THE DESIGN AND TESTING OF AN ARTIFICIAL ANKLE JOINT

by

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ABSTRACT

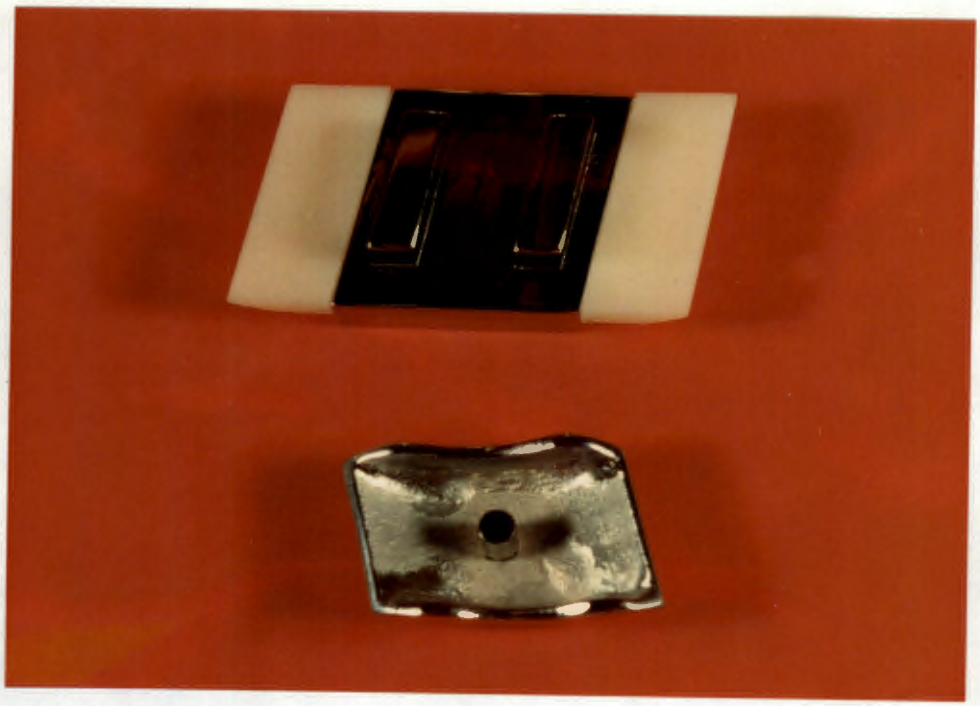
Arthritis is a crippling disease affecting one or more human joints and if not treated early with conservative methods, surgical management -- by replacing the diseased joint with an artificial substitute -- is often required. One of the joints that has received little attention in the past, despite its obvious importance in many daily activities, is the ankle joint. After reviewing the results of previous ankle replacement procedures it was found that these had an unacceptably high rate of loosening. This was due to the implant either failing to allow physiological motion of the ankle complex or having a method of fixation which was inadequate. For these reasons it was felt a new prosthesis -- designed to replace the tibio-talar joint -- could have a significant clinical impact.

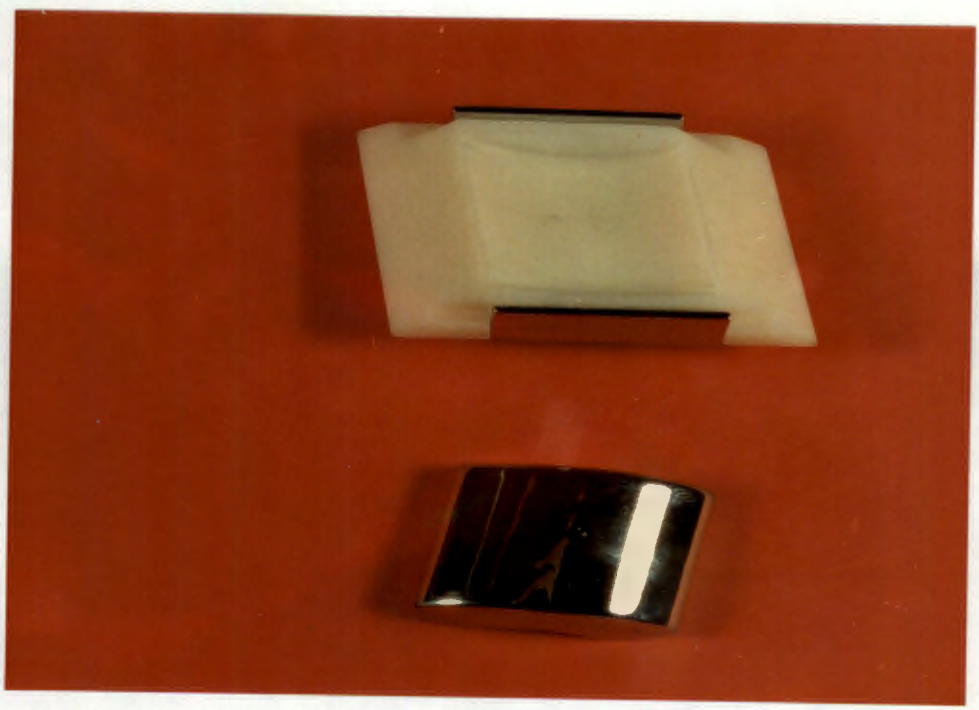
The design of the prosthesis was performed in two stages. The first stage was to determine the optimum shape of the articulating surfaces so that the chances of muscular contractions causing loosening would be minimised. The second stage was to determine the shape and size of the projections necessary to hold the prosthesis in place. In this case it was found appropriate to model the geometry of the ankle mathematically and to simulate the effect of different fixation methods using a computer.

Once a theoretical design had been formulated, a trial prosthesis was made and laboratory tests were started. These were of a comparative nature in which commercial implants were evaluated together with the prototype. Extensive use was made of polyurethane models of the ankle joint since it was desirable that biological variability be eliminated. The results of these

tests showed the new prototype to be superior to the other prostheses: it required very little bone resection, placed little extra loads on the ligaments, had a range of movement which approximated the normal motion at the ankle complex and which was unlikely to loosen in either the antero-posterior or medio-lateral directions. Besides this it was designed in such a manner that if the plastic articular surface were to wear thin, it could easily be replaced without endangering the integrity of the bond between bone and prosthesis. This feature makes the use of bone ingrowth an attractive alternative for enhancing stability since the bone bed need not be disturbed.

It is envisaged that the next stage of the design process should be to develop instrumentation to facilitate the correct orientation of the prosthesis **in** vivo. In this regard it is vitally important that the axis of rotation post-operatively be compatible with the ligaments crossing the ankle. If this is achieved it is felt there is every chance of ankle replacement being as successful as hip arthroplasty.





VIEWS OF THE HELICAL PROSTHESIS

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GLOSSARY

abduct	move away from the median line
adduct	opposite of abduct
ankle complex	ankle and subtalar joints
ankle joint	synovial joint between the distal tibia and fibula and the dome of the talus
arthrodesis	surgical fusion of the bones of a joint
arthroplasty	the formation of an artificial joint by plastic surgery
cadaver	a lifeless human body used for dissection
cancellous bone	soft or spongy bone
carcinogenic	cancer forming
compression	stress tending to compress a body
cortical bone	outer hard layer of bone
distal	furtherest from a reference point (usually the torso)
eversion	turning outward
fibula	the outer and small of the two bones of the leg below the knee
inversion	opposite of eversion
'in vitro'	in laboratory
'in vivo'	in body
lateral	side on the outer side of the medial plane
malleolus	protuberance on either side of the ankle joint
medial	inner (nearer the median line)
moment	product of force and leverage
necrosis	death of a portion of tissue

osteotomy	cut through a bone
prosthesis	a replacement for part of the body
proximal	opposite of distal
shear	stress tangential to the surface of a body
strain	fractional increase in length of a material when it is subjected to stress
stress	force per unit area
talus	the highest of the tarsal bones
tension	opposite of compression
tibia	inner and larger bone of the leg distal to the knee
torsion	"twisting" moment applied to a body

CHAPTER 1

INTRODUCTION

1.1 The Problem

One of the most painful and crippling diseases still prevalent in the Western World is arthritis (Gr. **arthron** = joint and itis = inflammation). (Dorland's Illustrated Medical Dictionary, 1965). This disease makes it either impossible or very uncomfortable to have smooth coordinated movement of the affected joint(s). Another characteristic of the condition is that it mainly afflicts older people. In 1973, 20-million Americans had arthritis, with 75% of sufferers between 45 and 65 years of age (Huiskes, 1980).

Degenerative joint disease (also referred to as osteo-arthritis or OA) involves the wearing away of the joint so that articulation becomes increasingly difficult. When degeneration begins, the amount of mucopolysaccharide in the cartilage decreases (because less is produced) and the cartilage becomes less resilient. (Mucopolysaccharides, such as chondroitin sulphate and keratan sulphate, are important in determining the stiffness of cartilage. They form part of the basic structural unit - called the proteoglycan sub-unit.) Pieces of cartilage may even break off and become engulfed by synovial cells, setting up slight inflammation. Eventually, clefts develop in the articular surface and friction increases correspondingly. The most severe result of this condition is a joint devoid of cartilage, with irregular bone surfaces surrounded by osteophytes. This type of joint is extremely inefficient from a mechanical viewpoint.

Rheumatoid arthritis (RA) is a chronic inflammatory disease of the synovium resulting in destructive changes within the

joint. In this case, no age group is exempt from the disease although 40 to 50 year old people are most commonly afflicted. The most probable cause of RA is an initiating factor followed by immune over activity. The former has not been positively identified and further research is still needed. As far as the perpetuation of the disease is concerned, there is a high incidence of antibodies that are produced as a result of stimulation by altered blood proteins in the blood of rheumatoid arthritics. The pathological changes that occur in the synovium (e.g. presence of lymphocytes and plasma cells) indicate excess activity of the immune system. This in turn indicates that RA is a generalised form of illness rather than one limited to a single joint.

Once the synovium has become inflamed and excess fluid exuded, the joint swells, stiffens and becomes painful. Once again, cartilage is lost, bone is destroyed and the capsule is stretched. In severe cases, joint destruction leads to dislocation of the joints, and deformity, with subsequent disability.

1.2 Possible Solutions

Mild cases of arthritis may be treated with drugs or antibiotics to diminish the inflammation. However, severely afflicted patients require much more radical forms of treatment. Two such methods are: arthrodesis (a surgical procedure in which the joint is abolished and the bones fused together); and joint replacement (also a surgical procedure, in which the diseased joint is replaced by an artificial one).

Before the technical achievements regarding prosthesis design had been made (especially those of the correct choice of materials) the options open to orthopaedic surgeons were rather limited. Either some form of osteotomy (an operation involving the changing of anatomical proportions of bones or joints) or an

arthrodesis were the main alternatives. (see Figure 1.1)

Nowadays, however, with the advent of materials which are physiologically compatible with the body, mechanically robust and which have excellent wear properties, the surgeon is faced with the possibility of an engineering solution to a medical problem. Just how popular artificial joint replacement has become can be seen in Tables 1.1 and 1.2 (Huiskes, 1980).

As is evident from these tables, as far as the lower limb is concerned, the importance of artificial joints decreases as one moves distally. This is understandable since the hip, being a ball-and-socket joint, has the greatest range of movement of all the joints of the leg. It would be most beneficial for this joint to remain mobile - hence the concerted efforts that have been made at replacing it artificially.

This bias towards the more proximal joint replacement also manifests itself in the variety of designs which are commercially available. (see Table 1.3)

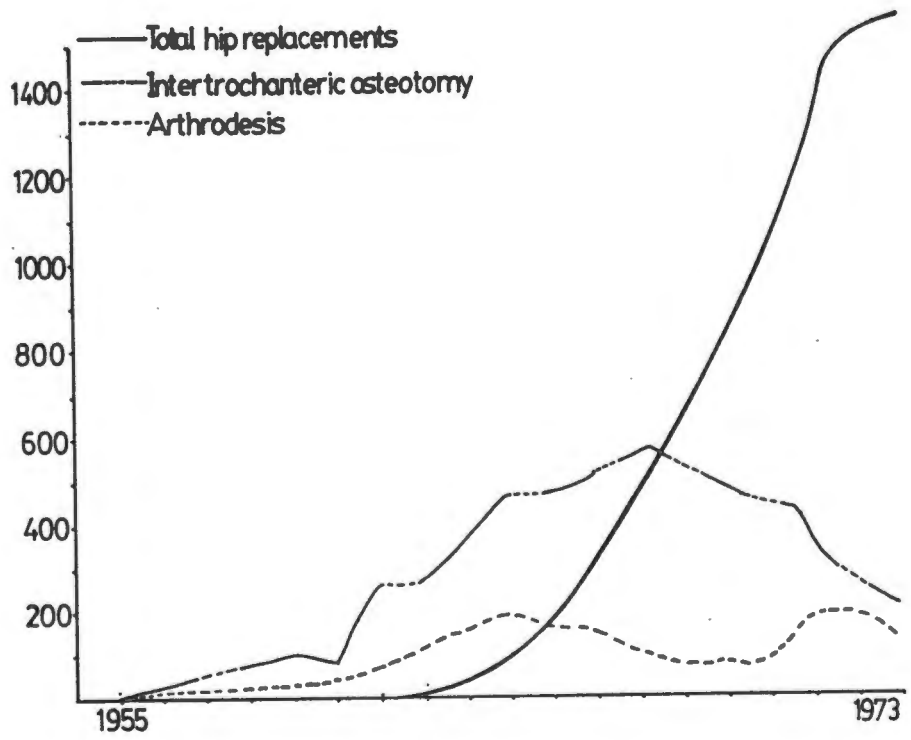


Fig. 1.1 Number of Hip Operations in Nine Swiss Orthopaedic Clinics (1955-1973) (Huiskes, 1980)

Joint	Number
hip	80000
knee	40000
others	10000

Table 1.1 Replacements in USA (1976) (Huiskes 1980)

Joint	Number
hip	7277
knee	643
ankle	no data
shoulder	29
elbow	30
hand	uncertain

Table 1.2 Arthroplasties in the Netherlands (Huiskes, 1980)

Artificial joint	Number of types
hip	more than 100
knee	48
ankle	6

Table 1.3 Artificial Joints (Huiskes, 1980)

1.3 The Ankle

Even though the hip and knee have a greater functional role than the ankle, the latter cannot be ignored when considering the factors affecting gait. If a successful ankle replacement was available it would eliminate some of the side effects experienced by people with fused ankles. At this point it must be noted that arthrodesis of the ankle is usually successful in relieving pain and by the use of a shoe with a rocker sole, the patient's gait is practically indistinguishable from that of a "normal" person. However, complications that are associated with a fused ankle are:

(a) Increased stress on subtalar joints, which may lead to severe pain in this region (Ahlberg, Henricson 1981).

(b) Difficulties in walking over rough terrain or for long distances on flat terrain, even with special shoes (Morrey and Weiderman, 1980).

(c) Difficulty in running. Mazur et al. (1979) found that 9 out of 12 patients who had arthrodesis to correct traumatic arthritis, could not run.

A complete review of recent surveys of arthrodesis is given in Appendix A. From these surveys it is apparent that, on average, one in five arthrodesis attempts fails to form a bony union. However, when a sound arthrodesis is obtained, the aims of surgery to obtain a normal gait pattern, a pain free foot and a return to normal daily living, can be fulfilled.

Unfortunately a detailed analysis of the success rate of this procedure is difficult due to the variety of methods of arthrodesis, and also the variety of pathological conditions necessitating ankle fusion. Since 1879 the number of surgical approaches has increased to about 23 (Scanton, 1980). This fact has led some people (Evanski, 1977) to believe that no particular

method of fusion has met with complete satisfaction. Thus, in certain cases the correct choice and insertion of an artificial joint may be an acceptable alternative and may help prevent overloading the other joints of the foot. This would seem to be especially relevant if these joints were also in danger of developing arthritic changes, as in a general disease such as RA.

As is the case with artificial replacement of most joints (except the hip), the present knowledge concerning ankle replacement is still developing from basic principles. Efforts are being directed at solving the problems that have become apparent from the initial ankle arthroplasties. Aspects such as improvement of ankle motion, more secure fixation, absence of postoperative talofibular impingement, are now being studied. Once these and other difficulties have been solved, ankle joint replacement will offer a definite viable alternative to ankle arthrodesis.

The purpose of this study is to design and test a total ankle prosthesis bearing in mind the biomechanics of the normal ankle joint. It is felt that only by means of a rigorous investigation of the many interrelated medical and engineering factors, will a successful artificial ankle joint be designed.

CHAPTER 2

REVIEW OF RELATED LITERATURE

2.1 Joint Replacement

The first question one may ask when reviewing the subject of joint replacement is, "How many patients could benefit from such a procedure?" It has already been shown in Chapter 1 that the ratio between hip, knee, and "other" joint replacements in the USA is about 80000:40000:10000. These figures however are under estimates since, if each arthroplasty had a success rate of 100%, far more operations would be performed. Hori et al (1978) suggests that if a perfect system for each category of joints could be developed 12% more hips, 60% more knees and 239% more ankles, shoulders, elbows would be replaced. These figures also indicate that hip arthroplasty is the most developed procedure and enjoys more success than the others.

