Forces Measured During Femoral Lengthening in Children

by

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FORCES MEASURED DURING FEMORAL

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ABSTRACT

The forces generated during femoral lengthening in humans have not yet been studied, and existing studies of tibial lengthening have not addressed the forces acting during static or dynamic weight bearing. In this study a system was developed to measure forces during femoral limb lengthening by the Ilizarov technique, using a distraction rate of 1 mm per day applied as four lengthenings of 0.25 mm. The system was used to measure the distraction force in the limb overnight, and the forces applied to the frame during static and dynamic weight bearing in three teenage subjects. Axial load, and the magnitude of the bending moment and the orientation of the plane with respect to the anterior direction were calculated.

A progressive increase in axial load secondary to distraction was seen in all three subjects during the distraction period, peaking towards the end of distraction at 428, 447 and 673 N. Bending moments reached peak values of 26.3, 16.3 and 34.7 Nm, orientated in a plane at 77°, 120° and 79° lateral of anterior with respect to the femur. It was found that the change in the axial load in the external fixator between free suspension of the leg and active weight bearing was small in comparison to the resultant ground-foot reaction. A similar result was seen for dynamic weight bearing. Changes of bending moment magnitude and orientation were also small. Measurements taken immediately before and after each individual lengthening showed no significant increase in axial force or bending moment acting on the frame ($p>0.01$).

A diurnal variation of axial load was found, with mean forces measured over a fifty minute period in the evening, at midnight, 5.00 am and in the morning showing significant differences ($p<0.01$). Forces showed a consistent pattern increasing from evening to midnight and then decreasing towards morning. Forces at midnight were significantly greater than in the morning in all the subjects, with a mean difference of 113 N ($p<0.01$). A diurnal variation was also seen in measures taken during static weight bearing, with evening forces being on average 61 N higher than the morning forces ($p<0.01$). These patterns were not found in bending moment magnitude or orientation. It was concluded that the callus played a significant role in load bearing during standing and in resisting distraction during limb lengthening.

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DEDICATION

To my wife, Erin.

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1. INTRODUCTION

Limb length deficiency is a condition which has been treated conservatively over the last 100 years, despite numerous variations and modifications of operations used to address the problem. As each new technique appeared, its use and subsequent assessment showed that the complications of treatment outweighed the benefits in all but the severest cases.

The appearance of the Ilizarov technique of limb lengthening, and the Ilizarov frame for distracting the limb has brought renewed hope for the treatment of limb deficiency. Research by Professor Ilizarov in Siberia in the 1950's allowed a better understanding of the factors affecting bone formation. The introduction of the Ilizarov system to non Soviet bloc countries in the early 1980's has led to a revival of limb lengthening operations using the technique and associated hardware.

The technique is not without complications: Paley (1990) has published a classification system for complications secondary to Ilizarov limb lengthening. A knowledge of forces within the limb and their orientation may lead to a better understanding of the cause, and hence prevention of complications. Muscle contractures, joint luxation, axial deviation, traction injury to nerves and vessels, premature and delayed consolidation are worthy of mention from a biomechanical viewpoint. Pin tract infection and subsequent deep infection are complications that may be indirectly ameliorated by better knowledge of forces during limb lengthening. Further developments using existing technology and the designing of new technology requires these forces to be determined.

From the subject's perspective movement is uncomfortable due to the presence of wires transfixing the soft tissues. Pain can make the subject's experience at the end of distraction miserable.

Knowledge of the biomechanical nature of the callus is uncertain. The distraction rate required has been determined as 1 mm per day, regardless of species, bone operated on or age of the subject (Ilizarov 1989). A study on the forces within the femur during distraction may lead to a better understanding of the nature and biology of distraction, and help determine whether 1 mm per day is the most appropriate distraction rate.

Two papers have been published on forces during distraction of the tibia in humans for a total of three subjects (Wolfson *et al.* 1990 and Leung *et al.* 1979). Similar animal studies have been performed (Kenwright and White 1989). Two papers have looked at distraction forces required to lengthen the lower limb during physeal distraction (Kenwright *et al.* 1990 and Jones *et al.* 1989). No work has been published on forces during distraction of the femur either in humans or in animals.

1.1 OBJECTIVES.

1. To develop and assess a system allowing the measurement of forces during Ilizarov femoral limb lengthening.
2. To determine the axial force required to distract the femur at a rate of 1 mm per day, with respect to the time since operation, overnight variations and effect of each lengthening.
3. To determine the axial forces transmitted through the frame during dynamic and static weight bearing.
4. To determine the changes of direction and magnitude of bending moments acting on the frame with respect to the time since operation, overnight variations and effect of each lengthening.
5. To determine the change of orientation and size of bending moment through the frame during dynamic and static weight bearing.

1.2 GLOSSARY OF TERMS.

Axial force. The sum of the longitudinal forces in the frame being the addition of force in all three load cells.

Bending moment:

magnitude. The numerical size of the bending moment vector.

plane. The plane in which the bending moment lies. Values are quoted in degrees lateral to the anterior plane.

vector. Orientated at 90 degrees to the bending moment plane, being $\phi + 90$ if referring to the bending moment vector on the frame, and $\phi - 90$ if referring to the bending moment vector on the bone.

Compression washers. Washers placed between the load cell and the distal nut on the rod to maintain frame rigidity and allow permanent compression of the load cell.

Days are quoted as days since the operation, the day of operation being day one. Synonymous with postoperative days.

Distraction osteogenesis. The process of new bone formation stimulated by distraction.

Distraction period. The period of days during which the leg is being lengthened at a rate of 1 mm per day.

Dynamic weight bearing. Weight bearing during walking with active movement.

External fixator. A device for maintaining apposition of bone ends with components in direct contact with bone and components external to skin.

Latency period. The time between surgery and distraction (usually seven days) when lengthening is not done.

Lengthening is the 0.25 mm length gained four times a day to effect distraction.

Limb lengthening. The total procedure (ie. operation, latency period, distraction, neutral fixation and frame removal).

Neutral fixation. The period after distraction with the frame still in place allowing ossification of the distracted segment.

Physeal lengthening. Distraction of the epiphysis away from the metaphysis to lengthen the bone through the physeal plate.

Static weight bearing. Weight bearing with no active movement taking place.

12 MN is twelve midnight, or 12 am.

Valgus. Referring to angulation of the lower limb with the distal segment deviating away from the midline.

2. LITERATURE REVIEW.

2.0.1 History of Limb Lengthening.

The methods used for limb lengthening have been as diverse as the aetiologies treated. Subperiosteal stripping (Sola *et al.*, 1963), implantation of foreign material, repeat osteotomies, drilling and curettage, sypathectomy, and alteration of blood supply have all been used to produce an unpredictable amount of leg lengthening (Coleman 1986, Mercer 1983, Paterson 1990).

Distraction of the limb using force was described in 1904 by Codivilla (Codivilla 1904, Freiberg 1912). The leg was distracted using an intense pull on a pin through the *os calcis* after fracture of the bone. Forces of 222 to 444 N over 20 to 30 minutes were required to effect the distraction. The elongation was held with plaster until union. The process was repeated until the desired length was obtained. Complications included epileptiform fits two to three days after distraction (Patterson 1990). Magnuson described a similar technique using ivory pegs to maintain length (Magnuson 1913). A subsequent review of this technique showed that in 14 cases all subjects were profoundly shocked and one died (Patterson 1990).

Subsequent improvements included the slowing of the distraction time; Putti (1934) described a technique where a continual force was used and increased until the desired length was achieved. Distraction would take 18 to 21 days to obtain a length of 6.25 to 10 cm. Forces of 245 N to 490 N were required, the traction force being increased each day.

Abbott (1927) described a method similar to Magnuson's for tibial lengthenings up to 5 cm. His apparatus used a screw and spring mechanism with 1.6 to 3.2 mm being gained per day. Modifications by other surgeons included the preservation of a periosteal sleeve to hasten bone formation (Paterson 1990).

Bosworth (1938) reported his results using Abbott's method and stated he had no mortalities, no loss of extremities, and no failure of lengthening. However all of these early techniques required the patient to remain in bed for the distraction period with the associated complications of long term immobility.

Analysis of clinical results of these early leg lengthening techniques showed unacceptable levels of complications (Compere, 1936), and so other techniques such as shortening the normal leg were recommended. As a result the operation was done infrequently until new techniques were introduced after 1945.

The Anderson technique was popular from the 1950's until the 1970's, and was different from other techniques as the periosteum was preserved (Patterson 1990). A progressive sleeve of periosteal new bone was formed in the distraction gap. The Anderson technique used a distraction rate of 1/16 th of an inch (1.37 mm) once a day using an Abbot type external frame. Various procedural modifications followed, including a delay in the starting of distraction and the preservation of the medullary blood supply to assist fracture vascularization. The patient remained bed bound using this technique as the equipment used was not stiff enough to allow weight bearing. Non union occured in approximately 13% of subjects in a series of 31 tibial lengthenings studied by Coleman and Noonan (1967). Four subjects had transient hyperaesthesia over the distribution of the superficial peroneal nerve. Furthermore, the discrepancy tended to recur in younger subjects as the bone formed compressed on weight bearing. A modified external fixator was used for femoral lengthenings; Manning (1978) reviewed 33 subjects with femoral lengthenings by this technique. Non union in femoral lengthening was less of a problem compared with tibial lengthening, but tension in the fascia lata caused knee stiffness and valgus deformity.

The Wagner technique was developed in the 1960's in Germany, and has been the leg lengthening technique of choice until recent years (Wagner 1978). A distraction rate of 1.5 mm once daily is used in this technique. The bone is supported by an adjustable unilateral external fixator. The patient is mobile during distraction allowing active physiotherapy and prevents the complications of long term bed rest. Angular corrections can be performed due to the mechanics of the fixator. However the lack of knowledge of the best conditions for new bone formation requires most patients to need bone grafting and plating at the end of distraction, involving a second and third operation with increased risk of infection. Complications reported in clinical reviews were collapse of the distracted segment (Paley 1988) and fracture of the bone after the end of treatment in up to 37% of leg lengthenings (Luke *et al.* 1990). Guarniero and Barros (1990) reported 6 plate fractures, 2 deep infections and 6 pin tract infections in 38 leg lengthenings.

The Ilizarov technique has changed the outlook for leg lengthening operations in North America since the beginning of the 1980's. The major difference between this method and the Wagner is the rate and rhythm of distraction allowing new bone to be formed during the distraction process, thus obviating the need to graft the distraction gap. The frame used allows the subject to weight bear and provides the correct biomechanical conditions to induce new bone formation. The design of the frame makes pin tract infection and mechanical failure less likely (Paley 1988). The improved results have broadened the range of conditions meriting limb lengthening.

Wasserstein (1990) introduced his modification of the Ilizarov technique in 1963. If there is inadequate bone formation after the distraction period he recommends the replacement of the new bone with a cylindrical allograft from the bone bank. This is held in place using a thin intramedullary nail allowing earlier removal of the fixator 6 to eight weeks after grafting.

Physeal lengthening (chondrodiastasis) has also been described and extensively investigated in the last 10 years. In this technique the epiphysis is transfixed using wires or pins and distracted from the metaphysis using an external fixator. This technique was described initially by Ring *et al.* in dogs (1958) and by Ilizarov in 1969 (Connolly *et al.* 1986). The bone does not need to be divided and hence the initial operation is less invasive. However, there appears to be a higher incidence of complications compared with callostasis, particularly in maintaining correct alignment and length (Price and Cole 1990). In a clinical review of 102 lengthenings, 10 patients had loss of length of up to 2 cm (Revenko, 1983). The lengthening procedure may damage the growth potential of the growth plate such that the procedure is only indicated in children approaching maturity (Monticelli and Spinelli, 1981).

2.0.2 Forces During Limb Lengthening.

Few studies have examined the forces during gradual distraction of the limb.

Leung *et al.* (1979) studied 2 patients undergoing tibial lengthening using the Anderson technique. Lengthenings of 2 mm per day were made at 9.00 am and 4.00 pm. Lengthening was started immediately postoperatively.

The first subject (a 14 year old girl) obtained a 37 mm length increase over a 28 day period. She developed a neuropraxia and delayed union requiring grafting as complications. A force of 39.2 N was recorded across the fixator postoperatively rising to 122.6 N on the 10 postoperative day, at which time the distraction rate was slowed to 1 mm per day and the force remained constant around 120 N. After the distraction period was finished the force dropped to 29.4 N on the 49 th postoperative day.

Their second subject (a 15 year old boy) gained 39 mm over a 22 day distraction period. The force rose from 20 N to 147 N at the end of distraction. During the period of neutral fixation the force across the frame fell to 59 N.

For both subjects a diurnal variation was seen secondary to each lengthening. An increase in force of 29 N was seen at the time of lengthening. Gradual relaxation occured between lengthenings, and was attributed by the authors to the viscoelastic properties of tissue. They hypothesized that the soft tissues of the lower limb caused the force resisting lengthening, and hence the force required would be proportional to the rate of distraction and the cross sectional area of the lower limb.

The forces during Ilizarov limb lengthening during the distraction period were recorded for one subject by Wolfson *et al.* (1990). The subject was an 11 year old girl undergoing a tibial lengthening. A total length of 50 mm was obtained with an increase of 1 mm per day in four lengthenings per day. An increase from 44 N postoperatively to 233 N was seen during the distraction period, with most of the increase occuring in the first 20 days. This was in contrast to a cadaver tibia lengthened in a materials testing machine where an exponential increase in force was observed (Wolfson *et al.* 1990). Stiffness was calculated (as normalized units) the results having considerable variation. They hypothesized that the force resisting distraction was due to passive stretch or muscular activity and suggested that the plateau of force was due to the "biologic response of the tissue to distraction in combination with some short term mechanical relaxation under load."

Kenwright and White (1989) have studied forces during distraction in New Zealand white rabbits. At a distraction rate of 0.5 mm daily the force rose to 29 N after 20 days.

Some studies have looked at the force required to distract the physis during physeal distraction. These experiments were done to determine if fracture of the physis was a necessary part of leg lengthening. Jones *et al.* (1989) studied the forces in 10 lengthened segments in 7 children. Lengthening of 0.5 mm per day was performed in 2 sessions of 0.25 mm. The length gained varied between 4.5 to 11.5 cm. The distraction force increased in their subjects until the physis fractured, requiring a force between 466 and 780 N. Sometimes the force increase was single peaked, indicating physis fracture, subsequently falling and increasing again to 98 N towards the end of distraction. Other subjects displayed a double peak where a second peak was seen in later lengthening. Pain was associated with increasing force. They noted a rate determined from animals was unlikely to be the optimum rate for humans, and the optimum rate may vary dependent on sex and age factors.

Kershaw and Kenwright (1989) studied distraction forces during physeal lengthening of rabbits after fusion of part of the growth plate. The force during fracture of the physis was greater on the united side. The force pattern corresponded to fracture of the bone bridge in the physeal cartilage.

Kenwright *et al.* (1990) repeated their studies in patients and showed a similar peak during distraction of the physis. The force was dependent on the skeletal maturity of the subject and ranged between 569 N to 804 N. An increase in force early in distraction was seen. A diurnal variation in force with peak-to-trough differences of approximately 98 N over a 24 hour cycle was present in their graphs, although the authors made no comment. A study of distraction in the rabbit reported in the same paper showed that a slow rate of distraction could be used without physeal fracture. If no fracture occured, gradual increase in force was seen up to 16 N after 20 days distraction. A force of 24 N was recorded at fracture when faster rates were used.

Forces across fracture calluses (without distraction) have been monitored on external fixators during tibial fracture healing. Nishimura and Asada (1989) described a number of healing curves, with the bone gradually taking more stress and the frame less. A hyperbolic curve was seen in those subjects with normal healing, and the curve interrupted in those cases with delayed or arrested healing. Order of magnitude was not quoted. Burny and Donkerwolcke (1987) had similar graphs reflecting these patterns for 500 patients with fractured tibiae.

To summarize, forces during tibial metaphyseal distraction after corticotomy, and forces during distraction of the intact tibial and femoral physis are available. Force during Ilizarov distraction callotasis of the tibia peaked at 235 N and was greater than 2 subjects distracted at a faster rate using the Anderson technique when a peak of 157 N was observed. However patient numbers for both studies are too few to draw positive conclusions regarding comparative forces.

Distraction of the physis requires a force in humans of up to 780 N to fracture the growth plate which appears to be a necessary step for physeal distraction.

2.0.3 Forces in the Femur.

Dynamic forces during normal walking have been calculated biomechanically for the knee and the hip joint , but not for the midshaft of the femur. Calculations of joint force at the knee (for 12 subjects) shows load to be an average of 3.03 times body weight ranging from 2.06 to 4.0 times body weight (Morrison 1970). McLeish and Charnley determined the hip joint reaction force to be 1.8 to 2.7 times body weight during one legged stance (1970). Forces calculated during walking are 4.3 times body weight (range of 1.6 to 5.0 times body weight) in Crownshield's *et al.*'s study (1978). Forces of 3 to 4 times body weight have been recorded from instrumented hip prostheses during walking (Rydell, 1966, Davy *et al.* 1988, English and Kilvington 1979). These joint forces and the fact that nails are able to support 5 to 6 times body weight without fracturing *in vivo* (Johnston *et al.* 1986) would suggest that the forces in the midshaft of the femur during dynamic loading would be somewhere within the limits of 1 to 5 times body weight. The ultimate compressive strength of the femur is around 100 times body weight (Evans 1957).

A femoral fixator may be subjected to the dynamic loads of normal activities as well as the forces generated during distraction. Distraction forces in the femur may be up to 30% of body weight determined by extrapolation of forces measured in the tibia. Hence it is hypothesized that the total compressive force in the femur may be in the region of two to three times body weight if the two bone ends act as free bodies, which is close to the failure point of 1500 N for an Ilizarov frame (Galpin *et al.* 1990). The axial load on the fixator device consists of reaction forces from ground contact and limb acceleration, the dynamic muscle forces acting on the bone and the viscoelastic resistance of the soft tissues to the distraction. The fixator shares the load with the callus depending on the elasticity of the callus.

Bending moments are present secondary to the anatomy of the femur, the lateral aspect being in tension and the medial aspect being in compression. Bending moments can also cause fixator failure (Johnston 1986). Soft tissue dynamics modify these moments, the resultant moments in the femur not being known.

2.0.4 Characteristics of External Fixators

External fixators are a means of reducing bone fragments to the anatomical position using a frame outside the skin. The bone segments are immobilized using pins or wires passing through the skin (Behrens 1989). Advantages of external fixation include the accessibility of the frame for manipulation or adjustment after initial fixation, easy access to the injury site, minimal interference with adjacent joints and ease of patient mobilization. Disadvantages of external fixators include damage to structures (nerves and vessels) during frame application. Furthermore, as the pins are continuous through the skin surface a potential route for infection exists, either locally (pin tract infection) or deep (osteomyelitis). Pins can loosen and cause bony sequestra to form. External fixators, particularly ring fixators, are bulky and as such inconvenient to the patient (Behrens 1989).

A number of different designs of external fixators exist each having unique biomechanical characteristics (Chao and Pope 1982). The biomechanical characteristics of the fixator affect it's performance as a fracture fixator and as a stimulator of bone repair and growth. Essentially a fixator that permits a small amount of movement in the axial direction (Kenwright and Goodship 1989) but prevents movement in torsion, bending (Woo 1981) and shear (Sevitt 1981) stimulates the greatest amount of bone repair.

A number of studies have compared the effect of a small amount of movement in the axial direction with a rigid fixation control group; in all cases significantly greater amounts of new bone formation was seen if axial micromovement was permitted (Kenwright *et al.* 1986, Goodship and Kenwright 1985, Wolf *et al.* 1981, Rubin and Lanyon, 1984). Present external fixators will allow approximately 1 mm of movement in the axial direction during weight bearing (Chao *et al.* 1989). Weight bearing has been shown to significantly speed up fracture repair in rats when compared with fractures managed with non weight bearing (Sarmiento *et al.* 1977).

Fixators used in limb lengthening are of a number of types; the Ilizarov frame is a circular fixator with tensioned wires used for fixation. A complete description of the Ilizarov frame is included in the methods. The Wagner (Hughes and Sauer, 1982), Oxford (Kenwright *et al.* 1990) and Orthofix (De Bastiani 1984) are unilateral fixators using rigid half pins of a cantilever design.

The mechanical characteristics of the Ilizarov frame (elasticity, movement at the bone ends, resistance to shear and bending etc) have been extensively studied *in vitro* and compared with other fixators (Paley *et al.* 1990, Gasser *et al.* 1990, Galpin *et al.* 1990, Podolsky *et al.* 1990, Flemming *et al.* 1989). Variations in the construction have been analyzed to determine the best configuration for optimal new bone formation.

Paley *et al.* (1990) studied the biomechanical characteristics of a number of fixator types. The Ilizarov fixator in a femoral and tibial configuration was compared with the Wagner, Orthofix and Oxford unilateral frames. The Ilizarov tibial fixator is the least stiff in all classes apart from lateral bending. The Ilizarov femoral configuration is stiff in torsion and anteroposterior bending, while flexible during axial loading. Unfortunately units for stiffness were not specified so application of their results is limited to these comparisons.

Gasser *et al.* (1990) did a similar study comparing the Ilizarov tibial configuration with a Hoffman Vidal bilateral fixator and an AO fixator in unilateral and quadrilateral configurations. The Ilizarov frame failed at compressive loads of 700 N, with stiffness in the axial direction being 60 N/mm for low loads and 125 N/mm for high loads. Galpin *et al.* (1990) showed the Ilizarov frame to fail at higher loads of 1400 N, and the unilateral fixators to fail at lower loads (620 N). All of the fixators tested were considerably stiffer than the Ilizarov in all modes, except for the unilateral AO frame which is torsionally weaker and weaker in mediolateral bending. The Ilizarov frame is the only frame to show an increasing resistance to axial loading with increasing load, also demonstrated by Podolsky *et al.* (1990). The Ilizarov fixator will react differently to dynamic loads in the axial direction as an increased resistance is seen with increasing displacement, a property not seen in the cantilever frames. The Ilizarov fixator is unique as axial load is not associated with a bending moment, so that axial load will cause a uniform displacement across the fracture zone. Cantilever frames have a variable displacement with axial load across the fracture zone (Paley 1988).

Flemming *et al.* (1989) studied the stiffness of a number of different fixators. The Ilizarov fixators were more resistant than unilateral fixators in AP bending, whereas the unilateral fixators (attached on the lateral side) were more resistant to lateral bending. In axial compression the Ilizarov frame was more flexible than all the other frame types tested, having a stiffness of 50 N/mm. In shear loading the Ilizarov frames were stiffer than average.

Variations in construction of the frame changes its biomechanical characteristics. Ilizarov in his original experimentation found untensioned wires led to fibrous non union of the distraction zone. In Flemming's study (1989) the bone was off centered in the ring and the position of the wires changed from the right angle configuration to 45/135 degree orientation. These changes reproduce the clinical setting. Bone asymmetry increases resistance to axial loading, anteroposterior and lateral bending and does not affect shear or torsional rigidity. Changing the wire orientation increases stiffness in one direction of bending and decreases it in the other. No change was seen in resistance to shear, axial loading and torsion. Decreasing the tension of the wires from 1275 N to 883 N made no appreciable difference on stiffness characteristics.

In summary the Ilizarov frame is comparatively flexible compared with other frame types, with a consistent stiffness to bending moments in anteroposterior and lateral planes. Unlike other fixators the Ilizarov fixator has an increasing resistance to axial compression with increasing load, and is most flexible in the axial direction compared with other types of loading. By deduction, the overall resistance to bending and shear is not as important as the ratio of shear and bending elasticity to the elasticity in the axial direction.

2.0.5 Distraction Osteogenesis

Distraction osteogenesis is the process of new bone formation secondary to pulling two bone ends apart. Any area of bone can be stimulated to form new bone if the correct conditions of rate, frequency, preservation of blood supply and frame rigidity are provided. The bone is formed in an organized collagenous layer resembling intramembranous ossification (fig 2.1). The collagenous matrix ossifies by the invasion of osseous and vascular columns in a manner similar to the physis of a child (Ilizarov 1989).

Professor Ilizarov's technique has evolved from extensive animal studies. From these investigations the optimum distraction rate (1 mm per day), frequency (as often as practically possible), frame structure and operative technique has been determined (Ilizarov 1989, 1983).

Numerous experiments determined the best rate and frequency of distraction. In dogs a distraction rate of 0.5 mm per day using four lengthenings led to premature consolidation after approximately ten days distraction. If the same rate was used (0.5 mm per day) with twice daily lengthening then osteogenesis was considerably slower and union did not occur (Ilizarov 1989, 1983).

At a distraction rate of 1 mm per day in one daily step very little bone was formed. If the same rate was used with 0.25 mm lengthenings every six hours then considerable new bone formation was seen. Continuous distraction using a motor led to proliferative new bone formation. Osteogenesis in some animals in this group was fast enough to cause premature consolidation (Ilizarov 1989).

Rates of faster than 1 mm per day resulted in poor bone growth in the distraction zone. Poor bone growth was more noticeable in dogs with complete division of the bone (osteotomy) than compared with those dogs with intact medullary cavities (corticotomy) (Ilizarov 1989).

Aerobic activity, indicating the formation of bone rather than cartilage, was demonstrated using histochemical stains. The highest rate of aerobic activity was found in the distraction zone of dogs distracted continually at the rate of 1 mm per day, and the lowest activity in those distracted at 1 mm daily at a rate of four times a day. Faster rates and lower frequencies resulted in depressed aerobic activity. Adenyl triphosphatase and Alkaline phosphatase stains indicated new bone formation in the same areas reinforcing these findings (Ilizarov 1990).

To examine the effect of fixator stiffness a further set of rabbit experiments was performed. If the wires are untensioned or the fixator is unstable in construction then cartilage will be observed in the fracture gap indicative of poor bone regeneration. Bone regeneration appears to be stimulated if a small amount of movement along the length of the limb is permitted (axial micromotion). Hence subjects are encouraged to actively weight bear and walk with the frame on. This aids joint movement, prevents oedema, stimulates new bone formation and prevents osteoporosis that can lead to pin loosening and pin tract infection (Ilizarov 1989). As discussed earlier, osteogenesis can be stimulated by axial micromotion as shown by a number of separate investigators (Kenwright *et al.* 1986, Wolfe *et al.* 1981, Rubin *et al.* 1984, Aronson 1989, Kenwright *et al.* 1989,), or by weight bearing (Hulth 1989, O'Sulivan 1990).

A further set of experiments showed bone regrowth to be optimal when the blood supply to the marrow was preserved (Ilizarov 1989). More recent studies dispute the importance of the medullary blood supply (Kojimoto *et al.* 1988) and stress the importance of the blood supply from the surrounding tissues.

In Ilizarov's original dog studies, histology of the distracted tissue shows an inflammatory reaction after the corticotomy similar to fracture healing (Sevitt 1981). Once distraction starts fibroblast cells appear with their long axes orientated to the direction of distraction. These cells are very active having the appearance of type II collagenoblasts found in fetal tissue development as suggested by Ilizarov (1989). These cells actively secrete the organized collagen matrix, hence collagen is formed along the axis of distraction. Capillaries are found in between the collagen bundles. Osteoblasts with histological evidence of high metabolic activity are found next to the capillaries. The new osteoid turns to lamellar bone and became continuous with the original cortex (Ilizarov 1990). Aronson *et al.* (1989) have studied bone formation in dogs and have measured the size of the new bone columns. These columns take on the shape of stalagmites and stalactites with the bases towards the original bone cortex. The tip has a diameter of 10 microns, increasing in size to 200 microns at the base. The central gap is comparatively avascular and contains cells similar to those in the zone of Lacroix in the physis. Similar patterns were found by Lavini *et al.* (1989) and Peltonen *et al.* (1988) in sheep, Kojimoto *et al.* (1988) in rabbits, and Deloye *et al.* (1989) and Aronson *et al.* (1990) in dogs. Sevitt's warning (1981) on the extrapolation of results found in animals to man should be remembered; bones in small animals remodel less and form more periosteal callus. However Tajana *et al.* (1989) showed the histology of distraction bone biopsy specimens were similar in both dogs and man.

Ossification of the callus occurs rapidly. Seven days postoperatively the cortex in the distraction site is 25% as calcified as the contralateral bone. This rises to 75% after 28 days, and then decreases to 40% at the end of lengthening. A rise to almost normal occurs during the neutral fixation period (Aronson, 1988). The strength of the femur on axial loading has been linearly correlated to the degree of calcification by Alho *et al.* (1988). Although the load to cause failure was significantly correlated, the load to compress the femur a specified amount (1 mm and 5 mm) was not, indicating that poorly mineralized bone has similar elastic properties to normal bone, but is more brittle. Although the distraction callus is considerably different in structure from elderly osteoporotic bone, it may be that the distraction callus with a degree of calcification present will be similar to the osteoporotic bone. Hence, it will have similar elastic

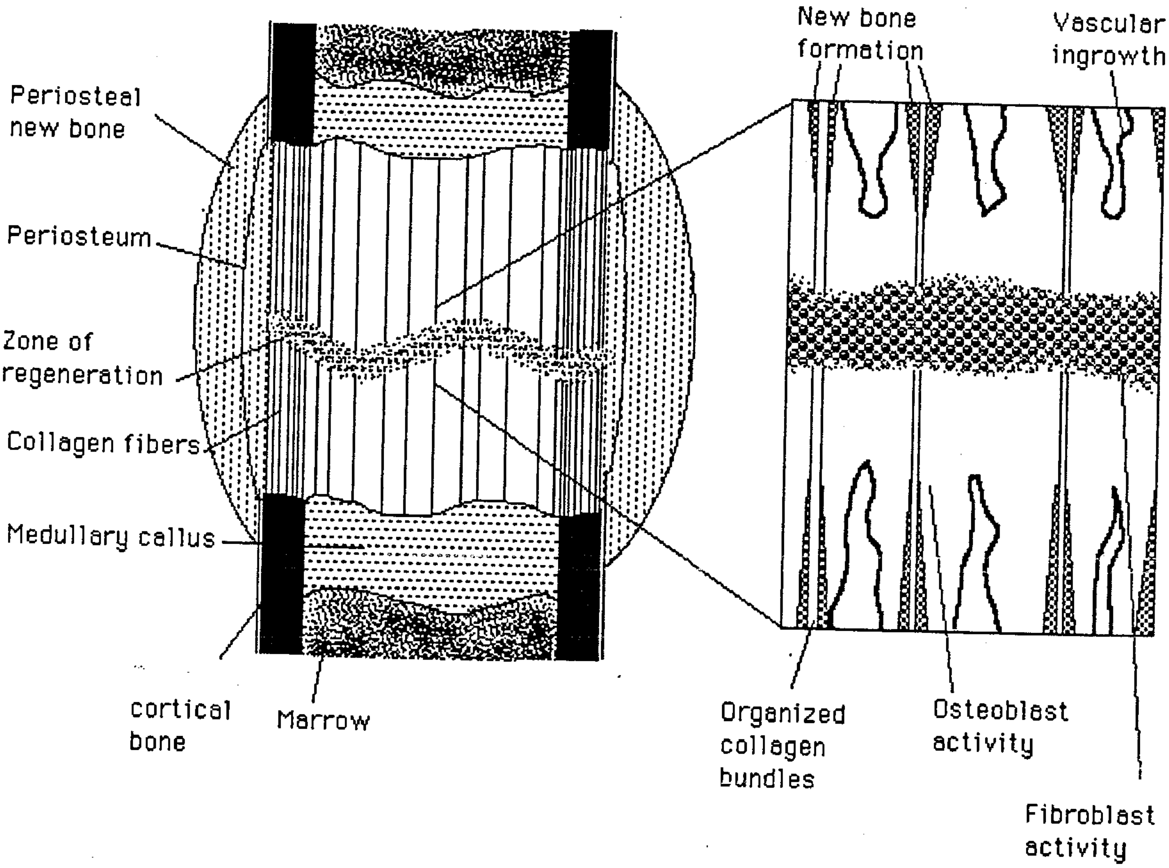

Figure 2.1. A diagrammatic representation of the distraction zone based on histology.

properties to the normal bone, but fail at a lower load. From this limited evidence, the distraction callus will be inelastic and brittle.

Tajana *et al.* (1989) classified the histological changes seen in human bone biopsy specimens taken at different periods during distraction into four stages. The first is the colloidal phase, in which a fibrin clot is found with loosely arranged mesenchymal cells. The fibrillar stage follows, in which disorganized collagen bundles and the beginnings of primitive vasculature are found. The third stage is the lamellar stage, in which the collagen fibres are organized into lamellae, and the surrounding cells are fusiform in shape. The final stage is the inorganic phase, in which the precipitation of calcium salts is seen. No cartilage formation occurs.

In contrast to osteogenesis the fracture callus has a disorganized collagen matrix associated with woven bone formation in the fracture site. Fracture movement (such as found in rib fractures) leads to the formation of cartilage in the callus (Sevitt 1981, Urist 1980). Organization and strength returns with Haversian remodelling of the callus after initial bridging by periosteal and cortical new bone. Neither cartilage nor woven bone are found during distraction osteogenesis.

In a dog study, Delloye *et al.* (1990) have shown the callus during distraction osteogenesis to arise from the periosteum, medulla and cortex and to fill the whole of the cavity between the bone ends, similar in that respect to fracture healing (Sevitt 1981). Recanalization of the marrow occurs after approximately 16 weeks (Zembo *et al.* 1989).

There is considerable debate as to the origin of osteoblasts during fracture healing. The origin is presumably the same in distraction osteogenesis. McKibbin (1978) in his review summarizes the arguments. One view is that osteoprogenitor cells exist both in the bone marrow and bone. Fracture haematoma stimulates division, differentiation and new bone formation. The other view is that fibroblasts of any origin (for instance, those found on periosteum) become osteoblasts as the microscopic appearances of the two are hard to distinguish. A decrease in marrow activity surrounding the distraction site has been observed during animal experimentation. An experiment on rabbits shows bleeding a volume of blood equivalent to 1% of body weight before operation results in stimulation of the marrow and more complete bone regeneration (Ilizarov 1989). This would support the hypothesis that osteoclasts and marrow cells are from the same cell line.

A central growth zone between the two original cortices is formed, and remains between 2 to 4 mm wide during distraction. In the repair phase the growth zone gradually ossifies and the bone becomes cortical in nature (Aronson *et al.* 1990).

Presently two types of fixator may be used in femoral limb lengthening with different biomechanical characteristics. Aronson *et al.* (1989) compared the callus formed by lengthening with a circular Ilizarov type frame to a unilateral Orthofix frame. The callus formed in the leg transfixed with the Orthofix frame showed differences in the collagen bundles formed, not being uniform from the medial to the lateral side of the distraction zone. However as all dogs in this study healed well the advantage of the Ilizarov system is not necessarily the frame but the technique and rate of distraction.

Kenwright *et al.* (1989) have shown the effect of delay distraction in rabbits. A significantly greater amount of callus volume is formed if distraction is delayed for a week after operation.

Kojimoto *et al.* (1988) performed histological studies in rabbits to determine the effect on osteogenesis during distraction of periosteal division. Periosteal removal results in compromised callus formation, whereas endosteal removal results in almost normal callus formation. The periosteum is therefore important for normal bone regeneration. Yasui *et al.* (1989) placed metal markers on the periosteum and found the periosteum becomes integrated within the callus. This indicates that the periosteum stimulates osteogenesis in the surrounding tissue, rather than being solely a surface for osteogenesis and a limiting membrane. The periosteal response to fracture initially occurs along the whole length of the injured bone and subsequently localizes at the fracture site during the first week (Simmons 1980). Bone healing requires both the presence of periosteum and soft tissue coverage. A deficiency of either leads to delayed bone healing. This is thought to explain the difference in repair rates of the femur (completely covered with soft tissue) compared with the tibia (partially covered) (Sevitt 1981).

In physeal distraction similarities are seen in the histology of the bone regenerate compared with distraction callostasis. After fracture of the physis in the early stages of lengthening the gap is filled by haemopoetic tissue. Subsequently fibroblasts are found accumulating along the length of collagen fibers organized longitudinally in the direction of distraction. Calcification occurs along the collagen fibers, contributions being made from the both the perichondrium and periosteum (Peltonen *et al.* 1989, Monticelli *et al.* 1981). Radiological examination shows the bone to have a radiolucent central zone similar to that seen with distraction callostasis (1981).

De Pablos and Canadell (1990) have studied physeal distraction in sheep. Different distraction rates (2mm per day, 1 mm per day and 0.5 mm per day) were used. Fractures are seen radiologically in all cases. Histology shows initial hypertrophy of the growth plate until fracture, and at the end of distraction the germinal layer is thin. New bone formation in the gap after fracture is intramembranous in type, and although all the growth plates studied healed successfully, the slower rates are associated with more advanced remodelling. Thinning of the germinal layer of the growth plate would indicate an insignificant contribution to new bone formation, hence the bone formation in this type of lengthening is similar to distraction osteogenesis. Problems with extrapolation of results from sheep to humans should be considered.

2.0.6 Soft Tissue Regeneration.

For distraction to occur successfully not only must new bone be formed but the soft tissues of the limb must lengthen proportionately. Rapid distraction can lead to sympathetic effects and shock as described by Magnuson (1913). Nerve palsy, vascular damage and compartment syndrome also occur. An optimal rate of distraction not only stimulates new bone formation but also stimulates soft tissue generation.

Fascia initially responds to distraction by a degree of resorption. After 14 days of distraction swelling is seen and fibroblasts appear indicating regeneration (Irjanov and Asonova, 1983). Increasing distraction frequency (using autodistraction) shows less damage to the fascia, and the fascia shows less evidence of stretching as it maintains its normal wavy appearance (Ilizarov 1989).

The number of capillaries within the fascia is also dependent on the distraction rate and lengthening frequency. Optimal distraction rates form extensive capillary beds, whereas rapid distraction rates lead to an avascular fascia (Ilizarov 1989).

Extensive damage was found within rapidly distracted arterioles with evidence of necrosis of the cells of the wall. More optimal distraction rates lead to active arteriolar growth, indicated by hypertrophy of organelles within the cytoplasm and preservation of myocyte contractile elements. The smooth muscle cells found within the walls showed evidence of proliferation and reorientation (Ilizarov 1989).

