographic techniques is its inability to identify the formation of collagen or osteoid matrix before the actual mineralisation of the tissue. Because the actual strength of the callus is due to the presence of this tissue and not the mineralised component, it may result in unnecessary delay in removal of the support.

It is possible for callus to achieve reasonable strength without showing any mineralisation, which could be delayed for reasons other than those affecting the formation of osteoid matrix (Edholm et al 1983, Burns and Young 1942). If such is the case, manual stressing would pick up the stiffness, whereas x-rays would show no callus at all. Such a situation in a clinical environment leads to the clinician preferring the radiologic evidence to his own clinical assessment. This may result in over treatment and associated hazards.

This discussion highlights the need for a non-invasive method of monitoring fracture healing. It is logical that such a system would be a mechanical method of measuring strength/stiffness of the callus. Such a system when used in conjunction with clinical assessment would provide a safe and objective alternative to radiographic assessment.

THE PROBLEM OF JOINT STIFFNESS: In the modern era, conservative methods of fracture treatment have always relied on immobilisation of the joints above and below the fracture. It was only with the popularity of functional bracing that clinicians realised that it was not essential to immobilise the joints above and below the fracture for the whole duration of the treatment. This belief led to early mobilisation of joints, with support to the fracture fragments being maintained by the use of suitably designed braces.

The problem of maintaining the position of the fragments still required immobilisation of the joints above and below the fracture. This led to stiffness of the joints which persisted when the cast was removed.

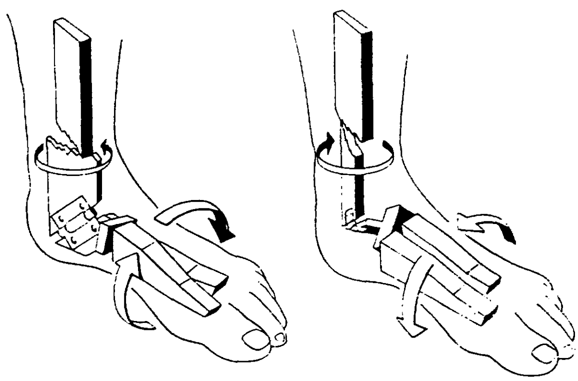
To overcome this problem Sarmiento suggested his design of functional cast, based on the principles of below knee prosthetics. This cast called short leg cast, popularly known as Sarmiento cast, allowed free movement of the knee joint while still maintaining the immobilisation of the ankle joint at an early stage of healing. Sarmiento suggested its application at 2-4 weeks post injury (Sarmiento and Latta 1981). This overcame the knee joint stiffness resulting from conservative treatment of tibial fractures using long leg casts, but was unable to prevent the stiffness of the ankle and sub-talar joints (Digby et al 1983).

Sarmiento (Sarmiento and Latta 1981) then proposed the use of a gaiter with a heel cup, to allow ankle joint movement, either after application of the "Sarmiento cast" or by-passing the stage of Sarmiento cast application in certain selected cases.

This regime led to improvement in ankle and sub-talar joint movement after treatment, but also increased the total treatment cost. The use of the gaiter with heel cup at a later stage of fracture healing, such as 6 weeks post injury, is acceptable but its use at the early stage of 2-3 weeks post injury should not be recommended based on the current knowledge of the biomechanics of the lower limb.

Sarmiento did not advise routine early application of the gaiter with a heel cup in his treatise on the subject of functional bracing except in special circumstances (Sarmiento and Latta 1981). Recently surgeons have advocated its use at an earlier stage of fracture healing as a solution to overcoming the problem of ankle and sub-talar joint stiffness. This practice is inadvisable on the grounds that supination and pronation of the foot leads to external and internal rotation of the tibia (Inman 1976), because of the mechanism of "torque transfer". This rotation is of the order of 15-25 degrees depending on the range of movement in the forefoot. This fact implies that in cases of fractured tibias where the foot is allowed free mobility at an early stage of fracture healing, the mechanism of torque transfer results in production of "internal moments" which produce rotational and shear stresses at the fracture site (figure 1.1.A). These stresses are not only liable to introduce rotational deformities during fracture healing, but would also affect the healing process itself.

MECHANICAL MODEL DEMONSTRATING EFFECT OF
FORE FOOT MOVEMENT ON TIBIAL SHAFT FRACTURE.



With fracture of tibial shaft, distal fragment rotates externally relative to the proximal one on supination.

With fracture of tibial shaft, distal fragment rotates internally relative to the proximal one on pronation.

(ADAPTED FROM Inman et al - 1981)

FIGURE 1.1.A: Shear stresses on tibial fracture if movement of foot is allowed early in the stage of fracture healing.

In the literature little attention has been paid to quantifying the rotational deformities of tibial shaft as a result of fracture, primarily because no reliable method exists of measuring this rotation non-invasively. Upadhyay and Moulton (1985) reported results of determination of femoral neck anteversion following femoral shaft fractures using ultrasound scanning. They were able to show that differences of up to 20 degrees existed between the fractured side and the normal side.

This highlights the fact that differences in diaphysial rotation following a fracture may exist without any overt signs unless specifically looked for.

It is possible that development of a similar method for measuring rotation of a tibial shaft may identify the effect of "torque transfer" mechanism on the rotational deformities of the tibia during fracture healing, if the foot is allowed free movement during the early stages of healing.

It is recognised by the clinicians that although axial loading is beneficial for healing, shear and rotational stresses are detrimental. Richardson (1989) believes that loading which is consistent or unidirectional is beneficial to healing whereas a combination of axial loading and shear is not, he calls it the principle of "consistency of direction" (figure 1.1.B). The callus of sheep osteotomies subject to controlled cyclic movement has a distinct pattern of trabeculae and blood vessels (Goodship and Kenwright 1986). It is likely that only those blood vessels that run in the direction of the applied movement survive, but are very susceptible to injury from movements in a different plane. Cyclic movements of an axial or bending type allow blood vessels to form in similar directions (Richardson 1989).

Translation or rotation however produces shear forces across the plane of fracture and would thus disrupt such vessels. This being the case it would seem that ankle joint immobilisation has a place in the early stages of fracture healing, as leaving it free allows rotational and shear stresses to disrupt these blood vessels and possibly lead to delayed or non-union. Considering the above reasons it seems that design rationalisation of functional bracing for treatment of tibial shaft fractures is required to overcome the problems of joint stiffness without compromising fracture alignment and union.

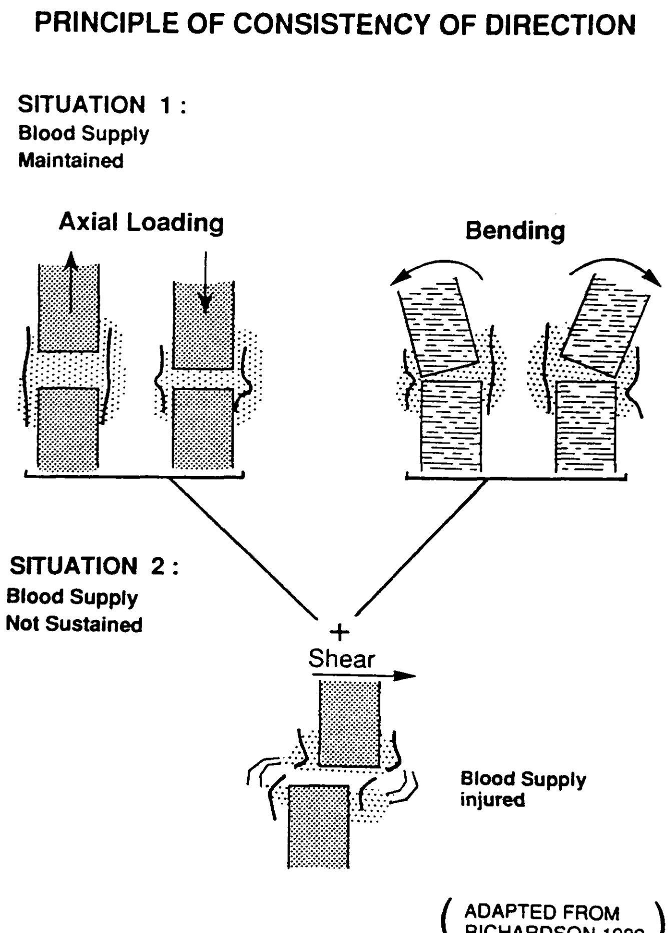


FIGURE 1.1.B: Combination of axial and shear forces are deleterious to the fracture healing (adapted from Richardson 1989).

1.2 AIMS OF THE STUDY

The study was designed to investigate these three problem areas in the management of tibial shaft fractures with functional bracing. In order to accomplish this the study was conducted and is presented in 3 parts.

The first part (Part 1: Load Transducer study) deals with the problem of clarifying the biomechanical function of the brace. A method was developed for estimating the three orthogonal forces and moments carried by the functional brace at the level of the fracture site. It was hoped that the information gained would not only validate the new design of 2 in 1 functional brace, but might also suggest further improvements.

The second part (Part 2: Fracture Stiffness Measurement) of the study was aimed at the development of a non-invasive method for measuring fracture stiffness. This was in response to the problem of determining the duration of functional bracing. It was hoped that such a system would satisfy most of the criteria of an ideal system for monitoring fracture healing (section 4.8), and would prove its efficacy in a clinical trial.

The third part (Part 3: 2 in 1 Functional Brace - Clinical Trial) of the study was concerned with testing the new design of the functional brace, 2 in 1 brace, in a clinical trial. The trial was designed to test its efficacy in a clinical environment and also to assess if any improvement in joint function was achieved after healing of the fractures.

This thesis presents these three arms of the study and discusses how successful each part was in achieving its aims.

1.3 HEALING OF FRACTURES

Fracture healing is commonly described morphologically (grossly or histologically) since all of the classic descriptions have been in this form (Gallie and Robertson 1919, Urist and Johnson 1943, Cruess 1984 and McKibbin 1978). Non-morphologic (chemical, mechanical) descriptions have recently become important. The morphologically conceptualised sequence of repair is more or less constant under natural conditions and there is little disagreement about this sequence.

Cruess (1984) described the fracture healing process as occurring in three overlapping stages; an initial inflammatory phase, a reparative phase and a remodelling phase. He stressed that the events described in one phase persist into the next and the events occurring in the subsequent phases begin in an earlier phase (figure 1.3).

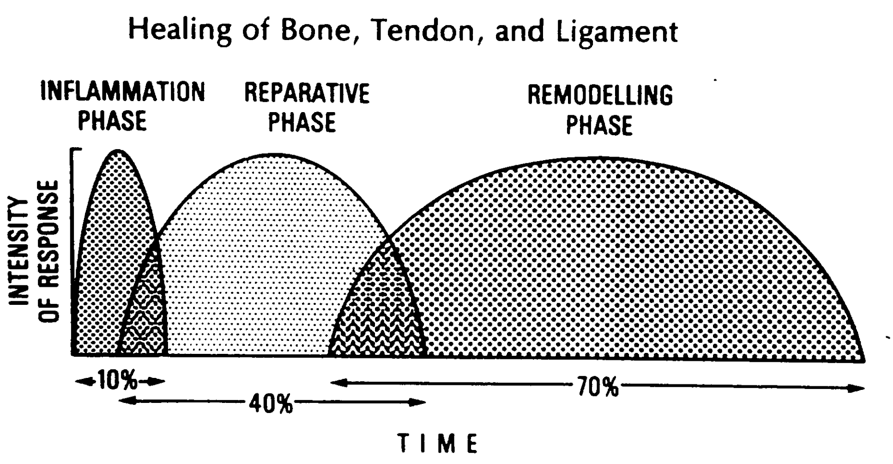


FIGURE 1.3: Three stages of fracture healing (from Cruess 1984).

Sevitt (1981) divided the healing process into two stages. The first preparatory stage essentially consists of the inflammatory and reparative phases of Cruess. The second stage of Sevitt also involves remodelling of the callus as does the third remodelling phase of Cruess.

The inflammatory phase begins when fracture leads to bone damage, the soft tissue envelope including the periosteum and surrounding muscles is torn and numerous blood vessels crossing the fracture line are ruptured. Hematoma accumulates within the medullary canal, between the ends of fracture fragments and beneath any elevated periosteum. This accumulation of blood rapidly clots. Sevitt believed that histologically, fibrovascular invasion of a hematoma in or immediately around a fracture is not a prominent phenomenon because most extravasated blood disappears through lysis, phagocytosis and other means. Studies by Flatmark (1964) had indicated that fracture union in haemophiliacs took place normally unless the fracture was badly positioned or unstable. This supports the view that haemorrhage does not significantly affect bone repair. The blood vessel damage deprives the osteocytes of their nutrition and as a result they die as far back as the junction of collateral channels.

The presence of necrotic material leads to an immediate and intense acute inflammatory response, which is aseptic in nature (Sevitt 1981). Vasodilatation and plasma exudation results in the oedema seen in the region of a fresh fracture. Acute inflammatory cells, including polymorphonuclear leukocytes followed by macrophages, migrate to the region (Cruess 1984, Sevitt 1981). As the acute inflammatory response subsides, the second phase begins to take over and gradually becomes the predominant pattern. The early response occurs as a result of the release of histamine from tissue mast cells and granules of circulating basophils and other mediators. The circulating neutrophils, basophils and mononuclear phagocytes are attracted to the site by chemotaxis. Release of tissue factors activate clotting mechanisms causing clotting of most of the blood vessels within 24 hours with little subsequent bleeding.

The formation of a fibrin clot provides the network to collect cells and proteins for the reparative stage. Mediators like kinnin generating systems, prostaglandins and complement systems may play an important role in the subsequent responses. Tissue death of bone as well as soft tissue, may result from a combination of direct injury, ischemia, and probably mediators (such as prostaglandins) together with the toxic products released by the inflammatory and dead tissue cells.

Physical and biological changes also occur during the inflammatory phase. Yasuda et al (1955) recognised the existence of electric potentials in stressed dry bone and concluded that the dynamic energy exerted upon bones is transformed into electrical energy, and the latter plays an important part in callus formation. It is also recognised that oxygen tension is reduced and pH increased in the vicinity of the cathodes, which is consistent with the alterations of the microenvironment of a fresh fracture. It is believed that such early changes contribute directly or indirectly to the healing response.

The inflammatory phase continues for several days during which time the hematoma organises while the cellular responses debride the necrotic tissues by phagocytosis and lysosomal mechanisms. The inflammatory phase, which is the shortest phase of the three, is considered complete when the predominant activity is the formation of new tissue rather than the removal of old injured tissue.

The first step in the reparative phase is organisation of the hematoma. This hematoma probably plays a small role in immobilising the fracture and serves primarily as a fibrin scaffold over which repair cells perform their function. Stirling in 1932 showed that the microenvironment about the fracture is acid. This could well be an additional stimulus to cell behaviour during the early phases of repair. During the repair process the pH gradually returns to neutral and then to a slightly alkaline level.

The initial stimulus resulting in cellular activity aimed at fracture repair is probably quite complex and undoubtedly includes the alterations in pH, as well as chemotactic factors released from inflammatory tissue. Bioelectrical stimuli also appear to play an important role. Friedenberg and Brighton (1966) reported electro-negativity in the regions of a fresh fracture. Their studies showed a characteristic curve pattern of Direct Current potentials from the skin over the intact tibia and femur in human subjects. The epiphysis was positive with respect to sub-epiphysial area; the metaphysis was negative with respect to the epiphysis, and two to three centimetres below the epiphysis in the metaphysis the greatest electronegative value was reached, the voltage then decreased to isopolarity and became electropositive in the diaphysis. The curve pattern of skin potentials over fractured tibiae in human subjects showed a marked departure from the established pattern. The entire shaft became electronegative, and the metaphysial electro-negativity became even higher. A secondary increase of electro-negativity appeared over the fracture site. With healing of the fracture, the curve pattern reverted back to normal. This electro-negativity is dependent on cell viability and unlike the currents measured in intact bones, is non-stress generated. It is believed that this electrical signal is the stimulus for early osteogenesis and repair.

Unequivocal microscopic signs of cell proliferation are first seen a few days after injury in most human fractures, reparative activity in fractured ribs is first visible at 3 or 4 days after fracture and a day or two later in medulla near femoral pertrochanteric fractures (Sevitt 1981). The cells which are directly involved in the repair of fractures are of mesenchymal origin and are pluri-potential. Bassett (1962) believed that during the process of fracture healing cells of common origin form collagen, cartilage and bone. His experiments showed that small variations in the microenvironment of these cells and the stresses to which they were subjected probably determine which behaviour predominates. Some cells are derived from the cambium layer of the periosteum and form the earliest bone particularly in children, in whom this layer is active and important. Endosteal cells also participate while surviving osteocytes do not take part in the process and are destroyed during resorption (Tonna 1972). Most of the cells involved in fracture repair reach the fracture site together with the granulation tissue which invades the region from the surrounding vessels (Trueta 1963). Fracture repair is indivisibly linked with the ingress of these capillary buds.

It is notable that the entire vascular bed of an extremity is increased shortly after fracture, but the osteogenic response is limited largely to the zones surrounding the fracture itself (Rhinelander 1974). Rhinelander (1974) described the normal circulation of a typical mammalian long bone as comprising an "afferent vascular system" carrying arterial blood and the "efferent vascular system" carrying venous blood. The link between these two systems in compact bone is the intermediate vascular system, composed of thin walled vessels of capillary size within the smallest bone canals. Compact bone, unlike the soft tissues, has no true capillary network. The flow of blood through the cortical canals appears to have a resting level and a stimulated level. The difference between the two represents the potential for increased blood supply which may be on a physiologic basis, or on a pathologic basis in response to fracture. Blood flow through cortex as a whole is normally centrifugal i.e from medulla to periosteum. The three primary components of the afferent vascular system of a long bone are; the principal nutrient artery, the metaphysial arteries and the periosteal arterioles, which appear to enter a long bone only under the protection of fascial attachments, to supply the outer third of cortex where they enter. In bone undergoing repair, the components of the afferent vascular system increase functionally above their resting levels. Additionally, there is an extraosseous blood supply, derived from the periosseous soft tissues, to furnish blood initially to periosteal callus and subsequently to necrotic cortex which has been isolated from its normal medullary arterial supply.

The cells invade the hematoma and rapidly begin producing the tissue known as callus, which is made up of fibrous tissue, cartilage and young immature fibre bone. The callus thus formed quickly envelopes the bone ends and leads to a gradual increase in stability of the fracture fragments. The mechanisms that control the behaviour of each individual cell at this stage of the repair process probably derives from the microenvironment in which the cell finds itself. Formation of the fibrous tissue is discouraged by compression or the absence of tension to the cells. Variations of oxygen tension led to either the formation of bone or cartilage. Cartilage is formed where the oxygen tensions are relatively low (Bassett 1962), presumably owing to the distance of the cell from its blood supply.

Cartilage thus formed is eventually resorbed by a process which is indistinguishable from enchondral bone formation, except for its lack of organisation. Bone is formed by those cells which receive enough oxygen and are subjected to the proper mechanical (Lanyon 1989) or electrical stimuli. During the early part of the repair process cartilage formation is predominant and glycosaminoglycans (mucopolysaccharides) are found in high concentrations. This is followed by more obvious bone formation in the later phases of fracture repair.

It is necessary for bone resorption to take place coincidentally with bone formation. The fracture bone ends which have been deprived of their blood supply and are necrotic need to be removed. Gothlin and Ericsson 1976 showed that the derivation of bone resorbing cells is totally different from those responsible for bone formation. Osteoclasts which are derived from circulating monocytes in the blood are responsible for bone resorption. Because these cells are not recruited locally, bone resorption depends on the ingress of blood vessels. The stimulus for this function is unclear but Dekel et al (1981) have identified significant amounts of Prostaglandins in the region of a fresh fracture in experimental animals. These substances are powerful mediators of bone resorption by causing recruitment of new osteoclasts as well as increasing the activity of osteoclasts already present (Dominguez and Mundy 1980, Dekel et al 1981).

Kuhlman and Bakowski (1975) reported considerable amounts of enzymes mediating carbohydrate metabolism in the fracture callus. This indicates that the process of bone repair relies upon carbohydrate metabolism to obtain structural intermediates and energy. The biochemical evidence for fracture callus dependence upon oxidative carbohydrate underscores the known clinical importance of an adequate blood supply for successful bone union.

As the mineralisation progresses the bone ends gradually become enveloped in a fusiform mass of internal and external callus. This changes from a "soft" form to hard callus. Immobilisation of the fragments becomes more rigid leading to eventual clinical "union". The concept of union as an end point does not exist because in the middle of the reparative phase the remodelling phase begins leading to resorption of unneeded or inefficient portions of the callus and laying down of the trabecular bone along lines of stress.

The size and proportion of different tissues in the callus is dependent on a variety of factors. The first being the amount of motion at the fracture site which mediates increased callus formation probably through stimulation of prostaglandins as a result of trauma to surrounding tissues (Dekel et al 1981). More stable fixation generally results in smaller amounts of callus and less cartilage. The second factor is the degree of soft tissue injury, including periosteal stripping from intact bone adjacent to the fracture site. A third probable factor is the degree of blood supply and capillary ingrowth.

Urist and colleagues in 1972 stated with their observations on guinea pigs demineralised bone that the bone morphogenetic property is a Protein (BMP) which appears to stimulate osteoprogenitor cells. Mizutani and Urist (1982) had extracted from demineralised bovine bone matrix gelatin a bone morphogenetic protein (BMP) fraction which consisted of 17.5 K (17500) as well as three other low molecular weight components. They believed that 17.5 K component is the prime candidate for BMP. They were not clear about the relationships of the other low molecular weight components to the 17.5 K component in inducing differentiation of mesenchymal cells into cartilage and bone when implanted in the thigh muscles of mice.

A number of observations suggest that electrical phenomenon may play a role in stimulating the proliferation of the cellular components of the callus and the production of an appropriate matrix. Clinicians have used electricity in the treatment of fractures as far back as 1816 when a surgeon, in St Thomas hospital London, used it successfully for ununited tibial fracture (Peltier 1981). This stimulated the surgeons in America to use electrical currents in the treatment of ununited tibial fractures in the 19th century.

In 1971 Friedenberg and colleagues subjected undisplaced fractures of rabbit fibulas to galvanic currents of 10 microamperes. Each fracture was studied by roentgenogram, stressed for rigidity and evaluated microscopically. The evidence suggested that the cathodal current of this intensity placed within the fracture site stimulates fracture healing.

Bassett and colleagues in 1974 had suggested the possibility of applying an electrical stimulus to bone tissue using pulsed magnetic fields without the necessity of implanting electrodes (Spadaro 1989). In 1982 Bassett and colleagues stated that "pulsing electromagnetic fields may assume clinical importance in the treatment of fresh fractures if optimum pulse characteristics can be identified". They also suggested that certain wave forms that trigger resolution of a chronic repair process in bone (such as a non-union) are not effective in augmenting an acute repair process (such as a fresh fracture), and were of the opinion that attention must be focused on pulse specificity during any search for signals that will reduce fracture disability time. Recently application of electric currents through skin with surface electrodes has been improved and used clinically as a potential tool (Brighton and Pollack 1984).

Spadaro (1989) commented that though the biological effects of electrical and magnetic stimuli have been demonstrated under laboratory conditions, there still remains some controversy over their efficacy in human fracture healing and bone augmentation. It is felt that controlled clinical trials have been lacking despite active commercial development.

Bone possesses the intrinsic capability to identify changes in its functional environment and to subsequently stimulate an "appropriate" adaptive response (Rubin 1989). Skeleton is successful in withstanding the varied external loads, only because the adaptive remodelling of the bone tissue is so responsive to the functional mechanical demands made upon it. The concept that mechanical function can alter the course and balance of bone is one of the oldest in medical history. Julius Wolff stated his views on the subject in 1892, widely referred to as "Wolff's law" (Rubin 1989). He stated that "a change in the primary form and function of bone or even its function alone, results in definite changes in the internal architecture according to self ordered mathematical rules, as well as secondary changes in the external form of the bone, following the same rules" (Rubin 1989).

Rubin (1989) was of the opinion that throughout adult life, mechanically related stimuli are the primary agents responsible for the positive balance of bone remodelling, and thus the maintenance of the skeleton's structural competence. This hypotheses is supported by other studies (Woo et al 1981, Lanyon 1989, Kenwright and Goodship 1989). Woo and colleagues (1981) reported a 17 per cent increase in cortical thickness of the femora of swines, subjected to a twelve months period of exercise training. Interestingly their results suggested that prolonged exercise has a significant effect on the quantity of bone but not on its quality, because the mechanical properties of the femora were not significantly altered. Clinical observation of hypertrophy of bone after excessive use also confirms Wolff's observations (Jones et al 1977).

The mechanical environment is also intimately related to the bone healing after fractures. Bassett in 1962 demonstrated that compression and high oxygen tension of primitive (mesenchymal) cells in culture led to bone formation while compression and low oxygen tension formed cartilage. Tension and high oxygen tension formed fibrous tissue.

Lanyon (1989) believed that exposure of fractured bone to extremely short periods of dynamic strains not only prevents the resorption which normally accompanies reduced loading, but also results in an increase in bone formation proportional to the magnitude of the peak strain. This osteogenic stimulus saturates after as few as 36 consecutive 0.5 Hz loading cycles per day occupying only 72 seconds. As few as 4 loading cycles per day of a potentially osteogenic stimulus were sufficient to prevent resorption while being insufficient to stimulate formation.

Kenwright and Goodship (1989) have concluded from their studies that the application of appropriate applied strain through external skeletal fixation applied to clinical tibial fractures at a time shortly after injury, when most patients would be very inactive, appears to enhance the healing process.

These findings indicate that the mechanical environment is not only capable of stimulating bone response after injury but is also active during the normal physiological turnover of bone. It is not yet clear whether this effect is mediated biochemically by mediators, such as prostaglandins, or as suggested by Lanyon (1989) that functional strains within bone tissue are a controlling variable for bone modelling and remodelling. The product of structural architecture, material properties and applied load is described as strain within the tissues.

Fracture repair is probably stimulated by changes in the extracellular milieu. Happenstall et al (1975) reported relative hypoxia at the fracture site which persists for many weeks. This decrease in oxygen concentration is believed to stimulate fracture repair, although it seems a contradictory finding to the increase in blood flow observed in and around the fracture site. It must be assumed that the active cells have a greatly increased oxygen consumption which outstrips the increased blood flow. Other changes of probable importance include the pH and enzymes levels.

Remodelling phase is the final and longest phase of bone healing extending over years. It is characterised by the conversion of the strong but disorganised hard callus of woven bone into relatively organised lamellar bone of normal or near normal strength. By the time this phase predominates, the fracture is sufficiently healed to allow normal function. During this phase of bone repair, the bone tends to slowly resume its original shape. Resorption of the unnecessary portion of the collar of the callus occurs. The medullary canal is gradually reformed and the osteonal architecture of the cortex is restored. Angular deformities tend to decrease with the laying down of the bone on the concave (compression) side and removal from the convex (tension) side. Rotational deformities are by contrast not affected very much by the remodelling process. These processes require the resorption of woven bone, with at the same time formation of new lamellar bone.

Histologically the osteoclast is the most prominent cell in this phase, although osteoblasts and osteocytes are also responsible for the accretion and resorption of bone. Osteoblasts have the well recognised ability to form bone, whereas the osteocytes are also thought to be involved in the formation of the matrix and bone resorption at a lesser rate (Jande and Belanger 1973). The precise role of the osteocytes in bone remodelling is not known. Trabecular bone resorption in the hard callus occurs primarily by the osteoclasts. The tubular appearance of the bone is restored by the appearance of new lamellar bone. The compact bone formed initially is less well organised than normal because the increased uptake of mineral for months or years implies a high rate of continued bone remodelling.

The coupled processes of bone resorption and bone formation continually resculpture bone. This remodelling occurs in discrete localised areas of bone known as bone metabolic units or bone remodelling units and results in the formation of discrete packets of bone called bone structural units (Mundy 1987). This sequence occurs both in cortical and trabecular bone.

Osteoclasts mediate the bone resorption phase which takes about 7-10 days followed by a formation phase mediated by osteoblasts, which lasts for about 3 months. The period between the osteoclastic resorption phase and osteoblastic formation phase is called the reversal phase and during this time the resorption lacunae is occupied by mononuclear cells. It is believed that the factors responsible for these phases are local, produced in bone marrow environment. The nature of these factors is still a mystery, the factors responsible for formation phase stimulating the osteoblasts have been called the coupling factors, since they couple formation to resorption (Mundy 1987). The cellular events involved in the formation phase include recruitment of osteoblastic precursors to the site of defect, replication, maturation and then formation of bone. It is not yet known whether all these processes are mediated by one factor or a family of factors.

Release of bone mineral and degradation of bone matrix occurs during the resorption phase. These processes occur together and are mediated predominantly by the multi-nucleated osteoclast. A number of systemic and local factors regulating the number and activity of the osteoclast have been identified. Humoral stimuli of osteoclastic bone resorption include parathyroid hormone, active metabolites of vitamin D, thyroid hormones, prostaglandins (particularly of E series), cytokines and epidermal growth factor. The inhibitors of osteoclast activity include cortisol, phosphate, calcitonin, colchicine and gamma interferon (Mundy 1987).

Osteoclast resorbs bone across a specialised area of the cell membrane called ruffled border. It is associated with the release of lysosomal enzymes and collagenase by the osteoclasts, as well as the local production of acid, responsible for causing release of mineral from bone. The precursor cell for osteoclast has not been identified definitely, but evidence is clear that it is of extra-skeletal origin and circulates (Mundy 1987). Circumstantial evidence indicates that it arises from hemopoietic tissue. There is also evidence that mononuclear cells such as monocytes, tumor cells and osteocytes are also capable of bone resorption in vitro, but the role of these cells in physiologic or pathologic bone resorption in vivo is not yet clear.

It is believed that the principal stimulus for remodelling, whether in fractured or normal bone, is physical stress. Genetic factors are also thought to play a role which is not yet clear. Embryonic bones are self differentiating and they continue to develop their normal form more or less in the absence of any applied load.

Kenwright and Goodship in 1989 concluded that the fracture healing process is very sensitive to small periods of daily strain applied axially within two weeks of fracture. They believed that there are boundaries of strain magnitude and force of application of applied movement that if exceeded inhibit the healing process.

1.4 TIBIAL SHAFT FRACTURES

"The object of treatment is the restoration of complete function with least risk and inconvenience to the patient and with least anxiety to the surgeon".

(Robert Jones 1913)

HISTORY OF TIBIAL FRACTURE TREATMENT: The results of treatment of tibial shaft fractures have improved significantly in the past fifty years. Leach (1984) quotes the results of 54 consecutive leg fractures, published in Speed's Textbook of Fractures and Dislocations printed in 1928. In this series of cases from St. Michel's Hospital in Toronto there were four deaths, two amputations, six infections, seven delayed unions and one non-union. Wilson in 1938 referred to a non-union rate of 20% in tibial fractures (Leach 1984). The extent of improvement achieved by recent methods, becomes apparent when these results are compared with the recent series of Sarmiento et al (1989) who reported a non-union rate of 2.5% in a total of 780 cases. No shortening was reported in 40% of the cases, while the rest healed with an average shortening of 7.1 mms. Angulatory deformity less than 5 degrees occurred in 53% of the cases. Similar improvements in healing rates have been described by Brown and Urban (1969) and Nicoll (1964).

CONSERVATIVE METHODS OF TREATMENT: The views of James Ellis (1964) could be taken as representing those of the "conservative" school in the management of tibial fractures. In his opinion "however attractive the possibilities of operative treatment may seem, operation still entails the conversion of a closed fracture into an open one, and the consequent risk must be weighed against the theoretical advantages". Ellis believed that a surgeon could not promote union, he could only create conditions that favour the natural process. He had also cautioned his colleagues to "treat the patient and not the radiographs", implying that anatomical reduction was not the sole aim of treatment and functional results could still be exceptional without achieving a perfect reduction.

Similar views have been expressed by Oni et al (1988), who observed the natural history of 100 closed fractures of the adult tibial shaft treated by closed methods. They reported that by 20 weeks 81% of the fractures had united with another 15% uniting by 30 weeks. Only 4% required operation as no further progress in healing was anticipated. They concluded that "with regard to healing, open reduction and internal fixation is rarely justified in closed adult tibial shaft fractures".

Although the conservative methods of treatment have been successful they are not without problems. Different forms of conservative treatments have been used such as skeletal traction, long leg cast, below knee cast and functional bracing.

Dehne et al (1961) popularised the concept of early weight bearing in a long leg cast. The cast was applied with the knee straight and the patient was encouraged to bear as much weight on the leg as desired. They reported a series of 207 cases treated by this method. All the fractures united, the average time for healing and rehabilitation was 5 months. They concluded that the consistency and rapidity of union obtained was attributable to the avoidance of surgery or traction with the acceptance of some minor degree of shortening. The favourable results were attributed to the functional stimulation of continuous weight bearing and closer attention to rehabilitation.

Functional bracing of fractures could be defined as a method of management which allows physiological function of the limb while at the same time maintaining the fracture fragments in alignment. Functional bracing for the lower limb would imply weight bearing as well as use of the joints of the limb. In the management of tibial fractures this could take several different forms. A weight bearing below knee cast allowing movement of the knee joint, a short leg brace allowing free movement of the knee joint with controlled movement of ankle joint, or the Delbet gaiter allowing free movement of both knee and ankle joints. Among the conservative methods, functional bracing has been accepted as the best option based on the concept of "controlled motion" which is physiologically induced and is perhaps the single most important factor in osteogenesis (Sarmiento 1967, Dehne 1980, Rowley and Lee 1989). Functional bracing which results in movement between bone fragments constitutes an irritant leading to a number of changes, electrical, thermal and vascular, all disposing to osteogenesis.

In the late 60's and early 70's Sarmiento (1967 and 1970) presented his ideas on the use of a below knee cast for treatment of tibial fractures based on the principle of the patellar tendon bearing prosthesis used for the below knee amputee. Sarmiento (1967) reported a series of 100 consecutive tibial fractures treated by this method. All fractures united and the average time for healing was 101.5 days. Maximum amount of shortening was 2.2 cm while the maximum amount of angulation was 8 degrees. He noted that in several patients less than anatomical restoration of length or alignment, or both was accepted since the position tended to remain unchanged after the application of the first total contact cast.

Although the results with the Sarmiento casts improved over the years (Sarmiento 1974), there was still a problem of ankle joint stiffness experienced by the patients after removal of the cast (Sarmiento 1967, Digby et al 1983). To overcome this Sarmiento suggested the use of a short leg brace, which left the ankle free to move, with the use of a plastic heel cup.

The gaiter cast was originally proposed by Delbet (Leach 1984). This device allows movement of both the knee and ankle joint while supporting the tibial fractures during the late stages of healing. Weissman et al (1966) reported its use in a series of 140 patients. These patients were initially treated in a non-weight bearing long leg cast for 6-8 weeks, followed by a full weight bearing long leg cast until radiographic evidence of adequate amount of callus was seen. The patient was then converted into a Delbet gaiter cast till the union was complete. The average healing time was 127 days. There was 1 case of non-union, 8% showed residual angulation and 23.5% showed a residual step-off deformity. Weissman and his co-workers concluded that "closed treatment in its simplest form is a very reliable method for tibial shaft fractures".

The traditional use of long leg casts was associated with a number of disadvantages. When the cast was removed on completion of the treatment the ankle and knee joints were often found to be stiff (McMaster 1976), the muscles had undergone atrophy and the bone looked osteoporotic. These changes were broadly termed as "cast disease", resulting from restricted limb function. Improperly applied casts were also responsible for skin sores, neuro-vascular problems could result from tight casts, and thermal burns from the exothermic reaction during setting of the plaster.

Functional bracing overcame most of the problems associated with immobilisation of the tibia with a traditional long leg cast. The function of the limb maintained the muscular bulk and prevented bone porosity, while joint stiffness of the knee was completely avoided. Ankle joint stiffness still remained a problem with below knee casts (Sarmiento 1967) but was controlled to some extent with the use of a short leg brace or Delbet gaiter. Neuro-Vascular problems were avoided by a careful technique and proper care for the first 48 hours after application of the cast. Newer materials for casting have overcome the problem of thermal burns.

The residual shortening and angulation was cited as the main disadvantage of this method. It was thought that such deformities would result in unphysiological loads on the associated joints, leading to the development of early osteoarthritis. This was one of the reasons for the preference of the operative method by some surgeons. Merchant and Dietz (1989) looked at the relationship between angular deformity occurring after a fracture of the tibial and fibular shafts and post-traumatic changes seen clinically and radiographically in the knee and ankle joints, an average of twenty-nine years after injury. They also investigated the correlations between the length of immobilisation and the range of motion and between the level of the fracture and the clinical and radiographic outcomes. Their series consisted of 37 patients with closed or Grade I open tibial and fibular fractures treated with a plaster cast. Of these fractures 38% had more than 10 degrees of angulation in either plane. They found that the clinical and radiographic outcomes were unaffected by the amounts of angulation, as well as by the level of the fracture. The length of immobilisation, which did not exceed one year, also did not affect the outcomes. This evidence goes against the hypothesis that residual deformities could lead to long term problems of osteoarthritis.

METHODS OF INTERNAL FIXATION: The operative school proposes rigid internal fixation as the best method of treatment for tibial fractures. Allgower (1965) advanced the view that rigid immobilisation and exact apposition of fracture fragments allowed early function and encouraged healing of bone by first intention. This was much to be preferred to healing by secondary intention. Muller and his co-workers (1979) believed that "A satisfactory internal fixation is achieved only when external splinting is superfluous and when full active pain free mobilisation of muscles and joints is possible". In their opinion this was best achieved by rigid internal fixation for the whole duration of the bone healing.

Ruedi et al (1976) reported their experience with 418 recent fractures of the tibial shaft using the Dynamic Compression Plate (DCP) which represented a development on the AO-ASIF round-holed plate. The DCP provided a greater versatility of use and positioning as well as a self compressing action on the bone fragments.

They considered 90% of the cases as a good or very good result. In their experience breakage and bending of the plates occurred between 15 and 20 weeks after implantation, representing a race between fracture healing and metal fatigue. They concluded that the decisive factors in the healing process are; the rigidity of plate fixation, blood supply of the injured tissues, and early active motion.

Christensen et al (1982) reported a series of 96 patients treated with compression plates with 94% classified as excellent or good results. They concluded that AO internal fixation of tibial fractures can be performed without too much hazard to the patient provided the technical skill and proper facilities are present.

Intra-medullary nailing was first used by Hey Groves during the First World War (Zaslav et al 1989). In 1940 Kuntscher introduced his design of Intra-medullary nails (Rush and Rush 1986), which were extensively used for treatment of femoral shaft fractures by the German army surgeons during the Second World War. The concept was popularised in America after the war. In the late 40's Rush and Rush (1986) described the results of the use of nails for intra-medullary fixation of long bone fractures. Since then many different designs have been proposed (Ender 1978, Hasenhuttl 1981, Kempf et al 1985).

In contrast to the interfragmentary compression, this technique does not achieve rigid fixation. It merely acts as an internal splint and provides a method of maintaining accurate reduction and alignment while allowing early mobilisation of the patient and the adjacent muscles and joints. Modern radiographic techniques have allowed increasing use of closed, rather than open, Intra-medullary nailing techniques. This method is attractive because surgical dissection in the vicinity of the fracture is unnecessary.

Donald and Seligson (1983) reported their experience with percutaneous Kuntscher nailing in 50 tibial shaft fractures. Complete union was demonstrated radiographically at an average of 91 days. Angular deformities were minimal with 78% of cases having less than 2 degrees varus or valgus deformity, while no deformity greater than 4 degrees was observed. Antero-posterior angulation of less than 5 degrees was observed in 98% of cases. They concluded that with experience and technical skill even highly complex tibial fractures can be successfully treated by this method.

Shortening, rotational and angular malalignment were common sequelae when standard intra-medullary nails were used for treating comminuted proximal or distal shaft fractures. Inter-locking nail devices (Kempf et al 1985), have gone some way to improve the results. Klemm and Borner (1986) reported results in 401 tibial fractures treated by closed intra-medullary interlocking nailing with an overall 94.3% excellent or good result. The deep infection rate was 2.2%, while delayed union or non-union requiring bone grafts occurred in 0.7%.

The important complications associated with these methods of internal fixation are deep infection, implant failure, re-fracture, and errors of technique. The application of internal fixation changes a previously closed fracture to an open one making infection always a potential complication. Most wound infections following the internal fixation of closed injuries are superficial. Deep wound infections are a less frequent, but potentially disastrous, complication of orthopaedic surgery (Zaslav et al 1989). It is possible for a deep infection to lead to an infected non-union, which is considered the most difficult condition to treat in orthopaedics.

Rates of deep infection in plated tibial fractures have varied from 0.9% (Ruedi et al 1976) to 5.3% (Christensen et al 1982) in closed fractures, while the reported deep infections for compound fractures ranged from 0% (Christensen et al 1982) to 12% (Ruedi et al 1976). McMahon et al (1989) reported a 37% deep infection rate in plating of tibial fractures for delayed union.

Olerud and Karlstrom (1986) in a review article on intra-medullary nailing of the tibia concluded that "the greatest drawback to intra-medullary nailing of the tibia is the risk of infection. Therefore, it is important that the surgeon be experienced in the technique and that the operative environment be of the highest quality when reamed intra-medullary nailing of the tibia is to be performed". This prerequisite limits universal use of intra-medullary nailing of tibial fractures, to advanced trauma centres.

Merritt (1988) reported a study which looked at the factors contributing to infection in open fractures. This study involved 70 open fractures from which debrided tissue was cultured, taken at the beginning and end of excision before closure of the wound. The overall infection rate was 19%. The infection rate was correlated with the use of fixation devices and was found to be 5% in patients with no implant. The rate rose to 19% in patients with external fixation devices and 26% with internal fixation. Most infections were caused by Gram-negative bacteria and there was little correlation between the bacterial counts in the first piece of tissue and the development of infection. However, there was a significant correlation between the bacterial count in the last piece of tissue taken at debridement and the development of later infection. Merritt (1988) concluded that the infection was correlated with what was in the tissue when the patient left the operating room and not with what was in the tissue when the patient entered the operating room. It seems that, in view of the above findings, a case could be made for debridement under "laminar flow" conditions.

Failure of the implant could be the result of material defect, poor operative technique, delayed or non-union of the fracture or excessive, premature weight bearing. The result is bending, breaking, loosening or even migration of the internal fixation devices. Implant failure rates for AO plates have varied from 2.1% (Ruedi et al 1976) to 5% (Jensen et al 1977). Failure of intra-medullary nails is not as common as compression plates, probably because they do not provide as rigid a fixation, thus sharing stresses between the implant and the skeleton. Bending, breaking and migration of the tibial nail into the knee have all been reported (Browner 1986, Donald and Seligson 1983). Interlocking nails are more likely to break at the sites of the transfixion holes, because these act as stress risers (Browner 1986).

Stress shielding, leading to bone resorption, is the end result of a rigid plate or a tight, load bearing intra-medullary rod. This increases the risk of re-fracture at the site of implant, which persists for months or years following its removal. Jensen et al

(1977) reported an 11% re-fracture rate following removal of AO plates at one year after application, for tibial shaft fractures. Intra-Medullary nailing is less likely to be complicated by re-fractures because it usually produces a mass of periosteal callus due to its loss of rigid fixation.

Closed interlocking intra-medullary nailing also has peculiar technical problems associated with the insertion technique. The Grosse-Kempf tibial nail has a bend in its proximal portion and is designed with two screw holes in different planes for added fixation. Due to this bend, the sagittal screw takes a diagonal course making it essential to exercise caution when drilling this hole, since over-penetration of the posterior cortex can result in injury to the popliteal artery. It is also essential to implant the nail deeply enough in the proximal tibial fracture, so that the sagittal screw reaches the posterior cortex of the tibia. If the nail is not inserted deeply enough the sagittal screw may pass into the condylar portion of the tibia, where it cannot achieve adequate purchase resulting in motion of the proximal fragment and non-union (Browner 1986).

EXTERNAL FIXATION METHODS: External fixation of tibial shaft fractures has also become increasingly popular (Burny 1979b, De Bastiani et al 1986, Behrens and Searls 1986), primarily because it is a less extensive operation then internal fixation. There has been a proliferation of new and improved fixator designs based on a decade of controversy about the ideal geometrical and mechanical properties of the frame (Burny 1979b, De Bastiani et al 1984, Ilizarov 1989, Edge and Denham 1981). There has been a movement away from bilateral to unilateral frame designs, as their low rigidity induces a large amount of fracture callus

(Behrens and Searls 1986, Burny 1979b, Andrianne et al 1989). Newer designs also allow provision of "dynamisation" (De Bastiani et al 1984, Richardson 1989) of the fracture. This is based on the concept of "controlled motion" and has been practised successfully for decades in the treatment of tibial shaft fractures by functional bracing.

Behrens and Searls (1986) reported a series of 75 consecutive cases of complex tibial injury treated with an AO/ASIF tubular fixator. Shortening did not exceed 5mm while the limb was in the fixator. There was a mean loss of 30% ankle range of motion in compound fractures while in simple fractures the loss was 11%. Angulatory deformities of 10 - 17 degrees developed in 4% of the fractures. Pin track infections occurred in 12% of cases. Insertion of pins within the "safe corridor" prevented neuro-vascular lesions and impalement of muscles and tendons. They believed that the incidence of pin track infection could be controlled by reduction of soft tissue irritation around the pins by their placement only where the tibia was sub-cutaneous. They also suggested using fewer, stiffer pins which have smooth shafts at skin level and pre-drilling of each pin track with a sharp drill bit to eliminate heat necrosis of soft tissues and bone. They also advised effective pin and frame care with the transfer of the major responsibility for this to the patient.

De Bastiani et al (1984) reported the results obtained with a lightweight dynamic axial fixator. This comprised a single bar with articulating ends which clamp self-tapping screws and can be locked at an angle appropriate for axial alignment. A telescopic facility allows conversion from rigid to dynamic fixation once periosteal callus formation has commenced. The success rate for fresh fractures as well as ununited fractures in this series of 338 patients was 94%, with healing times varying from 102-195 days. The incidence of pin track infection was small (3%) compared to other studies (Burny 1979b, Edge and Denham 1981, Behrens and Searls 1986). Angulatory deformities did not exceed 5 degrees in any plane in any patient. The re-fracture rate was 2.1% and limitation of joint movement only occurred in 2.1% of cases.

The important complications associated with external fixators are pin tract infection, malunion, neuro-vascular damage and ankle stiffness. Pin tract infection is common and when it occurs may preclude salvage by any other type of internal fixation. The reported incidence of pin tract infection varies from 10 to 100%, depending on its definition (Green 1983). It is probable that colonisation of the pin tract occurs in 100% of cases, while development of true cellulitis or dermal infection is seen in less.

Edge and Denham (1981) reported a 42% pin track infection rate in a series of 38 patients treated with a unilateral frame. Kimmel (1982) reported a 50% rate with the use of a bilateral frame. Clifford et al (1987) reported their experience with both bilateral and unilateral external fixators. Pin track infection occurred in 78% with the bilateral type, while only 17% were infected with unilateral fixators. They postulated that the high incidence associated with systems incorporating transfixion pins is a direct result of transfixion of muscle.

Although the unilateral frames are safe and provide excellent wound access, they are not rigid enough to hold unstable fractures, or to permit early weight bearing. A high malunion rate has been reported with the use of such designs; Edge and Denham (1981) reported an incidence of 55%, while Clifford et al (1987) reported a malunion rate of 38%. Bilateral frames being more rigid rarely result in loss of position, but malunion still occurs, a rate of 38% reported by Kimmel (1982).

Neuro-Vascular damage is also a potential risk when inserting pins without respect to the anatomical topography. This complication is more common with bilateral frames then in the unilateral types. In Kimmel's (1982) series with bilateral frames 50% had neurologic impairment, while 15% had major vascular injuries. The most common neurologic sequela was footdrop.

Ankle joint stiffness commonly occurs when transfixion pins are used in the bilateral forms of external fixators and less commonly when half pins are used for unilateral frames. This complication results from transfixion of the ankle and foot dorsiflexor muscles distally and may result in permanent ankle stiffness (Behrens and Searls 1986).

Sarmiento and Latta (1989) stated that an inappropriate external fixator holding the fracture rigidly apart may be viewed as an "Instrument of the Devil", a device specifically designed to create non-union. This is more likely to occur with bilateral designs due to their rigidity than with the currently favoured unilateral frame designs.

A non-union rate of 13% was reported by Kimmel (1982) with the use of bilateral frames. Edge and Denham (1981) reported a non-union rate of 8% with unilateral frames, while De Bastiani et al (1984) reported a rate of 6% with their use of unilateral form of external fixation. In this last series the average healing times for different long bones ranged from 3 to 6 months, thus some of the individual fractures could be considered to fall in the group of delayed unions.

CURRENT TRENDS IN MANAGEMENT: During the past 20 years there has been a movement away from operative methods of treatment, that were popular in the 1940's and 1950's, toward the non-operative methods (Leach 1984). The complications of internal fixation (Fisher and Hamblen 1978, McMahon et al 1989, Den Outer et al 1990), when they occur, are a heavy price compared to the advantages of anatomical union. Hamblen (1979) has stated that "Ideally internal fixation should be used only when there is no alternative method of conservative management with a predictable satisfactory outcome". This has been recognised by the proponents of operative treatments. In the light of excellent results produced by closed treatment of tibial fractures (Dehne 1969, Dehne 1974, Sarmiento et al 1989), Olerud and Karlstrom (1986) have professed to follow the basic rule formulated by Gotzen et al that states "as conservative as possible and as operative as necessary", during treatment of tibial shaft fractures.

Robert Jones in 1913 had stated that the aim of fracture treatment was the complete restoration of the function with the least risk and inconvenience to the patient and least anxiety to the surgeon (Rang 1966). The proponents of the operative school believe that complete restoration of function and optimum healing could only be achieved by anatomical restoration of the fracture by internal stabilisation and immediate weight bearing. The conservative school opposes this view and contends that function can be restored and healing achieved without resorting to internal fixation.

This review suggests that there is a place for both the philosophies to complement each other in the management of tibial shaft fractures. Sarmiento and Latta (1989) believed that optimal treatment cannot be provided by the surgeon who "braces all fractures", any more than it can be by the surgeon who "plates all fractures" or treats all fractures with "external fixation". The various techniques should be viewed as complimentary to each other.

If different options are considered in the management of tibial shaft fractures then it can be appreciated that among the options from the "Internal Fixation" group, plating has not been very successful (Fisher and Hamblen 1978, McMahon et al 1989). Intra-Medullary fixation, especially the interlocking nails have given better results in specialised centres. External fixation has been proposed as an alternative. It was initially proposed for open tibial fractures, where internal fixation was inappropriate due to the high incidence of infection and non-union, but is now being proposed for wider application (De Bastiani et al 1984). The method is not devoid of problems and Clifford et al (1987) have concluded that "the external fixator, although undoubtedly invaluable in the management of severe open fractures, should not be used indiscriminately".

Considering the options from conservative methods, the use of long leg casts for the whole duration of treatment is not appropriate because of the problems of "cast disease". The use of functional bracing has overcome the problem of "cast disease", but still has the problem of ankle joint stiffness. John Charnley (1981) stated that the failures of operative treatment were worse than the failures of conservative methods, because of the limited capability of a secondary procedure to salvage them. It is only a minority (approximately 20%) of tibial shaft fractures which are unsuitable for treatment with functional bracing, either due to their axial instability, or in open fractures requiring associated wound management. It would seem logical to improve the method of functional bracing to manage the majority of tibial shaft fractures. This could be achieved by using scientific methods, to investigate the biomechanical function of the brace and to develop a non-invasive method for measuring fracture stiffness to allow objective assessment of the time for removal of the brace.

Functional bracing could also be used as part of "sequential treatment" where unstable or open fractures are treated initially in an external fixator and then converted into the brace as soon as axial stability is achieved. This routine may decrease the incidence of complications because of the shorter period in the fixator and would also make the treatment more cost-effective by decreasing the number of external fixators required in the hospital.

PART 1: LOAD TRANSDUCER STUDY

CHAPTER 2

HUMAN GAIT ANALYSIS

A step is defined as a walking cycle. It starts and ends in the normal state with heel strike of the same limb. The walking cycle is divided into two phases. A stance phase, which at walking speed of 120 steps per minute, occupies about 62 per cent of the cycle and a swing phase which occupies 38 per cent of the cycle (Mann 1988). Stance phase is further sub-divided into two periods of double limb support and one period of single limb support. Double limb support is the period when both feet are on the ground and occurs from the beginning of the cycle to 12 per cent and from 50 per cent to 62 per cent of the cycle. Single limb support occurs from 12 per cent to 50 per cent of the cycle (figure 2.A).

If the normal walking cycle is analysed further, it is observed that by 7 per cent of the cycle the foot is flat on the floor while at 12 per cent the contra-lateral foot comes off the ground beginning the single limb support phase. Heel rise of the stance limb begins at 34 per cent corresponding to the period during which the swinging leg has just crossed the stance leg. Double limb support once again begins with the heel strike of the swinging leg at 50 per cent of the cycle lasting until the toe-off of the stance leg, when its swing phase begins (figure 2.B).

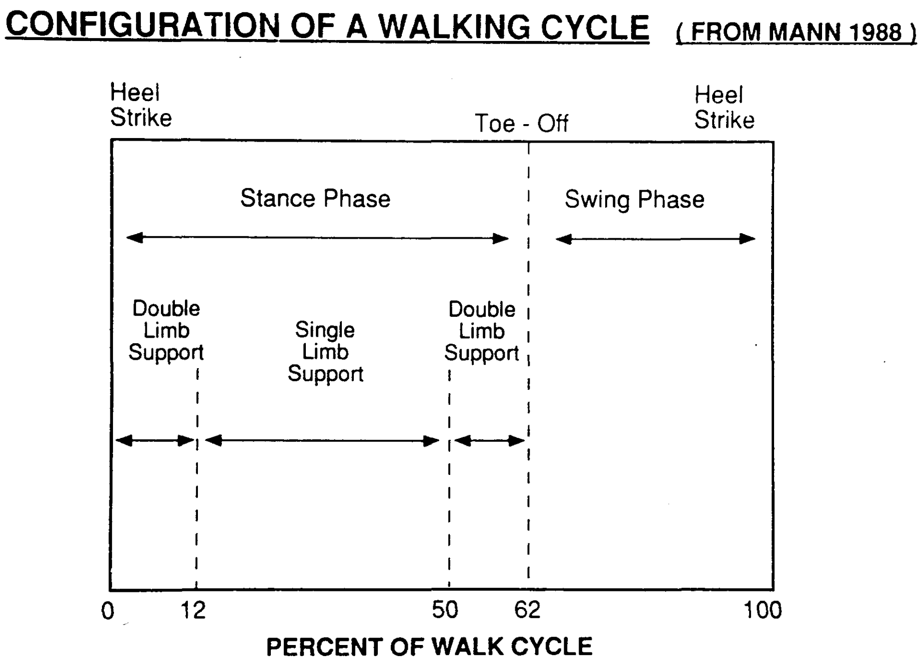


FIGURE 2.A: Walking cycle - It can be sub-divided into stance and swing phases (from Mann 1988).