Some reasons for the dominance of hip over ankle replacement were given at a symposium on rheumatology (Tyer, 1978). At this meeting the following points were made:

(a) one of the main causes of arthritis of the ankle (especially in young people) is trauma. In this category it is impossible to insert a prosthesis and guarantee that it will last for any length of time.

(b) in cases of rheumatoid arthritis, the talus (part of the ankle joint) may have undergone osteoporosis.

(c) the ankle is an area prone to oedema, varicose vein problems and delayed skin healing.

Although these factors limit the number of patients that could benefit from ankle arthroplasty, the point was made that there still remained candidates who were ideally suited for such a procedure if a suitable prosthesis was available.

Once it has been accepted that artificial joint replacement could be a solution to the problem of arthritis, the next question which may be asked is, "What criteria should be used in the design of the various prostheses?" Elloy et al (1976) listed what they regarded as the basic requirements for the procedure and thirteen criteria which should be used to design a prosthesis to meet these requirements. They discussed each of these criteria separately and explained that the final design depended on which aspects received greater attention. It is thus possible to get two or more satisfactory solutions to the initial problem. They also mentioned that as the gaps in our knowledge are diminished, so the science of joint replacement will benefit. An example of this progress is that metal-on-metal prostheses (such as the McKee-Farrar hip) are no longer used.

Swanson (1977) in the first of three papers in a series, reviewed the historical development of joint replacement and the features common to all good prosthesis designs. These included the following:

(a) both articulating surfaces should be replaced

(b) the bone that is removed need not be more than a few millimeters deep

(c) secure fixation is essential for relief from pain

(d) materialsused must be compatible with the humanbody and with each other

(e) the operation of inserting the prosthesis must be feasible.

Besides these aspects, Swanson discussed the materials used for surgical implants, their biocompatibility, mechanical properties and the manufacturing techniques that are employed.

In the second paper, Swanson (1977) described representatives of the designs used for the various joints that can be replaced. He concentrated on the hip and knee, but the ankle, shoulder, elbow, wrist and finger joints were considered briefly. The last of the series (in 1978), dealt with the results that had been obtained, the causes of failure, and problems and trends in the following areas;

(a) Mechanical design

(b) Choice of materials

(c) Fixation

(d) Surgical techniques

(e) Organisation and economics

Swanson contended that, although the success rate in the case of hip replacement is of the order of 80-95%, there still remained some problems with regard to loosening, corrosion-fatigue, infection and malalignment of the prosthesis. These problems (with the exception of loosening) have largely been overcome as the cooperation between surgeon and engineer has become closer. He suggests that when the difficulties experienced with the replacement of other joints are overcome, further facilities at hospitals will be needed to cater for all the additional patients.

A paper which reiterated many of the points made by Swanson was that by Lettin (1980). He also concentrated on hip and knee joint replacement with special emphasis on the problems that may be encountered. These included

(a) loosening due to

* metal sensitivity
* frictional torque between the articular surfaces which is transmitted to the bone-cement interface

* improper preparation of the bone cavity prior to introducing the cement
* not pressurising the cement into the trabecular spaces
* infection
* using a prosthesis which does not mimic the anatomy of a joint (such as a hinged device)

(b) dislocation

(c) mechanical failure

(d) cardiovascular complications.

According to Lettin, the last three problems are of a far lesser magnitude than the first one. Although some of the factors which can cause loosening have almost been eliminated, cases are still reported where the fixation between bone and cement has broken down and movement between bone and implant has resulted.

Another article concerning joint prosthetics in general, was written by Weightman in 1981. He concentrated on the shape and material of the implants together with the methods of fixation. Since the bone cement that is used in joint replacements does not adhere to the bone (or the prosthesis), the shape is a crucial factor in determining the success of the device. An example given by Weightman is that intramedullary stems should not be circular in cross-section, since any torsional load transmitted across the joint would place the stem/cement interface in shear. On the other hand, a stem with a triangular cross-section would transmit compressive stresses which the cement is capable of withstanding (see Figure 2.1).

Weightman went on to discuss a means of fixation which need not involve the use of cement. This method in which a finned peg is used (see Figure 2.2) combines excellent immediate fixation

with the possibility of bone ingrowth increasing the strength of fixation. Each fin forms a cantilever which wedges itself in the trabeculae of the bone. If the surgeon so desires, cement can be used together with the finned peg.

There are, however, problems associated with "biological" fixation. Swanson and Freeman (1977) explain that the contact area between prosthesis and bone must be high (to avoid fatigue failure of the involved bone). Thus, if cement is not used, very precise surgical techniques are needed to shape the bone to fit the prosthesis. In addition, the ability of bone to grow into a "dead space" is limited. They estimate that a gap of two millimetres represents the practical limit of bone ingrowth.

They further point out that even if the bone can be shaped correctly for a particular prosthesis, it must not be killed in the process. After such a procedure, the prosthesis must not be allowed to move such that new bone projections are sheared or torn off. It is thus necessary to employ stringent immobilisation techniques to prevent joint movement.

Due to these difficulties, the use of bone cement has remained popular ever since Charnley started using the material to distribute stresses between the bone and the prosthesis. In a comprehensive study (Huiskes, 1980), the thermal properties of this filler-material were looked at in detail using finite element analysis. Huiskes recommended specific procedures that could be followed to prevent bone-tissue necrosis due to the elevated temperatures that occur during the curing stage. Besides the characteristics of bone cement, other aspects which were covered in this study were: the mechanical stresses imposed on femoral intramedullary stems; some guidelines for better design of prostheses and their implantation; and other, general, concepts of human joint replacement.

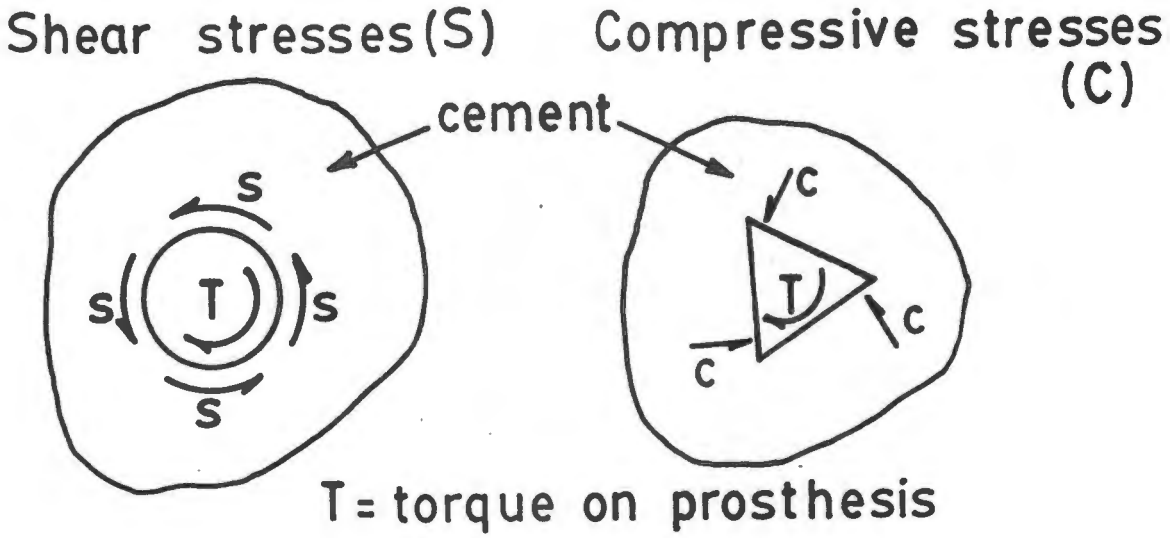


Fig 2.1 Effect of Intramedullary Stem Shape on Prosthesis-cement Interface Stresses (Weightman, 1981)

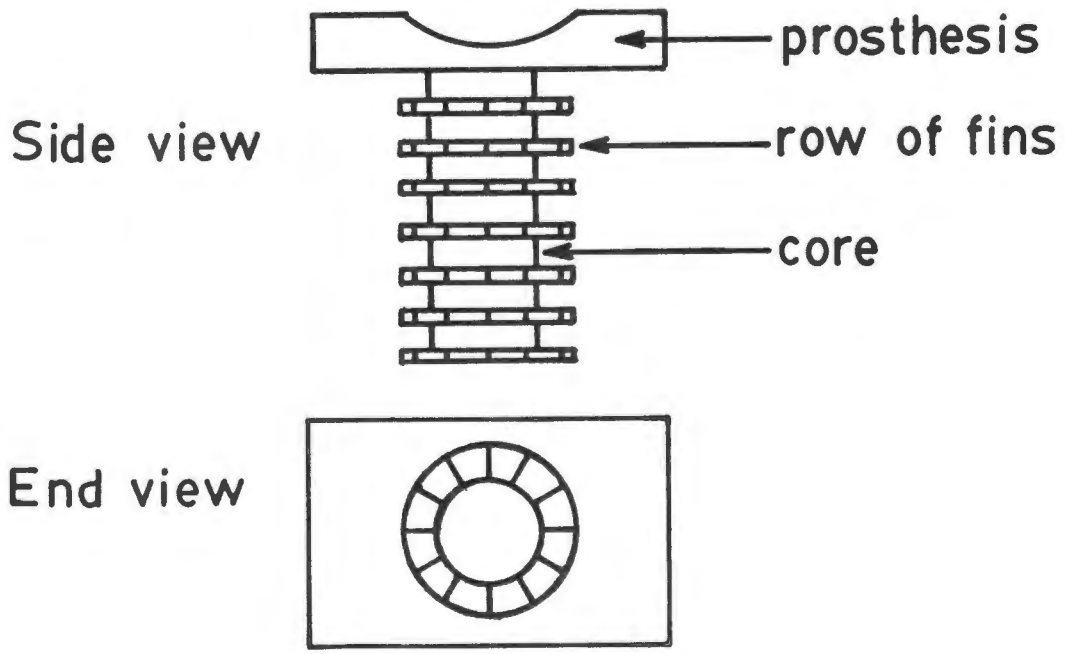


Fig. 2.2 Finned Peg (Weightman, 1981)

In a book entitled "Human Joints and their Artificial Replacements" Walker (1977) discussed many fundamental concepts concerning joint arthroplasty. His work included a review of the properties of PMMA cement, the stresses that can be expected in bone-prosthesis systems and the fixation of artificial knee joints. He also described the tremendous impact that "cold curing" acrylic cement has had on the success of hip replacement procedures together with the relatively good combination of metal and high-density polyethylene. Other aspects covered by Walker included the biomechanics of joints, properties of biological materials, lubrication and wear of normal and artificial joints and the different types of prosthesis that are available for the major joints of the upper and lower extremity. A notable exception in the latter category is the replacement of the ankle joint.

This omission of a section concerning ankle joint arthroplasty is shared by another book on the biomechanics of joints and joint replacement (Dowson and Wright, 1981). In this book the authors describe the replacement of the hip, knee, shoulder, elbow and finger joints. They do, however, in the sections on the biomechanics of joints, include the ankle joint.

More basic concepts concerning bio-engineering topics are illustrated in chapters such as experimental stress analysis, mechanical properties of materials (such as strength, stiffness), properties of tissues (e.g. cartilage, bone) and manufacturing processes that are used to make prosthetic components. At a slightly higher level are the sections on lubrication of natural and artificial joints.

2.2 Materials used in Joint Prostheses

The practice of implanting non-biological materials into

ankylosed or painful joints dates back over a hundred years. Surgeons have used wood, celluloid, silver plates, rubber sheets, magnesium, zinc, gold foil and glass in an attempt to separate diseased joint surfaces (Dunn, 1980). From these primitive beginnings the science of joint replacement advanced (often through trial and error) to reach a level now where engineers can design prostheses that have little chance of suffering mechanical failure. One of the important lessons that have been learnt is that although the friction between artificial articulating surfaces may be negligible, the wear rate may be unacceptably high. An example of this phenomenon (Dunn, 1980) is to be found in Charnley's experience of using steel-on-teflon prostheses. (Wear will be discussed later in this section.)

In order that other poor selections of prosthetic materials are not made, Elloy et al (1976) drew up six requirements for joint implant materials.

(a) they must have adequate strength to withstand physiological loads

(b) they must not corrode **in vivo**

(c) they must not cause adverse tissue reactions

(d) they must be non-toxic

(e) bearing surfaces must be wear-resistant and

(f) should have a low coefficient of friction between them

Based on these requirements, they listed four metals and three polymers that are suitable for implantation;

Metals
* Wrought Austenitic Stainless Steel (type 316)
* Cobalt-chromium-molybdenum-cast alloy (Vitallium)
* Pure titanium and titanium alloy

* Cobalt-chromium-tungsten-wrought alloy (Wrought Vitallium)

Polymers
* Ultra-high molecular weight polyethylene (UHMWPE)
* Silicone rubber (or Silastic)
* Acrylic bone cement (PMMA)

With the exception of silicone rubber, Weightman (1981) tabulated the mechanical properties of these materials together with others that have been used in orthopaedic applications. He included seven metals, one ceramic and four polymers in the summary. Although a ceramic, such as alumina, offers chemical inertness, low friction and wear rates, and innocuous wear debris, its extreme brittleness makes it unsuitable for applications in which it is loaded in tension. The combination of a metal and a polymer, on the other hand, has been used extensively in total joint replacements. Weightman favoured titanium-alloy together with high molecular weight polyethylene as a combination for the future. The use of annealed stainless steel may decline since after long periods in vivo, breakdown and pitting are likely.

2.2.1 Failure of Metal Components

With regard to the failure of stainless steel implants, Harris (1979) suggested that much of the material was not of a sufficiently high metallurgical quality. Some failed devices did not comply with the basic specifications as laid down in the relevant British Standards. In other cases the level of nickel or molybdenum in the alloy was only marginally above the specified minimum level for use in prostheses.

Other reasons for corrosion of stainless steel that were cited were;

(a) galvanic couples caused by differing alloy compositions in mating stainless steel components (e.g. a screw and its associated steel implant). The cause of galvanic corrosion is the potential difference that exists between two dissimilar metals when they are in contact in an aqueous environment. This potential difference causes ions to migrate from one metal to the other: The more active metal (the anode) will thus be corroded away at a rate which is dependent on the magnitude of the potential difference.

(b) non-metallic inclusions which may pierce the implant's surface and initiate pitting (a localised form of corrosion)

(c) crevices under the head of a screw. These cause sheltered points and hence local differences in the surrounding environment are possible. The slow rate at which oxygen in the electrolyte can be replenished at such points leads to crevice corrosion (Redford, 1975).

(d) splinters from surgical tools which can, once again, form a galvanic couple.

Still on the subject of stainless steel, Elloy et al (1976) pointed out that this metal is especially useful during the development phase of new prostheses. Its main drawback is that for implants it may not be welded or cast. This was also noted by Swanson and Freeman (1977) in the chapter concerning the manufacture of prostheses. They further described the forging of steel and titanium alloys, investment casting of cobalt-chromium alloys, the finishing of bearing surfaces and various aspects concerning plastics and ceramics.

Besides corrosion, another cause of failure of artificial joints is fatigue. Walker (1977) in his review of implant materials, described how a metal may be strong enough when subjected to a static load and yet fail under repeated loads of the same or

lesser magnitude. He gave the failure of prosthetic stems as a typical example. This type of failure may not, however, be solely due to fatigue, but a combination called "corrosion-fatigue". This occurs when a metal is subjected to a fluctuating stress in a corrosive environment. Pits produced by corrosion act as stress raisers, and fatigue cracks are accelerated (Swanson, 1977).

Although defects in the metal have been shown to facilitate failure, cell-mediated immunity may also play an important role. Christiansen et al (1979) devised an **in vitro** test which makes it possible to know pre-operatively whether the patient is sensitive to a particular metal. This "lymphocyte transformation" test can also be carried out on patients post-operatively, if there are signs that the prosthesis is becoming loose. A positive response in such cases would indicate that the implant should be removed.

2.2.2 Failure of Plastic Components

It was mentioned earlier that Teflon components are unsuitable due to their low resistance to wear. This phenomenon is a complex process since it is dynamic and undergoes successive stages, each one unfortunately eliminating the evidence of the earlier events (Barwell, 1967). Another difficulty is that often very little material is removed and hence precise measurements are necessary. Barwell discussed the intricacies of assessing wear together with instrumentation that has been employed in the measurement. The methods mentioned included;

(a) weighing

(b) radioactive tracing of the debris

(c) interference microscopy

(d) electron microscopy

(e) halography

(f) amplifying irregularities picked up by a stylus which traverses the worn surface

The last method in this list was used by Dumbleton et al (1974) to evaluate the wear rates of various plastics used in joint replacement. They bathed each test sample in blood plasma and simultaneously rotated a polished stainless steel annulus on the plastic specimen. Their findings were that the wear resistance of polyethylene increases as the molecular weight and the amount of carbon fibre reinforcing increases. Gamma radiation also had a beneficial effect.