Nerves also react to distraction. Axon changes occur at rapid distraction rates with uneven diameters and irregular accumulations within the cytoplasm. Clinically rapid distraction leads to peripheral neurological signs. Optimal distraction rates result in a normal axonal appearance during lengthening. Newly formed nerve fibers are seen if each lengthening is 0.25 mm per six hours or slower. The features are similar to those seen in developing foetal nerve trunks (Ilizarov 1989). In the peroneal nerve of a dog 7.5 N tension, or an acute strain of 0.5%, is sufficient to totally block conduction (McLaren 1989) indicating nerve regeneration must occur during lengthening or distal paralysis would soon ensue.

Skeletal muscle shows changes both in the mitochondria and the contractile elements. The mitochondria hypertrophy and the christae enlarge. These mitochondria are found around the region of the sarcolemma where actin and myosin microfilaments are formed. The muscle fibres increase in length by elongation of existing fibres and the generation of new muscle fibers (Ilizarov 1989) . Yasui *et al.* (1989) put markers within rabbit muscle during elongation and showed the whole muscle elongates during the distraction process, and not solely the muscle overlying the distraction zone.

Recently reported work (Paley 1988) shows the muscle response depends on the lengthening achieved. If the lengthening is under 10% of the total bone length the muscle responds by a sliding of filaments and tighter packing of fibers. The fascia accommodates by straightening of the cross meshing of fibers. Between 10 to 20% of lengthening, myogenesis and fibrogenesis results in the production of new muscle, tendon and fascia along the whole length of the segment. Over 20% lengthening causes regeneration to occur mostly at the level of distraction. In a study on rats, muscle was seen to increase in length at the musculotendinous junction with 15% lengthening (Mackenzie, 1990).

Similar changes are found in tendons, the dermis, the epimyseum and perimyseum of muscles, the adventitia of blood vessels and the epineurium and perineurium of blood vessels. Hair cells and sebaceous glands also regenerate (Ilizarov 1989).

Changes have been found in the blood and the immune response during callostasis. Delay of secondary immune response from the 4 th day to the 8 th day after injection of the allergen is found as demonstrated in dogs. No decrease in intensity of response is seen. (Grigencha and Matveenko 1983). Medullary haemopoesis increases with an increase in reticulocytes and immature white cells being seen in the peripheral blood film (Ilizarov *et al.*, 1983).

2.0.7 Clinical Experiences with Lengthening.

Clinical publications on the technique are beginning to appear in the literature as experience expands. A large number of publications exist in Russian, but only abstracts are available making interpretation and comparison difficult.

Retrospective clinical review can determine complication rates and the number of successful outcomes (limbs completely corrected after treatment). Paley (1990) classifies the complications of Ilizarov leg lengthening into problems (difficulties requiring no operation to resolve), obstacles (requiring operative treatment) and complications (any problem or obstacle not resolved by the end of treatment). This classification is summarized in table 2.1.

Paley (1989) has reviewed results in children. Comparisons of the Ilizarov technique with the Wagner technique shows a lesser rate of complications in the former. In one review the Wagner resulted in 60 complications in 63 lengthenings; pin tract infection complicated 25, refracture in 16, malunion in 13, knee contracture in 16, subluxation in 8 and nonunion in 6.

An average of 3.7 cm was obtained in the femoral lengthenings studied. In a study of 237 Ilizarov femoral lengthenings the length attained was greater (average 7.4 cm) and planned lengthening was achieved in 233 of these subjects. Complications occured in 5.7% of the subjects (12 patients); 6 patients developed transient peroneal nerve paralysis during the distraction phase, 4 developed staphlococcal sepsis, and 1 osteomyelitis. Two subjects with hip dysplasia developed hip dislocation.

Paley (1990) has reviewed 60 limb lengthenings at his own institution using his classification system of complications (see table 2.1):

Of the 35 problems there were 20 pin infections, 10 axial deviations, 2 premature consolidations, 2 delayed consolidations, and 1 knee subluxation. The 11 obstacles requiring surgical intervention included 2 pin infections, 1 pin failure, 2 axial deviations, 1 premature consolidation, 2 incomplete corticotomies, 2 incorrect constructs of the frame and 1 bone cyst.

The 17 minor complications included 3 axial deviations, 3 contractures (recovered), 4 sensory nerve injuries (recovered), a length loss of 1 cm in 3 subjects, 2 delayed consolidations, 1 pseudocompartment syndrome and 1 haematoma.

The 11 major complications included 1 reflex sympathetic dystrophy, 1 equinuus ankle, 1 nonunion, 2 late bowing, and 4 motor palsies. Three were deemed to affect the final outcome; a bowing of the distal femur by 25 degrees in the plane of the knee, 1 recurrent varus deformity of the tibia, and 1 non union of an ankle arthrodesis lengthening. Premature removal of the frame was the cause in all cases.

Recent results from the Kurgan institute show complication rates to be even lower. Nerve injury or transient paralysis rarely occurs in lengthenings under 10 cm. In lengthenings over 10 cm transient nerve palsy occurs in 12%. Refracture rarely occurs. Permanent loss of motion occurs rarely in lengthenings under 10 cm. Delayed union occurs in 10%, although malunion is rare.

Symptom	Problem	Obstacle	Minor Complication	Major Complication
Muscle Contracture	Treated during lengthening nonoperatively	Treated successfully operatively during treatment	Persistent Contracture.	Requires further surgery.
Joint Luxation	"	"	"	"
Axial Deviation	" (under 5^0)	" (over 5^0)	Under 5^0 residual deformity	Over 5^0 residual deformity
Neurologic Injury	Distraction related nerve dysfunction resolving spontaneously	Distraction related nerve dysfunction decompressed during treatment	Nerve dysfunction after treatment: All intraoperative nerve lesions	Significant nerve dysfunction after Rx: All intraoperative nerve lesions
Vascular Injury	Hypertension and Oedema	—	Intraoperative and delayed pin related vascular injury	DVT., Pulmonary Embolism, Compartment Syndromes.
Premature Consolidation	Non operative rupture	Operative treatment such as osteoclasis	Premature termination of lengthening under 1 cm below expected	Premature termination of lengthening over 1 cm below expected
Delayed Consolidation	Treated by slowing distraction, etc	Treated by operative addition of wires, etc	Treated by bone grafting	
Pin Site Infection	Grade 1; Soft-tissue inflammation; Grade 2: Infection treated by antibiotics.	Grade 2 lesions requiring removal of pins.	Grade 3; Bone infection 2ry to grades 1 +2.	
Refracture	—	—	Under 1 cm loss or under 5^0 axial deviation	Over 1 cm loss or 5^0 axial deviation
Joint Stiffness	—	—	All; dependent on degree of stiffness.	Severe restriction
Pain	Treated by analgesics	—	—	—

Table 2.1 Paley's classification of complications after Ilizarov lengthening.

De Bastiani (1987) reported a series of 100 lengthenings in a number of limb segments. There were 14 complications. Premature consolidation of the femur occured in 4 subjects, premature consolidation of the fibula (in tibial lengthenings) at the osteotomy site in 3 subjects, and osteolysis of the pin sites in 2 subjects. Fracture after frame removal occured in 4 femoral lengthenings and after 1 tibial lengthening.

Dahl and Fisher (1990) compared complication rates using the Wagner and Ilizarov techniques. They reported a lower rate of complications and a shorter duration of treatment with callus distraction. Atar *et al.* (1990) had a similar complication rate to other techniques of leg lengthening on reviewing 29 children lengthened by the Ilizarov method; this included pin tract infection (10), joint contractures (5), transient nerve palsy (4), vascular injury with gangrene (1), joint dislocation (1), premature consolidation (5), skin irritation (2) and fractures after apparatus removal (2).

Treatment of Achondroplasia with lengthening of all eight limb segments has been reported with good clinical results (Canadell, 1989, Aldegheri *et al.* 1988).

Similar results for limb lengthening by the Ilizarov technique have been shown in clinical reviews by other authors (Glorion *et al.*, 1989, Dal Monte 1987, Yasui 1989).

2.0.8 Biomechanical Properties of Tissues.

The biomechanical properties of the external fixators used for lengthening have been well investigated, but the biomechanics of the fracture callus still remains largely unknown. However extensive work has been done on the biomechanical properties of the individual parts of tissues making up the lower limb, and so some idea of the expected elasticity of the callus can be estimated.

Yamada (1970) has done extensive biomechanical testing of bone. A summary of significant constants is shown in table 2.2.

Table 2.2. Young's Modulus for tissues found around the distraction zone. (estimated from graphs by Yamada *et al.*.)

Tissue type	Youngs Modulus (N/mm^2)	Elongation to failure
Cortical bone in tension	165.5400	1.41
Cortical bone in compression	76.8400	2.20
30% mineralized bone¥	Similar to Cortical bone.	
Cartilage in Compression	4.9100	15.00
Tendon	2.4500	10.00
Fibrous Interzone †	0.9800	
Fascia	0.6100	16.70
Cartilage in tension	0.2600	25.90
Sciatic nerve	0.0820	17.00
Skin	0.0410	140.00
Elastic ligament	0.0060	120.00
Coronary artery	0.0012	99.00
Skeletal muscle	0.0003	108.00

¥Bone mineral content and strength has been correlated for autopsy specimens by Alho *et al.* (1988).

† From Aronson *et al.* (1989).

2.1 AIMS AND HYPOTHESES TO BE TESTED.

A. The purpose of this study is to determine the magnitude of the axial force in the femur resisting distraction; and whether the configuration of distraction forces produce a bending moment at the osteotomy site.

It is hypothesized that a variation of force over the 6 hourly lengthenings will occur, the force after lengthening being greater than the force before lengthening and decreasing non linearly with time until the next lengthening. Second, there will be an overall increasing trend in axial load during the distraction period, as demonstrated previously in the tibia by Leung *et al.* (1979) and Wolfson *et al.* (1990). Differences between the resistance of soft tissue surrounding the femur should cause a bending moment to act on the frame.

B. A secondary purpose is to determine the magnitude of the axial load and bending moments on the frame during limited weight bearing and walking.

Three components will contribute to the load across the frame: The forces of muscle contraction, the joint reaction force and the forces of distraction. It is hypothesized that a baseline force will exist due to the distraction, with static and dynamic forces due to external loading being superimposed. The muscle forces during dynamic loading of the femoral shaft may well be considerably less than those recorded in in vivo studies of hip prostheses. The decrease in force in the femoral shaft is to be expected. The muscle mass around the midshaft of the femur is less than in the gluteal region, force production being related to muscle cross sectional area (Haxton 1944). Hence it is hypothesized that much of the muscular force acting across the hip generating large articular forces will be transferred to the femur proximal to the distraction site, resulting in relatively low axial loading in the femoral shaft, as recorded on the Ilizarov frame.

3. METHODS

3.1 Apparatus.

3.1.1 The Ilizarov Frame.

The standard femoral frame used on the three subjects consists of proximal and distal fixation attached across the distraction zone (see figure 3.1). Distal fixation is achieved using 2 rings joined to each other by 2 cm spacers. The two rings are fixed to the underlying bone by four tensioned wires (2 per ring). The tensioned wires act like spokes of a wheel resisting movement of the bone. Proximal fixation is achieved using one ring fixed to the bone using two tensioned wires and three threaded half pins drilled into the greater trochanter of the femur. These are rigidly attached to each other by rods. The proximal and distal fixations are held apart using three rods. These rods are threaded with a pitch of 1 mm along their whole length allowing progressive distraction, each quarter turn moving the two rings apart by 0.25 mm. As each lengthening is performed four times daily a total distance of 1 mm per day is achieved. In all subjects tested an angular correction was performed. Hinges were placed in two of the three rods to allow progressive correction of the deformity by changing the alignment of the proximal and distal halves of the frame.

3.1.2 The Ilizarov Technique.

Professor Ilizarov determined the best rate for distraction to be 1 mm per day, as this rate allows gradual distraction of forming bone which ossifies during the distraction procedure, gaining strength and further ossifying during the neutral fixation period.

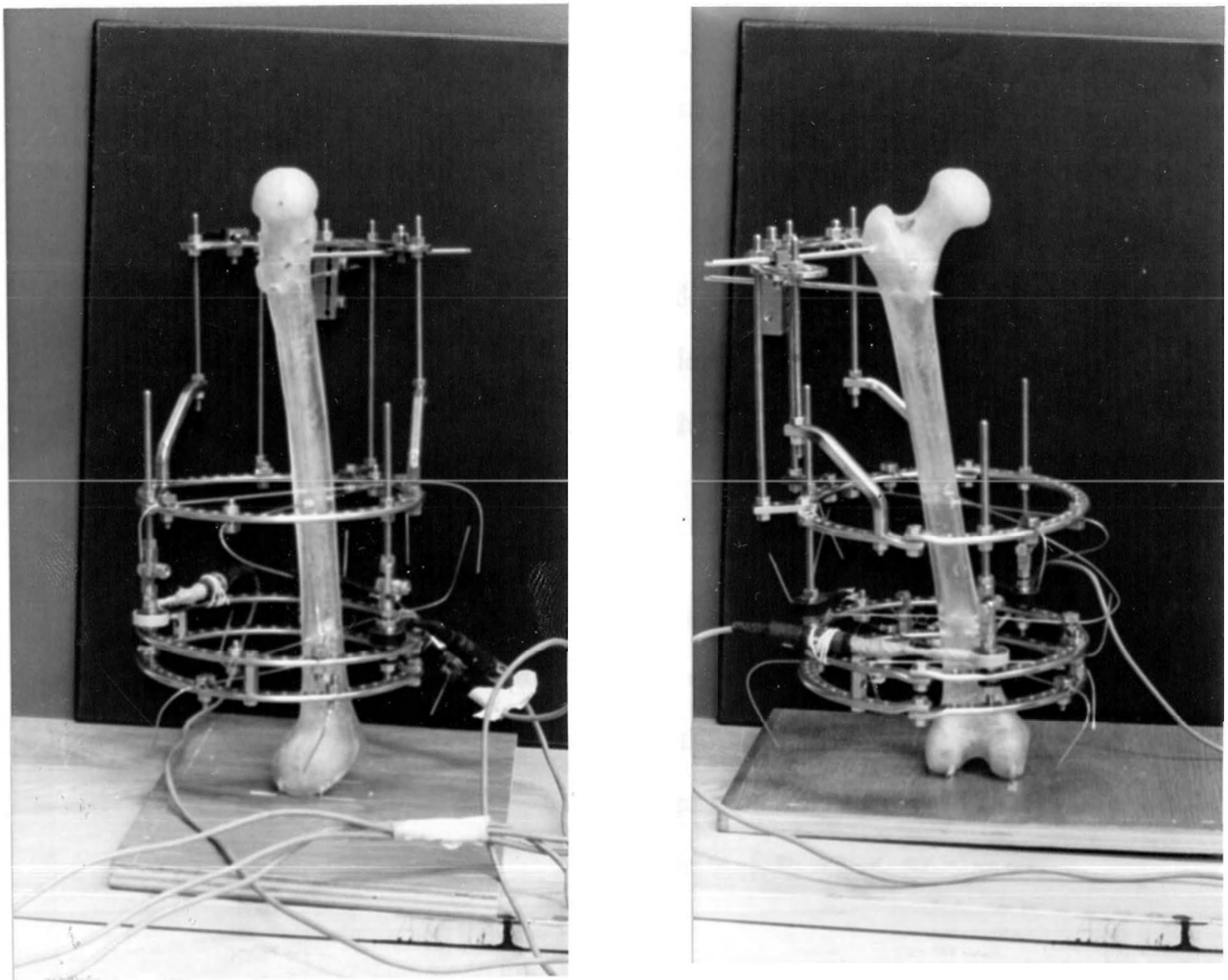

Figure 3.1. The Ilizarov frame in the femoral configuration.

The photographs shows the proximal, middle and distal rings, position of hinges and load cells with respect to the femur.

The operation is performed after preliminary evaluation including clinical examination, CT scan and a radiological assessment of discrepancy between the legs, which also determines in which segment the deficiency lies (femoral or tibial). The frame is constructed preoperatively using the X-ray plates to model the design.

During the operation wires are drilled through the bone proximal and distal to the planned corticotomy site. They are attached to the frame and the wires tensioned to 1270 N force. Using a lateral approach the femur is carefully divided preserving the marrow cavity and the periosteum (a "corticotomy").

A standard lengthening after operation will consist of four periods; a latency phase, a distraction phase, a neutral fixation phase and a remodelling phase after frame removal.

The latency phase is a rest period of 7 days postoperatively with no lengthening performed to allow a callus to form.

The distraction period is of variable time dependent on the length to be attained. Many patients may also have correction of an angular deformity during the distraction period. This may be performed at the beginning or the end of the distraction period by the use of hinges and distracting the rods at different rates.

After the lengthening has been completed the distraction gap is incompletely ossified. To allow satisfactory ossification the frame is kept on for a period approximately twice the time taken to complete the lengthening. The subject is encouraged to weight bear to stimulate bone healing. Hence, the total time in the frame in months is approximately the same as the length in centimeters obtained. For instance, if 6 cm is gained then the frame will be in place for 6 months. The healing index is the total time of fixation (in days) divided by the total length achieved, and is usually 30 days per cm gained.

3.2. Instrumentation.

3.2.1. Load Cells.

In order to measure loads transmitted through the frame a compression load washer was inserted on each supporting rod of the frame (see figure 3.1 and 3.2). The ALD-W 5 load cell made by ALD designs (New York) had suitable dimensions to fit the frame, having a 9 mm bore, a height of 8 mm and external diameter of 25 mm. Nine load cells were used in the study to allow simultaneous recording of two subjects with 3 spare load cells in case of failure, and to facilitate calibration. The load cells chosen had a range of recording between 223 N to 2229 N. All load cells were waterproofed.

The load cells were placed in the frame between the distal end of the distraction rods and the middle ring. The manufacturer's request that the load cells be mounted on steel of Rockwell hardness of 44c or greater. Hardened washers were made to specification. One of the washers was made flat on one side and semicircular on the other to allow incorporation within an alignment jig to ensure that the two surfaces adjacent to the load cell were always parallel (see figure 3.2).

As the load cells were not accurate below 222.9 N force the load cells had to be preloaded to above this value. In order to preload the load cells plastic washers were used distal to the ring (see figure 3.2). By using high compressions (typically 2000 N force across the frame) across the load cell and washers the frame was kept stiff, maintaining its mechanical characteristics. In order to allow the load cells to register distraction forces acting on the frame, it is necessary that the compression washers have suitable elastic characteristics. After considerable searching, ABS (Acetyl Butyl Sterene) plastic was found to be the most dependable, being resistant to high loads while maintaining its elastic properties. These washers were used for the second and third subjects after the material used for the first subject (Neoprene) was found to be too viscous. The amount of distraction force recorded at the load cell depends on the ratio of elasticity between the plastic washers and the elasticity of the load cell and adjacent washers. The distraction load is applied to the assembly through the ring located between the compression washer and the load cell. Compression of the load cell due to distraction loading will tend to unload some of the compression in the elastic washers. As a result, part of the distraction load applied is masked by the reduction of the initial compression load exerted by the load washer (see fig 3.3).

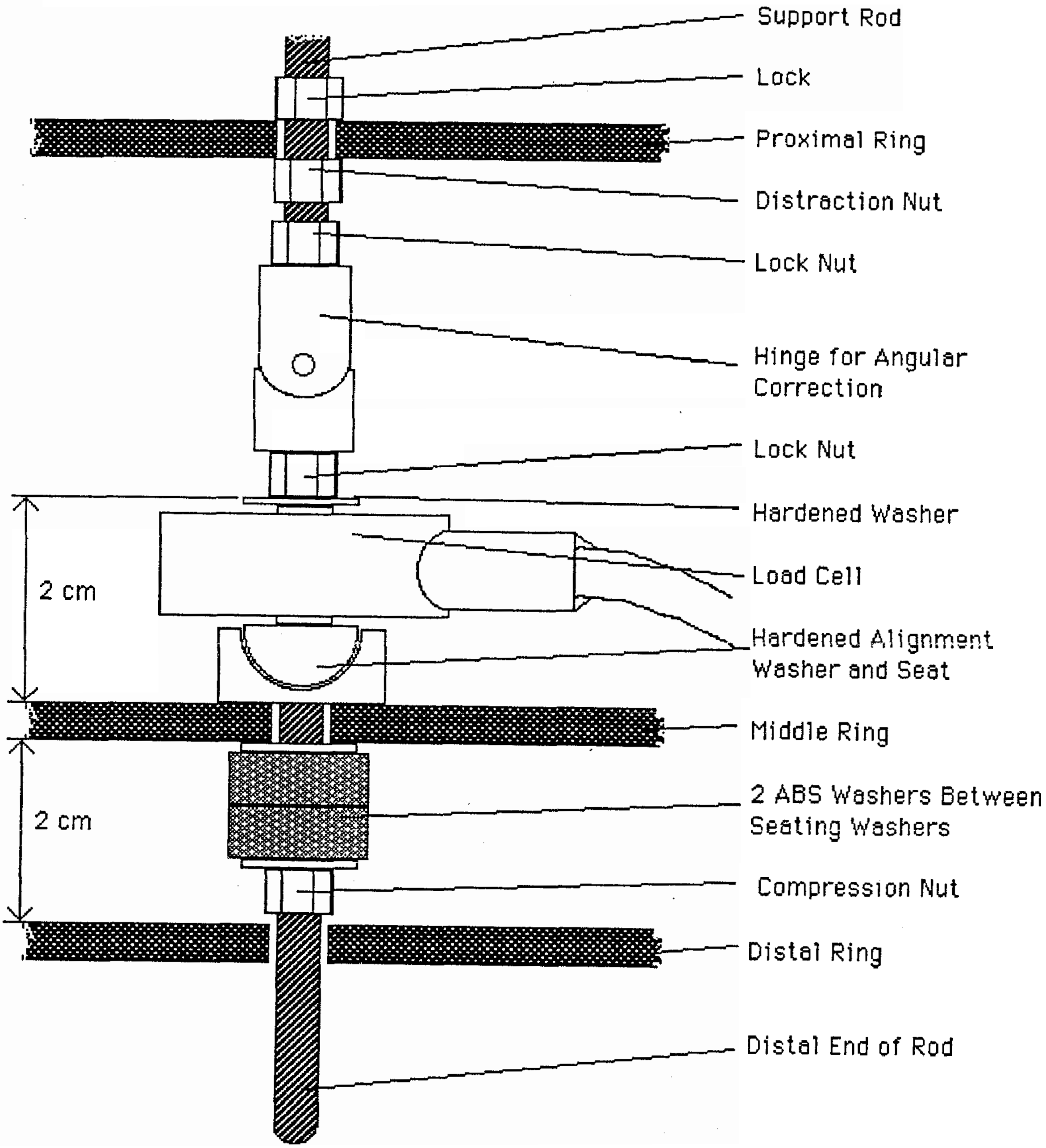

Figure 3.2. The mounting of the load cells on the frame.

The equipment must fit in a 2 cm space above and below the middle ring.

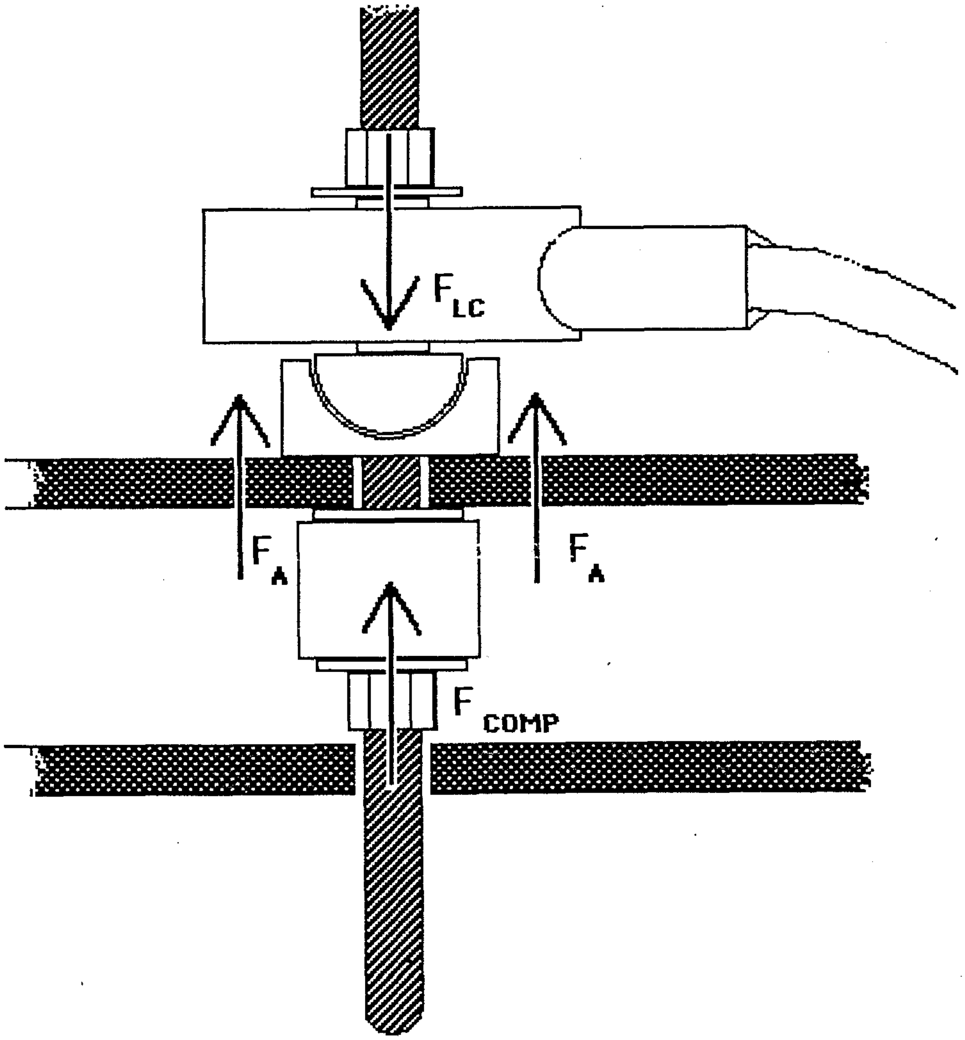

Figure 3.3. The transfer of force in the distal end of the frame.

The compression force (F_{comp}) will act on the distal ring, washers and load cell. The applied load (F_A) will tend to compress the load cell and decompress the washer depending on the ratio of elasticity of the components on each side of the distal ring. The resulting force seen at the load cell is F_{LC}.

Other types of load cells may have been preferable, but the design had to fit within a 2 cm space above the ring and a 2 cm space below the ring. Using this system the integrity of the frame was preserved. The system allowed rods to be repositioned and cells to be removed for recalibration during the course of treatment.

3.2.2. Force Measurement Aspects of the Frame.

The rods of the frame and load cells will support different loads depending on the nature of the applied load to the frame.

An axial load (from the resistance of the tissue to distraction, the muscle forces and the distal joint reaction force either singly or in combination) will be transmitted through the wires to the frame (see fig 3.4). The total axial load at any one time will be the sum of the forces in all the rods.

When the frame is loaded only with a bending moment the rods on one side of the frame will be in compression and on the other side will be in tension (fig 3.5). The magnitude of the bending moment in one plane can be calculated using the distance between the rod and the axis of the femur obtained from the X-ray plates of the limb.

In pure shear load with the neutral axis of the frame in the center, each of the rods will carry a constant shear load along its length, and will experience a bending moment at the rod frame junction as shown in fig 3.6. Ideally there should be no change in axial load in each of the rods and shear should not affect the load cell readings provided the frame is rigid.

In conclusion (figure 3.7), the sum of all the loads in the rods will be equivalent to the axial load at any instant. A bending moment will cause a difference of load cell readings from the mean value. Shear loading or the magnitude of shear cross talk on axial forces cannot be measured with the proposed configuration of load transducers.

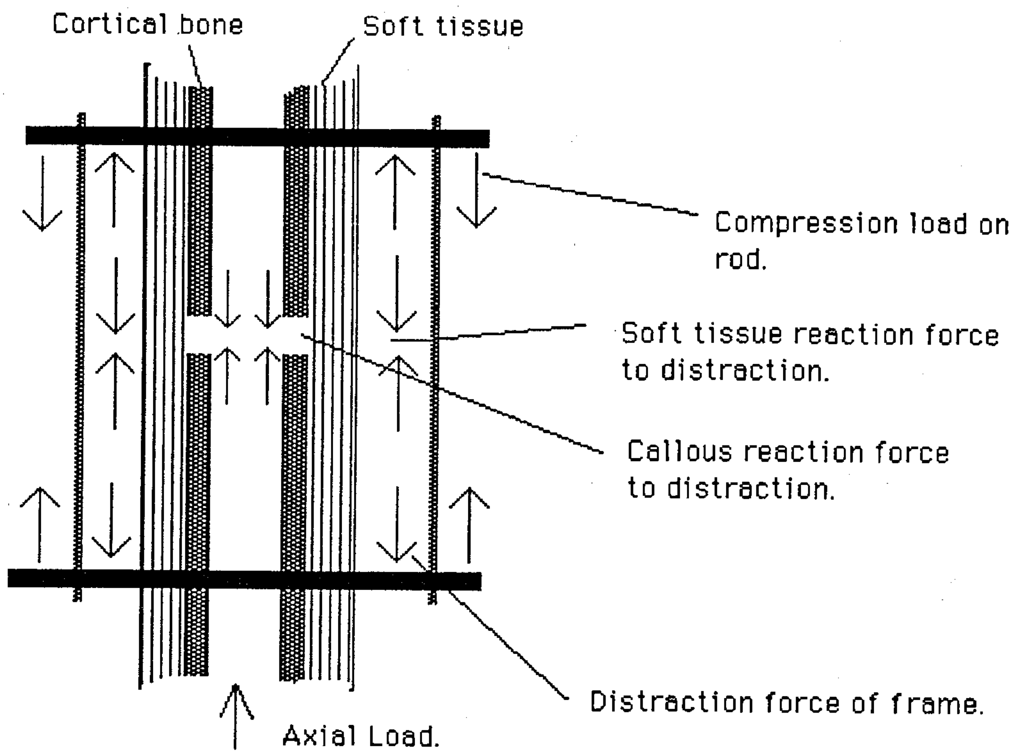

Figure 3.4. The effect of pure axial load on the frame and rods.

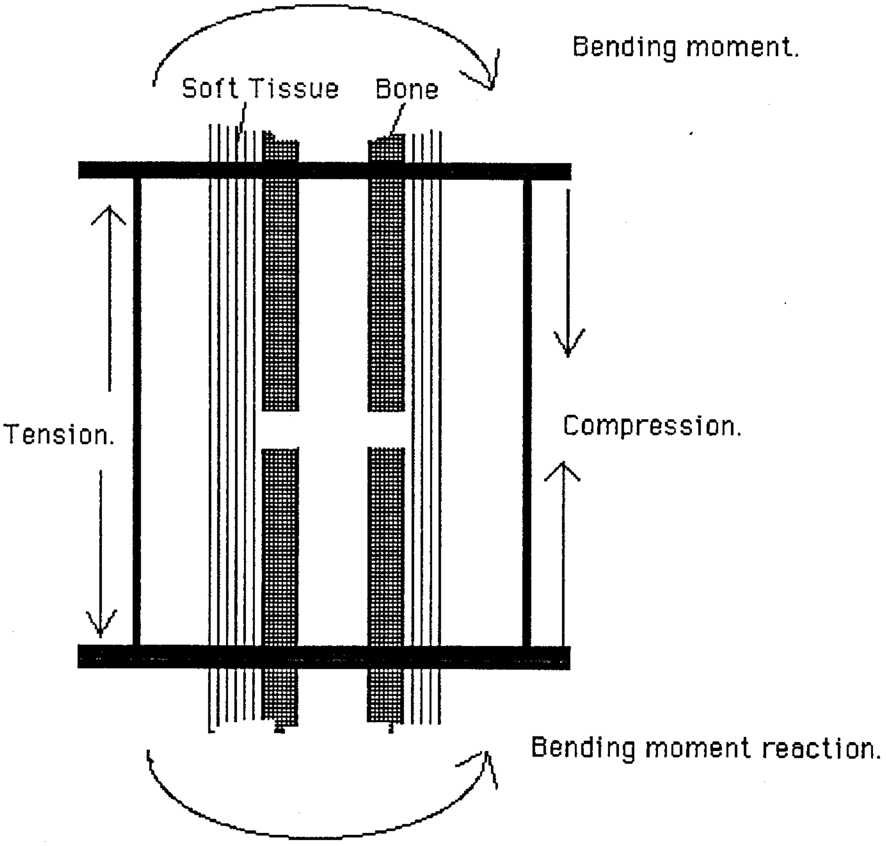

Figure 3.5. The effect of a bending moment on the frame and rods.

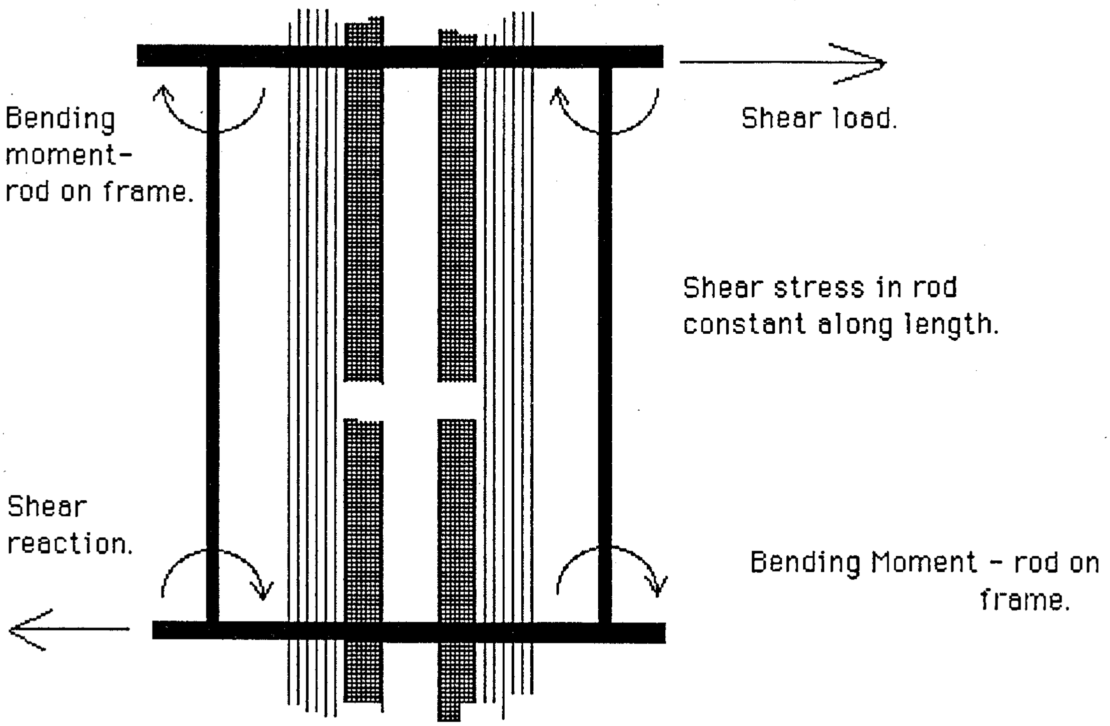

Figure 3.6. The effect of a pure shear load on the frame.

A Bending moment will be seen in each rod.

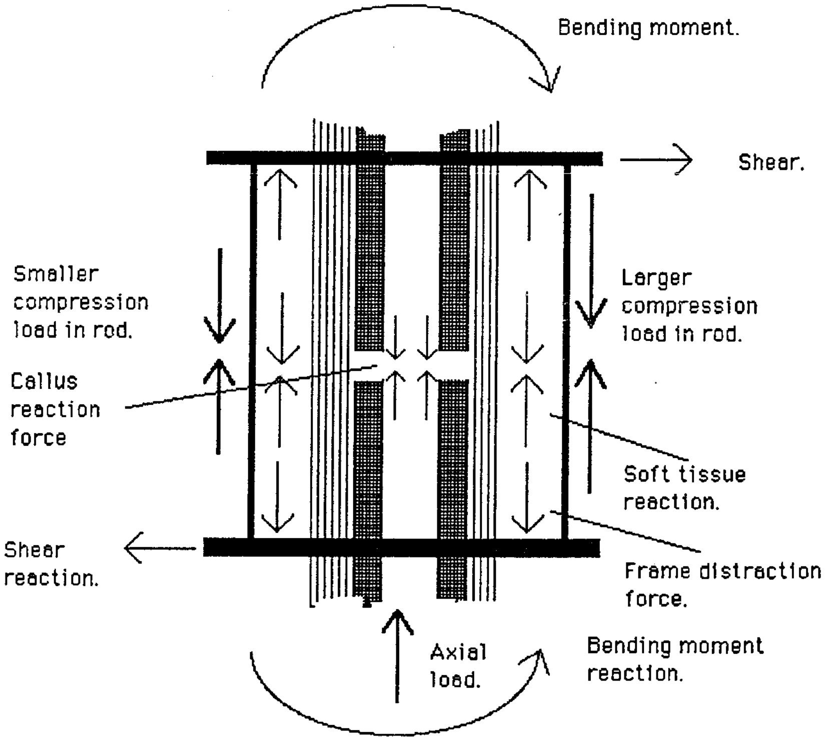

Figure 3.7. The combined effect of shear, bending moment and axial load on the frame.

Axial load and distraction will cause an increase in force in all rods, and the bending moment will cause a differential in force in each of the rods. The shear component will require calibration.

3.2.3. Recording Equipment.

Recordings were made using a PC compatible lap top computer (Zenith Supersport) with a 20 megabyte internal hard drive.

The load cells with a 2 cm length of cable and a DIN plug were permanently attached to the frame. During recording the 3 load cells were connected to a 12 volt DC supply using a 3 meter length of multicore shielded cable. The millivolt output signal was returned through the same multicore cable to an amplifier. After amplification the signal was passed through an external expansion chassis with an Analog to Digital converter to the lap top computer (figure 3.8).

The recording programs were written in C allowing recordings to be taken in three settings:

1. Overnight recordings were taken from the three load cells every five minutes. During this data collection, a mark in the recording could be made by pressing the "L" key each time the subject lengthened the frame.
2. Data were recorded at 10 hertz during static loading and free hanging of the leg.
3. During dynamic loading the voltages from the force platform were recorded at the same time as the outputs from the three load cells. Measurements were taken at 100 hertz over a period of time selected during each trial.