Analysing an abnormal gait pattern requires a clear understanding of the normal events that occur during a walking cycle. A lateral view of the gait enables one to detect when heel rise occurs in relation to the swinging leg. During abnormal gait, it is possible that a gait cycle might not start with heel strike, but may begin with toe contact. In such a case it could be considered initial ground contact. In patients with contracture of the Achilles tendon it is possible that foot flat may not occur by 7 per cent of cycle or not at all. Similarly in a patient who has a certain degree of spasticity of the posterior calf muscles or an Achilles tendon contracture, heel rise will not occur at 34 per cent of the cycle but rather prior to it. If on the other hand the posterior calf muscles are weak, secondary to surgery or nerve damage, then heel rise will be delayed beyond 34 per cent of the cycle. It is also possible for the stance phase to be altered in relation to the swing phase. An example being a person who has suffered a stroke. The stance phase of the involved extremity being prolonged while the swing phase is diminished.

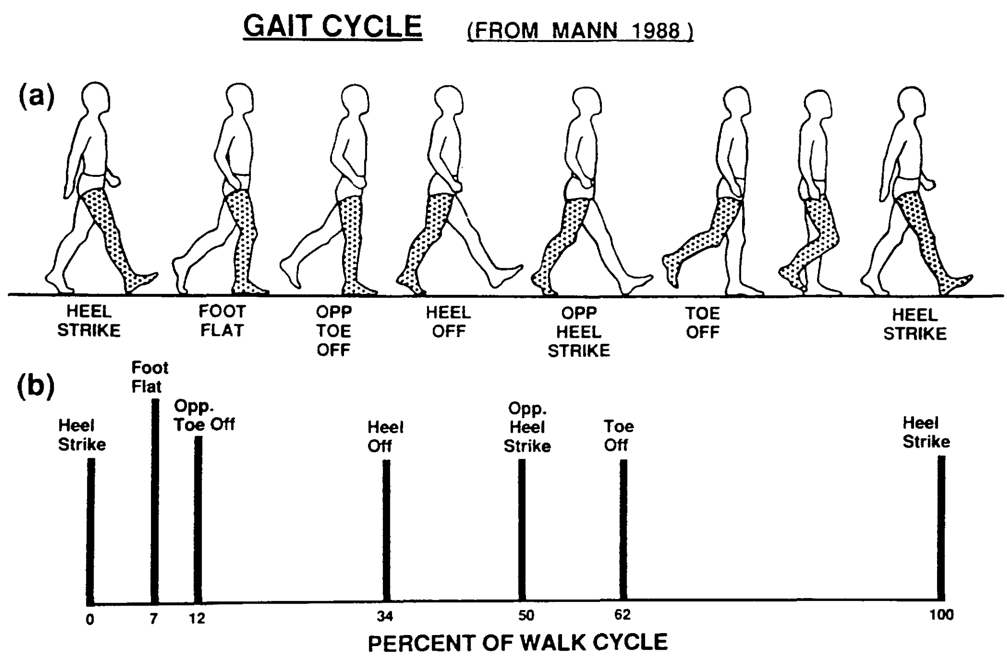


FIGURE 2.B: Sub-divisions of the gait cycle (from Mann 1988).

a) JOINT RANGE OF MOTION DURING WALKING - HIP JOINT: During walking maximum flexion is demonstrated by the hip joint at the time of ground contact while maximum extension is seen at the time of toe-off. Near the time of toe-off, flexion of the hip begins with the contraction of the ilio-psoas muscle (figure 2.C). Deceleration of the hip joint occurs just prior to the time of the initial ground contact by an eccentric contraction of the gluteus maximus and hamstring muscles (Mann 1988).

b) KNEE JOINT: At the time of ground contact (heel strike) the knee joint is in full extension following which rapid flexion of about 15 degrees occurs, in order to help the absorption of the impact of striking the ground (figure 2.C).

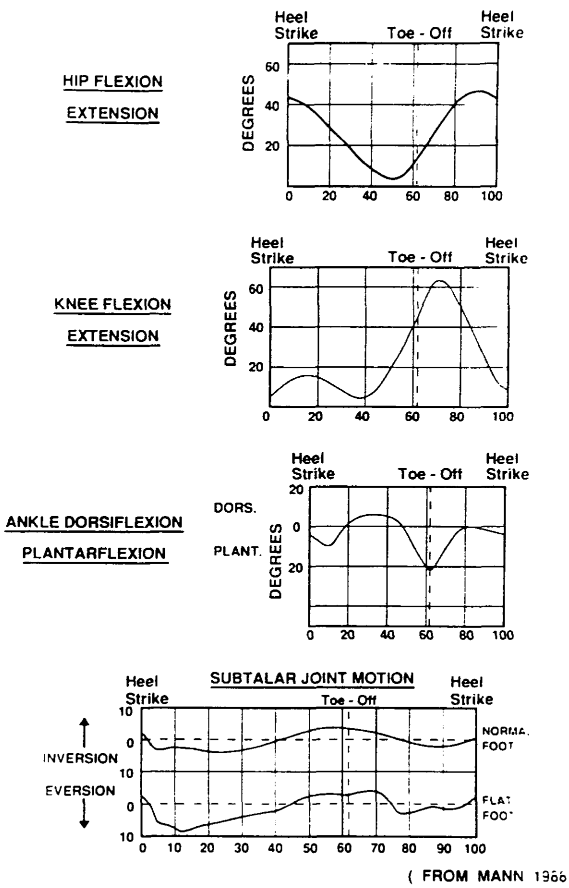


FIGURE 2.C: Joint ranges of motion during walking (from Mann 1988).

The knee joint undergoes a second period of extension which reaches its peak at about 40 per cent of the cycle, at the time when the opposite leg is swinging by. This corresponds to the time when the body reaches its peak elevation, thus permitting the swinging leg to advance without the toes catching on the ground. The quadriceps muscle, which becomes active late in the swing phase, extends the knee while controlling the initial flexion of the knee joint.

The second period of the knee extension does not require any muscle activity by the quadriceps. During this phase of knee extension the foot is on the ground, while the body moves over the fixed foot at a more rapid rate than the tibia over the fixed foot. The forward movement of the tibia over the fixed foot is being controlled by the eccentrically contracting posterior calf muscles, thus permitting the second period of knee extension to occur. Knee flexion during the swing phase after toe-off results from the rapid flexion of the hip joint aided by a short contraction from the biceps femoris muscle (Mann 1988).

c) ANKLE JOINT: At the time of heel strike rapid plantar flexion of the ankle joint occurs which is followed by progressive dorsi-flexion until about 40 per cent of the cycle has been completed, when plantar flexion begins once again (figure 2.C). This initial phase of plantar flexion is under the control of an eccentrically contracting anterior compartment musculature, which prevents the foot slap. The posterior calf muscles act as a group by an eccentric contraction controlling the forward movement of the tibia over the fixed foot and also initiate plantar flexion at 40 per cent of the cycle. It is worth noting that the muscles are no longer electrically active after about 55 per cent of the cycle, when rapid plantar flexion is occurring. Mann (1988) believes that the posterior calf muscles by a concentric contraction, help initiate plantar flexion but are not necessary to bring about full plantar flexion, which probably results from the unloading of the foot.

d) SUB-TALAR JOINT: The movements of inversion and eversion occur at the sub-talar joint. At the time of heel strike and loading of the foot, the sub-talar joint goes into eversion followed by progressive inversion until the time of toe-off (figure 2.C). In a normal person, the total range of motion of the sub-talar joint during walking is about 6-8 degrees, whereas in a person with a flat foot, it is about 10-12 degrees (Mann 1988). In a patient with flat feet, the initial eversion is quite marked which is followed by progressive inversion throughout the stance phase. In contrast, in a normal foot minimal eversion occurs until about 30 per cent of the cycle when inversion begins.

e) FORCES DURING WALKING: Forces are exerted by the body as its "centre of gravity" (C.G) moves in its sinusoidal path through space. These forces are related to the motion of the centre of the gravity of the body. These forces are generated in response to the joint motions and muscular actions of the body, as well as to the force of gravity working upon the body. Commonly measured forces are the vertical (Fy), the fore-aft shear (Fx), the medio-lateral shear (Fz) and torque (My). It is also possible to measure moments around the x-axis (Mx) and z-axis (Mz) as shown in figure 3.1.D. The magnitude of the forces is directly proportional to the speed of gait. In slow walking, less force is exerted while with increase in speed the magnitude of the force also increases.

f) VERTICAL FORCE (Fy): The graph showing vertical force during normal walking demonstrates an initial spike, usually equal to about 70 per cent of the body weight, which is related to the impact of the body against the ground at heel strike (figure 2.D). This initial brief spike rapidly falls off followed by the first peak which is the reaction of the ground to the acceptance of the body weight as well as the initial upward acceleration of the centre of the gravity.

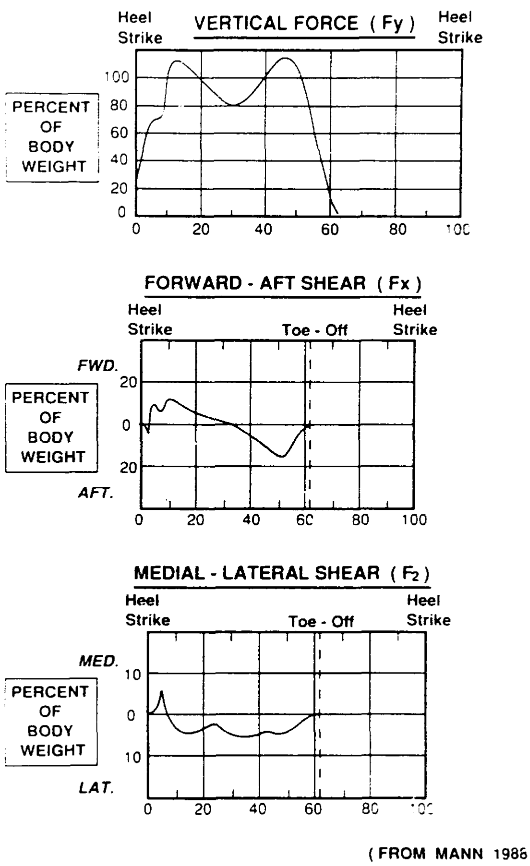


FIGURE 2.D: Forces exerted by the body during walking (from Mann 1988).

The graph next shows a dip in the force curve depicting less than body weight being exerted against the ground by approximately 20 per cent. This 'unloading' of the foot is in response to the upward movement of the centre of gravity of the body and the fact that once the body has been accelerated upward it follows an upward trajectory type pattern, so that as it reaches the top of its arc, the force against the ground is diminished. The second peak in the vertical force curve is brought about by the falling centre of gravity, and the force exerted against the ground by the stance foot in preparation for toe-off (Mann 1988).

g) FORE-AFT SHEAR (Fx): The fore-aft shear (Fx) measures the horizontal plane forces in the line of progression. The force curve (figure 2.D) shows an initial forward shear at the time of heel strike of about 10 per cent of body weight, which is followed by an aft shear of a slightly greater magnitude at the time of toe-off.

h) MEDIAL LATERAL SHEAR (Fz): The medial lateral shear measures the horizontal plane forces at 90 degrees to the plane of progression and is related to the medial and lateral sway of the body (figure 2.D). At the time of heel strike a medial shear of about 5 per cent of the body weight is exerted against the ground, followed by a progressive lateral shear until the time of toe-off (Mann 1988).

j) TORQUE (My): This is the measurement of the reaction to the transverse rotation which is occurring in the lower extremity during gait. At the time of heel strike internal rotation of the tibia occurs and an internal torque (My) is noted on the force plate (figure 2.E). This is followed by progressive external rotation in the lower extremity corresponding to the external torque noted against the ground.

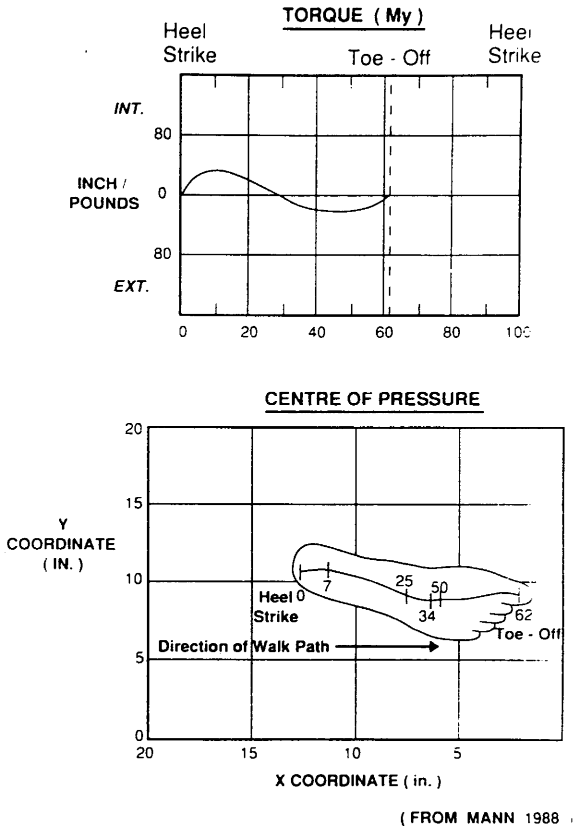


FIGURE 2.E: Torque (My) and centre of pressure progression during walking (from Mann 1988).

Forces are directly proportional to the speed of the gait. Analysis of the vertical force during running shows that the initial spike observed at the time of heel strike, which is about 70 per cent of the body weight during walking increases to about 150 per cent. The peak force is about two and a half times that of the body weight as against 120 per cent of body weight during walking.

k) CENTRE OF PRESSURE: When the centre of gravity along the plantar aspect of the foot is plotted, demonstrating the summation of the forces which are occurring beneath the foot, it is seen that these forces progress from the heel to the toe but not at a uniform rate (figure 2.E).

The centre of pressure moves rapidly from the heel and tends to dwell in the metatarsal head region and then moves rapidly to the tip of the great toe. Patients suffering from metatarsalgia tend to keep their centre of gravity towards the back of the foot, which then very rapidly progresses across the metatarsal head area. To let pressure dwell in this area would only result in added discomfort, altering their gait pattern.

CHAPTER 3

MODIFIED LOAD MEASURING SYSTEM

"In the collection of evidence upon any medical subject, there are but three sources from which we can hope to obtain it: VIZ. from observation on the living subject; from examination of the dead; and from experiment upon living animals."

(Astley Cooper 1768-1843)

3.1 INTRODUCTION

A system to analyse the loads and moments across a functional brace was developed and tested in a pilot study undertaken at the Bioengineering Unit, Strathclyde University. This study has been documented fully by K S C Kwong (1988). At the start of the pilot study there existed two different measuring systems in the Bioengineering Unit. A Television Computer system (Andrews et al 1981) for the acquisition of kinematic data and an Orthoses Load Measuring system (Lim 1985) which allows synchronised measurement of the ground reaction and the load in the orthoses. As a first step, it was undertaken to devise a system which would measure the loads in a femoral functional brace-limb complex. This system utilised the above mentioned two systems separately. The data was merged for analysis on the assumption that the patterns of loading action and that of the walking gait were comparable in both parts of the tests.

The pilot study allowed identification of certain shortcomings of the system, for measuring loads across the functional brace and the femoral fracture as follows:

a) The acquisition of kinematic and load data was carried out separately from each other by repeating the test. This was primarily due to the limitation of the software for the running of the testing program. The software routines were not capable of collecting data from the forceplates, load transducers and the television cameras at the same time. Available computer program in the gait laboratory allowed collection of the forceplate data with television data or load transducer data but not all three together. It was thus necessary to collect data from all the three sources in two runs. First with the television cameras and forceplate, and the next one with the load transducers and the forceplate. The data thus collected was then merged.

   Analysis of the data showed that the pattern of gait was essentially repeated, but the results would be more realistic if the system software could be modified to accommodate the collection of data from all the three sources (forceplate, load transducers and television cameras). It was decided to undertake this modification for the study to be presented in this thesis.

b) It was observed that the design of the blank plates/mating pieces used for attachment of the load transducers during the testing procedures did not allow easy attachment of the transducers. The mating pieces faced inwards, towards the cast, and the transducers had to be slipped up from below for attachment. This sometimes caused problems, if sufficient clearance was not allowed during incorporation of the mating-pieces to the functional brace. It was decided to re-design the mating pieces so that they faced outwards, and allowed easier application of the transducers at the time of testing.

c) <u>The system utilised for the pilot study did not attach the markers for the orientation of the limb during the load data acquisition</u>. The reason was the nature of the software program utilised for the purpose of the study. As explained above, the kinematic data was acquired separately from the load data and then the ground reaction was compared in both the runs. If the ground reaction was similar, the two sets of data were merged. This method was not accurate because there was no direct way of estimating the forces across the transducers at any particular instant during the gait cycle. This could only be done by fixing the markers on the transducers and collecting the kinematic data along with the transducer data. It was decided to carry out the modification of the attachment of the markers to the load transducers, during the acquisition of the present data. This modification coupled with the changes in the software acquisition programs, allowed more accurate orientation and positioning of the limb during acquisition of data from the load transducers.

d) The load transducers used for the pilot study, were manufactured for the analysis of loads across the uprights of the orthotic devices. They were found to be too long and limited the levels of fractures suitable for study. It was felt that smaller, more compliant transducers would be more appropriate. It was decided to utilise the same transducers because manufacture of new transducers, their calibration and testing would have required a time period of at least six months.

IMPROVEMENTS/MODIFICATIONS MADE IN THE PILOT STUDY SYSTEM: The pilot study led to the following detailed modifications in the existing system (Kwong 1988).

a) DATA ACQUISITION SOFTWARE: The software program was modified allowing simultaneous acquisition of forceplate, load transducers and television data (figure 3.1.A). This improved the accuracy of the system, and cut down on the number of runs required to be made by the patient.

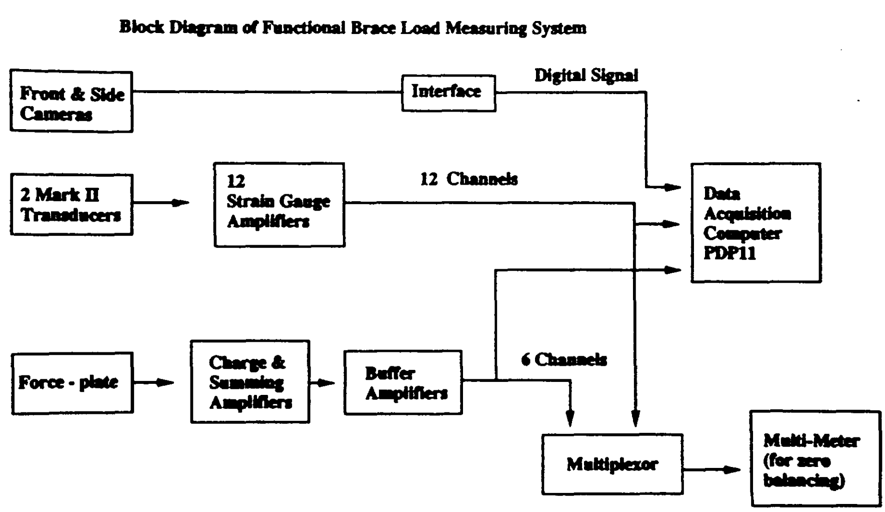
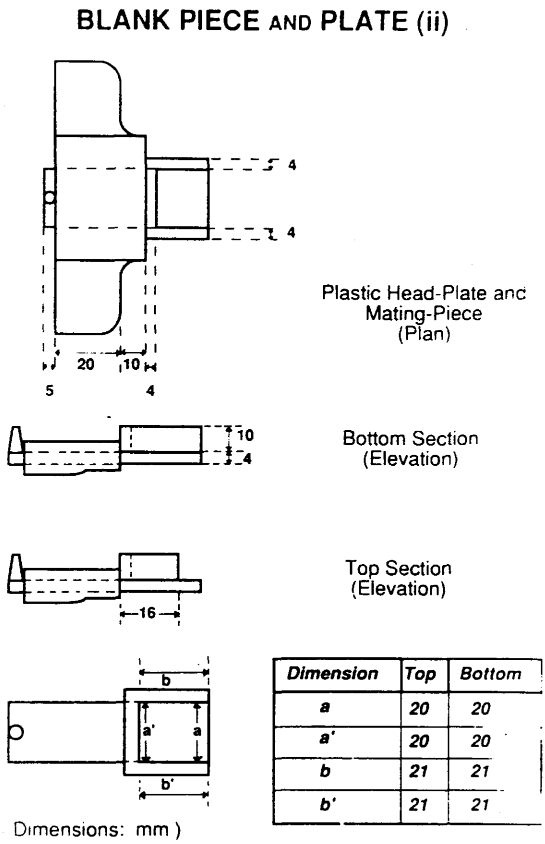


FIGURE 3.1.A: Block diagram of the modified functional brace load measuring system.

b) MODIFICATIONS TO THE MATING PIECE/BLANK PLATE DESIGN: The mating pieces were re-designed to allow easier attachment of the load transducers during testing in the gait laboratory (figures 3.1.B and 3.1.C). As the mating pieces faced outwards it was quite convenient for the load transducers to be pushed into them after removal of the blank plates before carrying out the tests.

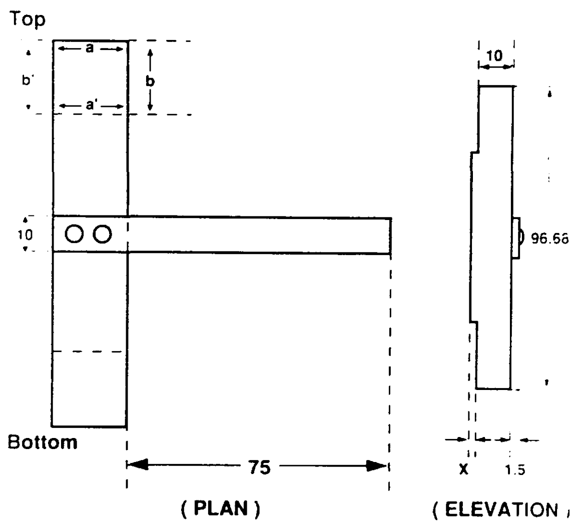


Dimension	Top	Bottom
a	20	20
a'	20	20
b	21	21
b'	21	21

FIGURE 3.1.B: Diagram of the mating pieces for attachment of the load transducers.

c) The design modification of the blank plates allowed attachment of the markers for orientation and positioning of the limb during kinematic analysis. Because the markers were attached to the load transducers, the calculation of the forces across the load transducers relative to the limb axis was more accurate.

BLANK PIECE AND PLATE (i)



Dimension	*Top*	*Bottom*
a	*20*	*20*
a'	*20*	*20*
b	*21*	*21*
b'	*21*	*21*

(Dimensions: mm

FIGURE 3.1.C: Diagram of the mating pieces for attachment of the load transducers.

d) SUBSTITUTION OF THE CO-ORDINATE SYSTEM FOR THE TIBIA: The pilot study (Kwong 1988) had looked at the loads across the functional brace used for the treatment of the fracture of the femur. This had required the co-ordinate system of the femur to be related to the lateral transducer. The present study was to investigate the biomechanical function of the 2 in 1 functional brace in the treatment of tibial shaft fractures. The co-ordinate system for the femur in the original program was therefore substituted by that of the tibia.

The modifications allowed the system to be used for assessment of loads across the functional brace-limb complex, more accurately and more efficiently. The time required to prepare and carry out the tests on the patient was cut down by almost 50 percent.

The modified software program is versatile enough to be used for measuring loads across functional braces for either the treatment of tibial or the femoral fractures, with minimal changes in the co-ordinate systems depending on the bone. Theoretical analysis of the data acquired by the present programs is not discussed, as the principles are the same as used in the pilot study and are described in detail by Kwong (1988).

SIGN CONVENTION FOR FORCES AND MOMENTS: In this study the Cartesian system, using the right hand rule, was used for the analysis of the results (figure 3.1.D). According to this system the orthogonal axis are as follows:

X axis: Horizontal and positive in the direction of progression.

Y axis: Vertical and positive in the upward direction.

Z axis: Horizontal and positive from left to right.

For angular measurements, a positive rotation is taken as a clockwise rotation viewed in the positive direction of an axis (Lim 1985). The same argument is applied for both force and moment measurements, where a positive load is taken as one which tends to accelerate the body segment in the positive direction (figure 3.1.D).

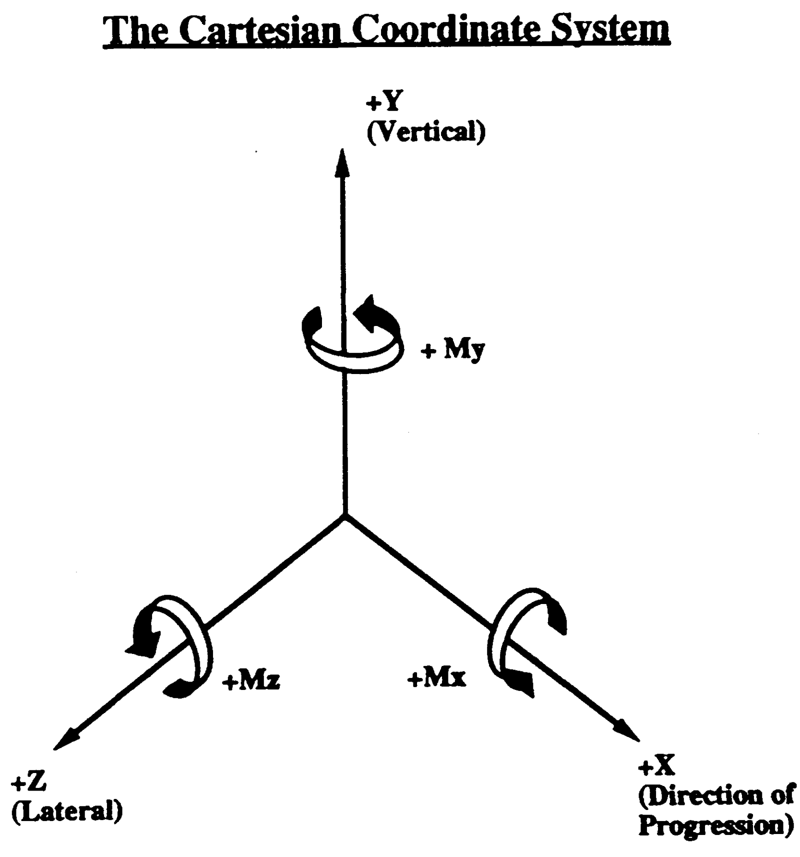


FIGURE 3.1.D: The cartesian co-ordinate system used for the analysis of data in the study.

Applying the above sign convention to the biomechanical analysis of a body segment, a positive force (or moment) is one that is being applied by an external body, such as ground or orthoses, onto the body segment at the distal end. Similarly, the positive load actions recorded by the transducers are assumed to be acting from an external source onto the distal end of the device.

3.2 MATERIALS

The study was carried out on 5 volunteer patients (4 males and 1 female), who were being treated for their tibial fractures with the 2 in 1 functional brace. The details of its fabrication and clinical application are given in part 3 of this thesis. The patient details are given in appendix-3A.

The patients were tested on 3 separate occasions between October 1989 and April 1990. The 1st, 2nd and 3rd visits occurred on approximately 6th, 10th and 12th week post-injury. On the 1st visit they were tested with and without the "foot-piece". Some of the patients used elbow crutches as walking aids during their 1st visit. On the subsequent visits (2nd and 3rd) all but two patients were instructed not to use any walking aids. On the 2nd visit, 2 patients (patient 03 and 04) were tested with and without a walking stick. This was to assess, if any, the effect of the walking stick on the loads at the fracture site. When the patients arrived at the gait laboratory for their 2nd and 3rd visits, the foot-pieces had already been removed.

In performing a complete analysis of the load action in the limb-brace complex during the stance phase of a walking cycle, three sets of data are required.

1 Kinematic data which reveals the limb's orientation and position in space.
2 Ground reaction at the stance phase to determine the total limb load.
3 The load in the functional brace at the level of the fracture site.

The modified load measuring system (figure 3.1.A) consisted of the following major components:

a) Multi-Component force plate.
b) Six channel load measuring transducers and attachment accessories.
c) Strain gauge bridge amplifiers.
d) Multiplexer.
e) Light reflective markers and attachment accessories.
f) Television cameras and infrared LED light source.
g) Calibration board.
h) Data acquisition computer.
j) Data processing computer.

a) MULTI-COMPONENT FORCE PLATE: To measure the ground reaction, this system utilises two "Kistler" type 9261A multi-component force plates. These force plates have dimensions of 600mm by 400mm, mounted flush with the floor of the Biomechanics Laboratory and covered with the same material as the rest of the floor, to make them as unobtrusive as possible. These force plates measure forces and moments in three orthogonal directions. The force plate Centre is defined as a point 39mm below the floor level, at the Centre of each individual force plate. The exact location with respect to the ground origin is shown in figure 3.2.A.

The force plates are piezo-electric multi-component measuring system. The overall error claimed by the manufacturer is +/- 2 percent for the force channels and +/- 3 percent for the moment channels (Kistler Manual). It is possible to reset the force plates by a single "push-button" switch. During this project only the force plate 1 (FP1) was utilised.

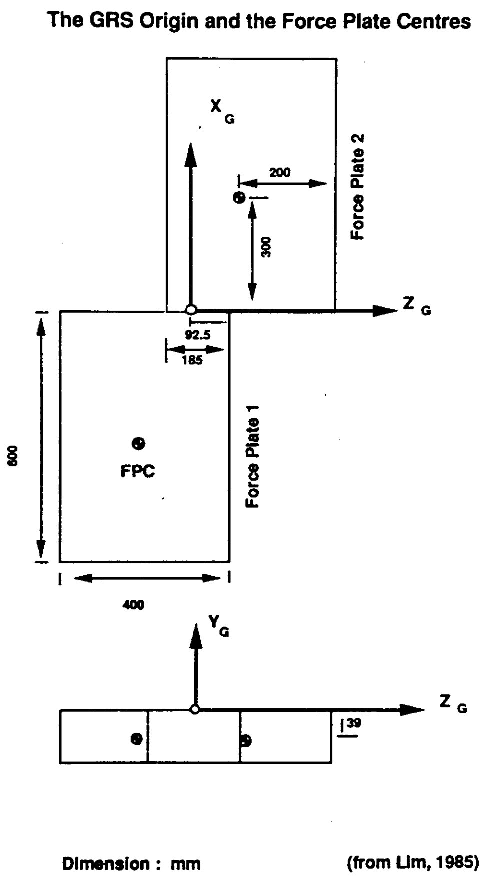


FIGURE 3.2.A: Location of the force plates relative to the ground reference system - GRS (from Lim 1985).

b) SIX CHANNEL TRANSDUCERS AND ATTACHMENT ACCESSORIES: For use with this system there are four Mark II KAFO (Knee Ankle Foot Orthoses) transducers available for measurement of loads. These transducers are custom built, with an overall size of 96mm by 20mm The dimensions are shown in figure 3.2.B. The mounting ends of the transducers were designed to couple with the uprights of the orthoses.

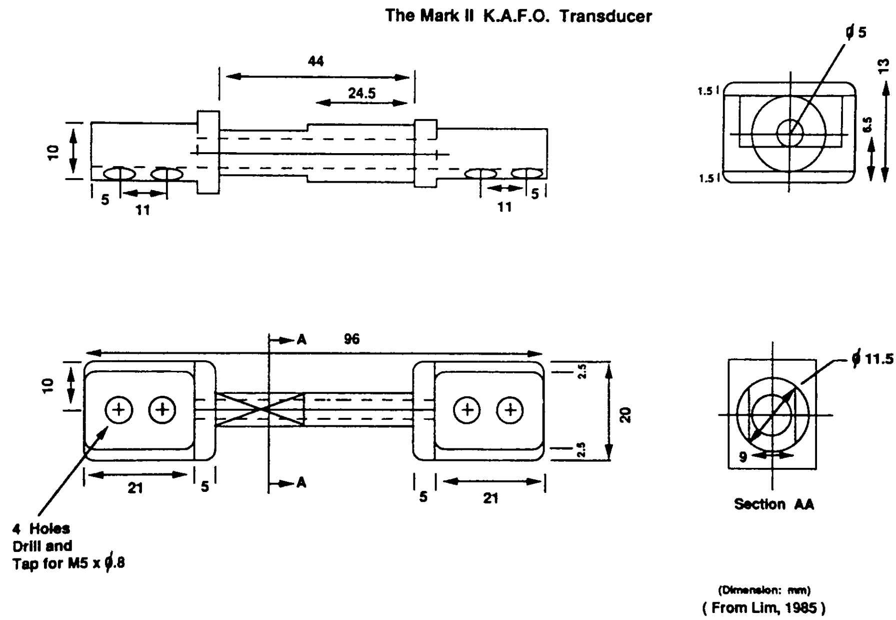


FIGURE 3.2.B: Diagram showing the dimensions of the load transducers (from Lim 1985).

Lim (1985) had recommended that the optimal bridge supply voltage for the transverse force and the axial force channels be 6V, and that for the moment channels be 3V. The transducer origin, to which the calibrations of loads were referred, is defined as an imaginary point at the centre of the cylindrical part of the transducer. It was found to be 40mm from the near end. This was also confirmed by Kwong (1988) during calibration.

The Mark II transducers were designed to have minimum overload capacities as follows:

Antero-Posterior shear	Fx	400N
Axial force	Fy	1600N
Medio-lateral shear	Fz	400N
Medio-lateral bending moment	Mx	50Nm
Axial torque	My	30Nm
Antero-posterior bending moment	Mz	70Nm

The maximum service loads are half that of the minimum overload capacities. Good linearity of the transducers was reported in the main channels throughout the service load range by Lim (1985), although he did observe some non-linearity in the cross talks.

In this study only two of the four available transducers were utilised. One each was mounted on the lateral and medial aspect of the functional brace, at the level of the fracture. The transducers utilised were Transducer 1 (TR1) and Transducer 4 (TR4). Special mating pieces had to be designed for the mounting of the transducers to the functional braces (figures 3.1.B & 3.1.C). These mating pieces were machined from mild steel, one end of which fits the mounting end of the transducer while the other end sits in the "plastic head plate" modified from that supplied by "Incare Ltd.". The plastic head plates along-with the attached "blank plates", are incorporated into the functional brace at the time of its fabrication. The spikes on the surface of the head plate interlace firmly with the net-work of synthetic bandages and the structure is strong enough to take all the load put on it.

As the methodology for the analysis of forces and moments across the functional brace-limb complex, required a circumferential cut to be made at the level of the fracture, therefore two "blank plates" were used to link up the proximal and the distal parts of the functional brace, one on each side. The blank plates were made to have the same length and the same design of the mounting ends as the transducers. During the load measuring tests the blank plates were replaced by the pair of transducers.

c) STRAIN GAUGE BRIDGE AMPLIFIER: All the channels of the above mentioned transducers are connected to an amplifier which supplies a regulated bridge voltage (-12V to +12V), and allows coarse and fine adjustment for the zero balance of the bridge. It also amplifies the output from the transducers in 7 stepwise gains (20, 50, 100, 200, 500, 1000, 2000), so that each of the output channels from the transducers can be adjusted to fit the input range of the analogue to digital converter. The amplifiers are set up in 4 banks of 6's and they share the common power supply in each bank. There are output facilities which allow accurate monitoring of the bridge voltage and the output voltage by a digital multimeter.

d) MULTIPLEXER: The multiplexer was not used for the actual acquisition of "load" and "kinematic" data during the patient test. The software in the modified system allowed the above data to be collected directly by the data acquisition computer, PDP11 (figure 3.1.A). The function of the multiplexer in this system was to allow "zero balancing" of the "load transducers" and the "force-plate" before commencing data acquisition. In order to achieve the same, the signals from the transducers and the force-plate were channelled through the multiplexer to a "Multi-Meter" (figure 3.1.A). This allowed corrections, if any, to be made and confirmation of the system readiness for acquisition of patient data.

e) LIGHT REFLECTIVE MARKERS AND ATTACHMENT ACCESSORIES: Spherical beads of 16mm diameter were used as markers in the study. The surfaces of these beads are covered with Scotchlite, a thin self adhesive plastic sheet with uniformly bonded very small spherical glass lenses. These optical glass lenses focus and retro-reflect incident light rays back in the direction of the light source, thus facilitating the pick-up of the marker image by the TV cameras, especially against the background of low intensity lighting. The markers are seen as small spots of light on the TV screens.

A total of five markers were applied to the cast. A marker (marker E) was attached to the marker-plate by double sided adhesive tape, after securely fixing it to a semi-spherical piece of wood (figure 3.2.C).

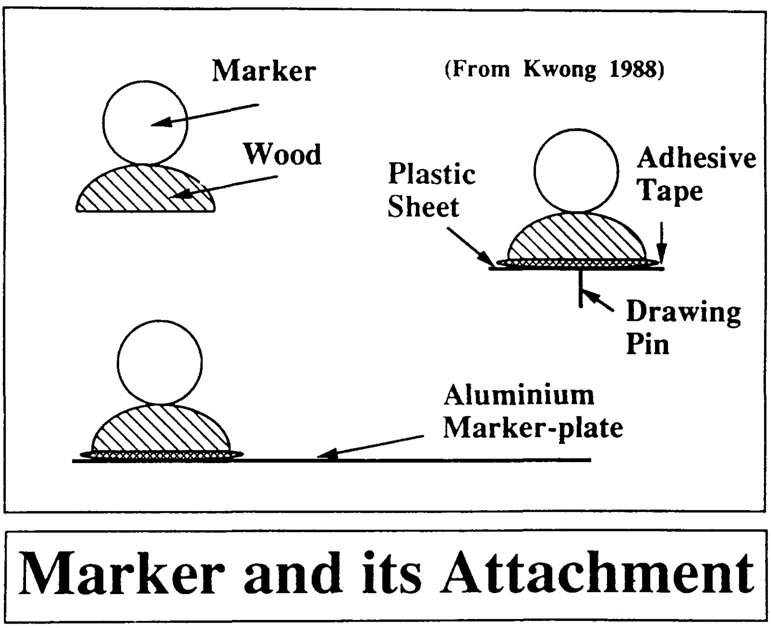


FIGURE 3.2.C: Construction of the marker and its attachment.

The marker-plate was constructed from aluminium sheet of 1.5 mm thickness and was painted matt black. It was secured onto the lateral blank-plate through two screws in the middle. Two markers (markers C & D) were attached on the anterior aspect of the functional brace by means of the modified drawing pins, each of which had a thin plastic sheet on them to facilitate the attachments of the markers by double sided adhesive tape (figure 3.2.D). Two more markers (markers A & B) were attached on the mating pieces.

FIGURE 3.2.D: Attachment of the five markers on the "2 in 1 functional brace".

f) TELEVISION CAMERAS AND INFRARED LED LIGHT SOURCE: The Biomechanics Laboratory has three cameras for use with this system. The front camera looks horizontally down the negative x-direction of the ground reference system (GRS) and has the optical axis parallel to the x-axis. The other two cameras are placed on either side of the walkway, with their optical axes horizontal and parallel to the z-axis of the GRS. Left camera looks in the positive direction of the z-axis while the right one in the negative direction (figure 3.2.E).

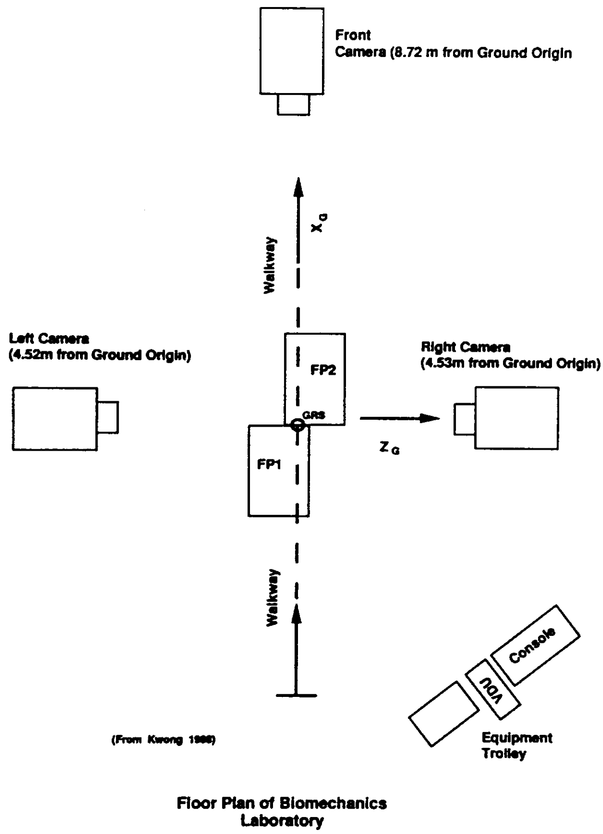


FIGURE 3.2.E: Floor plan of the biomechanics laboratory, University of Strathclyde, Glasgow.

The lenses used on the front and side cameras are Fujicon 1:1.4/50 and 1:1.7/25 respectively. The rims of the lenses are encircled by arrays of 200 infrared LED's. The optical filters in the lenses are chromatically matched with the light emitted from the LED's. The light from the LED's is reflected back from the markers to the camera lenses.

The images were monitored on two TV screens. It is possible to adjust the threshold levels of the TV cameras to suit the reflectivity of the markers, to optimise the image formation. It is advisable to cut off unwanted images from other light spots on the TV screens. In the study two cameras were used at one time, front camera with one of the side cameras.

g) **CALIBRATION BOARD:** A calibration board can be used to determine the positions of the functional brace markers in the Ground Reference System (GRS), it has 5 markers made from the same light reflective material and placed at known positions on the front surface of the board (figure 3.2.F).

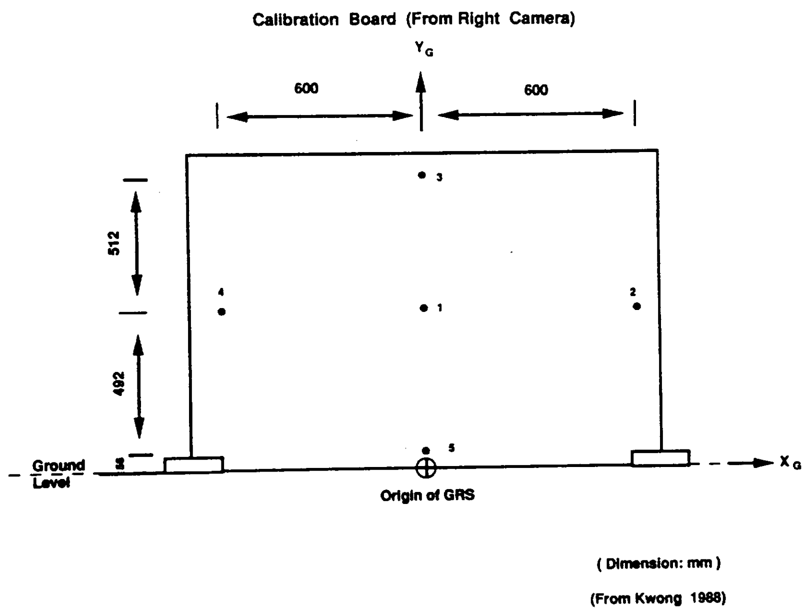


FIGURE 3.2.F: Calibration board as seen from the right camera.

The distances between the markers and from the ground level are measured to the nearest 0.1mm. The placement of the calibration board is such that its front surface is vertical and perpendicular to the optical axis of the camera. The board is placed at the origin of the GRS, while the marker 1 is immediately above the ground origin. Levelling screws ensure that the front surface of the board is vertical while markers 1, 2 and 4 are horizontal.

h) DATA ACQUISITION COMPUTER: To acquire data, a PDP11/34 minicomputer system was utilised. This is a 16 bit multi-user computer system. The data acquisition software is a menu driven program sampling data at 50 Hz and allows averaging and sorting of data. The software is also capable of editing the relevant datafiles and their reformation into ASCII format to allow easy transferability. These datafiles can then be transferred to the VAX 11/782 main-frame computer for data processing.

j) DATA PROCESSING COMPUTER: Data analysis on a microcomputer provides the advantage of portability. It was therefore decided to develop software for data processing on a 16 bits, Intel 8088 based microcomputer, for its accessibility (Kwong 1988).

RELIABILITY AND CALIBRATION OF THE LOAD MEASURING AND THE TV COMPUTER SYSTEMS: The tests for the reliability of the systems were not repeated by the author as the duration between the pilot study and the present study was not long enough to raise doubts about the accuracy of the instrumentation as determined and described by Kwong (1988). This section summarises the results and conclusions reached by him.

a) STABILITY OF THE FORCE-PLATE (FP1) AND LOAD TRANSDUCERS: Kwong (1988) reported errors due to the instability of the force-plate (FP1) channels to be about 0.22%, while the errors in all the channels of both the load transducers (TR1 and TR4) were found to be about 0.8%.

b) CALIBRATION OF THE TRANSDUCERS: The mark II transducers were first calibrated by Lim (1985) in 1983. Kwong (1988) repeated the calibration to see if there was any change in the mechanical behaviour of the transducers after several years. He agreed with the results reported by Lim (1985) and observed good linearity in the main channels, while non-linearity was found in some of the cross talks. Hysteresis was also seen. There was a mean decrease of about 3.3 percent in the output of the main channels (except Mz of TR4), whereas that of the cross talks was varied. Kwong believed that this could be due to a decrease in the sensitivity of the transducers, or due to some degree of mismatch in the references between this calibration and that performed by Lim.

c) CALIBRATION OF THE FORCE PLATE: Kistler force plates are accurate and stable instruments, and do not need frequent calibration. Kwong (1988) verified the calibration of the force-plate (FP1) by checking only the Fy channel. He found the weight of a 20 Kg dead weight to be 192.5 N. Taking acceleration due to gravity, "g" as 9.81 m/s^2, this reflects a 0.19% of mismatch. This value is small when compared with the error percentage of the force plate system.

d) REPEATABILITY OF KINEMATIC DATA ACQUISITION: Kwong (1988) investigated the stability and repeatability of the kinematic data acquisition procedure. He concluded that the kinematic data acquisition is repeatable and reliable, apart from some contamination from noise which could be filtered later by using suitable digital filtering in the data processing.

e) REPEATABILITY OF THE PLACEMENT OF THE CALIBRATION BOARD: The calibration board utilised in this study is a removable type, and requires to be placed at the origin of the ground reference system for calibration before each session. The repeatability of this procedure was checked and found to be reliable and repeatable for the calibration of kinematic data (Kwong 1988).

f) REPEATABILITY OF THE MEASUREMENT OF DISTANCES BETWEEN THE MARKERS: During actual testing procedure five markers are applied to the functional brace (figure 3.2.D). Three markers are applied on the blank plates on predetermined places while the two markers on the brace are placed anteriorly and spots marked, for attachment during subsequent tests. The distances between the markers were noted for each session. The discrepancies in the distances measured were within 1mm. This indicates that the method of measuring distances between the markers is reliable and repeatable.

3.3 METHODS

All the patient tests were performed at the Gait laboratory in collaboration with the Bioengineering Unit, University of Strathclyde. The detailed protocol for the experimental procedures carried out in the Gait laboratory during patient testing is described in the appendix-3B. This section highlights certain features of the method. Details of the tests undertaken were recorded on a form (appendix-3C).

PREPARATION OF THE LABORATORY: It is important to reduce noise levels and carefully control the light intensity during testing. The background, within the fields of view of the TV cameras was screened by black curtains. All objects reflective to light were removed out of view of the TV cameras.

PREPARATION OF THE INSTRUMENTS: The instrumentation in the biomechanics laboratory was switched on following the steps as detailed in appendix-3B. The transducers were connected to the input cables along with the other necessary connections (appendix-3B). The instruments were switched on and allowed to warm up for at least thirty minutes before the tests.

A digital multimeter was utilised to check the bridge voltages which were set to 6 volts for force channels (Fx, Fy, Fz) and 3 volts for moment channels (Mx, My, Mz). The gains for all channels were set to 2K except for the Mz channels where the gains were set to 1K. Depending on the output signals the gains were reset after the first run if the amplification was found to be too high for certain channels. Forceplate 1 (FP1) was set to 50 mech. unit per volt for the upper amplifiers; and 200 mech. unit per volt for the lower amplifiers.

The alignment and synchronisation of the cameras were checked, and their distances from the ground origin and heights from the ground surface were measured and recorded (appendix-3C). The threshold levels of the TV cameras and the brightness and contrast of the TV monitors were adjusted for optimum images. This adjustment also got rid of the unwanted light spots from other sources. Care was taken to cover the reflective parts of any walking aids being used by the patients, such as walking sticks etc, with black polythene sheets.

EXPERIMENTAL PROCEDURES: Experimental procedures included acquisition of kinematic data and the measurement of the loads in the functional brace. The details of the steps involved are given in the appendix-3B. The tests were supervised by a member of the medical staff to ensure patient safety. The patients were allowed to rest between the tests.

MARKER ATTACHMENTS TO THE CAST: Two markers A and B for dynamic testing were attached to the mating pieces for the lateral blank plate. A third marker E (for static tests only) was attached to the lateral blank plate, using a marker plate which attaches onto the blank plate. Two more markers (C and D) were attached to the anterior aspect of the brace about 200 mm or more apart, these markers were used in case of missing data from markers A and B during testing (figure 3.3.A).

The points of attachment were marked with permanent ink, for ease of attachment in future tests. The distances between the markers were measured and recorded to the nearest 0.1mm. Distances were also recorded between the reference points on the two blank plates. A black sock, modified to have holes so as to expose the markers, was then put onto the cast.

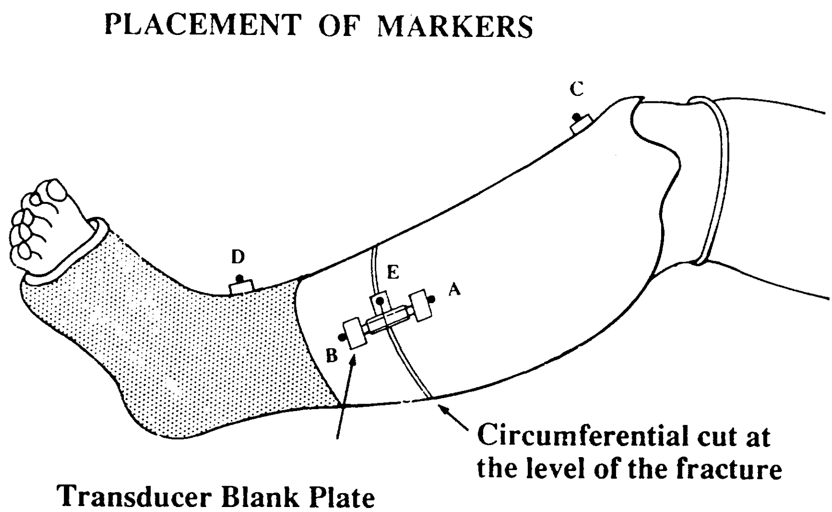


FIGURE 3.3.A: Sites of attachment of the markers on the 2 in 1 brace.

STATIC VIEWS OF THE MARKERS: After noting the above details, the first part of the test involved taking static views of the markers. The patient was instructed to stand still, in front of the cameras, while the images of the five markers were checked on the TV monitors and their positional data was acquired in this static posture.

MEASUREMENT OF BODY WEIGHT WITH THE FORCEPLATE: Static views of the markers was followed by the measurement of the body weight using the forceplate 1 (FP1). A stool was put on the FP1 while the patient stood away from the forceplate. The forceplate was reset and the patient instructed to sit on the stool with the good leg resting on the bar between the legs of the stool, while the injured leg was kept lifted off the ground. The patient held that position for about 10 seconds while the body weight was recorded.

CALIBRATION OF THE POSITIONAL DATA: This was carried out by placing the calibration board at the ground origin and acquiring the positional data of the markers on the board using the front and the side cameras. The calibration board was put at the origin of the ground reference system (GRS), with the surface of the board perpendicular to the optical axis of the lens of the camera and marker 1 vertically above the origin of the GRS.

ACQUISITION OF KINEMATIC AND LOAD DATA: The above procedures were followed by the removal of the sock and the blank plates, as well as the marker "E" along with its marker plate. The blank plates were replaced by transducer 1 (TR1) on the lateral and transducer 4 (TR4) on the medial side (figure 3.3.B). The connection cables for these transducers were held by a belt worn round the waist. The black sock was again put on after attachment of the transducers.

FIGURE 3.3.B: Replacement of the blank plates with load transducers on the medial and lateral sides, before acquisition of data.

ZERO BALANCING THE BRIDGE OUTPUTS: Before acquisition of the kinematic data and the loads measured in the brace the patient was instructed to sit very still on a chair with the injured leg placed horizontally, well supported on a pillow, on a stool in front. The bridge voltages were checked and the bridge outputs were then zero balanced. The base-line levels of the output channels were then recorded by running the acquisition program while the patient kept the injured leg immobile.

DATA ACQUISITION: Kinematic data and loads across the 2 in 1 functional brace were acquired by asking the patient to walk along the walkway (figure 3.3.B). They were advised to walk as naturally as they could, taking as much weight as they could, on the injured leg. The starting point was about 1 to 2 metres from the forceplate 1 (FP1), and was adjusted so as to ensure that only the foot of the injured leg came to lie on the forceplate as the patient walked over it.