It may be argued that a test such as this has little relevance to the situation **in vivo**. Neale (1967) was aware of this when he made the following points;

(a) data on the actual variation of loads on the human joints in both magnitude and direction, together with the timing relative to the joint movement is needed, as is

(b) a better understanding of the types of plastic materials which are biologically acceptable for use in artificial joint prostheses.

Nowadays, however, due to the excellent combination of UHMWPE-on-metal, the emphasis has shifted from studies of wear to other pressing problems. The tests done on models are thus more for academic interest than for improving the clinical results of joint replacement.

2.3 Biomechanics of the Ankle

The biomechanical features of any joint include a host of interrelated aspects such as;

(a) General Anatomy

(b) The articulating surfaces and their range of motion

(c) The axes of rotation and the ligaments

(d) Muscles crossing the joint and their phasic activity

(e) The transmission of forces.

For a joint such as the hip, there is a wealth of information on each of these categories. Unfortunately, this is not the case with the ankle, but interest in this joint has recently increased. The knowledge on the ankle that has been acquired, although incomplete in some areas, will be reviewed in this section under the headings listed above.

2.3.1 General Anatomy

The ankle complex consists of two joints: the ankle and subtalar joints. The former consists of joints between the fibular and talus and the tibia and talus (see Figure 2.3). It is common though for the ankle joint to be referred to as the "tibio-talar" joint since the articular surface on the fibular is small compared to the total joint surface.

In some earlier publications the ankle complex was likened to a universal joint (see Figure 2.4). As will be shown later, this is a slight oversimplification since the axes of rotation are not orthogonal. The arrangement of the ankle and subtalar joints does, however, allow a normal foot to adapt to uneven terrain with relative ease.

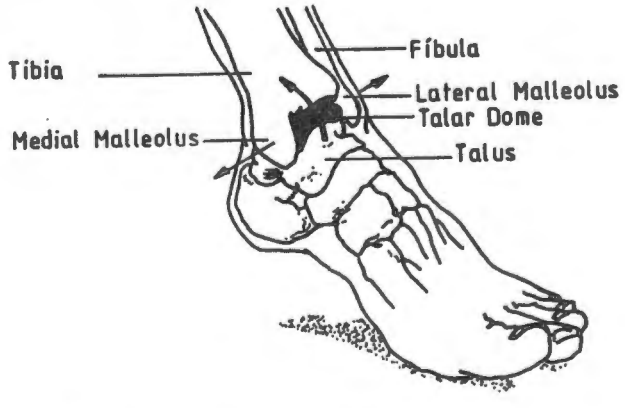


Fig. 2.3 Left Ankle Joint (Stauffer, 1979)

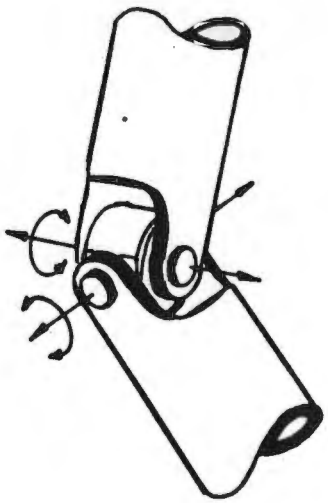


Fig. 2.4 Universal Joint

2.3.2 Joint Surfaces and Range of Motion

Since the main aim of any joint replacement procedure is to replace the articulating surfaces (and hence eliminate pain) it seems appropriate to consider in detail this aspect first. An in-depth investigation (Inman, 1976) showed that the trochlea of the talus closely resembles a section of a frustrum that is cut from a cone (see Figure 2.5).

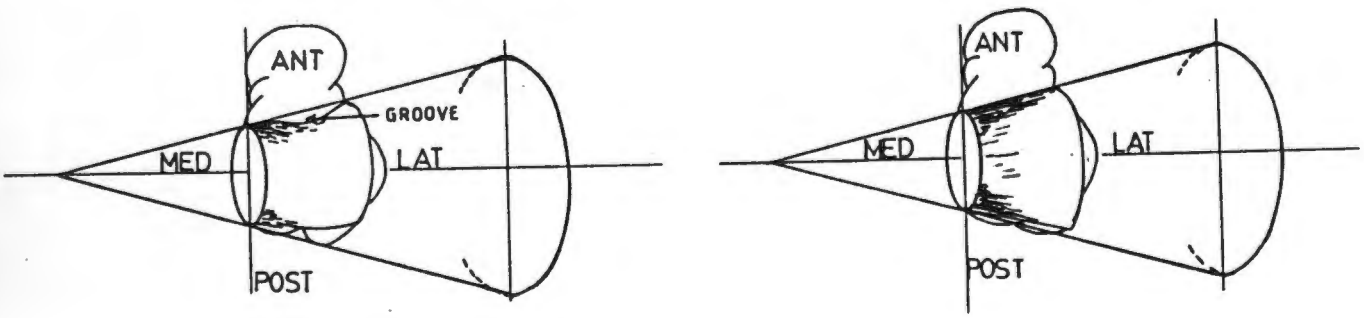
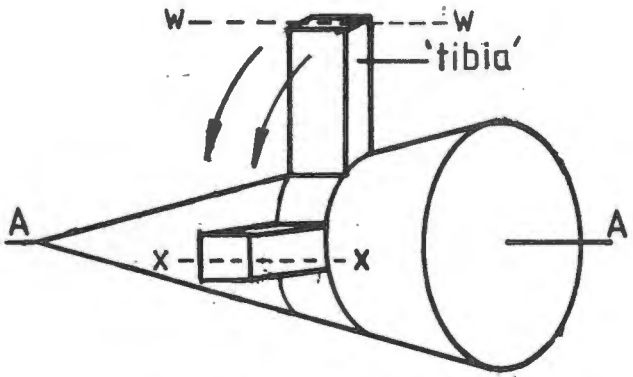


Fig. 2.5 Superior Views of Talus (Inman, 1976)



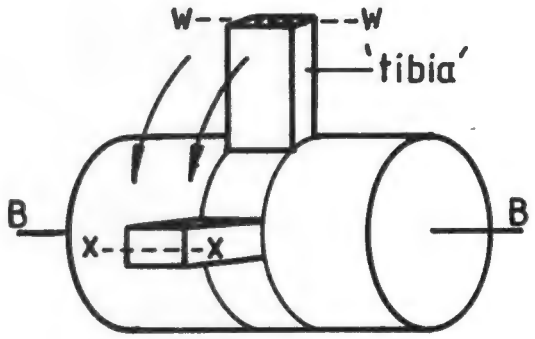
Model 1

Tibia ⊥ to axis A-A

Problems with this model:

i) w-w remains parallel to x-x

ii) in vertical position, 'tibia' will slide off 'talus'

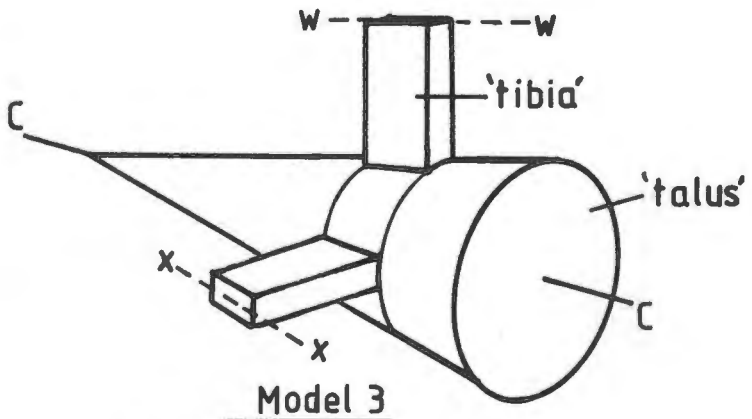


Model 2

Tibia ⊥ to axis B-B

Problem with this model:

w-w remains parallel to x-x



Model 3

Tibia at an angle to C-C

Note:

i) internal/external rotation accompanies flexion/extension

ii) superior surface of 'talus' is horizontal, so the 'tibia' will not tend to slide off.

Fig. 2.6 Models of the Ankle Joint

Inman determined the average conical angle of eighty-six tali to be $24^{o} \pm 6^{o}$ and that of the mortises, $22^{o} \pm 4^{o}$. He also determined that the axis of the frustra was virtually horizontal. Bearing these facts in mind, it is relatively simple to explain the clinical observation that lateral rotation of the foot accompanies dorsi-flexion, whilst plantar-flexion is accompanied by medial rotation (see Figure 2.6).

Other observations made by Inman were:

(a) when viewed from above the posterior width may be up to 25% less than the anterior width. (5% of his sample of 100 had no wedging)

(b) The curvature of the trochlea always approximates a circle on the lateral side and on the medial side this is true for 80% of the cases

(c) the radius of curvature of the trochlea on its medial side is usually shorter than on the lateral side; the angle subtended is the same however. (This correlates with the idea that the trochlea is a section of a cone.)

(d) the articular surfaces between the tibia and talus are more congruent than those of the other main joints of the lower extremity;

and concerning the malleoli

(e) the malleoli converge posteriorly (as with the trochlea)

(f) the articular surfaces of the malleoli are always in close contact with the sides of the trochlea

(g) the lateral malleolus moves 2mm at most as the ankle is dorsi-flexed. The amount of movement is not related to the degree of wedging of the trochlea of the talus.

It may seem, at first glance, that some of these observations are contradictory in nature. The 2mm movement of the

lateral malleolus would hardly seem sufficient to accommodate the wedging of the trochlea. Inman was aware of this and found a surprisingly simple solution : if, instead of measuring the widths of the trochlea perpendicular to the tibial facet, they were measured with the apex of the "cone" as a reference point, the anterior and posterior differences were less than 2mm (see Figure 2.7).

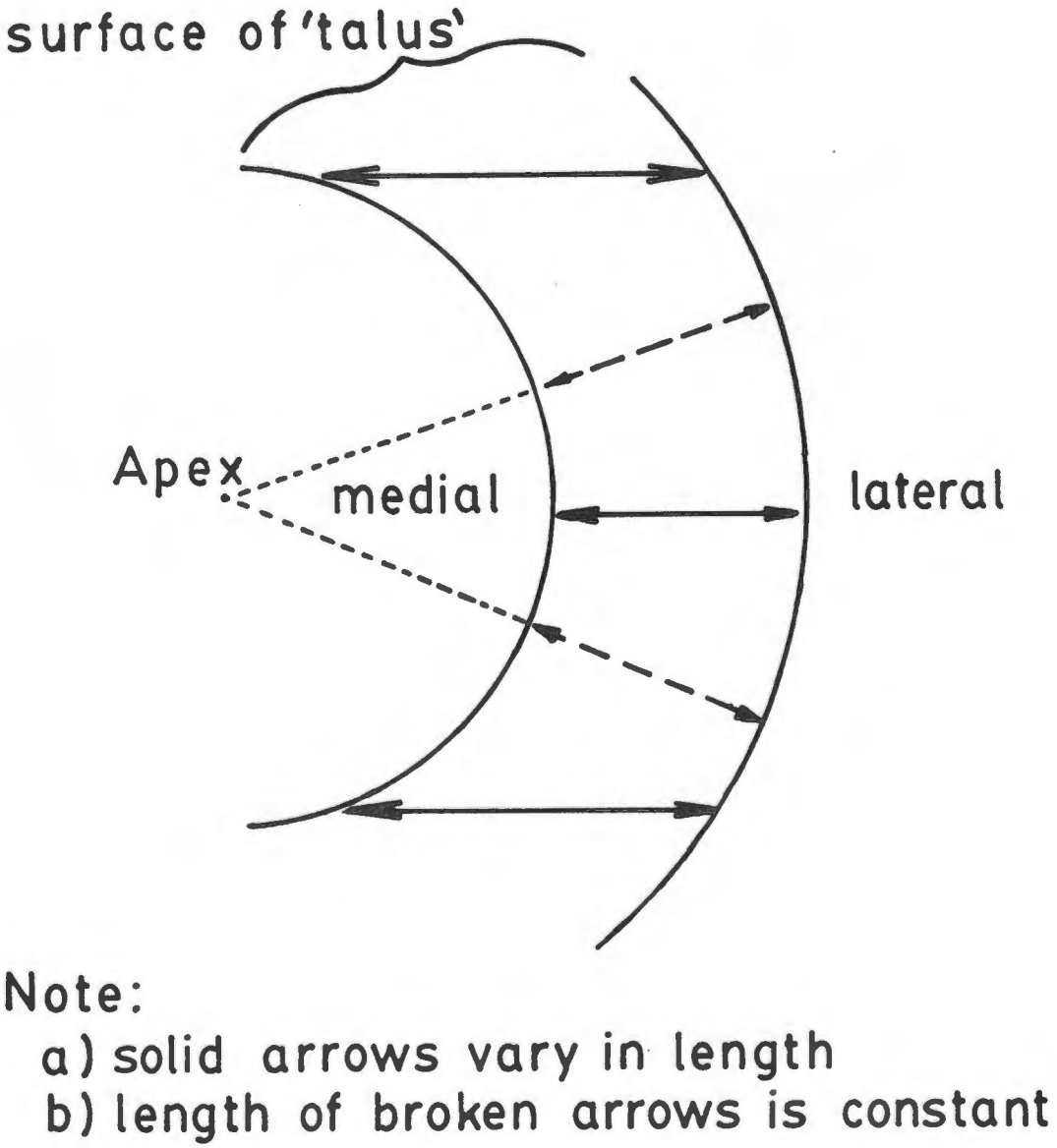


Fig. 2.7 Schematic Representation of Two Methods of Measuring the Widths of the Trochlea

It must also be remembered that during full dorsi- and plantar-flexion of the ankle, the mortise accepts about half of the surface of the talus at any one time. Thus the most anterior part of the trochlea never reaches the posterior part of the malleoli. This means that the lateral malleolus need only move about 1mm to accommodate the trochlea in all of its positions.

The fact that the apex of the "cone" lies on the medial side of the foot explains the following anatomical features:

(a) The deltoid ligament is concentrated into a single structure on the medial side (since the medial malleolus exhibits less antero-posterior movement).

(b) The tibial facet is small whilst the fibular facet is longer

(c) The fibular facet on the lateral side of the trochlea appears curved whilst the medial facet is flat and vertical (see Figure 2.8).

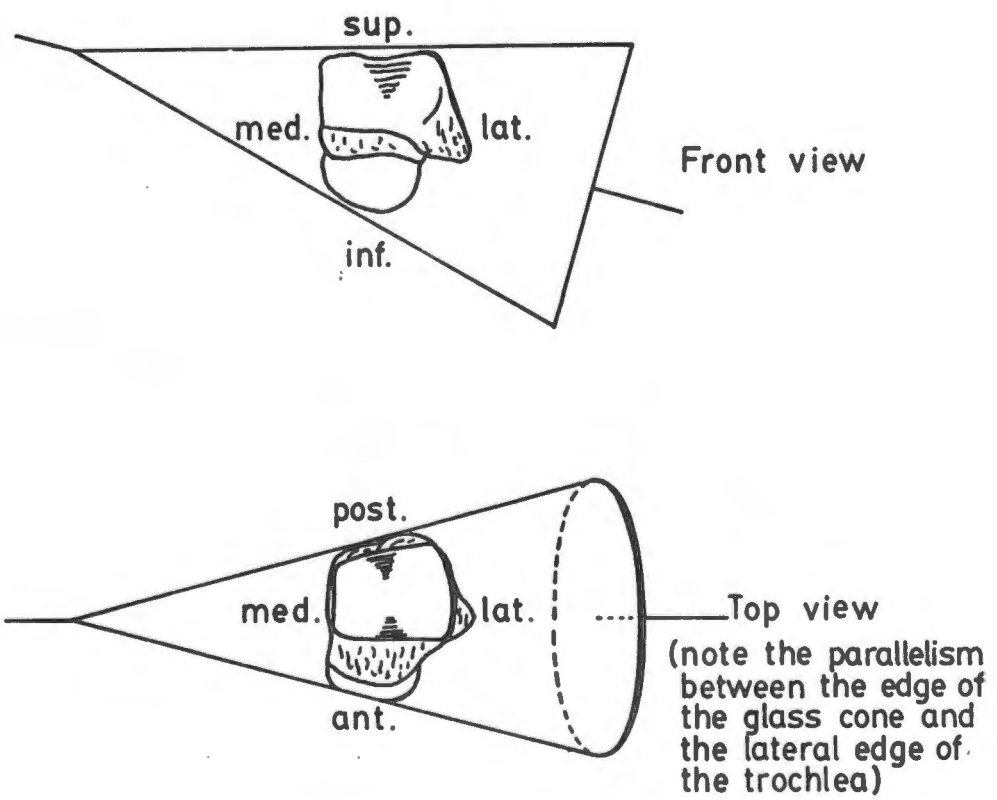


Fig. 2.8 Talus in a Glass Cone (Inman, 1976)

One aspect not discussed by Inman was that the trochlea has a concavity in its middle when viewed in a coronal section. Barnett, Davies and MacConnaill (1962) recognised this as playing an important role in the biomechanics of the ankle. They performed a simple experiment to show that as the tibia moves forward over the talus, it moves slightly laterally and then medially. Since it is at the same time rising and descending over a "hump", there is a resultant curve that it follows. This curve is much flatter than one in a sagittal plane, due to the concavity on the front of the trochlear surface. If there was no concavity, the resultant curve would still be flatter but to a lesser degree. An analogy presented was that of a cyclist travelling over a hump-backed bridge that has no camber. As he prefers a less arduous journey, he follows an oblique path up the rise instead of one parallel to the central white line.