3.2.4. Safety.

Before the investigation started, the equipment was taken to the Children's Hospital Bioengineering department to ensure that it complied with electrical safety standards. In accordance with their recommendations the equipment was isolated from the mains electricity using a transformer.

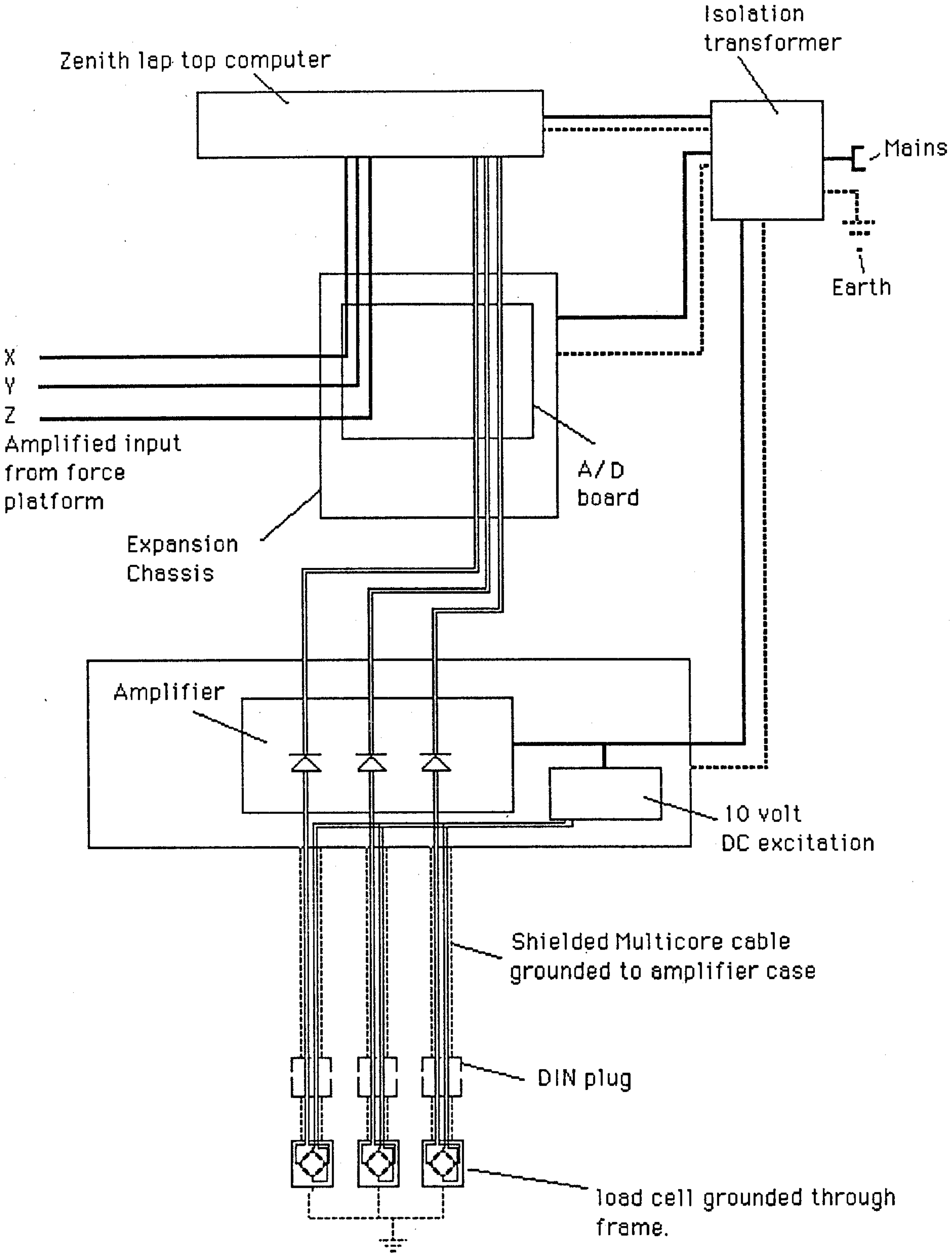

Figure 3.8. The circuit diagram of the recording apparatus.

An incident of electrical shock occured during recording due to a faulty appliance in one household. As a result of this experience the grounding of the equipment was made independent of the load cells and frame.

3.2.5. Calibration.

Calibration of load cells.

Each load cell was calibrated before and after each leg lengthening procedure. A total of three calibration runs were made for each load cell. The load cells were calibrated using a force platform and lever system (see fig 3.9) as an accurate materials testing machine or equivalent was not available. During calibration the manufacturer's instructions were observed; namely, that the two recording surfaces were kept parallel and the applied load was maintained above 223 N.

During each procedure the force platform was first leveled and one hardened surface supplied by the manufacturer placed on the force platform. The load cell was placed on this surface with another hardened surface placed above. A steel bar was placed on top with the load cell acting as a fulcrum and an adjustable rod as a reaction point. The bar was leveled so it was parallel to the force platform and the floor. Weights were placed on the opposite end of the rod with a mechanical advantage of 10:1 so that application of up to 20 kilograms on the end of the bar would be sufficient to cover the full range of the load cell calibration. A minimum force of 50 lbs (222.7 N) was maintained on the load cell. Four recordings of 10 loads were recorded from the force platform during each calibration. The average output voltage from each load was used to plot a calibration curve.

In situ calibration of the rod assembly.

To determine the most appropriate washer material, the resilience and resistance to shear of each material was determined using a rod and load cell assembly. Some materials were unacceptable as they were too viscous as determined by the loss of tension within the washer after a day of compression. Other washers and designs were unacceptable as they were too elastic, allowing the movement of the rod to affect frame rigidity and causing cross talk with shear loading. Some washers were too stiff, not allowing sufficient transfer of applied load to the load cell.

To determine the transfer of straight axial load to the load cell from each rod in the standard assembly an individual rod and load cell compressed with the washer material was calibrated on the force platform. Seven runs were used for each calibration. The applied load was plotted against the measured load at the load cell.

During loading the applied load will push down on the rod and increase the force on the distal ring. For this transfer to occur the load cell will be slightly compressed. At the same time the compression washers on the distal side of the frame will be slightly decompressed. As the total load in the load cell is the compression load plus the applied load, the load measured at the load cell will increase. If the distal compression washer is much more elastic than the load cell and seating washers then the loss of compression will be minimal.

Two types of compression washers were used in the study after a number of different designs and materials had been tested.

Bending moment calibration.

To determine the response of the frame to pure bending moment a frame was constructed incorporating three load cells and fixed with the long axis perpendicular to the ground. A bar was attached to the upper ring of the frame and weights suspended from it. In each test the weight was moved out along the bar to change the magnitude of the bending moment. Successive tests using 1, 2 and 3 kilogram weights were performed. The distance of the weight from the center of the frame was measured and the applied bending moment determined.

The bending moment was also calculated from the load cell outputs in the manner described under "Calculations" (section 3.5) and the applied and measured bending moments plotted against each other.

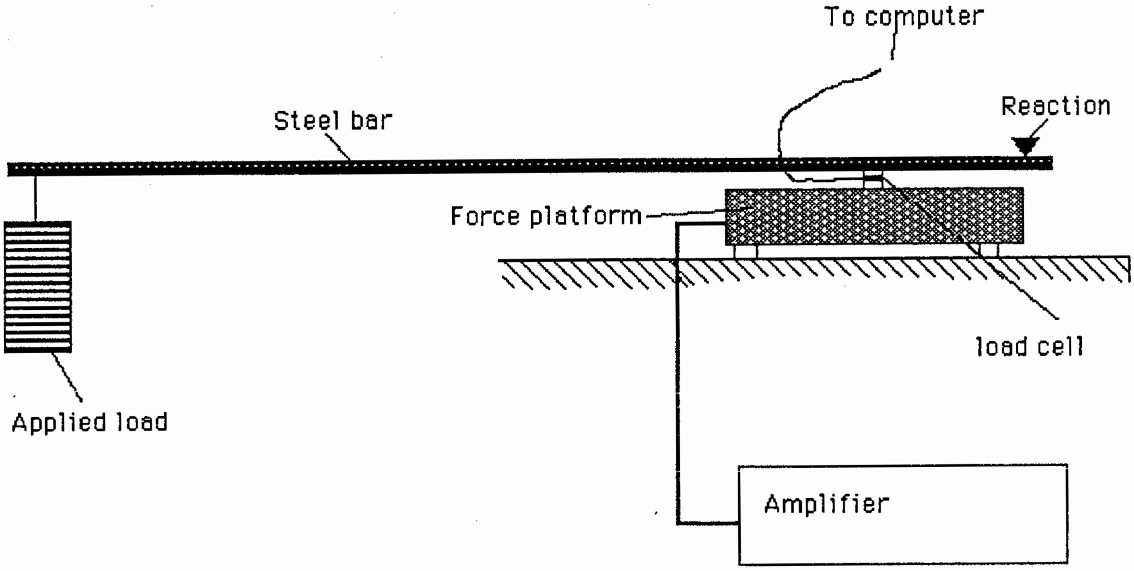

Figure 3.9. A diagram of the calibration system.

The steel bar acts as a lever on the force platform with the recording surfaces and the load cell in between.

Shear Calibration.

To determine the effect of shear loading on the readings from the load cells on the frame a testing frame was assembled with hinges in two of the three rods and fixed horizontally to the ground. Forces of up to 202 N were applied to the free ring by 10 N increments. Recordings were taken with the weight applied (to calibrate cross talk) and with the weight removed (to calibrate baseline shift). Four runs were performed, the frame being rotated by 90 degrees between each run. A full calibration was performed for both ABS (Acetyl Butyl Sterene) and Neoprene washers.

Calibration of the frame.

To model the response of the frame mounted on a femur, an Ilizarov frame in the femoral configuration was mounted on a plastic femur and tested. The assembly was constructed to replicate the in vivo state with the femur lying anterior to the central axis of the frame (see fig 3.1).

The frame was then loaded on the force platform after a 1.5 cm length had been cut out from the distraction zone of the plastic bone. Forces of up to 300 N were applied to the head of the femur. Recordings were made from the load cells and the axial load calculated as described in section 3.5 (Calculations). The applied axial load was then plotted against the measured values to determine the nature of force transfer within the frame.

Calibration of the force platform.

Before each biomechanics session the force platform was calibrated using standard weights.

3.3 Subjects

Four patients undergoing femoral limb lengthening were asked to take part in the study. All subjects were approached some time before operation and their participation was discussed in detail. Informed consent was obtained before operation. Full ethical approval was granted from both Simon Fraser University and the University of British Columbia. One subject and the family refused consent, leaving three subjects who participated.

Subject 1.

Subject 1 was a 14 year old girl undergoing a right femoral lengthening to correct premature closure of the distal femoral epiphysis. This was of unknown aetiology and became apparent after she presented to her family practitioner. As she is active in a number of sports the aetiology was suspected to be traumatic.

Prior to operation she had a leg length discrepancy of 2.1 cm and a varus deformity requiring correction. Distraction was started one week after the operation with the angular correction being performed at the same time until the 19 th day* (see fig 3.10 and fig 3.11). From the 19 th to the 46 th day straight correction was performed, resulting in a distraction period of 39 days. The frame was kept in place for a further 44 days of neutral fixation to allow ossification, giving a total of 90 days in the frame. A total of 3.1 cm length was obtained to compensate for future growth of the left leg.

During the course of treatment subject 1 had a pin tract infection, and suffered some non specific discomfort during the last week of lengthening and the first week of repair.

A good range of knee joint flexion and extension was maintained throughout, being lowest at the 90 th postoperative day with a range of 0-25 degrees of flexion. Knee range of motion was largest on the 24 th postoperative day, being from 25 degrees extension to 65 degrees flexion. This range of motion then gradually decreased over the remaining distraction period.

As the recording technique was original, the information from the first subject was therefore used to develop the protocol for the subsequent two subjects.

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* All days quoted are days since the operation, the day of the operation being day one.

Subject 2.

Subject 2 was a 15 year old boy undergoing right femoral lengthening for a congenital short limb secondary to congenital femoral hypoplasia. Until the present operation no surgical correction had been undertaken.

Prior to the operation he had a 7.3 cm discrepancy and a valgus deformity at the knee. On the 7 th day the distraction period began and continued for 98 days until 7.1 cm length had been obtained. From the 77 th day to the 105 th day an angular correction was performed (fig 3.12 and fig 3.13).

Neutral fixation commenced on the 105 th day. During his lengthening he suffered from viral gastroenteritis, and had a pin tract infection.

Knee range of motion decreased over lengthening from 80 degrees on the 14 th day to 45 degrees on the 86 th day.

Subject 3.

Subject 3 was a 13 year old girl undergoing right femoral lengthening for a limb length discrepancy secondary to polyostotic osteomyelitis as a neonate. She had had numerous operations to correct the valgus deformity. Prior to the operation she still had a leg length discrepancy of 4.8 cm, valgus deformity and and a flexion deformity (fig 3.16 and fig 3.17).

On the 7 th day distraction was started with the flexion being corrected. Subsequently on the 10 th day standard distraction was continued until the 51 st day, when a valgus correction was started. The neutral fixation phase started on the 74 th day.

During the course of treatment subject 3 had pin tract infections treated with antibiotics, and suffered discomfort during late lengthening and early repair.

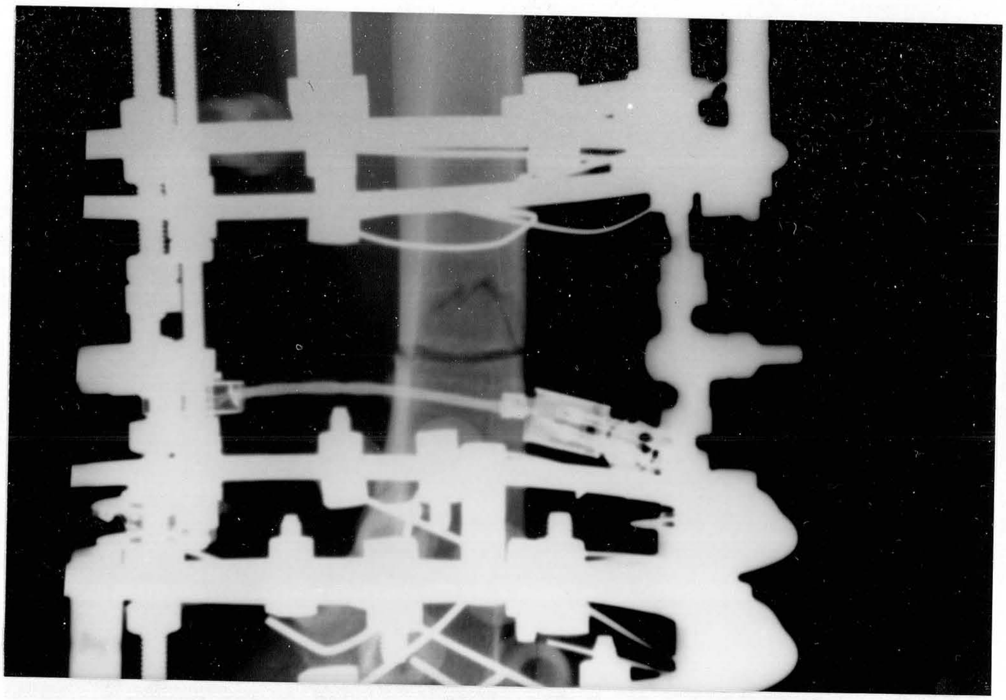

Figure 3.10. Subject 1. A lateral radiograph immediately postoperatively.

The frame and site of corticotomy is shown.

Figure 3.11. Subject 1. A lateral radiograph on the 90 th day.

This shows the distraction zone just prior to frame removal.

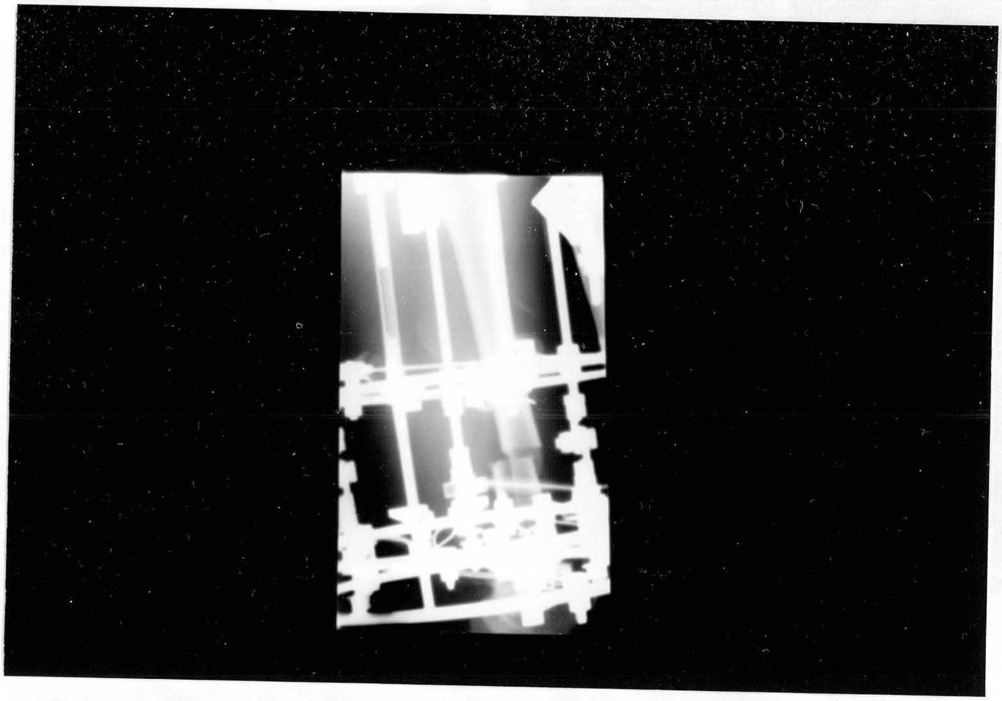

Figure 3.12. Subject 2. A lateral radiograph on the 7 th day.

Figure 3.13. Subject 2. A lateral radiograph on the 105 th day.

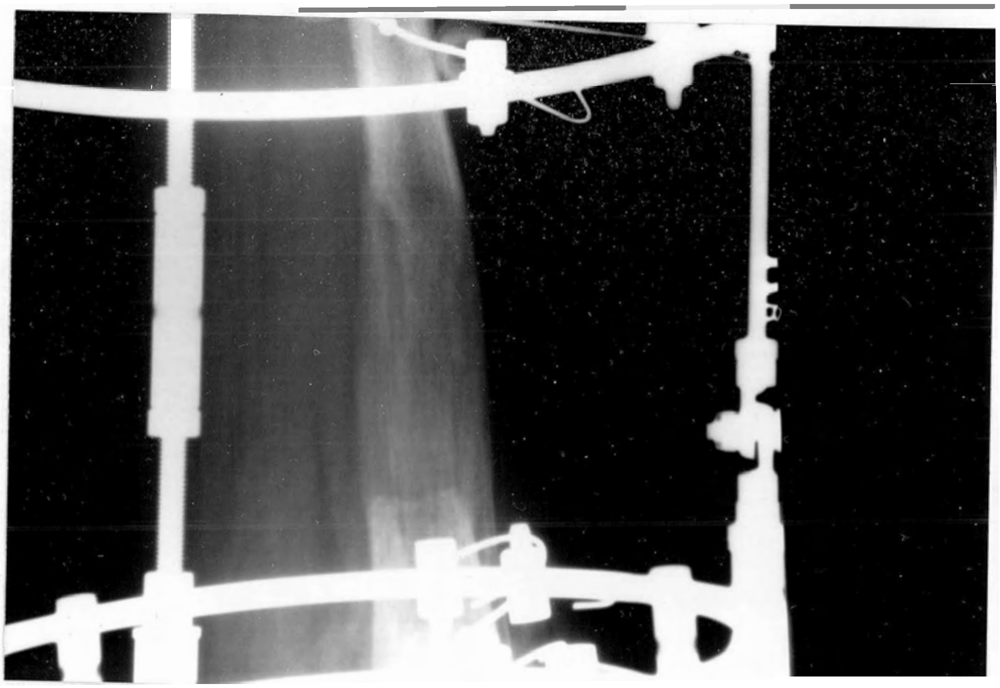

Figure 3.14. Subject 2. A close up of the distraction zone.

This shows the columnar nature of new bone formation and the central lucent zone.

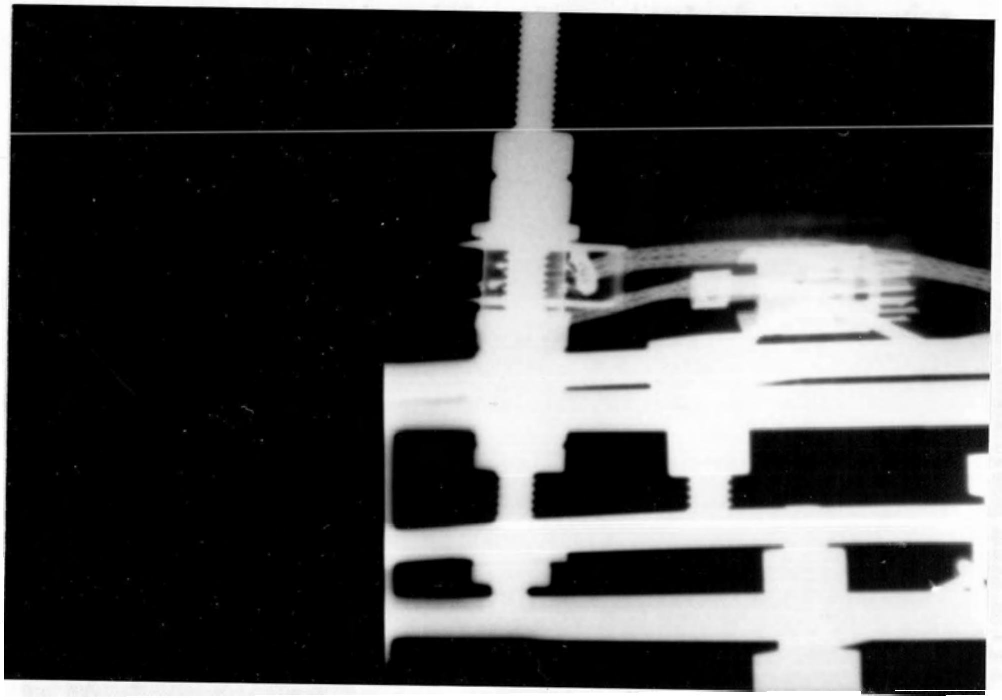

Figure 3.15. A close up view of a load cell.

This is on subject 2's frame and shows the position of the load cell with respect to the support rod. The compression washers are radiolucent and are between the washers on the distal end of the rod.

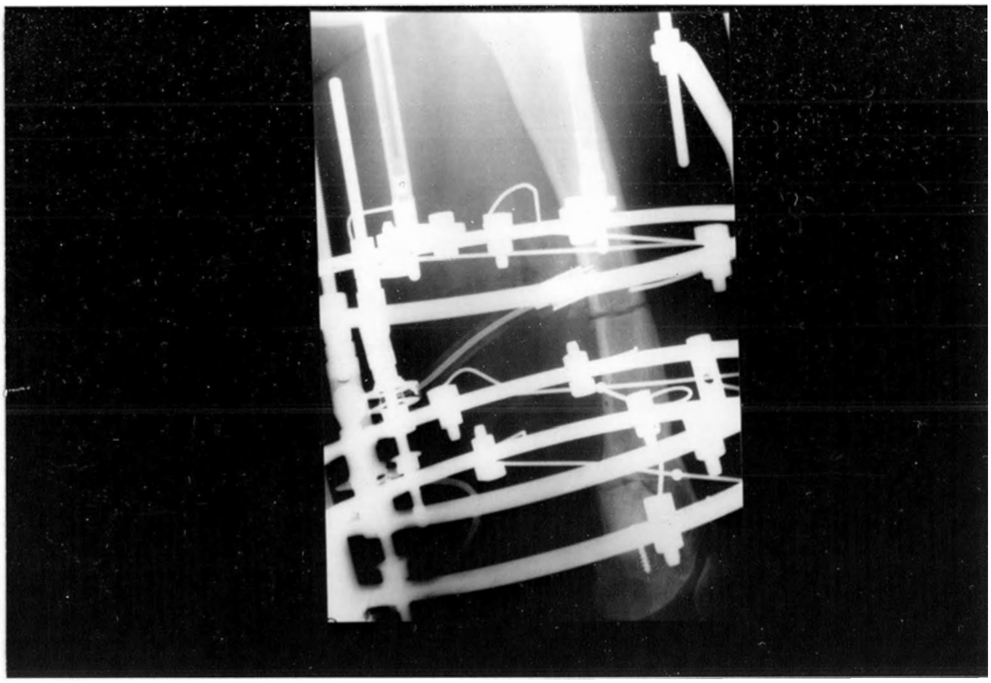

Figure 3.16. Subject 3. A lateral view of immediately after the operation.

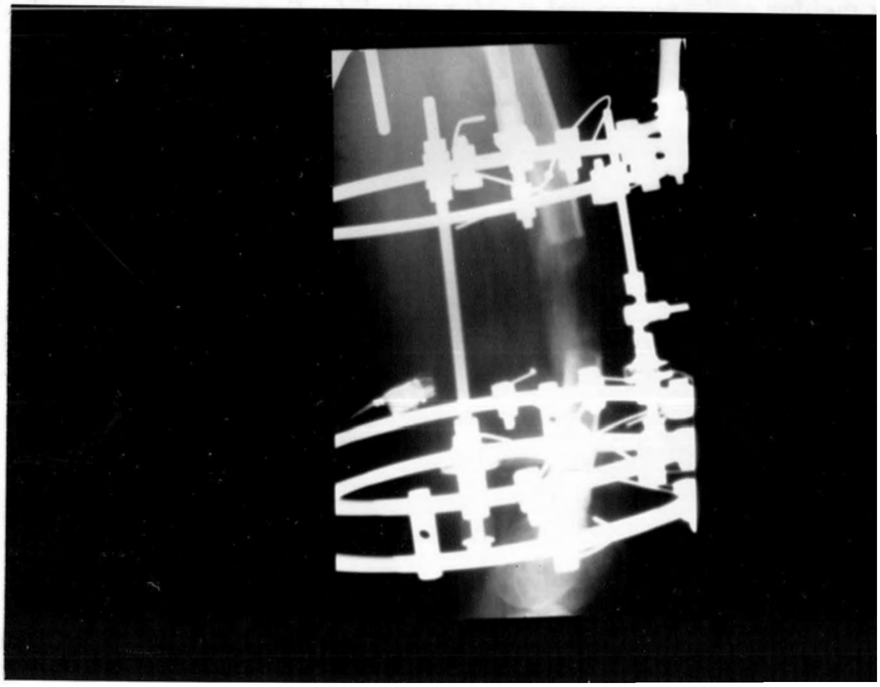

Figure 3.17. Subject 3. A lateral view on the 74 th day at the end of the distraction period.

3.4 Procedure.

3.4.1.Overnight Recordings.

Baselines were measured by inserting a duplicate rod into the frame and removeing the load from the instrumented rod. The compression force acting on the load washer was used for the calculation of the load in each rod for the overnight recording. Baseline compressions were measured in the night and morning.

Overnight recordings were made for a twelve hour period at the subject's convenience. The recordings were made at the rate of one recording every five minutes. By pressing a key the subject could mark the time of lengthening on the file.

3.4.2 Static Weight Bearing.

Recordings for static weight bearing were taken in the evening and in the morning immediately after the baseline recording. The decision to adopt this protocol was made after recordings were obtained from the first subject.

After the baselines had been measured a 20 second, 10 hertz recording of forces was taken using program 2 while the subject lay supine. The subject then stood on the good leg and let the distracted leg hang free while a further 20 second recording was taken. Finally, the subject stood with the distracted leg on a scale, putting as much weight as possible on this leg for a further recording of 20 seconds at 10 hertz.

3.4.3. Dynamic Weight Bearing.

All dynamic weight bearing measures were performed in the biomechanics laboratory at Simon Fraser University. The first subject was recorded using a Watsmart digitizing system and A/D converter. The remaining two subjects were recorded using the microcomputer and program 3.

The axes for the force platform are +X to the medial direction, +Y to the posterior direction and +Z superiorly (with respect to the leg). These axes are different from the axes on the frame.

Baseline compression forces were taken before and after each dynamic recording session. Subjects were asked to walk across the force platform at a comfortable rate using whatever support they required. Aproximately eight recordings were taken at each session.

3.5 Calculations.

Axial load.

At any instant the axial force acting on the frame was calculated using the formula:

$$AF_t = \left[(f1_t - b1) + (f2_t - b2) + (f3_t - b3)\right].a$$

where AF_t is the axial force at time t; fn_t is the force recorded in one load cell at that instant; bn is the baseline force in the same load cell (n refers to load cells one, two and three); and a is a correction factor for the loss of force in the transfer to the load cell during axial loading, obtained from the single rod calibration.

Bending moment.

The bending moment acting on the distal end of the frame at any instant was calculated using the formula:

$$BM_t = \left[((f1_t - b1_t).d1) + ((f2_t - b2_t).d2) + ((f3_t - b3_t).d3)\right].a.c$$

where BM_t is the bending moment at time t; d is the distance between the center of the cortex of the femur and the load cell as measured from the radiographs; a is the correction factor for loss of force in the rod and c is a calibration factor for the frame for bending moments incorporating the transfer of load to the load cell.

Bending moments were calculated in two planes (anteroposterior and mediolateral) and the resultant moment and its orientation was calculated. The components of bending moment acting on the frame were defined as positive if anterior (i.e. compression of the anterior aspect of the frame) and positive if lateral (i. e. compression of the lateral aspect of the frame) (see fig 3.18).

The resultant bending moment was calculated using the formula:

$$M_R = \sqrt{M_{AP}^2 + M_{ML}^2}$$

where M_{AP} is the bending moment in the anteroposterior plane (positive anterior) and M_{ML} is the bending moment in the mediolateral plane (positive lateral). Note M_R is always positive.

To calculate the plane of the resultant moment M_R the following formula was used:

$$\tan\emptyset = \frac{M_{ML}}{M_{AP}}$$

All quoted degrees are with respect to anterior, with the vectors being at ninety degrees to the plane. The diagram in figure 3.18 is centered on the axis of the femur at the level of the distraction zone. The anteroposterior plane is saggital and the mediolateral plane is coronal.

Theta is the angle between the bending moment plane, the anterior direction and a positive angle being measured in the lateral direction. The bending moment has a vertical plane with its axis passing through the center of the femur. In the diagram 3.18 the bending moment plane is 30 degrees lateral to the anterior plane. According to the right hand rule, the vector lies at 90 degrees to the bending moment plane. If the bending moment acting on the frame is desired then 90 degrees is added to Ø. If the bending moment acting on the femur is wanted then 90 degrees is subtracted from Ø. Hence the bending moment vector of the frame on the femur is the negative of the bending moment vector of the femur on the frame. A possitive bending moment in the anteroposterior plane will cause compression of the anterior aspect of the frame implying tension on the anterior aspect of the bone. Similarly a positive bending moment in the mediolateral plane will cause compression of the lateral aspect of the frame and tension in the lateral aspect of the bone.

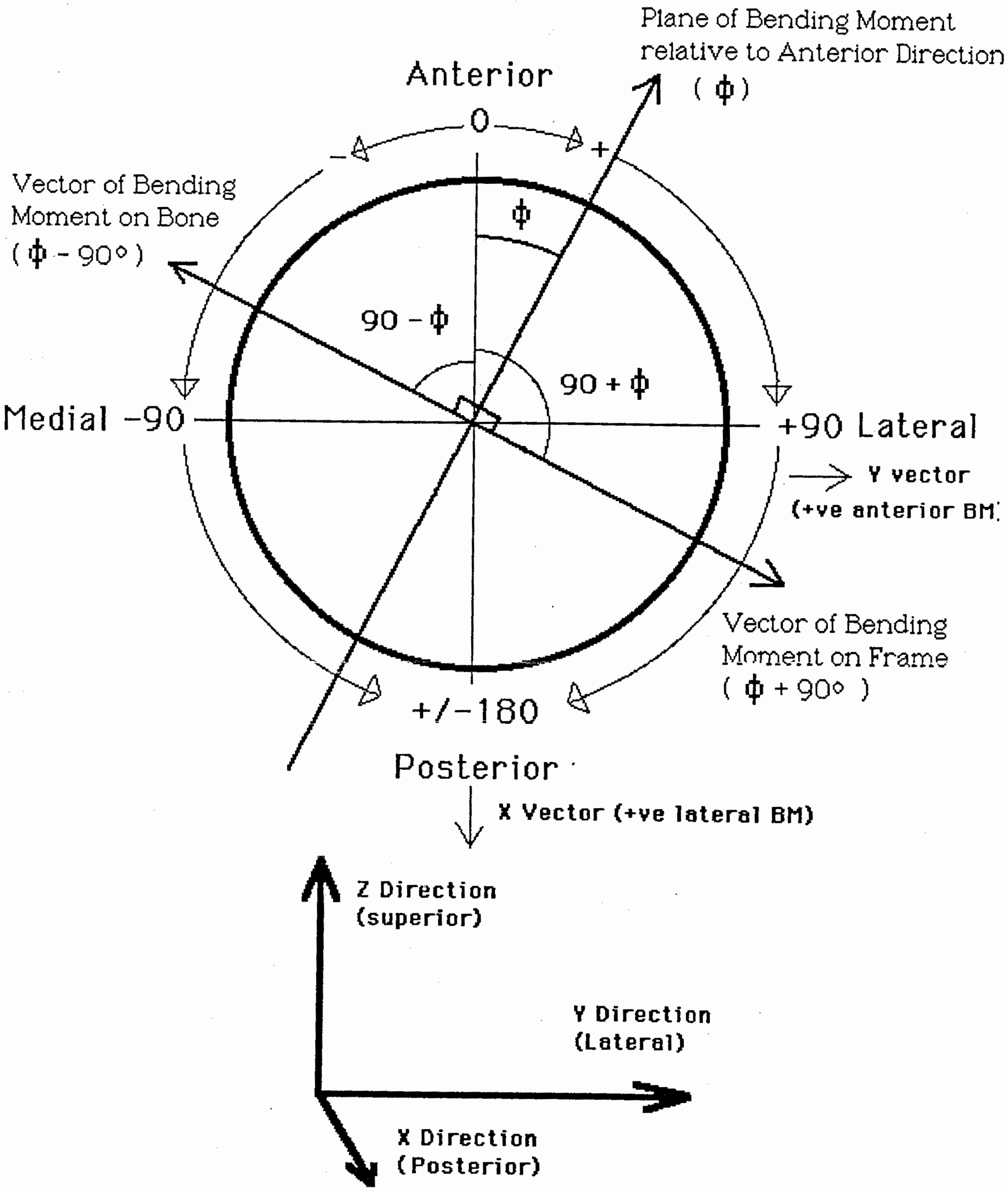

Figure 3.18. The orientation of the bending moment plane and vectors. See text for details.

3.7 Analysis.

The analysis described below was performed on three values; axial load, the bending moment magnitude and the bending moment orientation.

Overnight recordings.

1. To analyze the linearity of the increase in a value during distraction the average overnight value was plotted against postoperative days. Analysis of Covariance used to test significance. To examine non linearity, a second order polynomial was used to determine if the value tended to plateau (concave to the right) or to increase (concave to the left).

2. To determine the change of values overnight an average of 50 minutes recording from the early night, from 12 midnight, from 5.00 am and the morning were used. These values were compared for each subject during the distraction period using a repeated measures ANOVA to see if there was a change in value overnight.

3. To determine if there was any change in values with each lengthening manoeuvre an average reading for fifteen minutes before lengthening and fifteen minutes after lengthening was used and compared using a simple repeated measures ANOVA.

Static loading.

1. The three values during free hanging of the leg were plotted against postoperative days during the distraction period and ANCOVA used to analyze the slopes.

2. Comparisons were made between the value in the leg during free hanging, standing and lying supine. A repeated measures ANOVA was used to determine significance.

3. Comparisons were made between values taken at night and in the morning to determine if there was a diurnal variation in force. Pairs of values from night and morning readings for lying supine, free hanging and standing were compared using a simple repeated measures ANOVA.

4. To determine if there was a significant correlation between the three values and ground reaction force, the difference between standing and hanging (standing value minus hanging value) was correlated with ground reaction force using ANCOVA.

Dynamic loading.

1. The time prior to heel strike and maximum force in the Z direction was used for this analysisand the change in the values between these two times was determined. Across all the subjects the three parameters were compared with zero using a simple random groups design ANOVA to determine which trials showed a significant change compared with zero.

Significance was taken if $p<0.01$ for all analyses except for dynamice loading, where due to the use of a random groups design ANOVA across subjects significance was taken as $p<0.05$.

All values are quoted ± one standard error of the mean.

4. RESULTS

4.1 CALIBRATION.

Load cells.

The calibration graph and manufactures's specifications for one load cell is shown in Appendix 1. Good correlations between applied load and load cell output voltage were obtained for all load cells. As no distinct pattern of drift was seen an average of three separate calibrations was used for the force calculations.

Calibration of the load cells in situ.

It was found that approximately 70% of the applied load was returned through the load cell when mounted on the rod assembly. This indicates that the plastic washers were 2.3 times more elastic than the load cell.

The Neoprene washer and load cell assembly used on the frame of subject 1 gave a linear relationship with straight axial force with an R^2 value of 0.997. The equation of the closest fit straight line is:

$$F_A = 1.343 \times (F_{LC} - F_{COMP}) + 9.77.$$

The ABS (Acetyl Butyl Sterene) washers used for the other subjects had a straight line relationship with axial force with an R^2 value of 0.992. The equation of the closest fit straight line is:

$$F_A = 1.465 \times (F_{LC} - F_{COMP}) + 18.09.$$

Where F_A = Force applied to frame due to distraction and other forces (N).

F_{LC} = Force at load cell (applied force and compression force) (N).

F_{COMP} = Initial compression force applied by the compression washer when frame is unloaded (N).

Calibration graphs are presented in Appendix 1.

Bending Moments.

A linear relationship with a slope of approximately 1.0 was determined between applied and calculated bending moment in the anteroposterior and lateral planes. The calibration graphs of bending moments are presented in Appendix 1.

Shear.