Positional data of the markers, loads on the forceplate 1 and the loads across the transducers were recorded. This part of the test was repeated so as to acquire 3 successful runs, as sometimes the patient would overshoot the forceplate thus resulting in scrapping of that particular run. This occurs because the patients are not advised of the location of the forceplate in the walkway, so that they walk as naturally as possible without making an effort to step over the forceplate by breaking their strides.

The test was concluded after ensuring that the data had not been corrupted. Then the transducers were removed and replaced with the blank plates.

MEASUREMENTS ON THE X-RAY FILMS: Measurements were made on the x-rays taken at the time of attachment of the mating pieces/blank plates to the brace, to provide information required for data analysis as described by Kwong (1988).

DATA PROCESSING IN THE MODIFIED SYSTEM: The flow diagram (figure 3.3.C) describes the major aspects of the processing of the data after its acquisition.

a) PROCESSING OF KINEMATIC DATA: The kinematic data acquisition program in the modified system resulted in the following files:

1 Filename.ICL
2 Filename.MD1
3 Filename.MD3 or .MD4

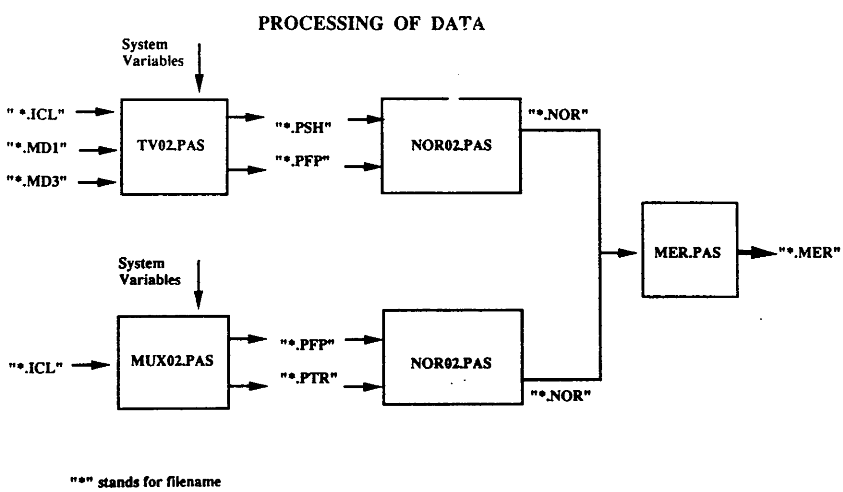


FIGURE 3.3.C: Flow diagram showing the processing of the data after its acquisition.

The ".ICL" files recorded the loads in forceplate 1 and the transducers while the ".MD1" and ".MD3 or .MD4" (depending on the side of injury) files recorded the co-ordinates of the markers as acquired by the front and the side cameras respectively. They were processed by a software program "TV02.PAS" which calculated the ground reaction in the ground reference system. The positional vectors of the fracture centre and the direction cosine of the tibial system with respect to the ground reference system were also determined. These calculations were also performed by the program "TV02.PAS" and allowed the estimation of the total limb loads at the fracture site in the tibial shaft. The output datafile from this program was (figure 3.3.C):

Filename.PSH (total limb loads in the tibia)

b) PROCESSING OF LOAD DATA: The output datafiles "Filename.ICL" from the load measuring program recorded the loads in forceplate 1 and the transducers. They were processed by a software program "MUX02.PAS" which calculated the transducer forces in the transducer reference system and the ground reaction in the ground reference system. The loads in the transducers were transformed to the tibial system, and summed to obtain the loads in the brace at the fracture level in the tibia. The output datafile from this program was (figure 3.3.C):

Filename.PTR (loads in the brace)

NORMALISATION AND DIGITAL FILTERING: While walking, the time intervals of the stance phases vary from subject to subject and even in the same subject they vary from test to test. In order to compare different sets of data and to overcome the above problem, use is made of the technique of normalisation in terms of the stance phase. This procedure transforms the data (forces and moments) so that it is presented relative to the percentage of the cycle.

Normalisation of the data was followed by further processing, by a low pass digital filtering technique to cut off noise at higher frequencies. The output datafiles obtained after this procedure were "Filename.NOR".

MERGING OF DATA: The files obtained after processing of the kinematic data and the load data were then merged using the program "MER.PAS" to obtain one single datafile "Filename.MER" (figure 3.3.C). This allowed direct comparison to be made of the total limb loads at the fracture site and that in the brace at the level of the fracture in the tibial shaft.

BREAKDOWN OF TIME TAKEN TO ACQUIRE/ANALYSE DATA: Average times to undertake different aspect of the test were worked out with the following results:

1	Preparation of laboratory and equipment	2 Hr.
2	Acquisition of data	3 Hr.
3	Calibration of data	2 Hr.
4	PDP computer analysis (Kinematic data)	5 Hr.
5	IBM computer analysis (Main analysis)	4 Hr.
6	Transfer of data to VAX main frame and plotting of results	2 Hr.
7	Assessment of results	3 Hr.
	TOTAL TIME TAKEN FOR ONE TEST	21 Hr.

During the study, 5 tibial fractures were tested three times each. The average times post-injury for the three tests in each patient were 6, 10 and 12 weeks. This involved, approximately, a total of 315 hours of laboratory and computer time. The time involved in writing, modifying and testing the software and equipment for the study was in addition and was performed in collaboration with the expertise available at the Bioengineering Unit, Strathclyde University Glasgow.

ANALYSIS OF GRAPHICAL PRINTOUTS OF THE DATA: The data acquired during patient testing was processed as described and then printed out in graphical form. These graphical print-outs were then analysed by assessing the following five parameters on each graph:

Parameter A/- Off-loading part of stance phase.

Parameter B/- Maximum percentage off-loading during stance phase.

Parameter C/- Maximum force/moment observed during stance phase.

Parameter D/- Maximum percentage increase in load (force or moment) observed during stance phase.

Parameter E/- Increase in load (force or moment) part of the stance phase.

The way in which the above mentioned parameters were calculated is described with reference to the figure 3.3.D. It shows two graphs of A/P shear (Fx) recorded on a patient with a foot-piece on (graph 1), and then with the foot-piece off (graph 2). The solid line in the graphs represents the A/P shear (Fx), recorded from the force-plate and expressed at the level of the tibial fracture in the tibial reference system. The broken line represents the A/P shear (Fx), measured from the load transducers applied on the cast at the level of the fracture also expressed in the tibial reference system.

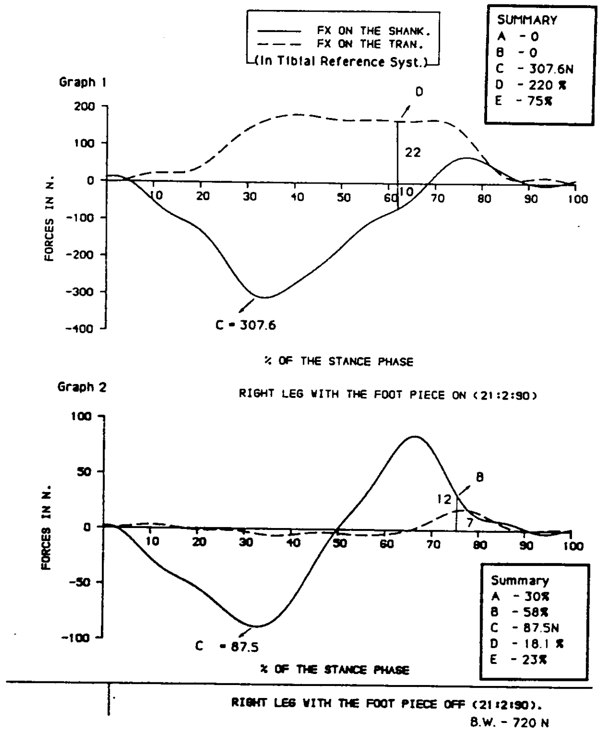


FIGURE 3.3.D: Analysis of the graphical printouts of the data.

If both the solid and broken lines in the graph are on the same side of the zero axis, then it implies that the cast is off-loading the amount of force acting on the fracture. Whereas, if the above mentioned lines are on the opposite sides of the zero axis , then it implies that the cast is somehow adding to the force experienced at the fracture. These inferences are based on the following equation for the total force at the level of the tibial fracture:

F (total in tib. ref. syst.) = F (transducer in tib. ref. syst.) + F (fracture)

thus F (fracture) = F (total in tib. ref. syst.) - F (transducer in tib. ref.syst.)

where

F (total in tib. ref. syst.) is the force recorded by the force plate and expressed at the level of the fracture in the tibial reference system.

F (transducer in tib. ref. syst.) is the combined force measured by the two transducers at the level of the fracture also expressed in the tibial reference system.

F (fracture) is the unknown entity and is the force experienced at the fracture in the skeleton.

The above equation applies equally to the estimation of the moments.

In this (figure 3.3.D) graphical presentation of A/P shear (Fx), the off-loading part of stance phase (designated "A" in the respective graphical summaries), was calculated by estimating the percentage of the stance phase during which the brace was able to decrease the amount of force on the fracture in the skeleton. In this case no off-loading was seen in graph 1, while off-loading was observed in graph 2 (28-48 and 67-77% of the stance phase), the total duration of which was approximately 30% of the stance phase as noted in the graphical summary against "A".

The maximum percentage off-loading was calculated by identifying the point on the graph where the cast was able to off-load to the maximum relative to the total force (solid line). This was then estimated as a percentage given in the summary for the particular graph as "B". In figure 3.3.D, graph 1 had no off-loading therefore no value for maximum percentage off-loading, whereas on graph 2 the point for maximum off-loading occurred at approximately 75% of the stance phase and was estimated to be 58.3% of the A/P shear recorded on the force plate expressed in the tibial reference system at the level of the fracture.

Maximum force/moment observed during stance phase was the point identified on the graph at which the force, in this case A/P shear force (Fx), recorded by the force-plate at the level of the fracture in the tibial reference system (solid line) was the maximum. In figure 3.3.D, this occurred on graph 1 at approximately 33% of the stance phase (value being 307.6 N) while on graph 2 it occurred at approximately 32% of the stance phase (value being 87.5 N). The respective values were noted in the relevant summaries against "C".

The fourth parameter of maximum percentage increase in load was measured similar to the 2nd parameter (maximum percentage off-loading) by identifying the point in the stance phase where the presence of the cast introduced extra loads. In figure 3.3.D, this point was observed in graph 1 at approximately 61% of the stance phase (value being 220% of the A/P shear recorded by the force-plate and expressed at the level of the fracture in the tibial reference system), while on graph 2 it was observed at approximately 53% of the stance phase (value being 18.1% of the A/P shear recorded by the force-plate and expressed at the level of the fracture in the tibial reference system). The respective values were noted in the respective graphical summaries against "D".

The fifth parameter was the estimation of the increase in load part of the stance phase. This was also calculated in a manner similar to that employed for the first parameter (off-loading part of the stance phase). The portion of the stance phase during which an increase in force due to the presence of the cast was observed in graph 1 (5-80% of the stance phase) was approximately 75%. The corresponding value for graph 2 (5-15 and 50-63% of the stance phase) was 23%. The values were noted in the respective graphical summaries against "E".

The above described routine for graphical analysis was followed for all six graphs (Fx, Fy, Fz, Mx, My and Mz) obtained for each test run. As described in a previous section the testing routine involved testing each patient on 3 separate occasions. From the first two visits, on an average, 4 test runs were analysed each time while 2 test runs were analysed from the 3rd visit. Thus for each tibial shaft fracture, approximately 10 test runs were analysed in the above manner (a total of 60 test runs and 360 graphs) and results tabulated as presented in section 3.4.

3.4 RESULTS

The general pattern of the gait was broadly the same among all the patients, though individual variations were observed. Some of the features of the gait pattern are discussed with reference to the two tests carried out on patient 03 on his first visit. These tests were carried out with and without the "foot-piece" (figures 3.4.A to 3.4.C). The figures 3.4.A to 3.4.C show two sets of graphs, the one on the left represent the test carried out with the foot-piece while the right one shows the result without the foot-piece. These graphs are not typical of all the patients. These tests were carried out approximately 6 weeks after the tibial shaft fracture.

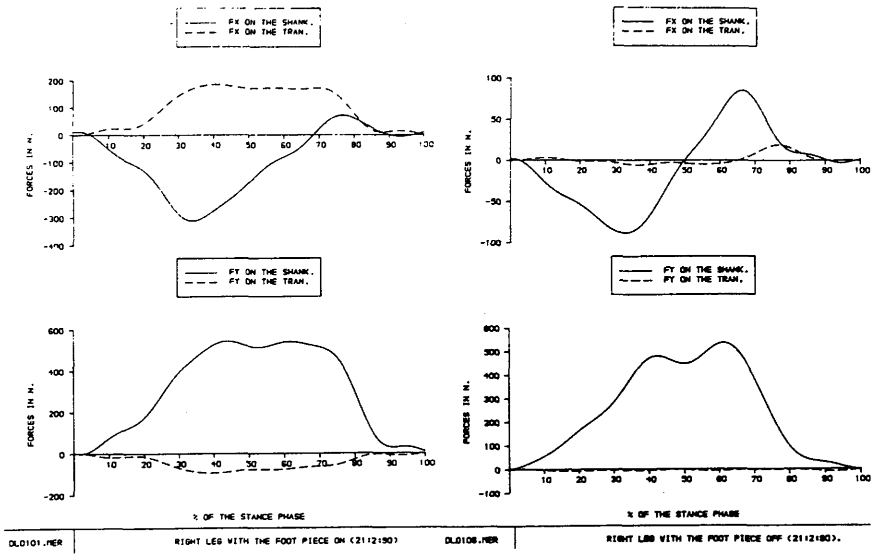


FIGURE 3.4.A: Graphs show A/P shear (Fx) and Axial force (Fy), with and without foot-piece.

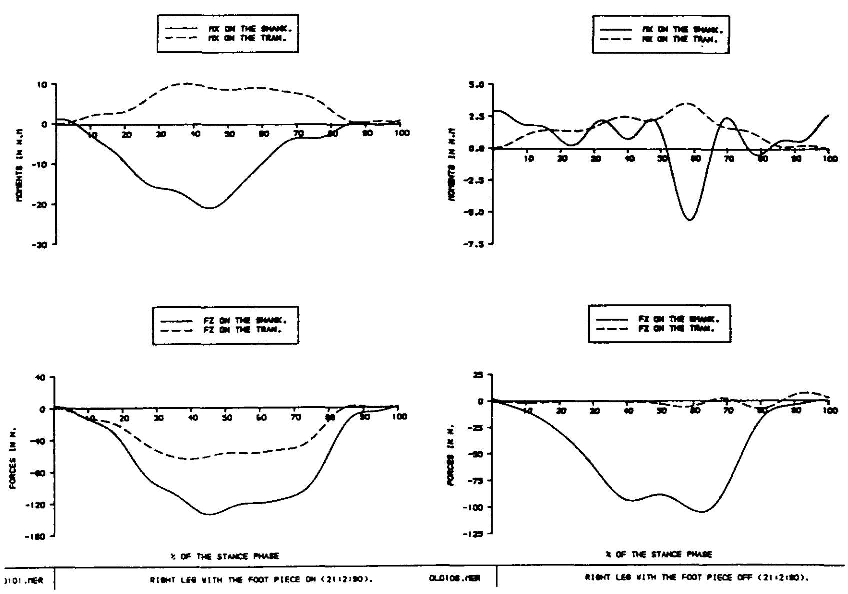


FIGURE 3.4.B: Graphs show M/L shear (Fz) and M/L bending (Mx), with and without foot-piece.

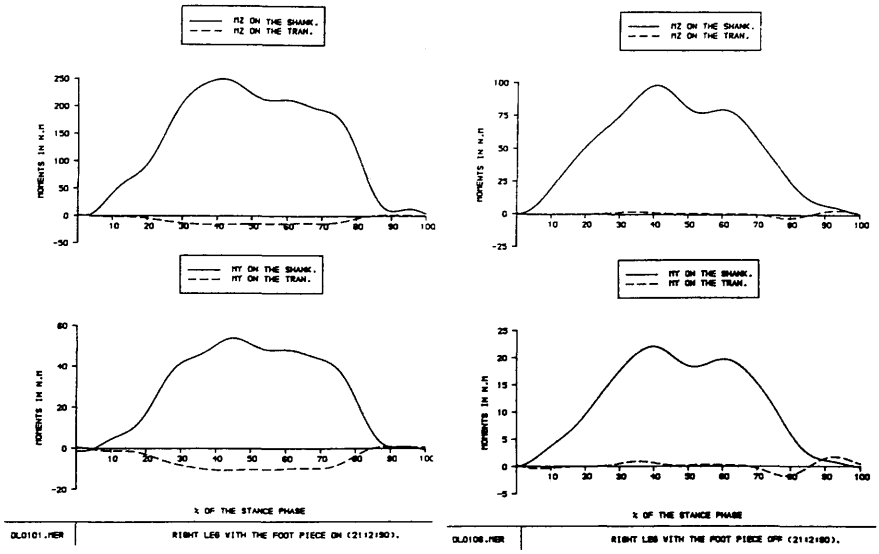


FIGURE 3.4.C: Graphs show Axial torque (My) and A/P bending (Mz), with and without foot-piece.

When the patients walked with the foot-piece on, no heel strike was observed (figure 3.4.A). As is apparent from figure 3.4.A, there was a gradual rise in the axial force (Fy) instead of a sharp peak indicative of heel strike. The patients tended to put their foot flat on the ground, instead of putting the heel first. The pattern of walking with regard to heel strike gradually reverted back to normal, when the patient started walking without foot-piece. This change was not seen immediately after removal of the foot-piece on the first visit (figure 3.4.A), possibly because the patients were apprehensive and still walked cautiously. As their confidence returned, due to the absence of pain and normal use of the ankle/sub-talar joint, the gait pattern improved.

It was also noted that the stride length was small and the speed of walking with the foot-piece on was slower than without it. This was noticeable during gait tests because the starting point for the walk in the laboratory had to be changed between walking with foot-piece on and off, indicating change in stride length and speed. This was expected because without the foot-piece the ankle/sub-talar joints were able to play their full role in smoothing out the gait.

The patients did not show a well defined "push-off phase" while walking with the foot-piece on (figure 3.4.A). This was corrected to some extent after removal of the foot-piece and resumption of the normal function of the ankle joint.

BIOMECHANICAL FUNCTION OF THE BRACE: The general patterns of loads in the brace were basically the same for all the patients, although individual variations were observed. All the five parameters, as discussed in section 3.3, are presented separately in tabulated form for each of the 3 orthogonal forces and moments. The values in the table for tests on each visit are the means of 2 tests.

From a statistical point of view it is not appropriate to make use of mean values to make comparisons for a group of this size and variability. But overall mean values were calculated for each of the 5 parameters for the 3 orthogonal forces and moments. This was done in order to generalise the results, for clinical application. The average value and the general trend of the values, are comparatively more important than the individual values, for decisions regarding design features of the brace.

A/P SHEAR (Fx): The results for the five parameters analysed are tabulated in figures 3.4.D to 3.4.H. Almost in all the patients, the brace was able to off-load A/P shear loads during variable parts of the stance phase (figure 3.4.D). There was variation between patients as to the total part of the stance phase during which off-loading occurred, and also where within the stance phase it occurred. These individual variations were probably due to the variation in gait patterns. To generalise it could be said that about 32% (S.D 22.58) of the stance phase showed off-loading of the A/P shear.

Maximum value for off-loading during stance phase also varied from patient to patient and also with the time post-injury (figure 3.4.E). It was observed that the amount of off-loading with the "foot-piece" on was generally higher, average being 45%, when compared to without foot-piece (32%). This supports the view that presence of a foot-piece is beneficial.

A/P SHEAR (Fx)
OFF-LOADING PART OF THE STANCE PHASE
[PARAMETER 'A']

	1st VISIT WITH FOOT-PIECE	1st VISIT WITHOUT FOOT-PIECE	2nd VISIT WITH STICK	2nd VISIT WITHOUT STICK	3rd VISIT
PATIENT 01	42	38	*	3.5	48
PATIENT 02	40	31	*	*	0
PATIENT 03	0	42.5	54	52	77
PATIENT 04	9.5	35.5	58.5	59.5	0
PATIENT 05	17	15	*	14	37

FIGURE 3.4.D: A/P shear (Fx), off-loading part of the stance phase (Parameter A).

A/P SHEAR (Fx)
MAXIMUM PERCENTAGE OFF-LOADING DURING STANCE PHASE
[PARAMETER 'B']

	1st VISIT WITH FOOT-PIECE	1st VISIT WITHOUT FOOT-PIECE	2nd VISIT WITH STICK	2nd VISIT WITHOUT STICK	3rd VISIT
PATIENT 01	66.3	18.3	*	10	47
PATIENT 02	64.5	22.7	*	*	0
PATIENT 03	0	62.1	65.8	32.9	37
PATIENT 04	41	42.5	23.3	11.6	0
PATIENT 05	54.1	16.7	*	32.5	28.2

FIGURE 3.4.E: A/P shear (Fx), maximum percentage off-loading during the stance phase (Parameter B).

A/P SHEAR (Fx)
MAXIMUM A/P SHEAR OBSERVED DURING STANCE PHASE
[PARAMETER 'C']

	1st VISIT WITH FOOT-PIECE	1st VISIT WITHOUT FOOT-PIECE	2nd VISIT WITH STICK	2nd VISIT WITHOUT STICK	3rd VISIT
PATIENT 01	254.8	288.0	*	235.2	168.7
PATIENT 02	268.7	127.5	*	*	291.8
PATIENT 03	334.5	76.5	171.6	205.7	252.5
PATIENT 04	110.9	117.7	285.7	321.9	330.0
PATIENT 05	52.6	55.4	*	87.7	75.1

FIGURE 3.4.F: A/P shear (Fx), maximum A/P shear observed during the stance phase (Parameter C).

A/P SHEAR (Fx)
MAXIMUM PERCENTAGE INCREASE IN A/P SHEAR OBSERVED DURING STANCE PHASE
[PARAMETER 'D']

	1st VISIT WITH FOOT-PIECE	1st VISIT WITHOUT FOOT-PIECE	2nd VISIT WITH STICK	2nd VISIT WITHOUT STICK	3rd VISIT
PATIENT 01	171.1	7.9	*	27.2	11.0
PATIENT 02	72.6	0	*	*	5.4
PATIENT 03	128.0	20.0	0	0	0
PATIENT 04	192.8	116.5	0	0	0
PATIENT 05	416.0	27.7	*	29.3	36.5

FIGURE 3.4.G: A/P shear (Fx), maximum percentage inc. in A/P shear during the stance phase (Parameter D).

A/P SHEAR (Fx)
INCREASE IN A/P SHEAR PART OF THE STANCE PHASE
[PARAMETER 'E']

	1st VISIT WITH FOOT-PIECE	1st VISIT WITHOUT FOOT-PIECE	2nd VISIT WITH STICK	2nd VISIT WITHOUT STICK	3rd VISIT
PATIENT 01	31.5	27.0	*	70.5	24.0
PATIENT 02	29.0	0	*	*	32.5
PATIENT 03	68.5	20.0	0	0	0
PATIENT 04	52.0	37.5	0	0	0
PATIENT 05	69.0	67.5	*	67.0	19.0

FIGURE 3.4.H: A/P shear (Fx), increase in A/P shear part of the stance phase (Parameter E).

The maximum value (figure 3.4.F) of the A/P shear was found to be on an average 196 N (S.D 98.10). There was variation between individual patients, with 2 patients (patient 04 & 05) giving values on the lower side, on their first visit. It was noted that almost all patients showed a dramatic drop in the value on the first visit when the patients were tested with and without the foot-piece. The values gradually picked up on the subsequent 2nd and 3rd visits, to match the value of the 1st visit with foot-piece on (figure 3.4.F).

Superficially, the difference in maximum A/P shear value on the first visit with and without the foot-piece might appear to be due to the removal of the foot-piece. This could lead one to conclude that as the foot-piece leads to high A/P shear therefore the patient would be better off without it. But if the whole trend is analysed, keeping in mind the gradual rise of the A/P shear values in the subsequent 2nd and 3rd visits then the above occurrence can be explained. The explanation being that when the patients are tested on the first visit with the foot-piece on, they walk with confidence as they are used to the brace, producing high values of A/P shear. When the foot-piece is removed on the same day and patients tested again, they are not comfortable with the new situation and walk cautiously resulting in low values. This situation changes on 2nd and 3rd visits which occur at an average interval of 2 weeks each, during which time they have recovered the ankle/sub-talar joint function and are more confident during walking.

This means that the dramatic change in A/P shear values observed on the first visit is not just because of the removal of the foot-piece, but is due to the lack of patient confidence and stiffness of ankle/sub-talar joint during walking. In 2 patients (patient 03 & 04), tests were also carried out on the second visit with and without walking sticks. It was seen that the use of a stick, off-loaded about 14% of the A/P shear load during walking.

Maximum percentage increase in A/P shear during stance phase varied widely from patient to patient (figure 3.4.G). The overall average was 60% (S.D 100.80). The part of stance phase showing increase in A/P shear load also varied from visit to visit (figure 3.4.H). The average for all the patients was about 29% of the stance phase. This increase in load on the limb-brace complex could be attributed to the brace, and because it primarily occurred with the foot-piece on, it could be argued that this feature of the design is inappropriate. Such a conclusion would be in error because it does not consider the whole picture. It has been discussed already that higher values of maximum off-loading of A/P shear occur with the foot-piece on rather then without it (figure 3.4.E). Another consideration is the importance of avoiding the shear stresses developed due to the mechanism of the torque transfer, when ankle/sub-talar joints are allowed free movement. It thus follows that the foot-piece is an important and essential feature of the brace design during early part of the healing.

It was also noted that a larger part (32%) of the stance phase off-loaded A/P shear force as against 29% of the stance phase during which the load was increased. This suggests that the tibial brace functions to off-load the A/P shear forces during most of the stance phase.

Axial force (Fy): No off-loading of the axial force (Fy) at all was observed with the brace during any of the tests in any patient, except for one patient (patient 05) on his first visit with foot piece on (figure 3.4.J). The value for maximum off-loading, relative to the above test in patient 05, was 17.7% (figure 3.4.K). This fact supports the view that the brace does not act primarily by axially off-loading the fracture site as proposed by Scott (1989).

The overall mean for the maximum axial force observed during stance phase was 683.3 N (S.D 140.4). Same pattern, as in A/P shear (Fx), of drop in maximum values on the first visit with and without the foot-piece was observed (figure 3.4.L), and could be explained on the same lines. The analysis of tests undertaken on the 2nd visit on patient's 03 and 04 showed that the average off-loading due to the use of a stick was about 14.7% (figure 3.4.L).

The overall mean (figure 3.4.M) for maximum percentage increase in axial force (Fy) observed during the stance phase was 8.5% (S.D 9.4). While the overall mean (figure 3.4.N) increase in axial force part of the stance phase was 42.2% (S.D 40.85). Variations in the above parameters were observed among the individual patients but the data clearly shows that the brace instead of off-loading the axial force (Fy) led to its increase, during parts of the stance phase, on the skeleton.

AXIAL FORCE (Fy)
OFF-LOADING PART OF THE STANCE PHASE
[PARAMETER 'A']

	1st VISIT WITH FOOT-PIECE	1st VISIT WITHOUT FOOT-PIECE	2nd VISIT WITH STICK	2nd VISIT WITHOUT STICK	3rd VISIT
PATIENT 01	0	0	*	0	0
PATIENT 02	0	0	*	0	0
PATIENT 03	0	0	0	0	0
PATIENT 04	0	0	0	0	0
PATIENT 05	34	0	*	0	0

FIGURE 3.4.J: Axial force (Fy), off-loading part of the stance phase (Parameter A).

AXIAL FORCE (Fy)
MAXIMUM PERCENTAGE OFF-LOADING DURING THE STANCE PHASE
[PARAMETER 'B']

	1st VISIT WITH FOOT-PIECE	1st VISIT WITHOUT FOOT-PIECE	2nd VISIT WITH STICK	2nd VISIT WITHOUT STICK	3rd VISIT
PATIENT 01	0	0	*	0	0
PATIENT 02	0	0	*	0	0
PATIENT 03	0	0	0	0	0
PATIENT 04	0	0	0	0	0
PATIENT 05	17.7	0	*	0	0

FIGURE 3.4.K: Axial force (Fy), maximum percentage off-loading during the stance phase (Parameter B).

AXIAL FORCE (Fy)
MAXIMUM AXIAL FORCE OBSERVED DURING THE STANCE PHASE
[PARAMETER 'C']

	1st VISIT WITH FOOT-PIECE	1st VISIT WITHOUT FOOT-PIECE	2nd VISIT WITH STICK	2nd VISIT WITHOUT STICK	3rd VISIT
PATIENT 01	599.0	584.7	*	578.7	381.2
PATIENT 02	882.7	875.1	*	937.5	914.1
PATIENT 03	530.0	506.0	577.2	671.2	691.2
PATIENT 04	718.8	606.3	606.3	717.8	687.5
PATIENT 05	769.7	675.0	*	757.8	765.3

FIGURE 3.4.L: Axial force (Fy), maximum axial force observed during the stance phase (Parameter C).

AXIAL FORCE (Fy)
MAXIMUM PERCENTAGE INCREASE IN AXIAL FORCE OBSERVED DURING THE STANCE PHASE
[PARAMETER 'D']

	1st VISIT WITH FOOT-PIECE	1st VISIT WITHOUT FOOT-PIECE	2nd VISIT WITH STICK	2nd VISIT WITHOUT STICK	3rd VISIT
PATIENT 01	13.4	20.0	*	7.3	10.0
PATIENT 02	8.1	0	*	0	0
PATIENT 03	18.2	0	0	0	0
PATIENT 04	17.4	13.1	21.1	14.0	10.8
PATIENT 05	32.7	0	*	0	0

FIGURE 3.4.M: Axial force (Fy), max. percentage inc. in axial force during the stance phase (Parameter D).

AXIAL FORCE (Fy)
INCREASE IN AXIAL FORCE PART OF THE STANCE PHASE
[PARAMETER 'E']

	1st VISIT WITH FOOT-PIECE	1st VISIT WITHOUT FOOT-PIECE	2nd VISIT WITH STICK	2nd VISIT WITHOUT STICK	3rd VISIT
PATIENT 01	91.0	50.0	*	77.0	68.0
PATIENT 02	65.0	0	*	0	0
PATIENT 03	87.5	0	0	0	0
PATIENT 04	75.5	82.5	93.5	92.5	90.0
PATIENT 05	55.0	0	*	0	0

FIGURE 3.4.N: Axial force (Fy), increase in axial force part of the stance phase.

M/L shear (Fz): The overall mean (figure 3.4.P) for the off-loading part of the stance phase for M/L shear (Fz) was 28.9% (S.D 30.3). The overall mean (figure 3.4.Q) for the maximum percentage off-loading of M/L shear (Fz) during the stance phase was 18.8% (S.D 22.44).

The overall mean value (figure 3.4.R) for the maximum M/L shear observed during the stance phase was 114.4 N (S.D 53.4). Individual variations were observed with 2 patients (patient 01 and 02) showing comparatively lower values then the rest of the group. The trend, of drop in values on the first visit with and without foot-piece, as observed with A/P shear (Fx) and axial force (Fy) was not observed with M/L shear (Fz) except in patient 03 (figure 3.4.R). This could be due to the use of walking aid (elbow crutch), on the contra-lateral side.

The overall mean (figure 3.4.S) for maximum percentage increase in M/L shear observed during the stance phase was 35.8% (S.D 49.0). Individual variations were observed, while patient 03 showed no increase at all during any of the tests (figure 3.4.S).

The overall mean (figure 3.4.T) for increase in M/L shear (Fz) part of the stance phase was 29.6% (S.D 30.92). The analysis of the above data shows that in general, as far as the M/L shear (Fz) is concerned,the stance phase had equal percentages of off-loading (28.9%) and increase in load (29.6%) parts (figures 3.4.P & 3.4.T). The rest of the stance phase was un-effected by the brace.

M/L SHEAR (Fz)
OFF-LOADING PART OF THE STANCE PHASE
[PARAMETER 'A']

	1st VISIT WITH FOOT-PIECE	1st VISIT WITHOUT FOOT-PIECE	2nd VISIT WITH STICK	2nd VISIT WITHOUT STICK	3rd VISIT
PATIENT 01	0	0	*	11.0	60.0
PATIENT 02	0	*	*	0	0
PATIENT 03	69.0	32.5	75.0	74.0	71.0
PATIENT 04	75.0	15.5	10.0	14.0	0
PATIENT 05	21.5	0	*	24.0	55.5

FIGURE 3.4.P: M/L shear (Fz), off-loading part of the stance phase (Parameter A).

M/L SHEAR (Fz)
MAXIMUM PERCENTAGE OFF-LOADING DURING THE STANCE PHASE
[PARAMETER 'B']

	1st VISIT WITH FOOT-PIECE	1st VISIT WITHOUT FOOT-PIECE	2nd VISIT WITH STICK	2nd VISIT WITHOUT STICK	3rd VISIT
PATIENT 01	0	0	*	15.0	68.4
PATIENT 02	0	*	*	0	0
PATIENT 03	75.4	25.0	19.7	19.0	31.7
PATIENT 04	48.7	10.0	3.3	5.2	0
PATIENT 05	15.1	0	*	35.8	22.0

FIGURE 3.4.Q: M/L shear (Fz), maximum percentage off-loading during the stance phase (Parameter B).

M/L SHEAR (Fz)
MAXIMUM M/L SHEAR OBSERVED DURING THE STANCE PHASE
[PARAMETER 'C']

	1st VISIT WITH FOOT-PIECE	1st VISIT WITHOUT FOOT-PIECE	2nd VISIT WITH STICK	2nd VISIT WITHOUT STICK	3rd VISIT
PATIENT 01	56.1	60.0	*	140.0	43.0
PATIENT 02	35.0	*	*	87.5	76.8
PATIENT 03	130.3	96.6	109.6	146.2	163.1
PATIENT 04	198.8	207.6	143.6	187.3	175.0
PATIENT 05	105.6	123.4	*	45.5	70.7

FIGURE 3.4.R: M/L shear (Fz), maximum M/L shear observed during the stance phase (Parameter C).

M/L SHEAR (Fz)
MAXIMUM PERCENTAGE INCREASE IN M/L SHEAR OBSERVED DURING THE STANCE PHASE
[PARAMETER 'D']

	1st VISIT WITH FOOT-PIECE	1st VISIT WITHOUT FOOT-PIECE	2nd VISIT WITH STICK	2nd VISIT WITHOUT STICK	3rd VISIT
PATIENT 01	77.4	75.0	*	15.8	83.0
PATIENT 02	160.0	*	*	0	0
PATIENT 03	0	0	0	0	0
PATIENT 04	0	10.0	24.5	32.1	13.3
PATIENT 05	145.3	4.6	*	81.2	29.0

FIGURE 3.4.S: M/L shear (Fz), maximum percentage inc. in M/L shear during the stance phase (Parameter D).

M/L SHEAR (Fz)
INCREASE IN M/L SHEAR PART OF THE STANCE PHASE
[PARAMETER 'E']

	1st VISIT WITH FOOT-PIECE	1st VISIT WITHOUT FOOT-PIECE	2nd VISIT WITH STICK	2nd VISIT WITHOUT STICK	3rd VISIT
PATIENT 01	75.5	80.0	*	60.5	20.0
PATIENT 02	90.0	*	*	0	0
PATIENT 03	0	0	0	0	0
PATIENT 04	0	22.0	60.0	47.5	25.0
PATIENT 05	59.5	15.0	*	46.0	21.0

FIGURE 3.4.T: M/L shear (Fz), increase in M/L shear part of the stance phase (Parameter E).

M/L Bending (Mx): The overall mean (figure 3.4.U) for off-loading part of the stance phase was 24.9% (S.D 27.59). The individual variations were also observed, with the patient 02 showing no off-loading of M/L bending (Mx) at all (figure 3.4.U). The overall mean (figure 3.4.V) for maximum percentage off-loading of M/L bending (Mx) during stance phase was 19.1% (S.D 20.58).

The overall mean value (figure 3.4.W) for maximum M/L bending (Mx) observed during the stance phase was 48.8 Nm (S.D 39.6). Drop in this maximum value was again observed, as in A/P shear and axial force, during the first visit when tested with and without foot-piece (figure 3.4.W). The same explanation applies to this phenomenon as given for A/P shear earlier. The maximum M/L bending (Mx) values were on the higher side in the majority of the patients except for the patient 03 (figure 3.4.W). This data also showed that increased off-loading of the M/L bending occurred with the use of a walking stick than without it. Although the percentage was relatively small (6.3%) when compared to A/P shear and Axial force, where it was approximately 14%.

The overall mean (figure 3.4.X) for maximum percentage increase in M/L bending observed during the stance phase was 15.9% (S.D 18.4). While the overall mean (figure 3.4.Y) for the increase in M/L bending part of the stance phase was found to be 18.8% (S.D 21.01).

M/L BENDING (Mx)
OFF-LOADING PART OF THE STANCE PHASE
[PARAMETER 'A']

	1st VISIT WITH FOOT-PIECE	1st VISIT WITHOUT FOOT-PIECE	2nd VISIT WITH STICK	2nd VISIT WITHOUT STICK	3rd VISIT
PATIENT 01	0	80.0	*	40.0	43.0
PATIENT 02	0	0	*	0	0
PATIENT 03	0	0	32.5	*	51.5
PATIENT 04	10.0	8.0	46.0	45.0	65.0
PATIENT 05	73.0	28.0	*	0	0

FIGURE 3.4.U: M/L bending (Mx), off-loading part of the stance phase (Parameter A).

M/L BENDING (Mx)
MAXIMUM PERCENTAGE OFF-LOADING DURING THE STANCE PHASE
[PARAMETER 'B']

	1st VISIT WITH FOOT-PIECE	1st VISIT WITHOUT FOOT-PIECE	2nd VISIT WITH STICK	2nd VISIT WITHOUT STICK	3rd VISIT
PATIENT 01	0	54.5	*	18.7	54.5
PATIENT 02	0	0	*	0	0
PATIENT 03	0	0	30.2	*	34.5
PATIENT 04	6.3	15.2	39.4	50.0	45.0
PATIENT 05	28.2	23.8	*	0	0

FIGURE 3.4.V: M/L bending (Mx), maximum percentage off-loading during the stance phase (Parameter B).

M/L BENDING (Mx)
MAXIMUM M/L BENDING OBSERVED DURING THE STANCE PHASE
[PARAMETER 'C']

	1st VISIT WITH FOOT-PIECE	1st VISIT WITHOUT FOOT-PIECE	2nd VISIT WITH STICK	2nd VISIT WITHOUT STICK	3rd VISIT
PATIENT 01	60.0	25.0	*	97.1	10.5
PATIENT 02	75.4	111.5	*	96.8	133.8
PATIENT 03	15.7	4.2	10.8	*	9.8
PATIENT 04	30.9	13.0	23.6	25.2	49.1
PATIENT 05	75.6	13.6	*	51.3	92.3

FIGURE 3.4.W: M/L bending (Mx), maximum M/L bending observed during the stance phase (Parameter C).

M/L BENDING (Mx)
MAXIMUM PERCENTAGE INCREASE IN M/L BENDING OBSERVED DURING THE STANCE PHASE
[PARAMETER 'D']

	1st VISIT WITH FOOT-PIECE	1st VISIT WITHOUT FOOT-PIECE	2nd VISIT WITH STICK	2nd VISIT WIHTOUT STICK	3rd VISIT
PATIENT 01	0	0	*	6.6	55.0
PATIENT 02	22.0	0	*	0	0
PATIENT 03	30.2	38.0	55.7	*	22.2
PATIENT 04	35.8	13.0	19.9	11.0	0
PATIENT 05	0	25.0	*	0	0

FIGURE 3.4.X: M/L bending (Mx), max. percentage inc. in M/L bending during the stance phase (Parameter D).

M/L BENDING (Mx)
INCREASE IN M/L BENDING PART OF THE STANCE PHASE
[PARAMETER 'E']

	1st VISIT WITH FOOT-PIECE	1st VISIT WITHOUT FOOT-PIECE	2nd VISIT WITH STICK	2nd VISIT WITHOUT STICK	3rd VISIT
PATIENT 01	0	0	*	31.0	45.0
PATIENT 02	70.0	0	*	0	0
PATIENT 03	39.0	35.0	32.5	*	8.0
PATIENT 04	50.0	33.0	20.5	12.5	0
PATIENT 05	0	19.0	*	0	0

FIGURE 3.4.Y: M/L bending (Mx), increase in M/L bending part of the stance phase (Parameter E).

The analysis of the above data leads to the conclusion that because the brace functions during part of the stance phase to off-load the M/L bending (Mx) therefore it also acts as an anti-buckling device as proposed by Meggitt et al (1981). The above data also shows that the brace acts to off-load M/L bending during most (24.9%) of the stance phase compared to increasing the same in 18.8% of the phase (figure 3.4.U & 3.4.V). During the remainder (56.3%) of the phase, the brace has no effect on the skeletal M/L bending (Mx) moments.

Axial Torque (My): The overall mean (figure 3.4.Z) for the off-loading part of the stance phase was 29.5% (S.D 28.31). These values varied from patient to patient, while patient 03 showed no off-loading at all (figure 3.4.Z). The overall mean (figure 3.4.AA) for the maximum percentage off-loading of axial torque (My) during stance phase was 16.5% (S.D 16.66).

The overall mean value (figure 3.4.BB) for maximum axial torque observed during the stance phase was 27.6 Nm (S.D 23.3). Wide variations were again observed with patient 05 showing relatively smaller values (figure 3.4.BB). In patient 04 the use of a walking stick on the 2nd visit, improved the off-loading of the axial torque by 22.6%, whereas in patient 03 the effect was the opposite (figure 3.4.BB).

The overall mean (figure 3.4.CC) for maximum percentage increase in axial torque observed during the stance phase was 40.1% (S.D 49.5). While the overall mean (figure 3.4.DD) increase, in axial torque part of the stance phase, was 36.3% (S.D 30.93).

AXIAL TORQUE (My)
OFF-LOADING PART OF THE STANCE PHASE
[PARAMETER 'A']

	1st VISIT WITH FOOT-PIECE	1st VISIT WITHOUT FOOT-PIECE	2nd VISIT WITH STICK	2nd VISIT WITHOUT STICK	3rd VISIT
PATIENT 01	18.0	60.0	*	47.0	56.0
PATIENT 02	0	52.0	*	53.0	0
PATIENT 03	0	0	0	0	0
PATIENT 04	0	30.5	72.5	79.0	72.5
PATIENT 05	8.0	40.5	*	29.5	32.5

FIGURE 3.4.Z: Axial torque (My), off-loading part of the stance phase (Parameter A).

AXIAL TORQUE (My)
MAXIMUM PERCENTAGE OFF-LOADING DURING THE STANCE PHASE
[PARAMETER 'B']

	1st VISIT WITH FOOT-PIECE	1st VISIT WITHOUT FOOT-PIECE	2nd VISIT WITH STICK	2nd VISIT WITHOUT STICK	3rd VISIT
PATIENT 01	16.7	33.3	*	11.8	15.7
PATIENT 02	0	13.6	*	50.0	0
PATIENT 03	0	0	0	0	0
PATIENT 04	0	27.8	20	21.1	6.6
PATIENT 05	41.7	45.4	*	37.7	22.5

FIGURE 3.4.AA: Axial torque (My), maximum percentage off-loading during the stance phase (Parameter B).

AXIAL TORQUE (My)
MAXIMUM AXIAL TORQUE OBSERVED DURING THE STANCE PHASE
[PARAMETER 'C']

	1st VISIT WITH FOOT-PIECE	1st VISIT WITHOUT FOOT-PIECE	2nd VISIT WITH STICK	2nd VISIT WITHOUT STICK	3rd VISIT
PATIENT 01	23.3	7.69	*	23.7	4.0
PATIENT 02	29.9	17.2	*	17.6	35.3
PATIENT 03	54.8	20.4	27.9	25.5	30.4
PATIENT 04	48.0	34.9	37.2	48.1	105.7
PATIENT 05	3.4	2.6	*	3.9	5.7

FIGURE 3.4.BB: Axial torque (My), maximum axial torque during the stance phase (Parameter C).

AXIAL TORQUE (My)
MAXIMUM PERCENTAGE INCREASE IN AXIAL TORQUE OBSERVED DURING THE STANCE PHASE
[PARAMETER 'D']

	1st VISIT WITH FOOT-PIECE	1st VISIT WITHOUT FOOT-PIECE	2nd VISIT WITH STICK	2nd VISIT WITHOUT STICK	3rd VISIT
PATIENT 01	123.3	0	*	6.6	100.0
PATIENT 02	148.5	0	*	66.6	0
PATIENT 03	19.9	6.6	22.1	17.2	15.5
PATIENT 04	32.9	25.0	0	0	0
PATIENT 05	143.5	81.3	*	69.4	4.1

FIGURE 3.4.CC: Maximum percentage increase in axial torque during the stance phase (Parameter D).

AXIAL TORQUE (My)
INCREASE IN AXIAL TORQUE PART OF THE STANCE PHASE
[PARAMETER 'E']

	1st VISIT WITH FOOT-PIECE	1st VISIT WITHOUT FOOT-PIECE	2nd VISIT WITH STICK	2nd VISIT WITHOUT STICK	3rd VISIT
PATIENT 01	63.5	0	*	17.5	24.0
PATIENT 02	64.0	0	*	22.0	0
PATIENT 03	71.5	30.0	84.5	75	81.5
PATIENT 04	74.5	28.0	0	0	0
PATIENT 05	62.0	36.5	*	50.0	15.0

FIGURE 3.4.DD: Axial torque (My), increase in axial torque part of the stance phase (Parameter E).

A/P Bending (Mz): The overall mean (figure 3.4.EE) off-loading part of the stance phase was 20.6% (S.D 25.83). While the overall mean (figure 3.4.FF) for maximum percentage off-loading of A/P bending (Mz) during stance phase was 8.6% (S.D 16.27).

The overall mean value (figure 3.4.GG) for maximum A/P bending observed during stance phase was 146 Nm (S.D 101.0). There was wide variations between the patients. Similar trend, as seen in A/P shear, Axial force, M/L bending and Axial torque, in drop in values on the first visit with and without foot-piece and gradual rise in the subsequent visits was also seen (figure 3.4.GG). It was also observed that the use of a walking stick increased the off-loading of the A/P bending, on the 2nd visit by about 13% (figure 3.4.GG).

The overall mean (figure 3.4.HH) maximum percentage increase in A/P bending observed during stance phase was 11.6% (S.D 24.78). While the overall mean (figure 3.4.JJ) increase in A/P bending part of the stance phase was 21.8% (S.D 26.81). The consideration of this data shows that as far as A/P bending (Mz) was concerned the stance phase had equal portions of off-loading (20.6%) and increase in A/P bending parts (21.8%). This means that the brace acts as an anti-buckling device for a part of the stance phase, while it has no effect at all on A/P bending during almost half of the stance phase.

A/P BENDING (Mz)
OFF-LOADING PART OF THE STANCE PHASE
[PARAMETER 'A']

	1st VISIT WITH FOOT-PIECE	1st VISIT WITHOUT FOOT-PIECE	2nd VISIT WITH STICK	2nd VISIT WITHOUT STICK	3rd VISIT
PATIENT 01	35.0	0	*	0	19.0
PATIENT 02	56.0	0	*	0	0
PATIENT 03	0	0	0	0	0
PATIENT 04	0	57.5	45.0	75.0	25.0
PATIENT 05	59.0	30.0	*	0	51.5

FIGURE 3.4.EE: A/P bending (Mz), off-loading part of the stance phase (Parameter A).

A/P BENDING (Mz)
MAXIMUM PERCENTAGE OFF-LOADING DURING THE STANCE PHASE
[PARAMETER 'B']

	1st VISIT WITH FOOT-PIECE	1st VISIT WITHOUT FOOT-PIECE	2nd VISIT WITH STICK	2nd VISIT WITHOUT STICK	3rd VISIT
PATIENT 01	11.8	0	*	0	5.8
PATIENT 02	11.1	0	*	0	0
PATIENT 03	0	0	0	0	0
PATIENT 04	0	16.8	4.4	7.9	1.9
PATIENT 05	65.7	41.5	*	0	21.9

FIGURE 3.4.FF: A/P bending (Mz), maximum percentage off-loading during the stance phase (Parameter B).

A/P BENDING (Mz)
MAXIMUM A/P BENDING OBSERVED DURING THE STANCE PHASE
[PARAMETER 'C']

	1st VISIT WITH FOOT-PIECE	1st VISIT WITHOUT FOOT-PIECE	2nd VISIT WITH STICK	2nd VISIT WITHOUT STICK	3rd VISIT
PATIENT 01	295.7	210.0	*	225.0	60.0
PATIENT 02	145.3	41.1	*	137.5	121.8
PATIENT 03	256.8	92.2	109.6	114.7	122.3
PATIENT 04	164.0	105.1	149.6	189.0	461.5
PATIENT 05	41.5	11.7	*	118.0	40.6

FIGURE 3.4.GG: A/P bending (Mz), maximum A/P bending during the stance phase (Parameter C).

A/P BENDING (Mz)
MAXIMUM PERCENTAGE INCREASE IN A/P BENDING OBSERVED DURING THE STANCE PHASE
[PARAMETER 'D']

	1st VISIT WITH FOOT-PIECE	1st VISIT WITHOUT FOOT-PIECE	2nd VISIT WITH STICK	2nd VISIT WITHOUT STICK	3rd VISIT
PATIENT 01	0	0	*	8.3	5.2
PATIENT 02	0	0	*	0	0
PATIENT 03	7.6	0	2.9	8.0	4.6
PATIENT 04	19.9	0	0	0	0
PATIENT 05	100.0	36.0	*	0	62.5

FIGURE 3.4.HH: A/P bending (Mz), max. percentage inc. in A/P bending during the stance phase (Parameter D).

A/P BENDING (Mz)
INCREASE IN A/P BENDING PART OF THE STANCE PHASE
[PARAMETER 'E']

	1st VISIT WITH FOOT-PIECE	1st VISIT WITHOUT FOOT-PIECE	2nd VISIT WITH STICK	2nd VISIT WITHOUT STICK	3rd VISIT
PATIENT 01	0	0	*	48.5	39.0
PATIENT 02	0	0	*	0	0
PATIENT 03	68.0	0	55.0	59.5	40.0
PATIENT 04	72.0	0	0	0	0
PATIENT 05	19.5	51.0	*	0	26.0

FIGURE 3.4.JJ: A/P bending (Mz), increase in A/P bending part of the stance phase (Parameter E).

3.5 DISCUSSION

This part of the study was conducted to define the biomechanical function of the 2 in 1 brace and to test the design modifications suggested by the author.

The literature highlighted that opinion on the biomechanical function of the braces was divided among those who believe it is primarily an "axially off-loading" device (Hardy 1981, Wardlaw et al 1981, Pratt et al 1982, Scott 1989) and those who believe it functions primarily as an "anti-buckling" device (Mooney 1974, Meggitt et al 1981, Kwong 1988).

The data in this study showed that no axial off-loading (figures 3.4.J & 3.4.K) occurred during the stance phase. This questions the hypothesis that the brace functions primarily as an axially off-loading device. It was observed that although the brace did not off-load the axial force, it did off-load the A/P shear (figure 3.4.D) and M/L shear (figure 3.4.P) forces.

The hypothesis that the brace functions primarily as an "anti-buckling" device was also questioned by this study. Although M/L bending and A/P bending moments were off-loaded by the brace (figures 3.4.U & 3.4.EE), but this occurred for less than 30% of the stance phase. This being the case it cannot be said that anti-buckling is the primary function of the brace.

It was also observed that the 2 in 1 brace off-loaded the forces (A/P shear & M/L shear) and moments (M/L bending, Torque & A/P bending) during parts of the stance phase, while at the same time increasing them during other parts of the same stance phase. It is proposed that this cyclic variation of loads within the same stance phase, in the absence of any gross movement, acts to stimulate fracture healing.

This hypothesis may explain the clinical observation of high union rate, for tibial shaft fractures treated with functional bracing. Studies (Richardson 1989, Lanyon 1989) have already shown that cyclic axial loading associated with micro-movement is beneficial for fracture healing. It was also suggested by Richardson (1989) that though axial loading is beneficial for healing, the combination of axial and shear forces is not.

This study has shown that the functional brace is unable to off-load the shear forces to a major extent. If bracing cannot eliminate shear forces how can we explain its apparent clinical success. It is possible that a combination of axial and shear forces is damaging to fracture healing only if associated with gross movement. It may be that any orthogonal force across the fracture site is stimulating if the movement is within the tolerance of neovasculature. This view is also supported by the clinical observation of absence of uniformity in callus formation. This could be the reflection of the above mentioned stresses, acting in particular directions, stimulating specific callus formation response.

The movement of the ankle/sub-talar joint producing rotational stresses during early stages of healing is an example of an internal moment which can lead to excessive movement at the fracture which could damage the process of healing. The phenomenon of "internal moments" is different from high shear forces in the presence of the brace producing "external moments". The difference is in the interface between the cast and the leg. This alters the environment of the fracture from "limb" to "limb and cast". If the same high loads are applied to a fractured limb without the cast, then deformation or movement at fracture site would occur. In the presence of a cast the same high loads are immaterial, as the rigidity of the cast material does not allow any excessive movement to occur.

An analogy could be given of wooden box containing foamy material (figure 3.5). If a 10 Kg load is placed over the box, it would have no effect on the foamy material. Whereas the same load, when placed directly, would compress it completely. A fractured limb with and without cast could be considered in the same manner.

If this argument is accepted then it seems the braces should be fabricated not with a view to off-load forces, but with a view to decrease gross movement of the fragments within the cast. This could be achieved by fabricating close fitting braces, utilising rigid materials. This is not to suggest, that the braces should not take advantage of "lever-arms" by extending the tibial brace as high and as low as possible without interfering with the joint functions. This study supports the suggested technique for fabricating "2 in 1 functional brace" as discussed in Part 3 of this thesis. This technique stresses the importance of close-fitting braces, and provides the option of removable "foot-piece", allowing normal ankle and sub-talar joint movement during later stage of fracture healing.