Another study on the articular surfaces of the ankle joint (Medley et al, 1983) concentrated on the role of these surfaces in the lubricating mechanism. Unfortunately hydrodynamic lubrication was assumed, which has been shown by Mow and Lai (1980) to be inappropriate. (Hydrodynamic lubrication depends on the fluid being viscous but experiments have shown synovial joint lubrication to be independant of fluid viscosity.) Nevertheless, some findings of theirs which are useful are shown in Figure 2.9.

An aspect which is closely associated with surface geometry is "range of motion". With regard to the ankle joint this parameter is difficult to measure since motion which occurs at the subtalar joint can make the ankle appear more mobile than it actually is. In addition, a study by Sammarco et al (1972) revealed that the range of motion varied for left and right ankles and for different age groups. It also depended on whether or not weight was being borne. Their findings showed however that under

non-weight-bearing conditions the average angle of maximum dorsi-flexion was 23 ± 7,5o and of plantar-flexion, 23 ± 9,9o. For weight-bearing, the corresponding figures were 21 ± 7,2o and 23 ± 8o respectively.

From these figures, it can be seen that the total range of motion (in the sagittal plane) is about 45o and is divided almost equally between dorsi- and plantar-flexion. This range is slightly less than that given by Hicks (1953) who reported a value of 62o as being normal. Kapandji (1970) included the motion that occurs at the tarsal joints and consequently the range was also greater (dorsi-flexion: 30-50o, plantar-flexion: 20-30o).

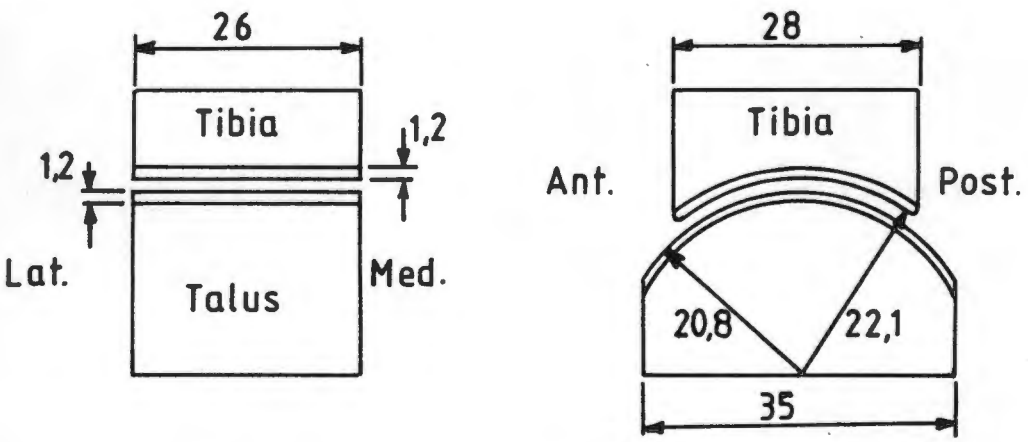


Fig. 2.9 Ankle Joint Dimensions (Medley et al, 1983)

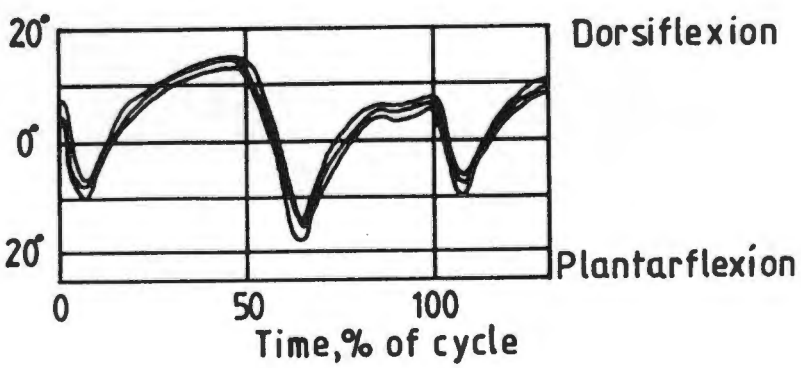


Fig. 2.10 Motion in the Sagittal Plane (Calderale et al, 1983)

It should be mentioned here that motion at the ankle during walking is less than these figures tend to indicate. An in-depth study of the ankle motion that occurs during gait was performed by Calderale et al (1983). Figure 2.10 depicts what they regarded as 'normal'.

2.3.3 Axes of Rotation

Besides the actual articular surfaces which constrain motion at a joint, there are ligaments which do likewise. The ligaments usually prevent subluxation or dislocation but allow movement to occur about some axis. Rupture of these structures results in an unstable and often painful joint.

The ligaments of the ankle are as follows (see Figure 2.11);

(a) lateral collateral ligament, comprising
    - anterior talofibular ligament
    - calcaneofibular ligament
    - posterior talofibular ligament

(b) medial collateral ligament, comprising
    - anterior talotibial ligament (deep)
    - posterior talotibial ligament (deep)
    - deltoid ligament (superficial)

(c) anterior ligament

(d) posterior ligament

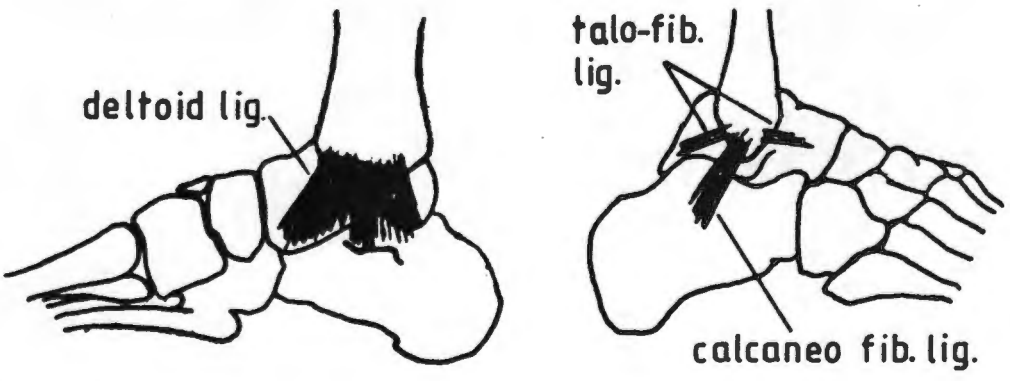


Fig. 2.11 Ligaments of the Right Ankle (Basmajian, 1979)

The latter two ligaments are merely localised thickenings of the joint capsule (Kapandji, 1970). The other ligaments, however, being collateral ligaments, enhance the stability of the ankle joint. Their strength is such that excessive inversion or eversion of the foot can cause either the lateral or medial malleolus to fracture.

Another feature of these ligaments is that they do not constrain motion at the ankle to occur about a single, fixed, axis. Hicks (1953) reported two axes;

(a) dorsi-flexion axis: "1,5cm anterior to the tip of the medial malleolus to 0,5cm inferior to the tip of the lateral malleolus"

(b) plantar-flexion axis: "1,5cm anterior and 1cm inferior to the tip of the medial malleolus to 0,5cm superior to the tip of the lateral malleolus".

These axes (see Figure 2.12) explained the abduction and pronation that accompanied dorsi-flexion and the supination that accompanied plantar-flexion.

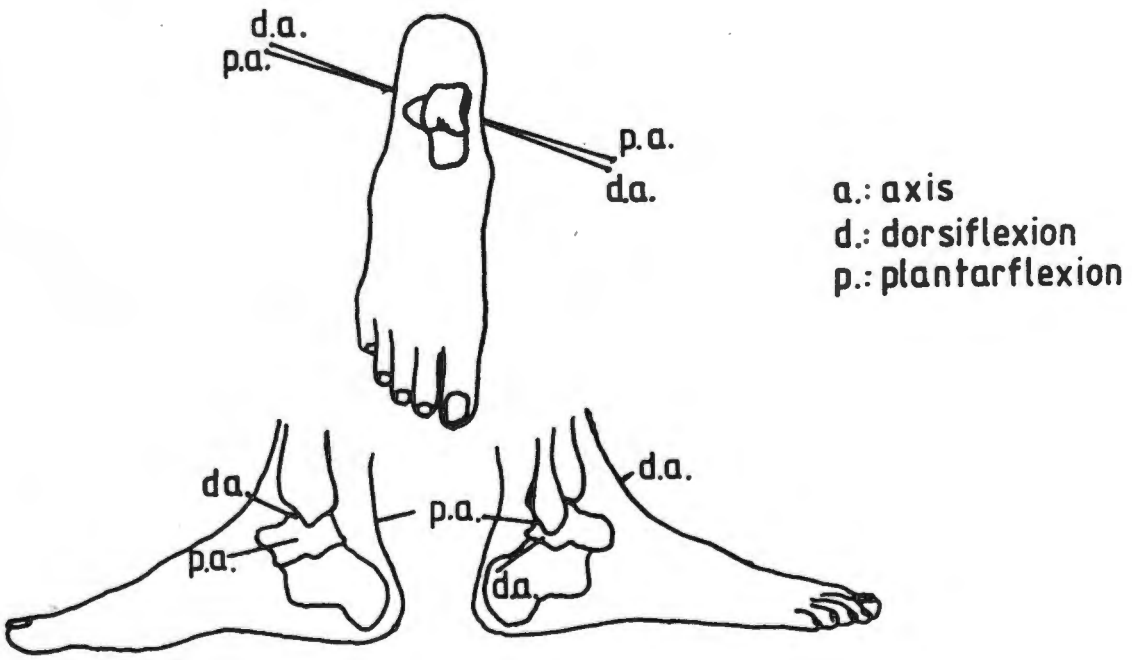


Fig. 2.12 Location of Axes (Wright et al, 1964)

Inman (1976) showed that the above description of the axis could be simplified in the majority of cases. His findings were as follows;

(a) 80% of the specimens studied had a single axis. The remainder had an axis that deviated about 10^{o} in the transverse plane

(b) on a transverse plane it is directed laterally and posteriorly

(c) on a coronal plane it is directed laterally and downward

(d) the axis passes just distal to the distal tips of the malleoli

2.3.4 Muscles crossing the Ankle Joint

Muscles are sometimes referred to as "dynamic ligaments", since they too can prevent excessive motion at a joint. An example of the added stability that muscles can provide is to be found when the agonists and antagonists act together to brace a joint. Besides this function, muscles are commonly activated to initiate or continue movement of some body segment (such as the foot).

Figure 2.13 shows one system of classifying the muscles that cross the ankle joint. Those that pass anteriorly are dorsi-flexors and can, in addition, either cause supination or pronation. In a similar manner the plantar-flexors which pass behind the tibia and fibular can be divided into supinators or pronators.

The muscles that cross the ankle can thus be divided into four groups;

(a) Dorsi-flexors, Adductors and Supinators

Muscles which cause these movements are Tibialis Ant-

erior and Extensor Hallucis Longus (see Figure 2.13)

(b) Dorsi-flexors, Abductors and Pronators

In this category are Peroneus Tertius and Extensor Digitorum Longus (see Figure 2.14)

(c) Plantar-flexors, Abductors and Pronators

Muscles in this group are Peroneus Brevis and Peroneus Longus (see Figure 2.15)

(d) Plantar-flexors, Adductors and Supinators

Examples of muscles which cause these movements are Tibialis Posterior, Flexor Digitorum Longus, Flexor Hallucis Longus and Triceps Surae (see Figure 2.16)

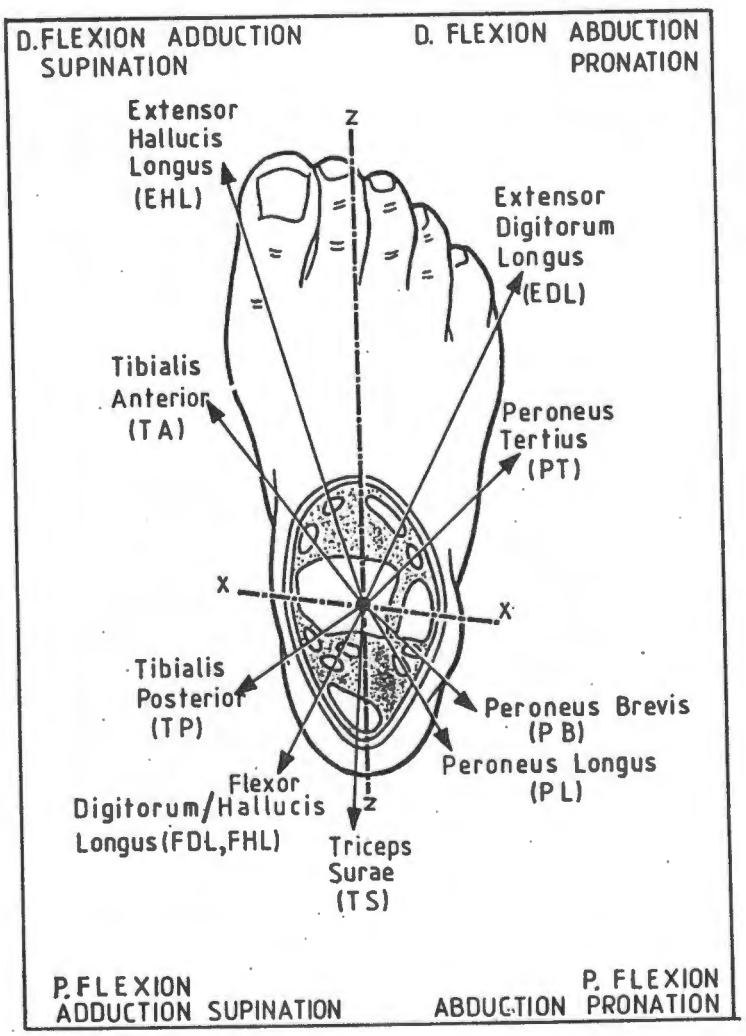


Fig. 2.13 Muscles Crossing the Ankle (Kapandji, 1970)

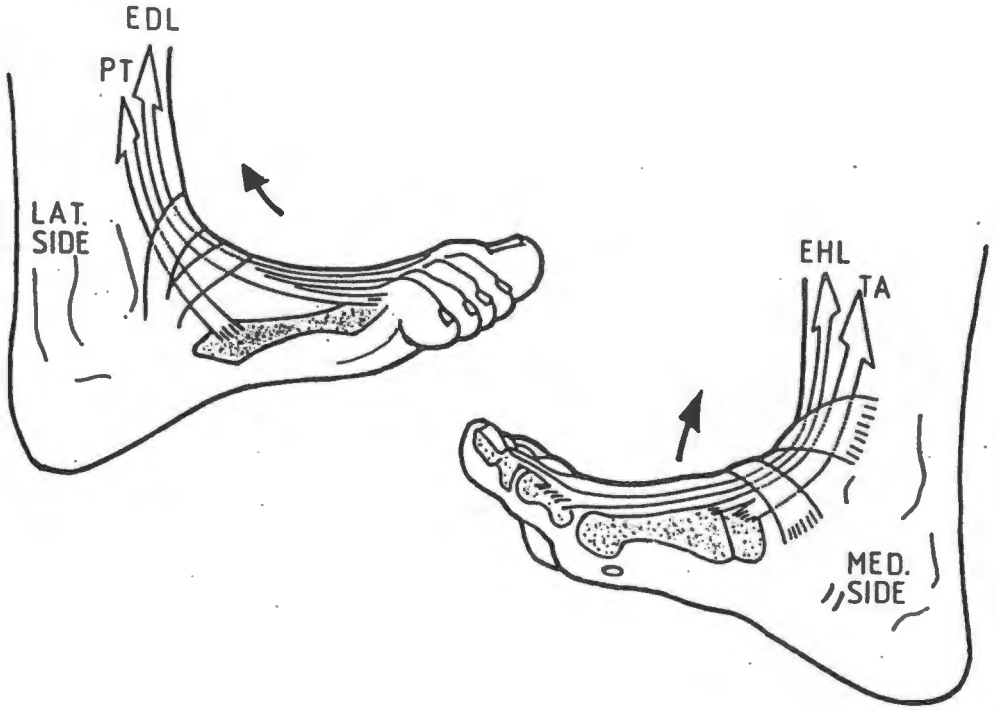


Fig. 2.14 Dorsiflexors of the Ankle (Kapandji, 1970)