Shear loading could affect the readings at the load cell in two ways. During the application of the shear load an increase in force in the axial direction was seen at the load cell. This was termed shear cross talk. Once the shear load was removed a change in the baseline force could also be seen. This was termed as shear baseline shift. In the shear calibration (see methods), readings were taken during load application and after load removal permitting baseline shift and cross talk to be calibrated. The ABS washers had a cross talk during load application over four trials of between 85 N to 414 N for an applied force of 203 N. The baseline shift associated with this load was between 14 N to 76 N. The magnitude of the shear baseline shift and crosstalk depended on the orientation of the frame. That is, whether the load was applied in the same plane or perpendicular to the hinges in two of the three rods).

The Neoprene washers had a cross talk of 110 N to 458 N and a baseline shift of 63 N to 199 N at the maximum loading of 203 N.

The calibration graphs for shear cross talk and baseline shift are presented in Appendix 1.

Frame Calibration.

The in vitro frame reconstruction showed an accurate transfer of axial load with close to unity relationship between applied load and calculated load ($R^2 = 0.999$ for ABS and Neoprene washers). This graph is presented in Appendix 1.

The measured and applied bending moment magnitude showed considerable diference. There was considerable movement seen of the frame during loading in a manner not to be expected in a subject (see fig 4.1). With loading there was lateral translation of the proximal fixation compared with the distal fixation. The shape of the frame distorted considerably with most of the load transfer occuring on the lateral side. As the presence of callus in a subject would prevent such movement this bending moment calibration was rejected as invalid.

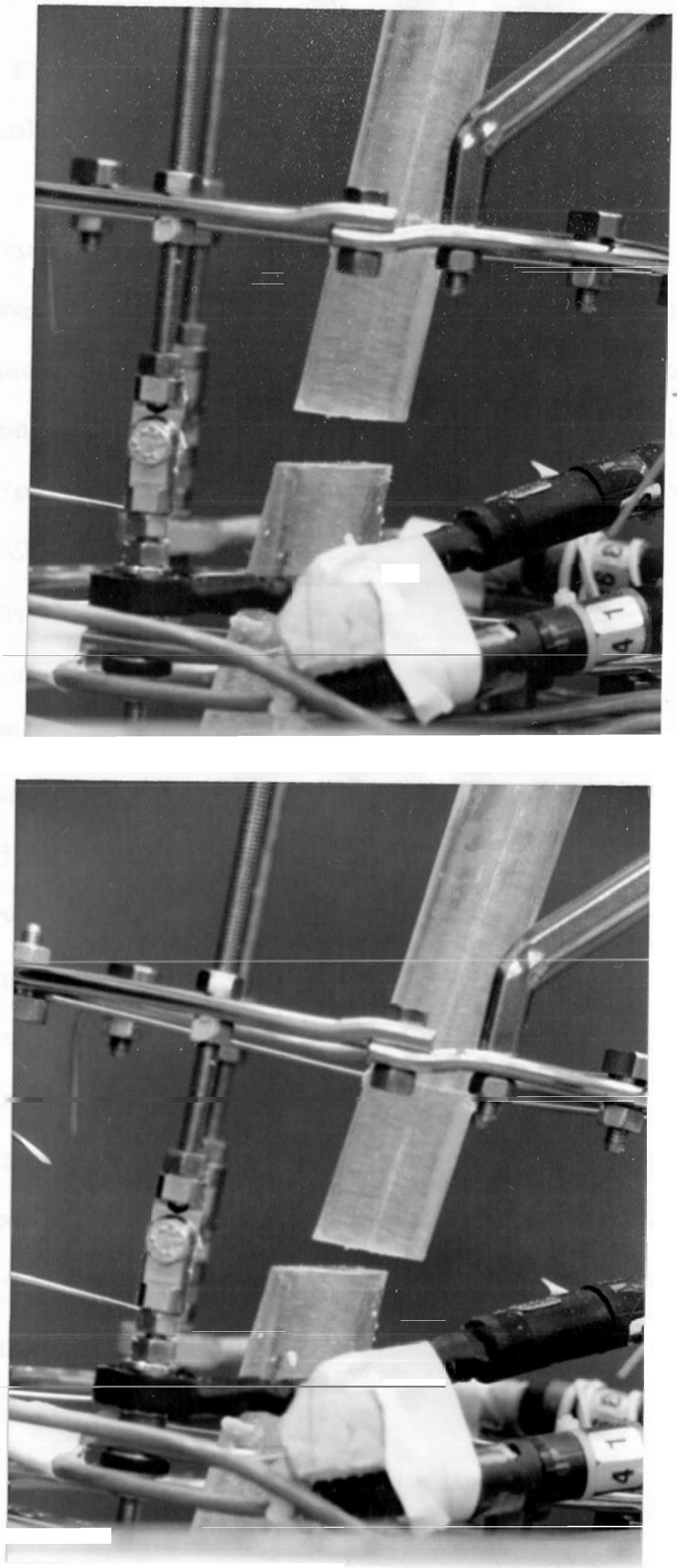

Figure 4.1. The effect of load applied to a plastic femur on the calibration frame.

The change of position of the plastic femur shown before loading (above) and after loading (below).

4.2 AXIAL FORCES

4.2.1 Recumbent.

Subject 1.

The first overnight recordings were taken on the 5 th day, two days before distraction started. The average overnight force at this time was 22 N. After distraction was started on the 7 th day, an increase in average overnight force measurements was seen until a peak of 428 N was reached on the 41 st day, when a length of 3.4 cm was attained. Thereafter, the average nightly force fell to 47 N on the 70 th day, and rose slightly to 201 N on the day before frame removal, the 89 th day (see figure 4.2).

A considerable variation in force measurements was seen in this subject which lead to the modification of technique fdor subjects 2 and 3. Problems encountered at this time included a noticeable cross talk with shear which was subsequently reduced by bench testing additional washer materials. The relationship between distraction force (N) and time (days) approximated to a straight line ($R^2 = 0.816$, $f=66.7$, $p<0.01$). A second order polynomial fitted the curve with the curve concave to the right indicating a slight tendency to plateau towards the end of distraction.

Forces recorded 15 minutes before and 15 minutes after each lengthening showed no increase in response to lengthening ($f=1.57$, $p>0.01$) (see table 4.1 for values).

Despite there being no significant change in force over each lengthening there was a consistent change in force ($f=10.0$, $p<0.01$) observed overnight, with the force being highest at 12 MN and lowest in the morning. The values are summarized in table 4.2. The fifty minute averages for each time period versus days since operation are shown in figure 4.3. An overnight plot of axial load for subject 1 is presented in Appendix 2.

Subject 2.

Overnight forces were first measured on the 3 rd day, the force being 79 N then. During distraction the force rose to a peak of 447 N on the 68 th day.

Table 4.1. Axial load and bending moment magnitude and orientation before and after each lengthening for all subjects.

Subject and Variable	before lengthening	after lengthening
1: axial load (N)	196 ± 25	200 ± 25
1: Bm Magnitude (Nm)	12 ± 2	12 ± 2
1: Orientation(°)	96 ± 16	106 ± 12
2: Axial load(N)	290 ± 36	264 ± 31
2: Bm Magnitude(Nm)	14 ± 1	15 ± 1
2: Orientation(°)	109 ± 6	116 ± 7
3: Axial load(N)	374 ± 33	362 ± 29
3: Bm Magnitude(Nm)	17 ± 1	15 ± 1
3: Orientation(°)	124 ± 8	118 ± 8

All figures quoted ± standard error of the mean. No significant differences seen (p>0.01).

Bm Magnitude = Bending moment magnitude.

Orientation = Orientation of bending moment plane.

Table 4.2. Average values recorded for four fifty minute overnight periods for all subjects.

	Evening force (N)	12 MN force (N)	5.00am force (N)	Morning force (N)	f value	p value
subject 1	182 ± 34 A	202 ± 37 BC	141 ± 31 B	137 ± 32 AC	10.0	<0.01
subject 2	190 ± 36 AB	320 ± 33 AC	316 ± 41 BD	203 ± 33 CD	14.1	<0.01
subject 3	220 ± 25 ABC	465 ± 43 AD	398 ± 40 BE	309 ± 46 CDE	37.8	<0.01

All forces are quoted ± standard error of the mean.

ABCD = Significant comparison pairs by post hoc testing. For instance, for subject 1 the evening force is significantly different from the morning (A), and the 12MN force is significantly different from the 5.00 am and morning force (BC).

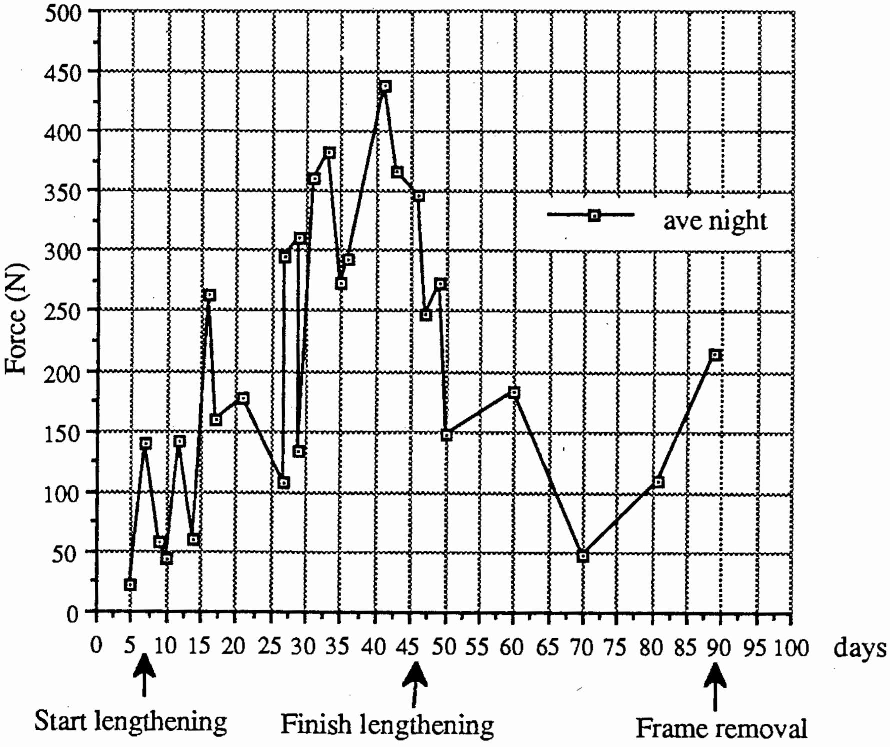

Figure 4.2. Subject 1. Average night force versus postoperative days.

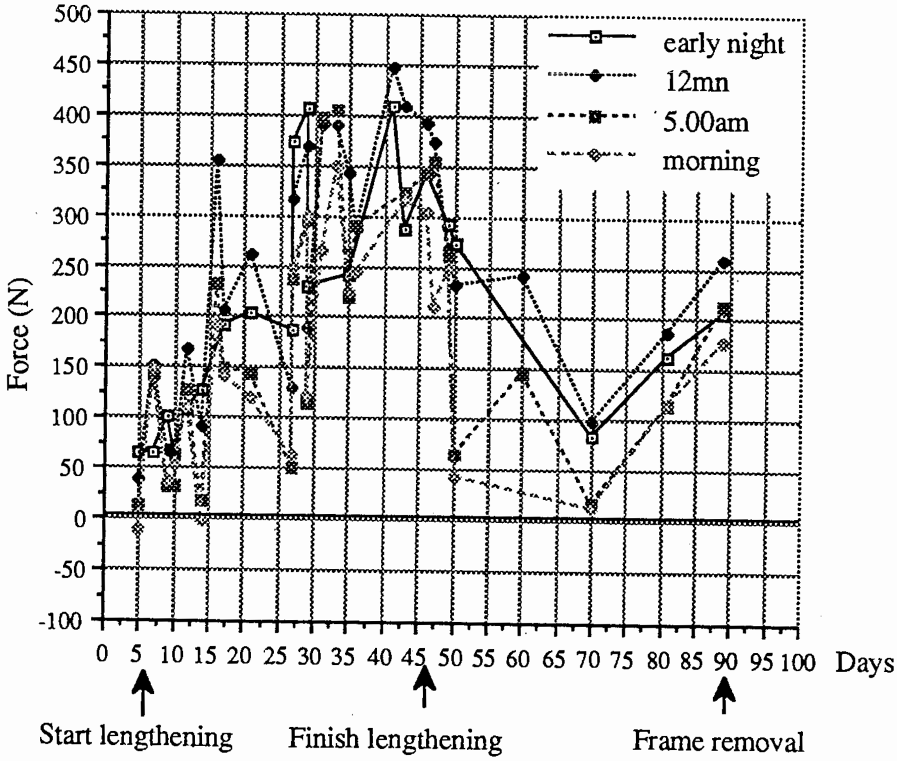

Figure 4.3. Subject 1. Mean forces recorded for four fifty minute overnight periods versus postoperative days.

The trend of average overnight values appeared more consistent in the second subject than the first subject secondary to refinement of technique. The increase corresponded to a second order polynomial with an R^2 value of 0.825 ($f=21.2$, $p>0.01$). The plateau phase in this subject was reached after 35 days lengthening and the force remained constant between 387 and 445 N until the end of distraction. The number of points on each graph are less than for the other two subjects as this subject lived a considerable distance from the city, recordings being taken when he returned to the clinic.

No change was seen in the size of the force recorded before and after each lengthening ($f= 3.95$, $p >0.01$) (see table 4.1 for values).

Despite there being no significant change in force in response to each lengthening, a consistent variation in force was observed overnight during the distraction period ($f=14.1$, $p<0.01$) (see table 4.2 for values). Forces were lowest in the evening and in the morning, and higher at 12 MN and 5.00am. Comparisons for each fifty minute period during the distraction period is shown in figure 4.5. An overnight plot of axial load for subject 2 is presented in Appendix 2.

Subject 3.

Overnight forces were first measured on the 2 nd day, the force being 109 N at that time. After beginning of distraction on the 7 th day, forces rose to a peak of 673 N on the 57 th day. The forces peaked at this point and dropped to 530 N on the 74 th day, at which point the lengthening was stopped (see figure 4.6).

The spread of average overnight values was not as marked in this subject as in the first subject secondary to refinement of technique, the closest fit straight line having an R^2 value of 0.874 ($f=66.02$, $p<0.01$). No distinct plateau was seen in this subject. The drop in force seen at the end of distraction may have been secondary to the change of lengthening regime to an angular correction with slightly less distance gained daily.

No change was seen in the force recorded fifteen minutes before and after each lengthening ($f=0.6$, $p>0.01$) (see table 4.1 for values).

There was a consistent change in force for subject 3 seen overnight during the distraction period (f=37.85, p<0.01). Post hoc comparisons showed the forces at 12 MN and 5.00 am to be similar. These forces were significantly greater than the evening and morning forces. Figure 4.7 shows the change in overnight force for subject 3. The same tendency was observed for all of the subjects studied. The variations in overnight force for the fifteen minute periods are shown in figure 4.8.

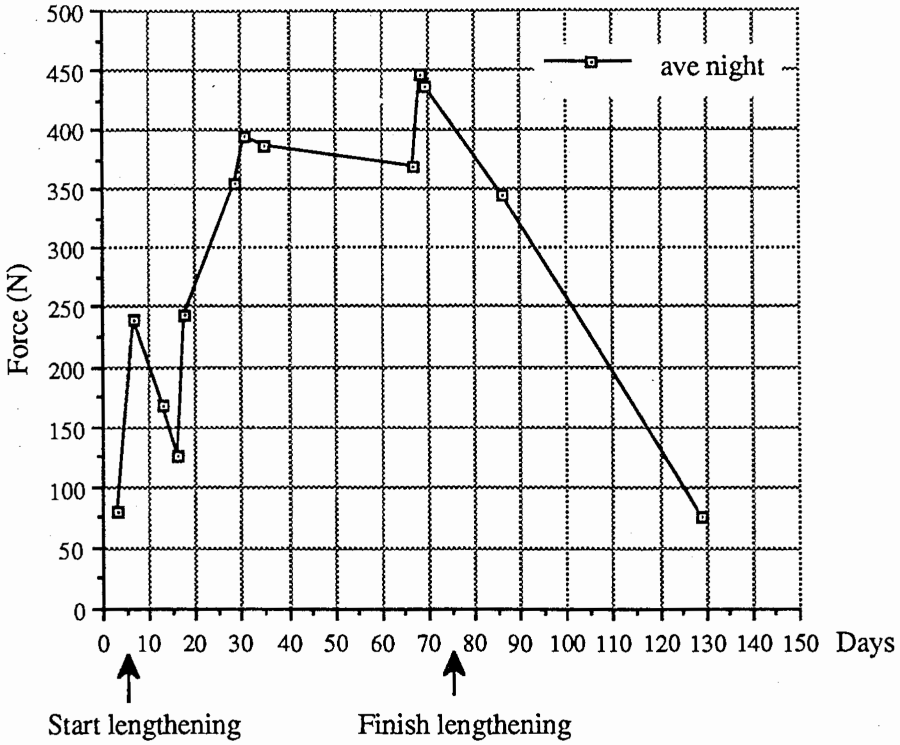

Figure 4.4. Subject 2. Average overnight force versus postoperative days.

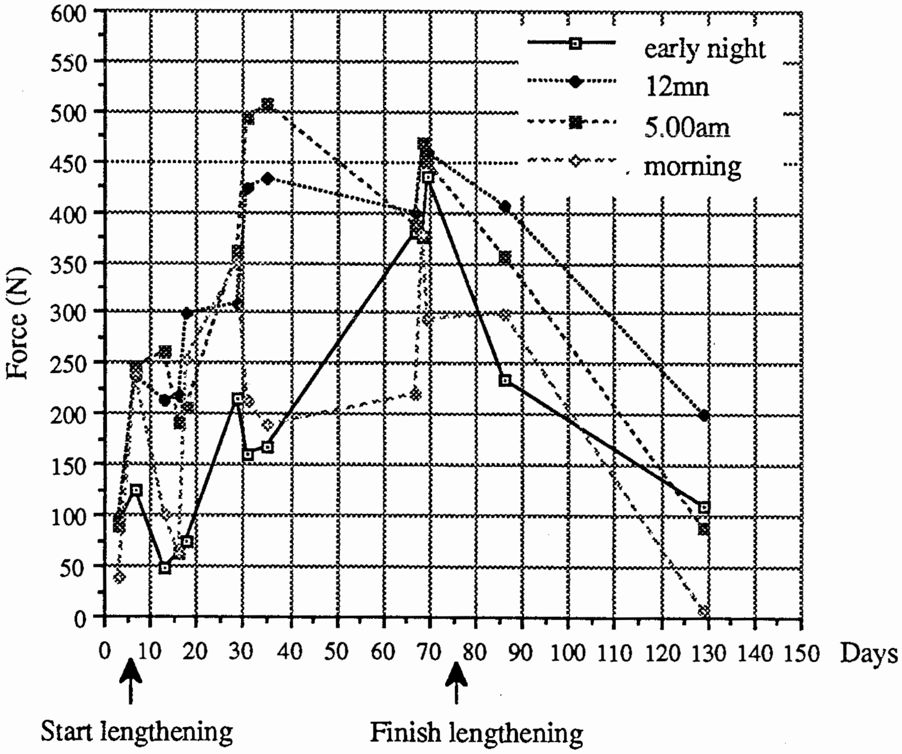

Figure 4.5. Subject 2. Mean forces recorded for four fifty minute overnight periods versus postoperative days.

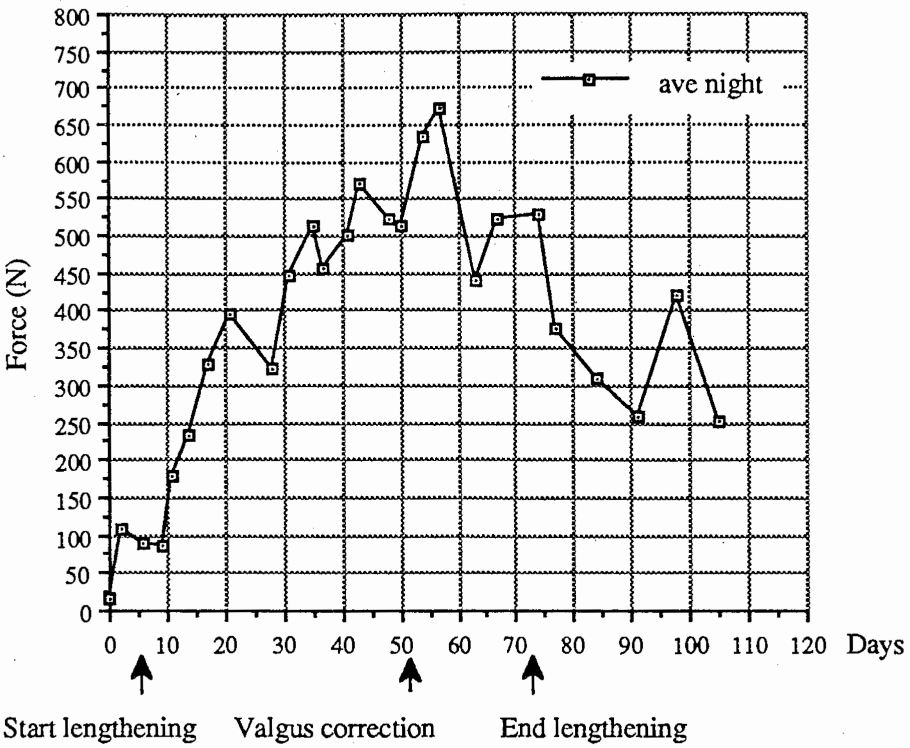

Figure 4.6. Subject 3. Average overnight force versus postoperative days.

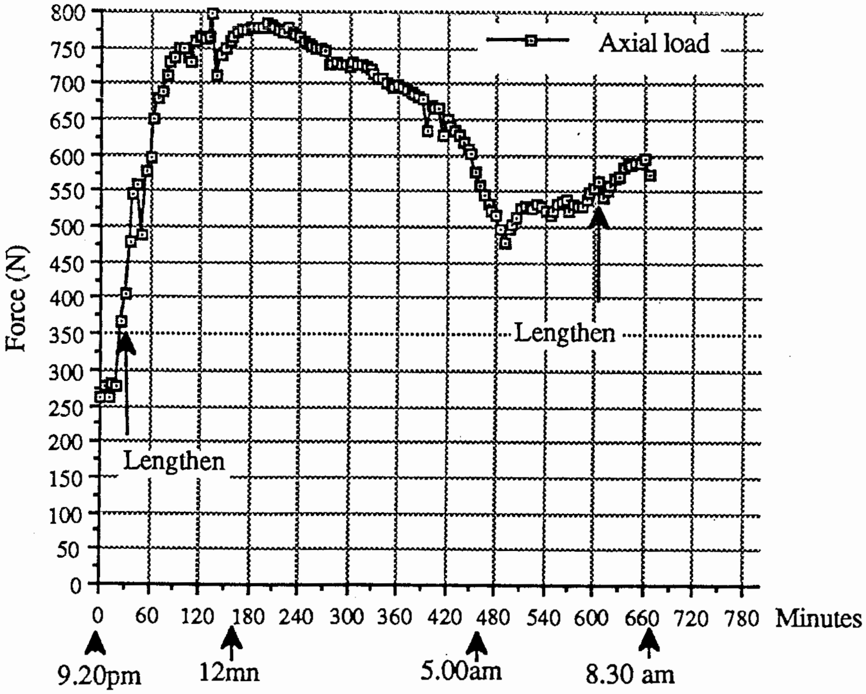

Figure 4.7. Subject 3. The axial force recorded overnight on the 53 rd postoperative day. Lengthen refers to the time at which the subject lengthened the frame by 0.25 mm.

4.2.2 Static Weight Bearing, Free Hanging and Lying Supine.

Subject 1.

The force acting on the frame, when the subject was standing was first recorded on the 10 th day and during hanging of the leg on the 30 th day.

The forces acting on the frame during free hanging rose from 185 N on the 30 th day to 344 N at the end of distraction. Forces fell to 143 N on the 82 nd day, and rose slightly to 180 N on the day the frame was removed (figure 4.11).

Standing forces rose from 89 N on the 10 th day to 382 N towards the end of distraction. There was no significant difference in the force recorded during standing, hanging, and the average of the nighttime forces ($f=6.25$, $p>0.01$). These values are presented in table 4.3.

If the femur acted as two free bodies around the distraction zone then the difference between hanging force and standing force would be the same as the ground reaction force. No change between the standing and hanging force was an unexpected result and lead to a change in protocol for the second two subjects. For these subjects the ground reaction force was measured during standing using a weight scale.

A diurnal variation was seen between the night and morning pairs of forces recorded during free hanging and standing ($f=10.44$, $p<0.01$) with the morning force being lower than the evening force (table 4.4).

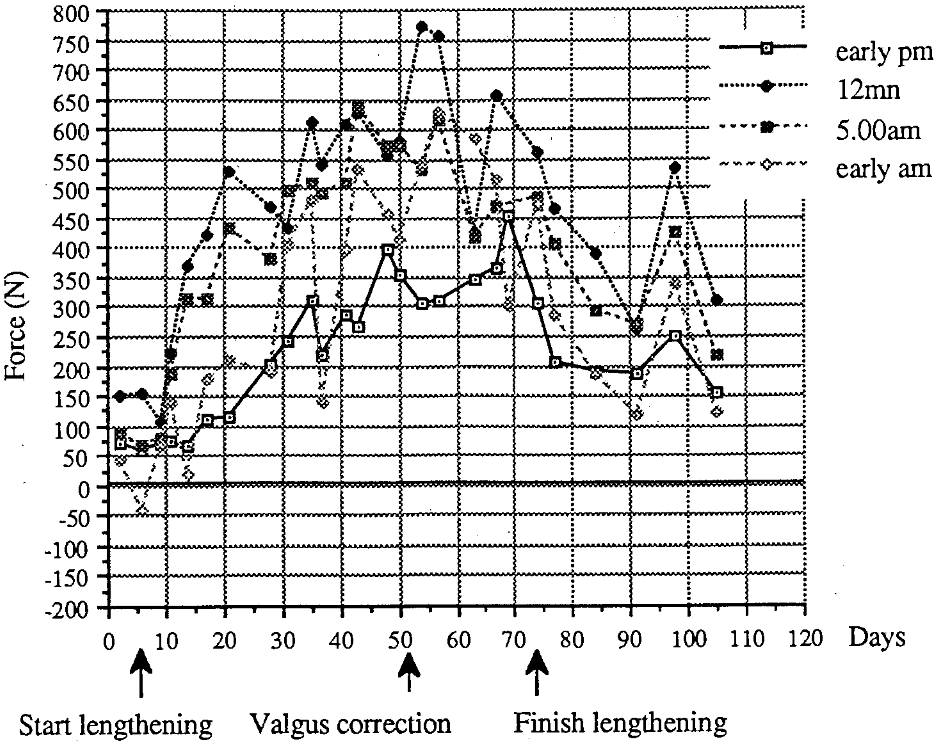

Figure 4.8. Subject 3. Mean forces recorded for four fifty minute overnight periods versus postoperative days.

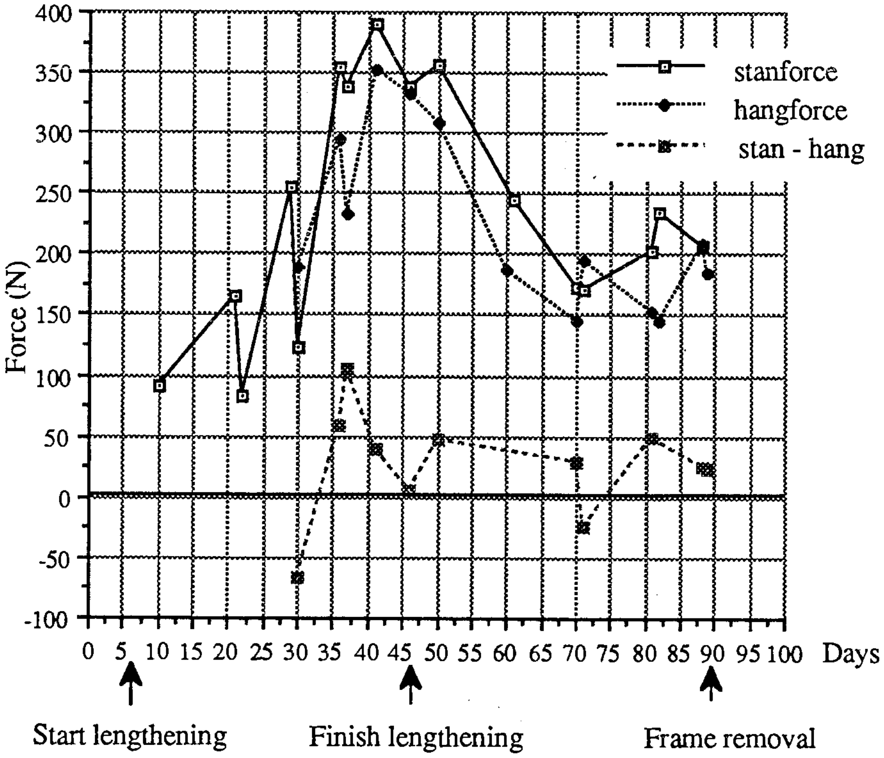

Figure 4.9. Subject 1. Axial load during static weight bearing.

Forces recorded during free hanging, standing, and the difference between standing and free hanging versus postoperative days.

Table 4.3 Forces during free hanging, static weight bearing, lying supine and the average overnight values for all subjects.

Subject and Variable.	ave night	lying supine	free hanging	standing	hang-stand	force on scale (N)
1: Axial load (N)	220 ± 13		220 ± 43	261 ± 35	41 ± 50	
1: Bm Magnitude (Nm)	12 ± 2		5 ± 1	7 ± 3	1 ± 1	
1: Orientation (degrees)	67 ± 16		123 ± 54	49 ± 38	5 ± 45	
2: Axial load (N)	282 ± 37	307 ± 22	229 ± 28	327 ± 45	114 ± 17	445 ± 30
2: Bm Magnitude (Nm)	12 ± 1	11 ± 1	11 ± 1	18 ± 3	7 ± 3	
2: Orientation (degrees)	114 ± 9	60 ± 5	93 ± 12	110 ± 5	16 ± 16	
3: Axial load (Nm)	375 ± 42	196 ± 19	220 ± 23	192 ± 20	-18 ± 11	345 ± 17
3: Bm Magnitude (Nm)	20 ± 2	9 ± 1	9 ± 1	8 ± 1	-1 ± 1	
3: Orientation (degrees)	128 ± 10	63 ± 10	61 ± 9	68 ± 11	7 ± 12	

Bm Magnitude = Bending moment magnitude.

Orientation = Orientation of bending moment plane.

Table 4.4. Axial load, bending moment magnitude and bending moment orientation averaged for the morning and evening values.

subject and variable	evening	morning
1: Axial load (N)	237 ± 21	188 ± 15*
1: Bm Magnitude. (Nm)	8 ± 2	5 ± 1
1: Orientation (degrees)	113 ± 17	3 ± 40*
2: Axial load (N)	354 ± 29	259 ± 33*
2: Bm Magnitude (Nm)	15 ± 2	14 ± 2
2: Orientation (degrees)	95 ± 9	91 ± 10
3: Axial load (Nm)	218 ± 15	137 ± 15*
3: Bm Magnitude (Nm)	10 ± 1	8 ± 1
3: Orientation (degrees)	102 ± 7	42 ± 6

* significant change ($p<0.01$).

Bm Magnitude = Bending moment magnitude.

Orientation = Orientation of bending moment plane.

Subject 1 had no recordings taken for lying supine so free hanging and standing pairs were used.

Subject 2.

The forces during standing and free hanging of the leg were measured from the 17 th day.

Forces during free hanging of the leg rose from 88 N on the 17 th day to 410 N on the 65 th day increaseing with a linear relationship ($R^2 = 0.688$, f=35.4, $p<0.01$). A force plateau was seen in this subject (see figure 4.10).

Forces during lying supine were first recorded with this subject. These recordings were made as a result of the diurnal effect seen in subject 1. The aim was to determine if the force with the subject lying supine was different from free hanging and standing if recorded in a similar manner.

Lying supine forces, first recorded on the 65 th day, were 380 N. They remained arround this magnitude for the duriation of the distraction phase. The magnitude of this force reflected the overnight fifty minute average for night and morning, and closely followed the force seen during free hanging of the leg (see figure 4.10).

Standing forces rose from 93 N on the 17 th day to 598 N on the 68 th day. There was a significant difference between the average nighttime force, standing and free hanging force (f=11.06, $p<0.01$). Lying supine forces were not included in the comparison as few readings had been taken. Post hoc comparisons show there to be a difference between the average night force and free hanging force, and between the free hanging force and the standing force. This last comparison shows there to be a significant increase in force during weight bearing.

The ground reaction force measured on the weight scale rose from 43 N to 578 N on the 86 th day (see figure 4.10) The ground reaction force correlated with the difference between the hanging and standing leg forces with an R^2 value of 0.395, the correlation being significant (f=10.43, $p<0.05$).

A diurnal variation was found between the night and morning pairs of forces recorded during lying supine, free hanging and standing (f=11.4, $p<0.01$), with the night time forces always being higher (table 4.4).

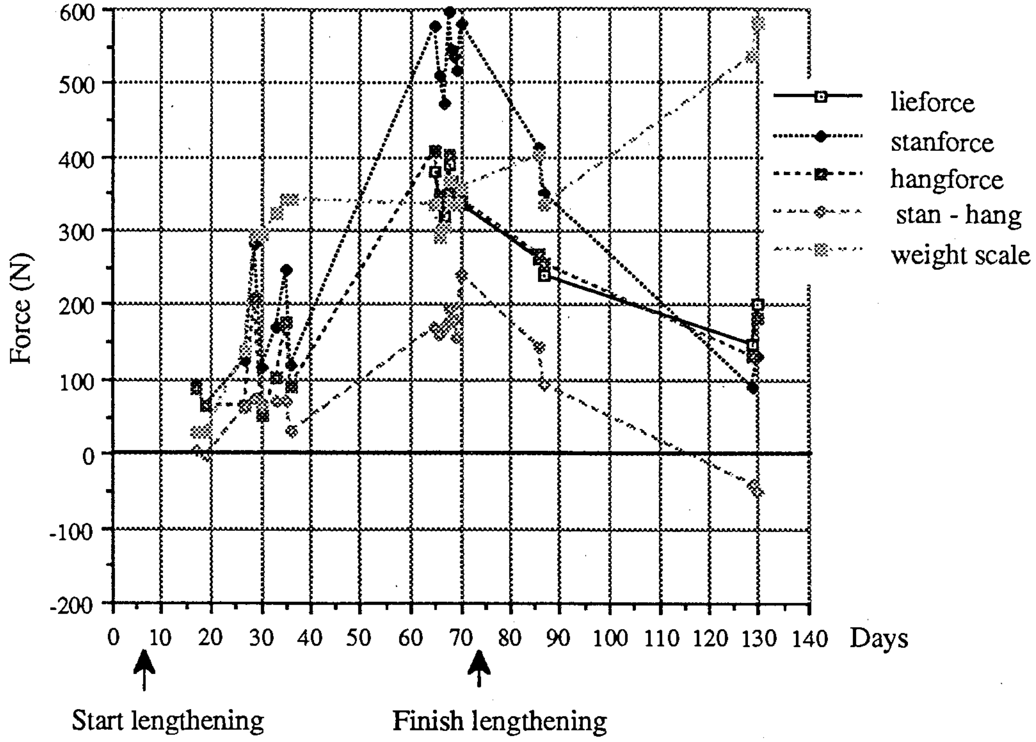

Figure 4.10. Subject 2. Axial load during static weight bearing.

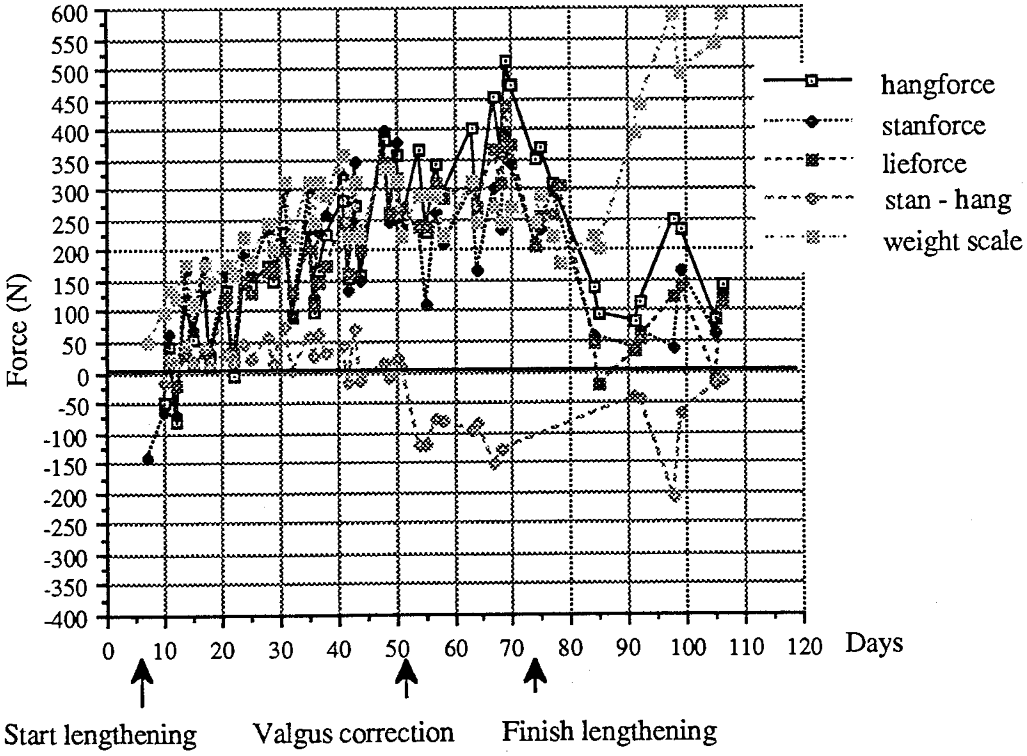

Figure 4.11. Subject 3. Axial load during static weight bearing.

For both graphs forces shown were recorded during lying supine, free hanging, standing and the difference between standing and hanging with the ground reaction force versus postoperative days.

Subject 3.