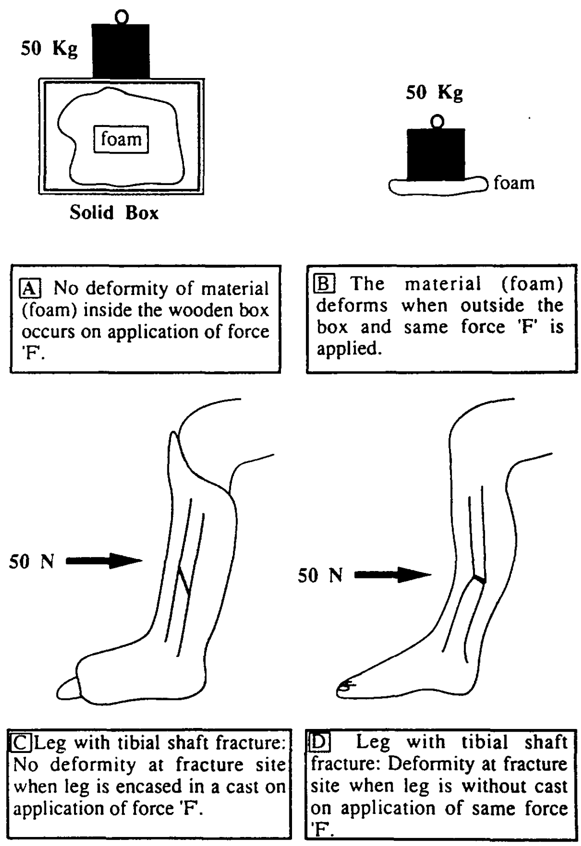


FIGURE 3.5: Effect of shear force on tibial shaft fracture with and without the brace.

FUNCTION OF THE "FOOT-PIECE": Studies have shown that the use of a patellar tendon bearing (PTB) top, as in a cast popularised by Sarmiento, functions as a device that prevents rotation by its accurate fit to the limb (Sarmiento & Latta 1981, Pratt et al 1986). It is also accepted that the effectiveness of a PTB top to control rotation in tibial fractures is increased with the use of a cast design which incorporates the foot (Pratt et al 1986). It is therefore logical to expect increased off-loading of the rotational stresses (Axial

Torque - My), when such stresses are measured in a cast encasing the foot. This study measured the rotational stresses in the 2 in 1 functional brace. The design of the brace allowed comparisons to be made with and without encasing the foot. This was possible because of the removable foot-piece.

The results were interesting because instead of decreasing the axial torque (My), the use of a foot-piece led to its increase (figures 3.4.Z & 3.4.DD) during most of the stance phase. Increases in axial torque on the limb-brace complex were also seen in part of the stance phase, without the foot-piece.

This data would question the basis for encasing the foot in a cast designed for treating tibial fractures. This contradiction could be explained if consideration is given to the primary function of a foot-piece in a functional brace design.

The foot-piece overcomes the "torque transfer" mechanism due to the movement of the ankle and sub-talar joint (chapter 1). This is accomplished by immobilising the foot in a foot-piece, as a heel cup or any articulating ankle component is ineffective. It is accepted that the axial torque produced by the foot-piece is greater than that produced by the ankle and sub-talar joint movement. The damage to the fracture healing is likely to be more with the latter because it being an internal moment is difficult to control and could lead to gross movement at the fracture site. Whereas the former is an external moment and is effectively controlled by the limb-brace complex and does not lead to gross movement at the fracture site. It could therefore be concluded that despite its drawbacks the "foot-piece" is an important and essential feature of the tibial brace design.

Rowley et al (1985) had stated with regard to the comparative properties of cast materials that "it is interesting that the commercial world should be flooding the market with more and more of these products (Plaster of Paris substitutes) when we do not yet know, in any detail, how strong a cast actually needs to be to support a fracture or a limb". This study provides some indication of the expected loads on a tibial cast during walking, and could be used to rationalise the use of casting materials in clinical practice. The study also highlights the importance of the strength or rigidity of the cast material in order to overcome the high forces and moments experienced by the limb-brace complex during walking.

This study utilised the software to calculate the loads (forces and moments), in the tibial reference system, at the level of the fracture. These calculations were based on the estimated external forces and moments during walking. The calculations did not consider one important aspect of this dynamic situation. This was the effect of the muscular action on the forces and moments at the fracture site.

The external forces and moments result in appropriate muscular responses to maintain equilibrium during walking. This muscular action modifies the forces and moments experienced at the fracture level. It follows that the values estimated in this study although providing a reasonable basis, and indicating the expected levels have an in built error. It is essential that a future study incorporates a reasonable muscle model, of the lower leg, for improved accuracy.

3.6 CONCLUSIONS

1/- The tibial functional brace does not axially off-load the fracture.

2/- The brace is primarily, neither an off-loading nor an anti-buckling device, but functions with a combination of the above mechanisms.

3/- The brace allows cyclic variation of loads (forces and moments) within the same stance phase.

4/- The provision of "foot-piece" in the design of a "2 in 1 functional brace" overcomes torque transfer mechanism.

5/- It is essential that the functional braces be fabricated with materials, capable of withstanding the high levels of stresses shown to occur during walking.

PART 2

FRACTURE STIFFNESS MEASUREMENT

This part describes a system for non-invasive measurement of fracture stiffness to assess the healing of tibial fractures. The evolution of the system and a pilot study to assess the potential of the method are described. The pilot study led to computerisation of the system and its application in the clinical environment.

The system was developed primarily to provide a method for assessment of tibial fractures treated conservatively by functional bracing. Such a system would monitor the progress of healing and also allow prediction of time to union by plotting the stiffness over a period of time. It would thus allow a more objective answer to one of the controversial aspects of functional bracing "How long should the brace be kept on?".

CHAPTER 4

INTRODUCTION: MONITORING OF FRACTURE HEALING

"The modern's are, in relation to the ancients, as a dwarf placed on the shoulders of a giant, he sees all that the giant perceives plus a little more".

(Henri de Mondeville 1260-1320)

Fractures are still one of the commonest reasons for spending prolonged periods of time away from work, and this morbidity occurs particularly following fractures of the long bones (Kenwright 1985). It is essential that a reliable method of assessing the progress of fracture healing be employed, to determine when it is safe to recommence normal activity. The following methods for monitoring fracture healing have been utilised in clinical practice.

4.1 CLINICAL ASSESSMENT

Over the years many different methods have been used by surgeons to help them evaluate the strength and rigidity of fractures. The most commonly utilised method is physical examination of the fractured limb. Watson Jones advised "Union is sound when tenderness has disappeared, when no pain is elicited by straining the fracture, and when there is no longer elasticity or springing of the fragments" (Wilson 1976). Matthews et al (1974) carried out a simulated study using an instrument giving the feel of a fractured forearm. They concluded that the majority of orthopaedic surgeons use an appropriate bending force in testing for fracture stability. Most surgeons were able to sense a two degree angular deformation at the fracture site and tend to continue immobilisation of fractures which bend to a greater degree. Deformations less than two degrees were difficult to perceive by majority of surgeons. Manual assessment although reliable is not very accurate and depends on subjective perceptions liable to errors.

4.2 RADIOLOGICAL

Since the introduction of x-rays, they have been used to evaluate the stage of healing by observation of the callus. Callus is radio-opaque because of the deposition of calcium. Bone repair is a two stage process, ossification followed by calcification, and studies have shown that the callus is sufficiently strong to unite fractures, even before it calcifies and becomes apparent on x-rays (Mooney et al 1970). Kenwright (1985) states that "clinical methods combined with radiological examination are satisfactory for defining the end-point of fracture union in approximately 90 per cent of patients, though with an accuracy of +/- 3 weeks for an average long bone fracture". Nicholls et al (1979) concluded that a physician, whether an orthopaedist or radiologist, is not very reliable at determining early osseous union, using x-rays alone. This being the case the likelihood of over treating fractures, if monitored by x-rays only, increases the possible complications of different methods of treatment.

4.3 SCINTIGRAPHY

Tucker (1950), first reported the use of radioactive phosphorus, P32, for the diagnosis of avascularity of the femoral head. Johannsen (1973) studied the process of healing fractures after intravenous injection of 87m Sr (Strontium). His study identified two maxima of uptake of the isotope at the fracture compared to the symmetrical area on the normal leg. The first, called initial maximum (IM) occurred between day 8 and day 32 after initial injury and the second called stress maximum (SM) occurred between day 8 to day 45 after weight bearing without plaster fixation. This was not observed with weight bearing inside the plaster cast. He believed this was due to the reorganisation of the fracture in response to stress and higher values were continuously observed for 6 months or longer after clinical fracture healing indicating the continuity of the process of reorganisation. This study supports the hypothesis that functional loading is beneficial because loading stimulates bone remodelling.

Jacobs et al (1981) reported their experience with bone scanning of tibial fractures, they concluded that static images were of little use. They also investigated dynamic uptake over the fracture and compared the result with a normal part of the same bone. Percentage uptake between 7 1/2 and 15 minutes was calculated for both sites. The difference between fracture and control site was interpreted as due to new bone formation. Four months after injury the normal difference between the fracture and control side was 10 to 15 per cent, but in delayed union the value was 5 per cent. This measurement was made serially at monthly intervals and the results were expressed graphically against time. For fractures that went on to heal normally, the net uptake was 3 per cent per month, for delayed union 1.42 per cent per month and non union 0.5 per cent per month. They concluded that using this method delayed union could be predicted at 6 weeks and non union at 10 weeks.

Auchincloss and Watt (1982) reported a study on 60 patients with tibial shaft fractures using Technetium scans obtained 6 weeks after injury. They analysed the scans both qualitatively and quantitatively and used their results to predict the healing time. They concluded that "scintigraphy cannot be justified as a routine in the management of tibial fractures. However, a single scan at 6 weeks with or without computation facilities may afford useful information in those patients whose injury maybe expected to be associated with unsatisfactory or delayed union".

McDougall and Keeling (1988) in a review article considering the role of nuclear medicine in predicting delayed union of fracture concluded, that "dynamic imaging over the fracture site and comparison with simultaneous uptake in an adjacent segment of normal bone is of some predictive value in differentiating healing fractures from those that will progress to non-union. The procedure is not advised routinely since most fractures will heal normally; however, in cases where problems in healing are anticipated, scintigraphy provides additional information along with clinical and roentgenographic data".

This review suggests that scintigraphy may be helpful in evaluating fracture healing in a limited number of cases, it is not advisable for routine use. The specialised equipment and invasive nature of the procedure also restricts its repeated use in patients.

4.4 ULTRASOUND

Ultrasonics is defined as the study of sound waves whose frequency is above the audible limit (greater than 16000 Hz). Sound waves travel in a material, with velocities which are characteristic of that material and its physical attributes. It is known that changes occur in bone mineral composition as a result of fracture healing. These changes are reflected by variations in the ultrasonic wave velocity as a result of change in the modulus of elasticity, the density, or both. Therefore ultrasound velocity measurement could be used to reflect the status and progress of fracture healing.

Abendschein and Hyatt (1972) described the use of ultrasonics for calculating the modulus of elasticity of bone in experiments on guinea pigs. It involved multiplying the square of the velocity of ultrasound through the specimen, by its mass density. The method gave values for identifiable groups of normal bone, bony union, partial union, sequestrated graft and non union but had considerable overlap of values among them. They did not suggest a method for the clinical application of the above technique.

Gerlanc et al (1975) reported that "results on the normal population indicate a significant variation in the ultrasound velocity reading from individual to individual. Therefore, information on the status and progress of the healing process can best be generated by sequential measurements using the unfractured limb as the norm". They reported results of serial measurements of the ultrasound velocity in the fractured tibia, calculated as a percentage of that in the intact tibia.

Although researchers (Abendschein and Hyatt 1972, Gerlanc et al 1975, Upadhyay and Moulton 1985) have concluded that ultrasound velocity measurement in bone is a useful clinical tool that will accurately and objectively monitor the progress of fracture healing, there are problems. Firstly, the method relates the ultrasound velocity to a mechanical property (modulus of elasticity of bone) of healing bone, it would seem logical to measure the mechanical properties of healing bone directly than to stay one step removed by measuring the ultrasound velocity through it. The possibility of errors increases, the further removed one gets from the property one is aiming to measure. Secondly, the change in ultrasound velocity, is dependent on the changes in the mineral content of the bone. It has been shown that the mechanical properties of the bone are primarily dependent on the collagen and not the mineral content of the bone (Sevitt 1981, Dee and Sanders 1989). This being the case the ultrasound velocity would be primarily a reflection of the mineral content of the bone and not a true representation of the mechanical strength. This could in turn lead to over-treatment by the clinician.

4.5 BONE PERCUSSION AND AUSCULTATION TECHNIQUES

Sekiguchi and Hirayama (1979) described percussion of a bone (percussion note), resulting in a wave signal which was used to evaluate the extent of bony consolidation after fracture. The medial malleolus of the tibia was struck with a tapper and the vibration signal was picked up by a detector at the medial region of the tibial tuberosity. The changes with time in the signal waveform of the percussion note were investigated. They classified the waveforms into three types; type I and type II were pathological, whereas type III was observed in intact bones. They observed variations between the waveforms but this classification helped in evaluating the stage of healing. They noted that the average period (4.4 months) for the normalisation of the signal wave was 1.9 months longer than the average period (2.5 months) for clinical and roentgenographic union and thus concluded that this method was more sensitive to pathological changes in bones than x-rays. This implies that the method is less sensitive to the mechanical properties of the bones and would lead to over-treatment of the fracture.

4.5.1 MADAMS - PERCUSSION TECHNIQUE

Cornelissen et al (1985) described a percussion technique given the acronym "MADAMS" which identifies the "vibration modes" and opens the possibility of correlating vibration analysis results with mechanical properties. When a structure is excited by any kind of force, it starts vibrating. This vibration is a superposition of some modes (vibration shapes) which are characteristic for the structure. Each mode has its own vibration frequency (natural frequency) and damping co-efficient. To correlate vibration with mechanical characteristics a knowledge of the vibration mode associated with a measured natural frequency is necessary. Cornelissen et al (1985) classify vibration analysis methods into the "one-point" and the "multiple point" methods. They state that only the modal analysis (multiple point method) gives as results the natural frequency, mode shape and damping coefficient, while the one point techniques make an assumption about the mode shape. They present the results of a series of 5 patients with tibial fractures who were followed for some time with the technique and concluded that the technique has potential for clinical application.

The method is an experimental procedure and requires further refinement. It relies on mathematical models for a healing bone to predict (i) its vibrational behaviour, (ii) the axial stability and (iii) the transverse stiffness. As with all mathematical models certain assumptions are made which introduce an element of error into the calculations.

4.5.2 SPECTRAL ANALYSIS - PERCUSSION TECHNIQUE

Doemland et al (1986) described a spectral analysis - percussion technique, for monitoring fracture healing. Their device is a microprocessor based instrument which performs the "Fast Fourier Transform" of the pulse response of the bone. In the case of a tibia the excitation is introduced by gently striking the medial malleolus with a percussion hammer and picking up the response at the antero-medial aspect of the proximal tibia. It is known that the frequency (spectral content) of vibration of a rod is directly proportional to its stiffness. If the rod is made less stiff by altering its dimensions its natural modes of vibration will be altered. Since the tibia and other long bones can be modelled as complex rods of non-uniform dimensions it is suggested that the spectral content of the pulse response of a fractured tibia will be different than that of the intact tibia. It is the difference that is quantified and used as an index to fracture healing.

Doemland et al (1986) reported that with their method, there does not appear to be a "standard" resonant frequency when tested on tibias of different subjects. But they believe this variability does not invalidate the usefulness of the method because the variation between the left and right tibia of a single subject is not unreasonable, ranging from 10 to 27 per cent. They do not present the serial change in the resonant frequencies of tibial fractures as healing progresses, but expect the resonant frequency of a fractured tibia will be much lower than that of the intact tibia. Therefore, as the fracture heals the resonant frequency will rise to that of the intact contra-lateral leg.

The method might cause problems in practice because the factors which will prevent the resonant frequency of the normally healing fracture reaching the "normal" frequency are, a large amount of callus formation which adds mass to the system, and synostosis which will couple the fibula to the system. In conservatively treated fractures the possibility of this occurring is very likely, which could lead to erroneous results.

4.5.3 SONIC DIAGNOSIS - PERCUSSION TECHNIQUE

Sonstegard and Matthews (1976) pointed out three disadvantages of the non-invasive "percussion and auscultation" techniques for monitoring fracture healing as follows:

(a) Clinical application has to be restricted to those bones which have readily accessible landmarks for excitation and measurement, such as the tibia and ulna.

(b) The electrical devices used are not placed in intimate contact with the bone, but rather sense or excite through the overlying soft tissue thus introducing errors.

(c) Response interpretation is tempered by the influence of adjacent bones, muscles, ligaments and associated tissue.

Sonstegard and Matthews presented a method, the aim of which was to mitigate these influences by direct attachment of hypodermic needles to the bone at excitation and sensing sites. The needles were inserted into the periosteum and were thus lying adjacent to the bone providing sites for "disturbance" and "excitation" measurement. They concluded from a study of 11 patients that their approach overcame the limitations of the other methods, and that the influences of adjacent soft tissues were effectively removed from measurement observations. The drawbacks of this method are its invasive nature, which requires sterile operative precautions and restricts its repeated use in the patients.

4.6 RADIO-OPAQUE DYE INJECTION

Puranen and Kaski (1974) presented Osteomedullography, demonstration of the veins in the bone by intraosseous phlebography, as a method for monitoring bone healing. They injected contrast medium into the medullary cavity of the distal fragment of a tibial diaphysial fracture and exposed the bone to serial x-rays. If the contrast medium was seen crossing the fracture then it was concluded that the fracture would heal. This examination was usually done 3 months from injury. If the result was negative at this stage then a decision to operate and graft the fracture was taken. They considered their method reliable enough to identify fractures of the tibial shaft that would heal and those that would progress towards non-union. The disadvantages were that it was an operative procedure and it could not be performed repeatedly.

4.7 MECHANICAL METHODS

Many researchers have studied the physical and mechanical properties of callus to utilise them in the assessment of its strength . Burny (1979a) described a method based on the deformation of a fixed beam for fractures treated by external fixators. Eight types of graphs were obtained depending on the type of healing (normal, pseudoarthrosis etc). He concluded that the mechanical properties of callus when 50% of normal is compatible with normal activity but can re-fracture. He did not specify what "normal activity" means and the method could only be applied to the fractures being treated in external fixators.

Jorgensen (1979) described a method of measuring fracture stiffness using a simple dial micrometer attached to the pins of an Hoffman external fixator from which the steel bar had been removed. He then loaded the bone so that it bent in the plane of the Hoffman pins and noted the deflection in degrees. He considered a deflection of 0.25 to 0.5 degrees in the plane of the Hoffman pins to be normal stiffness of the bone and allowed full weight bearing. Partial weight bearing was advised when a deflection of 1 degree was observed. Although this method is simple and has the potential of application in the clinical environment, it can not be utilised in situations where fractures are being treated by other conservative techniques.

Hammer et al (1984) reported the clinical application of a method for calculating fracture stiffness non-invasively, as proposed by Edholm et al (1983), with the aid of "shift comparator". A bending moment is applied perpendicular to the longitudinal axis of the tibia in the horizontal plane. Two antero-posterior x-ray films are exposed, one without a load and the other with a load varying from 20 to 80 N. The deflection of the distal fragment in relation to the proximal fragment is then measured. They contend that the technique measures the induced deflection with an accuracy of 0.19 degree. The quotient of the deflection by the bending moment is assumed to be inversely proportional to the stability of fracture union. This quotient is corrected for the patient's weight (W) by multiplying by the factor W/75 and is then referred to as the deflection ratio (DR). When the DR is less than 0.08 the strength of union is sufficient for the plaster cast to be removed and full unprotected loading of the leg permitted. Values above DR 0.3 were considered extremely unstable fractures. Although this method is non invasive, the use of x-rays limits its frequent application as a tool for the follow up of patients.

Rymaszewski (1984) investigated the clinical use of a conductive polymer "Flexigage", which responds to deformation in any plane by a change in electrical resistance when a small current is passed through it. A rectangular shaped sensor is used made from sheets of the polymer with a conductive core connected to a read out wire. The device was glued to a cast sock and applied over the fracture site along the subcutaneous surface of the tibia. A cast brace was then applied and the patient tested at two weekly intervals, by loading the fracture in several different ways. It was hoped that the movement at the fracture site would be detected by the sensor and that the signal recorded by read out instruments would gradually decrease as the tibia regained its original rigidity. The results did not correlate with the increasing stiffness of the healing tibiae, because of shortcomings in the method of application of the "Flexigage".

Evans et al (1985) reported the use of a system for measurement of fracture stiffness using a strain gauge transducer on a rigid type of single-sided fixator. The method was based on the concept that, when a fractured limb is supported through bone screws to a unilateral fixation frame and subjected to external loading, the distribution of the load would be shared between the limb and the frame. This distribution would depend upon their relative stiffness's, as well as the stiffness of the screw fixation to the bone and in the clamping system between screw and frame. As the fracture stiffness increases during healing so the proportion of load carried by the fracture will increase, while that by the frame decreases. As the fixator has an offset from the axis of the bone, the loads in the fixator frame would be predominantly bending and torsional.

Evans and his co-workers developed a clamp-on load monitoring transducer which was fitted onto the fixator of patients attending regular fracture clinics. The device was capable of measuring bending in two planes as well as torsion. They were able to chart the progress of fracture healing as the loads progressively increased through the skeleton. The method is useful for patients treated with external fixators, but because of its invasive nature could not be applied to other conservatively treated patients. The accuracy of any method which utilises fixator pins in the bone is also directly proportional to the integrity of the fixation of these pins. If the pins get loose, which they usually do after mobilisation in the external fixators, then the readings could be in error up to 20 per cent or more.

Tanner (1985) described a system which measured three dimensional movements at the fracture site in patients being treated with external fixators, using infrared light emitting diodes attached to fixator pins. Tanner claimed that the system was able to measure the movement at the fracture site to an accuracy of approximately 0.03mm. The progressive decrease in this movement indicated healing and increasing stiffness of the fracture. The system is only appropriate for fractures being treated with external fixators, and its accuracy would also depend on secure fixation of the bone pins. If the pins were to become loose, then the movement measured would not represent the movement at the fracture site.

The utilisation of the mechanical properties of healing fractures such as bending stiffness seems more appropriate (Richardson 1989), because the main function of the skeleton is mechanical support and this function is impaired when the bone breaks. The return of these mechanical properties to normal would thus be the best parameter to judge progress of fracture healing. Most of the methods that measure the mechanical integrity of a bone have limitations because of their invasive nature. An ideal system for monitoring fracture healing would be the one which measures the mechanical integrity of the bone, while being non-invasive both physically and radiologically.

4.8 FRACTURE STIFFNESS MEASUREMENT

Fracture stiffness is an objective measure of the mechanical properties of the fracture callus. When a load is applied to a material, it results in its deformation. The slope of this load-deformation curve is called the material's "stiffness" (figure 4.8.A).

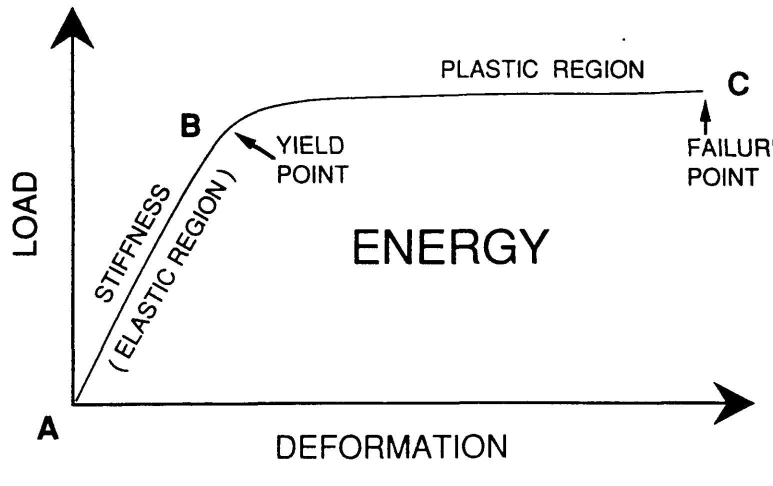


FIGURE 4.8.A: Load-deformation curve, showing the "stiffness" slope.

The gradual change in the structure of the tissue during healing can be characterised by its stiffness, changing from a Young's modulus of $49 * 10^3$ N/m^2 for granulation tissue to $19.6 * 10^9$ N/m^2 for mature bone, representing a 400,000 fold change (Perren 1979).

As the healing progresses the fracture becomes mechanically stronger and stands stresses better in tension and compression (figure 4.8.B). The measurement of fracture stiffness during this period would provide objective evidence of progressive healing or otherwise, thus allowing clinical decision-making with regard to the requirement of surgical intervention or not.

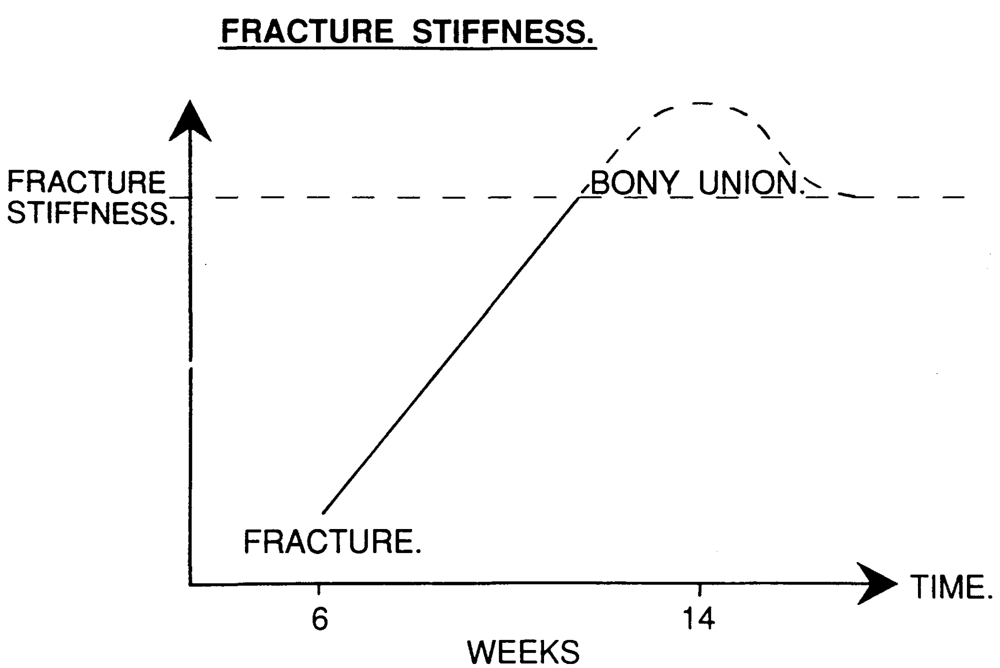


FIGURE 4.8.B: Fracture stiffness increases with time as healing progresses.

The principal demands on the measuring system will be for accuracy in the matter of comparison between patients and for precision of stiffness measurement in the assessment of an individual patient's progress.

Accuracy describes how close a measurement is to the true value, and precision reflects how close repeated measurements are to each other, irrespective of how far the group of results is from the true value. If low levels of stiffness persist, compared to the normal progress of individuals with a similar injury, operative intervention may be indicated.

The bending stiffness of intact tibiae has been measured in vivo by Jernberger (1970) as 63.5 Nm/deg for men and 41.3 Nm/deg for women (26 and 14 subjects respectively, with errors of 5 and 8 percent). Using two tibiae from adults who had died without known bone disease the intact tibial stiffness was measured by direct measurement in 3 point bending at room temperature with precautions to maintain bone moisture, stiffness's were 65 Nm/deg and 72 Nm/deg (Shah et al 1989).

It is possible from their original data to calculate the stiffness at which both Jernberger (1970) and Edholm et al (1984) allowed patients to walk free of support (figure 4.8.C). In the radiological method of Edholm et al (1984) this is 12 Nm/deg. Jernberger had developed a method based on a strain gauged frame fixed to the patients tibia in the clinic by percutaneous bone screws. These were inserted under local anaesthesia and allowed accurate measurements of stiffness, patients walking free of support between 5.5 and 9.4 Nm/deg.

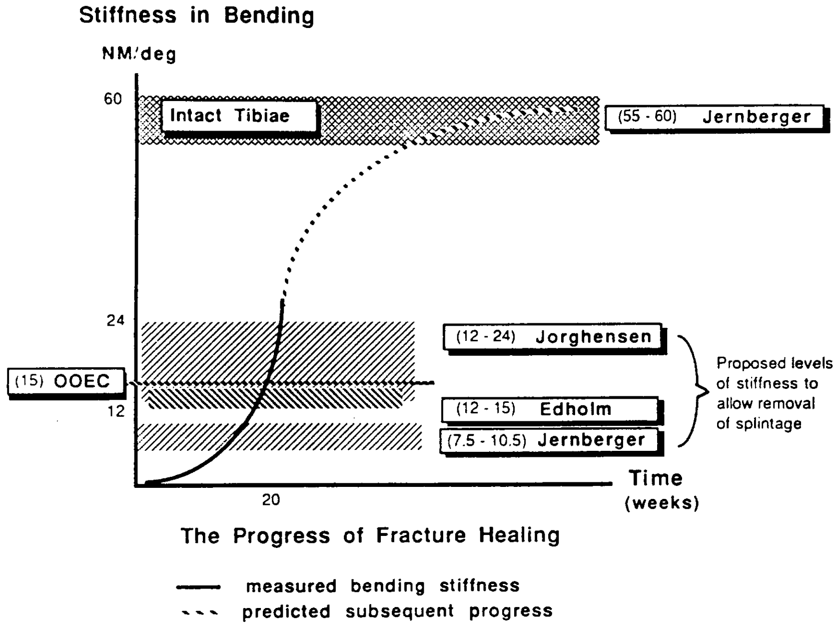


FIGURE 4.8.C: Stiffness in bending: Levels of stiffness at which different researchers allowed independent weight bearing.

The stiffness at which patients were allowed independent weight bearing in the Oxford Orthopaedic Engineering Centre (OOEC) series is seen in figure 4.8.D (Richardson 1989). Six cases of re-fracture or significant loss of alignment occurred in those allowed free of support at lower levels of stiffness. They recommended the use of 15 Nm/deg in bending as a safe level to allow independent weight bearing. If a patient was heavy or a fracture angulated, then higher levels of stiffness might be appropriate, but for purposes of a comparative trial, or to allow for instance, international comparisons, one level of healing stiffness seems appropriate.

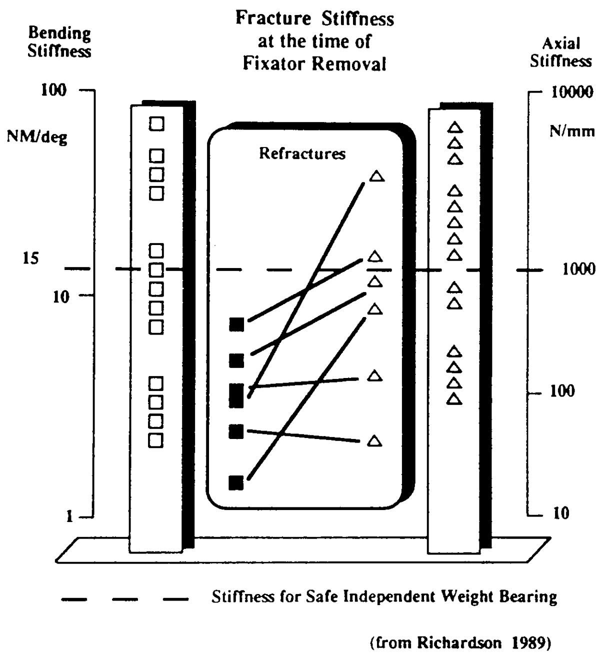


FIGURE 4.8.D: Stiffness levels at which independent weight bearing was allowed in OOEC series, patients were treated by external fixator.

Although assumption of one value as the normal stiffness of intact tibia would facilitate evaluation of fracture healing and comparison between patients, it is felt to be too simplistic. Tibial bone does not have a uniform structure and considerable variation in shaft diameter as well as cortical thickness and alignment are observed. It would thus seem that different portions of the same bone would exhibit different strength/stiffness in the same plane. If the same portion of bone is tested for stiffness in different planes then it is likely that it would exhibit different values. This anatomical variation at different levels of the same bone could be a reason for variation in values for intact tibiae obtained by different workers. It would therefore seem reasonable to conduct tests at different levels of the bone and designate stiffness values specific to those areas.

The progress of healing of fracture in external fixation can be particularly difficult to assess, it is to note that the commonest major complication in the series of patients treated using external fixators reported by Burny (1979b) was re-fracture (2.6%), after removal of the fixator. Work on developing the Oxford fixator (Dynabrace) has been greatly facilitated by the use of fracture stiffness measurement and allowed objective testing of the effect of passive cyclic micromovement applied in the early weeks following injury (Richardson 1989).

There is a particular need to compare the use of external fixators with functional bracing for tibial fractures, particularly as the proposed indications for each method of management increase and overlap considerably in tibial fracture management. A stiffness measuring system would allow objective and sensitive comparison. Such a system would need to be independent of fixator pins so that it could be applied equally to both externally fixed and conservatively treated fractures. Any system which is utilised for monitoring fracture healing should ideally be able to satisfy the following features:

1 Non-invasive.
2 No morbidity.
3 Simple in methodology.
4 Portable.
5 Mechanical measure.
6 Direct reading.
7 Repeatability of results during testing.
8 Reproducibility.
9 Errors - within 10%.

CHAPTER 5

MEASUREMENT OF FRACTURE STIFFNESS: A PILOT STUDY.

"I think your solution is just; but why think? why not try the experiment ?".

(John Hunter 1728-1793)

5.1 AIM OF THE STUDY

This method employs commercially available instruments to measure stiffness of the fracture. It was decided to undertake an initial pilot study (Shah 1988) to assess the potential of the instrumentation and the methodology.

5.2 MATERIALS

The system consisted of the following:

ELECTRO-GONIOMETER: The electro-goniometer (figure 5.2) marketed by Penny and Giles Biometrics consists of a wire of steel, with a single strain gauge wire along each quadrant. These act as strain gauges, their output having a linear relationship with the angle subtended. It has infinite resolution, linearity and hysteresis is better than 1 percent, is relatively stable to temperature changes and has very little resistance to movement (Penny and Giles specifications).

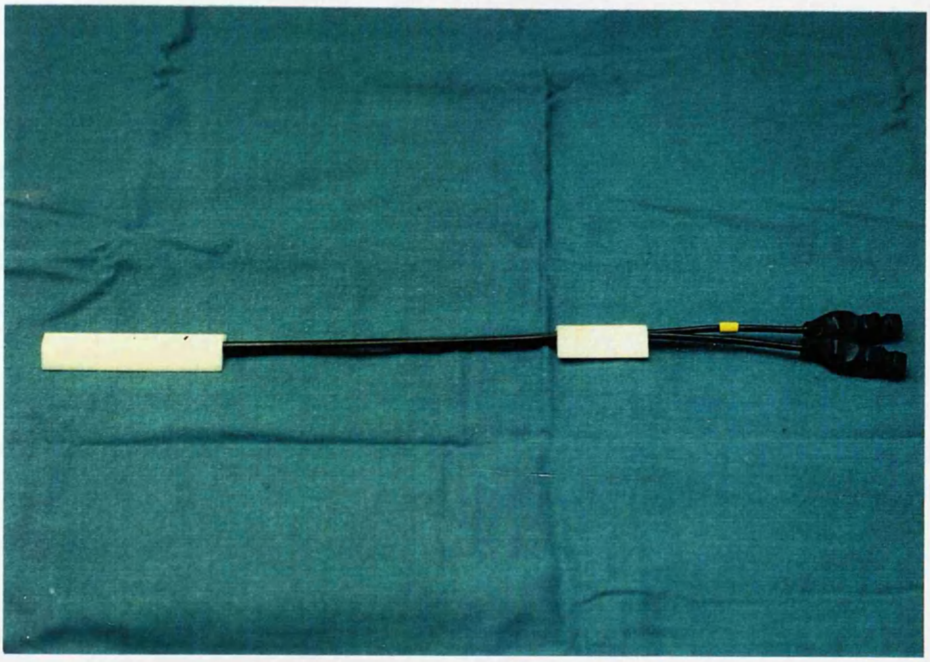


FIGURE 5.2: Penny and Giles electro-goniometer.

LOAD CELL: This can be either a simple bathroom scale or for more accuracy a strain gauged transducer, connected to an amplifier and data collection system.

AMPLIFIER: This is required if the instruments are connected to an output system like a chart recorder, to amplify the signals from the electro-goniometer and load cell. A simple system would not require this as the electro-goniometer comes with its own hand held read out and if bathroom scales are being used to record the loads then necessary calculations could be done. But this would expose the method to larger human errors.

CHART RECORDER: The input signals from the load cell and electro-goniometer are amplified and a chart recorder utilised for the output signals.

ORTHOPLAST BRIDGES: These are needed for applying the electro-goniometer across the fracture site. If the electro-goniometer is attached directly onto the skin, it is likely to give larger errors because of the free movement of the skin over the tissues. Fixation of the "bridges" over the anterior aspect of the tibia using elasticated strapping, provides a 3-point fixation which helps reduce the errors by fixing the skin over the soft tissues.

ELASTICATED CAST SOCK: The limb being tested is covered in a elasticated sock to decrease the movement of the soft tissue under the "bridges" and thus reduce the errors.

5.3 PRINCIPLE

The proposed method works on the principle (figure 5.3) that if the load (F) applied at a certain known distance (y) from the fracture is measured, thus giving the moment (Fy) at the fracture site, then by measuring the angle/deflection (θ) occurring at the fracture site monitored by a suitable instrument (electro-goniometer), necessary data to calculate fracture stiffness (Fy/θ) would be available. The stiffness being expressed in Nm/deg.

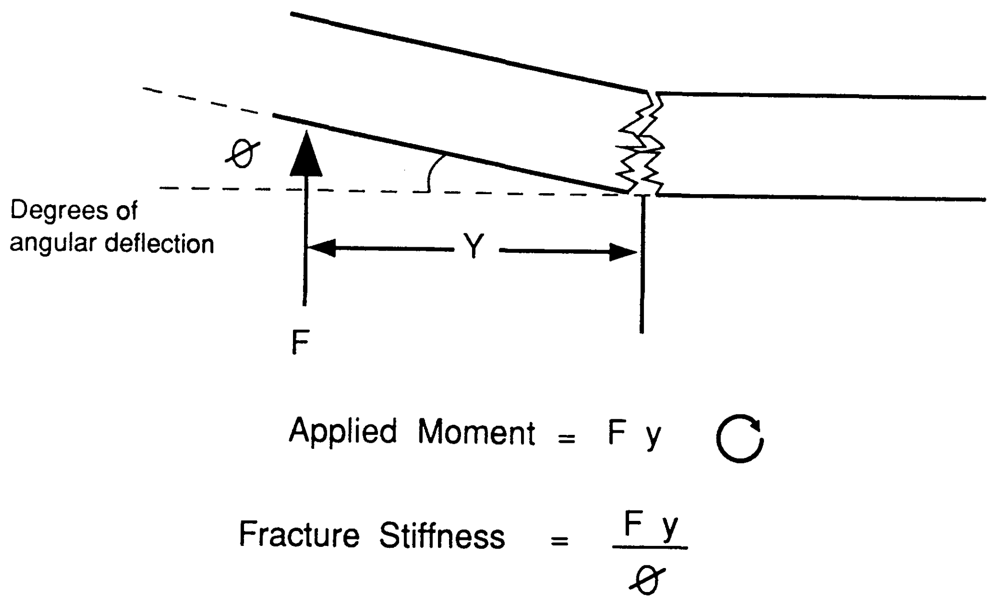


FIGURE 5.3: Principle for calculating fracture stiffness.

5.4 METHOD

1/- The leg to be tested was covered with an elasticated cast sock.

2/- An "Orthoplast bridge" was applied on either side of the fracture with the ends of the electro-goniometer attached to their sides (figure 5.4).

3/- The patient's leg was placed on a suitable load cell, in this method an orthopaedic cast shoe was modified so that it could be hung from a metal bar with a strain gauged force transducer and the patient sat in front on a chair at the same level with his foot encased in the modified shoe. The signal from the transducer was amplified and exhibited on a chart recorder (figure 5.4).

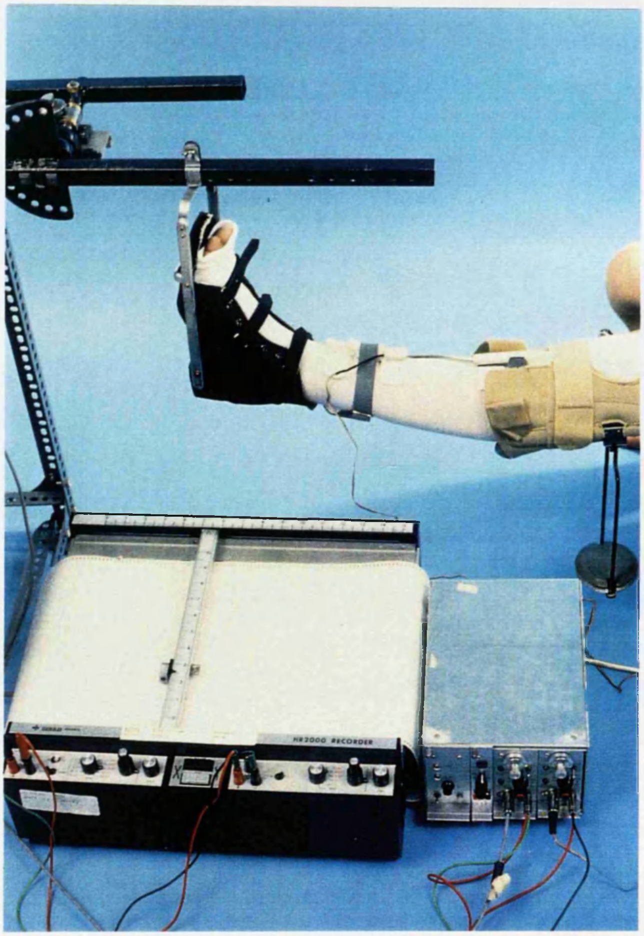


FIGURE 5.4: Method of testing the fracture stiffness in a patient.

4/- The output from the electro-goniometer was channelled through the amplifier to the same chart recorder as above so that during testing a simultaneous plot was achieved. The leg was loaded by pressing at the knee.

5/- The chart recorder provided the simultaneous readings for deflection at the fracture site to the amount of force applied. The force was assumed to be acting at the centre of the heel and by calculating the distance of the fracture from the heel on an x-ray the moment (Fy) at the fracture could be known. Although the force was applied at the knee joint, it was being measured at the heel, therefore the magnitude of the force applied at the knee is immaterial for our calculations.

6/- Calibrating the chart recorder to both force and deflection made it possible to know the simultaneous deflection relative to the applied moment (Fy) and allowed the calculation of fracture stiffness (Fy/θ) expressed in Newton-Metres/degree.

7/- The same process was repeated on the normal leg with care taken to place the bridges at similar sites and utilising the same value of "y" for calculating fracture stiffness on the normal limb at symmetrical position. This allowed comparison of the stiffness of the fracture callus to the symmetrical level on the normal contra-lateral leg, acting as a control.

The method evolved from a very simple concept of measuring loads using bathroom scales and taking the deflection readings from a hand held digital read out attached to the electro-goniometer. It was felt that there was no control on the element of human error in taking the simultaneous readings and thus the results obtained would have a higher percentage of error. This method was also cumbersome and time consuming because the results had to be tabulated by the examiner. The output via a chart recorder, cuts down on human error, although the effort involved in tabulation of the results is still there. It was felt that computerisation of the method would allow instant tabulation of the results and would also make it possible to repeat the tests many times, thus decreasing the overall error.

5.5 RESULTS AND DISCUSSION

STAGE I - PRECISION AND ACCURACY ASSESSMENT: Evaluation of any method of measurement requires assessment of its precision and accuracy. The method was assessed for its precision by repeating tests on the same subject. The electro-goniometer was applied and several readings were taken (test I). The bridges were then removed and re-applied on the same limb at the same level (test II). The "Intra-test" (test I) readings showed a mean error (coefficient of variation) of 8.64%, whereas in the "Inter-test" (test II) the mean error was 19.58% (appendices 5A & 5B). These calculations show that the cumulative error could be of the order of about 27%.

These errors were felt to be mostly due to the soft tissue interface and to a lesser extent due to human element (patient and observer errors) because the system components themselves are fairly accurate (electro-goniometer has a linearity of better than 1 % while the scales were believed to be 98 % accurate).

Clinically, for an individual patient, the precision of the system is more important than its accuracy for making treatment decisions, but improvement in the cumulative error is desirable. The soft tissue error can be minimised by testing the normal side at a symmetrical level and expressing fracture stiffness as a percentage of normal for that individual patient. If 60 Nm/deg is considered as the stiffness for intact tibiae and 15 Nm/deg as a safe level to allow unprotected weight bearing (figure 4.8.C) then converting the above figures gives a value of 25% of normal tibial stiffness to be compatible with unprotected weight bearing (figure 5.5.A). This figure was utilised for assessment of fracture healing in an individual patient by comparing it to the normal leg.

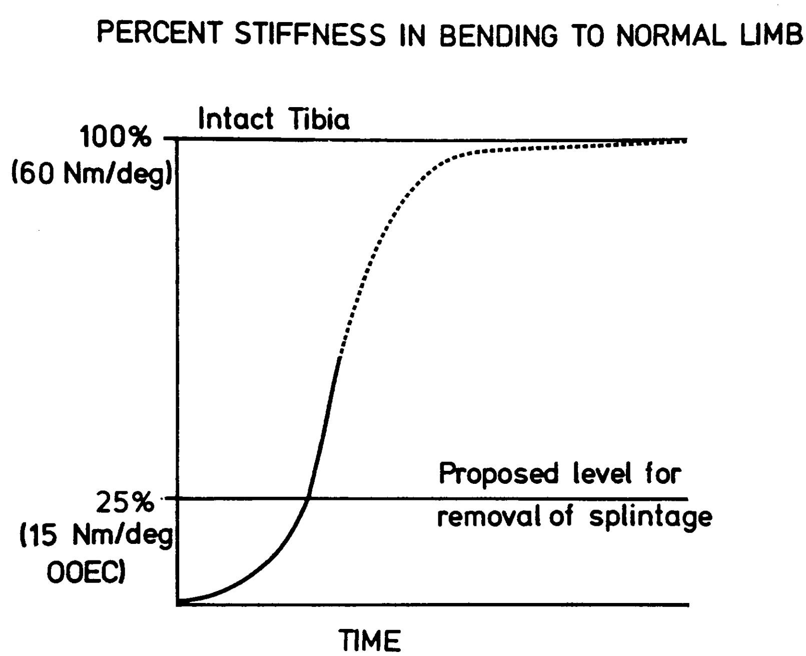


FIGURE 5.5.A: Percentage stiffness of tibial shaft fractures compatible with unprotected weight bearing.

To improve the accuracy of the system all possible sources of error were considered and the total error could be represented as follows:

Total error = Instrument error - "IE" (electro-goniometer and load transducer) + Human error - "HE" (patient and observer) + Soft tissue error - "SE"

By expressing the above in RMS - root mean square form (Pearcy 1985):

$$\text{RMS total error} = \sqrt{IE^2 + HE^2 + SE^2}$$

The instrument error (IE) is quite small and would not affect the total error appreciably. The human error

(HE) can be improved by better instrumentation to avoid the need for the observer to make simultaneous readings, and allow the subject to relax, so that muscular contractions do not influence the electro-goniometer deflections. This leaves the soft tissue (SE) component as the major source of error. This can be improved by modifying the attachment system for the electro-goniometer with bridges which conform to the leg, and improved 3 point fixation.

STAGE II - IMPROVED INSTRUMENTATION/SOFT TISSUE INTERFACE ATTACHMENT: To reduce the observer error the bathroom scales were replaced by a strain gauge on a steel bar to act as the load transducer and the signal was fed through an amplifier to a chart recorder. The electro-goniometer signal was similarly fed through the amplifier to the same chart recorder instead of to a hand held read out. The bridges were re-designed and in some cases customised to each subject to improve fixation. This improved the testing procedure and allowed an increased number of readings to be taken in a shorter time.

The problems encountered with this system were as follows:

1 The system had to be static requiring patient transfer from clinical areas.
2 The calibration of the chart recorder for the deflections of the electro-goniometer was not sensitive to one decimal point making the tabulation of results less accurate.
3 The method carried a potential electricity hazard because of its connection to the mains supply.

STAGE III: In this stage the chart recorder was changed to provide sensitivity to one decimal point allowing estimation of the deflection in degrees. It was felt that tabulation errors could be reduced further by computerisation of the data (figure 5.5.B). This would also expedite the results and testing by allowing repeated readings in a shorter time and provide portability to the system. The data base of the computer would provide instant access to data from previous patients, allowing comparison and prediction of healing times.

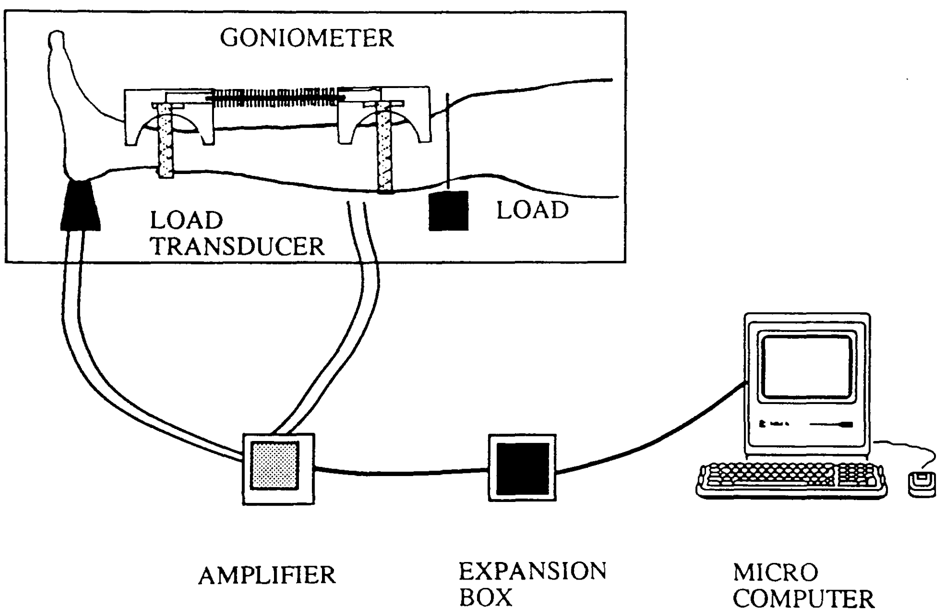


FIGURE 5.5.B: Diagrammatic representation of a computerised system of measuring fracture stiffness non-invasively.

5.6 CONCLUSIONS

1. The pilot study resulted in the development of a workable non-invasive method for evaluation of fracture stiffness in a clinical environment.
2. The electro-goniometer was found to be capable of measuring fracture stiffness in patients under treatment with external fixators as well as by other conservative methods.
3. Improvement in the instrumentation resulted in a considerable decrease in errors, and the ability to undertake increased numbers of readings led to an overall improvement in the precision and accuracy of the system.
4. The soft tissue interface between the electro-goniometer and bone was the biggest factor responsible for errors in the accuracy of the measurements. Further improvements in the method of attachment of the electro-goniometer are required to overcome this problem.
5. The results for the precision of the system gave errors less than the target of 15%. This permits utilisation of the system for decision making in individual patients.
6. Computerisation is essential for further improvement of the results.
7. Research should be directed to further standardisation of the method thus improving reproducibility of the system.
8. Clinical trials should be undertaken to evaluate the efficacy of the system in a clinical environment.

CHAPTER 6

COMPUTERISATION OF NON-INVASIVE METHOD OF MEASURING FRACTURE STIFFNESS.

Computerisation of the stiffness measurement system was undertaken in collaboration with the Department of Clinical Physics and Bioengineering (DCPB), Southern General Hospital Glasgow.

SYSTEM HARDWARE: The computerised system consists of the following instruments:

ITEM	MODEL	MANUFACTURER	RANGE
Lap top computer	T1200	Toshiba	
Expansion Box	PA7310V/E	Toshiba	
Expansion Interface	PA7312E	Toshiba	
A/D Converter	PC-26A	Amplicon	
Acquisition Software	PC-28A	Amplicon	
Load Cell Amplifier	PS 30A	Entran	
Load Cell	ELM 600	Entran	500 N
Electro-goniometer	G110	Penny & Giles	180 deg
Analogue Display Unit	ADU 201	Penny & Giles	200 deg
Signal Conditioning Amplifier	FSP 001	DCPB Glasgow	

This equipment was assembled as shown in figure 6.A. The diagram shows alternative connections for grip assessment units as well as the fracture stiffness measurement instrumentation.

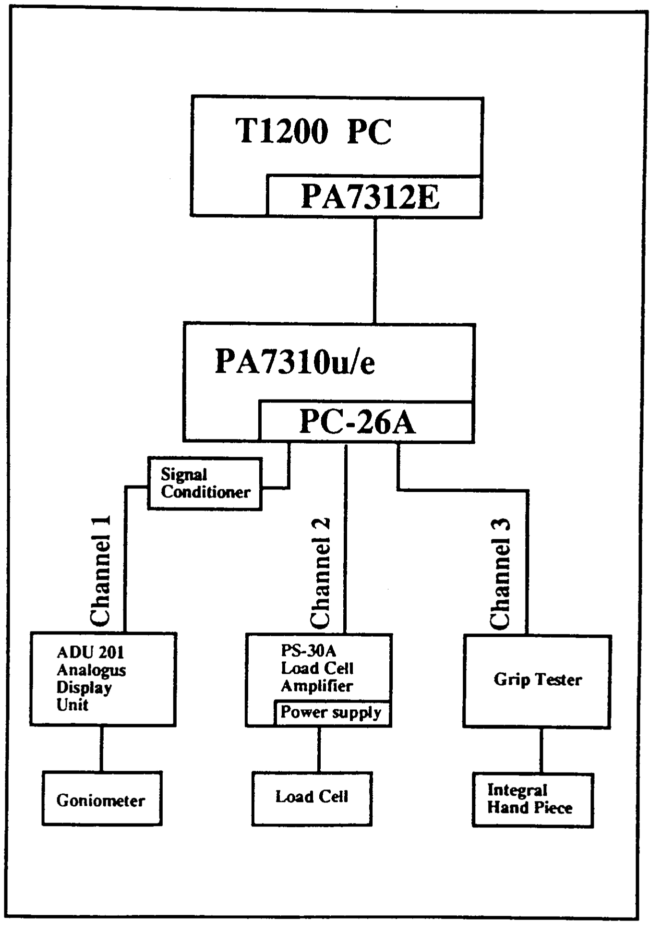


FIGURE 6.A: Schematic diagram of the system for measuring fracture stiffness non-invasively.