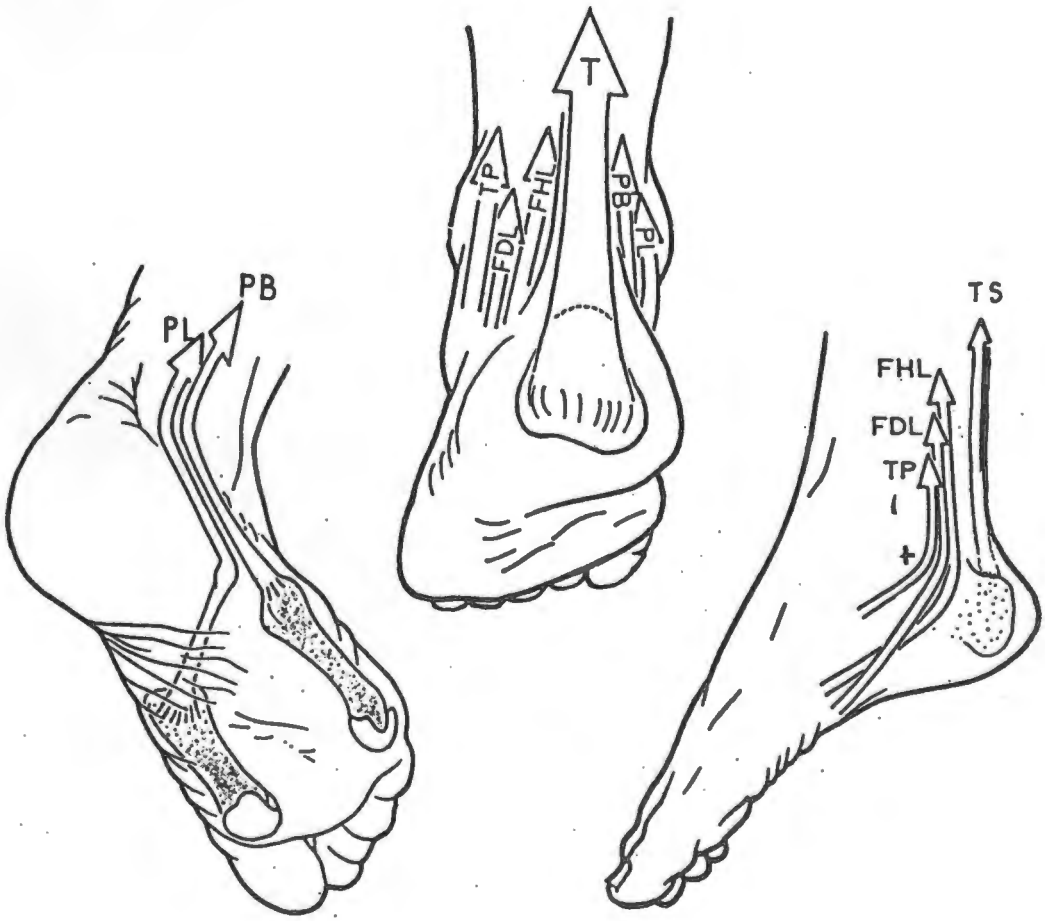


Fig. 2.15 Plantarflexors of the Ankle (Kapandji, 1970)

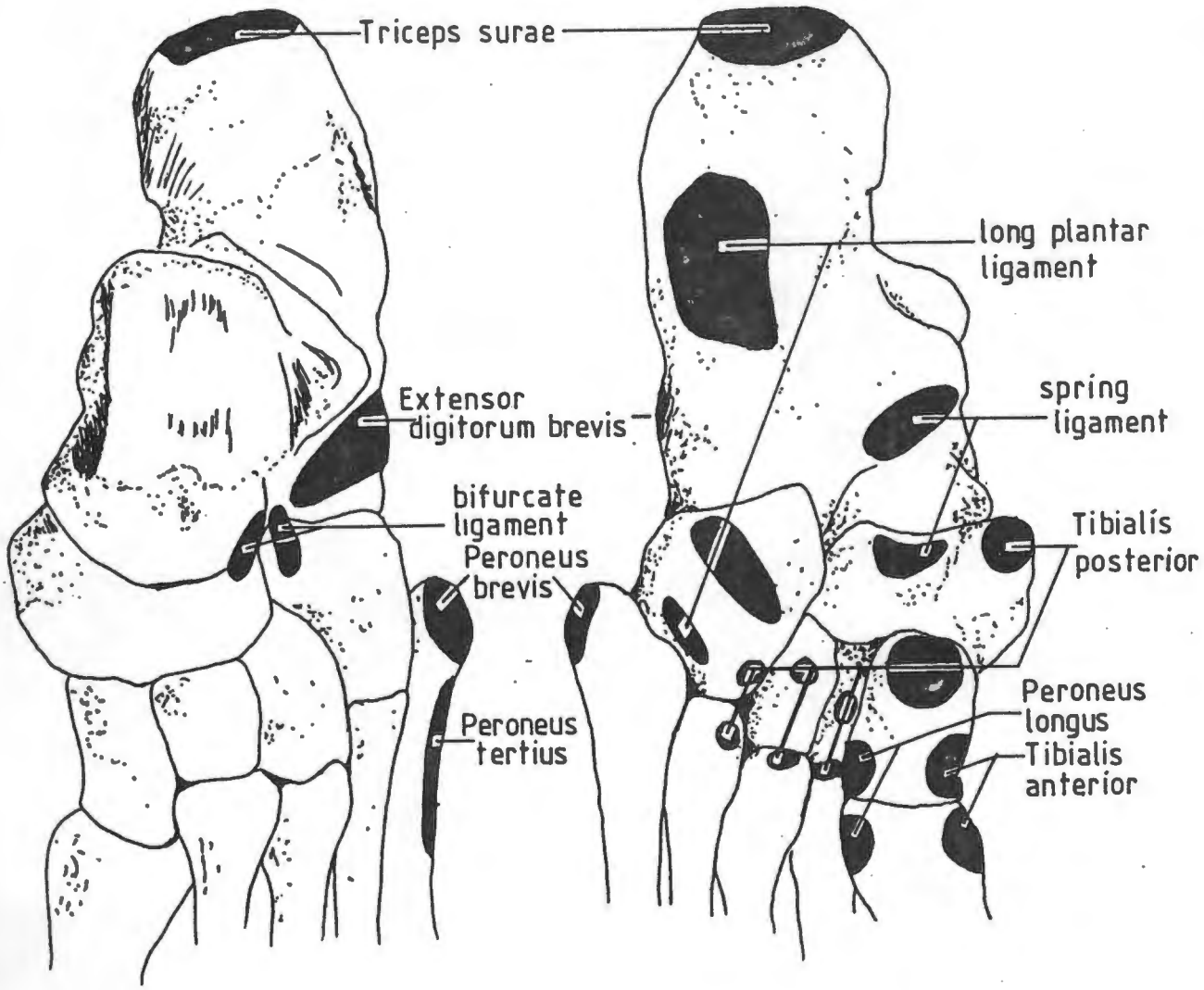


Fig. 2.16 Insertions into the Hindfoot

Of the dorsi-flexors which cross the ankle (see Figures 2.13 and 2.14) the most powerful adductor and supinator is Tibialis Anterior (Kapandji, 1970), whilst the strongest abductor and pronator is Peroneus Tertius. Thus if these two were to act together the resulting motion would resemble pure dorsi-flexion.

Of the six plantar-flexor muscles (see Figures 2.15 and 2.16) the most important are Gastrocnemius and Soleus. Their

combined strength is thirteen times that of all the others (Kapandji, 1970). Both Soleus and Gastrocnemius share a common insertion into the calcaneus (through the Achilles tendon) and are often collectively referred to as the "Triceps Surae".

When the Triceps Surae contract maximally, the resulting plantar-flexion is associated with adduction and supination as is shown in Figure 2.17 (Kapandji, 1970). Kapandji ascribes this to the fact that the subtalar joint is mobilised as well as the ankle joint. This is advantageous from a biomechanical point of view: if one looks at the line of action of the Triceps Surae, it is apparent that the tension produced as the muscle contracts is directed upwards but lateral to the sagittal plane through the ankle joint. It is reasonable thus to assume that the ankle complex should move so as to bring the insertion of the Triceps Surae closer to the sagittal plane through the middle of the tibia. This would minimise the bending moment in the coronal plane and thus reduce the stress which the ligaments would have to endure. Inman (1976) showed that due to the insertion of Triceps Surae passing medial to the subtalar axis (see Figure 2.18) this motion can easily be achieved.

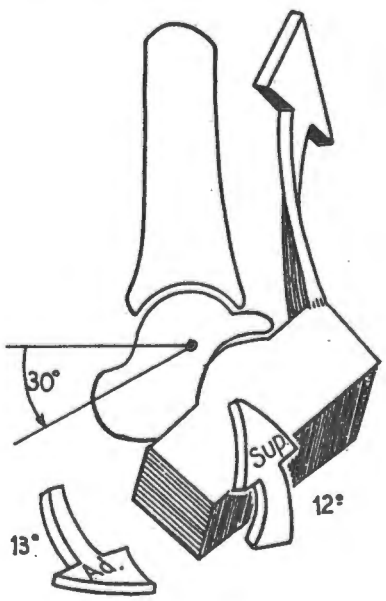


Fig. 2.17 Motion of Ankle Complex (Kapandji, 1970)

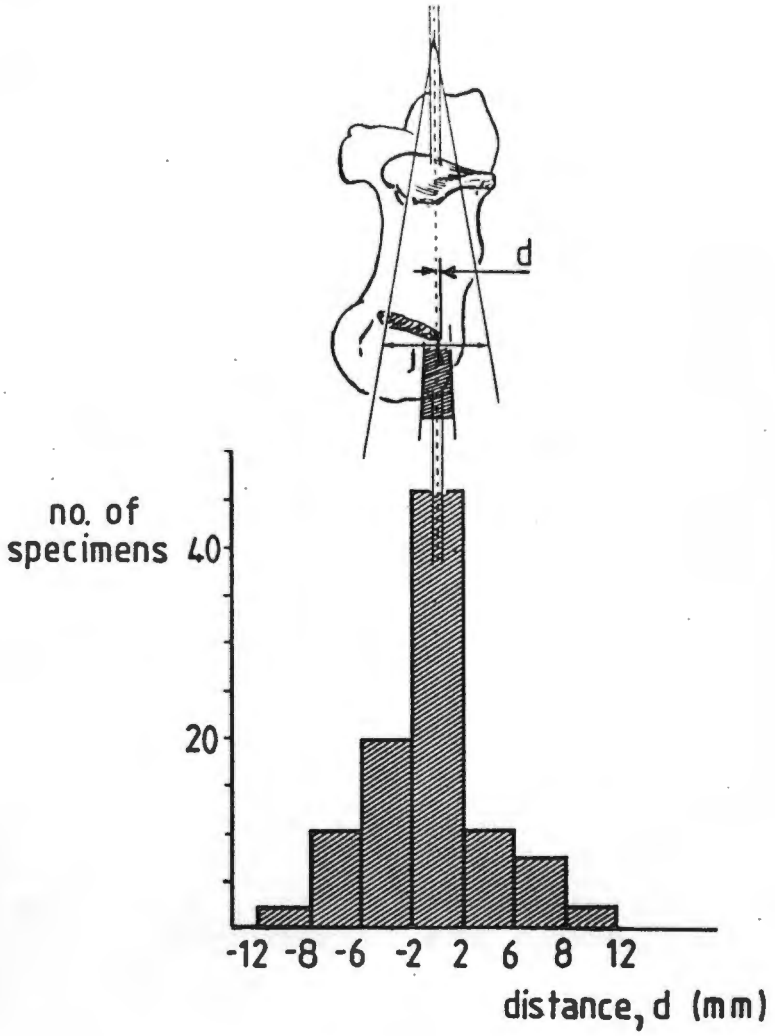


Fig. 2.18 Diagram Showing Position of Subtalar Axis Relative to Achilles Tendon (Inman, 1976)

2.3.5 Phasic behaviour during walking

Figures 2.19 and 2.20 show the temporal activity of muscle groups as reported from EMG studies (Perry, 1967; Procter and Paul, 1982). Procter and Paul simplified some earlier studies which were somewhat confusing by considering the behaviour of four major groups of muscles;

(a) calf group

(b) anterior tibial group

(c) posterior tibial group

(d) peroneal group

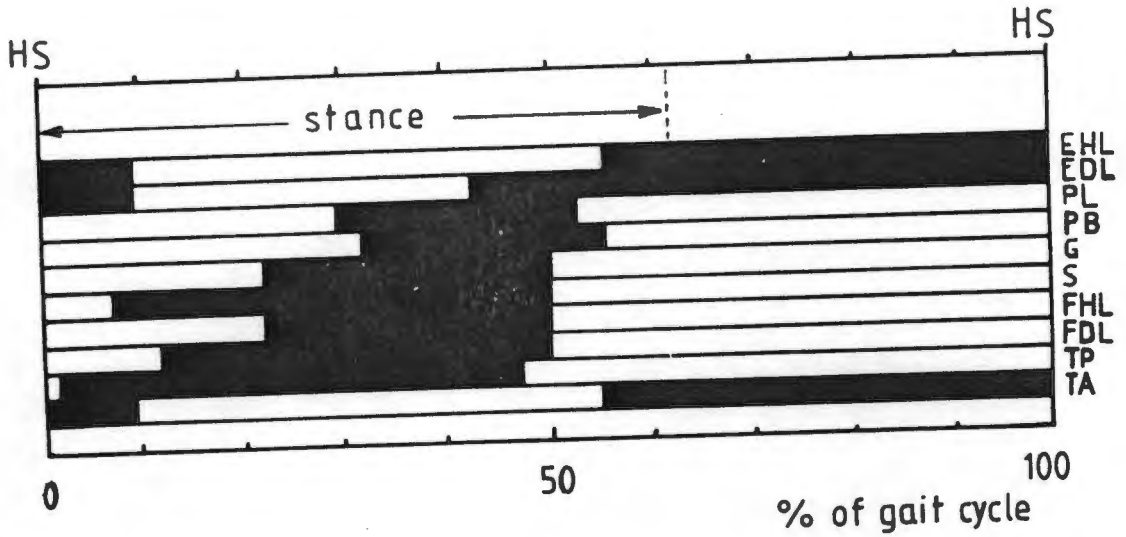


Fig. 2.19 Phasic Behaviour of Muscles (Perry, 1967)

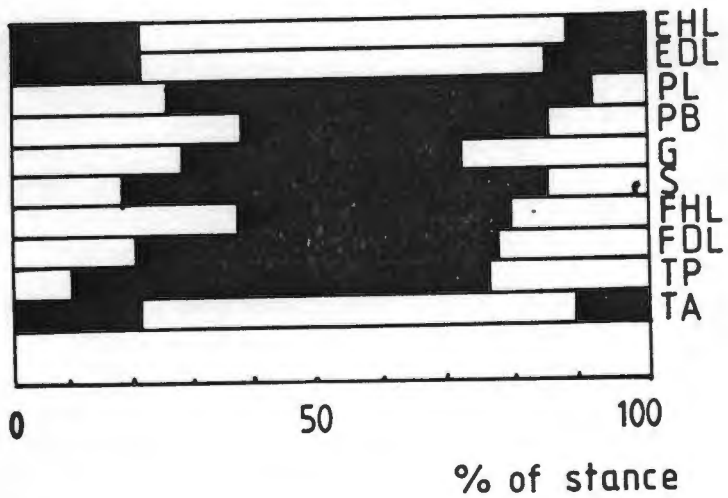


Fig. 2.20 Phasic Behaviour of Muscles (Procter and Paul, 1982)

The first two groups alternated with each other as did the latter two (i.e. it was assumed that antangonistic behaviour did not occur). Figures 2.21 and 2.22 show the results they obtained.

An even simpler model of the musculo behaviour across the ankle was presented by Inman et al (1981). They confined their atten tion to the Tibialis Anterior and Triceps Surae muscles. Since these muscles are the major ones, and both are capable of producing considerable torque about the ankle joint (Stauffer et

al, 1977) it is not surprising that the results obtained by Inman et al. are very similar to those predicted by Procter and Paul (see Figure 2.23).