Forces during standing on the leg were measured from the 7 th day, free hanging of the leg from the 10 th day, and lying supine from the 11 th day.

Forces during free hanging of the leg rose from -48 N on the 10 th day to 511 N on the 69 th day. A linear rise in force versus days since operation was found ($R^2 = 0.788$, $f=67.0$, $p<0.01$). A plateau phase of force was not seen (see figure 4.13).

The force recorded with the subject lying supine before standing was 20 N on the 11 th day (when first recorded) and rose to 420 N towards the end of distraction. This force tended to be lower than the corresponding overnight recording, and lay between the free hanging and standing forces.

Standing forces rose from -140 N on the 7 th day to 394 N on the 69 th day. There was a significant difference between the force in the leg during standing, the average of the nighttime force, lying supine forces and during free hanging of the leg ($f=59.2$, $p<0.01$). Post hoc comparisons showed the average night force to be greater than the hanging force and the standing force. There was no difference between the hanging, standing and lying forces. The values for the average night force were higher than those recorded during static weight bearing as forces in the middle of the night were larger (see figure 4.7 and table 4.2).

The ground reaction force measured on the scale rose from 72 N to 524 N on the 41 st day and remained arround this force for the rest of distraction. The difference between free hanging force and standing force did not provide a significant correlation with the ground reaction force ($f=0.322$, $p>0.01$). The force time relationships are shown in figure 4.11.

A significant difference was found between night and morning forces recorded during lying, hanging and standing ($f=75.3$, $p<0.01$) (values in table 4.4). There was a trend towards diurnal variation in the difference between standing and free hanging force. There was also trend towards diurnal variation in ground reaction force recorded on the weight scale. This variation can be seen in figure 4.6 creating the saw toothed pattern of the force increase during the distraction period.

4.2.3 Dynamic Loading.

Subject 1.

Two trials were performed during distraction; on the 14 th and 37 th days. Axial load was compared with the ground reaction force measured in the vertical (Z) direction on the force platform. In the first trial 7 walks were recorded. The mean force in the Z direction peaked at 112 ± 8 N. The increase in axial load in the frame was insignificant ($p>0.05$)[*] (see table 4.4). In the second trial 6 walks were recorded. The mean force in the Z direction peaked at 171 ± 16 N. The corresponding increase in axial load in the frame was 39 ± 3 N, being significantly different form zero ($p<0.05$). Table 4.5 summarizes the dynamic loading values for this subject.

Subject 2.

Two trials were performed for this subject during distraction; on the 31 st and 86 th days. Axial load was again compared with the ground reaction force measured in the Z direction from the force platform. For the first trial 9 walks were recorded. The peak ground force was 299 ± 12 N. The increase in axial load in the frame was not significant ($p>0.05$).

For the second trial over 6 walks the mean peak ground force was 378 ± 8 N. The increase in axial load in the frame was 120 ± 6 N, being significantly different from zero ($p<0.05$). One walk from each of these trials is presented in Appendix 3. Table 4.6 summarizes the dynamic loading values for this subject.

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[*] Significance of $p>0.05$ was taken for dynamic laoding as the ANOVA comparison was performed across all subjects using a factorial design reducing the chance of a type I error, a higher value for p being used to compensate. Through the rest of the results outside dynamic loading p is significant if <0.01.

Table 4.5. Summary of dynamic loading changes for subject 1.

Changes are shown between values prior to heel strike and peak force in the Z direction. Forces in the frame, and in the X, Y and Z direction at the force platform as well as bending moment magnitude and orientation are shown.

	Trial 1	Trial 2
Time to peak force (s)	0.34 ± 0.05	0.47 ± 0.05
Change in X (N)	1.9 ± 0.9	-3.6 ± 1.14
Change in Y (N)	6.9 ± 1.3	1.7 ± 1.9
Change in Z (N)	112.3 ± 7.5	171 ± 16
Change in load in frame (N)	19 ± 10	39 ± 3 *
Change in Bm Magnitude (Nm)	-1.16 ± 0.04	1.0 ± 0.4
Change in Bm Orientation (°)	25 ± 6	-3 ± 1

Table 4.6. Summary of dynamic loading changes for subject 2.

Values are the same as in table 4.5.

	Trial 1	Trial 2
Time to peak force (s)	0.66 ± 0.06	0.73 ± 0.04
Change in X (N)	31.4 ± 0.6	-26.8 ± 1.8
Change in Y (N)	15.7 ± 6.8	-12.3 ± 4.5
Change in Z (N)	299.3 ± 11.8	377.8 ± 8.2
Change in load in frame (N)	19 ± 12	120 ± 6 *
Change in Bm Magnitude (Nm)	-0.04 ± 2.1	1.0 ± 0.9
Change in Bm Orientation (°)	-15 ± 6	-24 ± 3

The change in bending moment magnitude may be negative (although the magnitude itself is always positive) if it decreases on weight bearing.

The orientation quoted is the plane of the bending moment with respect to the femur

* Significant differences using a factorial ANOVA ($p<0.05$).

Subject 3.

Three trials were performed for this subject during distraction; on the 16 th, 44 th and 64 th days.

In the first trial 8 walks were performed. The mean peak ground reaction force in the Z direction was 112 ± 4 N. The increase in axial load in the frame was not significant ($p>0.05$).

For the second trial 10 walks were recorded. The mean ground force was 280 ± 28 N. The increase in axial load in the frame was again not significant ($p>0.05$).

For the third trial 10 walks were recorded. The mean peak ground reaction force was 301 ± 5 N. A decrease in axial load in the frame of -59 ± 6 N, was measured ($p<0.05$).

Although the ground forces were larger in the later trials they did not reach the magnitude of the force seen in the Z direction during the preoperative assessment, when a peak of 575 N was seen.

An example of a walk from each of the three trials is presented in Appendix 3. Table 4.6 summarizes the values for this subject. Note the reversal of force seen in the frame for the second and third trials.

In summary, a change of force in the frame resulting from the ground reaction force was only noticeable for subjects one and two towards the end of distraction. Subject three did not exhibit this pattern, and showed a reversal of force for the third trial. The most plausible explanation of this may be a degree of shear cross talk confounding the result due to the offset between the two rings secondary to an angular correction late in the distraction.

Table 4.7. Summary of dynamic loading changes for subject 3.

Changes are shown between values prior to heel strike and peak force in the Z direction. Forces in the frame, and in the X, Y and Z direction at the force platform as well as bending moment magnitude and orientation are shown.

	Preop L	Preop R	Trial 1	Trial 2	Trial 3
Time to peak force (s)	0.50 ± 0.20	0.32 ± 0.06	0.53 ± 0.12	0.58 ± 0.04	0.61 ± 0.20
Change in X (N)			-13.7 ± 4.3	-34.4 ± 2.6	-24.1 ± 5.5
Change in Y (N)			15.5 ± 1.5	18.0 ± 13.6	16.2 ± 12.6
Change in Z (N)	574.5±23.0	528.1±12.7	111.5±11.5	279.9±98.9	300.6±16.0
Change in load in frame (N)			16 ± 5	-3.6 ± 6	-40 ± 13
Change in Bm Magnitude (Nm)			0.17 ± 0.2	-4.5 ± 0.4	-1.5 ± 0.7
Change in Orientation (°)			-3 ± 2	-5.3 ± 5.3	-34 ± 3

The orientation quoted is the plane of the bending moment with respect to the femur.

* Significant differnces using a factorial ANOVA ($p<0.05$).

Preop L and R: Preoperative assessment: Left (normal) and Right (shortened) legs.

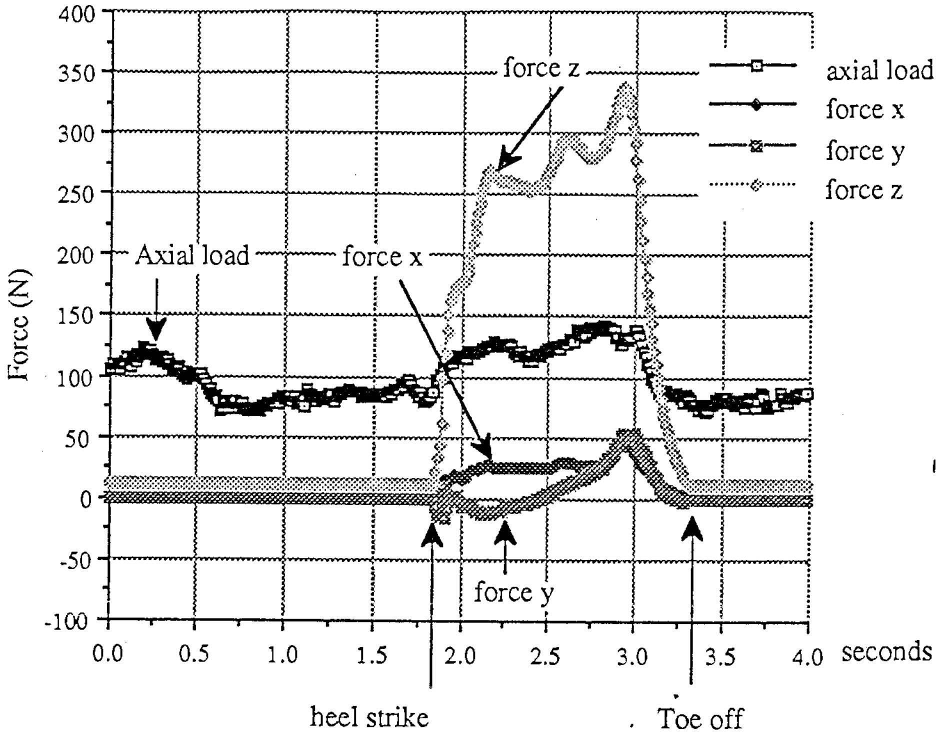


Figure 4.12. Subject 3. Force changes during one walk during trial one.

The reaction force in the X, Y and Z direction and the axial load in the frame versus time. Although there is a small change in the axial load this was not significant across all walks in this trial

4.3 BENDING MOMENTS.

4.3.1 Recumbent.

Subject 1.

The resultant bending moment and its orientation were first calculated on the 9 th day, the average overnight bending moment being 8.1 Nm orientated at 50°. A peak of 26.3 Nm was reached on the 43 rd day orientated at 77° lateral to anterior. The average bending moment fell during repair to 4.3 Nm orientated 6° lateral to anterior on the 89th day.

The bending moment magnitude did not plateau during distraction (see figure 4.13). The plane of the bending moment varied from -122° to +137° with no trend seen (see fig 4.20).

Bending moments recorded 15 minutes before and 15 minutes after each lengthening showed no change in magnitude ($f=0.01$, $p>0.01$) or orientation ($f=0.16$, $p>0.01$) (see table 4.8 for values).

A diurnal variation in the bending moment magnitude was not seen for the four 50 minute overnight periods ($f=0.54$, $p>0.01$). Nor was there a variation in orientation ($f=7.12$, $p<0.01$) (see table 4.7 for values). A sample recording of bending moment magnitude and plane of orientation overnight is presented in Appendix 2.

Subject 2.

The resultant bending moment and its orientation were first calculated for the 3 rd day. The average overnight bending moment was 9.21 Nm orientated at +135°. A peak of 16.3 Nm was reached on the 31 st day orientated at +120°. No tendency to plateau was seen in the recorded bending moment, nor was the increase linear ($R^2=0.011$, $f=0.11$, $p>0.01$). The orientation changed from posterolateral towards anterior in a linear manner during distraction ($R^2=0.813$, $f=43.6$, $p<0.01$) (see fig 4.14).

Bending moment magnitude from 15 minutes before and fifteen minutes after each lengthening showed no increase in size and the orientation did not change (see table 4.1).

Table 4.8. The mean bending moment values for four fifty minute periods for all subjects.

Subject and Variable	Evening	12 MN	5.00am	Morning	f	p
1: Magnitude (Nm)	11.7 ± 2.8	11.4 ± 2.5	9.7 ± 2.4	10.0 ± 2.2	0.54	>0.01
1: Orientation (°)	149 ± 24 **ab**	116 ± 16 **c**	57 ± 19 **a**	30 ± 19 **bc**	7.11	<0.01
2: Magnitude (Nm)	10.5± 1 **b**	11.7 ± 1 **c**	11.3 ±1 **a**	15.1±1**abc**	6.81	<0.01
2: Orientation (°)	108 ± 8	113 ± 8	114 ± 8	113 ± 11	0.761	>0.01
3: Magnitude (Nm)	10.1 ± 1**ab**	24.7 ± 8 **ca**	22.8 ± 9 **bd**	12.9 ± 9 **bc**	31.55	<0.01
3: Orientation (°)	106 ± 10	132 ± 10	126 ± 11	129 ± 14	3.03	>0.01

abc Significant difference in pairs using comparisons by posthoc testing. For instance, the magnitude of bending moment for subject 2 is significantly different for the 5.00am and morning pair (a) and evening and morning pair (b).

Magnitude refers to bending moment magnitude, and orientation refers to the orientation of the bending moment plane with respect to the anterior axis of the femur.

12 MN refers to 12 midnight.

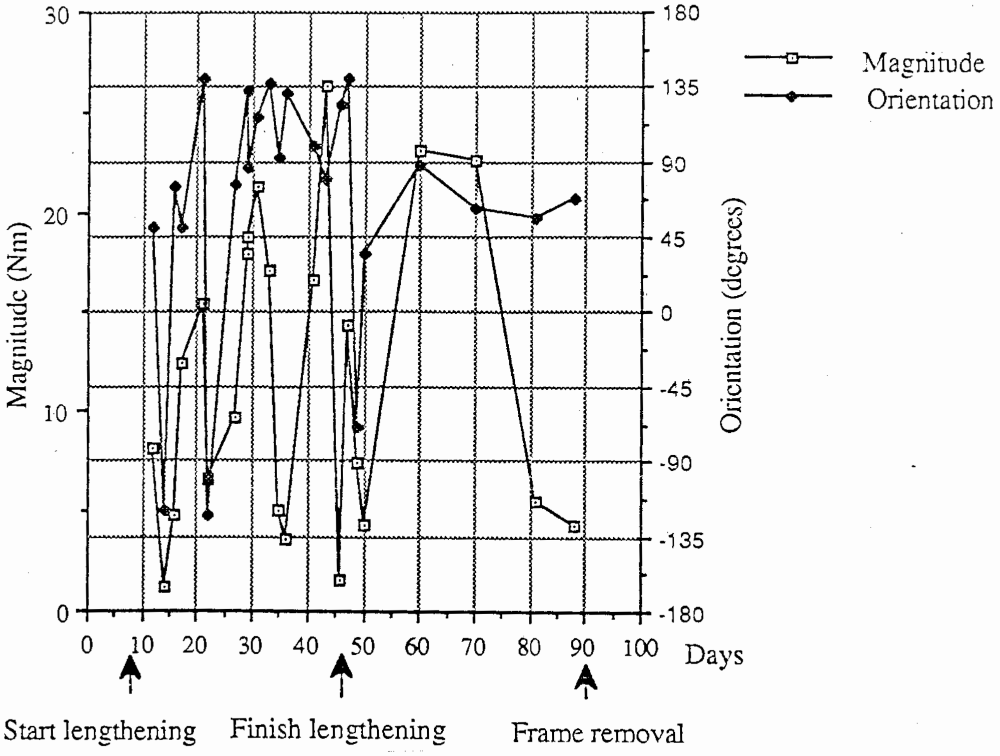


Figure 4.13. Subject 1. Average overnight bending moment magnitude and the orientation of its plane (from anterior) versus postoperative days.

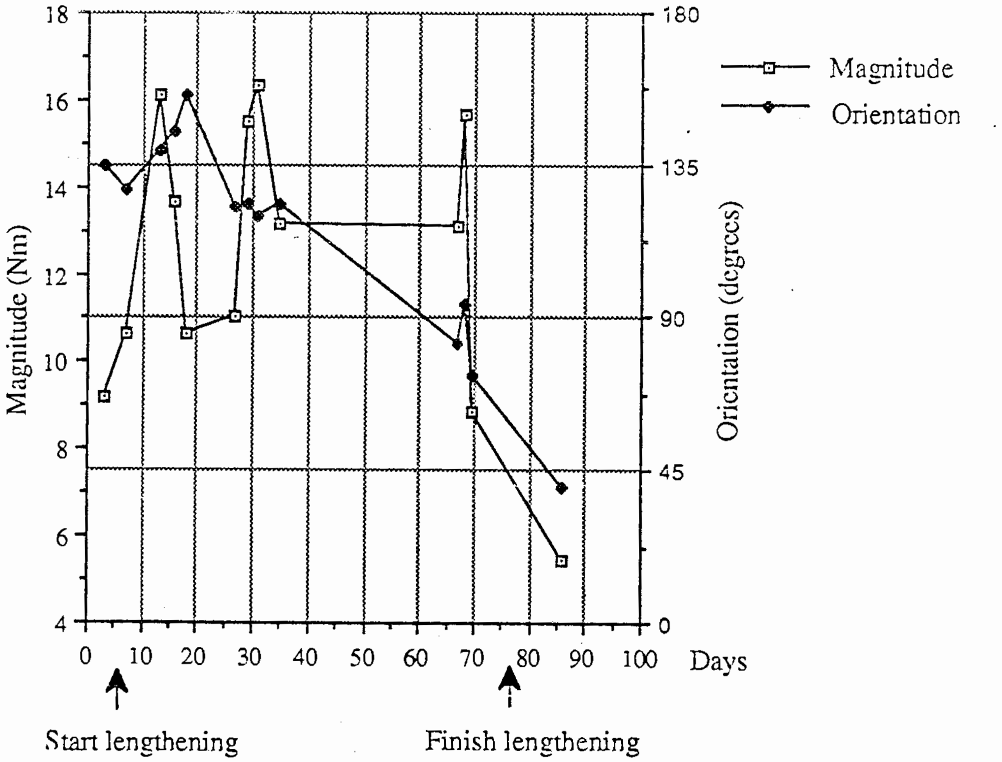


Figure 4.14. Subject 2. Average overnight bending moment magnitude and plane of orientation versus postoperative days.

A diurnal variation of bending moment magnitude was seen for the four 50 minute overnight periods was seen ($f=6.8$, $p<0.01$). The morning bending moment was larger than the 5.00 am moment and the early night moment. No change in orientation was seen. Table 4.8 and Appendix 2 display an overnight trace of bending moment magnitude and orientation.

Subject 3.

The bending moment magnitude and its orientation were first calculated on the 6 th day, average overnight bending moment being 4.7 Nm orientated at 9^{o}. Bending moments did not increase significantly. A peak of value of 34.7 Nm was reached orientated at 79^{o}. The orientation migrated from posterior to anterior via the lateral side during distraction remaining in the anterior quadrant from the 40th day on ($R^2=0.35$, $f=9.5$, $p<0.01$, see fig 4.15).

Bending moment magnitude averaged over 15 minutes before and after lengthening showed a decrease from 19.8 Nm to 14.2 Nm ($f= 11.5$, $p<0.01$). The orientation remained unchanged ($f=4.2$, $p>0.01$) (table 4.1).

There was an overnight change in the bending moment magnitude for the four 50 minute overnight periods ($f=31.6$, $p<0.01$) and there was no change in orientation (see table 4.8). Figure 4.16 shows how the bending moment magnitude and orientation changed over the 53 rd night.

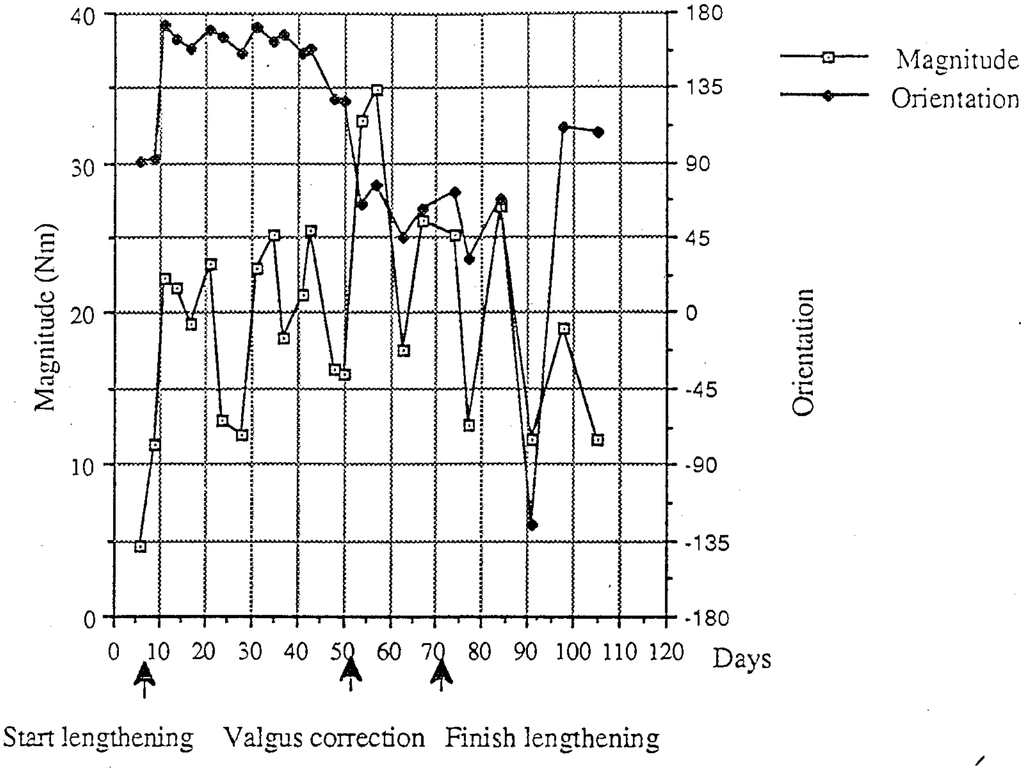


Figure 4.15. Subject 3. Average overnight bending moment magnitude and plane of orientation versus postoperative days.

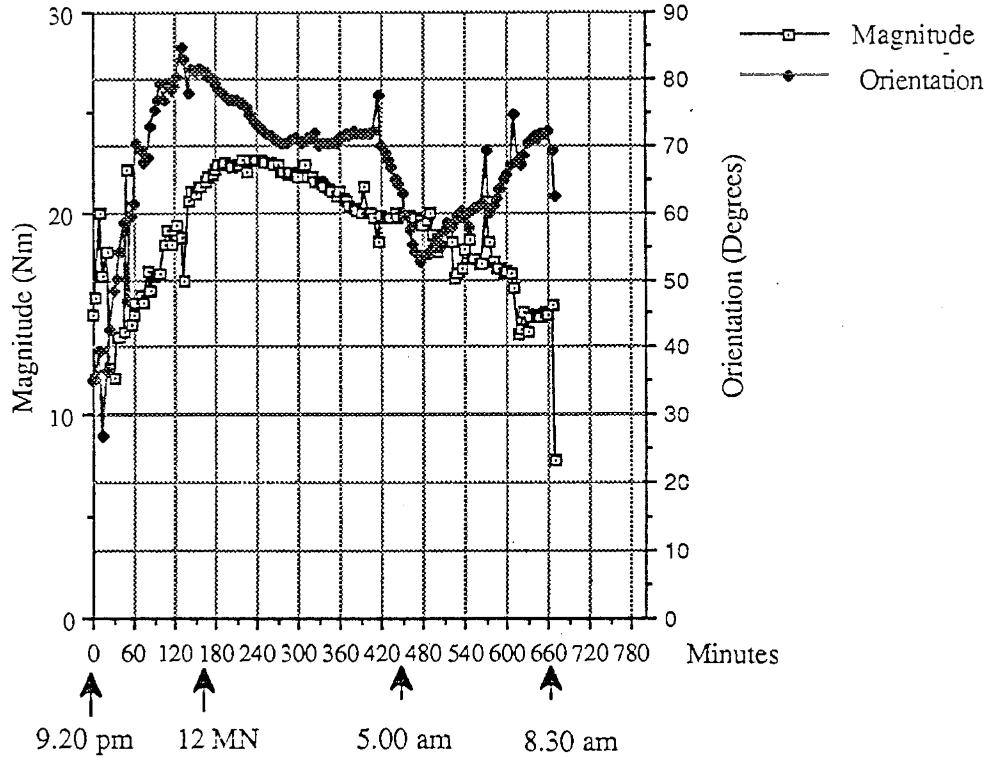


Figure 4.16. Subject 3. Bending moment magnitude and plane of orientation on the 53 rd postoperative day.

4.3.2 Static Weight Bearing, Free Hanging and Lying Supine.

Subject 1.

The bending moment mangitude did not change over the distraction period for free hanging and standing recordings. The difference between the bending moment magnitude during hanging of the leg and standing on the leg was not significant (f= 0.07, $p>0.1$). After distractiom was completed, the bending moment magnitude decreased during repair (neutral fixation) (see figure 4.17).

No trends were observed in the orientation of the bending moment plane during standing or hanging during the time of distraction or repair (figure 4.18), nor was there was a significant difference between the two groups (see table 4.3 for values).

There was no difference between evening and morning values for bending moment magnitude and orientation recorded during free hanging and standing.

Subject 2.

The bending moment magnitude increased over the distraction period for standing ($R^2 = 0.782$, f=50.32, $p<0.01$). No increase for free hanging was seen ($R^2= 0.099$, f= 1.53, $p>0.01$) (see figure 4.19). The difference between the bending moment magnitude during free hanging and standing on the leg and lying supine was not significant (f=4.5, $p>0.01$). Standing bending moments were larger than during free hanging or lying supine (see table 4.3).

The orientation of bending moments became lateral from posterior during distraction for standing ($R^2=0.99$, f=456.13, $p<0.01$) and hanging ($R^2=0.89$, f=117.4, $p<0.01$) (see figure 4.20).

Bending moments showed no difference between the evening magnitude and the morning magnitude recorded during free hanging, standing and lying supine, for either magnitude (f=0.02, $p>0.01$) or orientation (f=0.16, $p>0.01$) (see table 4.4).

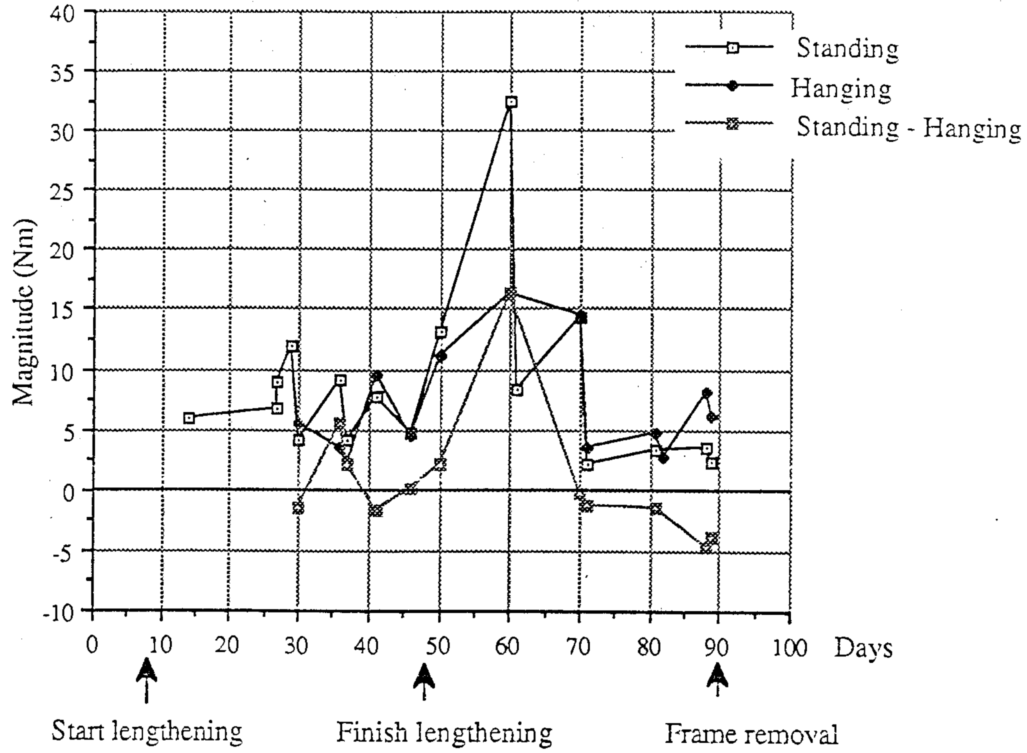


Figure 4.17 Subject 1. The magnitude of bending moments during free hanging, standing and standing hanging difference versus postoperative days.

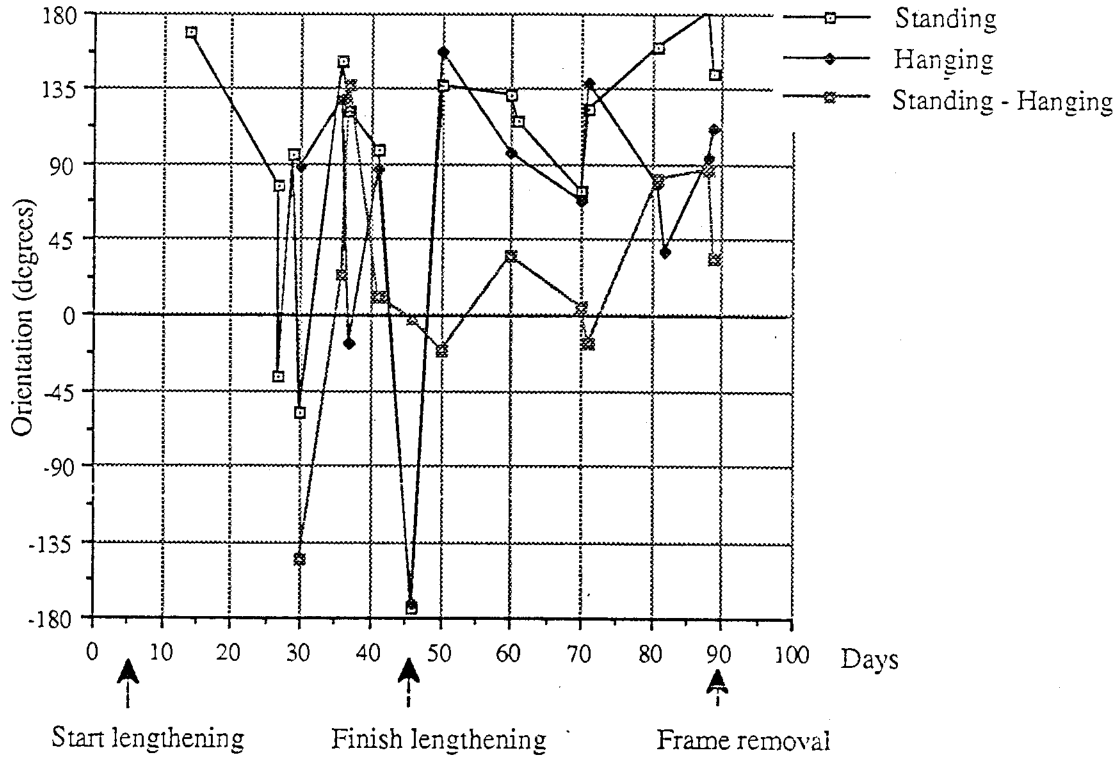


Figure 4.18 Subject 1. The orientation of the plane of bending moments during free hanging, standing and standing hanging difference versus postoperative days.

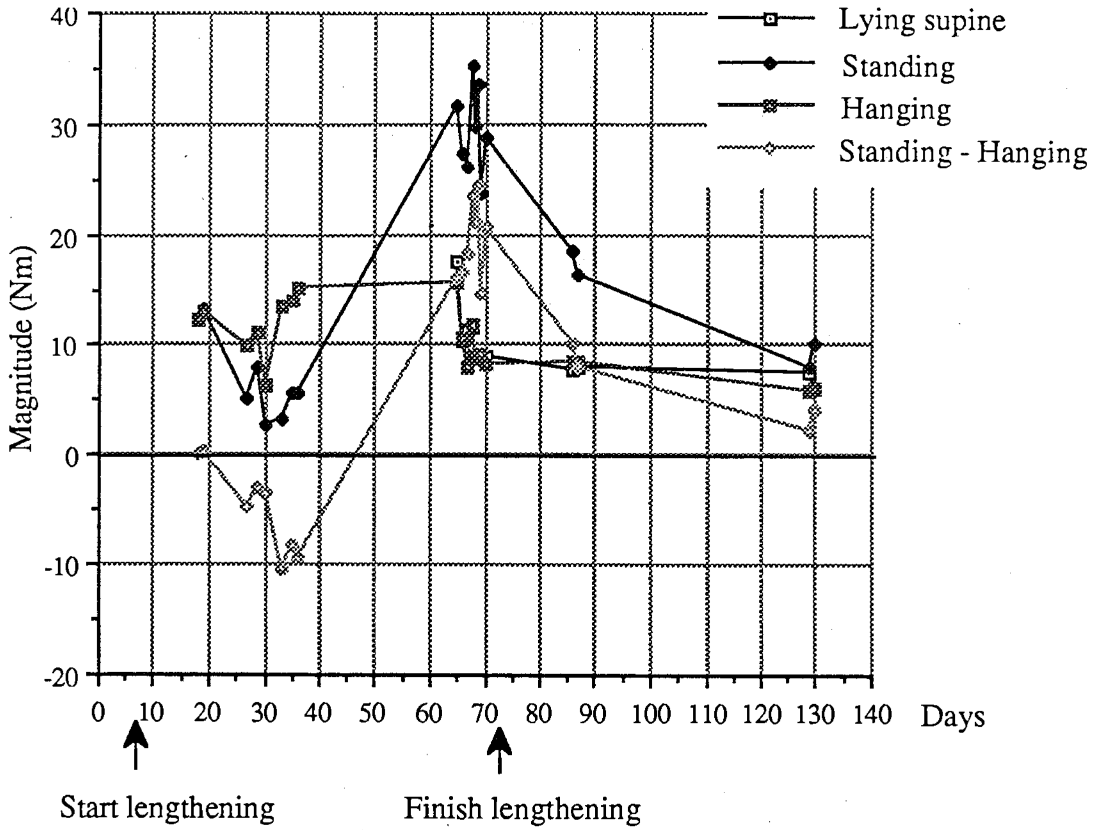


Figure 4.19. Subject 2. The magnitude of bending moments during lying supine, free hanging, standing and standing hanging difference versus postoperative days.

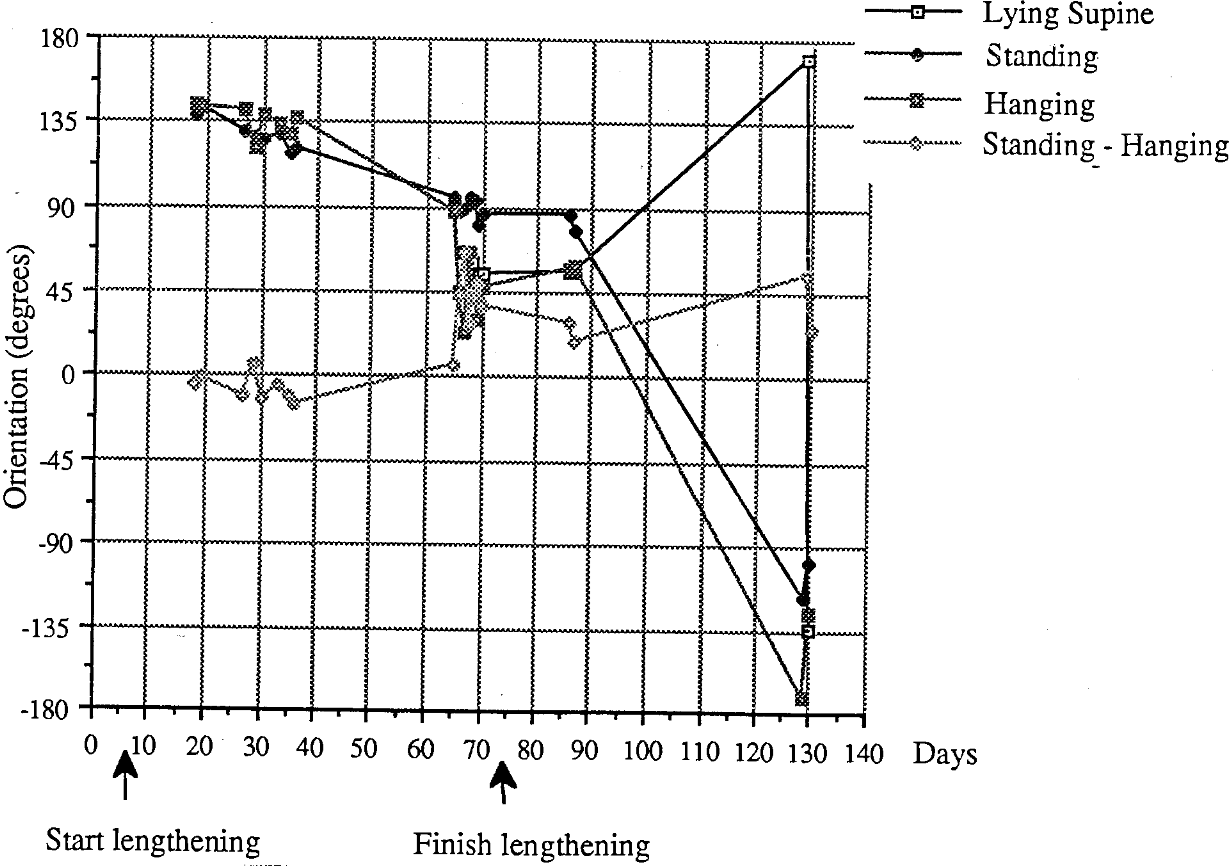


Figure 4.20. Subject 2. The orientation of the plane of bending moments during lying supine, free hanging, standing and standing hanging difference versus postoperative days.

Subject 3.

The bending moment magnitude increased over the distraction period for free hanging ($R^2 = 0.343$, f=19.8, $p<0.01$) and during lying supine ($R^2=0.50$, f=11.95, $p<0.01$) but not for standing ($R^2=0.037$, f= 1.5, $p>0.01$) (see figure 4.21). The difference between bending moments during each activity was not significant (f=2.41, $p<0.01$) (see table 4.3).

The orientation of bending moments became anterior from posterior via the lateral side after the first 30 days of distraction for standing, free hanging and lying supine, none of the correlations being significant ($p>0.01$) (see figure 4.22). The difference between the free hanging orientation, standing orientation, and lying supine orientation was not significant (f=1.8, $p>0.01$) .