An objective assessment of grip strength was not part of this study but was developed as a separate project, using the same hardware. This showed the versatility of the system and its consequent economic advantages. The connection diagram and details of the modifications are as shown in figures 6.B and 6.C. Modifications included addition of signal conditioning components in the above items.

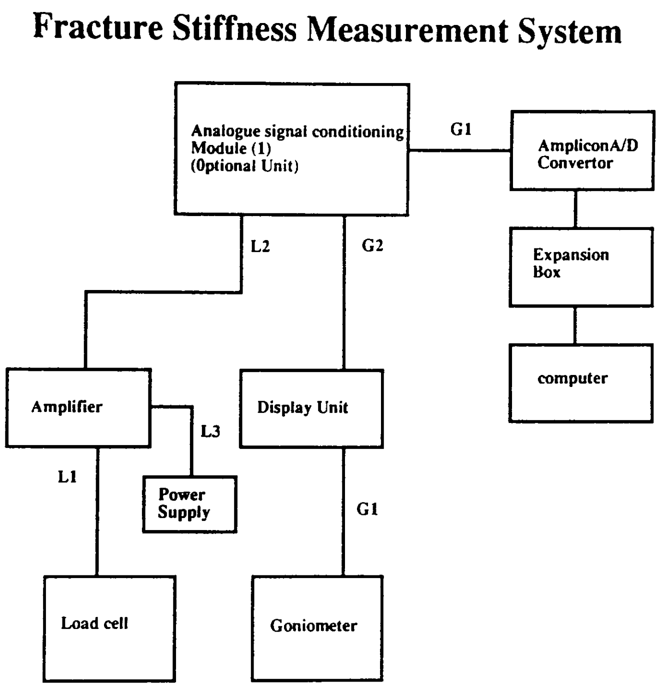


FIGURE 6.B: Computerised fracture stiffness measurement system.

CONNECTION SCHEDULE					
Cable Ref.	Cores	Cable Type	Identity/Colour	Function	Remarks
L1	4		Black White Green Purple Blue	+ signal -signal zero -supply +supply	Terminated to 5 pin Din Sachet
L2	3	0.5mm	Orange Brown Red	Earth -output +output	
L2	4	0.05mm silver	Red Black Green White	+ supply - supply + signal - signal	
L2	2	Twisted Pair	Red Black	Signal out Ov	
L3	3	0.5mm	Red Black Green	Positive Negative Shield	If the analogue signal conditioning option is not used; L2 links to C1 G1 links to C1 As per Amplicon Hand Book
G1	5	Multicore			Manufacturer supplied
G2	2	2 core 0.5mm	Red Black	Signal Ov	

FIGURE 6.C: Connection schedule for the fracture stiffness measurement system.

SYSTEM CALIBRATION: The system was calibrated in the electronics laboratory of the Department of Clinical Physics and Bioengineering, Southern General Hospital Glasgow. Calibration was not easy, because both the load cell and the electro-goniometer transducer types, had variable unit to unit non-linearity and hysteresis. It was decided to calibrate the system electronically as a first step followed by fine tuning of the calibration by software corrections, that is, by scaling and translation of data points to achieve a best fit response (Denholm 1989).

The accuracy of the computer and the analogue to digital (A-D) converter system, was assessed by loading and stimulating them as shown in figure 6.D. To check the linearity of these systems, test loads were applied to each of the transducers (load cell and electro-goniometer) as follows:

Electro-goniometer angular displacement	180 degrees
Load cell	25 kg

At the same time, a precision voltage source was applied to each of the remaining input ports in turn and the voltage was raised in 50 mV steps. The results were plotted against the ideal response of the system (figure 6.E). The mean error was found to be 0.1 % with a standard deviation of 0.05 %, which was well within the required system tolerance of 1 %. The accuracy values were calculated mathematically using the principle of least squares and statistical standard deviation (Bland 1987).

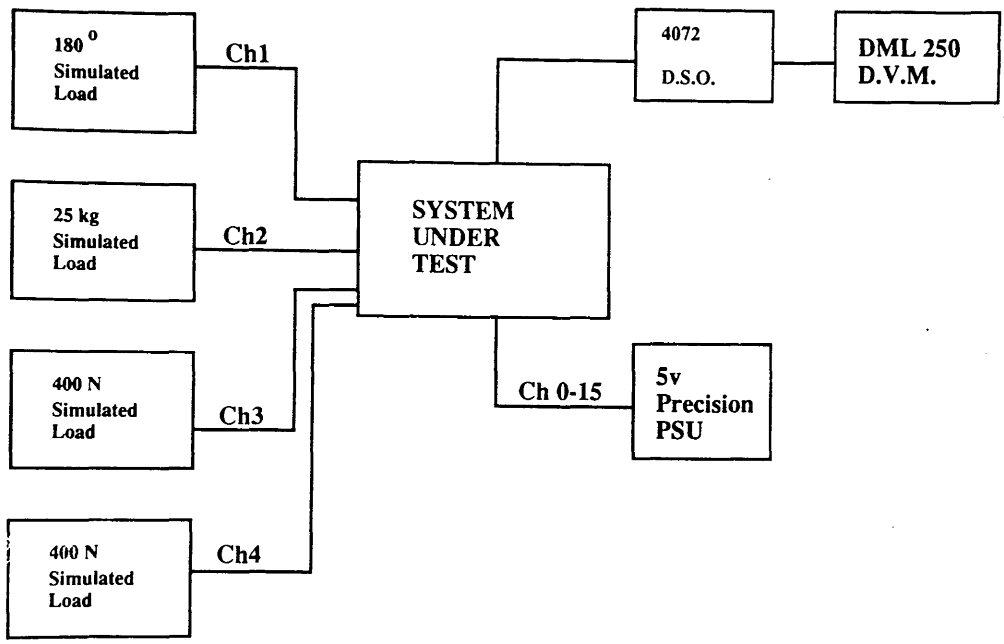


FIGURE 6.D: System configuration for testing the accuracy of the computer/A-D converter.

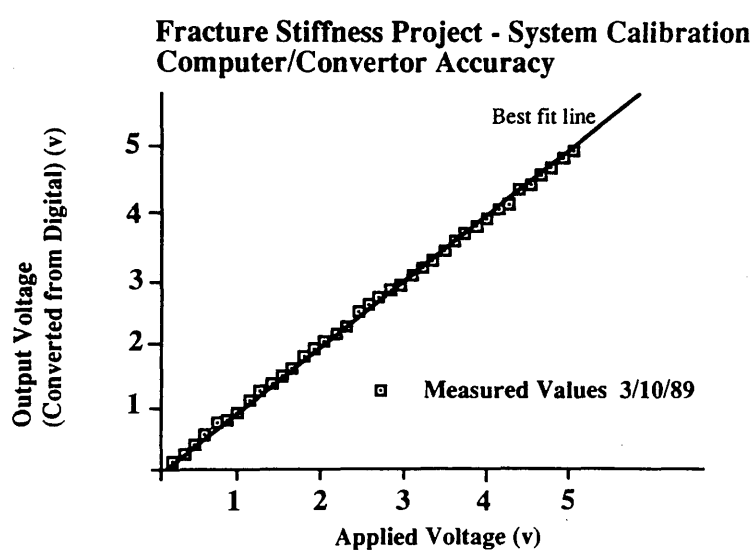


FIGURE 6.E: Data plot and errors when accuracy of computer/A-D converter were tested.

The load cell was calibrated by setting up the system and plotting the output data, as known loads were applied to the load cell. It was found that the load cell when under test had a greater amount of inherent non-linearity and hysteresis compared to the electro-goniometer. The mean error was found to be 0.28% with a standard deviation of around 0.032%. There was a parametric offset error of 0.25% on the graph (figure 6.F). This can be trimmed out by adjusting the "zero" on the load cell. However, the error is not significant when compared to measurement application of 50 to 100 N.

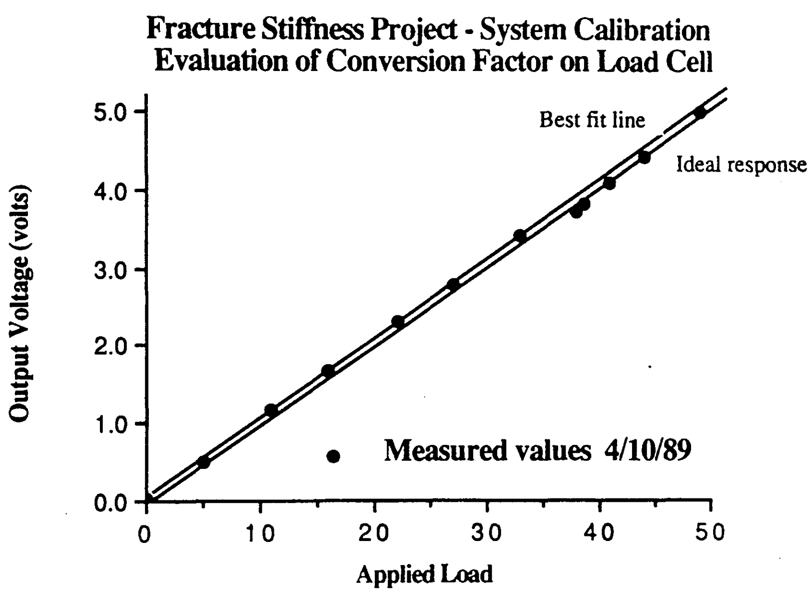


FIGURE 6.F: Output data during calibration of the load cell.

The electro-goniometer was similarly tested and the mean error of the data (figure 6.G) was found to be 0.1% with a standard deviation of 0.024%. The first and last five degrees (0-5 and 175-180 degrees) of the range in the electro-goniometer gave large deviations from the ideal, and were ignored for this particular application. The best fit was therefore obtained from the curve plotted from 5 to 175 degrees during the test. For fracture stiffness testing a maximum spread of 5 degrees is required and the errors could be avoided by selecting the most linear part of the curve.

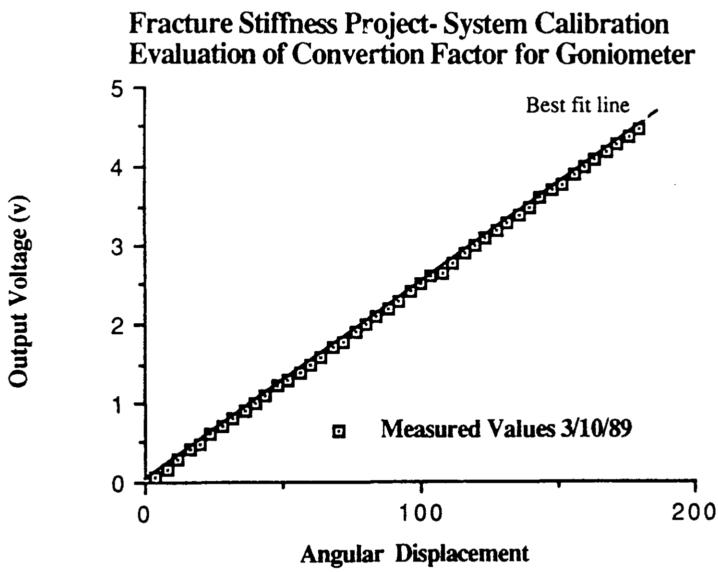


FIGURE 6.G: Output data during calibration of the electro-goniometer.

CALIBRATION DATA SUMMARY

INSTRUMENT	**MAX. ERROR**	**DEVIATION**
Computer and A-D converter	0.1 per cent	0.05 per cent
Load Cell	0.3 per cent	0.032 per cent
Electro-goniometer	0.1 per cent	0.024 per cent

SYSTEM SOFTWARE PACKAGE: To run the system hardware (instrumentation) the software utilised, consists of the following functions:

1 Patient data capture
2 Test data capture
3 Test data analysis

The patient data menu prefaces the data capture menu as a separate program to the data capture software. This is basically a database to allow long term comparative analysis of the patients tested, and includes patient as well as fracture details. It comprises of the following input fields:

FIELD	**LENGTH**
Patient Name	(26 Characters)
Case number	(4 Characters)
Age	(3 Characters)
Sex	(1 Character)
Hospital Number	(10 Characters)
Date of injury	(6 Characters)
History of Mechanism	(2 Characters)
Injury side	(1 Character)
Fracture classification	(2 Characters)
Fracture site	(2 Characters)
Fracture type	(1 Character)
Method of treatment	(2 Characters)
Date of healing	(6 Characters)
Number of tests done	(2 Characters)
Remarks	(150 Characters)

Test data capture is primarily achieved using Amplicon's PC-28A software package, which was provided with the analogue to digital (A-D) conversion card. This software package cannot fulfil all the requirements of this application and it was decided to modify it to achieve the required output information. This was possible because the copyright owners did not impose any restrictions on such modifications. The following modifications were carried out to the software package (PC-28A):

1 Automatic preset to Toshiba T1200 lap top.
2 Preset channel selection for channels 1 and 2.
3 Preset sample frequency of 50 Hz per channel.
4 Preset test duration for 10 seconds.
5 Preset to normal trigger.
6 Collection of test data in two routines: first one for "zeroing" of the instruments followed by collection of test data.
7 Storage of data into predetermined files ("*.cal" for calibration data and "*.fra" for test data)
8 Facility for conversion of the test data into a "text" file

Analysis of data collected during fracture stiffness measurement required writing up of appropriate software to allow calculations of stiffness from the information acquired. Two types of transducer data are collected during measurement of the fracture stiffness with this method, as follows:

INSTRUMENT	**RANGE**	**DATA CHANNEL**
Load cell (after a gain of 2)	0 to 250 N (after amplification)	Channel 2
Electro-goniometer	0 to 180 degrees	Channel 1

The normal display output from PC-28A software is a bipolar graph of voltage against time, with the maximum positive voltage being 5 volts. During analysis of data, output was scaled so that it filled the whole screen. To accomplish this, correction factors for each transducer were incorporated in the software. Conversion factor for converting the load cell data from pounds (lb.) into Newtons was also incorporated. Facility for providing the value for "Y" was also provided so that all the information required for calculating the fracture stiffness was available. The formula for calculating the fracture stiffness is as follows:

Fracture Stiffness (FS) = (F * Y)/ θ

Where "F" is the force in Newtons (from load cell)
"Y" is a constant for that particular patient (radiographically calculated from the ankle to the centre of the fracture)
"θ" is the angular displacement at the fracture (from the electro-goniometer)

The above equation is applied to each data point within the ten second test time and stored. From this stored data the mean value of fracture stiffness is calculated using the "least square" method (Bland 1987) of analysis and is stored with a cross reference to that patient. Standard deviation from the mean is similarly calculated and stored. Using the above data, a graph of fracture stiffness against time is produced with a "linear regression curve" superimposed on the data points. In addition, selected information from the patient data, mean value of the fracture stiffness, file name and date of test are overprinted on the graph (figure 6.H). The graph is stored in the patient file along with other patient data.

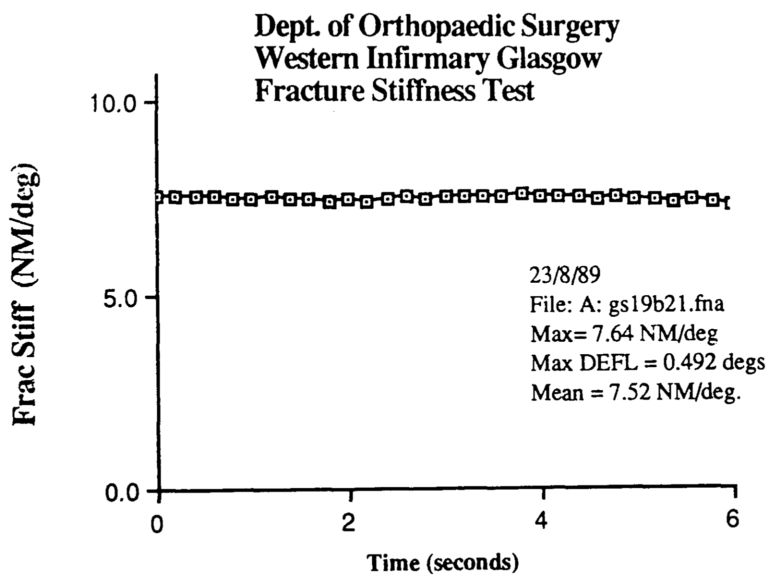


FIGURE 6.H: Presentation of the fracture stiffness test performed on a patient.

6.1 CLINICAL TRIAL: INTRODUCTION

A clinical trial to test the efficacy of the computerised system, was conducted from June 1989 to March 1990. The aim was to standardise the method of testing the patients in a clinical environment. Patients with tibial shaft fractures which were under review for surgical treatment with bone grafting were included in this trial. These were cases in which the radiological evidence suggested delayed union while the clinical assessment contradicted it.

6.2 METHOD OF TESTING

If a tibial fracture to be tested is in a cast, then the cast is bi-valved. If such a cast is a cast brace (2 in 1 functional brace) then it can be bi-valved without permanently damaging it, so that it could be re-used after the fracture stiffness measurement. The bi-valving is done antero-posteriorly because this does not interfere with the design features of the 2 in 1 brace. When the two portions of the brace are put back on the leg after the test the brace can be reconstituted using a single layer of synthetic bandage so that it still performs its functions biomechanically.

The pilot study had shown that to decrease the major error due to the presence of the soft tissue interface, it was important to use a standardised method of testing on all patients, and during all the tests on the same patient. The following steps were followed for all the patients in the trial:

1/- Before commencing testing, the fracture tibia was examined clinically to judge the level of stiffness and to decide on the amount of load to be used during testing.

2/- The fractured tibia was always tested first, followed by the contra-lateral normal tibia as the control.

3/- A documented record (appendix-6A) was maintained of all the tests carried out. Computer files of the tests were also kept for future reference and analysis.

4/- The instrumentation was switched on at least 20 minutes before the start of the test. This precaution was undertaken to allow the load transducer to warm up and stabilise, thus decreasing the chances of instrument errors.

5/- The patient was seated on a high chair so that when the leg was put in a heel cup, placed over a load transducer in a customised apparatus (figure 6.2.A), the leg was kept horizontal. This meant that the chair in front had to be shorter by approximately 12 cms. It is essential that the leg is kept horizontal during the test for optimum results.

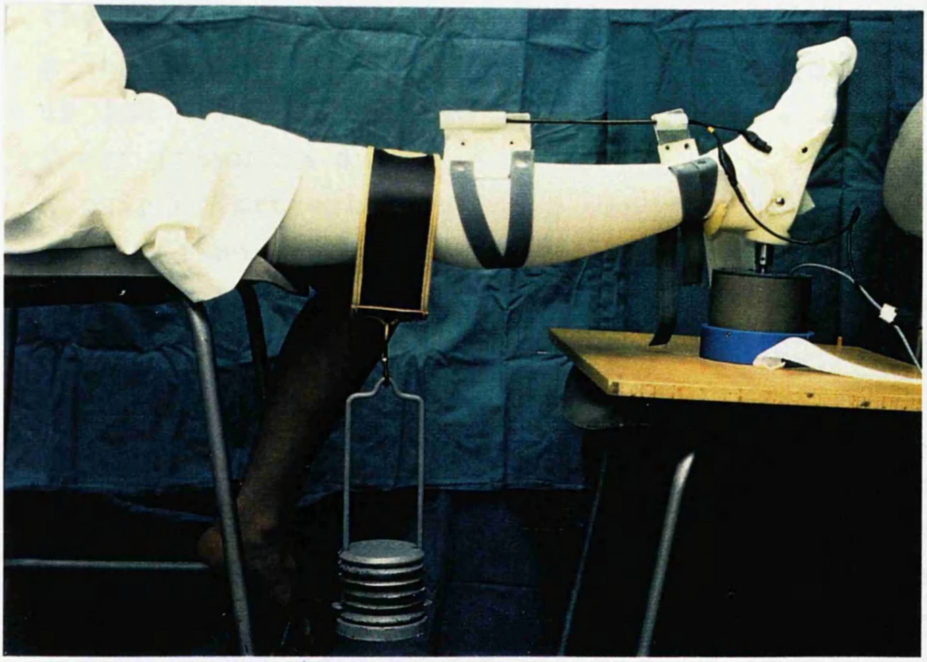


FIGURE 6.2.A: Method of measuring fracture stiffness non-invasively.

6/- The box containing the load transducer with the heel cup attached to it was fixed on a flat platform (figure 6.2.A) so that the leg was kept balanced during the period of testing. Any movement of the leg during the test would give erroneous results by influencing the deflection of the electro-goniometer. To ensure that the foot was properly secured in the heel cup, velcro straps were attached to the platform. The velcro straps also ensured that the leg was kept slightly internally rotated during the test. This step was taken to decrease the influence of an intact fibula on the stiffness of the fractured tibia. An intact fibula would act as a strut increasing the measured stiffness of the leg. This effect would be proportional to the amount of external rotation of the leg at the time of the test.

7/- The leg to be tested was covered with an elasticated cast sock to decrease the movement of the soft tissue.

8/- A leather cuff was put on the leg, before placing it horizontally on the heel cup, on a chair in front (figure 6.2.A).

9/- A pair of orthoplast bridges was applied on either side of the fracture and their positions measured from a fixed point on the heel cup, so that they could be placed in identical positions during future tests.

10/- The foot was fixed in the heel cup using velcro straps. The electro-goniometer on the orthoplast bridges and the load cell under the heel, in the box, were connected to the lap top computer (Toshiba T1200) via the amplifiers and the expansion box (figure 6.2.B).

11/- The patient was encouraged to relax as much as possible so that muscular contractions would have a minimal effect on the deflection of the fracture when the load is applied.

12/- The computer program "dtamangr" is run, which displays the opening menu. The option "fracture stiffness measurement" is selected. The program then requests certain information as to the drive to be used for data storage and the file name under which the test data is to be stored. Provision of the above information leads to the display of a sub-menu.

13/- The sub-menu displays five options. Option number 5 is the calibration routine which is selected.

14/- Before running the options, by pressing the return key on the computer, the patient is warned and instructed to keep the leg steady. At this stage no weight is attached to the leather cuff around the knee. This calibration routine runs for 10 seconds taking the base line readings from the load transducer and the electro-goniometer to act as zero values.

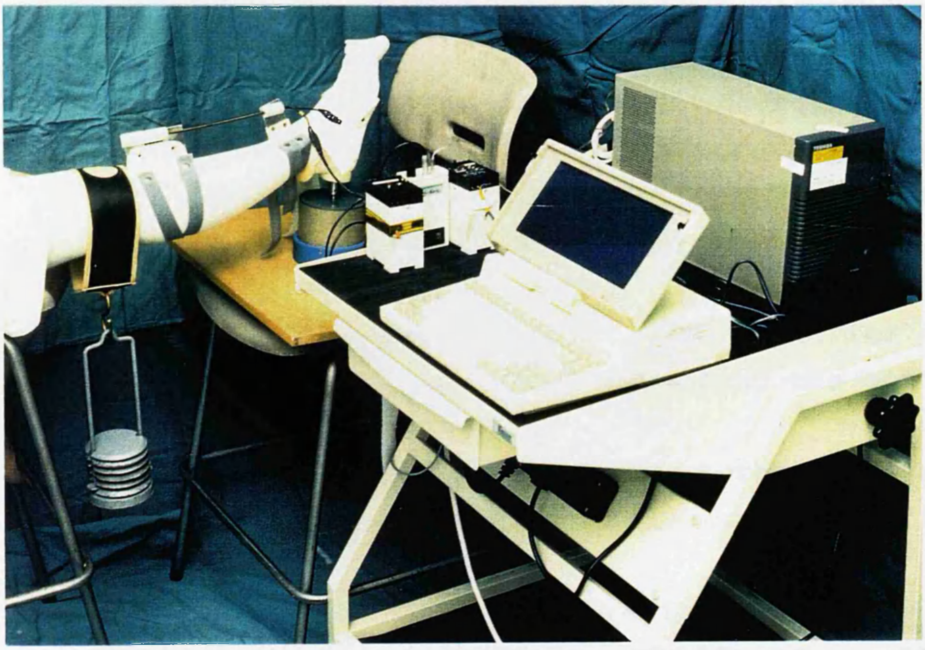


FIGURE 6.2.B: Set up of the instrumentation during non-invasive measurement of the fracture stiffness.

15/- After completion of the calibration routine the computer automatically stores the calibration data in a file with extension "*.cal" and reverts to the sub-menu with the five options.

16/- Option number 1, which says "collect data" is now selected for the second part of the test.

17/- Before running this second routine a suitable weight is applied to the leather cuff using the hook attached inferior to it (figure 6.2.A). Preferably a 5kg weight is used for all patients, but the decision as to the exact weight is dependent on the clinical evaluation of the stiffness carried out before commencing the test.

18/- A 5 second interval is allowed between the application of the load to the leather cuff and start of the data collection routine by pressing the "return" key on the computer. The reason for this delay is the viscoelastic nature of the bone and the layer of soft tissues around it. The bone and soft tissue composite responds to the rate of application of loads by showing a hysteresis curve. This hysteresis is minimised and a more repeatable value of stiffness is recorded, if the tissues are given sufficient time to stabilise in response to the load applied.

19/- The data collection routine also runs for 10 seconds. The data is stored by selecting the option number 3 ("to store file").

20/- Data can be analysed by selecting the analysis option from the main menu and calling up the file desired.

21/- The analysis of data provides the information as to the mean value of fracture stiffness, after requisite value of "Y" distance has been keyed in for that particular patient on demand by the computer program. The computer screen displays the data points for the fracture stiffness for the last 6 seconds of the test with superimposed linear regression curve. This provides an indication of the variability in stiffness values over that period. The program also provides an option to convert the data into a "text" file, which allows further statistical analysis on the raw data if required.

22/- The test is repeated three times followed by the same test procedure on the contra-lateral normal leg. Attention is paid to the application of the orthoplast bridges at the same positions as on the fractured leg. The test load for the normal leg is the same as for the fractured leg so as to give a realistic comparison. It is important to duplicate all the details of the testing methods for both legs so as to give as valid a comparison as possible.

6.3 RESULTS

A series of 10 patients was evaluated using the computerised system for measuring fracture stiffness. There were 8 males and 2 females in this series. These were patients with tibial shaft fractures who were not showing sufficient callus formation on radiological examination after passage of, on an average, 16 weeks time in treatment. The supervising clinicians were considering whether to intervene surgically to bone graft these fractures so as to stimulate healing. Clinically these fractures appeared quite stiff on manual stressing and there was no tenderness on palpation at the fracture site. These patients were referred for objective assessment of fracture stiffness to decide on the future course of treatment.

Some of these patients had been treated initially with an external fixator and then converted to a functional brace, while others were treated for a suitable period in a long leg cast followed by a functional brace. Patient details are given in appendix-6B.

As the fracture types and site of fracture were variable in this series they could not be considered as a homogeneous group. Despite this, when the measured percentage stiffness of the fractures were plotted over a variable period of time (figure 6.3.A), it was observed that there was a definite trend towards increasing stiffness relative to the passage of time on treatment. This fact, combined with increasing values of percentage fracture stiffness in individual patients signifying progressive healing, was the basis for the decision not to intervene surgically in the patients and to continue with conservative management. This policy of delay was successful, as all the patients went on to satisfactory union without the need for surgery.

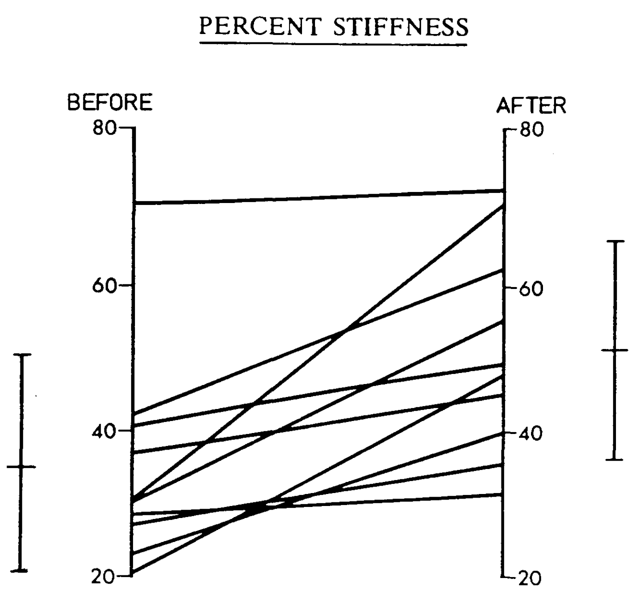


FIGURE 6.3.A: Measured percentage stiffness's of the fractures plotted over variable period of time.

The repeatability of the system was assessed clinically by performing the test twice on the two legs of the same patient and comparing the results. These repeatability tests were performed on two patients (A.M and G.S) [figure 6.3.B]. The "coefficient of variation" was calculated as follows:

Coefficient of variation = Standard deviation/Mean * 100

The coefficient of variation varied from 0.9-8.5%, the mean being 3.6% (S.D - 3.4). This was well within the range of errors as identified for an "ideal system" for monitoring fracture healing.

REPEATABILITY OF THE SYSTEM

	Fracture Stiffness (NM/deg) RIGHT LEG		Coeff. of Var. (%)	Fracture Stiffness(NM/deg) LEFT LEG		Coeff. of Var. (%)
	First Test	Second Test		First Test	Second Test	
A.M.	9.551	9.674	0.9	10.384	10.119	1.8
G.S.	5.059	4.832	3.2	11.023	12.445	8.5

Coeff. of Var. = Coefficient of Variation
Mean Coefficient of Variation = 3.6 Per Cent

FIGURE 6.3.B: Repeatability of the computerised fracture stiffness measurement system.

To assess the precision of the system "within the test", 150 data points for the last 3 seconds of the fracture stiffness tests for the same two patients were extracted, utilising the analysis software program. Using the Minitab (Ver 6.1.1) statistical package the mean and standard deviations were calculated and used to calculate the "coefficient of variation" as explained above for repeatability testing.

The coefficient of variation in the 8 individual tests analysed varied from 1.4 - 11.1% (figure 6.3.C), with a mean of 5.16 (S.D - 3.40). Again the error range was acceptable as set for a clinically appropriate non-invasive system for measuring fracture stiffness.

PRECISION WITHIN THE TEST

		A.M.		G.S.	
		FRACTURE STIFFNESS (NM/deg)	COEFFICIENT OF Variation (%)	FRACTURE STIFFNESS (NM/deg)	COEFFICIENT OF Variation (%)
RIGHT LEG	First test	9.55	5.4	5.06	2.4
	Second test	9.67	6.7	4.83	2.6
LEFT LEG	First test	10.38	8.5	11.02	1.4
	Second test	10.11	11.1	12.44	3.2

Mean Coefficient of Variation = 5.1 Per Cent

FIGURE 6.3.C: Precision "within the test" of the system.

6.4 DISCUSSION

The successful development of this non-invasive computerised system for measuring fracture stiffness achieved one of the main aims of the study. Technical problems were encountered during assembly of the hardware for the system, because individual component specifications were incompatible and electronic modifications had to be made to overcome these. The laboratory testing required meant that insufficient time was left for a long term clinical trial to assess the efficacy of the system in the hospital environment.

A short term clinical trial was therefore carried out to standardise the method of testing to be followed in any long term clinical assessment of the system. This was achieved as shown by the "repeatability" and "precision" testing within the test reported earlier. The clinical assessment of the system at this small scale is very encouraging and indicates its potential.

Laboratory testing had shown that the total system errors were less than 1 % which is a substantial improvement from the system and observer errors noted during the pilot study using the chart recorder (chapter 5). The expected errors in this computerised system are due to the limitations of the methodology for clinically measuring fracture stiffness non-invasively. The guidelines for an ideal system of measuring fracture stiffness enumerated earlier (section 4.8) suggested errors to be within +/- 10 per cent. This means that even with the methodology errors of 9 per cent, the system would still fulfil the guidelines for clinical applications. This was an encouraging factor in further development of the system.

This study highlighted the weak link in the methodology, which was the error due to the presence of the soft tissue interface between the orthoplast bridges and the lower leg. To overcome this problem attention was paid to standardising the methodology as well as to improving the method of attachment. This improved the results, but had to be balanced with the time taken in carrying out individual tests. In the later part of the study, the test time was found to vary from 10-15 minutes per patient. The first test usually took longer because the patient had to be briefed and prepared, whereas the successive tests were accomplished in lesser time.

Attention to detail and consistency in the method of application of the electro-goniometer to the leg, has kept the errors within these limits. Errors within 10 %

are acceptable considering the advantages of the non-invasive nature of the system. Other mechanical methods of measuring fracture stiffness using bone pins for attachment of the transducers measuring deflection have similar levels of errors. This is because the accuracy is dependent on the status of the bone pins, which if loose introduce errors. This implies that if the preliminary figures regarding repeatability and precision of this system are borne out by a long term clinical trial, then it seems that repeatability and precision are not confined to the methods developed for external fixators.

During development of this system the effect of an intact fibula on measurement of tibial fracture stiffness was also assessed. Theoretical calculations were carried out and the following simple assumptions were made:

1 Both bones (tibia and fibula) are cantilevers.
2 Both bones are hollow rods of same material and uniform diameters.
3 The tibia has an external diameter 3.5 times that of the fibula, while internal diameter is 5 times that of fibula.
4 Tibia and fibula are lying side by side, as is the case when fracture stiffness is measured in a sagittal plane.

The deflection for a material is given by the following equation (Roark 1954):

$$\text{Deflection} = WL^3/3EI$$

$$\text{while} \quad I = \pi/64 * (D^4-d^4)$$

where W = Force
L = Length of the bone
E = Young's modulus
I = Moment of Inertia

D & d = Outer and Inner diameters of the bone
π = 3.1416

It is apparent that if all other variables are the same the contribution to the total deflection in the complex would depend on the external and internal diameters of the rods raised to power four. On the basis of the above assumptions the contribution of the fibula is approximately 1.5%. Despite the simplicity of the model it is unlikely that the above value differs markedly from the true value.

It was shown repeatedly using this system that where clinical union was not correlated with radiological union, the fracture stiffness measurement supported the clinical impression. Edholm et al (1983) had also mentioned similar observation in his study. This implies that if radiological union is the sole criteria for fracture healing, then it is quite possible that fractures are over-treated when conservative methods are utilised. This measurement system could provide additional evidence to support clinical impressions and its utilisation in decision making may reduce the treatment times.

This study has shown that fracture healing in conservatively treated fractures could be assessed more objectively, but did not assess the suitability of this method for fractures being treated with external fixators. These patients could be assessed, either using this non-invasive method, or the electro-goniometer could be attached to the bone pins and stiffness measured. The method is thus equally applicable to fractures being treated by external fixators and provides a means of comparing different methods of treatment for tibial fractures.

The initial investment in setting up of this system was determined to be around 3500 pounds Sterling (as per prices in December 1989). The method is still believed to be cost-effective, because this expenditure is offset to a great extent if consideration is paid to the following points:

1 This is not a "dedicated system" and it is possible to use the same hardware for many other different applications, such as grip assessment.

2 Clinical use of this method would reduce by about 50% the amount of x-rays required during follow-up of tibial shaft fractures, while at the same time decreasing the total radiation exposure to the patient.

3 This system may reduce treatment times and could avoid unnecessary bone grafting operations in cases where clinical evidence favours union while radiological evidence is to the contrary.

4 The computer could be used for other word processing and research analysis purposes when not in use for stiffness testing.

6.5 CONCLUSIONS

1/- This study has shown this non-invasive method of measuring fracture stiffness to be a reliable objective measure.

2/- This method fulfils most of the criteria for an ideal system.

3/- The method is simple in application, reproducible and relatively inexpensive. A small clinical trial has indicated the potential of this system in the clinical situation. However the error rate remains high and study of a larger series is required before recommendations for its routine use for monitoring tibial fracture healing could be made.

PART 3: 2 IN 1 FUNCTIONAL BRACE

CHAPTER 7

HISTORY AND PHILOSOPHY OF FUNCTIONAL BRACING

"Far from being a crude and uncertain art the manipulative treatment of fractures can be resolved into something of a science".

(Sir John Charnley)

7.1 HISTORY OF FUNCTIONAL BRACING

The development of modern concepts of functional bracing began with the work of John Hunter in 1791 (Home 1837) but the illustrations attributed to Hippocrates circa 460 BC (Adams 1849) suggest that the basic principles were understood in antiquity (figure 7.1.A).

The primitive bone setter of a stone age community applying sticks and mud to an injured limb was practising a form of functional bracing. Green twigs mimicked the action of hinges, while leaves bound around the limb compressed the soft tissues and held the fractured bone in position (Stenner and Harold 1989).

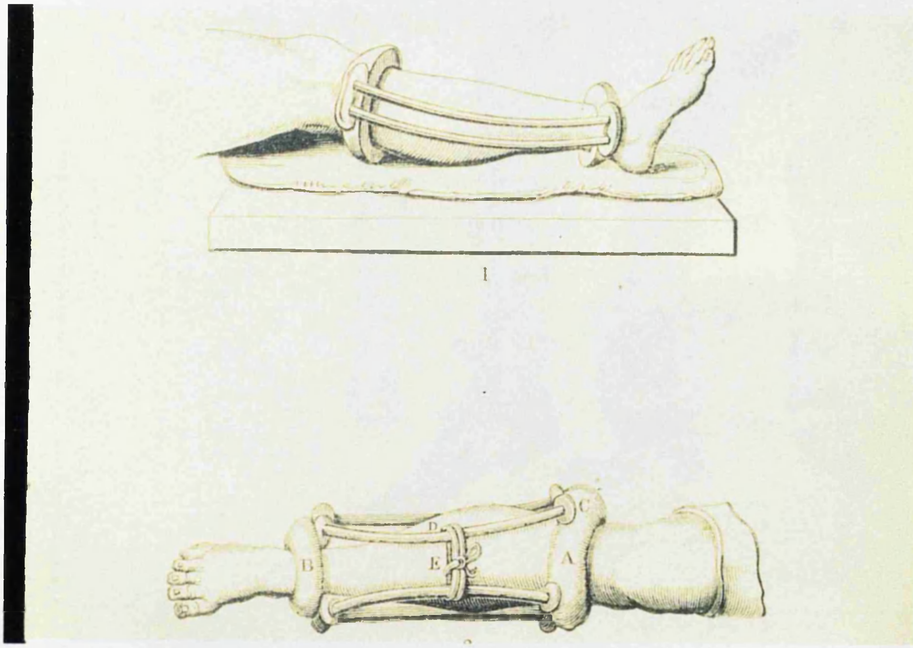


FIGURE 7.1.A: Illustrations attributed to Hippocrates.

Henceforth throughout the history of fracture treatment surgeons utilised the locally available materials and expertise to manufacture splints of various sorts. William Sharp (1767) described a form of splintage (figure 7.1.B) which could be considered a form of modular cast brace system for fractures of the tibia. He first used it to treat an oblique fracture of the tibia. The medial and lateral splints were made of strong paste board made with glue and were secured by straps. The lateral one had an opening in it to receive the lateral malleolus, while the extension for the foot kept it in 30 degrees of plantar flexion.

Sharp stated that he tried various other materials for the construction of the splint such as strong hide leather, wood and plate cooper. Although Sharp did not specifically discuss weight bearing, he mentions the advantage of knee mobility (Sharp 1767).

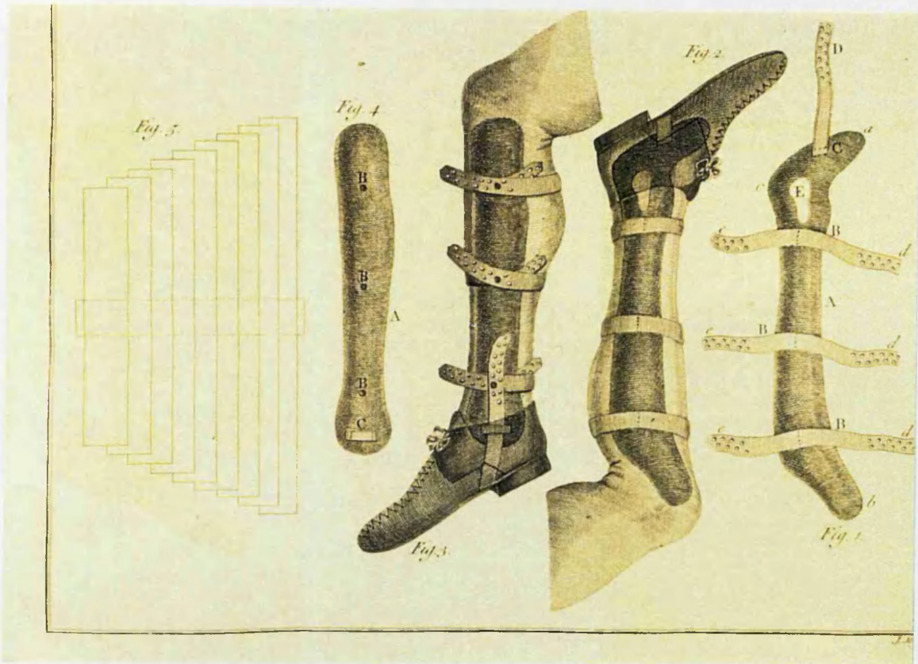


FIGURE 7.1.B: The form of splintage described by William Sharp (1767) for fractures of the tibia.

Benjamin Gooch (1767) also described a flexible type of wooden splint (figure 7.1.C) made by gluing a thin piece of timber about one tenth of an inch thick to leather and then cutting the timber in strips down to the leather so that the slats were hinged together and could be wrapped round a limb. He recommended its use for transportation of the patient with fractured tibias.

Benjamin Gooch (1767) also describes a splint which allowed extension of fractured tibia, a similar principle was also applied to fractured femurs. In this appliance (figure 7.1.D) the foot was bound to the sole plate with dimity or buff leather, the circular plates were adjustable and conformed to the upper tibia and thigh while extension of the fracture was achieved by traction applied through the threaded screws attached to the sole plate.

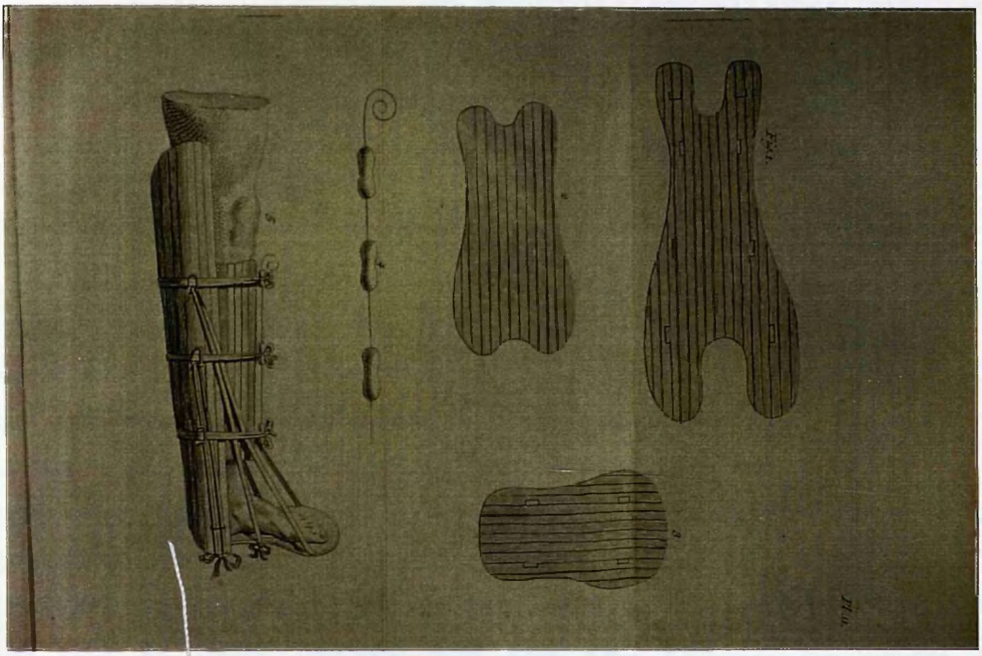


FIGURE 7.1.C: Flexible wooden splint for transportation of fractured tibia, used by Benjamin Gooch (1767).

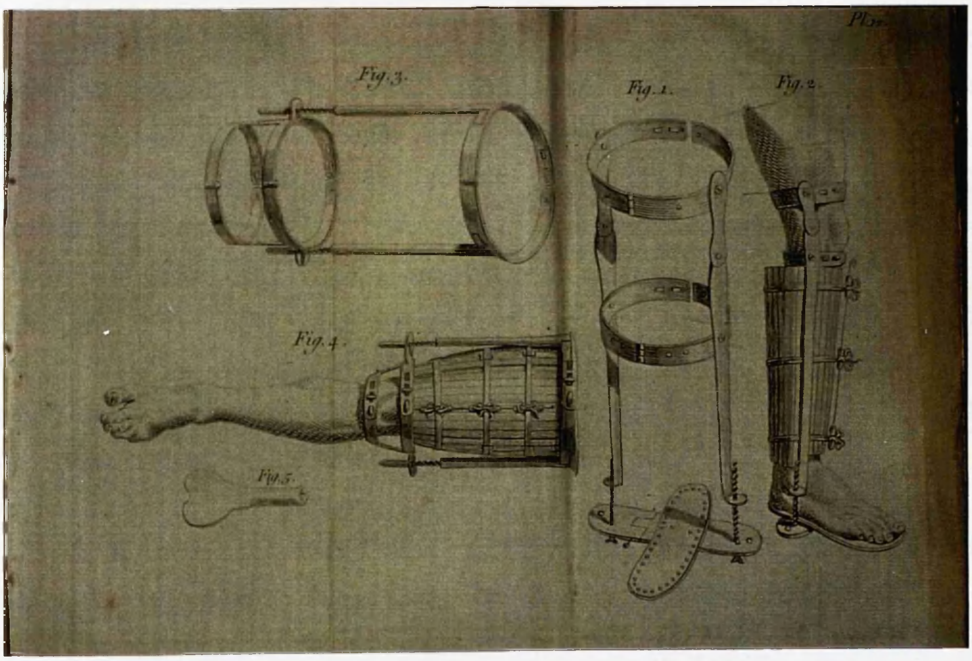


FIGURE 7.1.D: Splint for extension of fractured tibias and femurs described by Gooch (1767).

Benjamin Gooch considered this appliance particularly effective in controlling painful muscular spasms due to movements of the leg, by stabilising the leg in extension. The space between the splint and the leg also allowed easy access for wound dressings in compound fractures.

An early form of cast bracing was practised by Robert Chessher of Hinckley (1750-1831) in treating a severe compound fracture of the tibia in a young lady who had been thrown from her horse. He stated that "the parts were then carefully put together and placed in a temporary rest, until an effective support could be prepared. The next object was to make a model of the perfect limb, from which the support of the fractured one was in part formed and the leg was so adjusted in the support as to let in the foot ..... Eventually it was restored to its natural form, action and substance...." (Austin 1983).

Austin (1983) states that the principle of weight bearing on the femoral condyles and the patella was appreciated in the late 18th century when Benjamin Bell, in 1801, described a below knee prosthesis made of "firm hardened leather". "In this kind of leg the persons weight rests upon the condyles and patella, the stump itself hanging quite free within the leg". The interesting feature of this prosthesis was that its upper end is very similar to the moulding of the present day "Sarmiento" tibial cast.

The credit for the first documented use of the concept of weight bearing, to aid fracture healing, goes to James Hunter. He utilised it in 1791, when confronted with a man with non-union of a fracture in the proximal part of the femur. Hunter instructed him to "walk upon crutches and to press as much upon the broken thigh as the state of the parts would admit with a view to rouse the parts to action forcing them by a species of necessity to strengthen the limb". The result was a rapid union of the limb allowing the man to walk with a cane within two months (Home 1837).

The Femoral Functional brace, as it is known today - with knee and ankle hinges, was first reportedly used by Henry H Smith, an American frontier doctor, in 1855. His brace (figures 7.1.E & 7.1.F) was specifically designed for fractures, and he used it for the treatment of non-healing fractures referred to him.

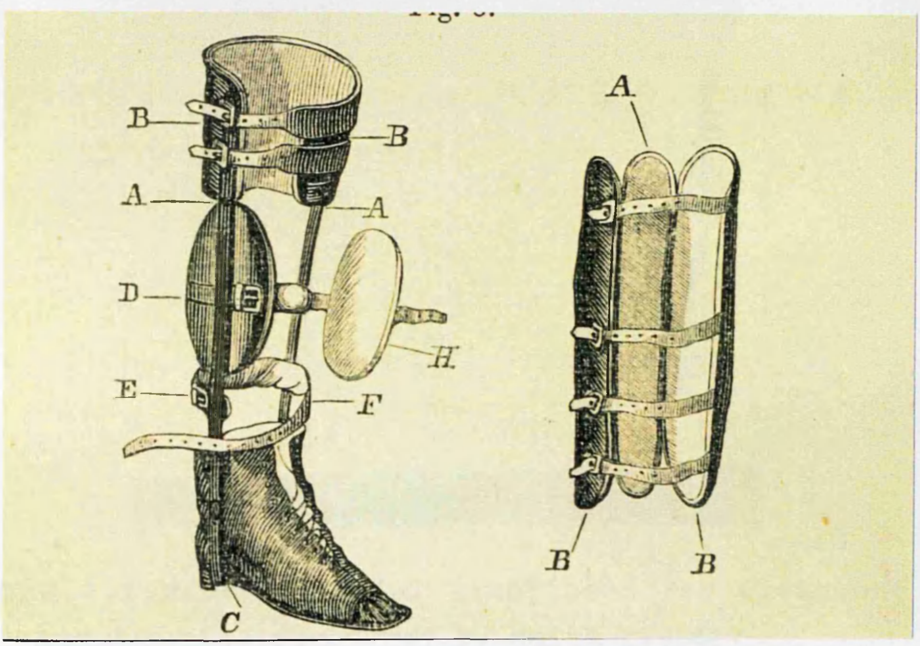


FIGURE 7.1.E: Tibial brace utilised for treatment of tibial fractures by Smith (1855).

He called this device an "artificial limb" (Smith 1855).It had a waistband ischial support and a thigh lacer, with knee and ankle hinges. The device was used with full weight bearing on the fracture site. This technique was disregarded in America but his walking therapy of "Gesundgehen" (Connolly et al 1973), the term used in the German literature, had a lasting effect in Europe.

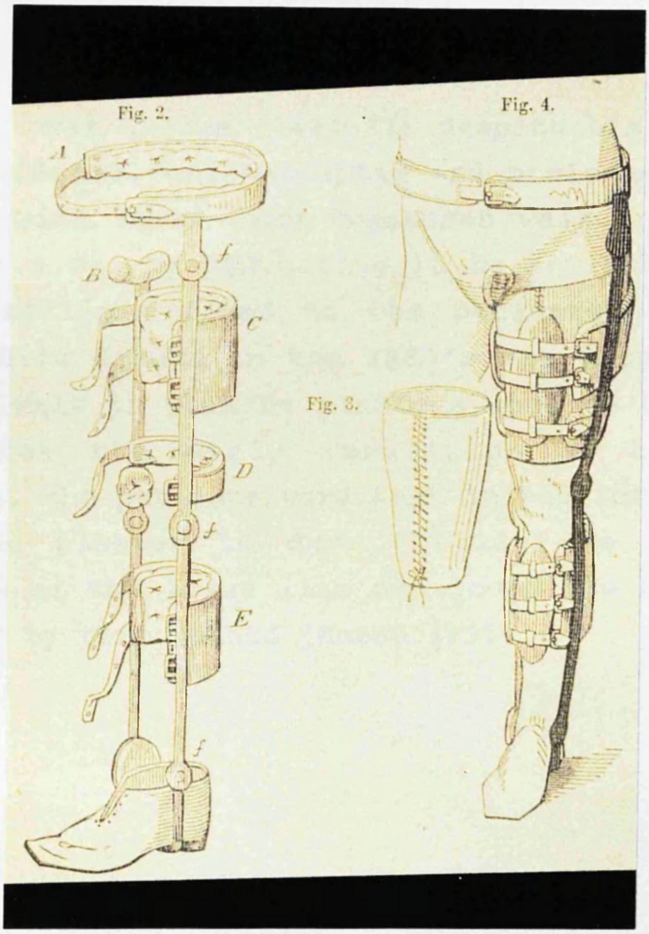


FIGURE 7.1.F: "Artificial limb" used for treatment of non-union of fractures by Smith (1855).

According to Smith (1855), "In the ordinary treatment of fractures, nature furnishes the bond of union and, therefore, but little aid is required from the surgeon - rest and apposition of fragments being sufficient to enable her to accomplish the cure. But, when she has failed in the performance of this important action, surgery has always been ready to step forward and interfere, and, in some instances, has done so with a rudeness that has terminated either in the loss of the limb or the life of the patient". He believed that his plan of treating "false joint", which embodied the principles of pressure and motion in the part was less dangerous and inconvenient method than seton, resection, caustic or wiring of the ends of a fracture.

Hugh Owen Thomas (1834-91) despite his doctrine of "Rest- enforced, uninterrupted and prolonged" made his patients with lower limb fractures walk in his splint (figure 2.2.G), by converting it to an ischial bearing walking calliper fixed to the patients' shoe (Monro 1935). While Krause in the 1880's was also making his patients walk in walking plasters applied to the tuber ischii for the early ambulation of the femoral fractures, the patients were kept in bed for two days to allow the plaster to dry. In 1893 he reported 98 fractures of the lower limb and found the healing time shortened by this method (Monro 1935).