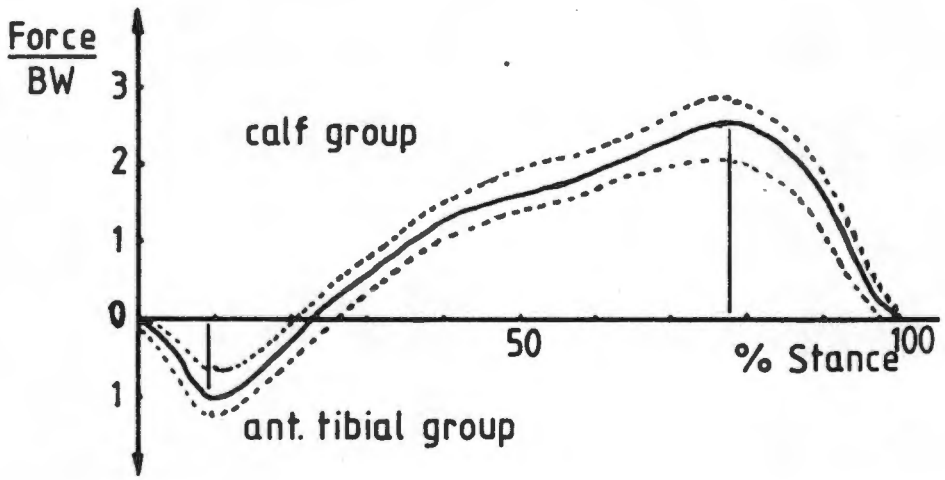


Fig. 2.21 Muscle Group Forces (Procter and Paul, 1982)

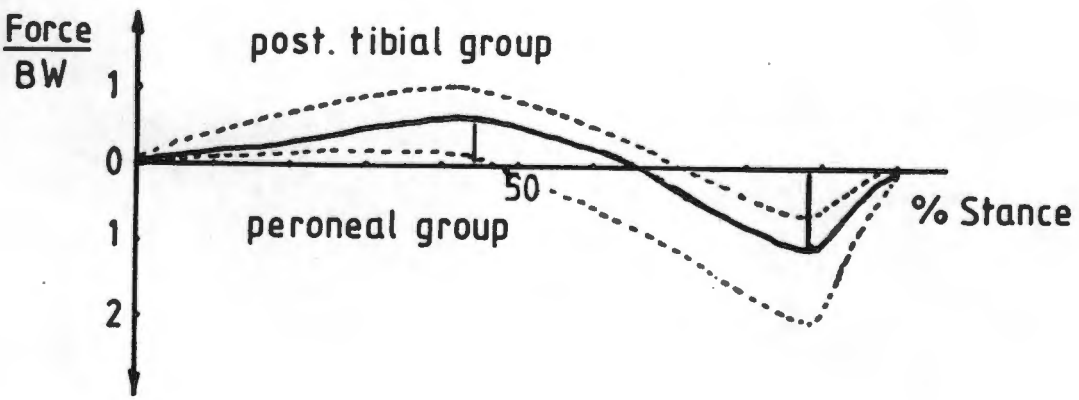


Fig. 2.22 Muscle Group Forces (Procter and Paul, 1982)

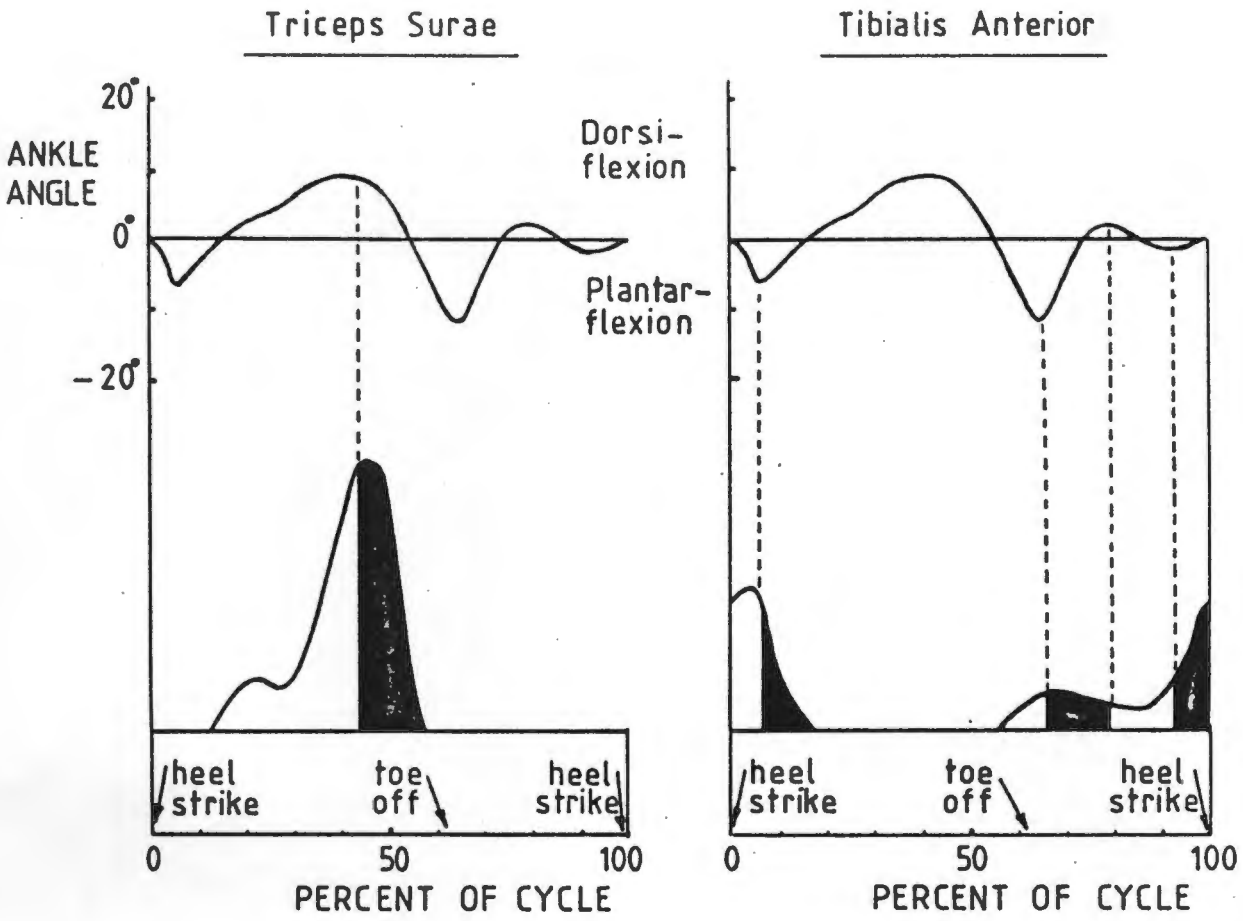


Fig. 2.23 Ankle Motion Related to EMG Data (Inman et al, 1981)

According to Inman et al (1981), the activity of the calf muscles can be summarised as follows: electrical activity starts after the foot is flat after heel-strike. (At this stage the muscles are being elongated.) At the peak of the EMG, the heel begins to rise as plantar-flexion begins. On the other hand, the EMG of Tibialis Anterior reveals that this muscle prevents foot "slap" after heel-strike. The EMG also indicates that at toe-off contraction occurs so that the foot clears the ground.

2.3.6 Ankle Forces and Range of Motion

Besides mimicking physiological motion, artificial joint prostheses must be able to withstand everyday loads that are

exerted on them. Unfortunately there is relatively little information concerning ankle forces and loading cycles, and some design aspects must therefore be based on disputed data or even "educated guesses".

Stauffer et al (1977) presented a simplified model of the ankle joint in which the movements and forces are considered to act in the sagittal plane only. Other simplifications included:

(a) Neglecting the inertial effect of the foot

(b) Including only the Achilles and anterior tibial tendons

(c) Restricting the analysis to walking

(d) Considering only the stance phase (this,however,isthe main part of the walking cycle as far as the ankle joint is concerned).

Stauffer et al separated the stance phase into three components (see Figure 2.24). They analysed films taken of the subjects and obtained a pattern of ankle joint motion and force components as shown in Figures 2.25a, b and c.

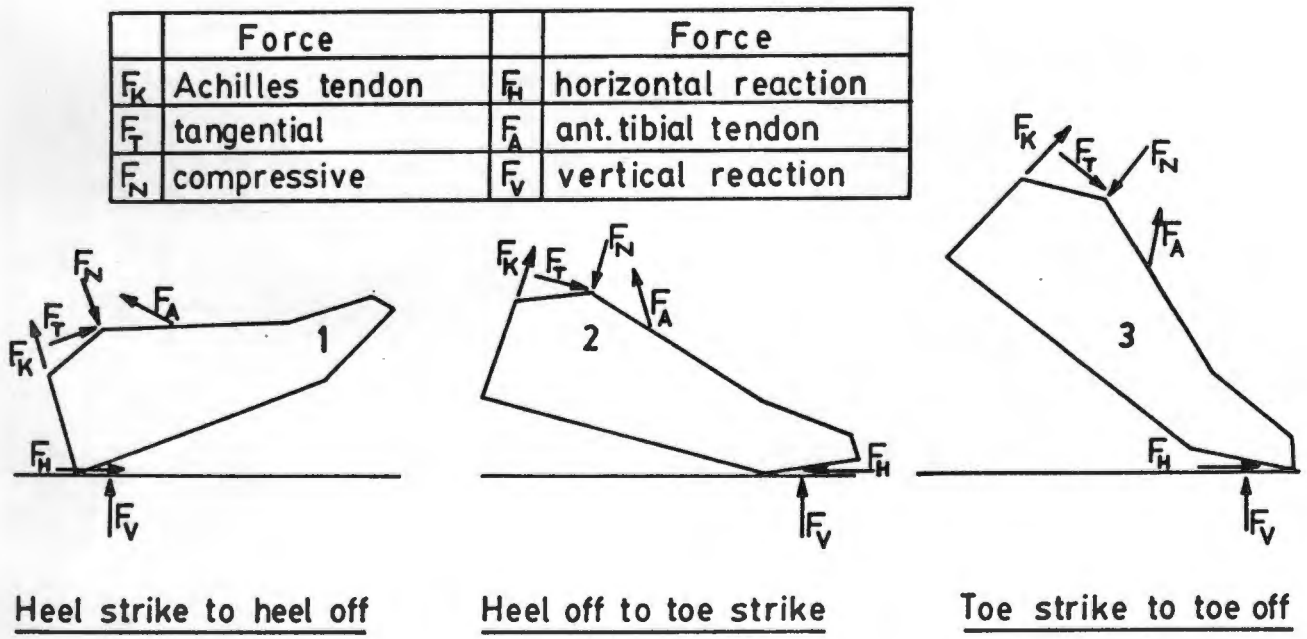
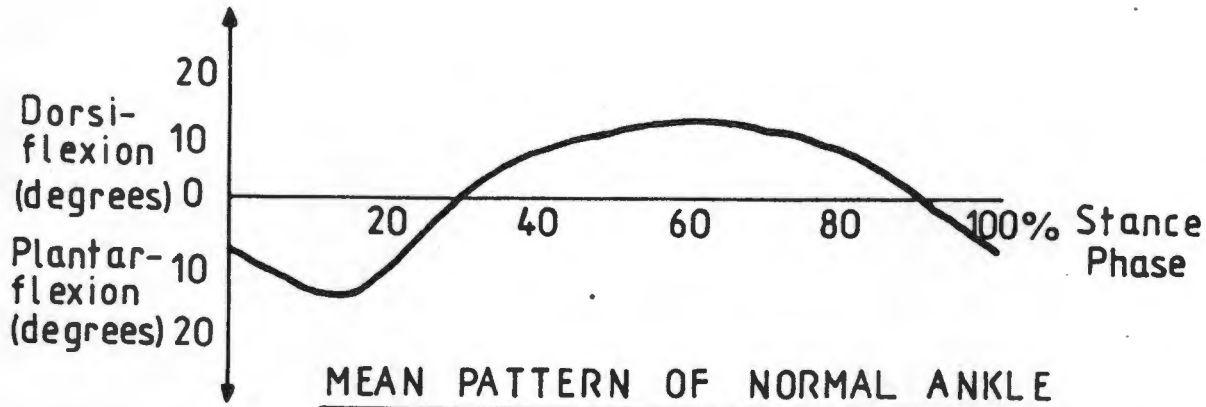
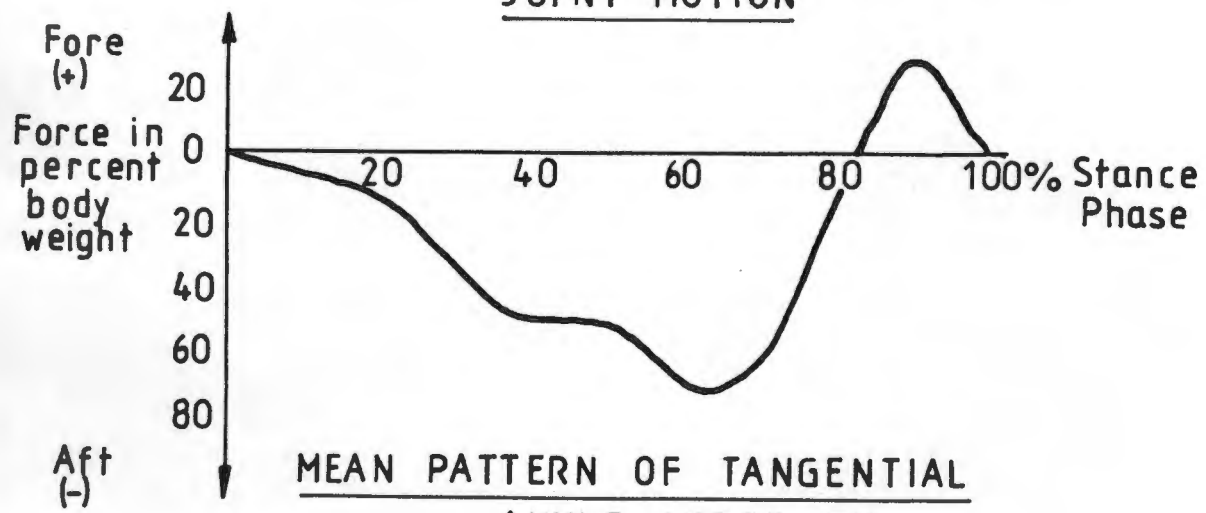


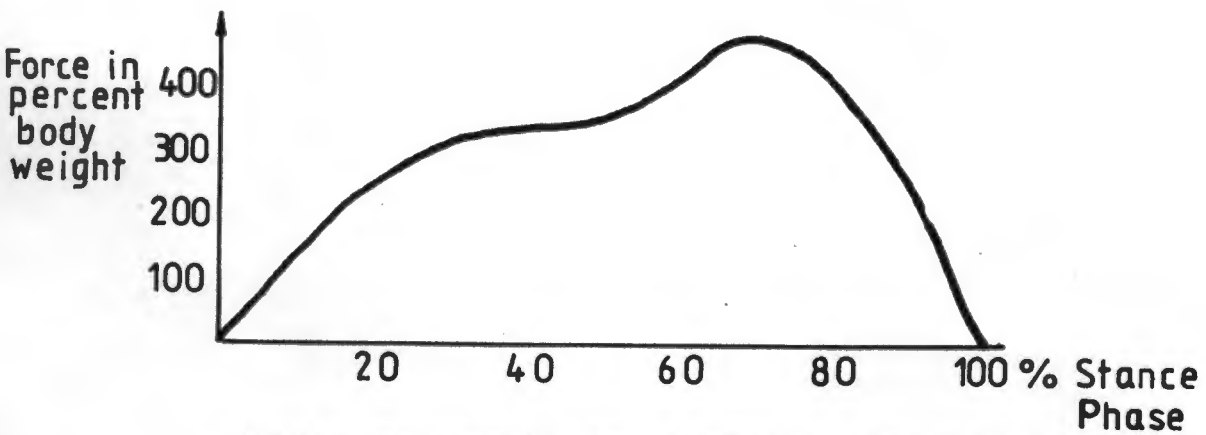
Fig. 2.24 Three Components of Stance (Stauffer et al, 1977)



MEAN PATTERN OF NORMAL ANKLE JOINT MOTION



MEAN PATTERN OF TANGENTIAL ANKLE FORCE (Ft)

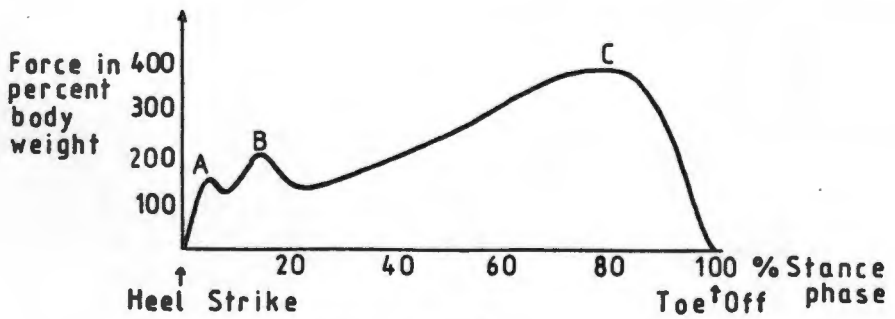


MEAN PATTERN OF NORMAL COMPRESSIVE ANKLE FORCE (F_n)

Fig. 2.25 a,b,c Results of Two-dimensional Study of Ankle Joint (Stauffer et al, 1977)

The tendon forces were also evaluated and it was found that F_K (Achilles) was similar to F_N but 100% body weight (BW) less. F_A (Anterior tibial) was never greater than 20% of body weight and operated only for 10% of the walking cycle (after heel-strike). These findings are in conflict with a recent study carried out by Procter and Paul (1982). These authors used a 3-dimensional model of the ankle and included the subtalar joint as well as the tibiotalar joint. They used three orthogonally placed cine cameras and a force plate to acquire the kinematic and kinetic data they needed. Four muscle groups were investigated using equilibrium methods; calf, anterior tibial, peroneal and posterior tibial. As a simplification the effects of the ligaments and inertia of the foot were omitted.