There was a difference in bending moment magnitude between the evening and morning, (f=9.5, $p<0.01$), and orientation (f+41.4, $p<0.01$) between the evening and the morning (see table 4.4 for values).

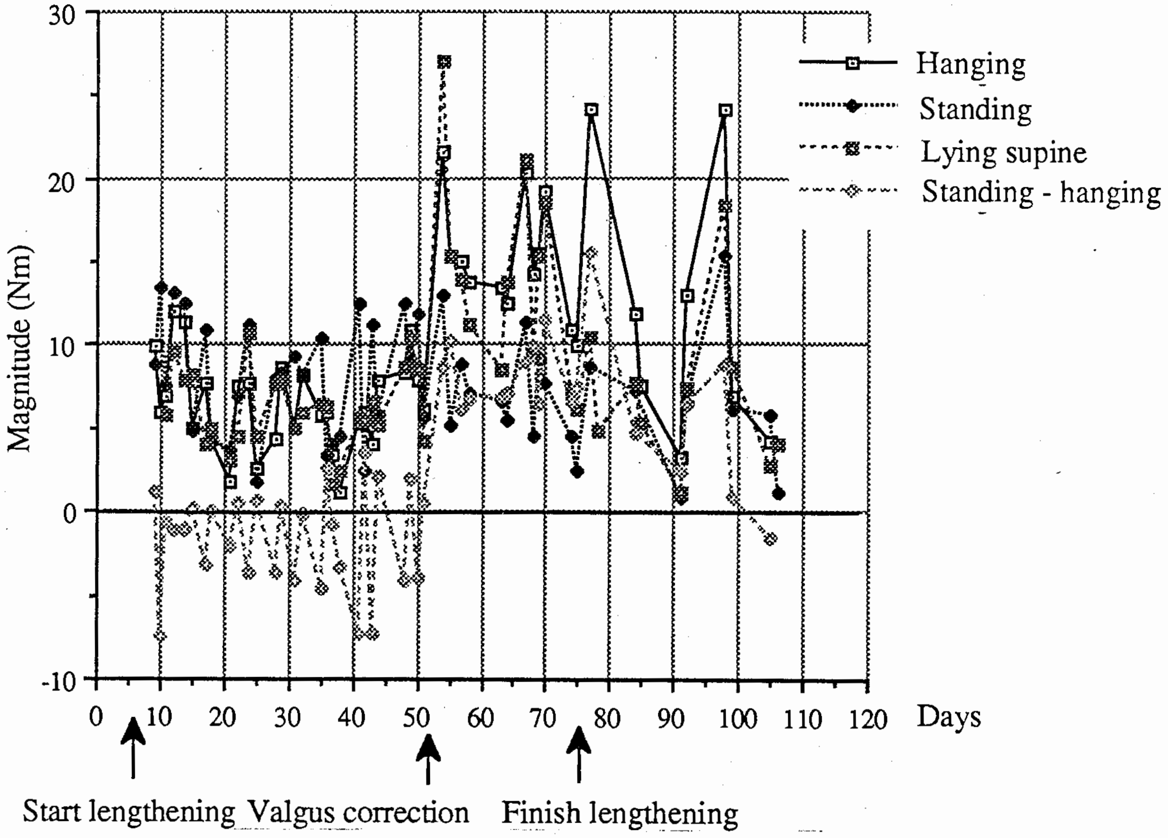
4.3.3 Dynamic Loading.

Subject 1.

Two trials were performed for this subject during distraction; on the 14 th and 37 th days. In the first trial 7 walks were performed. No change in bending moment was measured ($p>0.05$) but a significant change in orientation from lateral to anterior was seen ($p<0.05$). For the second trial, over 6 walks, neither the bending moment magnitude or orientation changed. Table 4.5 shows the summary information for this subject.

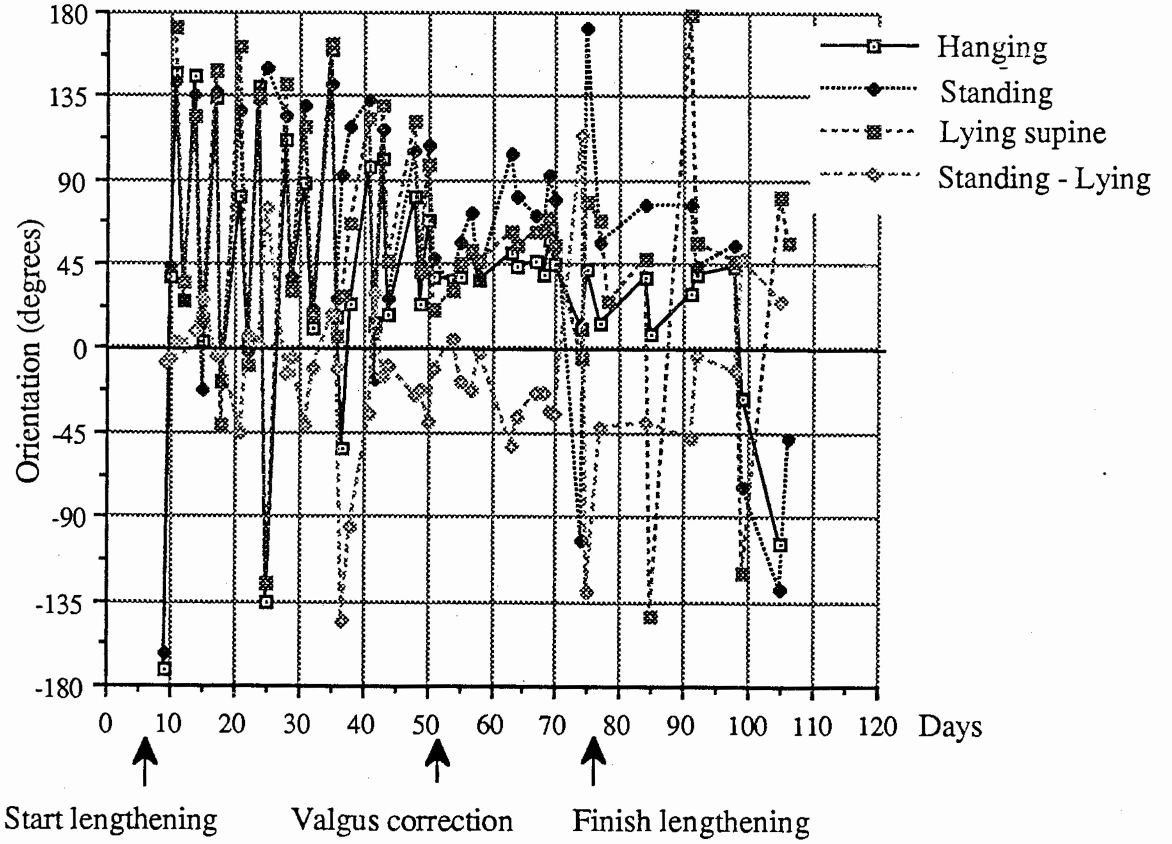
Subject 2.

Two trials were performed for this subject during distraction; on the 31 st and 86 th days. The only significant change seen was a change in orientation in the second trial, the orientation becoming more medial with weight bearing. Table 4.6 summarizes the forces during loading for these two trials. Appendix 3 shows a walk from each trial.



Start lengthening Valgus correction Finish lengthening

Figure 4.21. Subject 3. The magnitude of bending moments during lying supine, free hanging, standing and standing hanging difference versus postoperative days.



Start lengthening Valgus correction Finish lengthening

Figure 4.22. Subject 3. The orientation of the plane of bending moments during lying supine, free hanging, standing and standing hanging difference versus postoperative days.

Subject 3.

Three trials were performed for this subject during distraction; on the 16 th, 44 th and 64 th days. In the first trial over 8 walks the bending moment showed no change of magnitude or orientation ($p>0.05$). The second (over 10 walks) showed a significant decrease in bending moment magnitude ($p<0.05$). The third trial shows a change in orientation ($p>0.05$). One walk from each trial is shown in Appendix 3. Table 4.7 summarizes the results of dynamic loading for this subject.

5. DISCUSSION

5.1 Validity of Results.

The validity of the results depends on the accuracy of the load cells to measure pure axial load without cross talk from loads in other planes. As this is a new technique of measurement there was no previous information on method or comparisons with other results to be made. The load cells alone are well within the required accuracy for the study. As an initial study an order of magnitude figure was the desired outcome, so an accuracy of +/- 5% was deemed acceptable. Similarly the transfer of pure axial loads and bending moments from the rod to the load cell through the compression washer assembly was well within the accuracy required. The basic design of the system was therefore acceptable.

Confounding factors were a potential source of error. For example, cross talk from loads applied in other axes. The considerable flexibility seen in the frame during testing on the plastic bone lead to the frame being distorted. The proximal end of the frame sheared laterally on the distal end. The rings changed their orientation both with each other and with the horizontal plane. Despite this axial load was accurately recorded in the frame, with the applied load being in agreement with the measured load. A more accurate transfer would be expected in the subjects as the presence of callus will lead to greater rigidity of the frame bone unit. Also, most of the axial load on the frame was due to tension between the two halves of the frame secondary to distraction rather than external compression. As lengthening proceeds along the vertical axis of the frame the resistance to distraction will be seen as pure axial load. The effect of changing the alignment of the rings (as seen during correction of angular deformity) on the accuracy of the load cell system was not tested.

Shear loads on the frame can cause an increase in recorded axial load due to cross talk as shown in the calibration graphs presented in Appendix 1. Similarly a baseline shift in either direction would occur. The largest shear loads during the subject's daily routine are likely to have occured during the transfer on and off the bed, during which time the frame was held to support the leg. During static and dynamic loading the shear load cannot be estimated.

However with the rings on the frame correctly aligned with the floor (before angular correction has taken place) the shear load can be assumed as small.

With the patient lying supine (during overnight recording) the maximum shear load was generated when the leg was horizontal and supported solely at the hip and the ankle. In this position with the weight scale under the ankle 34 N was recorded from one subject. The corresponding cross talk with axial load using the shear calibration in this plane was insignificant unless the shear load was greater than 50 N.

When the frame was kept rigid bending moments were accurately transfered during the bending moment calibration. However during the testing of the frame as shown on the plastic femur with the associated flexibility of the frame greater bending moments were measured than applied. The frames on the subjects are unlikely to behave with this degree of flexibility. The callus will afford greater rigidity to the system, and the frame may respond differently to tension between the two halves of the frame compared with external compression as tested. The measured bending moments should therefore be a valid reproduction of the applied. If any confounding error occured then it is likely that the measured bending moment was larger than the applied.

5.2. Axial Forces.

5.2.1. Changes over the Period of Fixation.

The maximum axial loads seen during distraction for the three subjects were 428.1 N, 446.9 N and 672.8 N respectively. Force appeared to be dependent on the distance attained. Although a tendency to plateau towards the end of the distraction period was seen, it was not as marked as observed by Wolfson *et al.* (1990) and Leung *et al.* (1979). However in Leung's study the distraction rate and rhythm was different, and the rate was changed in later distraction. The only differences between Wolfson's study and this one was the bone studied (tibia) and the load cells used. It may be that a tendency to plateau is a characteristic of tibial lengthening not seen during femoral lengthening.

The maximum force measured in the two tibial lengthenings in Leung's study was 147 N and 120 N, being considerably less than the forces observed in this study, and in the study by Wolfson *et al.*. Their tibial lengthening subject attained a force of 233 N at the end of the distraction period. The technique used by Leung *et al.* (a modified Anderson technique) was associated with more soft tissue complications than the Ilizarov technique used for Wolfson's study and this study. Although the total numbers of subjects in our and other studies are few, a concept is suggested to explain these differences in forces between studies. A window of optimum distraction may exist. If the rate is too slow then high forces will result from the slow distraction of a uniting callus due to the inelastic nature of the callus. Alternatively the callus formed may be deficient due to a rapid distraction rate. Other causes of an insufficient callus include a rhythm of distraction associated with poor callus formation (such as used in the Wagner technique or the Anderson technique) and pathological reasons (e. g. infection). In the case where insufficient callus is formed smaller forces will be seen compared with a slowly distracting callus. When the callus is insufficient, an increase in traction on the soft tissue will cause an increase in force. If the force is sufficiently high in the absence of callus then soft tissue complications may result. In Codivilla's lengthening (1904) forces of 222 to 444 N were used to effect a single pull acute lengthening of 3 to 8 cm. All of this force was directly loaded onto the soft tissues causing severe shock in most cases and death in three (Patterson 1990).

The force required to distract and fracture the epiphysis in humans is between 569 to 804 N (Kenwright *et al.* 1990). This force is similar, if slightly higher than the maximum force seen in our subjects. Pain is associated with the higher forces (Jones *et al.* 1989) as was seen in our subjects. Subjects one and three both experienced considerable and persistent deep pain in the leg at the end of distraction and during the beginning of neutral fixation. The pain was never localized, and described as a sharp pain up and down the leg "as if someone was cutting up the inside of the leg with a knife" (quote from subject three). This was different than the pain associated with pin site infection which was localized and associated with redness or discharge from the pin site. This association of deep leg pain with force in our subjects, and the similarity of force and pain during physeal lengthening would suggest the callus to be the major resistance to axial distraction. Again, a faster rate of distraction may lead to less pain and a more comfortable subject.

In this study a number of findings support the window of optimum distraction concept. It would appear that distraction of the femur for these subjects is too slow, leading to a stiff mature callus during distraction. Specific features supportive of this view includes the high forces generated during distraction and the tendency for these high forces to occur in subjects with exuberant callus formation seen on the radiological views. The lack of plateau seen during distraction and the small change of force during weight bearing would support this view.

Previous authors (Leung *et al.* 1979, Wolfson *et al.* 1990) have suggested the soft tissues to be the origin of the resistance to distraction. This would explain the larger force seen in the femur as the thigh has a larger cross sectional area. However all the other features seen in this study, particularly the small change in force during weight bearing, are inconsistant with this view.

Premature consolidation, if allowed to occur, may lead to soft tissue damage of the segment concerned. For example, it is current practice for surgeons using the Ilizarov technique to sometimes try and break the callus causing premature consolidation towards the end of distraction by continuing the distraction. When the callus breaks ("pops") then considerable load will be transfered suddenly onto the soft tissues no longer shielded by the callus. As the soft tissues have already been distracted then they may be particularly vulnerable to the sudden increase in force, unlike the breaking of the physeal plate during physeal lengthening when soft tissues are as yet undistracted. The author is unaware of any reports of this specific complication.

This study suggests that force measurement during clinical management may be a useful tool in complicated cases of lengthening. Characteristics of premature consolidation include a rapid rise in force, an increase in force during each lengthening and no change in force during weight bearing. Poor callus formation would be associated with moderate forces and a large change in force during weight bearing, and no change in force with each lengthening.

Using transducers it may be possible to diagnose premature consolidation. Premature consolidation has been reported as a significant complication in recent literature (De Bastianni 1987, Atar *et al.* 1990, Bell *et al.* 1990, Dahl and Fisher 1990). As "popping" or operatively dividing the callus both have potential complications it is better to prevent premature consolidation form occuring in the first place. Our study indicates the femur may tend to consolidate more rapidly than the tibia, as the forces generated are higher and fail to plateau. The femur is known to have a faster healing rate after fracture, thought to be secondary to the larger soft tissue coverage (Sevitt 1981). It could be argued that to prevent premature consolidation a more rapid rate of distraction may be required. Ilizarov's research (1989) on dogs would suggest a rate of 0.25 mm per lengthening five or six times a day would be an appropriate rate. This rate should not compromise callus formation, although the results using this rhythm and rate of distraction on the femur in animals has as yet not been studied. It is stressed however, that this argument presupposes that the majority of the distraction force is resistance by callus rather than soft tissue. If distraction force is principally tension in soft tissue, then a slower rate would be appropriate.

The force at the same period of distraction for all subjects showed a similar magnitude. For instance, at thirty days distraction (3 cm) subject 1 has a distraction force of 360 N, subject 2 a force of 352 N and subject 3 a force of 448 N. Forces during distraction appear to be determined by the amount of distraction achieved. In Wolfson's *et al's* tibial lengthening (1990) a force of 223 N was required to effect distraction on the 30 th day. This is consistent with the lower peak force seen in the tibia.

Forces at the beginning of neutral fixation were all greater than zero before lengthening began, as seen in Wolfson *et al.*'s study (1990). As there is always a small gap across the corticotomy site after operation muscle contraction may be responsible for this baseline. Although the wires holding the bone are tensioned, they will compress the corticotomy site in some subjects and tension it in others. After distraction the force failed to return to zero showing there to be a small amount of traction present across the callus at union.

5.2.2. Changes During Weight Bearing.

It was hypothesized that the two ends of the femur would act as relatively free bodies. Information from previous studies suggested that the callus would carry an insignificant amount of force during weight bearing, the frame carrying the total force in the femur. If the callus was insufficient then a direct comparison between ground reaction and force within the femur could have been used to determine the validity of Paul's calculated force in the femur during dynamic weight bearing (1971).

Instead during weight bearing (either dynamic or static) in this study all subjects showed a change of axial load in the frame that was either insignificant or small compared with the ground reaction force. During recording of the first subject this was assumed to be a fault of the recording technique. Further calibration and measurement of the ground reaction force for the rest of the study confirmed this small change in axial load with weight bearing.

A new hypothesis had to be formulated to explain the small change in force in the frame compared with the ground reaction force. If the callus was stiff relative to the frame then a small movement upwards of the distal bone end would allow a large force change within the callus. This movement is possible due to the flexible nature of the transfixion wires. During weight bearing the ground reaction force transmitted through the lower limb will cause an increase in force on the transfixion wires on the distal part of the frame. As the wires are flexible the transmission of this load to the frame will cause the distal femur to move towards the proximal femur by a small amount. If the callus is comparatively inelastic this small movement will allow some tension within the callus to be offloaded. Hence with increasing ground reaction force, the force measured in the frame will change in origin with a small change in magnitude. The force will change from being a distraction force to a transmitted ground reaction force.

In figure 5.1 an example of one walk from trial two of subject two is shown. Before point "A" all the load in the frame is distraction in origin. Between points "A" and "B" the callus becomes shortened by a small amount. This is as a result of axial migration of the distal femur with respect to the proximal femur secondary to the ground reaction. The force in the frame increases slightly, having a decreasing component as a reaction to tension in the callus and an increasing amount of force being compression from the ground reaction. Between "B" and "C" the ground reaction is greater than the initial tension force in the callus. At this point the callus will be completely detensioned and increasing load will be partly carried by the frame and partly by compression of the callus. At point "C" the callus will be maximally compressed. From "C" to "D" the callus will become decompressed, and retensioned from "D" to "E". Hence with each load bearing cycle the callus goes through a large change in force, equivalent to the magnitude of the transmitted ground reaction minus the change of force in the frame, while the force in the frame changes little. This would appear to be one the benefits of the Ilizarov frame compared with other frames, as it stimulates bone growth through these changes in force while protecting the brittle immature callus from excessive axial load. The frame has an increasing resistance with increasing axial load and protects the callus from torsion, shear and bending moments.

For the sake of clarity in the above example the ground reaction has been assumed to be the same size as the reaction force in the distal end of the femur. In practice the force at the

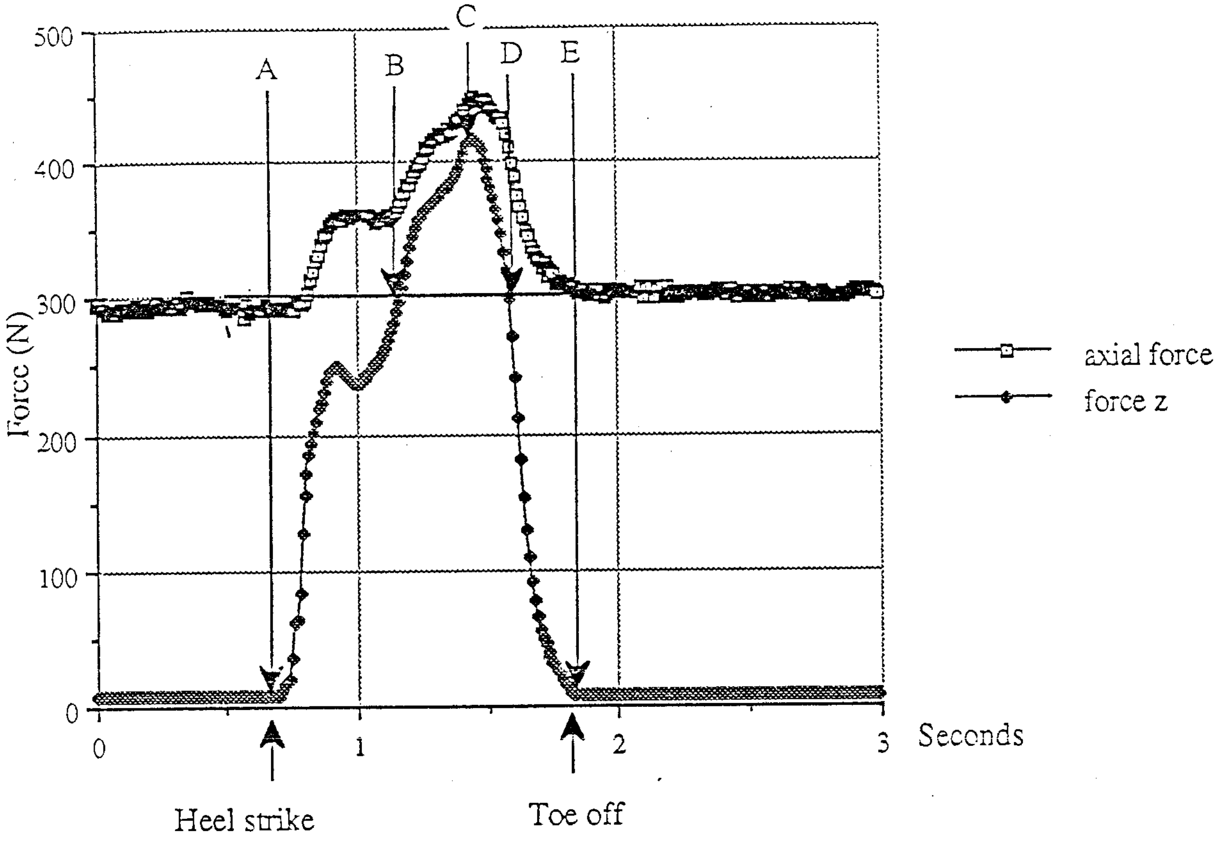


Figure 5.1. Significant points of force change within the callus during dynamic loading. Subject 2: Dynamic weight bearing for one walk of trial two. See text for explanation.

distal end of the femur secondary to ground reaction may be much larger due to muscle contraction and acceleration of body segments (Paul 1971). Hence the amount of compression force transmitted through the callus may be substantial, and cannot be measured by the experimental design.

The force change within the frame will be determined by a number of factors falling into two groups; those determined by the mechanical nature of the callus and factors external to the callus.

Factors external to the callus include the size of the ground reaction force, the nature of muscle contraction, and acceleration of the limb. The rigidity of the fixator and wires will determine how much detensioning the callus will experience for each unit of force applied across the frame.

Factors within the callus include the elasticity of the callus, its cross sectional area and its total length. As the least amount of force increase during active weight bearing was seen in subject three and the most in subject two, subject three's callus would appear to be the stiffest and subject two's callus the most elastic.

The whole relationship (for a fixed rigidity of transfixion of the distal segment of the femur) can be summarized in the following formula:

$$E_c = \frac{\frac{R_F}{A_c}}{\frac{\partial L}{L}}$$

where:

E_c is the elasticity of the callus,

R_F is the reaction force transmitted to the callus,

A_C is the cross sectional area of the callus,

δL is the change in length of the callus, and

L is the total length of the callus.

There is little literature available on the biomechanical nature of the distraction callus. Aronson (1990) has studied the degree of calcification of the distraction callus and found that the center of the distraction zone is calcified to 25% of normal, increasing to 90% of normal next to the normal cortex. Alho *et al.* (1988) have correlated bone strength with mineral content, but found no correlation when elasticity and mineral content were compared. Accepting that Alho *et al.* were studying elderly osteoporotic bone while the distraction callus is semi organized new bone, it may be postulated that the partially mineralized distraction callus will have a similar biomechanical nature to the osteoporotic bone: Increasing mineralization will lead to an increase in strength and have a small effect on elasticity. The callus will be relatively rigid throughout its length, and will get progressively stronger with increasing calcification. The purpose of the external fixation may therefore be not to supply rigidity to the callus but to increase its strength, and to protect the callus from large applied loads.

If the callus was as stiff as Aronson and Alho's studies would indicate, force during weight bearing would be explained. This is consistent with the negligible change between hanging and standing forces seen for all subjects during static weight bearing. Subject one (figure 4.11) showed no significant change between the forces during hanging and standing on the leg, as did subject three during the straight lengthening (until the 51 st day, figure 4.13). Subject two showed an increase of force transfer up to the end of distraction (see figure 4.12 and figure 4.15) consistent with an elastic callus.

The amount of force transmitted decreased to zero during the neutral fixation, despite an increasing ground reaction force measured at the scale, indicating a gradual stiffening of the callus during the repair period. As subject two had the appearance of a more elastic callus and also had a congenital cause for his limb deficiency, a potential link between the nature of the callus and congenital short femur may exist. A deficiency of the inorganic component in the distraction zone could be this link.

A unexplained effect was seen in subject 3 after the valgus correction was started, when a decrease of force was seen in the frame during weight bearing, both during static and dynamic loading (see figures 4.13 and 4.18). As this was only seen after the angular correction was started this may be a secondary effect due to shear cross talk. No sensible physiological explanation can be given, except perhaps muscle relaxation during standing.

The change of force in the frame during static and dynamic weight bearing is small, and at no time was the force in the frame close to the failure limit as described by Bianchi Maicchi (1985) of 1471 N, nor that described by Galpin *et al.* of 1400 N (1990). The force may reach these levels if premature consolidation occurs and distraction continues. The subject's pain may prevent lengthening from continuing to this point if pain increases in relation to force.

5.2.3. Force Change During each Lengthening.

The increase in force seen by Leung *et al.* (1979) and Wolfson *et al.* (1990) with each lengthening was not seen in this study. No change in force recorded before and after lengthening was seen for all subjects (p>0.01).

With respect to Leung's study, the difference in result may be due to differences of the distraction technique used. One millimeter lengthenings were used once or twice a day in their study, each lengthening being four times the distance of one Ilizarov lengthening.

Wolfson *et al.*'studied (1990) the tibia distracted by the Ilizarov technique. An increase in force with lengthening was seen. The distance gained for each lengthening was identical to this study. However in Wolfson's study readings were taken for a few minutes before and after each lengthening at midday, using a ten hertz recording signal. The stress relaxation with each lengthening occured in the first five minutes after lengthening (personal communication (Hearn 1990)). Forces after this time returned to a similar level as seen before lengthening. This may explain the difference between the results in Wolfson's study and this study.

In our study, one subject at one time showed an increase in force with lengthening. For subject 3, force towards the end of distraction, if analyzed independently showed a significant increase in force with each distraction. This is in agreement with the stiff callus this subject appeared to form in late distraction. In our study noise in the system may have obscured any change in force present. If the change in force was larger a change may have been detected. In Leung *et al.*'s study the increase in force will be more apparent as 1 mm lengthenings were used. This may be accentuated as the relationship between force increase and length attained acutely is non linear (Wolfson 1990). Hence the force created for a 1 mm increment compared with a 0.25 mm increment may be eight times as large rather than four times as large as would be expected with a linear relationship.

In our study the force must increase over each lengthening as force increases over distraction. For instance, subject three had an increase in force of 550 N over 45 days. The force increase on average would therefore be 3 N per 0.25 mm lengthening. The force increment per lengthening may have been larger if stress relaxation had been measured using a faster rate of recording.

In summary, the force increase during each lengthening is small and appears to be a characteristic of Ilizarov lengthening. The minimal force increase during each 0.25 mm increase during Ilizarov lengthening may be key to its success.

5.2.4. Diurnal Variation of Axial Load.

The diurnal variation of force followed the same pattern for all three subjects. Forces were highest at midnight, dropping to a low in the morning. Although exhibiting the same general pattern, differences in magnitude and timing were observed between subjects. Subject one was always late in starting recording (at 10.00 to 11.00 pm) compared to the other two subjects. As a result the evening and midnight forces were significantly different for the second two subjects but not the first.

As baselines were taken before recording of static forces the significant change between evening and morning recordings during static weight bearing was not due to any spurious baseline effect. As the same order of recording was followed at each recording a systematic error for all subjects would be unlikely.

There is no clear explanation of the diurnal change in force. Kenwright *et al.* (1989) showed a saw-tooth pattern in recordings taken twice daily over a number of days in their studies of physeal lengthening. This variation was of a similar magnitude to the variation seen in this study (95 N). No comment was made on this by Kenwright *et al.*. As a similar pattern has appeared in their results and ours, despite a difference in lengthening technique used. A physiological or biomechanical cause rather than a methological one is likely to exist. A mechanism within the physiology of bone growth may be postulated. The diurnal variation may be secondary to a direct or indirect hormonal effect, an osmotic effect on the collagen in the distraction zone, or a cellular effect. Of the three, the last is the only one for which a plausible explanation can be found in the literature. Oudet and Petrovic (1982) studied rats after fracture of the femur, and counted the number of mitotic cells in the fracture site after sacrificing the rats at different times of the day and night. The time of sacrifice was a significant determinant of mitotic rate, the rate being highest at 12 pm and lowest in the morning. Assuming that the majority of cells are in the cytoplasmic phase (i.e actively secreting) when not dividing, then the greatest amount of growth would occur in the morning. This would increase the content of callus in the morning, reducing the force seen in the distraction zone.

An alternative mechanical hypothesis may be suggested. As weight bearing occurs during the day and loading of the callus is taking place the callus may experience a time dependent visco-elastic effect which will alter the distraction force measured.

The rhythm of lengthening appears to have little effect on the diurnal variation, as there is no significant increase in force with each lengthening as measured using the fifteen minute average. The force 1 hour before the evening distraction during static weight bearing was higher than the force 1 hour after the morning distraction. If an increase in force occured with lengthening of greater magnitude than diurnal variation than the values would be higher in the morning.

It may be that the osteogenesis is not dependent on a constant rate of distraction, but on a constant tension over 24 hours. If the desired aim of distraction is to maintain a constant tension on the limb then it may be appropriate to change the lengthening times to reduce the force peaks. For instance, the night time lengthening could be performed earlier to decrease the size of the 12 MN peak. This needs to be researched using an appropriate animal model.

To summarize, a clear diurnal variation was seen with no obvious explanation. This feature may be a key as to the nature of bone regeneration and physiology during osteogenesis.

Using animal models, improvements to the distraction timing for better osteogenesis may be obtained.

5.3. Bending Moment Magnitude and Orientation.

Bending moments of considerable magnitude were seen in all subjects peaking towards the end of distraction, indicating the change in bending moment is distraction related.

The structures resisting distraction may be distributed round the femur in an uneven manner potentially causing the bending moment to arise. They may originate in the callus or in the surrounding soft tissue.

Callus may cause the bending moment to arise, considering the contribution it appears to make towards the axial load both in resisting distraction and in weight bearing. However in all subjects the bending moment plane lay in the anterior and lateral quadrant. Clinical experience shows the callus to be deficient in the lateral aspect. This is supported by the X-ray appearance with the lateral side ossifying the slowest. This is caused by the operative approach, the lateral periosteum being divided to gain access to the bone. Therefore the bending moments would be unlikely to arise in the callus.

Alternatively the bending moments may arise from the soft tissues. If a soft tissue was a major component resisting distraction then the resistance would be in the quadrant of the femur of that tissue. For instance, if the hamstrings were under strain then the bending moment would be orientated towards the posterior sector, and if the tensor fascia lata was resisting distraction then orientation would be towards the lateral sector. In all subjects the bending moment was orientated to the anterior sector, and towards the lateral side. The orientation became progressively anterior for subjects two and three during distraction. Bending moment magnitude tended to increase towards the end of distraction and to subsequently decrease in the neutral fixation period.

Although soft tissues may make less of a contribution to the axial load, as they are remote from the central axis of the femur a small amount of force, if not balanced on the contralateral side of the femur, could create a significant bending moment. The quadriceps muscle group would in combination create a bending moment orientated in the plane seen in the subjects, with tension in the tensor fascia lata creating the lateral component. From this study it is suggested that the bending moments seen in the femur originate secondary to distraction of the quadraceps and tensor fascia lata.

Similar orientations were seen during static weight bearing as was seen in the overnight moments of the subjects, with a change in orientation to anterior as the distraction progressed. Only Subject 2 showed a change in bending moment during dynamic weight bearing with no change in magnitude and an anterior migration of the orientation. This is consistent with the soft tissue origin of bending moments. The structures concerned are very elastic compared with bone (Yamada 1970). The small amount of movement seen between the bone ends would be insufficient to offload this tension during weight bearing. Hence no change of bending moment during loading is to be expected.

6.SUMMARY AND CONCLUSIONS.

Distraction of the femur using the Ilizarov technique was found to generate high forces (428 to 673 N) when compared to previous studies on the tibia (122 N and 147 N (Leung *et al.* 1979) and 233 N (Wolfson *et al.* 1990)). These forces were slightly less than the force required to disrupt the physeal plate during physeal lengthening (466 to 780 N (Kenwright *et al.* 1990)). Analysis of the results obtained during static and dynamic weight bearing shows the force in the frame to change little compared with the ground reaction force. From this it can be postulated that the callus is stiffer and therefore the frame supports a compressive load during weight bearing. It may be that the callus within the femur tends to form more rapidly than in the tibia, causing the observed difference in force between the two bones.

A diurnal variation of force was seen in all subjects, being consistent across overnight readings and evening and morning static weight bearing readings. No cause was identified, although a number of possible mechanisms are suggested.

The study confirms the benefit of using the Ilizarov frame as an external fixator for femoral lengthening as its biomechanical properties allow a large change in force in the callus (beneficial for callus formation) with little change in force in the frame. The particular aim of the study was to provide the basic information for the development of a distracting intramedullary nail. This has a potential to significantly improve patient comfort during leg lengthening and decrease infection risk. Mechanical and methological improvements of the Ilizarov technique and frame may result from this information.

Further research needs to be done to confirm the authors results. From the data obtained the biomechanical nature of the callus can be postulated, but needs confirmation by direct testing. By performing an animal study and distracting femoral segments while recording force the stiffness of each animal's callus could be ranked by observing the change in force during weight bearing. The stiffness can be confirmed by sacrifice at late distraction and the callus tested in a materials testing machine. The elasticity of the callus to different loads could be confirmed (shear, bending moments, compression and tension). These constants could form a basis for further design and modification of the frame and hence help the improvement of external and internal fixators used for fracture fixation and limb lengthening.

This study suggests that the rate of distraction may be too slow for the femur, leading to potential premature consolidation towards the end of distraction. This is associated with patient discomfort and less than satisfactory remedial maneuvers. Based on Ilizarov's work (1989) distraction rates of 0.25 mm five or six times a day may be more appropriate. Animal studies could be used to confirm the adequacy of bone formation with the different distraction rates.

The measurement system used was unique to this study. Overnight measurements and weight bearing measurements of tibial lengthening using this technique may determine the biomechanical nature of the tibial callus, and determine whether a diurnal variation exists in the tibia.

Confirmation of the diurnal variation needs to be made by independent researchers performing similar trials. If validated, its significance on the physiology of bone growth needs to be determined and appropriately incorporated within clinical orthopaedics.

APPENDIX 1.

CALIBRATION GRAPHS.

1. 1 load cell calibration (amalgamated over three trials) as a representative calibration.

2.1 The applied force to the rod assembly and the measured force at the load cell using ABS (Acetyl Butyl Sterene) washers for compression. The applied force (N) versus measured force (N). The formula for the closest fit straight line is given with the R^2 value.

2.2 The applied force to the rod assembly and the measured force at the load cell using Neoprene washers for compression. The applied force (N) versus measured force (N). The formula for the closest fit straight line is given with the R^2 value.

3.1 Calibration of bending moments in the anteroposterior plane. Applied versus measured bending moment (Nm). The closest fit straight line and R^2 value are quoted.

3.2 Calibration of bending moments in the lateral plane. Applied versus measured bending moment (Nm). The closest fit straight line and R^2 value are quoted.

4.1 The shear cross talk in the anteroposterior plane. Axial load measured at the load cells (N) versus applied shear load (N).

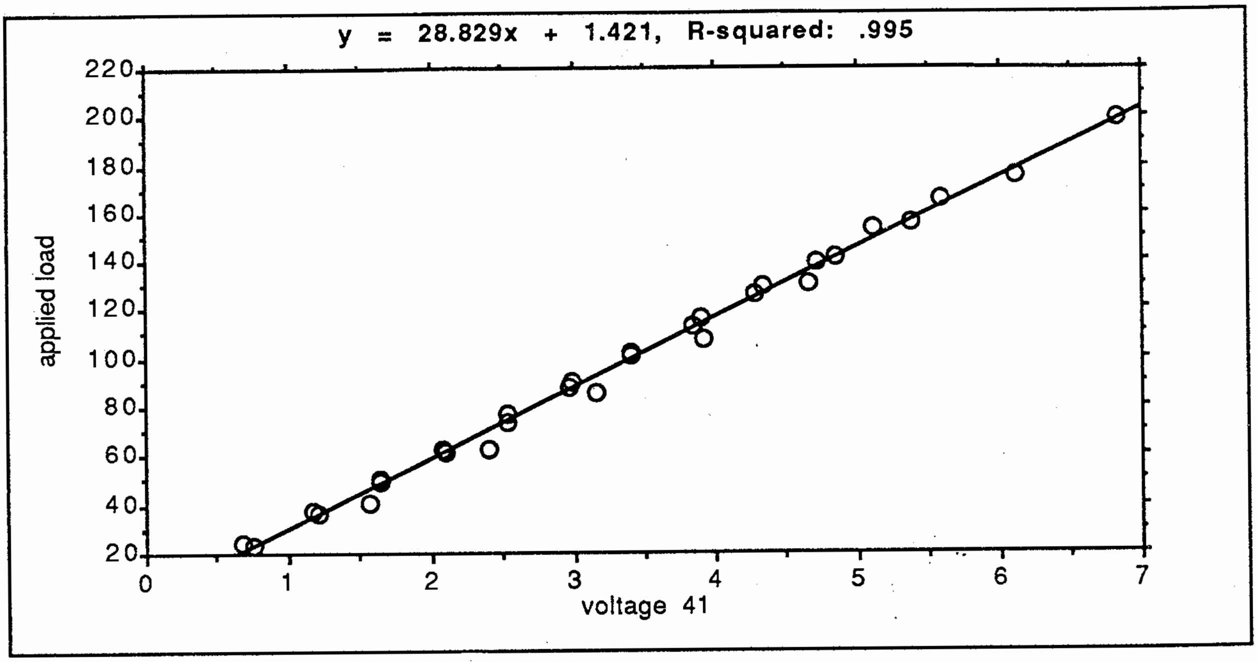
4.2 The shear baseline shift in the anteroposterior plane. Axial load measured at the load cells (N) versus applied shear load (N).