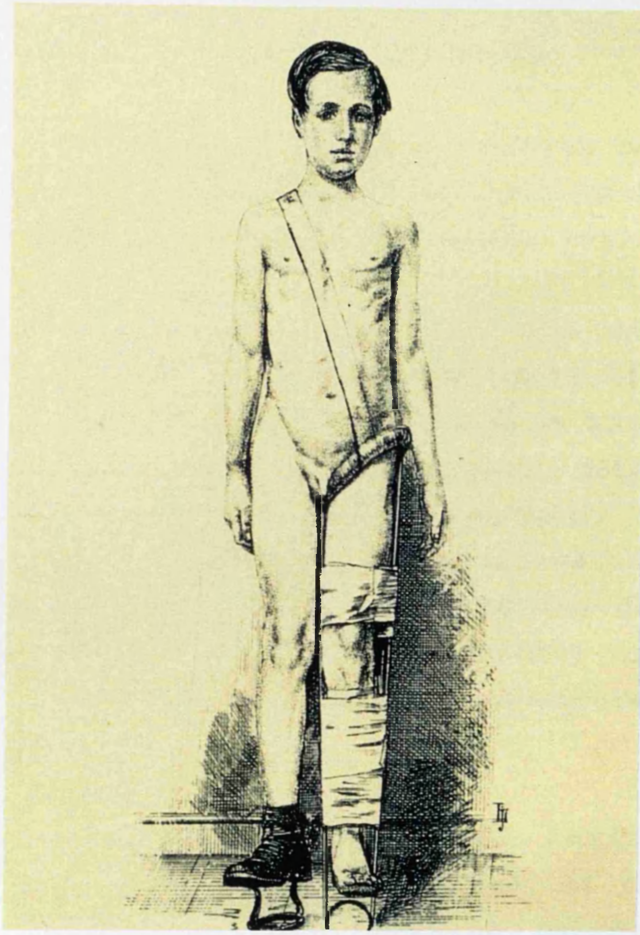


FIGURE 7.1.G: "Thomas" splint as used for weight bearing ambulation.

Just Marie Marcellin Lucas-Championnere (1843-1913) in 1910 was one of the first proponents of early ambulation and weight bearing on fractured tibiae in plaster cast. He had observed that a slight degree of movement at the fractured ends, far from retarding the progress of repair, rather accelerated it. He believed that mobility had to be given in limited doses and declared that "splints render joints stiff and often do them irrecoverable damage" (Keith 1919). Delbet in 1910 (Connolly et al 1973) devised a spring loaded traction apparatus that permitted ambulatory treatment of fractures of the femur, but advised against immediate weight bearing recommending a delay of 5 to 7 days to permit fracture to be reduced properly.

During the First World War, walking callipers were widely used to allow ambulation once union had taken place (Sherman 1924, Hurley and Weedon 1919).

Following Second World War the management of fractures was re-appraised on the basis of the wartime experience and the advances in science and technology. Improvements in anaesthetic techniques, material science and economics resulted in a tendency to surgical intervention of many types of fracture. Despite this Miles in 1961 could state the orthodox doctrine that "non-operative management is preferable as long as it succeeds to obtain and maintain adequate reduction" (Dehne 1974).

Also in 1961, Dehne, Metz, Deffer and Hall described the non-operative treatment of the fractured tibia by immediate weight bearing using a long leg walking cast with the knee in extension. They stated, "Our method of treating the fractured tibia arose from the simple premise that the severe complications resulting from surgery can only be eliminated by foregoing open reduction". They published results of a consecutive un-selected series of 207 fractures, 92% of patients had full functional recovery. The results clearly supported the use of ambulatory methods of treatment of tibial fractures.

The 1960's were also the years when Sarmiento (1967 and 1970) actively started proposing the closed method of ambulatory treatment utilising braces for fractures of both upper and lower limbs. He showed that tibial fractures could be treated by early ambulation in a below knee plaster of Paris cast which incorporated at the proximal end, the patellar tendon bearing configuration of a below the knee amputation prosthesis. It was applied at about 2 weeks after initial treatment in a long leg cast. He reported a selected series of 100 tibial fractures treated in this way with an average healing time of 14.5 weeks. In 1970 he reported another series (135 cases) of tibial fractures treated with below the knee brace with ankle hinges attached to the patients shoes. He advised that the patellar tendon bearing configuration of the cast be firmly moulded around the patellar tendon and into the popliteal fossa with the quadriceps relaxed. The distal portion of the cast should be firmly moulded around the malleoli and could be trimmed in front and the back to allow free ankle movements. He pointed out that the patients thus continue to use their muscles normally during the fracture healing, thus eliminating the need for rehabilitation.

Brown and Urban in 1969 presented 63 cases of fractured tibiae mostly open and injured in combat in Vietnam. They were treated with cast and immediate weight bearing. Results were 100% union rate with an average healing time of nineteen weeks. In their opinion "prompt return of the extremity, to its normal function of weight bearing and thereby re-establishing muscle function, improves the circulation", helping bone union. They showed that most compound fractures of the tibia with extensive skin and soft tissue damage united and soft tissues healed with early ambulation.

Ernst Dehne (1969) wrote a review article on the functional treatment of fractures of tibial shaft, and it was his enthusiasm as Colonel in the U.S. army, in charge of Orthopaedic service at Fort Sam which led Lt.Col Joseph H Moll (1973), one of his colleagues, to reason that factors which led to the union of tibial fractures treated by weight bearing ambulation should also be applicable to fractures of the femoral shaft. Initially a walking spica with a carefully moulded ischial seat was used and this metamorphosed to a quadrilateral thigh bearing cast brace which allowed both hip and knee motion. The principle was taken, from prosthetics where above knee amputee were fitted with a total contact quadrilateral thigh bearing socket which had an ischial weight bearing seat. The quadrilateral shape was moulded round the root of the limb and compressed the soft tissues. Moll reported 178 patients with 184 fractures with very satisfactory results.

In 1976 Adair successfully used a long leg plaster technique to allow early ambulation where the thigh part of the cast was moulded into a quadrilateral shape by applying an external box to shape the plaster. Adair was surprised to see the interest generated by this treatment in the patients. He found it interesting on ward rounds to hear the clamour from patients demanding this form of treatment. This he attributed to the great physchological advantage gained by the patient by being out of bed and discharged from hospital earlier.

1980's saw generation of increasing interest in functional bracing for tibial shaft fractures. A number of papers (Sarmiento et al 1989, Digby et al 1983, Suman 1983, Wardlaw 1981) reported excellent results with functional bracing. These reports highlighted the advantages of a high union rate (average 98 per cent), satisfactory functional results, non-existent infection and avoidance of the "fracture disease" associated with other forms of conservative management of tibial fractures. The acceptance of functional bracing as the most appropriate method for management of the majority of tibial shaft fractures (Leach 1984), was encouraged by reports which highlighted the problems with internal fixation of tibial shaft fractures (Fisher and Hamblen 1978, McMahon et al 1989).

7.2 PHILOSOPHY OF FUNCTIONAL BRACING

Functional bracing has been defined as "the use of braces to permit and encourage function of the fractured limb" (Sarmiento and Latta 1981). The present concepts are based on the belief that function is beneficial to the healing of bone by providing the natural environment with its consequent stimuli.

Latta et al (1980) stated that functional bracing is a philosophy rather than merely the use of orthotic devices in the treatment of fractures. It is based on the belief that immobilisation of the fragments and the joints above and below the fracture is not necessary for fracture healing. They also believed that the soft tissues of the injured extremity play a major role in providing the stability necessary to allow uninterrupted osteogenesis. They encouraged early function, weight bearing and motion of the joints and fracture fragments during treatment. Thus challenging the basic concepts of surgical as well as non-surgical fracture management which emphasise that rest and fragment immobilisation are prerequisites for fracture healing.

Dehne (1980) proposed his concept of "gate control" of motor function triggered by trauma, based on his experience of 50 years with regulated functional loading. He believed that trauma triggers nocioceptive impulses that set the affected region apart from the systemic homoeostasis. By rendering corresponding cord levels more sensitive to environmental stimuli and by inhibiting selective responses to central activation, they create the biologic environment conducive to cellular repair and tissue maturation. But this process is non-specific and highly labile. It easily escalates out of its range unless checked and regulated by application, in succession, of immediate, protected, permissive and progressive functional loading.

Dehne (1980) was of the opinion that over-dosage of loading could be disastrous, citing the example of Lucas-Championnere's proposed "mouvement dose", which was misunderstood and led to a wave of overly energetic massage and passive manipulation, resulting in a disastrous epidemic of non-union, stiff joints and Sudeck's atrophy. Dehne saw the doctor's role resembling the task of a coach - to analyse and guide. To him the patient is the main actor in the process of recovery, and he is to be understood and coached and supported but not pushed. He is to be warned against overdoing but encouraged if timid.

Sarmiento and Latta (1981) stated that "Immobilisation is unphysiological and is desirable only during the early days to reduce pain and provide comfort. Tissues that heal in the presence of immobilisation do not do so because of the immobilisation but in spite of it". They considered pain as the natural feedback mechanism determining in humans and animals how long to maintain immobilisation. Pain also dictates when to resume activity and how to increase it.

The main aim of the functional fracture brace is to permit and encourage the function of the fractured limb.

They are meant to replace the cumbersome casts and splints which allow only limited function. Functional braces ideally should be lightweight, small, cosmetic and compatible with normal garments. They are sometimes constructed to restrict motion of the joints, only if necessary, for the prevention of deformity. Use of the injured extremity is encouraged by the braces through the normal, intermittent, un-encumbered functions of daily living. Design evolution of present day braces have consistently reduced the size, weight and range of motion restrictions of the predecessors.

Sarmiento and Latta (1981) stated that function in a fracture brace allows for optimisation of the mechanical, vascular, chemical, thermal and electric environments surrounding the fracture. They postulated near normal levels of intermittent loading providing strain in the tissues, which results in the generation of electric potentials for bone formation. Whereas near normal levels of activity of the muscles results in a high degree of circulation in the limb which enhances the vascular invasion, resulting in increased capillary gradients which may provide streaming potentials in the environment for enhancement of fracture healing. The above views are also echoed by other workers in the field (Dehne 1980, Rowley and Lee 1989, Wardlaw et al 1981, Thomas and Meggitt 1981, Older 1989).

Lanyon (1989) believed that exposure of fractured bone to extremely short periods of dynamic strains not only prevents the resorption which normally accompanies reduced loading, but also results in an increase in bone formation proportional to the magnitude of peak strain. Kenwright and Goodship (1989) have concluded from their studies that the application of appropriately applied strain to clinical tibial fractures at a time shortly after injury, when most patients would be very inactive, appears to enhance the healing process when using external skeletal fixation.

There is a lot of controversy in the literature concerning the role of vascularity and oxygen supply in fracture healing (Rhinelander 1974, Holden 1972, Macnab and De Haas 1974). Sarmiento and Latta (1981) believed that vascularity and bone formation are closely associated and demonstrated the close proximity of osteoblastic and osteoclastic activity to the invading vasculature. They were able to show that when function was introduced early in the management of laboratory induced fractures, the activity levels of the osteoblasts and osteoclasts, the number of capillaries, and the formation of new bone was increased, demonstrable by light and electron microscopy.

Yamagishi and Yoshimura (1955) as well as Lindholm et al (1970) were of the opinion that when function and weight bearing are introduced in the early stages of healing, motion occurs at the fracture site and is associated with cartilage formation in that area prior to the revascularisation of the centre of the callus.

Sarmiento and Latta (1981) believed that in a fracture brace, which allows joint function and movement of the bone fragments, there is little measurable load borne by the brace. In their opinion the soft tissues carry most of these loads while allowing small amounts of motion of the bone fragments. These movements, however, are fully recoverable upon relaxation of load so that progressive deformity does not occur. The soft tissues control the amount of motion which is related to the fit of the braces and the extent of soft tissue damage.

The soft tissues are believed to provide stiffness and load bearing to the limb when encompassed in a fracture brace by virtue of the following two major mechanisms (Sarmiento and Latta 1981):

1 Incompressibility of the soft tissues.

2 Intrinsic strength in tension of the soft tissues.

The compartments of muscles could act as a fluid like structure bounded by an elastic fascial container. Dynamic loading deforms the compartments of fixed volume (incompressible fluid) causing changes in their surface which stretches the fascial boundaries. When these compartments are bound by a relatively rigid container such as a fracture brace, they can displace under load only until they have filled all the gaps within the container. Once this slack is taken up in the system the muscle mass becomes rigid since its boundaries (the walls of the brace) do not move (figure 7.2.A).

After the load has been relaxed the elastic, fascial boundaries of each muscle return to their original shape which brings the fragments to their original positions. Sarmiento and Latta (1981) believed that this mechanism is important in the early stages of management when little healing has taken place in the bone or soft tissues. The fragments are loose and must rely heavily on the soft tissues for support until callus forms. The soft tissues must rely heavily on the degree of fit of the fracture brace in order for this mechanism to be effective. They did not believe that the "hydraulic" effect of the tissues is responsible for the long term maintenance of length of the limb. They stated that with rapid dynamic loading, the soft tissue compartments act as incompressible fluids, causing the volume of the tissues to be fixed.

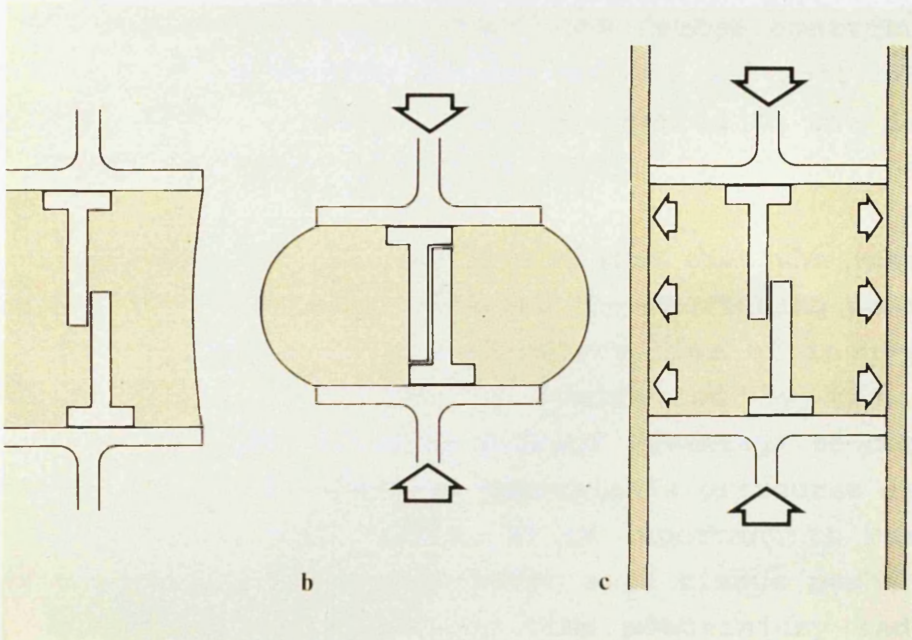


FIGURE 7.2.A: Incompressibility of fluid material when confined within a rigid boundary (from Sarmiento and Latta, 1981, published by Springer-Verlag Berlin).

In this manner "hydraulics" can control motion of the fragments and provide support for the intact tissues by increasing the stiffness of the limb and possibly protecting them from further damage. In their opinion hydraulics is responsible for the control of motion of the fragments before callus has developed and that it provides the significant degree of stiffness observed in loaded limbs with fresh fractures fitted with fracture braces. This means that the hydraulics control certain rapid fluctuations in the system but not slow progressive changes.

The second major soft tissue mechanism for load transfer involves their intrinsic strength in tension as they support the bone fragments at their natural attachments. Their ability to do so is inversely related to the degree of disruption of their attachments to bone at the time of initial injury. One factor contributing to intrinsic strength is the degree of soft tissue healing, which is also inversely related to the degree of damage (Sarmiento and Latta 1981).

Sarmiento and Latta (1981) stated that the inherent strength of the tissues prevents the shortening past the initial shortening developed at the time of injury. As the length of the limb is controlled by the soft tissues, the brace provides a lever advantage to control angulation without creating appreciable pressures in the soft tissues (figure 7.2.B). It is important to realise that the interplay between these soft tissue mechanisms is related to the amount of time post-injury and the degree of soft tissue damage at the time of injury. If severe soft tissue damage has occurred then the incompressible fluid effect or hydraulics is more important during the early stage of healing. Slack in the brace-soft tissue system is determined by the snugness of fit in the brace, which determines the amount of motion at the fracture site.

Sarmiento and Latta (1981) advised that if the initial shortening is unacceptable at the time of injury and it is corrected by traction the maintenance of reduction must be accomplished through hydraulics. This is because the fragments will not be supported by the intrinsic strength of the soft tissues until they have returned to the positions developed at the time of injury. Since hydraulics cannot be relied upon to control such slow progression of shortening, a high risk of losing reduction and recurrence of the initial shortening exists.

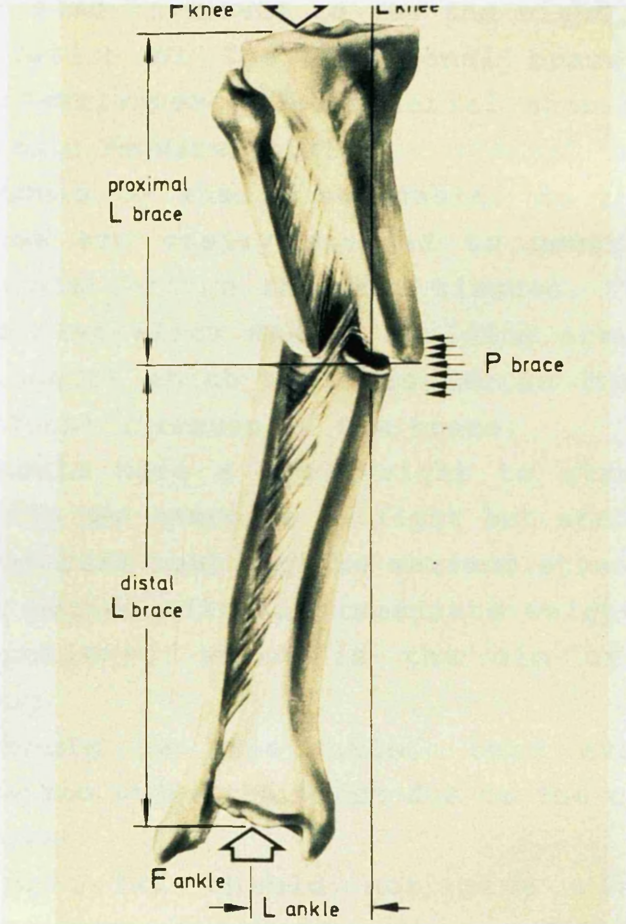


FIGURE 7.2.B: Relative leverages utilised by joint loads and fracture braces (from Sarmiento and Latta, 1981, published by Springer-Verlag Berlin).

Small loads would produce motion at the fracture site in a fresh fracture, but this motion would not increase proportionately with higher loads. The reason being that the first amount of motion seen at low loads represents the low resistance of the system due to the slack within it. But as this slack is taken up by the tension in the soft tissues or filling of voids in the brace, the system stiffens rapidly and its stiffness approaches that of an intact limb or an internally fixed limb (Sarmiento and Latta 1981).

It is also important to use the right material for the fabrication of the functional braces for their maximal effectiveness. The material should fulfil the following main requirements:

1 It should be easily mouldable, so that the soft tissues are easily moulded to control the bony fragments through the soft tissues. This property would also allow easier moulding around the bony prominences which would assist in the control of rotational stresses by the brace.

2 It should have a good weight to strength ratio, allowing the brace to be light but strong.

3 The material must acquire maximum strength within a short period allowing immediate weight bearing by the patient, which is the aim of functional bracing.

4 It should be breathable, thus avoiding skin maceration under the brace due to the collection of moisture.

5 The material should not give rise to skin sensitivity.

6 The material should be user friendly. Easy application of the material encourages its use.

7 The material should be cheaply available so that the brace remains economically feasible.

Unfortunately no material fulfils all the above requirements. It is therefore essential to compromise, depending on the requirements of the fracture and the availability of the materials. It could also be possible to use a combination of materials fulfilling different elements of the above criteria to result in a composite brace which provides optimum results.

CHAPTER 8

2 IN 1 FUNCTIONAL BRACE: CLINICAL TRIAL

"Tissues that heal in the presence of immobilisation do not do so because of the immobilisation but in spite of it".

(Sarmiento and Latta 1981)

8.1 INTRODUCTION

Contemporary tibial braces fall into two main types; those which encase the foot like the "Sarmiento Cast" and those which allow the movement of the ankle and sub-talar joints called "Gaiters" (Weissman et al 1966). The Sarmiento cast provides good rotational control of the fracture fragments by virtue of its lateral extensions, which grip the tibial and femoral condyles in extension, thus providing a good grip on the proximal fragment. The gaiter does not provide the same amount of rotational control because the distal fragment is under the influence of the mechanism of torque transfer (chapter 1). Both these braces have a place in the management of tibial fractures; the Sarmiento cast in the early stages of healing when rotational stresses are to be avoided, while the gaiter is useful in the late stages of healing when the callus is strong enough to withstand rotational stresses.

From the consideration of these factors it seems an ideal tibial functional brace should:

1 Encompass the advantages of the Sarmiento casts as well as the Gaiters.
2 Restrict ankle/sub-talar joint movement in the early stages of healing.
3 Allow free movement of ankle/sub-talar joint at a stage when fracture callus is sufficiently strong to withstand rotational stresses, without replacing the brace.
4 Be inexpensive and easy to apply.

If Sarmiento cast and gaiter are used in sequence it would increase the total cost of treatment relative to either one of them, which would be contrary to the design guidelines. The "2 in 1 functional brace" encompasses the design features of both these braces (Sarmiento cast and gaiters) retaining their advantages, while still being less expensive and less time consuming to apply (figure 8.1).

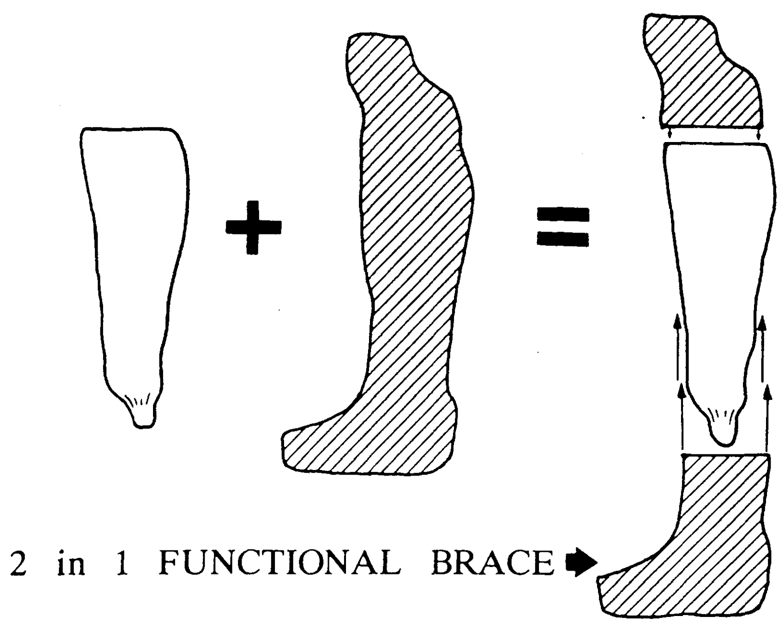


FIGURE 8.1: 2 in 1 functional brace combines the design features of "Gaiters" and "Sarmiento Casts".

The 2 in 1 functional brace is capable of restricting ankle/sub-talar joint movement, in the earlier stages of healing, by encasing the foot. The design also provides the facility of bi-valving and removing this part of the cast, termed the "foot-piece", allowing free movement of the ankle/sub-talar joint without replacement of the original brace. This step is undertaken at a later stage of healing when the callus is thought to be strong enough to withstand the rotational stresses.

8.2 MATERIALS AND METHOD

The following materials are required for the fabrication of the 2 in 1 brace:

Cast Sock (Below knee)	1
Stockinet 7.5 cms	1
Orthopaedic Felt 15*10 cms	1
Plaster Wool 10 cms	1
Elasticated P.O.P Bandages 12.5 cms	2
Synthetic Casting Bandage 10 cms	3

METHOD OF FABRICATION: Tibial fractures are treated conservatively as a routine with a long leg cast at the time of injury. The long leg cast is usually removed two weeks after the injury depending on the axial stability of the fracture. The lower leg is then put in an elasticated cast sock to provide a firm grip on the soft tissues, followed by a stockinet. Orthopaedic felts are applied on the pressure sensitive areas (figure 8.2.A) with the aim of providing minimal padding.

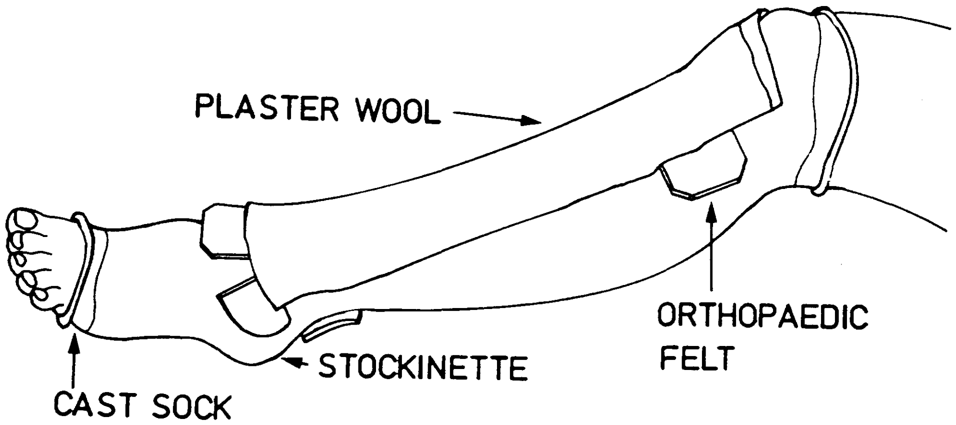


FIGURE 8.2.A: Showing application of tibial sock, stockinet, adhesive orthopaedic felt and plaster wool to avoid pressure sensitive areas.

A "Gaiter" with a Sarmiento shaped top is fashioned with a layer of elasticated plaster of Paris bandage (Orthoflex) applied as a base, followed by layers of synthetic casting material (figure 8.2.B). Attention is paid to moulding around the malleoli and the formation of a standard Sarmiento shaped top. Once the Gaiter has been fashioned, two layers of wool are applied around the foot and distal half of the Gaiter and covered with plaster of Paris bandage with the foot in a plantigrade position. This position minimises the cost of energy expenditure on walking, compared to dorsi/plantar flexion of the foot.

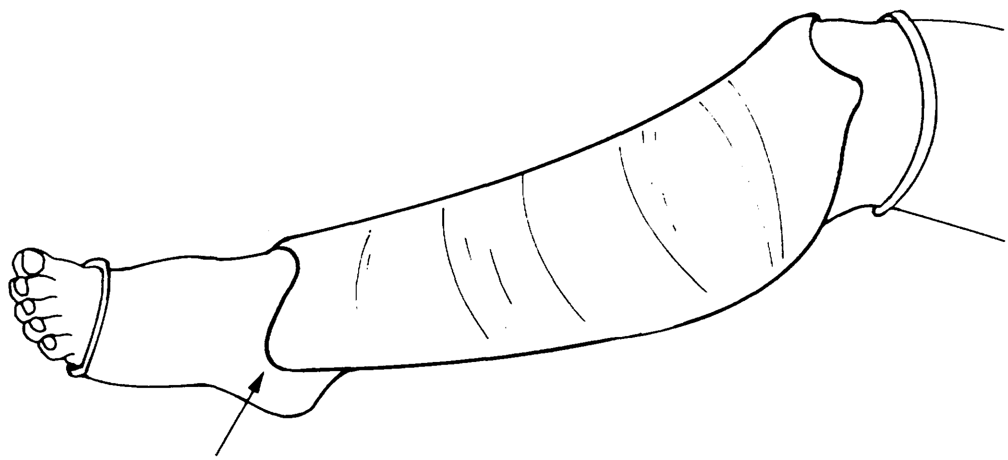


FIGURE 8.2.B: Completed "Gaiter" with Sarmiento top.

This is strengthened with a 10 cms bandage of synthetic material which covers only the underlying plaster of Paris bandage (figure 8.2.C). The plaster of Paris layer is used for the fabrication of the "Foot-Piece" in this manner, to avoid lamination of the strengthening layer of synthetic casting material with the underlying Gaiter. This avoids problems when the time comes for removal of the "Foot-Piece". Application of this composite brace after removal of the long leg cast at 2-3 weeks from the date of the injury achieves the advantage of a Sarmiento Cast (figure 8.2.D).

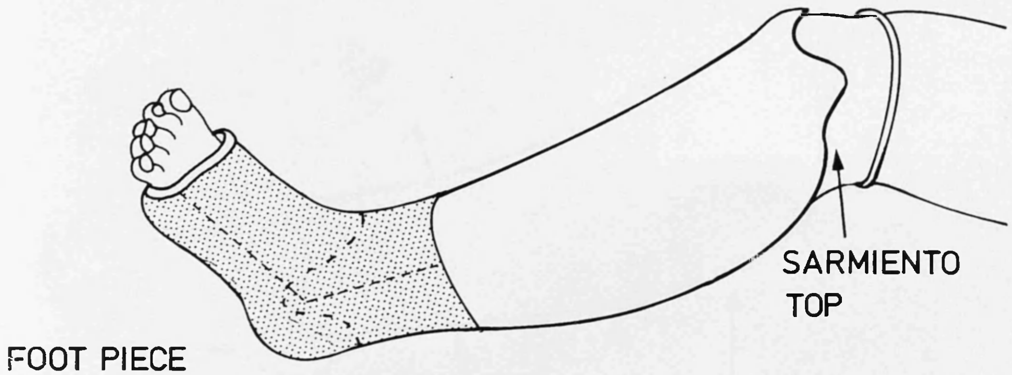


FIGURE 8.2.C: Completed 2 in 1 functional brace fulfilling the requirements of a Sarmiento Cast.

FIGURE 8.2.D: 2 in 1 functional brace as applied on a patient.

The "Foot-Piece" can be removed 6-7 weeks after injury (figure 8.2.E), leaving the undamaged underlying gaiter in place and allowing full ankle motion (figure 8.2.F).

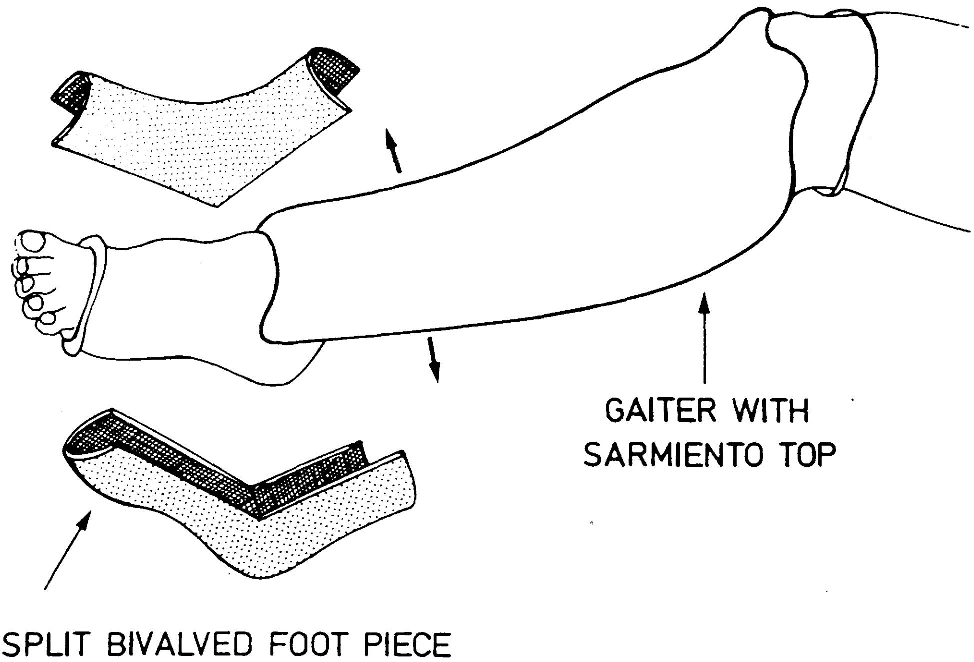


FIGURE 8.2.E: Method of bi-valving the foot piece which after removal leaves behind the Gaiter as seen in figure 8.2.B.

FIGURE 8.2.F: 2 in 1 functional brace with the "foot piece" removed.

PRACTICAL TIPS: The 2 in 1 functional brace can be fabricated using these principles with any suitable casting materials, such as plaster-of-Paris bandages only, to cut down on the cost, if circumstances demand.

Comparisons of cost and application time were made between the 2 in 1 functional brace and the available alternatives (figure 8.2.G). Management with the 2 in 1 brace was found to be cheaper by 25% and took less time to apply compared to management with a Sarmiento cast followed by a gaiter. It is possible to reduce the cost of treatment further by fabricating the above braces using plaster of paris instead of the costly synthetic bandages. This may involve more frequent hospital visits for repair and replacement introducing hidden costs of patient transportation thus making it more costly in the long run.

COMPARISON OF COST / APPLICATION TIME OF TIBIAL BRACES

(As per prices in April 1990)

TYPE	COST (POUNDS) P.O.P	COST (POUNDS) LIGHTWEIGHT	APPLICATION TIME (MINS.)
LONG LEG CAST	7.04	35.00	30
SARMIENTO CAST	4.26	22.00	20
GAITER	3.60	13.15	15
2 IN 1 FUNCTIONAL BRACE	6.00	28.30	20
ORTHOPLAST TIBIAL BRACING KIT (Johnson & Johnson - 1989 price)		67.10	15
PREFORMED TIBIAL BRACE (Smith & Nephew - 1990 price)		147.00	5

FIGURE 8.2.G: Comparison of cost/application time of tibial braces (as per prices in April 1990).

The "gaiter" could be cut in front and at the back and removed from the limb for examination or fracture stiffness testing of the leg without any damage to the brace. Thus the same two halves of the brace could be re-apposed after examination and the brace strengthened with a single layer of synthetic bandage. This method of bi-valving the gaiter avoids damage to the moulding around the malleoli and around the proximal half of the brace, thus the biomechanical integrity of the brace is maintained and so is its effectiveness (figure 8.2.H).

BIVALVING THE "GAITER"

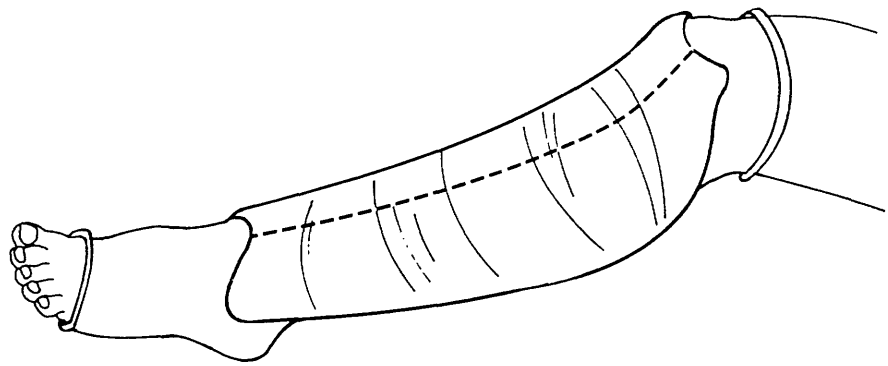


FIGURE 8.2.H: Method of bi-valving the gaiter without damaging its design characteristics.

TREATMENT DETAILS: A clinical trial was undertaken to assess the "2 in 1" brace in two treatment modalities, primary and secondary. The primary treatment group consisted of 63 fractures while 17 fractures came under the "secondary treatment group". 43 (54%) fractures were reduced under general anaesthesia while the rest were managed on analgesia or nitrous oxide/oxygen, during application of the long leg cast. An average of 1.2 braces were applied during management of the tibial fractures in this series. No replacement of the brace was needed in 58 (73%) of the fractures while only 1 patient required replacement of the brace twice due to its loosening (figure 8.2.J). This shows that the design and choice of material for this brace was cost-effective and capable of with-standing the stresses of normal daily activities.

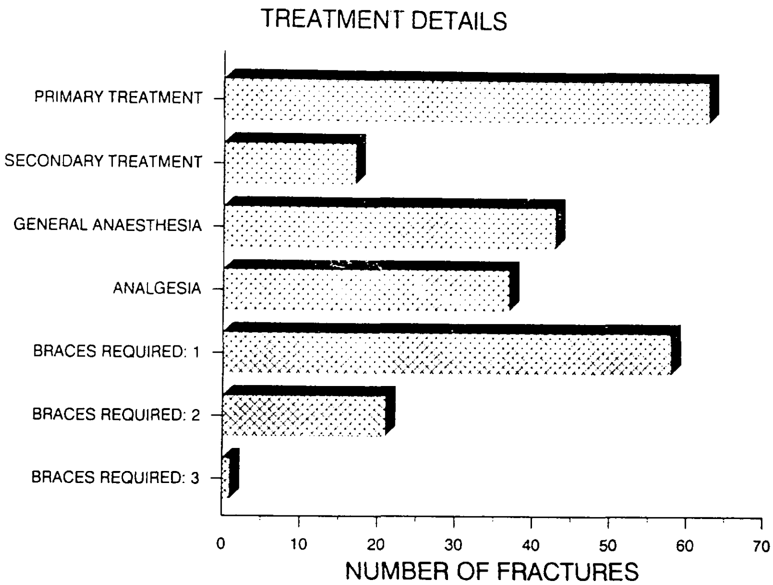


FIGURE 8.2.J: Treatment details in this series.

PATIENT CRITERIA FOR THE TRIAL: The patients selected were treated at the Western Infirmary Glasgow, during the period from August 1987 to March 1990. The decision regarding the initial management of their tibial fractures was taken by the consultant concerned and the fractures were then assessed and followed up by the author.

TREATMENT ROUTINES:

a) PRIMARY TREATMENT GROUP: The patients in the primary treatment group were treated in the following manner:

1 The patient was put in a long leg cast on day one. Manipulation under anaesthesia was undertaken, depending on the nature of the fracture.

2 The position of the fracture was reviewed by X-ray at one week in the long leg cast.

3 The long leg cast was replaced by a "2 in 1 functional brace" at 2-4 weeks post-injury, depending on the axial stability of the fracture concerned.

4 Radiographs were taken before and after application of the brace to confirm the maintenance of an acceptable position of the fragments. Two radiographs were taken at 90 degrees to each other and the "true angulation" was calculated by a technique to be described.

5 The patient was encouraged to weight bear immediately after the application of the brace. Discomfort at the fracture site was taken as the feedback for the control of the extent of weight bearing.

6 The radiological measurements were repeated in the brace one week after application, to confirm the maintenance of the reduction.

7 The "Foot Piece" portion of the brace was removed at 6-7 weeks post-injury. This was considered sufficient time for the healing callus to achieve the strength to withstand rotational stresses (internal moments) imposed by the free movement of the foot.

8 The "Modified Gaiter" thus left behind, was kept on for the remaining duration of the treatment.

9 The end point for union was considered to be the resumption of full weight bearing on removal of the brace. The decision to remove the brace was based initially on clinical and radiological assessment of the fracture. Later in the series, after development of the "Non-Invasive method of measuring fracture stiffness" (part 2) it was possible to use this new technique to make a more objective decision.

b) SECONDARY TREATMENT GROUP: This group consisted of tibial shaft fractures which could not be stabilised in a long leg cast, either due to associated soft tissue wounds, or because they lacked axial stability. These fractures were initially stabilised with either external fixators or pins incorporated in the plaster. This fixation was maintained until they showed sufficient axial stability to go into the brace. Treatment thereafter was as described for the primary treatment group.

PATIENT REHABILITATION: Patients fitted with the new braces were provided with instructions for mobilisation by the physiotherapists. They were instructed in the use of axillary and elbow crutches but told to use them as little as possible, except to maintain balance while walking on uneven ground during the early stages of mobilisation. Once the patient was able to mobilise with confidence, usually within one week of application of the brace, the crutches were exchanged for a walking stick to be used in the contra-lateral hand.

In some patients where the fractures had healed clinically and when supported by the fracture stiffness measurements, the brace was removed, even where radiological evidence of healing was not conclusive. Such cases were put in a removable gaiter to be used during ambulation as a precaution against sudden angulation.

PATIENT RECORDS AND CLASSIFICATIONS: After inclusion of the patient in the series, detailed clinical information using the following criteria was recorded (Appendix-8A).

a) MECHANISM/SEVERITY OF INJURY: The mechanism of injury was also related to the severity of injury and classified as high or low energy violence (Bauer et al 1962, Oni et al 1988). High energy violence included all accidents in which a motor vehicle or motor-cycle was involved, falls from a height of more than six feet and blows from heavy objects. Low energy violence included falls at ground level or from a height of less than six feet, injuries from sport and bicycle accidents in which motor vehicles or motor-cycles were not involved.

b) NATURE OF FRACTURE: The fractures were classified into simple and compound. The compound fractures were further classified into three types based on the classification devised by Gustillo and Anderson (1976).

Simple
Compound - Type I: Skin incision less than 1 cm
Type II: Skin incision between 1-5 cms
Type III: Skin incision more than 5 cms

c) LOCATION OF FRACTURE: The shaft was defined as being between the level of the tibial tuberosity and 2.5 cm above the horizontal articular surface of the ankle. It was divided longitudinally into equal thirds and the location of the fracture was determined by its lowest boundary (Oni et al 1988).

d) TYPE OR MORPHOLOGY OF FRACTURE: The initial radiograph was classified according to the morphology of the fracture based on the classification devised by Oni et al (1988):

Transverse	Angle of fracture line with the horizontal between 0-15 degrees.
Spiral	
Short Oblique	Angle of fracture line with the horizontal between 15-45 degrees.
Long Oblique	Angle of fracture line with the horizontal more than 45 degrees.
Comminuted	
Segmental	

e) STABILITY OF THE FRACTURE: A clinical assessment was made as to the axial stability of the fracture at the time of the injury, based on the morphology of fracture, displacement of the fragments and the initial soft tissue damage. A transverse fracture with completely apposed fragments is inherently stable while an oblique fracture or one with damage to the associated soft tissues is not (Sarmiento and Latta 1981). The extent of damage to the soft tissues in a closed fracture is apparent on the initial shortening of the fracture fragments at the time of injury, usually noted on the initial radiographs before reduction is attempted. Axial stability of the fracture provided the basis for early conversion to a "2 in 1 functional brace".

f) APPOSITION OF FRACTURE FRAGMENT: Radiological assessment of fragment apposition after fracture reduction was graded as follows:

Grade 1	Fracture fragment apposition, 0-25 per cent of the diameter of the shaft.
Grade 2	Fracture fragment apposition, 26-50 per cent of the diameter of the shaft.
Grade 3	Fracture fragment apposition, 51-75 per cent of the diameter of the shaft.
Grade 4	Fracture fragment apposition, 76-100 per cent of the diameter of the shaft.

This was selected, as a variable reflecting the severity of injury, rather than the displacement that occurred at the time of injury. It was felt that by the time the patient reached the hospital the initial management provided by the ambulance staff, including the application of transportation splints, had already aligned the fragments to some extent. Assessment of fragment apposition after fracture reduction is more objective and it may prove to be a better parameter in assessing the fracture prognosis.

h) HEALING TIME: A fracture was regarded as healed when all immobilisation aids had been discarded and unrestricted weight bearing was allowed. Normal union was defined as union occurring within 20 weeks and delayed union as lack of union after 20 weeks (Ellis 1958, Nicoll 1964, Oni et al 1988).

j) RADIOLOGICAL ASSESSMENT OF FRACTURES - INTRODUCTION: Fracture management, employs radiography for assessment of healing of the bones. X-rays are taken at regular intervals in two planes to ascertain the alignment as well as the stage of healing. If deterioration or loss of alignment is detected at an early stage, then a decision is taken to intervene by re-manipulation, or in a minority of cases by open reduction.

Sometimes if the clinician undertakes manipulation of the fracture he improves the alignment in one view while losing it in another. It then becomes difficult to decide whether there is any overall improvement from the initial X-rays. It would be much more convenient for him to consider one value for angulation and compare it with another one, when the patient comes for review and is X-rayed again.

From a biomechanical viewpoint it is the combined effect of the deformities in two planes, which determines the long term effects on the associated joints. It is therefore essential to take into consideration this composite angulation which could alter the line of weight bearing, leading to excessive joint stresses and the development of osteoarthritic changes. Determination of a single value (angle), representative of the combined two plane deformities, would determine the deviation of the line of weight bearing from the normal and the limits of such deviations compatible with normal function.

PRINCIPLE: To overcome this problem, it was decided to develop a method to extrapolate the two angles, calculated from the two X-rays, into one. If this extrapolated angle, called the "Standard angle", was observed to be increasing then the loss of alignment required further treatment. The mathematical method developed uses Pythagorus's theorem and a pocket calculator to provide the clinician with a value of the standard angulation. The accuracy of the method was also tested and proved radiologically. The extrapolated angle is the maximum deformity and can be represented as a radius from the zero point on a nomogram (figure 8.2.K), on an axis which is midway to the antero-posterior and lateral views (halfway plane-45 degrees).

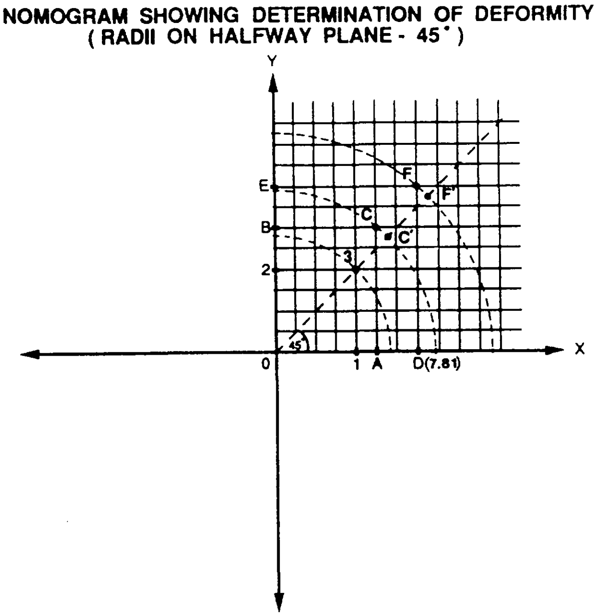


FIGURE 8.2.K: The extrapolated angle (standard angle), of two X-ray views taken at 90 degrees to each other, is the maximum deformity and can be represented as a radius from the zero point on a nomogram.

Angulation in a single plane can easily be measured from a radiograph of a long bone. Given two X-rays taken at 90 degrees to each other, two values for angulation are measured (a and a"). The "standard" value of the angulation will be greater than either a or a" and has a direction between the two planes of the X-rays. The magnitude of the standard angulation can be calculated from Pythagorus: if A = Standard Angulation

$$\text{then } A^2 = a^2 + a''^2$$

$$\text{therefore } A = \sqrt{a^2 + a''^2}$$

This simple principle allows the magnitude of standard angulation to be easily calculated. Though no direction is given, clinical decisions are made on the magnitude of the deformity rather than its direction. Progression of the deformity can be easily followed by comparing the standard angulation on consecutive X-rays. The measurement can be made on any pair of perpendicular X-rays, irrespective of limb positioning, though interpretation is easier if antero-posterior and lateral views are taken.

When angles are plotted on nomogram (figure 8.2.K), antero-posterior values on Y-axis and Lateral values on X-axis, the extrapolated values are the points where they meet in the x-y plane. For example in a hypothetical case if antero-posterior value (6 degrees) is denoted by "B" and the lateral value (5 degrees) is denoted by "A". The point "C" is the extrapolated value (7.81), which is the radius from point "O" and is shown as C′ on the 45 degrees axis (halfway axis between Sagittal and Coronal plane).

RADIOLOGICAL PROOF: The mathematics of the extrapolation has shown that the predicted value of the "standard angle" would lie on an axis halfway to the axes of the 2 views taken at 90 degrees to each other. It would seem reasonable to take two views at 90 degrees to each other, predict by extrapolation the standard angle, and confirm the accuracy of the value by obtaining another view in an axis halfway between the original two views. This hypotheses was tested by taking two views (true antero-posterior and true lateral) of a pre-bent metal rod (figure 8.2.La and 8.2.Lb).

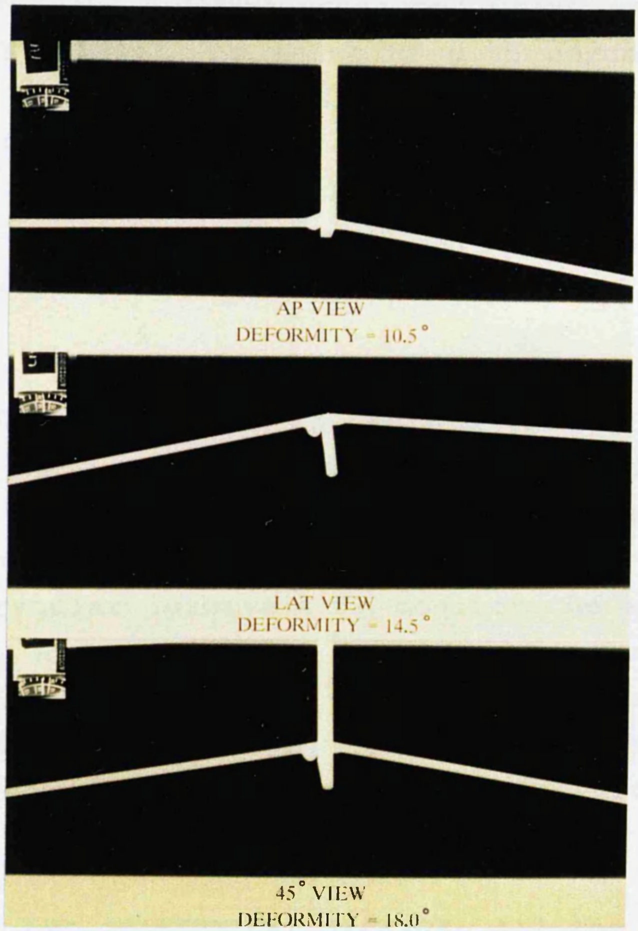


FIGURE 8.2.L: X-ray views (antero-posterior, lateral and 45 degrees) and angular measurements of a pre-bent rod.

Figure 8.2.Lc shows an X-ray of the rod in the half-way planes of the standard angulation, taken without moving the rod, which was measured as 18 degrees. Mathematically, the standard angulation was calculated thus:

$$\text{from figure 8.2.La } a = 10.5 \text{ degrees}$$
$$\text{from figure 8.2.Lb } a'' = 14.5 \text{ degrees}$$
$$\text{therefore Standard Angulation } (A) = \sqrt{(10.5)^2 + (14.5)^2}$$
$$= 17.9 \text{ degrees}$$

The difference between predicted value and actual value was 0.1 degrees. An error of 0.55 percent. This could be due to slight error in alignment of the X-ray machine (instrument error) or by the operator in aligning and measuring the angles (observer error). But even then the values are extremely close to support the original concept of extrapolating the angles in this way.

CLINICAL APPLICATION: The method was utilised to measure this angle at follow up of the tibial fractures treated with the 2 in 1 brace. X-rays were taken before and after conversion to functional braces from long leg cast and at regular intervals to monitor the alignment of fractures. A final set of X-rays were taken at the time of healing and removal of the brace. The calculated "standard angles" were then plotted to chart the progress of deformity from the day of application of the brace to the time of healing.

DATABASE AND STATISTICAL PACKAGE: All the recorded patient data was transferred from the record forms on to a database (PCFILE) in an IBM personal computer (IBM personal system/2, Model 50 Z) for ease of storage and analysis. Appendix - 8B summarises all the "raw data", in coded form, collected in this series of 80 tibial fractures. Appendix - 8C provides codes used for the "raw data" in the database.

Statistical analysis of different variables related to the series was performed using MINITAB (release 6.1). Groups of data were compared using the "Mann-Whitney test", this is a non-parametric test used for analysis of data which does not follow a normal distribution (Bland 1987). The variables related to the outcome of the fracture were also analysed using "linear regression" and "multiple regression" techniques (Ryan et al 1985). Healing time was considered as the "outcome" variable while all other variables were considered as "predictor" variables. These techniques provided significance levels for the relationships between the predictor variables and the outcome of the fracture healing times. A "p value" of less than 0.05 was taken to be significant for the above tests (Bland 1987).

DATA EXCLUDED FROM ANALYSIS: Some of the data in the following variables was excluded from the analysis for reasons given below.

a) FRACTURE HEALING TIMES: Healing times of 2 patients were not included in the analysis because they developed delayed union and required bone grafting. Both patients belonged to the "secondarily" treated group of fractures. One was initially treated with "pins in the plaster" while the other was managed with an "external fixator".

b) DURATION OF BRACING: In calculating the mean/total period, the brace was used, the data from the 2 patients with delayed union was excluded for the same reasons.

c) STAY IN HOSPITAL: Data from 9 patients was excluded in calculating the mean in-patient stay after injury. Four of these patients had "multiple injuries" while five patients were kept in hospital for "social/age related reasons". It was felt that their longer stays in hospital were not a true reflection of the morbidity due to the fracture of the tibial shaft.

PATIENT DETAILS: In this series of 80 tibial shaft fractures treated with 2 in 1 functional brace there were 58 males and 21 females. A male to female ratio of 2.76 to 1 (figure 8.2.M). 45 fractures occurred on the right leg while 35 on the left leg, giving a right to left ratio of 1.28 to 1 (figure 8.2.M).