Contrary to the findings of Stauffer et al regarding the importance of the anterior tibial muscle, Procter and Paul (1982) found that its contribution was 100% BW for about 25% of the stance phase. In addition they calculated the peak compressive force across the ankle joint as being 3,9 BW (as compared to 5 BW of Stauffer et al (1977)) (see Figure 2.26).



	PEAK CAUSE
A	Passive response of foot to heelstroke
B	Anterior tibial group activity
C	Calf muscles & peroneal group activity

Fig. 2.26 Ankle Force (Procter and Paul, 1982)

A drawback of Procter and Paul's paper is that they omitted to give the following information:

(a) The angular motion that occurs at the ankle joint

(b) The direction of the resultant force across the ankle at each stage of the gait cycle.

Besides reducing the unknown loads in the ankle to a level at which an equilibrium solution can be obtained, it is possible to use mathematical optimisation techniques to determine theoretical joint reactions. Seireg and Arvikar (1975) compiled a purely mathematical model of the lower extremity and used linear programming techniques to solve for the unknown variables. Their objective function was that the sum of all the muscle forces plus four times the sum of the moments at all the joints be kept to a minimum. This function is somewhat arbitrary as is their assumption of certain limb segment motion patterns. However, their results showed some agreement with typical electromyographic patterns for the major muscles (see Figure 2.27).

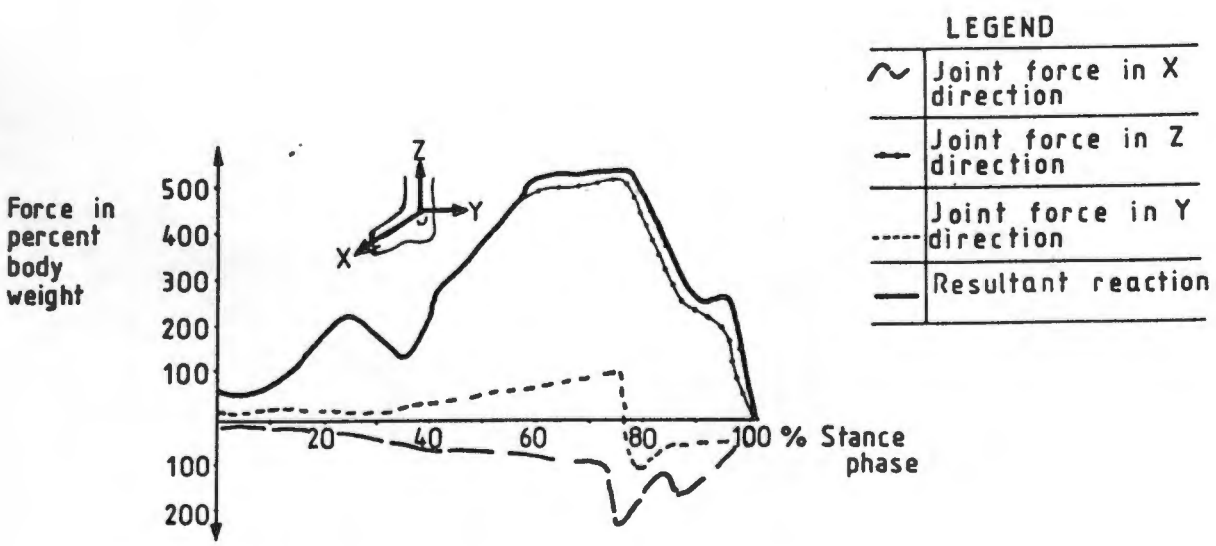


Fig. 2.27 Ankle Forces (Seireg and Arvikar, 1975)

As is evident from Figure 2.27, the maximum joint reaction force in the ankle is 5,2 BW. (This same study gave values for the hip and knee as 5,4 and 7,1 times body weight respectively.) The maximum tangential force (in the X direction) is just over 2 BW (i.e. about three times that predicted by Stauffer (1977)).

A study by Patriarco et al (1981) showed that the accurate determination of joint angles and torques is more crucial in ascertaining muscular forces than the optimisation criteria used. In the study performed by Seireg and Arvikar the phasic motion at the ankle joint was not shown so there is some doubt as to the validity of the results. The results of Patriarco et al, however, are also questionable. The joint reactions are given in units of Newtons and not in terms of the weight of the subject, and if this is assumed to be 600N then the peak forces across the joint are as follows;

vertically	:	1,12 BW
antero-posterior	:	0,18 BW
medio-lateral	:	0,08 BW

These results seem to be gross underestimates since one would expect much larger forces to be present at heel-strike and toe-off (due to inertial and other effects).

During an activity such as running it can be expected that inertia plays an even greater role. Burdett (1982) looked at this problem and predicted that for a subject running at 4,47 m/s, the peak resultant joint force would be between 9 and 13,3 times body weight.

Perhaps more important than the forces imposed on a joint, are the stresses to which the cartilage is subjected. (It is important to remember that even though there is usually a layer of fluid separating articular surfaces, these are still subjected to stresses which can be thought of as "contact" stresses.)

Since stress is inversely proportional to contact area, it is relevant to determine the latter parameter.

JOINT	CONTACT AREA (mm^2)	PEAK LOAD (N)	CONTACT STRESS (MPa)	ACTIVITY
HIP	2677	2500 (3,5 BW)	0,9	Walking
KNEE	1154	2100 (3 BW)	1,8	Walking
ANKLE	440	2800 (4 BW)	6,4	Walking

Table 2.1 Average Stresses Between the Joint Surfaces of the Lower Limb (Walker, 1977)

Walker (1977) gave the average contact area in the tibio-talar joint as 440mm2 (230-670). A portion of his work is given in Table 2.1. These values are difficult to reconcile since the stress at the ankle is given as being much higher than at the other joints and yet the ankle has the least amount of arthritic problems. Another study (Odland, 1979) showed a much greater contact area in the ankle joint - figures ranged from 830 to 1290mm2. If an average of 1050mm2 is taken then the stress corresponding to a load of 2800N will be 2,6 N/mm2.

Inanattempt to simulate the dynamicpressuresoccurring during gait, Wynarsky et al (1983) used a mathematical model of the human ankle joint. The model consisted of two idealised joint components; the talus was represented by a circular half-cylinder with varying sinusoidal radius (to mimic the concavity in the

centre of the trochlea) and the distal end of the tibia was represented by another circular cylinder, this time of constant radius.

During simulated loading conditions, it was found that at low loads, two localised areas (on each side of the concavity) were subjected to contact stresses. As the loads were increased, the areas gradually merged until there was one rectangular area which bore the load. Wynarsky et al felt that this efficient mechanism of load transmission, coupled with the possible influence of synovial joint incongruence on the lubrication and nutrition of articular cartilage were factors which helped explain the resistance of the human ankle to primary osteoarthritis.

2.4 Ankle Prosthesis Designs

The first ankle joint replacement was carried out in 1972 in Hamburg, West Germany. The implant was the "St. George" prosthesis designed by Buchholz and his co-workers and the patient was Buchholz himself! (Benjamin and Helal, 1980).

The prosthesis consisted of two components; a tibial part of high density polyethylene (HDPE) and a cobalt chrome talar part (see Figure 2.28). (There were four sizes for each of the left and right sides.) This design was started in 1971 and between 1972 and 1976 sixty operations were performed in which the St. George prosthesis was implanted. These cases were followed up by Engelbrecht et al. (1977) and 80% of the results were considered good or excellent. There was, however, a 36% occurrence of persisting pain.

The basic operative procedure involved stabilisation of the medial malleolus, a lateral longitudinal incision and exposure of the joint, transection of the fibula and preparation of the bone surfaces, insertion of the implant from the lateral side (using

cement), and stabilisation of the lateral malleolus. After this the soft tissues were returned to their normal position, suction drains inserted and the skin closed. Immobilisation lasted about four to six weeks.

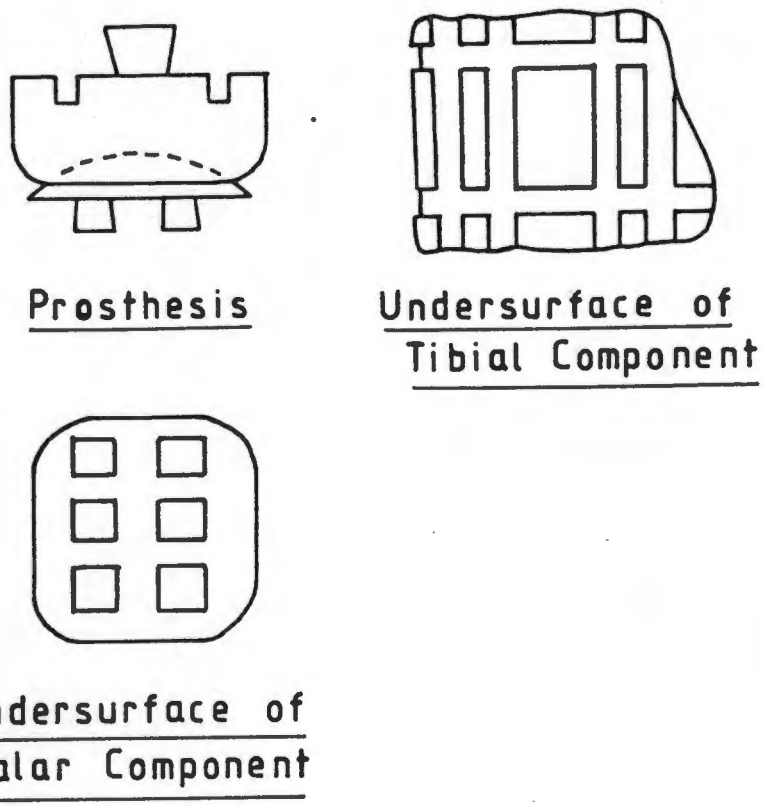


Fig. 2.28 "St. George" Prosthesis (Engelbrecht et al, 1977)

Another early design was the "Smith" total ankle prosthesis (Dini, Bassett, 1980). In this case the tibial component was metallic whilst the talar component was made from ultra high molecular weight polyethylene (UHMWPE) (see Figure 2.29). In twenty-one replacement procedures the function was good in 50% of the patients with traumatic degenerative arthritis and 40% with rheumatoid arthritis. Eleven patients had either a fair or a poor prognosis.

Waugh et al. (1976) presented an ankle arthroplasty design for highly selected patients. It had a torodial articular surface with either a major radius of curvature of 23mm and a minor

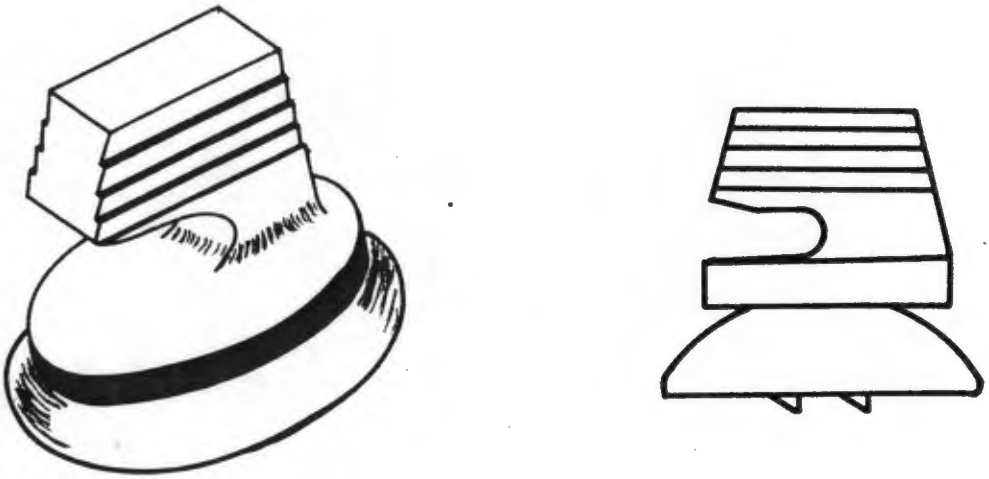


Fig. 2.29 Smith Domed Ankle Prosthesis (Benjamin and Helal, 1980)

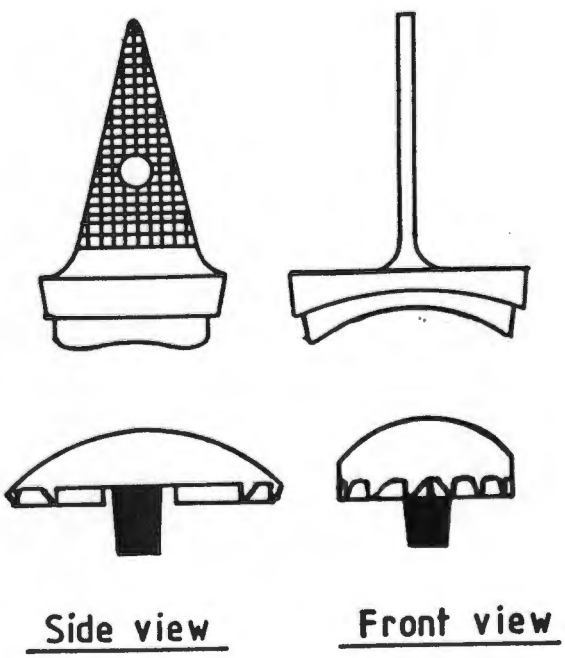


Fig. 2.30 Irvine Ankle Prosthesis (Smith, 1980)

of 15mm or alternatively, radii of 19mm and 15mm respectively. (The smaller figures are those applicable for a smaller person.) The width of the large size was 30mm as compared to 25mm for the small size (see Figure 2.30). The tibial component had an intramedullary stem and was composed of cobalt chrome, as was the talar piece. Between these two components, and connected to the tibial part, was an UHMWPE plastic insert. This prosthesis was inserted in twenty ankles (Waugh et al., 1976) using an anterior approach. The procedure involved the medial retraction of the neurovascular bundle and extensor hallucis, and the lateral retraction of the extensor digitorum and peroneus tertius. This enabled the anterior of the joint to be accessed with the subsequent resection of bone and implantation of the device proceeding. One problem sometimes encountered was the removal of the posterior distal tibia. Another was that the superficiality of the prosthesis meant that the skin edges had to be handled carefully.

Stauffer (1976) described the ankle as a stable joint with a simple planar type of motion. The sliding motion that occurred did so about a single axis and the forces transmitted through the joint were about five times body weight. Furthermore, the angular displacement in the sagittal plane was typically 25^{o}. The prosthetic ankle joint described by Stauffer (called the Mayo prosthesis) consisted of a UHMWPE tibial component and a stainless steel talar component (see Figure 2.31). The former was 31mm wide and 34mm deep, whilst together with the latter, the total height was 14mm. The bearing surfaces were cylindrical and had a surface area of $900mm^{2}$. Twenty-one patients had this artificial joint grouted into place with self-curing cement (see Figure 2.32). At the time of writing, Stauffer had not been able to determine its success rate (due to the follow-up time being too short).