4.3 The shear cross talk in the lateral plane. Axial load measured at the load cells (N) versus applied shear load (N).

4.4 The shear baseline shift in the lateral plane. Axial load measured at the load cells (N) versus applied shear load (N).

5. The calibration graph of the intact frame with respect to applied axial load for ABS washers.

1.1. 1 load cell calibration (amalgamated over three walks) as a representative calibration.



The calibration used for load cell serial no. 41 collapsed across three calibrations. Applied load (N) versus output voltage (V). The formula for the closest fit straight line and its R^2 value is given.

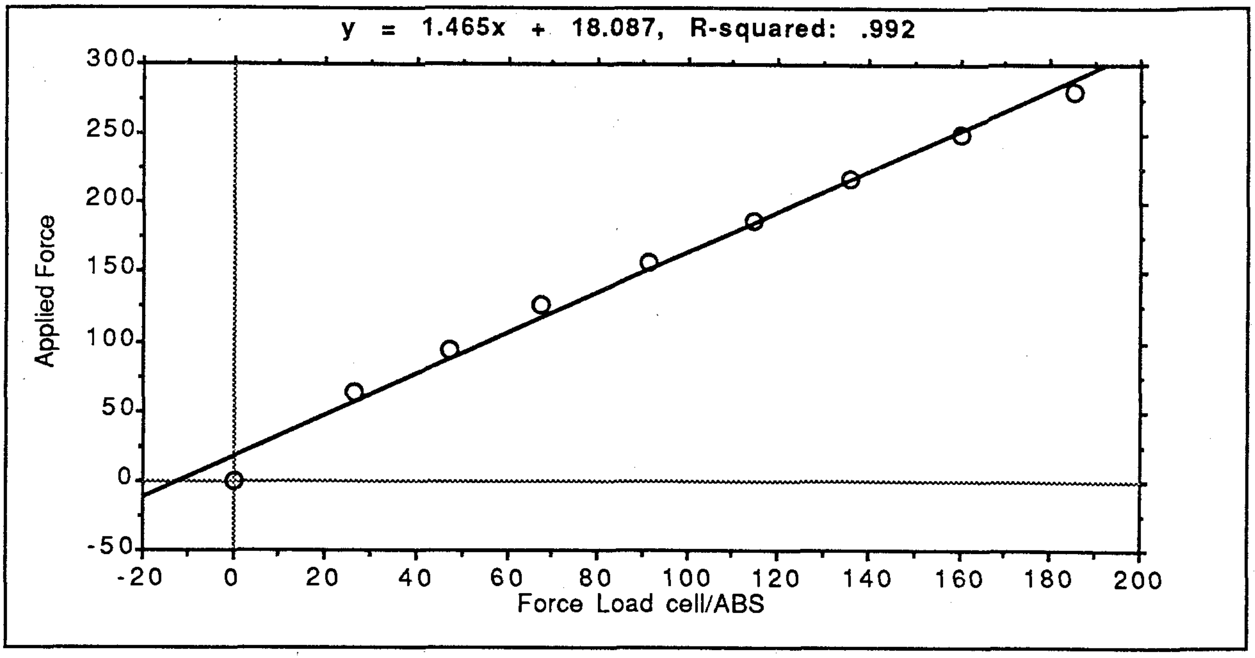
Manufactures specifications are:

Non linearity:	± 0.23 % F. S.
Hysteresis:	± 0.04 % F. S.
Repeatability:	± 0.19 % F. S.
Rated output:	29.52 MV.
Sensitivity:	2.95 MV/V
Best fit straight line:	f(x) = -0.2264 + (0.0592.x)

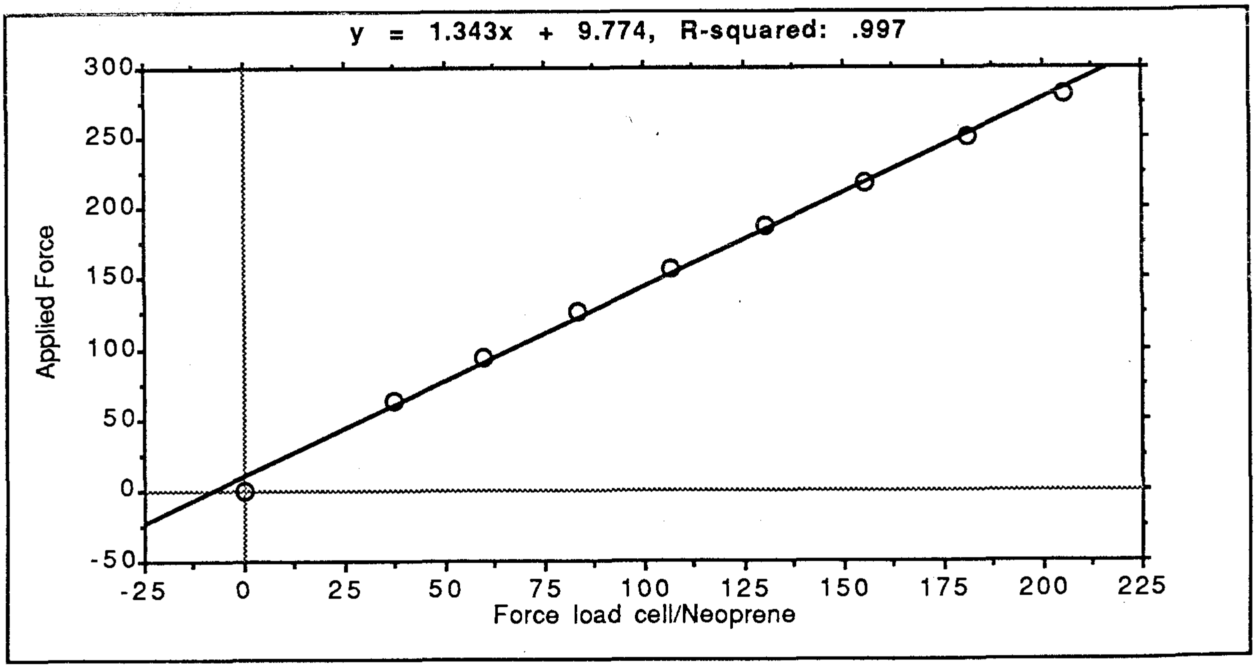
Coefficient of correlation: 0.99998.

Safe overload: 150% of rated capacity.

2. Calibration of load cells in situ

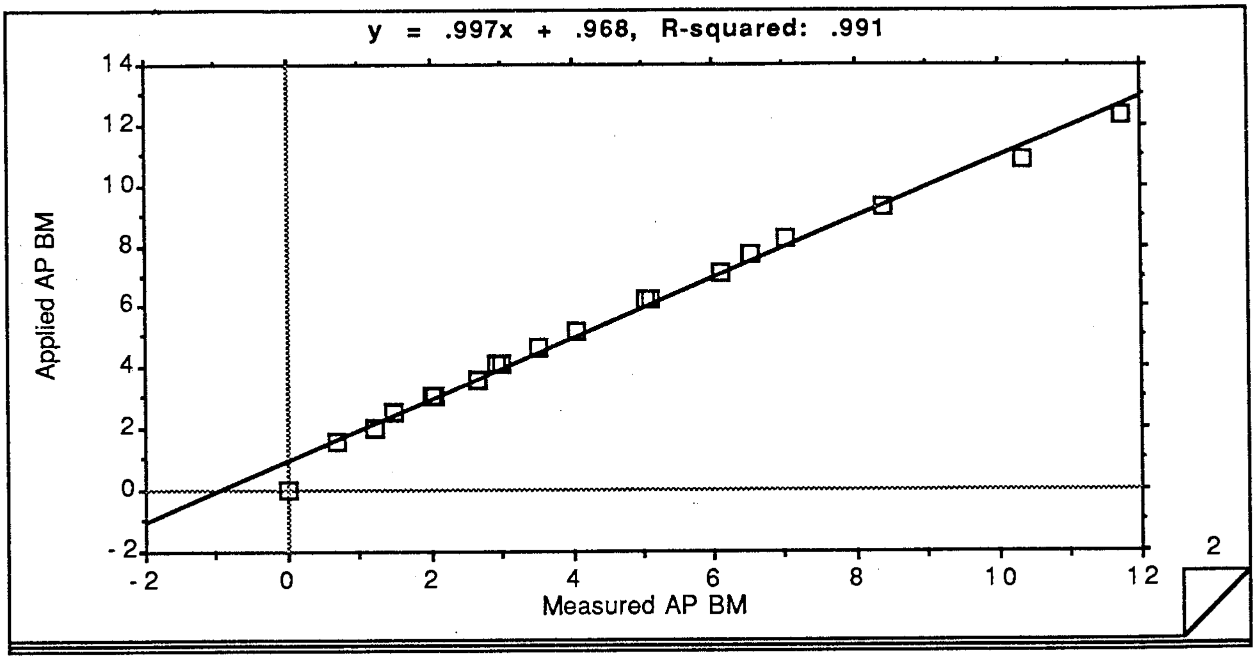


2.1 The applied force to the rod assembly and the measured for at the load cell using ABS (Acetyl Butyl Sterene) washers for compression. Applied force (N) versus measured force (N). The formula for the closest fit straight line is given with the R^2 value.

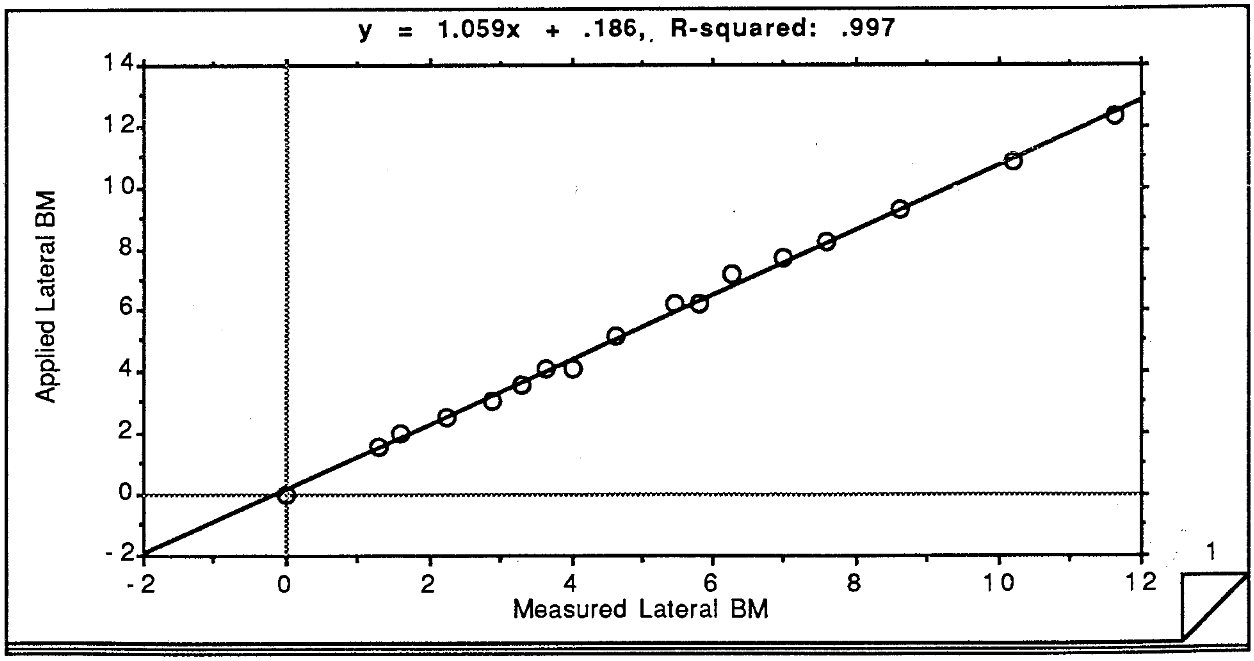


2.2 The applied force to the rod assembly and the measured for at the load cell using Neoprene washers for compression. Applied force (N) versus measured force (N). The formula for the closest fit straight line is given with the R^2 value.

3. Calibration of bending moments in the anteroposterior plane and lateral plane using ABS washers.

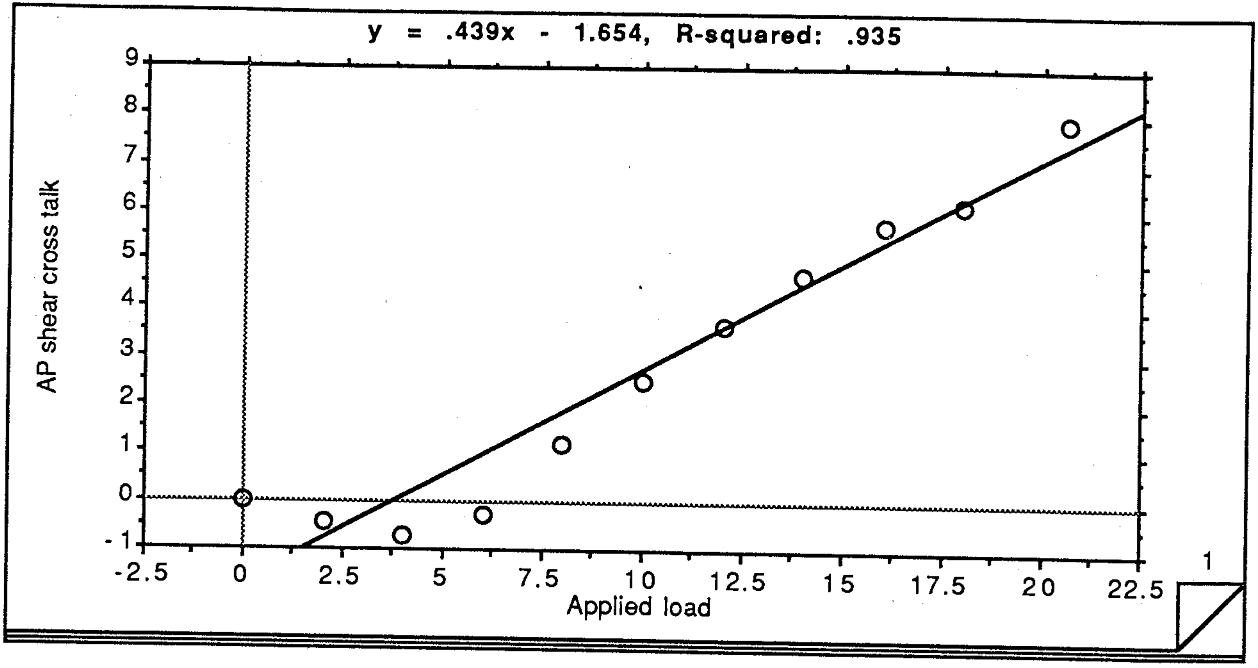


3.1 Calibration of bending moments in the anteroposterior plane. Applied (Nm) versus calculated bending moment (Nm). The closest fit straight line and R² value are quoted.

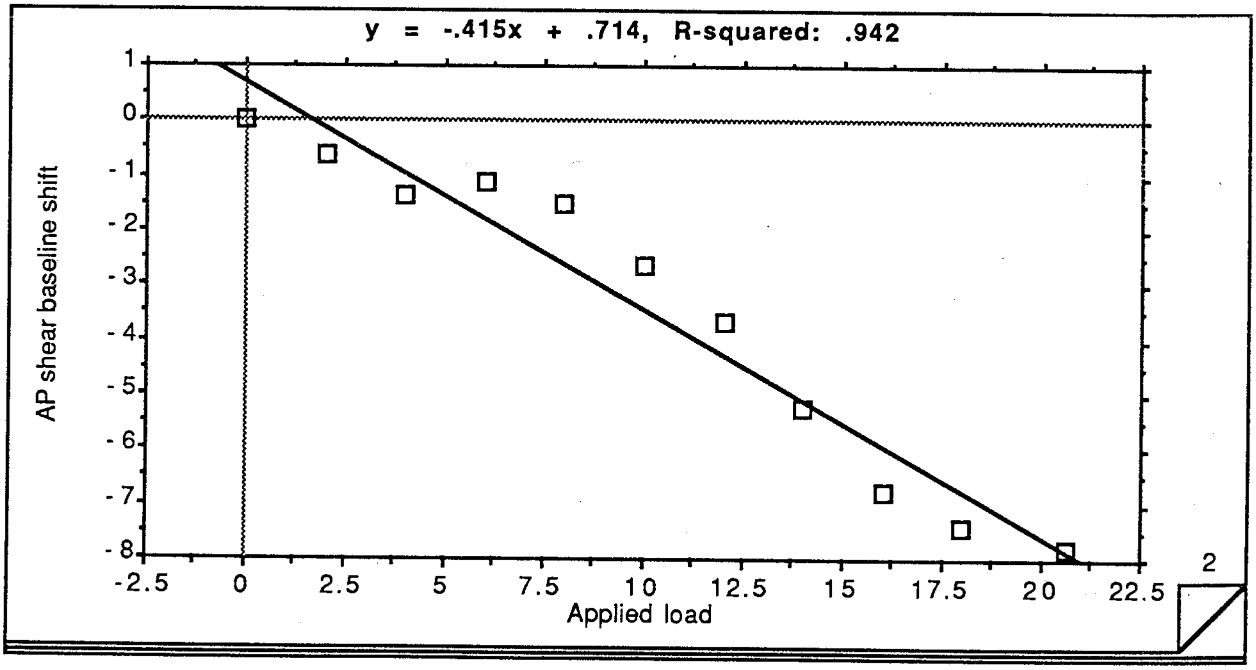


3.2 Calibration of bending moments in the lateral plane. Applied (Nm) versus measured bending moment (Nm). The closest fit straight line and R² value are quoted.

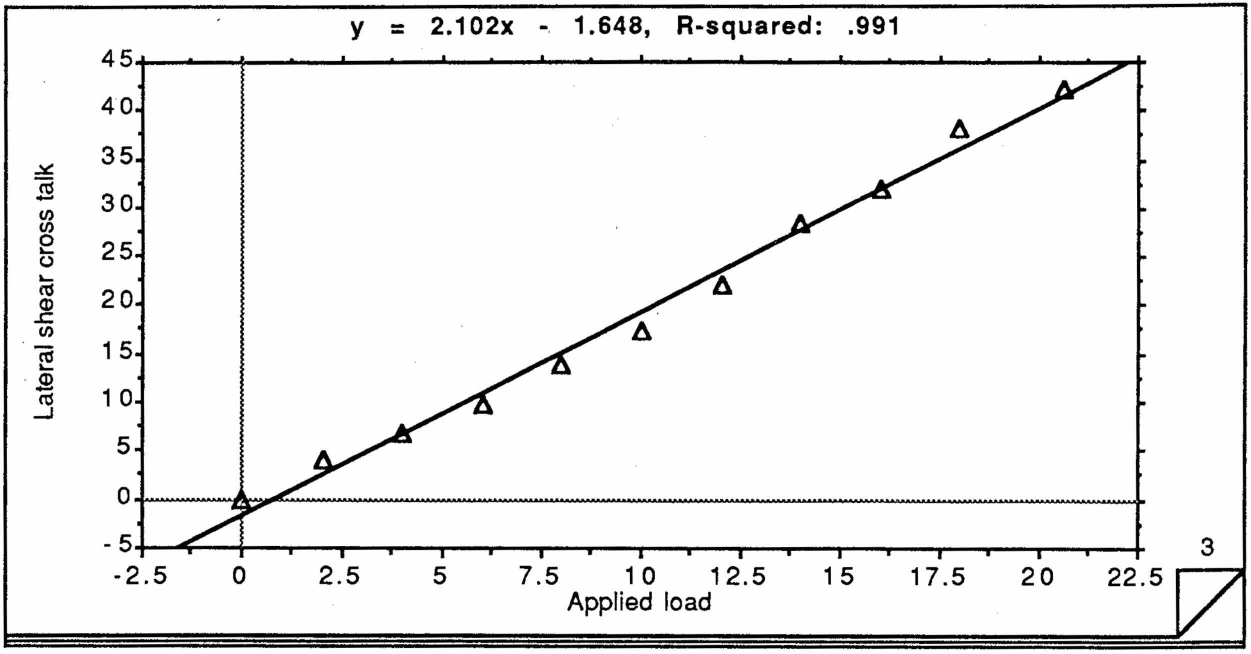
4. Calibration graphs of shear loading in two planes using ABS washers.



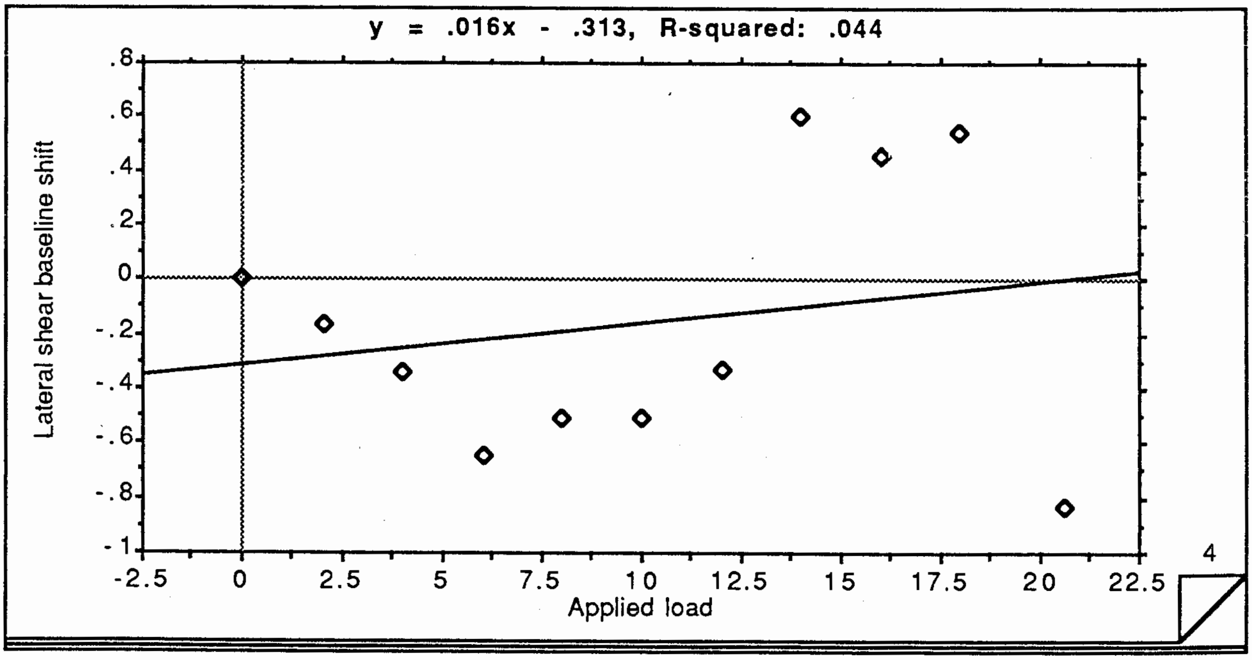
4.1 The shear cross talk in the anteroposterior plane. Axial load measured at the load cells (N) versus applied shear load (N).



4.2 The shear baseline shift in the anteroposterior plane. Axial load measured at the load cells (N) versus applied shear load (N).

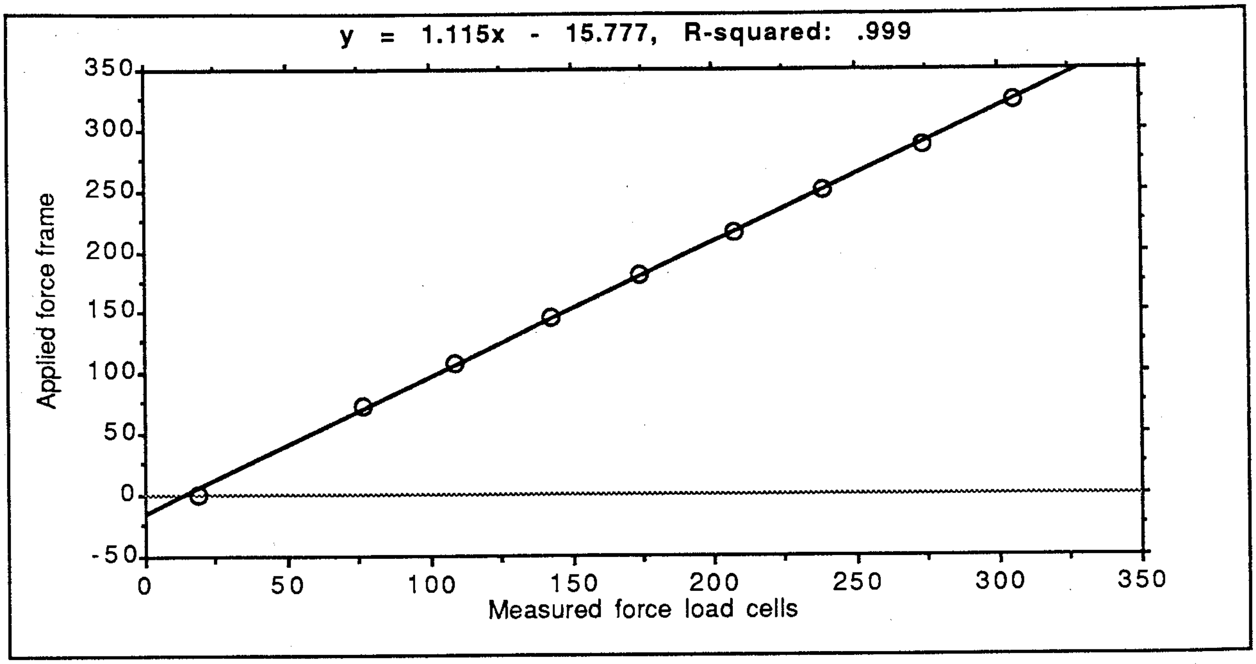


4.3 The shear cross talk in the lateral plane. Axial load measured at the load cells (N) versus applied shear load (N).



4.4 The shear baseline shift in the lateral plane. Axial load measured at the load cells (N) versus applied shear load (N)..

5. The calibration graph of the intact frame with respect to applied axial load for ABS washers.

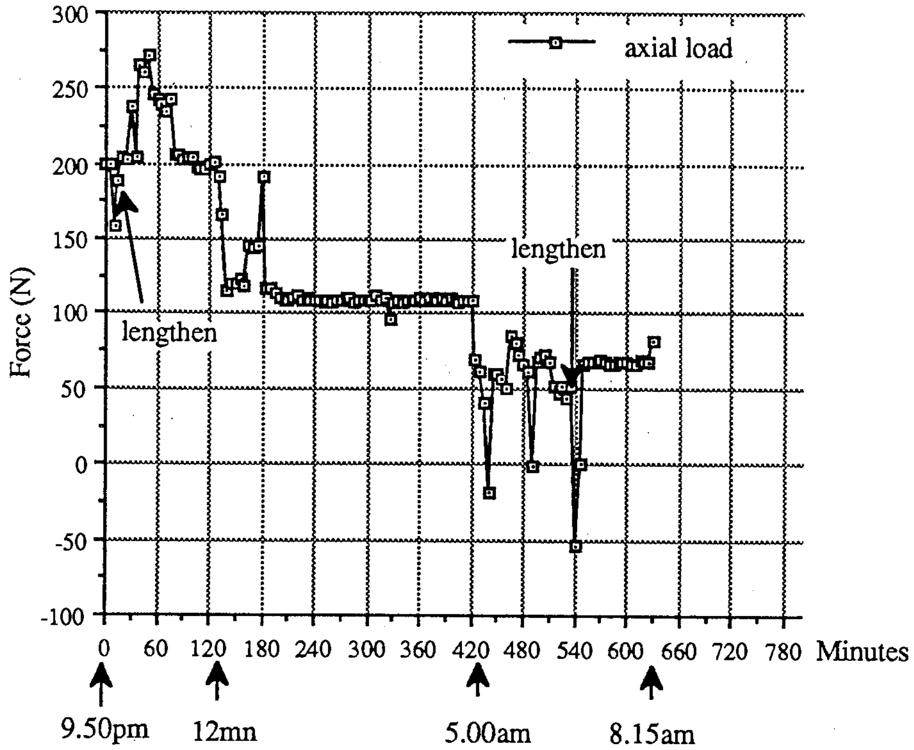


Applied load (N) versus measured load (N). Formula for the closest fit straight line is quoted, and R^2 value. This is the mean of 3 walks.

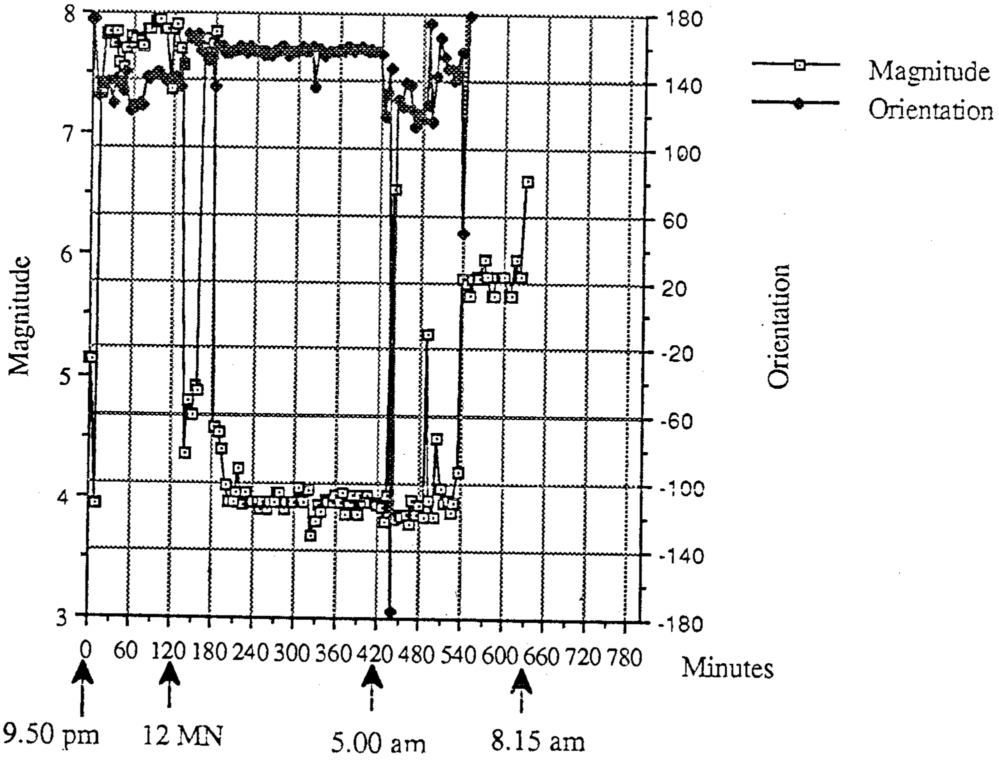
APPENDIX 2

EXAMPLES OF OVERNIGHT FORCES AND BENDING MOMENTS.

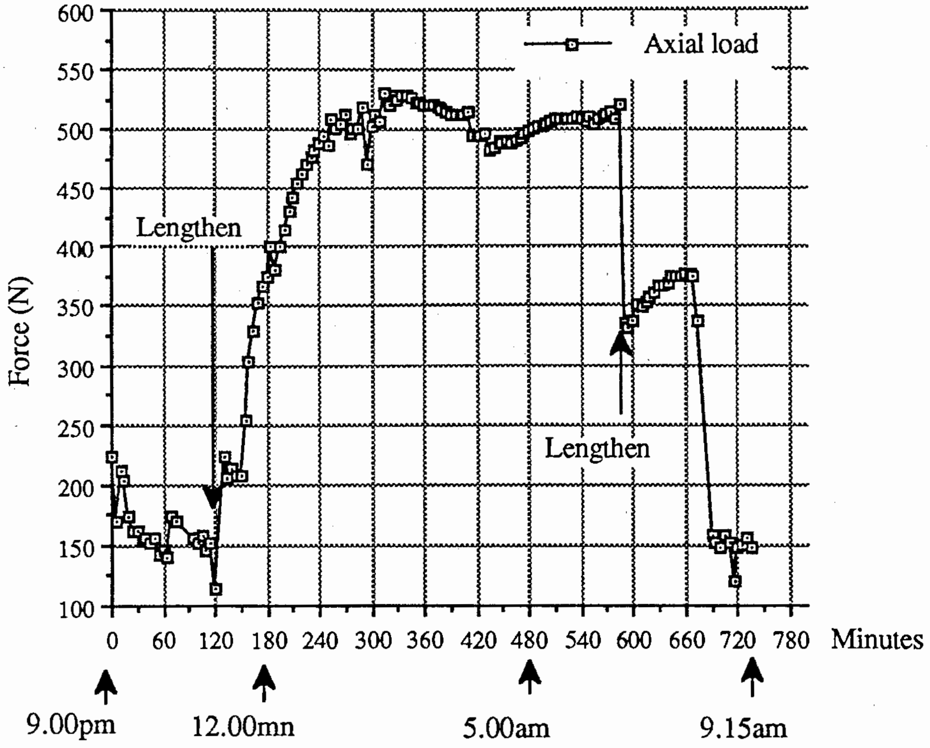
1. Subject 1. Average overnight force on the 21 st postoperative day versus time (minutes).
2. Subject 1. Bending moment magnitude and plane of orientation overnight on the 21 st postoperative day versus time (minutes).
3. Subject 2. Average overnight force on the 35 th postoperative day versus time (minutes).
4. Subject 2. Bending moment magnitude and plane of orientation overnight on the 35 th postoperative day versus time (minutes).
5. Subject 3. Average overnight force on the 53 rd postoperative day versus time (minutes).
6. Subject 2. Bending moment magnitude and plane of orientation overnight on the 53 rd postoperative day versus time (minutes).



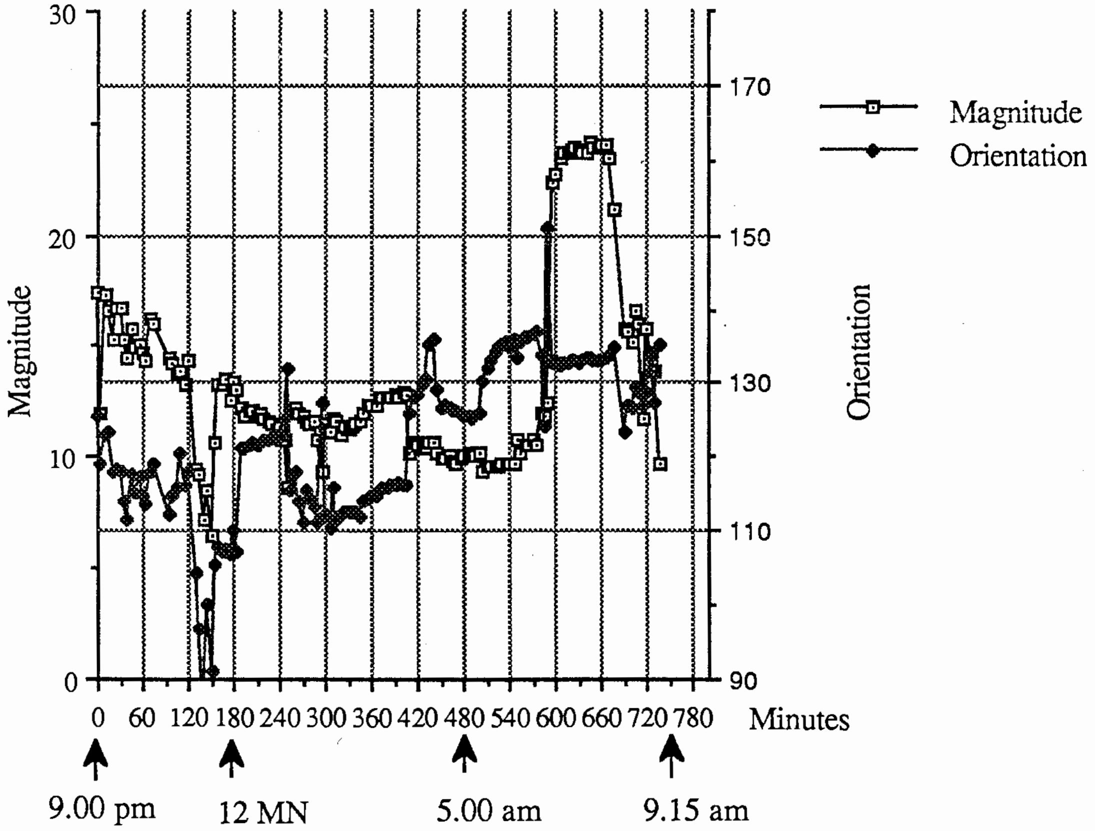
1. Subject 1. Average overnight force on the 21 st postoperative day versus time (minutes).