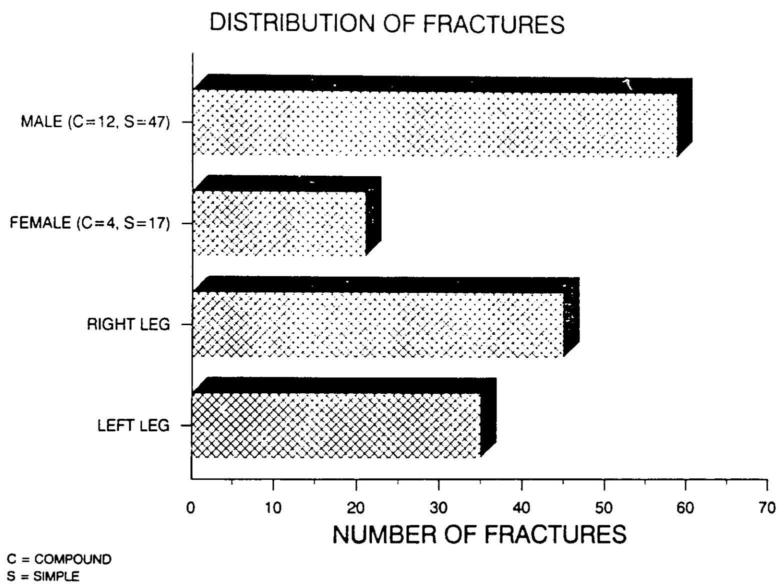


FIGURE 8.2.M: Distribution of fractures in this series.

The mean age for the patients was 34.2 years (figure 8.2.N). The mean age for patients with simple fractures was 33.6 years while for patients with compound fractures it was 36.5 years (figure 8.2.N).

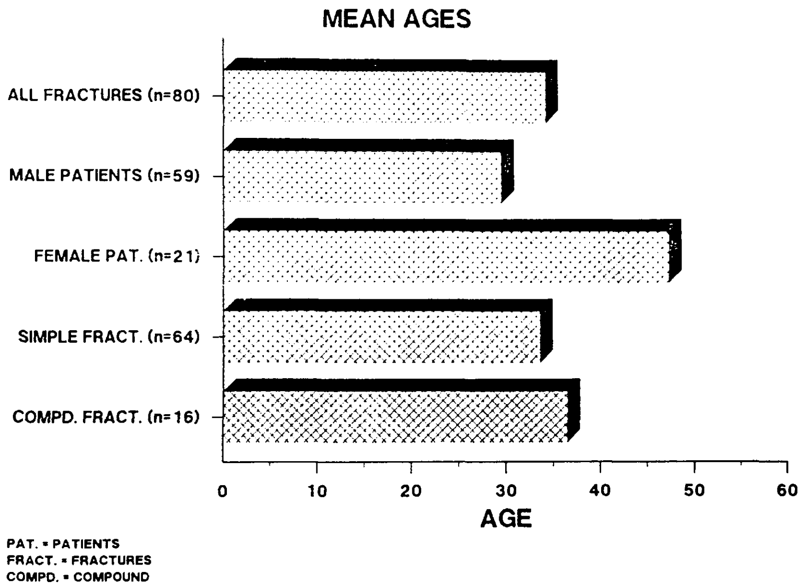


FIGURE 8.2.N: The mean ages in this series.

The majority (35 per cent) of the patients were manual workers while only 6 per cent were housewives. White collar workers accounted for 26%, students 15% while unemployed and retired people made up 18%.

Sports and road traffic accidents accounted for 71 per cent of the injuries in this series (figure 8.2.P).

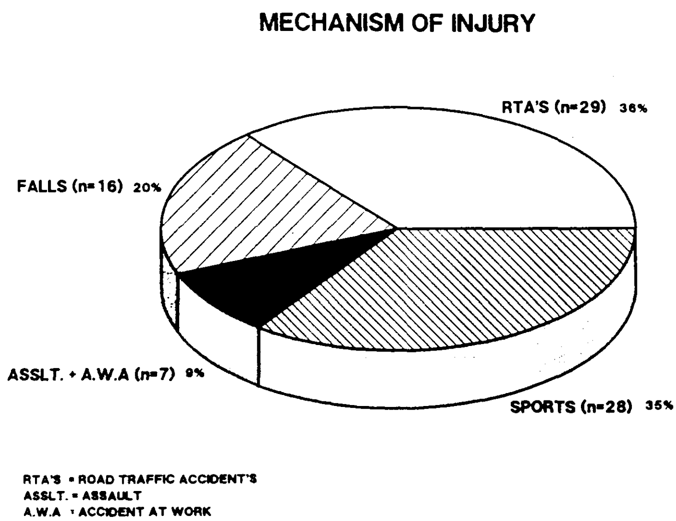


FIGURE 8.2.P: Mechanism of injuries in the series.

TYPE OF FRACTURE: In this series there were 64 simple and 16 compound fractures (figure 8.2.Q). Among the compound fractures 6 each were classified as Grade 1 and Grade 2, while 4 were classified as Grade 3. Over half (51 per cent) of the fractures occurred in the distal 1/3rd of the shaft while 39 per cent occurred in the middle 1/3rd (figure 8.2.Q).

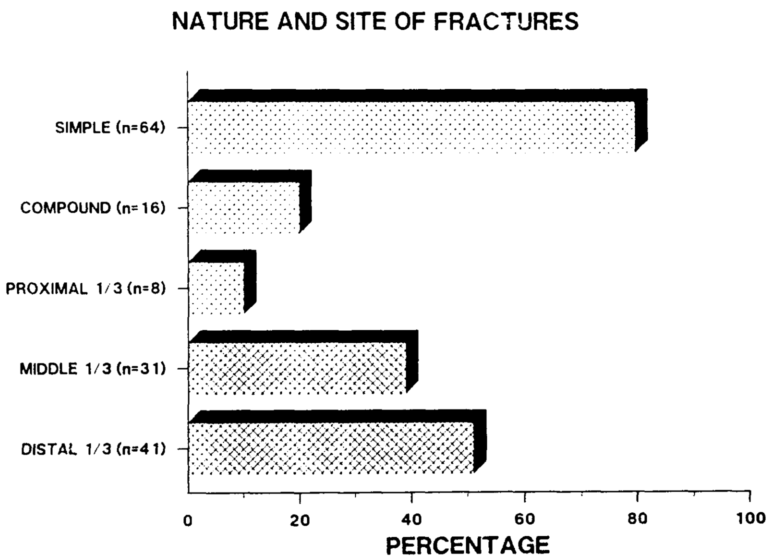
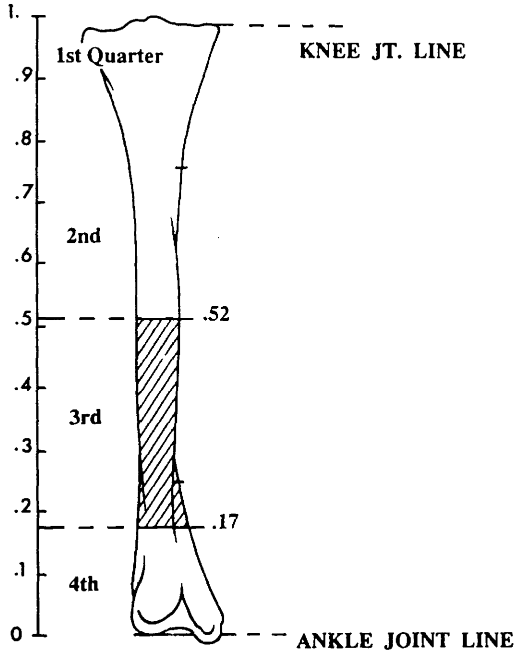


FIGURE 8.2.Q: Nature and site of fractures in the series.

The site of fracture was also measured from the ankle joint line, relative to the total length of the tibia. The mean length of the tibias in this series was 371.6 millimetres (S.D 26.32) while the mean height of the fracture line from the ankle joint was 129.8 millimetres (S.D 63.77). The mean of the ratios of the "height of fracture from the ankle joint" to the "length of tibia" for each patient was calculated and found to be 0.349 (S.D 0.175). This was used to determine the frequency distribution for the site of fracture and it was noted that almost 70 per cent (one standard deviation on either side of the mean), of the fractures occurred in the 3rd quarter of the tibial bone (figure 8.2.R).



CRITICAL AREA ON THE TIBIAL
SHAFT, PRE-DISPOSING TO FRACTURE

FIGURE 8.2.R: "Critical area" in the tibial bone predisposing to fractures.

This area overlaps parts of the middle and distal 1/3rd of the tibial shaft in the traditional classification for the site of the fractures. The fact that almost 70 per cent of the fractures occurred in the 3rd quarter of the tibia, suggests that the structural/anatomical differences in this part of the bone may predispose it to injury. It would also be appropriate that the classification for the site of fracture should divide the bone into 4 equal parts, instead of 3, as has been the practice until now. This would make the classification more sensitive to the differences identified above.

The most common fracture type was transverse (figure 8.2.S), though 6 segmental fractures were also successfully treated in this series.

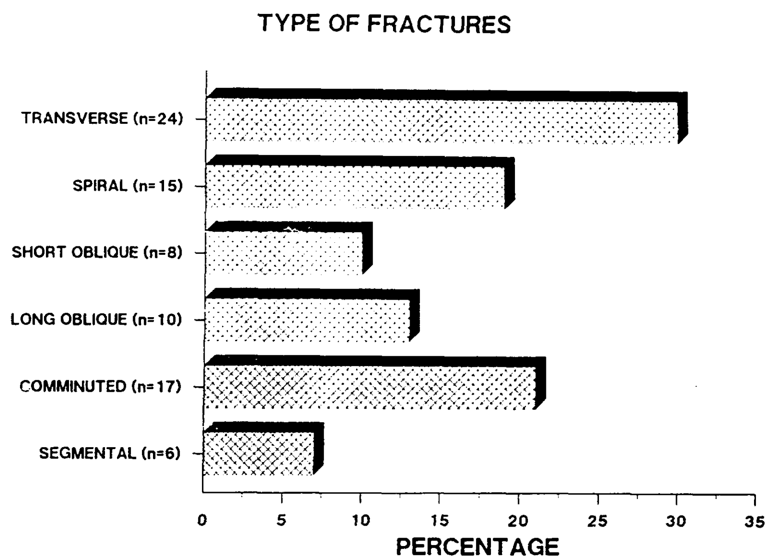


FIGURE 8.2.S: Type of fractures in the series.

38 (48 per cent) of the fractures were clinically stable at the time of fracture reduction (figure 8.2.T). In 29 (36 per cent) fractures the ipsilateral fibula was intact (figure 8.2.T), while 15 (19 per cent) had associated skeletal injuries, excluding ipsilateral fibula fractures (figure 8.2.T).

In 52 (66%) fractures the fragment contact was classified as Grade 4 (76-100 per cent apposition), after reduction of the fracture (figure 8.2.U). While 19 (24%) of the fractures were Grade 3.

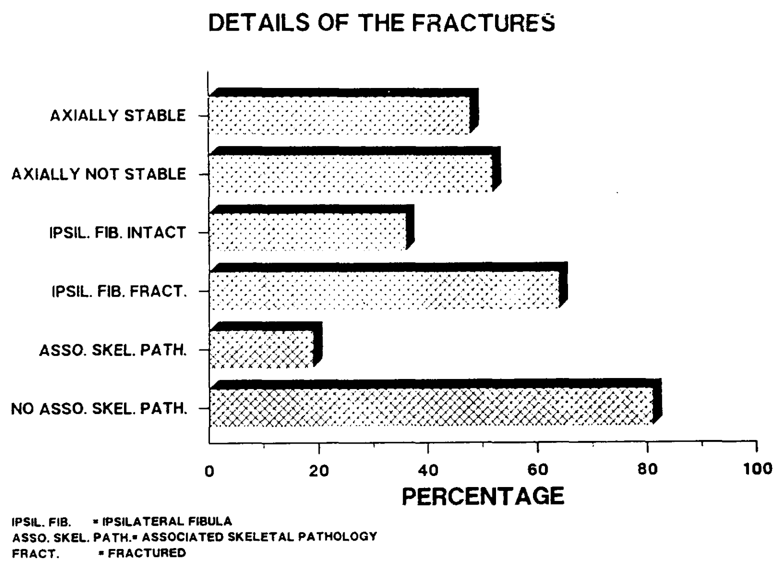


FIGURE 8.2.T: Details of the fractures in the series.

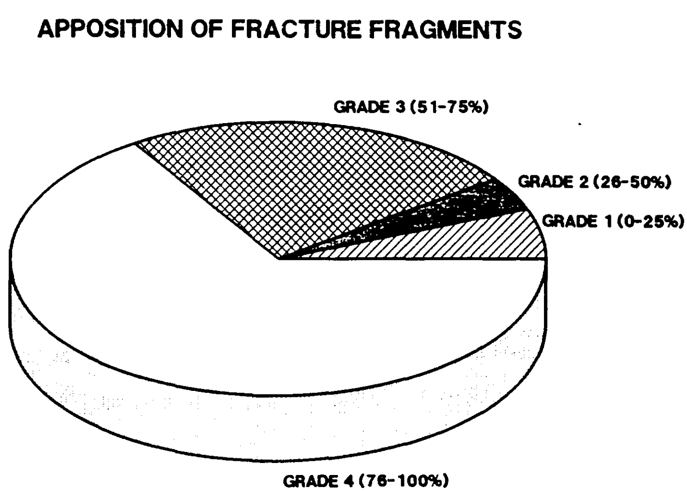


FIGURE 8.2.U: Apposition of fracture fragments after reduction.

8.3 RESULTS

The overall time to healing of the 80 tibial shaft fractures was 97.5 days (S.D 34.87). The mean stay in hospital was 3.6 days (S.D 4.55) and the mean duration of brace treatment was 61.4 days (S.D 28.85). During most of this period the patient was fully mobile and able to use both the knee and ankle joints for activities of daily living (figure 8.3.A).

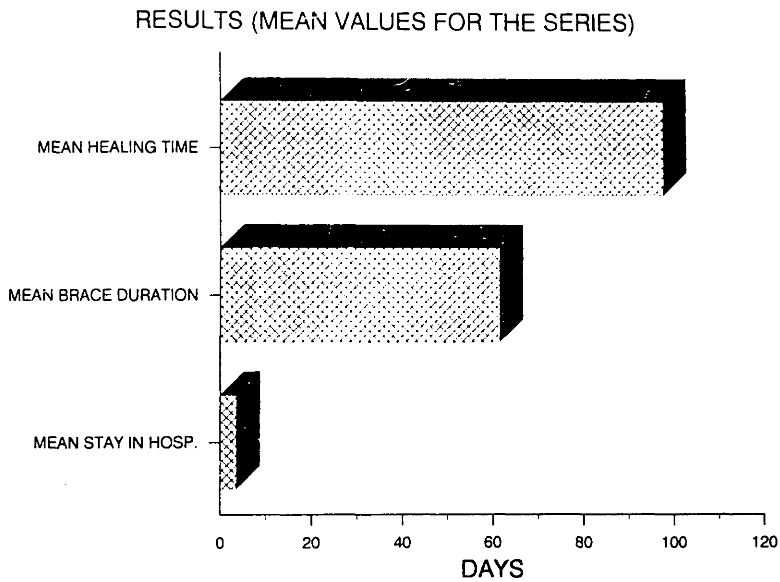


FIGURE 8.3.A: Mean values for the series.

In this series analysis of a number of different variables related to the fracture outcome was also performed with healing time as the main parameter.

AGE: The relationship of age to the healing time using "linear regression" showed no statistical significance (p = 0.077).

SEX: The male patients in this series, healed as a group with a mean of 97.6 days (S.D 35.55) compared to a mean of 97.3 days (S.D 33.72) for the females (figure 8.3.B). Their was no significant difference in the healing rates for the two sexes using both the Mann-Whitney test (p = 0.7704) and linear regression.

SIDE OF INJURY AND SEX OF THE PATIENTS

	n	PERCENTAGE	HEALING TIME MEAN (DAYS)	S.D
RIGHT LEG	45	56	95.5	37.80
LEFT LEG	35	44	100.2	30.78
MALE	59	74	97.6	35.55
FEMALE	21	26	97.3	33.72
ALL FRACTURES	80	100	97.5	34.87

FIGURE:8.3.B: Healing times relative to the sex and side of injury of the patients.

SIDE OF INJURY: No statistical difference (p = 0.1753) was shown between the healing times for the right and left sided fractures (figure 8.3.B) in this series.

OCCUPATION: Although tibial fractures were common in those engaged in heavy physical work, the occupation of the patient was found to be of no importance in determining the outcome in this series.

MECHANISM OF INJURY: Injuries due to sports related accidents healed at a faster rate compared to the injuries due to falls and road traffic accidents (figure

8.3.C). Statistical analysis using the "Mann-Whitney" test showed a significant difference between the healing times for sports related injuries and road traffic accidents ($p = 0.0053$). Significance ($p = 0.01$) was also shown between sports group and miscellaneous group (accident at work + assault). Their was no significance ($p = 0.6835$) between "sports" and "falls" group.

MECHANISM OF INJURY

	n	PERCENTAGE	HEALING TIME MEAN (DAYS)	S.D
SPORTS	28	35	83.4	21.32
FALLS	16	20	93.4	37.48
R.T.A'S	29	36	107.4	35.96
ASSLT. + A.A.W	7	9	123.4	47.40
ALL FRACTURES	80	100	97.5	34.87

ASSLT. = ASSAULT
A.A.W = ACCIDENT AT WORK

FIGURE 8.3.C: Healing times relative to the mechanism of injury.

This analysis was extended to see if the significance in results was purely due to the effect of the mechanism of injury, or if it was influenced by other variables such as the "method of treatment" (primary as opposed to secondary). This was done by comparing the group ($n = 26$) of tibial fractures belonging to sports related injuries treated primarily by bracing with the group ($n = 21$) of road traffic accident treated identically. The Mann-Whitney test did not show any significant difference ($p = 0.0627$).

This was evidence in favour of the concept that the mechanism of injury is not the primary determinant of the outcome of the fracture healing. The significance shown with a superficial analysis, was in fact due to the effect of the other variables which were not being considered at the time. This was confirmed by multiple regression, which looked at a number of different variables in conjunction with the mechanism of injury. This showed no significance when considered with the "time of application of the brace" and "grade of apposition of the fracture fragments after reduction of the fracture".

NATURE OF FRACTURES: Simple fractures, as a group, in this series healed faster than the compound fractures (figure 8.3.D). The healing times of the "simple" as against the "compound" fractures were significantly different ($p = 0.0029$), but when the data was further analysed by neutralising the effect of treatment (primary against secondary), no statistical significance ($p = 0.2007$) was noted. Similar result of no statistical significance ($p = 0.4519$) was noted when simple fractures treated secondarily were compared with compound fractures also treated secondarily.

These results indicate that the nature (simple or compound) of the fractures does not significantly effect the outcome but could be important in determining the outcome when considered in conjunction with other variables.

NATURE OF FRACTURES

	n	PERCENTAGE	HEALING TIME MEAN (DAYS)	S.D
SIMPLE	64	80.0	92.0	31.49
COMPOUND	16	20.0	120.7	39.80
ALL FRACTURES	80	100.0	97.5	34.87
COMPD. GD 1	6	7.5	108.5	16.88
COMPD. GD 2	6	7.5	118.5	47.60
COMPD. GD 3	4	5.0	147.7	56.60

COMPD. = COMPOUND
GD. = GRADE

FIGURE 8.3.D: Healing times relative to the nature of the fractures.

When linear regression of this variable was performed against healing time, significance was shown ($p = 0.001$). But when multiple regression was carried out using this variable as well as other variables (fracture fragment apposition, time of brace application and ratio of height of fracture to length of tibia) then although the nature of fracture was not shown to be statistically significant by standards of "$p < 0.05$" but it was found to be quite near that value ($p = 0.051$). This indicated that nature of fractures although not very important in determining the fracture healing outcome on its own, but could still prove to be of value in predicting it.

SITE OF FRACTURE: When the mean healing times of the fractures relative to site of injury are considered, it seems that the fractures in the distal third of the tibial shaft healed faster than the fractures in other parts of the shaft (figure 8.3.E). This inference could be in error because there are a number of other variables which could influence outcome. Comparison of the groups based on the site of fracture using the Mann-Whitney test did not show any statistical difference in the healing times.

SITE OF FRACTURE

	n	PERCENTAGE	HEALING TIME MEAN (DAYS)	S.D
PROXIMAL 1/3	8	10	105.0	46.00
MIDDLE 1/3	31	39	107.2	40.67
DISTAL 1/3	41	51	88.7	25.05
ALL FRACTURES	80	100	97.5	34.87

FIGURE 8.3.E: Healing of fractures relative to the site of fractures.

To assess the effect of this variable further, regression analysis was also performed. Linear regression did show significance ($p = 0.045$) but multiple regression did not. This evidence supported the results of Mann-Whitney comparison, which indicated that site of fracture is not an important determinant of healing outcome.

TYPE (MORPHOLOGY) OF FRACTURE: Transverse and short oblique fractures healed faster than long oblique and comminuted fractures (figure 8.3.F). Using the Mann-Whitney test, statistically significant differences in healing times were obtained when transverse fracture group was compared to long oblique group ($p = 0.0269$), comminuted group ($p = 0.0489$) and segmental group ($p = 0.0024$).

TYPE OF FRACTURE

	n	PERCENTAGE	HEALING TIME MEAN (DAYS)	S.D
TRANSVERSE	24	30	85.5	35.16
SPIRAL	15	19	91.8	25.31
SHORT OBLIQUE	8	10	84.4	12.41
LONG OBLIQUE	10	13	107.3	28.65
COMMINUTED	17	21	110.1	46.90
SEGMENTAL	6	7	122.7	19.15
ALL FRACTURES	80	100	97.5	34.87

FIGURE 8.3.F: Healing of fractures relative to the type of fractures.

To confirm whether the "type of fracture" was an important determinant of healing outcome. The various "types" of fractures were ordered as given in figure 8.3.F, with transverse fractures representing the least severe injury. This order could be debated but the assumption was that the majority of transverse fractures were the result of a less severe injury then comminuted or segmental fractures etc. This was followed by regression analysis of the type of fractures against the healing time. Linear regression did show statistical significance ($p = 0.033$) but when multiple regression was performed with inclusion of other variables (fracture fragment apposition and time of brace application), "type of fracture" as a variable was not significant anymore (p = 0.424). This was evidence in favour of the concept that fracture type's are not an important determinant in fracture healing outcome.

FRACTURE STABILITY: The mean healing time of the axially stable fractures at the time of reduction showed that these fractures healed faster than those which were not stable (figure 8.3.G).

AXIAL STABILITY OF FRACTURES AT INJURY

	n	PERCENTAGE	HEALING TIME MEAN (DAYS)	S.D
YES	38	48	85.6	30.09
NO	42	52	108.3	35.72
ALL FRACTURES	80	100	97.5	34.87

FIGURE 8.3.G: Healing time of the fractures relative to the axial stability of the fractures at the time of injury.

When the healing times of the above groups were compared, using the Mann-Whitney test, they were found to be significantly different (p = 0.0005). To verify the significance shown by the Mann-Whitney test, linear regression was performed which also showed significance (p = 0.004). Multiple regression analysis was then performed to exclude the influence of other variables and it was observed that axial stability of fracture at the time of reduction still came out as a significant variable to effect the outcome of the fracture. This implied that axial stability was an important parameter which could be used to predict the healing outcome of the tibial fractures. The only disadvantage with this variable is that it is a subjective evaluation.

FRACTURE FRAGMENT APPOSITION: The fractures which had 76-100 per cent (Grade 4) contact of the fracture fragments after reduction tended to heal faster then the rest (figure 8.3.H).

APPOSITION OF FRACTURE FRAGMENTS

	n	PERCENTAGE	HEALING TIME MEAN (DAYS)	S.D
GRADE 1 (0-25%)	5	6	123.2	40.20
GRADE 2 (26-50%)	2	4	104.0	7.07
GRADE 3 (51-75%)	19	24	107.4	31.50
GRADE 4 (76-100%)	52	66	91.2	34.86
ALL FRACTURES	80	100	97.5	34.87

FIGURE 8.3.H: Healing time of the fractures relative to the apposition of the fracture fragments after reduction.

To assess the effect of fracture fragment displacement on the outcome of the healing times, linear regression was performed which showed it to be a significant variable (p = 0.018). Multiple regression was also performed and it was observed that fracture fragment apposition was still an important factor in determining outcome when considered in conjunction with "axial stability of the fracture at the time of fracture reduction" and "the day of application of the brace" (p = 0.003). This implied that it could be used as a reliable determinant of the fracture healing time in a multiple regression equation predicting the same.

TREATMENT MODALITY: The mean healing time of the primary treatment group was 88.2 days compared to 136.7 days for the secondary treatment group (figure 8.3.J).

TREATMENT MODALITY

	n	PERCENTAGE	HEALING TIME MEAN (DAYS)	S.D
PRIMARY	63	79	88.2	25.84
SECONDARY	17	21	136.7	41.10
ALL FRACTURES	80	100	97.5	34.87

FIGURE 8.3.J: Healing time of the fractures relative to the type of treatment given.

On statistical comparison of the above groups, a significant difference (p = 0.0001) was shown by Mann-Whitney test. To confirm that the statistically significant difference shown by Mann-Whitney test was due to the type of the treatment given to the two group of patients and was not a reflection of other variables, linear regression was carried out which also showed statistical significance ($p < 0.001$). Multiple regression further supported the evidence, by showing statistical significance of the type of treatment, in the outcome of the healing time, even in combination with other variables.

These results support the view that primary treatment using the 2 in 1 brace directly after a suitable period in a long leg cast, does effect the outcome of the fractures when compared with the use of the brace after initial stabilisation in an "external fixator" or "pins in plaster cast". It is concluded that early and direct use of the 2 in 1 brace improves the outcome by decreasing the period of healing.

TIME OF BRACE APPLICATION: Relationship of the time of brace application to the total healing time was also assessed. It was observed that the braces that were applied within 28 days (4 weeks) of injury had healed faster than those put into the brace after 28 days (figure 8.3.K). These groups also showed a statistically significant difference using the Mann-Whitney test ($p = 0.0008$).

The importance of this variable was also analysed by linear regression which showed it to be highly significant ($p < 0.001$). Multiple regression which assessed the importance of the time of application relative to other variables in determining the healing outcome of the fracture also showed it to be highly significant. This evidence favours the concept that the time of application does effect the healing outcome and that earlier application of the brace leads to faster healing.

TIME OF APPLICATION OF THE BRACE

	n	PERCENTAGE	HEALING TIME MEAN (DAYS)	S.D
WITHIN 28 DAYS INJ.	36	45	84.8	27.65
AFTER 28 DAYS INJ.	44	55	108.4	36.97
WITHIN 42 DAYS INJ.	55	69	88.9	29.35
AFTER 42 DAYS INJ.	25	31	118.9	38.96
ALL FRACTURES	80	100	97.5	34.87

INJ. = INJURY

FIGURE 8.3.K: Healing times relative to the day of application of the brace.

The concept is also supported when the healing times of fractures put into braces at successive weeks post injury are plotted (figure 8.3.L). It is seen that those braced within the first 2 weeks heal faster than those put into a brace in the 3rd or 4th week post injury. There is a definite trend for the healing time to increase (x-axis) as the interval between fracture and bracing increases.

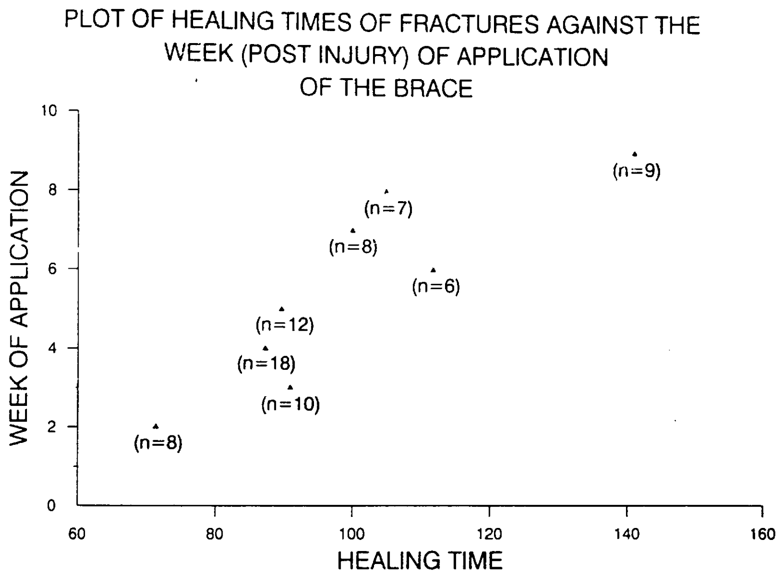


FIGURE 8.3.L: Plot of healing times of fractures against the week (post injury) of application of the brace.

STATUS OF IPSILATERAL FIBULA: A direct comparison of the mean fracture healing times, with and without intact ipsilateral fibulas, showed that the former group healed faster than the latter (figure 8.3.M & N). A statistically significant difference in the healing times of the two groups was also shown by the Mann-Whitney test ($p = 0.0172$). To see whether this significance was purely due to the "status of the ipsilateral fibula" or was a reflection of a combination of variables, a comparison was done using the Mann-Whitney test. The group of fractured tibias ($n = 28$) with intact ipsilateral fibulas primarily treated with bracing, compared with the group ($n = 35$) with fractured ipsilateral fibulas treated identically. This time no significance ($p = 0.1230$) was shown, indicating that the outcome was probably due more to the type of treatment undertaken. This implies that if the same treatment is used, then the healing rates of the tibial fractures with intact or fractured ipsilateral fibulas would essentially be the same.

INTACT IPSILATERAL FIBULA

	n	PERCENTAGE	HEALING TIME MEAN (DAYS)	S.D
TOTAL FRACT.	29	36	87.1	31.20
SIMPLE FRACT.	26	32	87.1	32.93
COMPD. FRACT.	3	4	86.7	8.39
PRIMARY TREAT.	28	35	84.6	28.85
SECOND. TREAT.	1	1	155.0	

COMPD. = COMPOUND
TREAT. = TREATMENT
SECOND. = SECONDARY

FIGURE 8.3.M: Healing times of fractures with intact ipsilateral fibulas.

The above impression was confirmed by performing linear regression analysis which showed statistical significance ($p = 0.041$) of the status of the ipsilateral fibula in determining the healing time. But when the same variable was analysed in combination with other variables during multiple regression, it lost its significance.

FRACTURED INPSILATERAL FIBULA

	n	PERCENTAGE	HEALING TIME MEAN (DAYS)	S.D
TOTAL FRACT.	51	64	103.7	35.75
SIMPLE FRACT.	38	48	95.4	30.43
COMPD. FRACT.	13	16	129.2	40.00
PRIMARY TREAT.	35	44	91.0	23.18
SECOND. TREAT.	16	20	135.4	42.40

COMPD. = COMPOUND
TREAT. = TREATMENT
SECOND. = SECONDARY

FIGURE 8.3.N: Healing times of fractures with fractured ipsilateral fibulas.

The effect of the status of the ipsilateral fibula on the angulation of the tibial fractures (figure 8.3.P & Q) was also assessed, but no significant difference was observed. It appears that occurrence of angulatory deformity is equally likely in fractures with intact or fractured ipsilateral fibulas. The only difference is an increased tendency for the fractured tibia with an intact fibula to go into varus angulation. On assessing the effect of the ipsilateral fibula on the overall shortening of the fractured tibia, it was found that those with a fractured fibula tended to shorten more than those where it was intact (figure 8.3.Q).

STANDARD ANGULATION AT HEALING
(IN DEGREES)

	INTACT FIBULA n = 29	FRACTURED FIBULA n = 51
NO ANGULATION	8 (27%)	7 (14%)
ANGULATION 0 - 5	13 (45%)	20 (39%)
ANGULATION 5 - 10	6 (21%)	20 (39%)
ANGULATION > 10	2 (7%)	4 (8%)
TOTAL FRACTURES	29 (100%)	51 (100%)

FIGURE 8.3.P: The effect of the status of ipsilateral fibulas on standard angulation of the tibial fractures.

	Intact Fibula n = 29	Fractured Fibula n = 51
Mean standard angulation before application of brace (degrees)	3.15	4.41
Mean standard angulation at the time of healing (degrees)	3.20	5.05
Mean increase in standard angulation in the brace (degrees)	0.05	0.64
Mean increase in shortening before application of brace(mm)	1.79	5.52
Mean increase in shortening at the time of healing(mm)	1.89	5.92
Mean increase in shortening in the brace (mm)	0.10	0.40

FIGURE 8.3.Q: Effect of the status of the ipsilateral fibulas on the shortening and angulation of the tibial fractures.

ASSOCIATED SKELETAL PATHOLOGY: Although the mean healing times for the tibial fractures with associated skeletal injuries (skeletal injuries other than those to the ipsilateral fibula) was comparatively longer than the group without associated injuries (figure 8.3.R), no statistical difference was shown by Mann-Whitney test ($p = 0.1863$). Linear regression showed that associated skeletal pathology was significant in determining healing time ($p = 0.026$). But this significance was lost when the variable was considered in combination with other variables during multiple regression. This evidence indicates that associated skeletal injuries do not significantly effect the outcome of healing of the tibial shaft fractures.

ASSOCIATED SKELETAL PATHOLOGY

	n	PERCENTAGE	HEALING TIME MEAN (DAYS)	S.D
YES	15	19	116.2	45.90
NO	65	81	93.4	30.92
ALL FRACTURES	80	100	97.5	34.87

FIGURE 8.3.R: Healing times of the fractures relative to the associated skeletal pathology.

JOINT RANGE OF MOVEMENTS: A follow up examination of the patients in this series was performed to evaluate the function in the joints of the lower limb, with the tibial shaft fractures. It was possible to review 51 (64%) of the patients, with a mean follow up period of 16 months (range 3-32 months). The remainder could not be examined because they had either moved out of the area or were not available at the given address.

Ranges of movement for knee, ankle, sub-talar and fore-foot joints were measured on the injured side and compared with the contra-lateral normal limb. The results were expressed as "percentage range of movement to the normal side". The mean ranges (figure 8.3.S) were near normal, indicating a very good functional outcome.

JOINT RANGE OF MOVEMENT ASSESSMENT
ON FOLLOW UP EXAMINATION

	n	Mean	S.D
Follow-up (Months)	51	16.0	8.46
Knee	51	99.5	1.52
Ankle	51	96.1	7.72
Sub-talar	51	96.8	5.49
Fore-foot	51	97.3	5.50

Range of movements for the joints are in percentages relative to the contralateral normal joint

FIGURE 8.3.S: Percentage range of movements to the normal contra-lateral side.

None of the patients complained of any joint symptoms. One of the patients had a 37% loss of ankle range of movement following treatment by an external fixator (bilateral frame) for a comminuted fracture. It is possible that this loss of movement resulted from pin transfixion of the muscles. There was also a delay in conversion to a functional brace (time of application = 103rd day post injury), in this case.

COMPLICATIONS: The complications that were observed in this series are shown in figures 8.3.T and 8.3.U. The major complications of delayed union, loss of position, restricted ankle movement, and pin tract infection totalled 20%. Of these only 4% occurred in the primary treatment group, while the majority (16%) occurred in those braced as a secondary procedure.

Complications	n	Percentage
Major		
Delayed Union	**11**	**13.75**
Loss of position > 5 degrees in brace	**1**	**1.25**
Restricted ankle R.O.M. > 30% of normal side	**1**	**1.25**
Pin tract infection	**3**	**3.75**

FIGURE 8.3.T: Major complications observed in this series.

Complications	n	Percentage
Minor		
Redness of skin under cast	3	3.75
Digging of brace into the skin underneath	1	1.25
Swelling of the foot	2	2.50
Loose brace	1	1.25

FIGURE 8.3.U: Minor complications observed in this series.

Among the 11 delayed unions, 9 occurred in the secondarily treated group, with only 2 in those treated primarily. There were no cases of non-union in this series. In 1 patient a loss of position greater than 5 degrees occurred in the brace. This fracture was high in the proximal shaft and the brace did not effectively control it, due to the short proximal moment arm.

The minor complications of skin redness and local pressure of the cast on the skin did not effect the treatment outcome. Swelling of the foot occurred in 2 patients when the "foot-piece" was removed, but this was overcome by elevation and active mobilisation.

a) STANDARD ANGULATION: 15 (19%) patients showed no angulatory deformity at the time of healing, while 6 (8%) patients had standard angulation greater than 10 degrees (figure 8.3.V). An assessment of the increase in standard angulation in the functional brace, showed no increase in 56 (70%) and an increase greater than 2 degrees in 7 (9%) patients (figure 8.3.W).

STANDARD ANGULATION AT HEALING
(IN DEGREES)

	n	PERCENTAGE
NO ANGULATION	15	19
ANGULATION < 5	30	37
ANGULATION 5 - 10	29	36
ANGULATION > 10	6	8
TOTAL FRACTURES	80	100

FIGURE 8.3.V: Standard angulation measured at the time of healing in this series.

INCREASE IN STANDARD ANGULATION
IN THE BRACE

	n	PERCENTAGE
NO INCREASE	56	70
INCREASE < 1 DEG.	7	9
INCREASE 1 - 2 DEG.	10	12
INCREASE > 2 DEG.	7	9
TOTAL FRACTURES	80	100

DEG. = DEGREE

FIGURE 8.3.W: Increase in standard angulation, observed while the fractures were in the functional brace.

The mean standard angulation at the time of healing was 4.38 degrees (S.D 3.98) while the mean increase in standard angulation during the period of functional bracing was 0.43 degrees (S.D 1.64) as presented in figure 8.3.X.

	Mean (deg)	STD
Mean standard angulation before application of the brace	3.96	3.37
Mean increase in standard angulation in the brace	0.43	1.64
Mean standard angulation at healing	4.38	3.98

FIGURE 8.3.X: Mean values of standard angulation in this series.

This analysis implies that the 2 in 1 brace is effective in controlling the antero-posterior and medio-lateral angulations. This evidence supports the view that a brace, if properly fabricated with a foot-piece, can be applied as early as the first week post-injury without loosing angulatory control of the fragments.

b) SHORTENING: 34 (42%) patients showed no shortening at the end of the treatment, while 12 (15%) patients showed a shortening of more than 10 millimetres (figure 8.3.Y). The increase in shortening while the fractures were braced was also assessed. In 65 (81%) of the fractures there was no increase in shortening (figure 8.3.Z), while only 15 (19%) showed minor increases in shortening while in the functional brace.

SHORTENING AT HEALING

	n	PERCENTAGE
NO SHORTENING	34	42
SHORTENING < 5 mm	15	19
SHORTENING 5 - 10 mm	19	24
SHORTENING > 10 mm	12	15
TOTAL FRACTURES	80	100

FIGURE 8.3.Y: Shortening observed in the fractures at the time of healing.

INCREASE IN SHORTENING IN THE BRACE

	n	PERCENTAGE
NO INCREASE	65	81
INCREASE < 3 mm	14	18
INCREASE > 3 mm	1	1
ALL FRACTURES	80	100

FIGURE 8.3.Z: Increase in shortening observed while the fractures were being maintained in the brace.

The mean shortening at the time of healing was 4.46 millimetres (S.D 5.45) and the mean increase in shortening in the brace was 0.29 millimetres (S.D 0.72) (figure 8.3.AA). This implies that the major component of the shortening was already present when the fractures were put into the brace. It is likely that this shortening was either accepted at the time of injury or occurred later in the long leg cast.

	Mean (mm)	S.D
Mean shortening before going into the brace	4.18	5.16
Mean increase in shortening in brace	0.29	0.72
Mean shortening at healing	4.46	5.45

FIGURE 8.3.AA: Mean values of shortening of fractures in this series.

8.4 DISCUSSION

The overall healing time in this series of 80 fractures was 97.5 days. This compares favourably with the healing time of 130.9 days in the largest reported series, of 780 tibial fractures treated with functional braces (Sarmiento et al 1989). Although this comparison between mean healing times is not statistically acceptable because neither the standard deviations, nor the raw data were given in the 1989 Sarmiento et al paper. The comparison is still valid because the average age, proportions of open and closed fractures, fractures in the proximal, middle and distal third of the shaft, different types of fractures and the ipsilateral fibular shaft fractures were similar in both series.

Burns and Young (1942) had specifically discussed the time to union in their series of fractured tibias, because of a widespread feeling at that time, that fractures took longer to unite than historical controls. They analysed 27 cases, from St. George's Hospital records of 1927-30, of closed tibial shaft fractures with an average time of union of 80.5 days. They then analysed 95 cases of closed tibial fractures treated at Botley's Park Orthopaedic Centre from 1941-42, which showed the average time of union to be 108.5 days. The comparison between these two groups led them to pose the question "what had gone wrong?". They had concluded that the reason for the deterioration in results was primarily the use of non-weight bearing immobilisation of fractures in long leg casts. The results were better anatomically but they concluded that "in seeking after anatomical perfection, we have paid the price of 4 weeks delay in union". They advised early weight bearing in order to reverse this trend, which is supported by the data in this series. The mean healing time of closed tibial shaft fractures in this series was 92 days and it is believed that it could be reduced further by the routine use of early weight bearing in the management of tibial fractures. As for the quality of reduction, the results show that no significant loss of position occurred while the fracture was being maintained in the functional brace. It may be possible to improve the results still further by paying more attention to reduction of the fracture at the time of injury even if it has to be undertaken under general anaesthesia.

The average time to application of the brace in this series was 35.1 days compared to 33.6 days in the series by Sarmiento et al (1989), while the ranges in both the series were quite wide. The analysis of results in this series has indicated that time of application of the functional brace is very important in deciding the outcome of the fracture healing. It would thus seem appropriate that every effort must be made to apply the brace as early as possible. The two factors which would determine the time of application, are the axial stability of the fracture and the nature of the fracture (open or closed).

There seems to be no reason why a closed stable fracture could not be put into a brace within the first week after injury once the pain and swelling have settled down. It could be argued that conversion at this early stage could predispose to loss of position or angulatory deformity in the brace. This view is not supported by this study as the results indicate that the increase in angulatory deformity occurring inside the brace was negligible. The residual deformity at the time of healing was primarily due to the acceptance of malalignment at the initial application of the long leg cast on the day of injury. If a less than ideal alignment is accepted during initial management in the hope that it can be corrected later, then delay or failure to institute corrective measures will produce an unsuccessful result. It is therefore recommended that every effort should be made to achieve an acceptable alignment at the time of the initial reduction, even if the procedure has to be performed under General anaesthesia.

Sarmiento and his co-workers (1989) highlighted the fact that their success with the use of functional bracing is dependent upon a clear understanding of its principles and a rigid adherence to technical details. This view is supported by this study and the biomechanical analysis performed on the "2 in 1 functional brace" (Part 4). Functional braces control the tendency to angulatory deformity of the fracture very well, but are unable to control shortening if the fracture is comminuted or axially unstable. This implies that such fractures should not be transferred to a brace at such an early stage as stable fractures, unless the anticipated shortening would be acceptable to the clinician.

The need for careful attention to technical detail in fabricating the brace also implies that the procedure should not be delegated to inexperienced staff and should be closely supervised by trained medical staff. It is recommended that a team approach be followed, with the surgeon supervising and maintaining reduction of the bone while the technician applies the brace. This would ensure that the initial reduction of the bone is maintained and would also lead to functional bracing be taken more seriously with further improvement of the method.

The problem of comparing average healing times between series has been noted by different authors (Austin 1977, Sarmiento et al 1989). This is primarily due to the unavailability of a common method of assessing fracture healing. Clinical criteria combined with radiological evidence are commonly utilised for this purpose. In this series fracture healing was also assessed using the "non-invasive method of fracture stiffness measurement" (Part 5). This method was not available during the early part of the study, but was found to be useful supportive evidence of fracture union during the later stages of the series. This evidence led to the development of the concept, that radiological evidence of callus formation was not essential for fracture healing. If a clinical impression of union could be supported with acceptable readings of fracture stiffness measurement, then healing should be considered sufficiently advanced to allow unsupported weight bearing (without a cast). This hypothesis is supported by the limited data in this study, but the treatment is not advocated for routine use until a larger series confirms it.

Statistical analysis was undertaken on the data to assess the importance of various variables in predicting the healing time. Linear and multiple regression as well as the Mann-Whitney test for comparison of groups was used. The variables age, sex, side of injury, mechanism of injury, site of fracture, morphology (type) of fracture, status of ipsilateral fibula and the presence or absence of associated skeletal injuries (other than ipsilateral fibula) were found not to be statistically significant in predicting the healing time in this series. The nature of the fracture (open or closed) was on the borderline of statistical significance, while axial stability, fracture fragment apposition after reduction, type of treatment (primary or secondary) and the time to application of the brace were statistically significant in predicting the healing time.

The regression equations for this group of statistically significant variables was then examined to determine whether these variables were also clinically significant or not. It is possible for a variable to be statistically significant but when used in the "regression equation", predicting healing time, the difference in the outcome could be small enough to be irrelevant clinically. If a variable made a difference of less than 7 days to the predicted healing time than it was considered to be not significant clinically. It was found that all the statistically significant variables were also clinically significant.

This information was then used to arrive at a "prediction equation" (figure 8.4.A) for tibial shaft fractures using 4 variables; site of fracture (expressed as a ratio of the height of fracture from the ankle joint to the length of the tibia - HTBYLNTB), nature of fracture (FRCLASSI), fracture fragment apposition (FRAGAPPO) and the time to application of the brace (DAYBRACE).

These four variables were selected because they can be assessed objectively, while axial stability of fracture is a subjective assessment which could vary from observer to observer. The type of treatment was not considered because it was decided to use this equation to predict healing time when only the 2 in 1 functional brace was used, in the primary form of treatment.

The regression equation predicting healing time is than given by:

$$88.1 + (31.7*\mathrm{HTBYLNTB}) + (7.94*\mathrm{FRCLASSI}) - (12.0*\mathrm{FRAGAPPO}) + (0.822*\mathrm{BRACEDAY})$$

Where 88.1 is a constant value

HTBYLNTB = Site of fracture expressed as a ratio

FRCLASSI = Nature of fracture, and as per classification, it could vary from 1 to 4

FRAGAPPO = Fracture fragment apposition, and as per classification, it could also vary from 1 to 4

BRACEDAY = Day of the application of the brace post injury

MULTIPLE REGRESSION EQUATION PREDICTING HEALING TIME

MTB > regr c21 4 c6 c13 c16 c40

The regression equation is

injdays = 88.1 + 7.94 frclassi - 12.0 fragappo + 0.822 braceday + 31.7 htbylntb

78 cases used 2 cases contain missing values

Predictor	Coef	Stdev	t-ratio	p
Constant	88.08	15.65	5.63	0.000
frclassi	7.936	3.994	1.99	0.051
fragappo	11.965	3.640	-3.29	0.002
braceday	0.8225	0.1415	5.81	0.000
htbylntb	31.74	16.99	1.87	0.066

s = 26.08   R-sq = 47.0%   R-sq(adj) = 44.1%

FIGURE 8.4.A: Multiple regression of healing time against 4 variables.

The accuracy of this prediction equation was assessed by plotting the predicted healing times calculated for the series from the raw data, against the actual healing times (figure 8.4.B). The plot shows a fair amount of concentration around the "ideal line". This is the line on which the values of the predicted and actual healing times are the same. The accuracy of the prediction was also assessed by plotting the difference in actual and predicted healing times against the case number (figure 8.4.C).

As is apparent from the plots 54% of the predicted values were within +/- 2 weeks of the actual healing time while 73% of the predicted values were within +/- 3 weeks of the healing time. Only a minority of the predictions were quite different from the actual values. This is understandable because the multiple regression equation from the statistical point of view was able to explain 44.1% [R-sq(adj)] of the data in the series (figure 8.4.A). Although this equation does not satisfy the whole population statistically, from a clinical point of view it is fairly accurate in predicting the outcome in a tibial shaft fracture treated with a 2 in 1 functional brace.

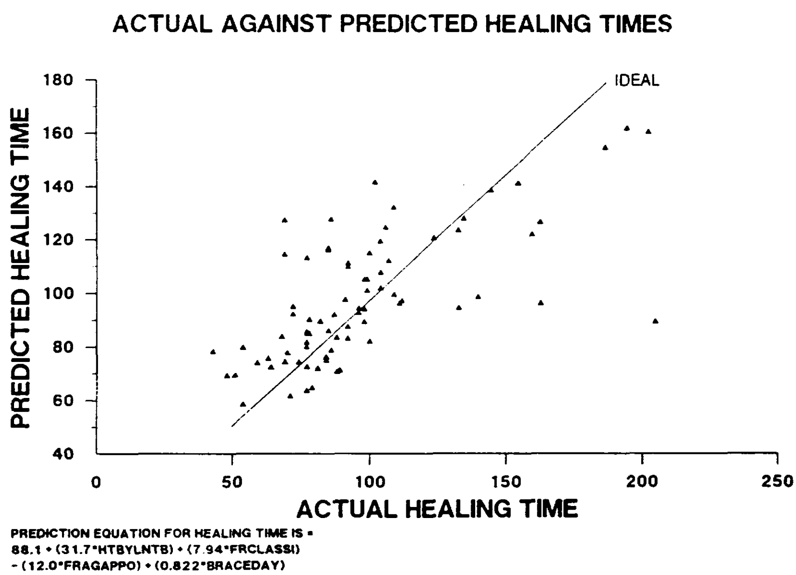


FIGURE 8.4.B: Plot of the actual against the predicted healing times, using multiple regression equation.

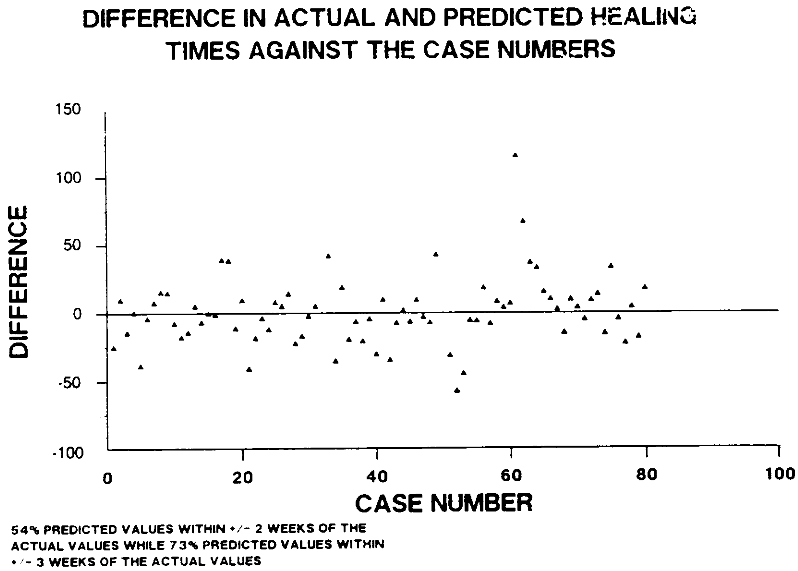


FIGURE 8.4.C: Plot of the differences in the actual and predicted healing times against the relative case numbers.

The equation is based on the data from this series of 80 fractures and could vary for another series with different numbers, selection of variables and protocol of treatment. It is felt that in spite of its limitations this equation would provide a reasonable basis for managing tibial shaft fractures.

It is apparent from a review of all the variables found to be statistically significant in predicting the healing time that they reflect the severity of the injury. Axial stability is dependent on the degree of soft tissue damage. The nature of the fracture (open or closed) and fragment apposition after reduction are similarly related to its initial severity. The only difference is that these last two variables could be assessed more objectively, while the first is subjective and difficult to use for prognosis. It could be inferred that the main factor in determining tibial shaft fracture healing is the severity of the injury reflected by different variables in different ways. It is thus possible to use different sets of variables for determining the prognosis of a fracture, but the best combination would use those that could be measured more objectively.

Consideration of the effect of the status of the ipsilateral fibula on the healing of tibial shaft fractures in this series was interesting. Sarmiento et al (1989) had concluded that tibial fractures with intact ipsilateral fibulas tended to heal faster then the group with fractured ipsilateral fibulas. They had attributed this to a lower energy injury in the former group. In this series no statistically significant difference in the healing times, with or without ipsilateral fibular fractures could be shown, supporting the findings of Oni et al (1988). It seems the difference in healing rates attributed to the status of the ipsilateral fibula was due to other variables, not considered at the time. It could be inferred that, provided all other variables were the same, tibial fractures with or without intact ipsilateral fibulas would heal at the same rate. It would follow, that osteotomy of an intact fibula to assist healing of the tibial fractures is unnecessary.

In this series 11 (13.7%) fractures took longer than 140 days (20 weeks) to heal and were classified as delayed unions. All of these later united, except 2 (2.5%) fractures which had to be operated and bone grafted. Both these fractures belonged to the secondary treatment group and were put into a functional brace as a salvage procedure after failure of the primary management with an external fixator and pins in plaster.

Among this group of 11 delayed unions a common factor was the delay in application of the functional brace and consequently return to full weight bearing. The mean time to application of the brace in this group was 63 days post-injury, almost double the mean application time (32 days) for the rest of the series. This fact also highlights the importance of early weight bearing and application of a functional brace for optimum results.

Oni et al (1988) reported a delayed union (healing time > 140 days) rate of 19% in their prospective series of 100 closed tibial shaft fractures. These were treated by functional bracing, with 4% requiring operative intervention. They concluded that open reduction was rarely justified in closed tibial shaft fractures, implying that functional bracing was the appropriate management. This view is supported by the results from this series.

The results with "2 in 1 bracing" in this study were very encouraging and the treatment is recommended for a larger controlled trial, comparing it directly with other forms of management. Experience with this series and historical evidence from the literature review suggests that functional bracing is appropriate for the management of the majority of tibial shaft fractures (Oni et al 1988, Sarmiento et al 1989). In view of this, an algorithm (figure 8.4.D) based on the nature (simple or compound) of the tibial shaft fracture and its axial stability is recommended, for management.