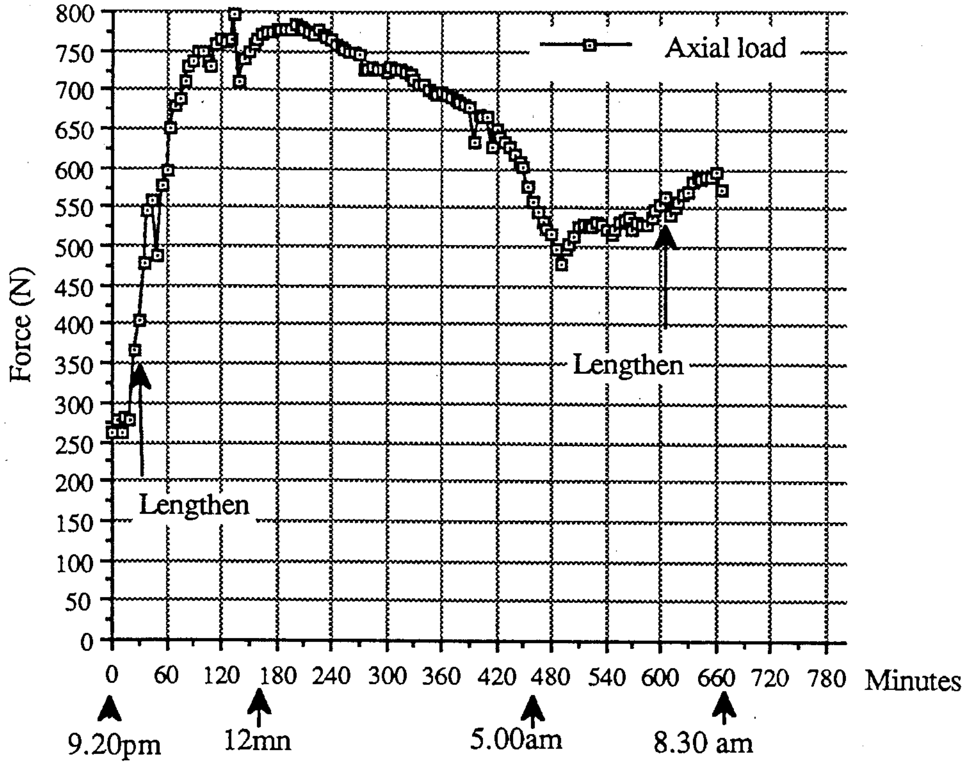
2. Subject 1. Bending moment magnitude and plane of orientation overnight on the 21 st postoperative day versus time (minutes).



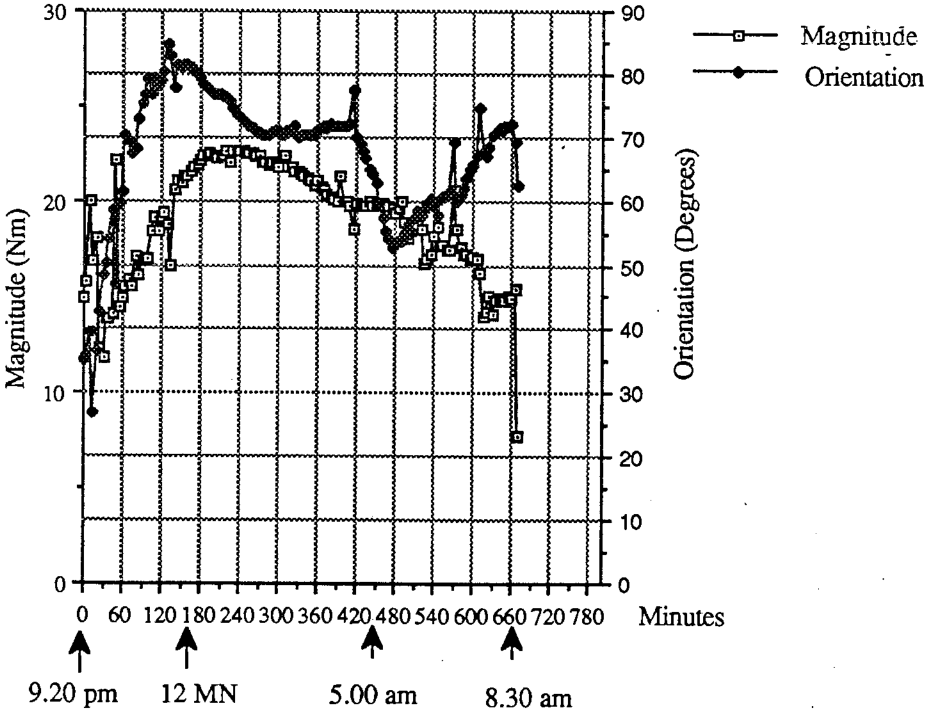
3. Subject 2. Average overnight force on the 35 th postoperative day versus time (minutes).



4. Subject 2. Bending moment magnitude and plane of orientation overnight on the 35 th postoperative day versus time (minutes).



5. Subject 3. Average overnight force on the 53 rd postoperative day versus time (minutes).

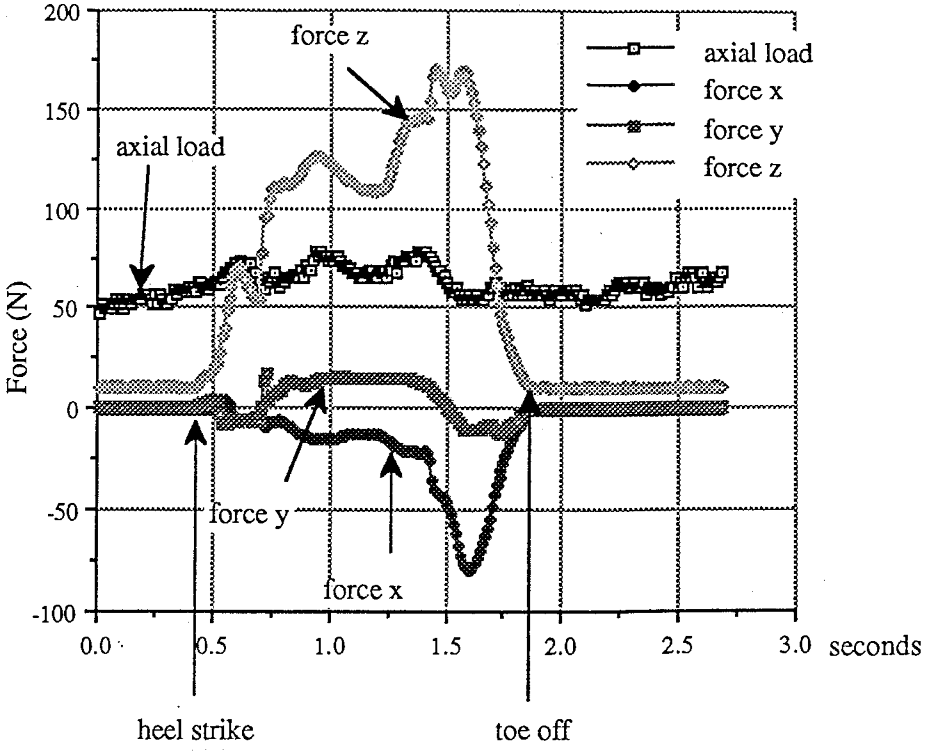


6. Subject 2. Bending moment magnitude and plane of orientation overnight on the 53 rd postoperative day versus time (minutes).

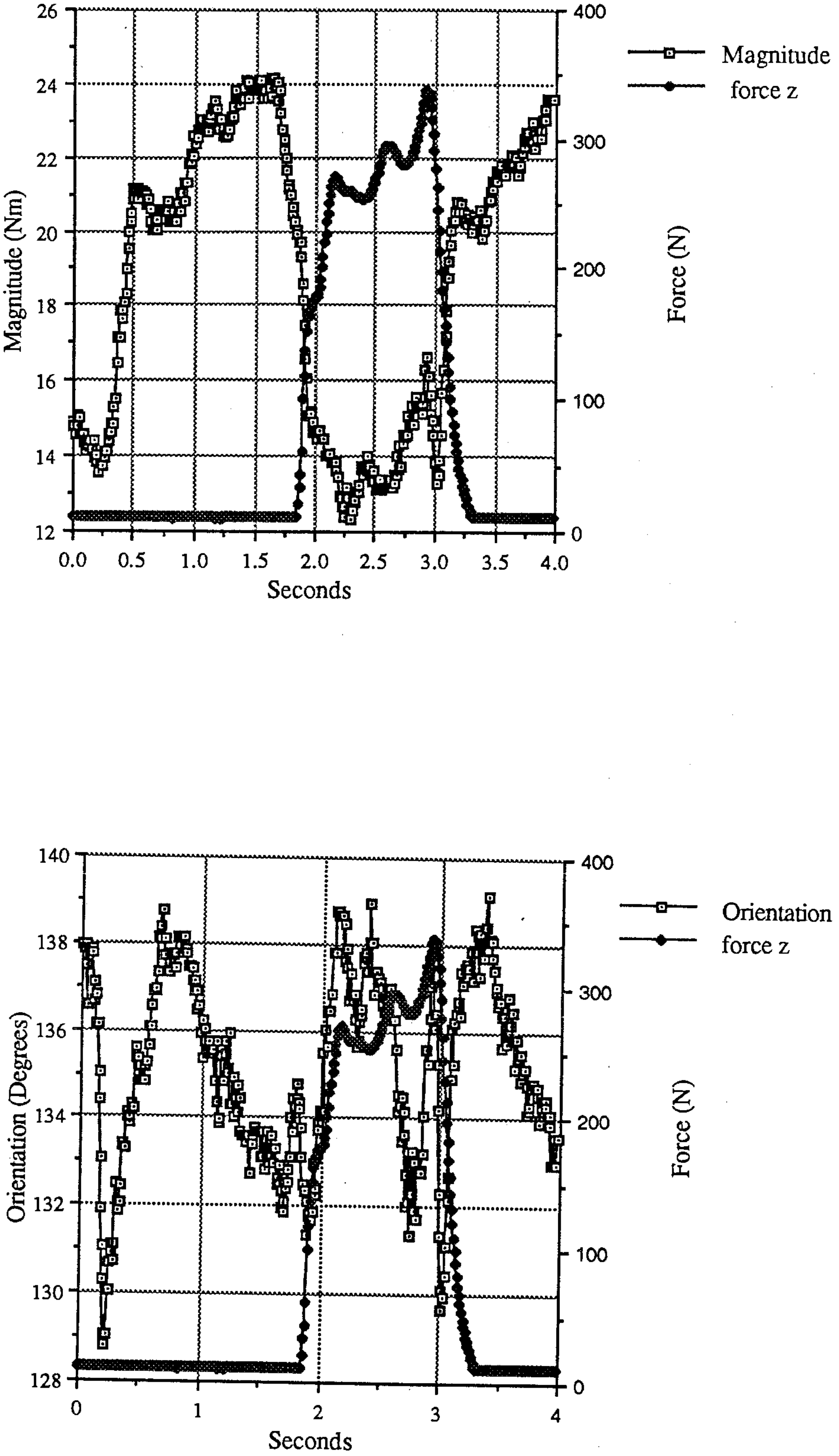
APPENDIX 3

FORCES AND BENDING MOMENTS RECORDED DURING DYNAMIC LOADING.

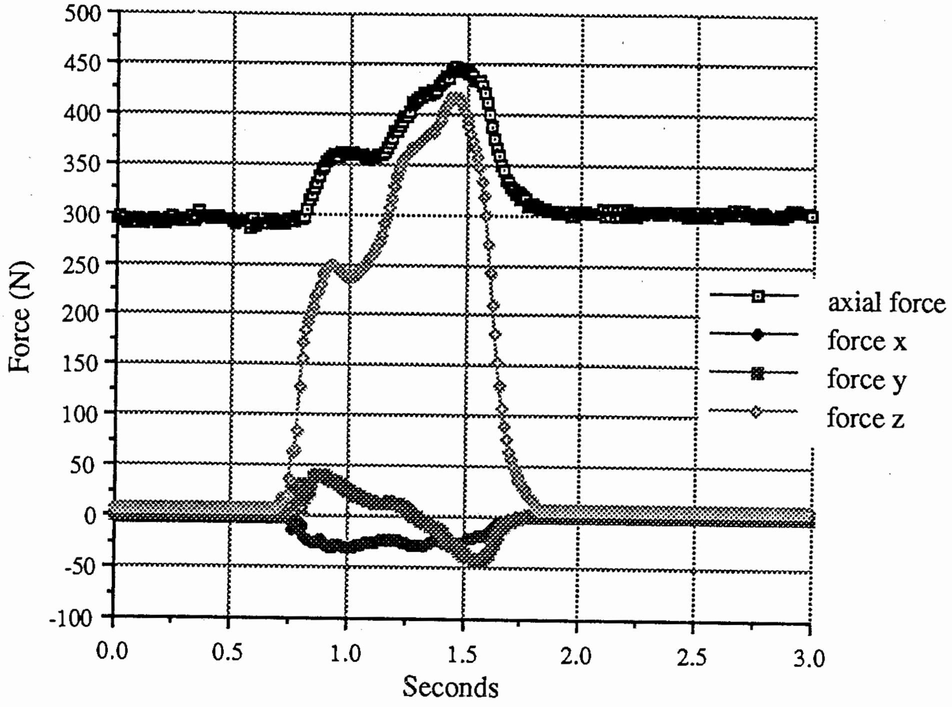
1. Subject 2. Axial load and forces in the X, Y, and Z directions for 1 walk during the first trial.
2. Subject 2. The magnitude and orientation of the plane of the bending moment and reaction force in the Z direction for 1 walk during the first trial.
3. Subject 2. Axial load and forces in the X, Y, and Z directions for 1 walk during the second trial.
4. Subject 2. The magnitude and orientation of the plane of the bending moment and reaction force in the Z direction for 1 walk during the second trial.
5. Subject 3. Axial load and forces in the X, Y, and Z directions for 1 walk during the first trial.
6. Subject 3. The magnitude and orientation of the plane of the bending moment and reaction force in the Z direction for 1 walk during the first trial.
7. Subject 3. Axial load and forces in the X, Y, and Z directions for 1 walk during the second trial.
8. Subject 3. The magnitude and orientation of the plane of the bending moment and reaction force in the Z direction for 1 walk during the second trial.
9. Subject 3. Axial load and forces in the X, Y, and Z directions for 1 walk during the third trial.
10. Subject 3. The magnitude and orientation of the plane of the bending moment and reaction force in the Z direction for 1 walk during the third trial.



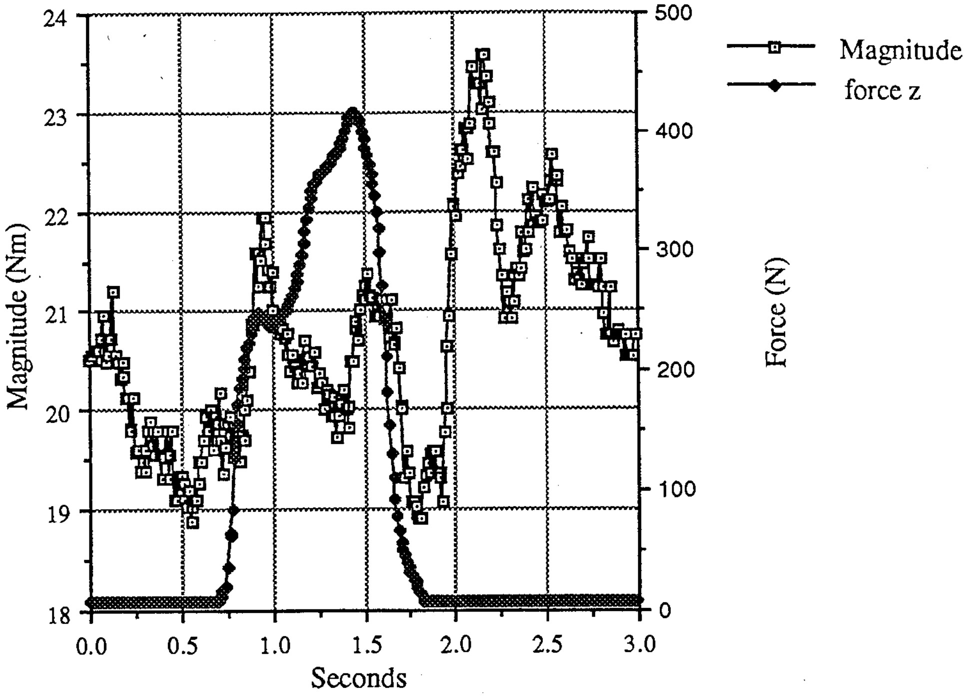
1. Subject 2. Axial load and forces in the X, Y, and Z directions for 1 walk during the first trial.

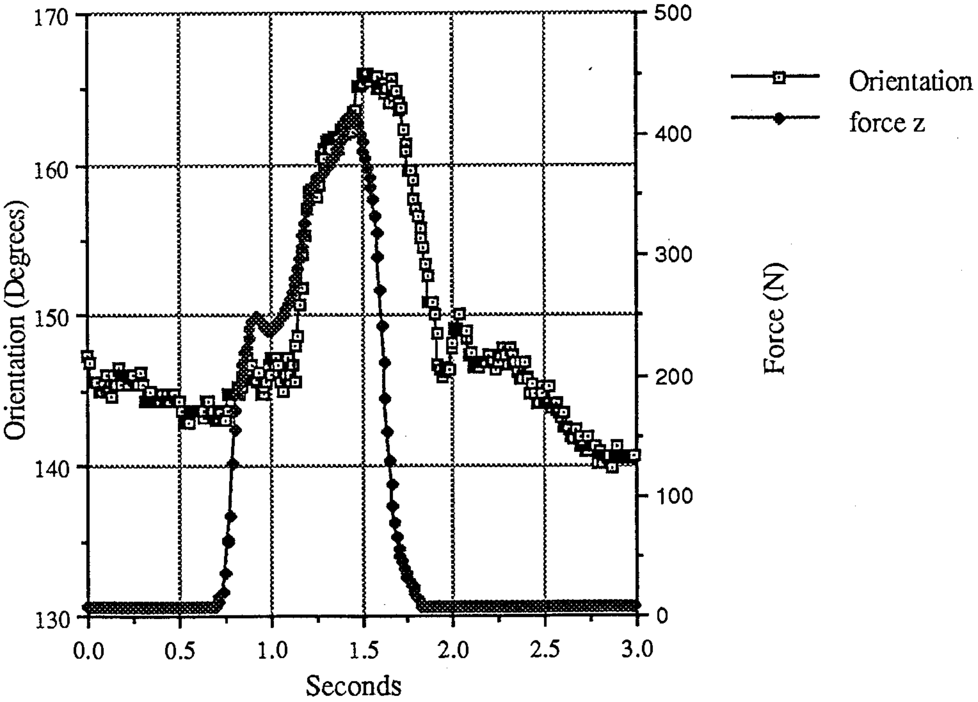


2. Subject 2. The magnitude (top) and orientation of the plane of the bending moment (bottom) and reaction force in the Z direction for 1 walk during the first trial.

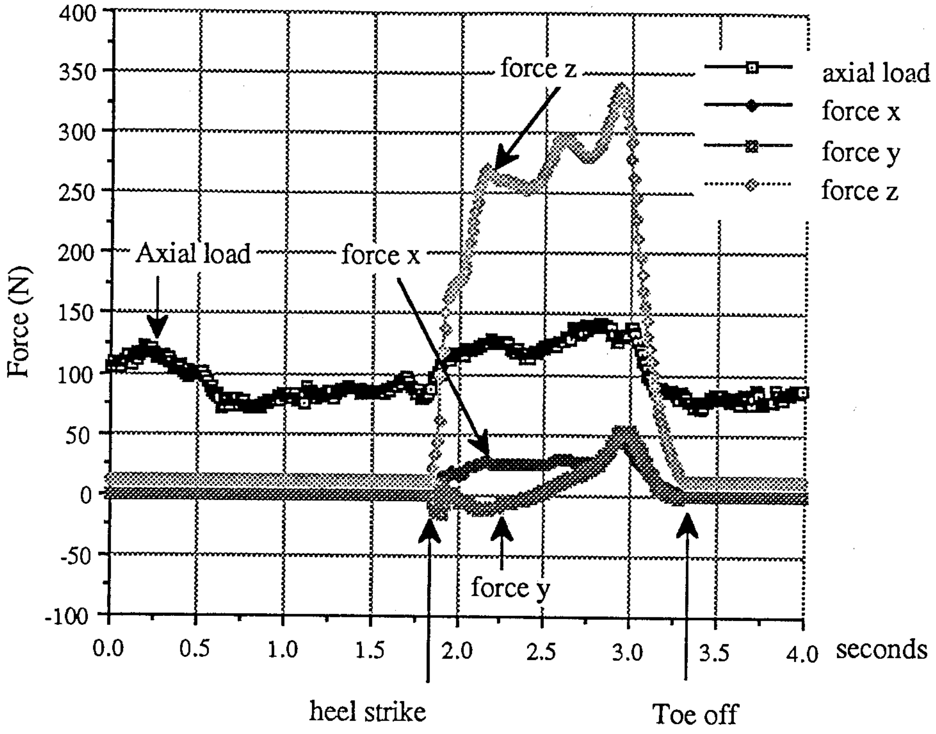


3. Subject 2. Axial load and forces in the X, Y, and Z directions for 1 walk during the second trial.

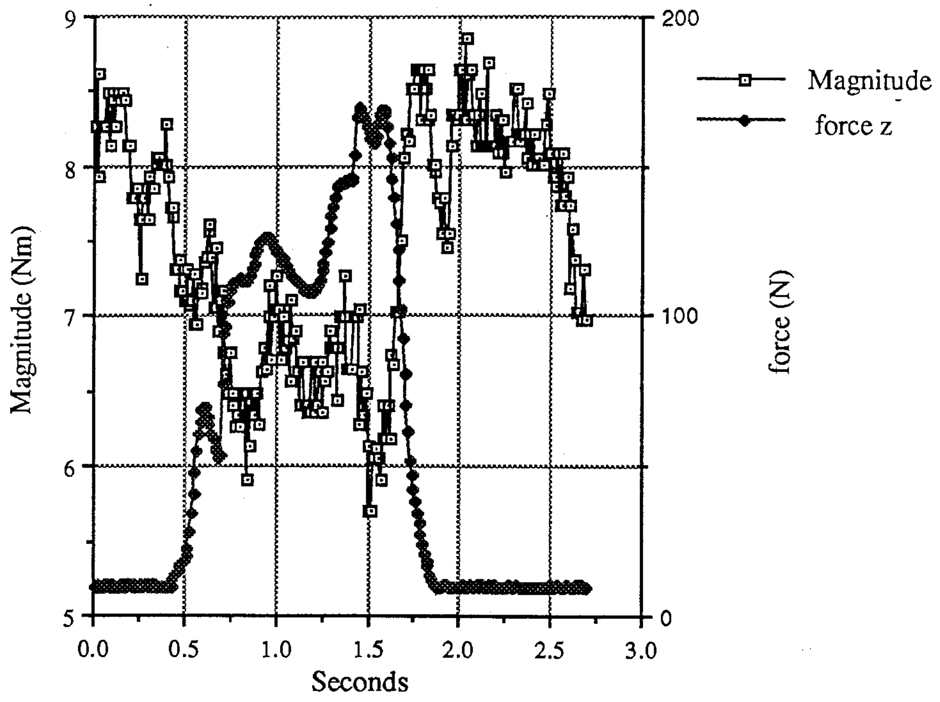


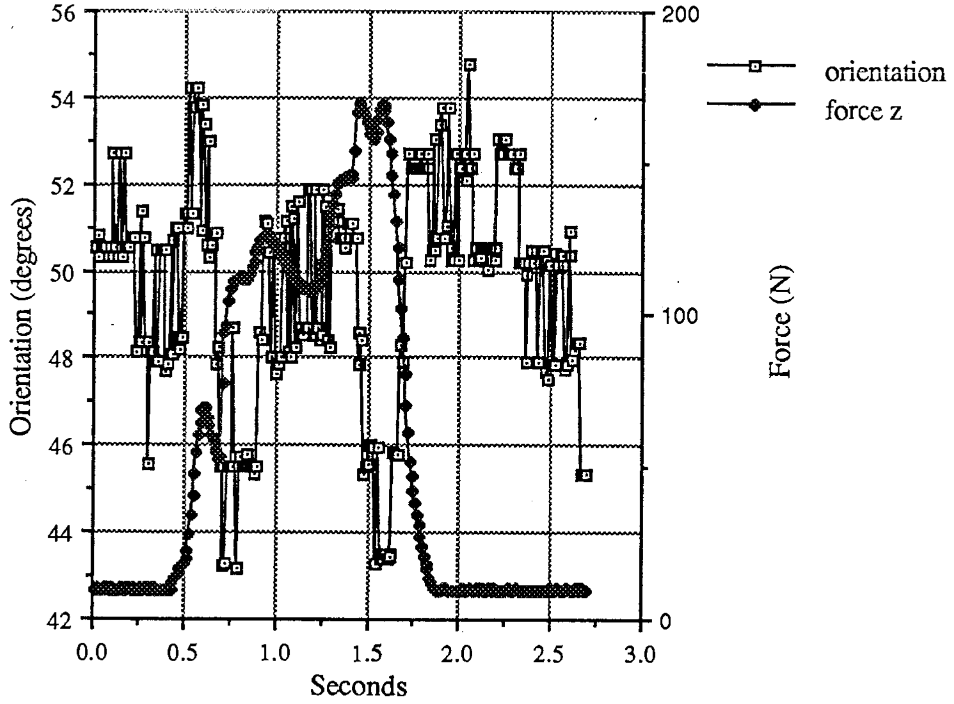


4. Subject 2. The magnitude (top) and orientation of the plane of the bending moment (bottom) and reaction force in the Z direction for 1 walk during the second trial.

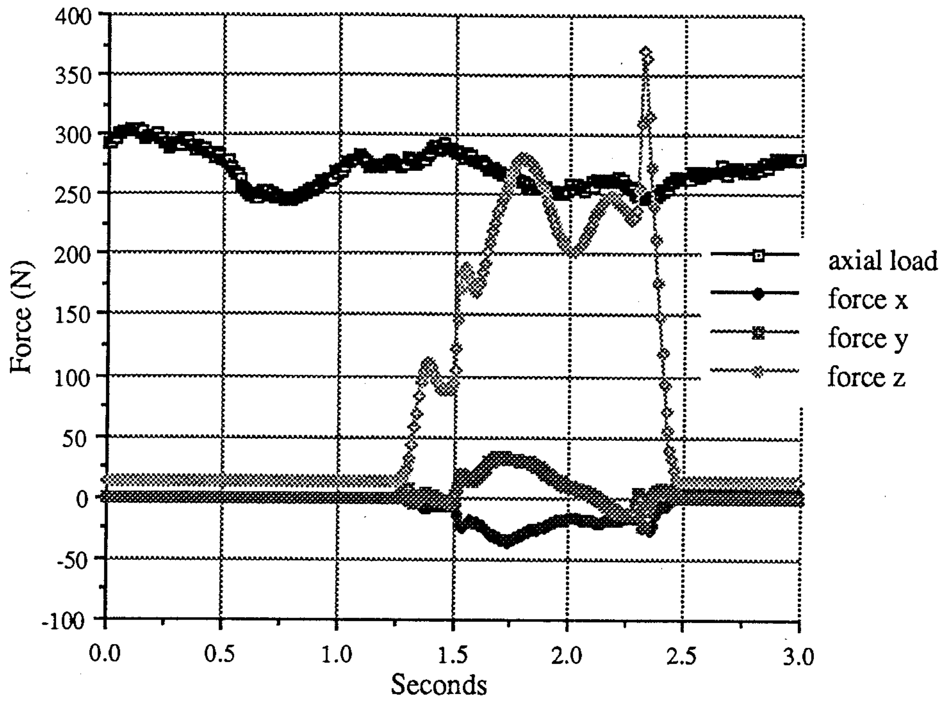


5. Subject 3. Axial load and forces in the X, Y, and Z directions for 1 walk during the first trial.

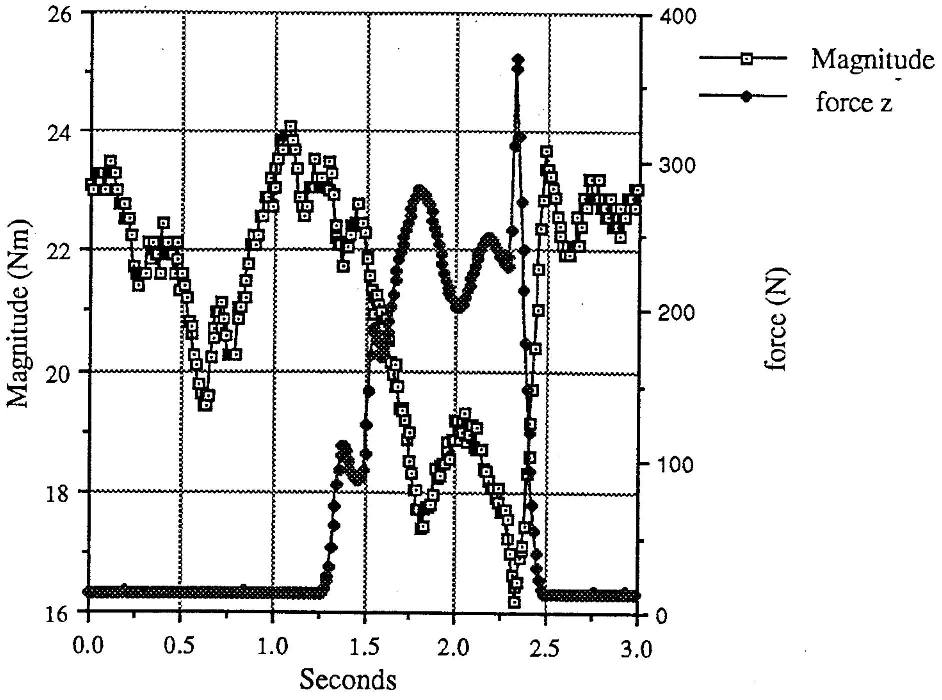


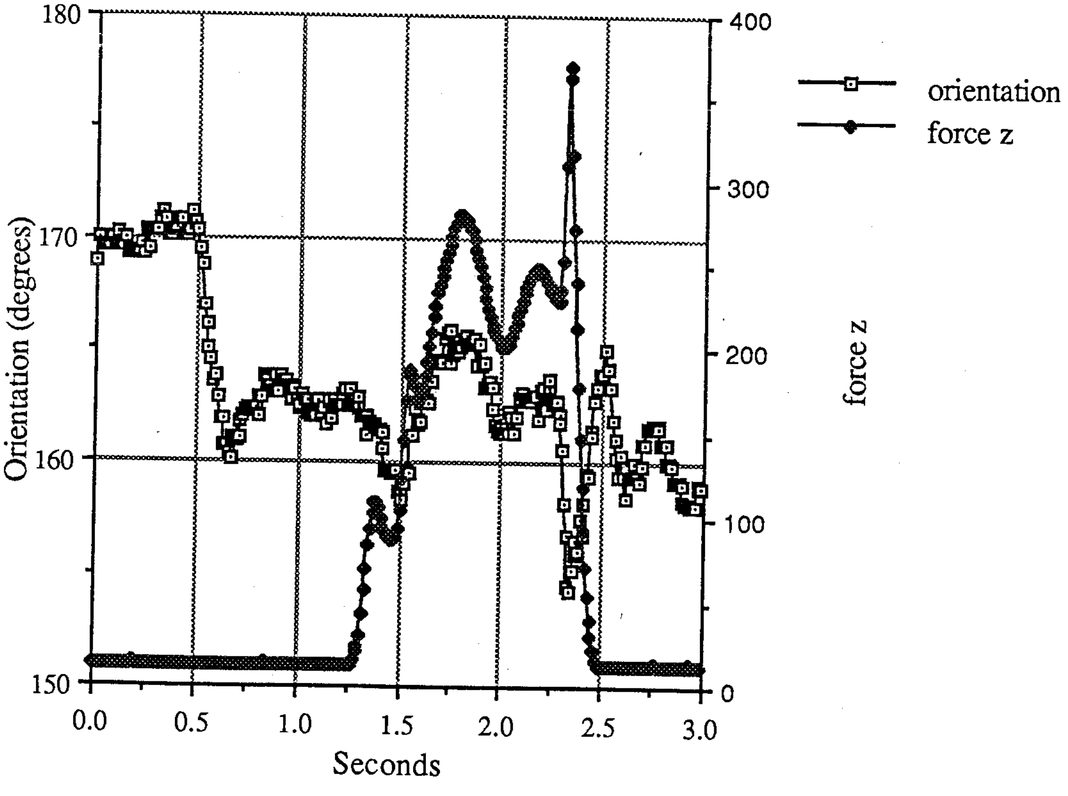


6. Subject 3. The magnitude (top) and orientation of the plane of the bending moment (bottom) and reaction force in the Z direction for 1 walk during the first trial.

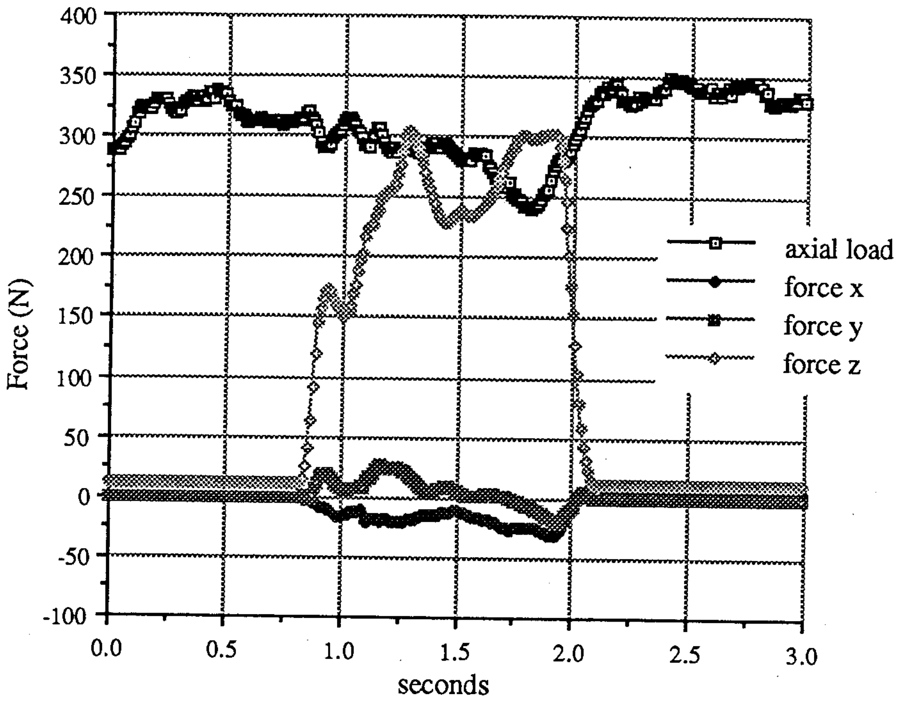


7. Subject 3. Axial load and forces in the X, Y, and Z directions for 1 walk during the second trial.

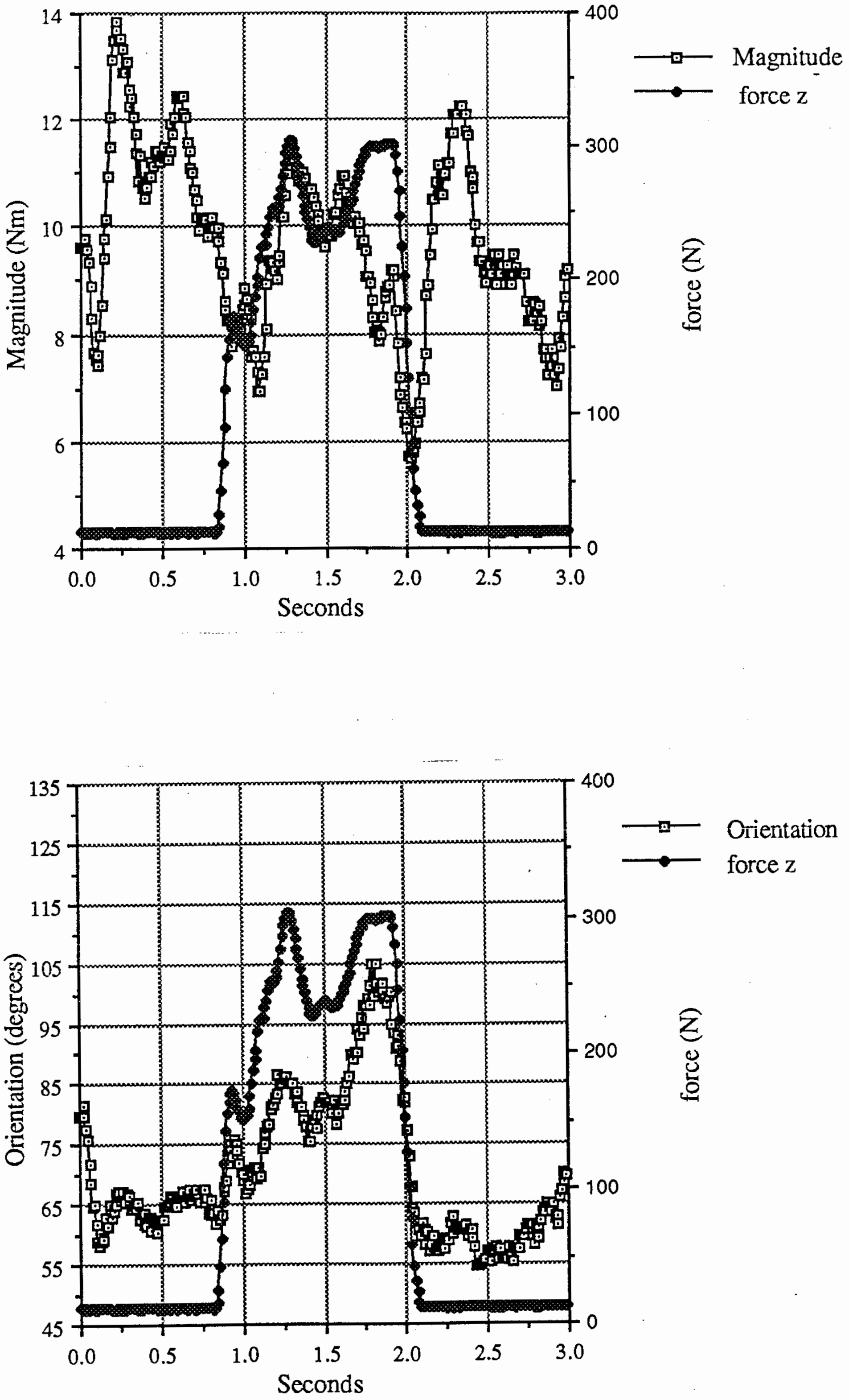




8. Subject 3. The magnitude (top) and orientation of the plane of the bending moment (bottom) and reaction force in the Z direction for 1 walk during the second trial.



9. Subject 3. Axial load and forces in the X, Y, and Z directions for 1 walk during the third trial.



10. Subject 3. The magnitude (top) and orientation of the plane of the bending moment (bottom) and reaction force in the Z direction for 1 walk during the third trial.

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