ALGORITHM FOR CLINICAL MANAGEMENT
OF TIBIAL SHAFT FRACTURES

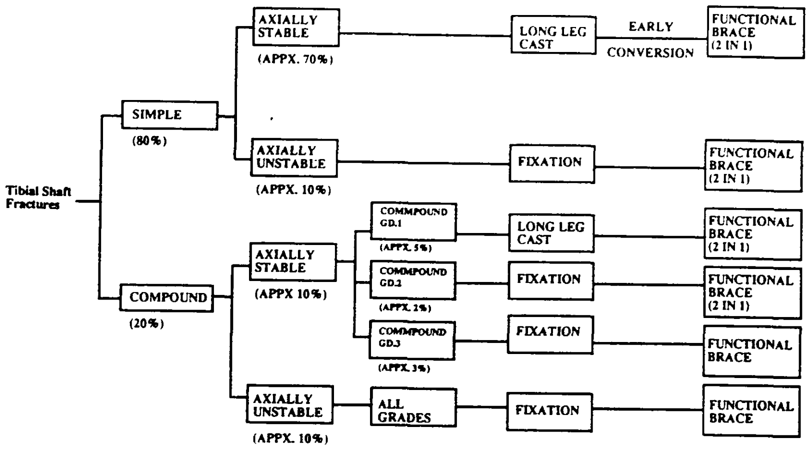


FIGURE 8.4.D: Algorithm for clinical management of tibial shaft fractures.

About 2/3rd of all tibial shaft fractures could be managed satisfactorily with functional bracing alone, while the remainder could be treated with "fixation" followed by functional bracing. Although the choice of method for fixation of such fractures would depend on the facilities available, soft tissue trauma, experience/preference of the surgeon and patient requirements etc, it is believed that the use of functional bracing in sequence with external fixator would achieve the aims of reasonable anatomical alignment and early union in difficult unstable or compound fractures. It would also provide early weight bearing as well as being cost effective. External fixation is preferred as a method of fixation in difficult fractures, because it is nearer to the philosophy of functional bracing while at the same time providing access to the wound for associated management.

It is accepted that in specific circumstances a case could be made for the use of a different form of fixation, such as intra-medullary nailing or compression plating.

8.5 CONCLUSIONS

1/- The 2 in 1 functional brace has given encouraging results in this series and is recommended for a controlled trial to compare its efficacy against other methods for managing tibial shaft fractures.

2/- Fracture of the ipsilateral fibula does not effect the healing rate of the tibial fractures but could influence the associated angulatory deformity.

3/- The initial severity of the injury, reflected by different variables, is the main factor determining the healing outcome of the tibial fractures. Use of objectively evaluated variables is likely to give a more accurate prognosis.

4/- Sex, age, side of injury, mechanism of injury, site of fracture, type (morphology) of fracture and associated skeletal pathology did not affect the healing outcome of the tibial shaft fractures.

5/- Nature (simple or compound) of fracture, axial stability of the fracture, fracture fragment apposition, treatment modality and time of brace application did effect the fracture healing outcome to some extent in this series.

6/- The 2 in 1 functional brace is a cost-effective form of management for tibial shaft fractures. On the basis of the cost and time of application, comparisons with available alternatives of conservative management showed that 2 in 1 functional brace led to a saving in cost of 25% and a decrease in application time of 23%.

CHAPTER 9

PROPOSALS FOR FUTURE RESEARCH

This study was planned to clarify the problems identified in managing tibial shaft fractures with functional bracing (chapter 1). The study was successful in achieving its aims. The information gained from the three arms of the study clarified certain issues, but also led to the identification of new ones and suggested avenues for further improvements. The following proposals are recommended for any future studies:

LOAD TRANSDUCER STUDY: This arm of the study led to the development of a method to estimate the 3 orthogonal forces and moments carried by the functional brace, during the stance phase, at the level of the tibial shaft fracture. This system gave a better insight into the biomechanical function of the brace in a dynamic situation. The information was valuable in the design rationalisation of the brace. It is believed that this system could also be used for research into estimating loads at the fracture site, and the information acquired could be useful in designing implants, external fixators and orthoses.

The system described in this study for measuring loads across a functional brace only estimated external forces and moments. It did not take into account the forces and moments generated by the muscles of the lower limb during ambulation. It is recommended that for a more realistic assessment of the forces and moments at the tibial fracture site a "muscle model" be incorporated in the system.

During analysis of the results of the load transducer study it was noted that during parts of the stance phase of the gait cycle, the functional brace was increasing loads instead of decreasing them. It was hypothesised that because of the presence of the rigid brace, these increased loads (forces/moments) were not accompanied by gross movement at the level of fracture, and were not damaging to the healing process. This hypothesis was based on the concept that the measured loads were external forces or moments at the level of the fracture in the brace. They would therefore only effect the fracture site if the brace allowed gross movement at the fracture site. In order to test this hypothesis, it is recommended that a similar study be undertaken, but with a provision to measure the relative movement or deflection of the cast (functional brace) during walking. If deflection or gross movement is observed between the proximal and distal parts of the functional brace, then it could be inferred that the increase in forces and moments was also resulting in movement at the fracture site likely to interfere with healing. Such an inference would require suitable design modifications as well as consideration of the use of more rigid materials for fabrication of the functional braces.

FRACTURE STIFFNESS MEASUREMENT: This part of the study resulted in a workable non-invasive computerised system of measuring fracture stiffness. Technical problems were encountered in setting up the "hardware" for the system. The components of the system were originally designed by their manufacturers for different applications. It is believed that this system could be further improved if the components are specifically designed for this application.

The electro-goniometer used in this study was designed to measure deflections of up to 360 degrees, whereas the deflections observed in measuring fracture stiffness were of the order of 2-3 degrees. A dedicated electro-goniometer would not only improve the accuracy of the system but would also make the use of a "preamplifier" in the system redundant.

In this prototype system the "expansion box" used for A/D conversion card, had 6 expansion slots. The system utilised only one slot for this application. In order to increase the "portability" of the system, it is recommended that the recently marketed (Toshiba) two slot expansion box be used in future systems.

2 IN 1 FUNCTIONAL BRACE: This new design of tibial functional brace gave very encouraging clinical results. The absence of a suitable non-invasive method to assess rotational deformities after tibial shaft fractures was one problem identified. Such a system could quantify the extent of the problem of rotational deformity following tibial shaft fracture healing. The use of ultrasound scanning could be explored for such a system. Upadhyay and Moulton (1985) described the use of ultrasound scanning for measuring femoral neck anteversion after femoral shaft fractures. A system which works on similar principles could be adapted to tibial shaft fractures.

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APPENDIX-3A
PATIENT DETAILS

COLUMN CODES FOR THE RAW DATA

A - CASE NUMBER
B - HOSPITAL NUMBER
C - SEX OF THE PATIENT
D - AGE OF THE PATIENT (YEARS)
E - DATE OF INJURY
F - HEIGHT OF THE PATIENT (cms)
G - BODY WEIGHT OF THE PATIENT (Newtons)
H - MORPHOLOGY (TYPE) OF FRACTURE
J - SITE OF FRACTURE
K - LEG TESTED

CODES FOR THE VARIABLES IN THE RAW DATA

SEX OF THE PATIENT (Column code - C):

FEMALE	1
MALE	2

MORPHOLOGY (TYPE) OF FRACTURE (Column code - H):

TRANSVERSE (0 - 15 degrees)	1
SHORT OBLIQUE (15 - 45 degrees)	2
LONG OBLIQUE (> 45 degrees)	3
SPIRAL	4
COMMINUTED	5
SEGMENTAL	6

SITE OF FRACTURE (Column code - J):

PROXIMAL 1/3rd OF THE SHAFT	1
MIDDLE 1/3rd OF THE SHAFT	2
DISTAL 1/3rd OF THE SHAFT	3

LEG TESTED (Column code - K):

RIGHT	1
LEFT	2

A	B	C	D	E	F	G
01	878326/M	2	30	060889	161	574
02	406832	1	55	011289	173	944
03	678911/K	2	23	181289	173	720
04	929328/K	2	32	110190	188	763
05	574535/A	2	30	170390	175	728

A	H	J	K
01	5	2	2
02	4	3	2
03	5	1	1
04	1	3	1
05	1	2	2

APPENDIX-3B

MODIFIED LOAD MEASURING SYSTEM
PROTOCOL FOR TESTING
KINEMATIC AND LOAD DATA ACQUISITION

EQUIPMENT

1 One front and one side TV camera with associated components.
2 Two TV monitors.
3 A calibration board.
4 One "T" plate, with one marker attached (marker E).
5 Two markers on modified drawing pins (markers C and D).
6 Two markers on modified screws for attachment on the mating pieces (markers A and B).
7 Two blank plates (already mounted on the 2 in 1 functional brace).
8 Black socks.
9 Black plastic sheets.
10 Force plate 1 (FP1) with associated equipment.
11 One stool.
12 Two six channel strain gauged transducers (TR1 and TR4).
13 Twelve strain gauge bridge amplifiers (banks 1 and 3).
14 One digital multimeter.
15 One storage type oscilloscope.
16 One PDP11 minicomputer with software program "TVDDH".
17 One vernier scale calliper.
18 Parallel bars or elbow crutches.
19 Interconnecting cables:
   a. For the amplifier
   i) Transducer connectors to junction box.
   ii) Junction box cable to strain gauge amplifier input.
   iii) Amplifier outputs to PDP11.
   b. For the computer console
   Biomech V7, switch up, connect to schmitt trigger input 1, threshold set to 580, switch down.

SETTING UP OF EQUIPMENT

Ensure that no other user is to be sampling data using the PDP11 minicomputer for the duration of the test. The DR11B TV interface uses the schmitt trigger which will override other "SAM" sampling. In addition, warn users of the tissue mechanics laboratory that the PDP hardwiring to that laboratory will be diverted into the biomechanics laboratory.

CAUTION: On "NO" occasion have the strain gauge bridge amplifiers on without the transducers correctly connected to the inputs. Do not plug or unplug standard jacks into the "Tardis" in the biomechanics laboratory with the corresponding mini-jack at the other end of the cable connected to the output from the amplifiers, always remove the mini-jack on the output before altering the standard jack on the tardis.

1 Connect transducers, TR1 and TR4 to the connecting cables, using the security screws.
2 Connect the TR1 and TR4 cables to the inputs of the strain gauge bridge amplifier banks 1 and 3 respectively.
3 Set the charge amplifiers of the force plates to 50 mech. units per volt on the top row and 200 mech. units per volt on the bottom row.
4 Set the buffer amplifiers of the force plates to 1, 1, 2, 1.25, 2 and 1.25 for Fx, Fy, Fz, Mx, My and Mz respectively.
5 Connect the appropriate cable to the back of the side camera TV monitor (cable CH3 for left and CH4 for right).
6 Change the DR11B interface thumb-wheels behind the central top black cowel on the front of the PDP11, room 3.05A, to 24 from its normal setting of 12.
7 Connect jack sockets 17-24 (in black letters) to sockets 25-32 (in white labels) on the front of the "Tardis" beside the PDP11, room 3.05A, in order of ascension.
8 Load the data disk into DL1: on the PDP11.
9 Set switch V7 on the "Tardis" next to the PDP, room 3.05A, UP and connect to Schmitt trigger input 1, threshold 580, slope switch DOWN.
10 Connect the jack leads to the biomech "Tardis", channels 21-32, and leave the mini-jack ends near to the strain gauge amplifiers. These leads will eventually plug into banks 1 and 3, channels in order of ascension.
11 Turn on the strain gauge amplifier banks 1 and 3.
12 Turn on the charge and buffer amplifiers for the force plates.
13 Turn on the side camera to be used and the front camera.
14 Switch on the equipment (strain gauge amplifiers, charge and buffer amplifiers for force plates and TV cameras) at least 60 minutes before the test commences. This allows the system to warm up and stabilises it.
15 Log on to PDP11 on terminal beside the force-plate console, mount DL1: , run software "TVDDH" by typing @[270,1]TVDDH.
16 At least 60 minutes after turning on the equipment, set the strain gauge amplifiers bridge voltages to

6.00V for the force channels and 3.00V for the moment channels:
- i) Place multimeter probes into "Bridge voltage" in appropriate bank.
- ii) Set meter switch to "Bridge Voltage".
- iii) Set "Amplifier monitored" to appropriate channel and set voltage by use of a small screwdriver in appropriate "Bridge Voltage".

17 Set the strain gauge amplifier gains to 2000 for Fx, Fy, Fz, Mx and My, while 1000 is set for Mz.
18 Set the TV system sensitivity and reset FP1.

PLACEMENT OF MARKERS

1 Place the removable markers (A and B) on the lateral side blank plate attachments.
2 Mount the Marker-Plate (with marker E) on the lateral side blank plate.
3 Place the markers C and D on the shank.
4 Measure the distances between the markers (as shown on the diagram in the record form - Appendix 11B)
5 Measure the distances PP′, QQ′ and RR′ (as shown on the record form diagram - Appendix 3C).

STATIC VIEW OF THE MARKERS

1 Set the switch of the TV interface to "ON".
2 Reset FP1.
3 The subject stands still over the origin of GRS.
4 Run the program "TVDDH".
5 Press "RETURN" on the computer key-board.
6 Program collects the data for 10 seconds.
7 Switch the TV interface to "OFF".
8 Check the acquired data with option 4.

APPLICATION OF TRANSDUCERS

1 Remove the Marker-Plate with marker from the lateral blank plate.
2 Remove the blank plates one at a time and replace with load transducers (TR1 - Medial side, TR4 - Lateral side).
3 Tie the interconnecting cables with a belt round the waist.

ACQUISITION OF BASE-LINE OUTPUT OF LOAD CHANNELS

1 The subject sits on the chair with the injured leg supported comfortably on another chair in front.
2 Balance the bridge amplifiers:
- i) Place multimeter probes into "Amplifier output" in appropriate bank.
- ii) Use coarse and fine zero adjustments on appropriate channel to balance to zero volts.

3 Run the program "TVDDH".
4 Press "RETURN" then switch the remote control box to "ON".

5 Program collects the output from the transducers/amplifiers for 10 seconds.
6 Sort and check data using option 13.

DYNAMIC TEST

1 Reset FP1.
2 The subject starts to walk from a suitable distance from FP1.
3 Adjust the starting point if necessary.
4 Run the program "TVDDH".
5 Check that the TV interface switch is "ON" and then press "RETURN" when the subject is about to step on FP1.
6 Switch the TV interface to "OFF" when the patient's foot is taken off from FP1.
7 Sort the collected data.
8 Check the acquired data with option 4 for TV data and 13 for force-plate data.
9 Repeat the dynamic test 3 times.
10 For the patient's first visit the routine for the dynamic test is repeated twice, once with the "foot-piece" and once with the foot-piece off.

CALIBRATION OF THE BODY WEIGHT

1 Reset FP1.
2 Ask the patient to stand away but near to the force-plate.
3 Run the program "TVDDH".
4 Press "RETURN" and then ask the patient to step on the force-plate.
5 Data is acquired by the program for 10 seconds.

CALIBRATION OF THE POSITIONAL DATA

1 Place the calibration board at the ground origin with the front surface facing the front camera.
2 Acquire the static view of the board by the front camera, by running program "TVDDH" and pressing "RETURN".
3 Repeat the same procedures for the side camera.

APPENDIX-3C
PATIENT TEST RECORD FORM

1. PATIENT PARTICULARS

NAME:
PATIENT CODE:
SEX:
AGE:
DIAGNOSIS:
DATE OF INJURY:
MECHANISM OF INJURY:
CLINICAL REMARKS:

LEVEL OF FRACTURE (FROM KNEE JOINT): m
BODY WEIGHT: N
HEIGHT: m

2. CAMERA SETTING

FRONT CAMERA:
- DISTANCE TO GROUND ORIGIN m
- HEIGHT FROM GROUND m

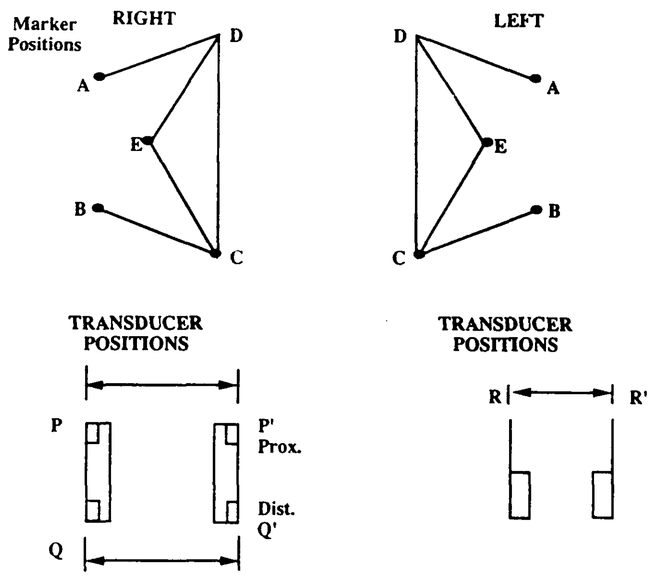
RIGHT CAMERA:
- DISTANCE TO GROUND ORIGIN m
- HEIGHT FROM GROUND m

LEFT CAMERA:
- DISTANCE TO GROUND ORIGIN m
- HEIGHT FROM GROUND m

3. DATA ACQUISITION

DATE OF TEST:
INJURED LEG: L / R

3.1 MARKER POSITIONS



3.2 X-RAY DATA

X-RAY NUMBER: DATE:
ROTATION ABOUT X-AXIS:
ROTATION ABOUT Z-AXIS:
DISTANCE OFF-SET: X = m
Y = m
Z = m

3.3 TRANSDUCER-FORCEPLATE DATA

FORCE-PLATE SETTING: FP1 / FP2
UPPER AMPLIFIERS: mech. units/volt
LOWER AMPLIFIERS: mech. units/volt
TRANSDUCER TR1: FACING (RIGHT/LEFT), (INVERTED)
TRANSDUCER TR4: FACING (RIGHT/LEFT), (INVERTED)
AMPLIFIER SETTING:
BRIDGE VOLTAGE: V (FORCE); V (MOMENT)

GAIN:	Fx	Fy	Fz
	Mx	My	Mz

3.4 TEST RECORDING FILES

a) CALIBRATION BOARD. L / R CAMERA CHANNEL 3 / 4
__BDFC01
__BDFC02
__BD_C01
__BD_C02

b) STATIC VIEW OF THE MARKERS
__STAT01
__STAT02

c) BODY WEIGHT CALIBRATION
__BWCB01
__BWCB02

d) DYNAMIC TEST
____001
____002
____003
____004
____005
____006
____007
____008
____009
____010

APPENDIX-5A

PATIENT'S NAME: MIGUEL GOVERNO
CLINICAL SUMMARY: SUSTAINED A CLOSED SPIRAL FRACTURE, LOWER 1/3 TIBIAL SHAFT (LT). FRACTURE STIFFNESS MEASUREMENT WAS DONE 17 WEEKS POST-INJURY.

FIRST SERIES

TEST	FORCE (NEWTONS)		"Y" DISTANCE (METRES)	DEFLECTION (DEGREES)	STIFFNESS (Nm/deg)
1	34.60	*	.12	/ 1.235	= 3.36
2	34.60	*	.12	/ 1.170	= 3.54
3	36.53	*	.12	/ 1.235	= 3.54
4	34.60	*	.12	/ 1.235	= 3.36
5	35.57	*	.12	/ 1.300	= 3.28
6	35.57	*	.12	/ 1.300	= 3.28
7	34.60	*	.12	/ 1.235	= 3.36
8	34.60	*	.12	/ 1.235	= 3.36
9	33.64	*	.12	/ 1.105	= 3.65
10	35.57	*	.12	/ 1.235	= 3.45
11	38.45	*	.12	/ 1.365	= 3.38
12	37.57	*	.12	/ 1.300	= 3.28
13	37.57	*	.12	/ 1.235	= 3.45
14	37.49	*	.12	/ 1.365	= 3.29

MEAN = 3.39 (S.D 0.11)
COEFFICIENT OF VARIATION = 3.24 %

SECOND SERIES

TEST	FORCE (NEWTONS)		"Y" DISTANCE (METRES)	DEFLECTION (DEGREES)	STIFFNESS (Nm/deg)
1	37.49	*	.12	/ 0.910	= 4.94
2	36.53	*	.12	/ 0.845	= 5.18
3	39.41	*	.12	/ 0.910	= 5.19
4	38.45	*	.12	/ 0.780	= 5.91

MEAN = 5.30 (S.D 0.41)
COEFFICIENT OF VARIATION = 7.73%
MEAN OF 1ST AND 2ND SERIES = 4.34 (S.D 0.85)
COEFFICIENT OF VARIATION = 19.58%

APPENDIX-5B

PATIENT'S NAME: STEPHEN CLUNESS
CLINICAL SUMMARY: FRACTURE TIBIAL SHAFT TREATED IN AN EXTERNAL FIXATOR. FRACTURE STIFFNESS MEASUREMENT DONE 7 WK. POST INJURY.

TEST	FORCE (NEWTONS)		"Y" DISTANCE (METRES)		DEFLECTION (DEGREES)		STIFFNESS (Nm/deg)
1	24.03	*	.18	/	1.82	=	2.37
2	29.80	*	.18	/	1.36	=	3.94
3	26.91	*	.18	/	1.36	=	3.56
4	32.68	*	.18	/	1.62	=	3.63
5	31.72	*	.18	/	1.62	=	3.52
6	34.60	*	.18	/	1.56	=	3.99
7	28.84	*	.18	/	1.30	=	3.99
8	24.03	*	.18	/	1.43	=	3.02
9	23.07	*	.18	/	1.23	=	3.37

MEAN = 3.48 (S.D 0.52)
COEFFICIENT OF VARIATION = 14.94%

APPENDIX-6A

DOCUMENTATION: FRACTURE STIFFNESS TEST

NAME________________
AGE____ SEX____
OCCUPATION__________ HOSPITAL NO.________
CONTACT ADD./TELEPHONE_________________________________
DATE OF TEST________ DISK NO.________
DIAGNOSIS___________ FRACTURE LEG________
DATE OF INJURY___________
TIME SINCE INJURY________
DISTANCE OF BRIDGE "D" FROM REF.________mm
DISTANCE OF BRIDGE "P" FROM REF.________mm
LOAD "F" ON FRACTURED LIMB______________kg
LOAD "F" ON INTACT LIMB_________________kg
SIZE OF CUFF USED________
"Y" DISTANCE_____________meters

FILE CODE REMARKS
_____1R
_____2R
_____3R
_____4R
_____1L
_____2L
_____3L
_____4L

APPENDIX-6B
COLUMN CODES

A - CASE NUMBER
B - HOSPITAL NUMBER
C - SEX OF THE PATIENT
D - AGE OF THE PATIENT
E - DATE OF INJURY
F - MORPHOLOGY (TYPE) OF FRACTURE
G - TYPE OF TREATMENT
H - DATE OF FIRST TEST
J - PERCENTAGE STIFFNESS - FIRST TEST
K - DATE OF SECOND TEST
L - PERCENTAGE STIFFNESS - SECOND TEST
M - DATE OF THIRD TEST
N - PERCENTAGE STIFFNESS - THIRD TEST

CODES FOR THE RAW DATA

SEX OF THE PATIENT (Column code - C):

FEMALE	1
MALE	2

TYPE OF TREATMENT (Column code - F):

FUNCTIONAL BRACING	1
PINS IN PLASTER	2
EXTERNAL FIXATOR	3

MORPHOLOGY (TYPE) OF FRACTURE (Column code - G):

TRANSVERSE (0 - 15 degrees)	1
SHORT OBLIQUE (15 - 45 degrees)	2
LONG OBLIQUE (> 45 degrees)	3
SPIRAL	4
COMMINUTED	5
SEGMENTAL	6

A	B	C	D	E	F	G
01	426453	1	75	060389	1	3
02	520532	2	34	010789	3	6
03	381231-V	2	34	050689	3	5
04	106038	2	81	181289	1	6
05	873492-M	2	55	180489	2	4
06	874434-V	2	25	280789	3	5
07	878922-K	2	29	170889	3	5
08	878326-M	2	30	060889	3	5
09	678911-K	2	23	181289	1	5
10	878006-W	1	85	290789	1	1

A	H	J	K	L	M	N
01	040789	21	180789	47	010889	55
02	211189	41	051289	51	191289	60
03	020190	24	160190	40	060290	61
04	290190	28	190290	31	190390	50
05	290190	29	190290	58	190390	70
06	300190	70	200290	72	200390	75
07	300190	33	150290	70	150390	78
08	300190	43	060290	63	270290	65
09	050290	37	190290	46	190490	63
10	060290	27	200290	36	060390	43

APPENDIX 8A
DOCUMENTATION: 2 IN 1 FUNCTIONAL BRACE SERIES

PERSONAL DETAILS

CASE NUMBER: ______
NAME: ______
SEX: ______
DATE OF BIRTH: ______
AGE: ______
HOSPITAL NUMBER: ______
ADDRESS: ______
TELEPHONE: ______
OCCUPATION: ______

INJURY DETAILS

DATE OF INJURY: ______
MECHANISM OF INJURY: ______
SIDE OF INJURY: ______

FRACTURE DETAILS

FRACTURE CLASSIFICATION: ______
SITE OF FRACTURE: ______
HEIGHT OF FRACTURE FROM ANKLE JOINT: ______mm
LENGTH OF TIBIA: ______mm
MORPHOLOGY OF FRACTURE: ______
IS FRACTURE AXIALLY STABLE: ______
FRACTURE FRAGMENT APPOSITION: ______
ASSOCIATED SKELETAL PATHOLOGY: ______

TREATMENT DETAILS

TREATMENT GROUP: ______
TYPE OF ANAESTHESIA: ______
FIRST OPERATION: ______ DATE: ______
SECOND OPERATION: ______ DATE: ______
FIRST CAST: ______ DATE: ______
SECOND CAST: ______ DATE: ______
THIRD CAST: ______ DATE: ______
FUNCTIONAL BRACE MATERIAL: ______
FIRST ADMISSION DATE: ______
FIRST DISCHARGE DATE: ______
SECOND ADMISSION DATE: ______
SECOND DISCHARGE DATE: ______
THIRD ADMISSION DATE: ______
THIRD DISCHARGE DATE: ______
TOTAL NUMBER OF DAYS IN HOSPITAL: ______
COMPLICATION 1: ______
COMPLICATION 2: ______
COMPLICATION 3: ______

FUNCTIONAL BRACE DETAILS

BRACE APPLICATION DATE: ______
FUNCTIONAL BRACE APPLICATION ON DAY: ______
FUNCTIONAL BRACE REMOVED ON DATE: ______
TOTAL NUMBER OF DAYS FROM DATE OF INJURY: ______
NUMBER OF DAYS IN FUNCTIONAL BRACE: ______
NUMBER OF BRACES USED: ______

RADIOLOGICAL EVALUATION

I. IMMEDIATELY AFTER APPLICATION OF FUNCTIONAL BRACE.
II. IMMEDIATELY AFTER REMOVAL OF FUNCTIONAL BRACE.

ANTERO-POSTERIOR ANGULATION: API___ APII___
MEDIO-LATERAL ANGULATION : MLI___ MLII___
SHORTENING : SHI___ SHII___
APPEARANCE OF CALLUS : CAI___ CAII___

CLINICAL EVALUATION FOR DISCONTINUATION OF BRACE

USE OF LIMB WITHOUT DISTRESS: DATE:_______
FULL WEIGHT BEARING : DATE:_______
ACTIVE USE OF KNEE/ANKLE JT.: DATE:_______

PHYSIOTHERAPY PROGRESS EVALUATION

A) R.O.M BEFORE APPLICATION OF BRACE
KNEE:_____ ANKLE:_____ SUB-TALAR:_____
FOREFOOT:_____
B) R.O.M AFTER REMOVAL OF THE BRACE
KNEE:_____ ANKLE:_____ SUB-TALAR:_____
FOREFOOT:_____
C) WEIGHT BEARING. BODY WEIGHT:_____
WEIGHT BEARING AFTER 2 WEEKS OF BRACE APPLICATION:_
WEIGHT BEARING ON REMOVAL OF BRACE:_____
D) EXTENSION LAG
EXTENSION LAG ON APPLICATION OF BRACE:_____
EXTENSION LAG ON REMOVAL OF BRACE:_____

APPENDIX - 8B

COLUMN CODES FOR RAW DATA

A - CASE NUMBER
B - AGE OF PATIENT (Years)
C - SEX OF PATIENT
D - HOSPITAL NUMBER
E - OCCUPATION OF PATIENT
F - DATE OF INJURY
G - MECHANISM OF INJURY
H - CLASSIFICATION OF FRACTURE
J - SIDE OF INJURY
K - SITE OF FRACTURE
L - HEIGHT OF FRACTURE FROM ANKLE JOINT (Millimetres)
M - LENGTH OF TIBIA (Millimetres)
N - MORPHOLOGY (TYPE) OF FRACTURE
P - AXIAL STABILITY OF FRACTURE
Q - APPOSITION OF FRACTURE FRAGMENT
R - STATUS OF IPSILATERAL FIBULA
S - ASSOCIATED SKELETAL PATHOLOGY
T - TYPE OF TREATMENT
U - TYPE OF ANAESTHESIA
V - TYPE OF FIRST OPERATION
W - TYPE OF SECOND OPERATION
X - TYPE OF FIRST CAST
Y - TYPE OF SECOND CAST
Z - TYPE OF THIRD CAST
AA - APPLICATION OF FUNCTIONAL BRACE POST-INJURY (Days)
BB - TOTAL STAY IN HOSPITAL (Days)
CC - HEALING TIME (Days)
DD - NUMBER OF DAYS FUNCTIONAL BRACE WAS KEPT ON (Days)
EE - NUMBER OF FUNCTIONAL BRACES APPLIED
FF - STANDARD ANGULATION AT THE TIME OF BRACE APPLICATION (Degrees)
GG - STANDARD ANGULATION AT THE TIME OF HEALING(Degrees)
HH - CHANGE IN STANDARD ANGULATION (Degrees)
JJ - SHORTENING AT THE TIME OF BRACE APPLICATION (Millimetres)
KK - SHORTENING AT THE TIME OF HEALING (Millimetres)
LL - CHANGE IN SHORTENING (Millimetres)
MM - COMPLICATION ONE
NN - COMPLICATION TWO
PP - PERIOD OF FOLLOW-UP (Months)
QQ - KNEE JOINT RANGE OF MOVEMENT AT FOLLOW-UP (In percentage relative to the normal side)
RR - ANKLE JOINT RANGE OF MOVEMENT AT FOLLOW-UP (In percentage relative to the normal side)
SS - SUB-TALAR JOINT RANGE OF MOVEMENT AT FOLLOW-UP (In percentage relative to the normal side)
TT - FORE-FOOT JOINT RANGE OF MOVEMENT AT FOLLOW-UP (In percentage relative to the normal side)

A	B	C	D	E	F	G	H	J	K
01	63	1	848014/W	5	151087	4	1	2	2
02	42	1	712983/E	6	121187	4	1	1	3
03	39	2	849567/M	2	141187	1	1	1	2
04	21	2	797231/H	2	281187	2	1	2	3
05	74	1	110113/K	5	140188	6	3	2	1
06	31	2	852499/M	1	190188	12	1	1	3
07	13	1	834687/R	3	010887	6	1	1	2
08	44	1	620496/K	2	020288	4	1	1	3
09	63	1	853467/K	6	060288	4	1	2	3
10	12	1	854516/V	3	220288	3	1	1	2
11	17	2	855185/E	3	120388	2	1	1	2
12	21	2	855168/W	3	120388	1	1	1	3
13	18	2	834848/M	2	130388	9	1	2	3
14	49	1	534427	5	190388	4	1	1	3
15	35	2	856398/H	1	100488	4	1	2	3
16	48	1	436141	2	170488	3	1	2	2
17	23	2	857035/M	1	220488	6	2	2	2
18	24	2	742641/H	3	240488	6	1	1	2
19	18	2	858046/X	1	150588	12	1	1	3
20	23	2	811672	1	180588	1	1	1	2
21	79	1	086579/K	5	280388	6	1	2	1
22	28	2	625410	4	140687	1	1	1	3
23	24	2	840372/R	2	110788	1	1	1	3
24	67	1	471721	5	110788	4	1	1	3
25	21	2	764579/R	1	160788	1	1	1	2
26	46	2	861313/K	1	250788	10	1	1	3
27	42	2	863538/W	1	210888	1	1	2	2
28	33	2	864579/K	1	081088	1	1	1	1
29	33	2	845406/E	1	091088	11	2	2	3
30	38	2	460434/W	2	101088	1	1	1	3
31	22	2	865262/K	4	221088	1	1	1	3
32	75	1	494517/L	6	100289	7	4	2	2
33	75	1	426453	6	060389	4	1	1	2
34	40	2	871905/H	1	100389	5	3	1	3
35	17	2	871925/E	1	120389	9	1	2	3
36	18	2	871927/M	1	120389	1	1	1	2
37	23	1	657597/V	2	160389	3	1	2	2
38	24	2	872336/V	1	180389	1	1	1	3
39	26	2	444719/M	2	150489	1	1	1	3
40	20	1	840434/L	4	171287	3	3	1	2
41	20	1	857055/R	1	240488	8	1	2	3
42	14	2	869615/X	3	240189	6	1	1	3
43	20	2	871439/A	3	010389	1	1	2	2
44	35	2	872756/V	2	010489	2	1	1	2
45	13	1	857060/E	3	050489	3	1	2	3
46	31	2	874659	2	140589	1	1	1	2
47	31	2	865954/E	1	150589	10	1	2	3
48	32	2	626616	1	020689	4	1	2	3
49	34	2	381231/V	2	050689	6	3	1	3
50	55	2	873492/M	2	180489	4	1	2	3
51	36	2	875376/E	1	290589	5	4	2	3
52	36	2	878762/V	1	260689	6	1	2	1

A	B	C	D	E	F	G	H	J	K
53	36	2	878762/V	1	260689	6	1	1	1
54	49	1	364989	6	170789	6	3	2	3
55	20	2	878455/A	1	080889	8	2	2	2
56	14	2	878919/H	3	170889	6	1	2	2
57	15	2	876021/V	3	120689	6	1	1	2
58	34	2	566731	2	160689	1	1	1	3
59	34	2	520532	2	010789	6	2	2	2
60	25	2	874434/V	2	280789	9	3	2	2
61	85	1	878006/W	5	290789	4	1	2	1
62	30	2	878326/M	1	060889	12	1	1	2
63	30	2	878356/M	1	060889	12	4	2	2
64	29	2	878922/K	1	170889	10	1	1	2
65	30	2	594076	4	300989	11	2	1	3
66	24	1	881935/A	3	221089	3	1	1	3
67	55	1	406832	2	011289	4	1	2	3
68	23	2	678911/K	2	181289	6	1	1	1
69	81	2	106038	5	181289	6	1	1	1
70	61	2	462587/L	5	060190	4	1	2	3
71	32	2	929328/K	2	110190	1	1	1	3
72	41	2	885415/X	2	160190	6	1	2	2
73	30	2	574535/A	2	170390	2	1	2	2
74	16	2	888937/E	3	010490	5	1	1	2
75	33	2	848678/X	1	030987	10	4	1	2
76	27	2	655014/B	4	111087	1	1	1	3
77	23	2	846562/A	1	131287	12	1	2	3
78	22	2	863115/H	1	020988	11	1	1	3
79	28	2	772399/H	4	040589	9	2	2	3
80	24	2	874638/A	1	120589	6	1	1	3

A	L	M	N	P	Q	R	S	T	U
01	115	360	4	2	4	2	2	1	1
02	035	350	3	1	4	2	2	1	2
03	130	350	5	1	4	1	2	1	2
04	135	410	1	1	4	1	2	1	2
05	283	335	5	1	3	2	1	1	2
06	120	380	1	1	3	2	2	1	1
07	110	410	6	2	3	2	2	2	1
08	087	339	3	2	3	2	2	1	2
09	035	320	4	1	4	2	2	1	2
10	115	310	4	2	4	1	2	1	2
11	170	390	1	1	4	1	2	1	2
12	117	363	6	2	3	2	2	1	1
13	045	365	1	2	4	2	2	1	1
14	085	338	3	2	3	2	2	2	1
15	085	390	4	2	3	2	2	1	1
16	124	372	6	2	2	2	2	1	2
17	189	389	3	1	4	2	2	2	1
18	171	370	3	2	4	2	2	2	1
19	070	367	2	2	3	1	1	1	2
20	199	378	1	1	4	2	2	1	2
21	250	325	1	2	4	2	1	1	1
22	120	370	1	1	4	1	2	1	2
23	115	390	1	1	4	1	2	1	2
24	048	349	2	2	4	2	2	1	1
25	135	370	1	1	4	1	2	1	2
26	081	365	3	2	4	2	2	2	1
27	130	350	4	2	4	1	2	2	1
28	255	365	1	1	4	2	2	1	2
29	079	373	2	2	4	1	2	1	1
30	101	363	1	1	4	2	2	1	1
31	102	365	2	1	4	2	2	1	1
32	195	347	1	1	4	2	1	2	1
33	147	339	3	2	3	2	2	1	1
34	100	384	5	2	3	1	1	1	1
35	107	373	3	1	4	1	2	1	2
36	127	365	2	1	4	1	2	1	2
37	130	400	4	2	3	1	2	1	2
38	122	374	1	1	4	1	2	1	2
39	099	388	5	2	1	1	2	1	2
40	210	400	1	2	4	2	2	1	1
41	068	359	5	1	4	2	1	1	1
42	067	345	1	1	4	2	2	1	1
43	168	385	1	1	4	2	2	1	1
44	168	402	2	2	4	2	2	2	1
45	072	321	4	1	4	1	2	1	2
46	102	375	3	2	4	1	2	1	2
47	077	398	3	2	1	1	2	1	2
48	082	399	4	1	4	1	2	1	2
49	064	383	5	2	4	2	2	2	1
50	110	400	4	2	2	2	2	2	1
51	043	362	4	2	4	2	2	2	1
52	288	388	5	2	3	2	1	1	2

A	L	M	N	P	Q	R	S	T	U
53	278	388	5	1	4	1	1	1	2
54	067	380	2	2	4	2	2	1	2
55	175	460	1	1	3	1	2	1	1
56	161	387	1	1	4	2	2	1	1
57	167	368	5	1	4	1	2	1	2
58	054	345	4	1	4	2	2	1	2
59	255	440	6	2	4	2	1	2	1
60	166	384	6	2	4	2	1	2	1
61	264	316	1	1	4	1	2	1	2
62	184	366	1	1	4	2	1	1	1
63	122	366	5	2	3	2	1	2	1
64	119	387	5	2	3	2	1	2	1
65	067	368	4	2	3	2	2	2	1
66	091	349	4	2	2	2	2	1	2
67	096	354	4	2	1	2	2	1	2
68	231	388	5	1	3	2	2	1	1
69	300	351	6	2	3	2	2	1	1
70	072	371	5	2	3	2	2	1	2
71	130	421	1	1	4	2	2	1	1
72	152	395	5	2	4	2	2	1	1
73	135	406	1	1	4	1	2	1	2
74	141	381	1	1	4	1	2	1	2
75	151	374	5	2	1	2	1	2	1
76	080	378	2	2	4	2	2	1	1
77	052	334	4	1	4	1	2	1	2
78	100	361	1	1	4	1	1	1	1
79	102	378	5	2	1	2	2	1	1
80	090	372	5	1	4	1	2	1	2

A	V	W	X	Y	Z	AA	BB	CC	DD	EE
01	1	999	1	3	999	026	002	054	028	1
02	999	999	1	3	999	025	002	081	056	1
03	999	999	1	3	999	017	000	059	042	1
04	999	999	1	3	999	019	000	074	055	1
05	999	999	1	3	999	047	888	102	055	1
06	1	999	1	3	999	014	002	077	063	1
07	4	999	2	3	999	072	006	135	063	1
08	999	999	1	3	999	035	002	112	077	1
09	999	999	1	3	999	016	002	079	063	1
10	999	999	1	4	3	015	001	064	049	2
11	999	999	1	3	999	009	000	051	042	1
12	1	999	1	3	999	054	002	100	046	1
13	1	999	1	3	999	043	002	092	049	1
14	4	5	2	3	999	026	006	082	056	1
15	1	999	1	3	999	023	002	085	062	1
16	999	999	1	1	3	022	000	099	077	1
17	2	999	3	999	999	028	004	133	105	1
18	2	999	3	999	999	072	004	160	088	1
19	999	999	1	3	999	029	005	078	049	1
20	999	999	1	3	999	022	001	092	070	2
21	1	1	1	1	3	067	888	086	019	2
22	999	999	1	4	3	064	000	092	028	2
23	999	999	1	3	999	001	002	054	053	1
24	1	999	1	1	3	028	008	063	035	1
25	999	999	1	3	999	023	001	086	063	1
26	4	999	2	3	999	021	004	077	056	1
27	2	999	3	999	999	099	003	155	056	1
28	999	999	1	3	999	030	001	072	042	1
29	1	999	1	3	999	057	003	092	035	1
30	1	999	1	3	999	028	001	077	049	1
31	1	999	1	3	999	032	002	088	056	1
32	2	6	3	4	4	056	888	888	888	2
33	1	999	1	3	999	030	888	140	110	2
34	1	999	1	3	999	035	013	077	042	1
35	999	999	1	3	3	030	001	100	070	2
36	999	999	1	3	999	040	001	072	032	1
37	999	999	1	3	999	042	000	098	056	1
38	999	999	1	3	999	013	000	048	035	1
39	999	999	1	3	3	024	001	107	083	2
40	1	999	1	4	3	043	003	085	042	2
41	1	999	1	3	999	009	013	071	062	1
42	1	999	1	3	999	029	002	043	014	1
43	1	999	1	3	999	028	007	077	049	1
44	4	999	2	3	999	040	002	096	056	1
45	999	999	1	3	3	036	002	078	042	2
46	999	999	1	3	999	022	001	084	062	1
47	999	999	1	3	999	021	002	104	083	1
48	999	999	1	3	999	028	002	070	042	1
49	2	999	4	4	3	111	888	203	092	3
50	4	999	2	3	3	036	001	888	888	2
51	4	999	2	3	999	050	015	085	035	1
52	999	999	3	4	3	053	002	069	016	2

A	V	W	X	Y	Z	AA	BB	CC	DD	EE
53	999	999	3	4	3	053	002	069	016	2
54	999	999	1	3	999	043	007	099	056	1
55	1	999	1	3	999	021	002	091	070	1
56	1	999	1	3	999	012	003	089	077	1
57	999	999	1	3	999	028	002	077	049	1
58	999	999	1	3	999	028	002	084	056	1
59	2	999	4	3	999	056	888	124	068	2
60	2	999	3	999	999	074	888	145	071	1
61	999	999	1	4	3	018	888	205	187	2
62	1	999	1	3	999	039	020	163	124	1
63	2	999	3	999	999	039	020	163	124	2
64	2	3	4	3	999	103	020	187	084	2
65	4	999	2	3	999	027	007	111	084	2
66	999	999	1	3	999	023	002	109	086	1
67	999	999	1	3	999	011	003	104	093	1
68	1	999	1	3	999	049	002	104	055	1
69	1	999	1	3	999	044	888	133	089	1
70	999	999	1	3	999	032	006	096	064	1
71	1	999	1	3	999	020	001	069	049	1
72	4	999	2	3	999	035	002	098	063	1
73	999	999	1	3	999	006	000	077	071	1
74	999	999	1	3	999	029	001	068	039	1
75	2	999	3	3	999	050	006	195	145	2
76	1	999	1	3	999	045	002	087	042	1
77	999	999	1	3	999	096	002	109	013	1
78	1	999	1	4	3	045	005	098	053	2
79	1	999	1	3	3	029	001	106	077	2
80	999	999	1	3	999	018	003	088	070	1

A	FF	GG	HH	JJ	KK	LL
01	06.32	05.65	-00.67	03	03	00
02	05.65	06.40	+00.75	03	03	00
03	00.00	00.00	00.00	00	00	00
04	00.00	02.23	+02.23	00	00	00
05	04.00	04.00	00.00	12	12	00
06	08.00	10.00	+02.00	03	03	00
07	02.00	02.00	00.00	16	17	01
08	01.00	01.00	00.00	09	09	00
09	00.00	00.00	00.00	00	00	00
10	02.23	02.23	00.00	00	00	00
11	00.00	00.00	00.00	00	00	00
12	05.09	05.09	00.00	07	07	00
13	08.94	05.83	-03.11	03	03	00
14	02.23	02.82	+00.59	02	02	00
15	01.00	00.00	-01.00	16	16	00
16	08.00	09.00	+01.00	04	04	00
17	01.00	01.00	00.00	02	02	00
18	07.07	08.48	+01.41	00	00	00
19	11.18	10.19	-00.99	06	06	00
20	08.94	08.94	00.00	00	00	00
21	13.15	24.02	+10.87	07	07	00
22	04.47	05.65	+01.18	00	00	00
23	00.00	00.00	00.00	00	00	00
24	03.16	04.12	+00.96	10	10	00
25	05.09	05.09	00.00	00	00	00
26	06.32	04.47	-01.85	02	04	02
27	01.41	01.41	00.00	00	00	00
28	00.00	00.00	00.00	00	00	00
29	11.18	10.44	-00.74	04	04	00
30	06.00	08.00	+02.00	00	00	00
31	02.82	03.60	+00.78	00	00	00
32	00.00	00.00	00.00	00	00	00
33	10.00	11.00	+01.00	08	11	03
34	11.18	08.94	-02.24	01	02	01
35	05.00	03.16	-01.84	03	03	00
36	00.00	00.00	00.00	00	00	00
37	05.00	05.00	00.00	00	00	00
38	00.00	00.00	00.00	00	00	00
39	06.08	06.00	-00.08	03	04	01
40	00.00	00.00	00.00	00	00	00
41	04.24	05.83	+01.59	00	00	00
42	02.00	02.00	00.00	00	00	00
43	00.00	00.00	00.00	00	00	00
44	00.00	00.00	00.00	00	00	00
45	06.32	06.32	00.00	05	05	00
46	04.00	04.00	00.00	00	00	00
47	02.23	02.23	00.00	12	12	00
48	01.00	02.00	+01.00	08	08	00
49	12.08	12.08	00.00	00	00	00
50	02.00	06.08	+04.08	10	12	02
51	05.65	04.24	-01.41	06	06	00
52	01.41	01.41	00.00	04	05	01

A	FF	GG	HH	JJ	KK	LL
53	01.41	01.41	00.00	03	03	00
54	07.81	10.00	+02.19	06	08	02
55	05.38	06.32	+00.94	02	03	01
56	06.00	07.00	+01.00	00	00	00
57	02.23	04.12	+01.89	00	00	00
58	01.00	01.00	00.00	05	05	00
59	04.47	07.28	+02.81	22	23	01
60	02.00	02.00	00.00	10	10	00
61	02.23	02.23	00.00	00	00	00
62	05.00	05.00	00.00	00	00	00
63	08.54	08.54	00.00	03	03	00
64	02.82	02.82	00.00	06	06	00
65	02.23	02.82	+00.59	05	05	00
66	05.38	05.38	00.00	09	10	01
67	02.82	06.32	+03.50	14	18	04
68	07.07	07.81	+00.74	04	05	01
69	03.00	03.00	00.00	06	06	00
70	06.08	06.08	00.00	13	14	01
71	02.00	02.00	00.00	00	00	00
72	05.00	05.00	00.00	14	14	00
73	00.00	00.00	00.00	00	00	00
74	03.00	03.00	00.00	00	00	00
75	03.16	03.16	00.00	14	14	00
76	05.38	05.38	00.00	07	08	01
77	00.00	00.00	00.00	05	05	00
78	01.00	01.00	00.00	00	00	00
79	07.07	10.04	+02.97	17	17	00
80	00.00	00.00	00.00	00	00	00

A	MM	NN	PP	QQ	RR	SS	TT
01	999	999	*	*	*	*	*
02	999	999	27	100	100	100	100
03	999	999	29	100	100	100	100
04	999	999	29	100	100	100	100
05	999	999	*	*	*	*	*
06	999	999	27	100	098	097	095
07	999	999	32	100	100	098	100
08	999	999	26	100	100	092	100
09	2	999	*	*	*	*	*
10	999	999	26	100	100	098	100
11	999	999	25	100	100	100	100
12	999	999	25	100	100	089	100
13	999	999	25	100	090	092	090
14	999	999	25	098	090	095	083
15	999	999	24	100	098	098	097
16	999	999	*	*	*	*	*
17	999	999	*	*	*	*	*
18	5	1	24	100	089	085	090
19	999	999	*	*	*	*	*
20	999	999	23	100	100	100	100
21	7	999	25	092	100	100	080
22	999	999	22	100	100	100	100
23	999	999	21	100	100	095	095
24	999	999	21	100	100	100	092
25	3	999	*	*	*	*	*
26	4	999	21	100	090	089	092
27	5	1	*	*	*	*	*
28	999	999	18	100	090	100	100
29	999	999	*	*	*	*	*
30	999	999	18	100	100	100	100
31	999	999	18	100	100	100	100
32	5	1	14	096	086	100	083
33	4	999	*	*	*	*	*
34	999	999	13	095	096	097	098
35	6	999	*	*	*	*	*
36	999	999	13	100	100	082	100
37	999	999	13	098	096	100	100
38	999	999	13	100	100	100	100
39	2	999	12	100	075	086	100
40	999	999	28	100	100	100	100
41	999	999	*	*	*	*	*
42	999	999	15	100	100	100	100
43	999	999	14	100	100	100	100
44	999	999	*	*	*	*	*
45	999	999	*	*	*	*	*
46	999	999	12	096	082	100	100
47	999	999	*	*	*	*	*
48	999	999	*	*	*	*	*
49	1	999	*	*	*	*	*
50	1	999	12	100	100	082	100
51	8	999	11	100	075	100	100
52	999	999	*	*	*	*	*

A	MM	NN	PP	QQ	RR	SS	TT
53	999	999	*	*	*	*	*
54	999	999	*	*	*	*	*
55	999	999	08	100	100	100	100
56	999	999	09	100	100	100	100
57	999	999	11	100	100	100	100
58	999	999	11	100	100	100	100
59	999	999	*	*	*	*	*
60	1	999	09	100	082	080	085
61	1	999	*	*	*	*	*
62	1	999	08	100	100	100	100
63	1	999	08	100	100	092	083
64	1	999	08	100	067	100	100
65	999	999	*	*	*	*	*
66	999	999	06	100	100	100	100
67	999	999	05	100	100	100	100
68	999	999	06	100	100	100	100
69	999	999	05	100	095	095	100
70	2	999	*	*	*	*	*
71	999	999	04	100	100	100	100
72	999	999	04	100	100	100	100
73	999	999	03	100	100	095	100
74	999	999	03	100	100	100	100
75	1	999	*	*	*	*	*
76	999	999	*	*	*	*	*
77	999	999	06	100	100	100	100
78	999	999	*	*	*	*	*
79	999	999	*	*	*	*	*
80	999	999	*	*	*	*	*

APPENDIX-8C
CODES FOR THE VARIABLES IN THE RAW DATA

SEX OF THE PATIENT (Column code - C):

FEMALE	1
MALE	2

OCCUPATION OF THE PATIENT (Column code - E):

MANUAL WORKER	1
DESK JOB	2
STUDENT	3
UNEMPLOYED	4
RETIRED	5
HOUSEWIFE	6

MECHANISM OF INJURY (Column code - G):

FOOTBALL	1
RUGBY	2
SKIING	3
FALL FROM HEIGHT < 6 FEET	4
FALL FROM HEIGHT > 6 FEET	5
PEDESTRIAN HIT BY A CAR	6
PEDESTRIAN HIT BY MOTOR-CYCLE	7
PASSENGER IN A CAR HIT BY ANOTHER CAR	8
M/CYCLIST HIT BY ANOTHER CAR	9
ACCIDENT AT WORK	10
ASSAULT	11
M/CYCLIST HIT BY M/CYCLIST	12

CLASSIFICATION OF FRACTURES (Column code - H):

SIMPLE	1
COMPOUND	
GRADE I (< 2 cm)	2
GRADE II (2 - 5 cm)	3
GRADE III (> 5 cm)	4

SIDE OF INJURY (Column code - J):

RIGHT	1
LEFT	2

SITE OF FRACTURE (Column code - K):

PROXIMAL 1/3rd OF SHAFT	1
MIDDLE 1/3rd OF SHAFT	2
DISTAL 1/3rd OF SHAFT	3

MORPHOLOGY (TYPE) OF FRACTURE (Column code - N):

TRANSVERSE (0 - 15 degrees)	1
SHORT OBLIQUE (15 - 45 degrees)	2
LONG OBLIQUE (> 45 Degrees)	3
SPIRAL	4
COMMINUTED	5
SEGMENTAL	6

AXIAL STABILITY OF FRACTURE (Column code - P):	
YES	1
NO	2
APPOSITION OF FRACTURE FRAGMENTS (Column code - Q):	
GRADE 1 (0-25%)	1
GRADE 2 (26-50%)	2
GRADE 3 (51-75%)	3
GRADE 4 (76-100%)	4
STATUS OF IPSILATERAL FIBULA (Column code - R):	
INTACT	1
FRACTURED	2
ASSOCIATED SKELETAL PATHOLOGY (Column code - S):	
YES	1
NO	2
TYPE OF TREATMENT (Column code - T):	
PRIMARY TREATMENT GROUP	1
SECONDARY TREATMENT GROUP	2
TYPE OF ANAESTHESIA (Column code - U):	
GENERAL ANAESTHESIA	1
ANALGESIA	2
TYPE OF OPERATION (Column codes - V & W):	
MUA + LONG LEG CAST	1
MUA + EXTERNAL FIXATOR	2
SKIN GRAFTING	3
MUA + PINS IN PLASTER	4
MUA + 2 IN 1 FUNCTIONAL BRACE	5
TIBIAL NAILING	6
TYPE OF CASTS (Column codes - X, Y & Z):	
LONG LEG CAST	1
PINS IN PLASTER	2
2 IN 1 FUNCTIONAL BRACE	3
SARMIENTO CAST	4
COMPLICATIONS (Column codes - MM & NN):	
DELAYED UNION	1
REDNESS OF THE SKIN UNDER THE CAST	2
DIGGING OF THE PLASTER INTO THE SKIN	3
SWELLING OF FOOT	4
PIN TRACT INFECTION	5
LOOSENING OF THE BRACE	6
LOSS OF POSITION IN THE BRACE > 5 Deg.	7
RESTRICTED ROM OF ANKLE > 30% OF NORMAL	8
MISCELLANEOUS NUMERICAL CODE FOR ALL VARIABLES	
NO VALUE	999
DATA NOT TO BE INCLUDED	888
MISSING VALUE	*