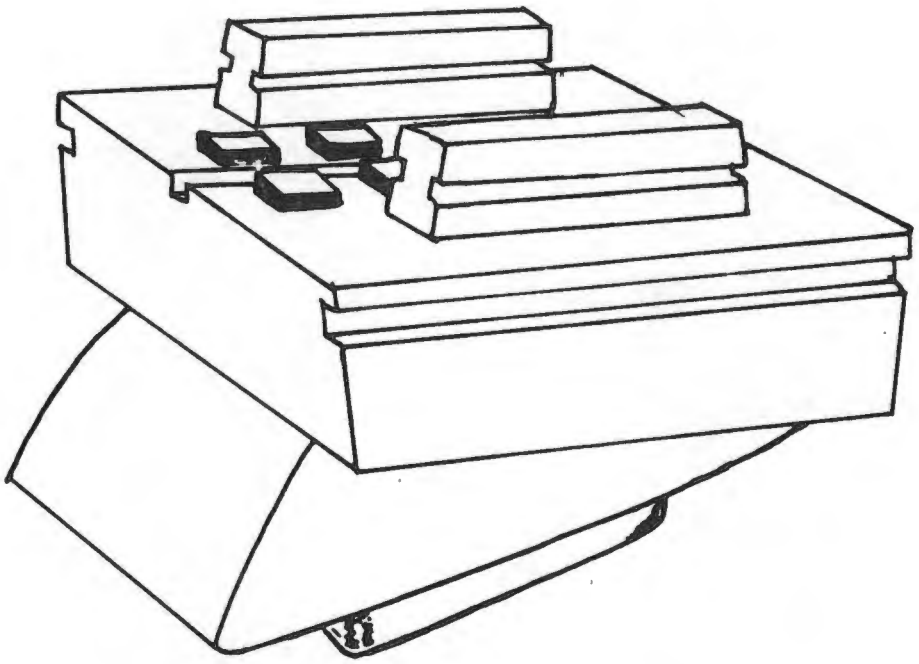


Fig. 2.31 Mayo Prosthesis

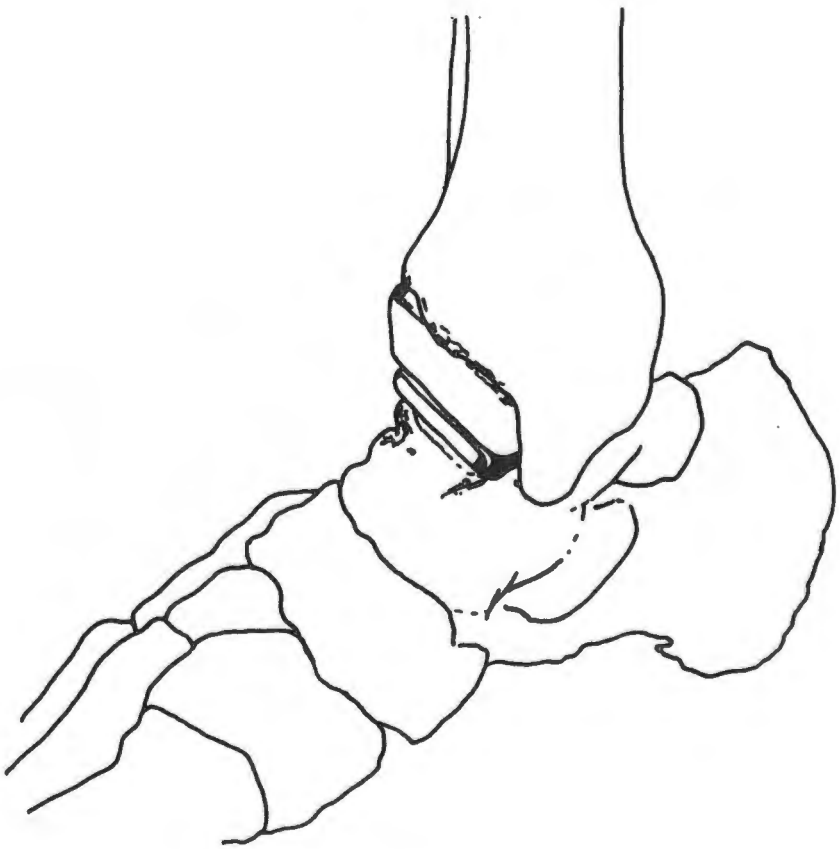


Fig. 2.32 Implanted Mayo Prosthesis

Another design, similar to that of Stauffer, was put forward by Pappas et al. (1976). The main differences were that the talar (and not the tibial) component was plastic and the tibial piece was made of cobalt chromium. Other differences were:

- 65^{o} of motion was provided
- articular area was $520mm^{2}$
- total height (excluding fins) was 10mm.

In reaching the final cylindrical prosthesis (called the 'New Jersey'), the authors disregarded incongruent surface designs due to their inherent poor wear and deformation resistances. They did not, however, mention any clinical results of their research.

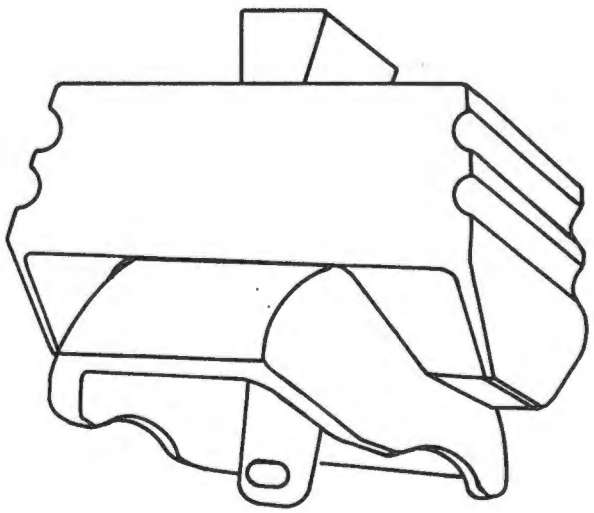


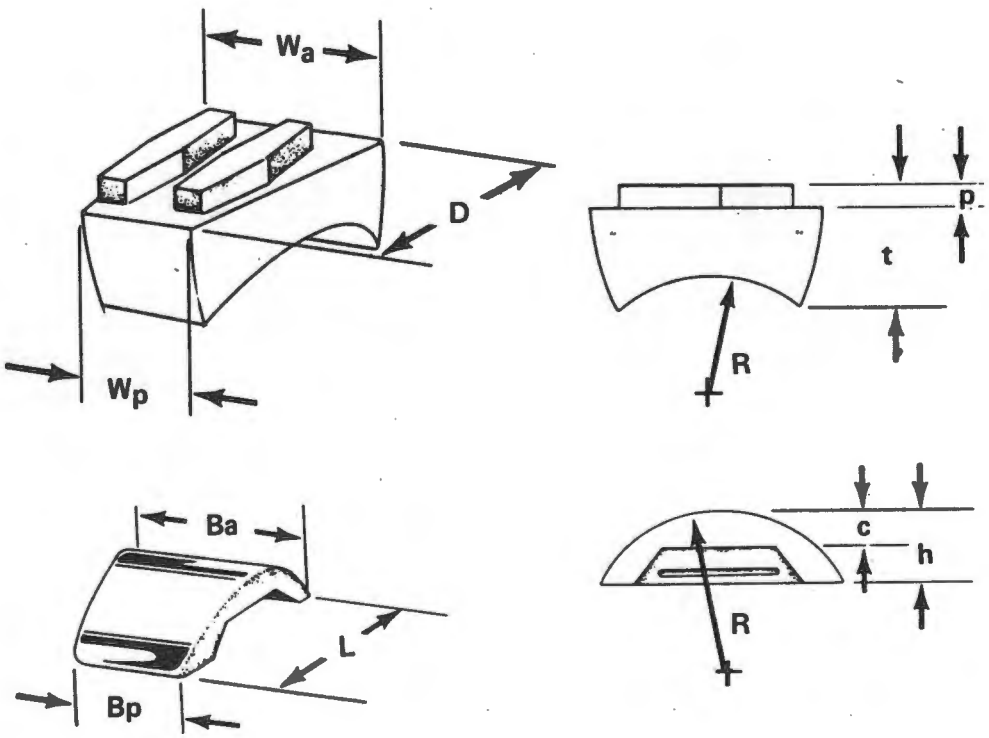
Fig. 2.33 Oregon Ankle

In 1977, Groth, Fagan and Shen developed the "Oregon" prosthesis to replace all three diseased surfaces of the ankle joint (i.e. between each of the two malleoli and the talus and between the tibia and talus). The central portion of the implant (see Figure 2.33) was a horizontal cylinder which allowed flexion and extension of 40^{o}. The lateral and medial surfaces were orientated at 30^{o} from the vertical and were shaped in such a manner that the left and right prostheses were the same. The tibial component was made of a cast cobalt-chromium-molybdenum alloy

whilst "Poly Two" was used for the talar unit. It was estimated that the maximum interfacial stresses (i.e. 7,3 - 9,9 MPa) would be in the same range as those encountered in a Charnley hip prosthesis. Tests on the strength of fixation showed that the parallel grooves offered better fixation than either a grid pattern or a single square projection. As far as the surgical procedure is concerned, an anterior approach was once again recommended. Special instruments were designed to facilitate bone resection and correct alignment of the prosthesis. (It should be mentioned that a relatively large amount of bone needed to be removed.) Small cement holes in the resected tibia and talus were recommended to improve fixation. It was emphasised that unless the fibula was fused to the tibia, no cement should be applied laterally (since it would fracture because of the fibular movement).

In 1979, another Zimmer prosthesis became available (the "Oregon" was the first one). This one, designed by Odland, was a two-piece, plastic-to-metal prosthesis made of the same materials as the Oregon prosthesis. The articulating surfaces were sections of a cylinder and the axis of rotation was mediolateral (see Figure 2.34). In an attempt to lessen the contact pressures during the dorsi-flexion part of the gait cycle, the prosthesis was made wider anteriorly than posteriorly. The contact pressures between the articular surfaces depended on the size of the prosthesis (there were three sizes) but were roughly 40% lower than those of the Oregon implant. Other design features included two runners on the superior surface of the tibial part and a central ridge on the inferior surface of the talar component. Both of these features were to enhance fixation. In addition a slight side-to-side motion was permitted since the tibial component was made wider than the talar part. The theoretical move-

ment in the sagittal plane was 45° of rotation. The surgical technique was similar to that used for the Oregon design. One difference was that two anterior approaches were available. (The surgeon could choose whichever one he preferred.)



Specifications of the Odland Total Ankle

Size	Tibial Component						Talar Component						Radius
	Cat. No.	Wa	Wp	D	t	p	Cat. No.	Ba	Bp	L	h	c	R
Small	5026-03	29	22	35	9	5	5026-05	25	18	37	11	6	21
Regular	5026-04	34	25	40	9	5	5026-06	27	19	41	11	6	24
Large	77-8025-58	40	28	45	9	5	77-8025-53	30	22	43	11	6	27

*All dimensions in mm.

Fig. 2.34 Odland Ankle Prosthesis (Odland, 1979)

The idea of using a prosthesis with a wider anterior articular surface has also been used in the design of the "TPR" implant. The advantage with this is that the motion at the joint is not restricted to the sagittal plane since slight rotation is permitted. Another advantage with the TPR system is that the cylindrical pegs used for fixation are directed slightly posteriorly (see Figure 2.35). This means that the procedure for drilling the holes into the tibia and talus is simpler than that used in other anterior approaches (e.g. ICLH and Oregon).

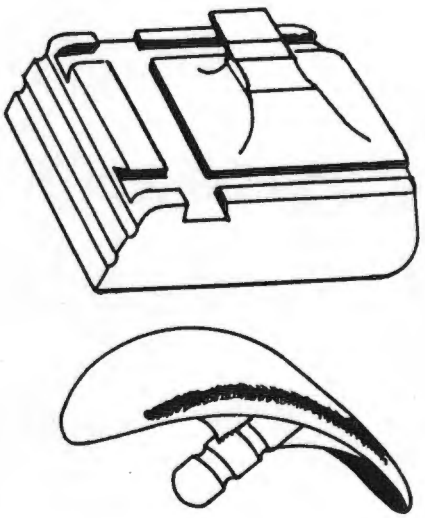
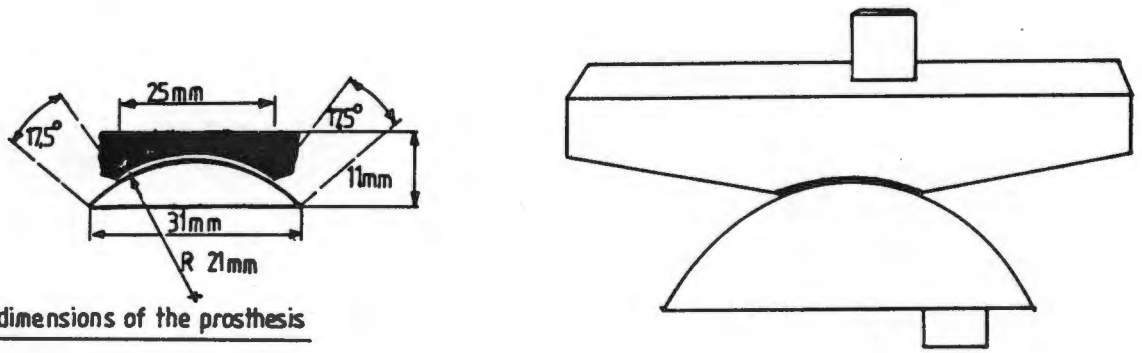


Fig. 2.35 TPR Ankle Prosthesis

A more recent prosthesis which has been modified in the light of clinical trials is the Imperial College London Hospital (ICLH) ankle prosthesis (Freeman et al, 1979). Although it has been slightly changed from its original form, Herberts et al. (1982) followed up eighteen ICLH ankle arthroplasties done with one of the earlier devices. The mean follow-up period was three years and the results were;

excellent	-	2
good	-	8
fair	-	6
poor	-	2

There was a relatively high incidence ofloosening which occurred more often in osteoarthritic cases. On the other hand, rheumatoid patients did much better, and it was thus felt that these people lend themselves more to arthroplasty than fusion.



The dimensions of the prosthesis

Fig.2.36ICLH Prosthesis (Without Side Walls) (Freeman et al, 1979)

The prosthesis developed by Freeman et al., had basic dimensions as shown in Figure 2.36. To prevent medial-lateral subluxation at the sides, retaining "walls" were provided on the tibial component. Freeman et al (1979) went on to describe the laboratory testing procedures, the instrumentation needed during surgery and some clinical results which, after about five years, generally looked promising. The average range of motion postoperatively was 13,5o; although the design itself allowed for 35o.

More extensive follow-ups were carried out by Newton (1979 and 1982). He designed an ankle prosthesis which allowed movement in every plane (in an effort to prevent loosening of the components). The HDPE tibial unit was 10mm thick and thetalar unit was made of Vitallium. No resection was required of the talar dome during insertion, so later fusion (if needed) should

Note: Tibial unit is a section of a cylinder
Talar unit is a section of a sphere
with a slightly smaller radius.

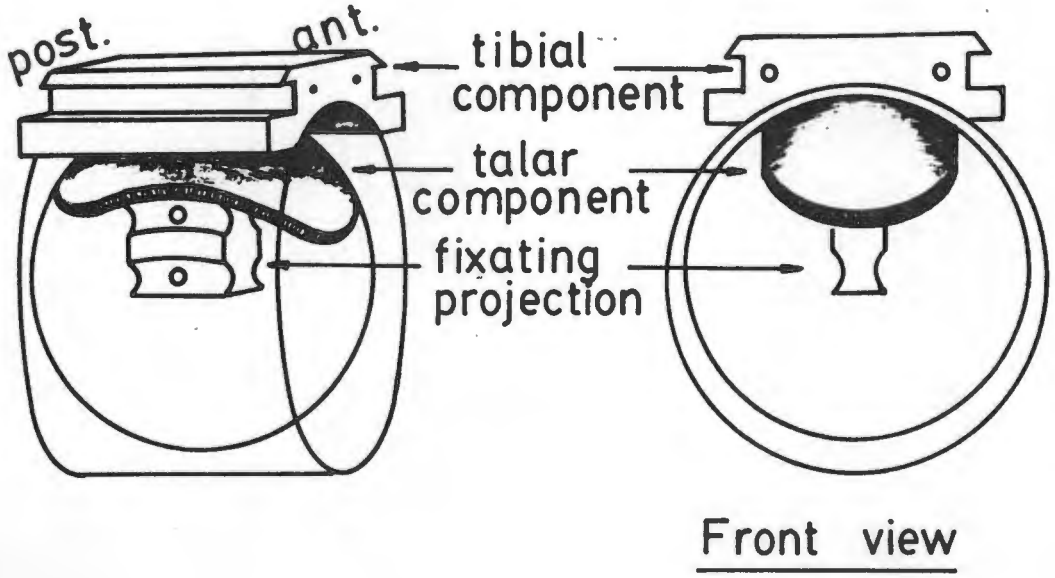


Fig. 2.37 Newton's Prosthesis

Number of patients	Problem	Failures	Cases in which the operation should not be performed
50	OA (34)	13	1) Varus / Valgus deformity > 20°
			2) Unstable ligaments
			3) Recent infection
			4) Abnormal anatomy
50	RA (6) on drug	5	All cases
	RA (4) no drug	0	
50	Avascular necrosis (3)	2	All cases
50	Pseudarthrosis of prior fusion (3)	3	All cases

Table 2.2 Summary of Clinical Results (Newton, 1982)

be easier to accomplish. Figure 2.37 shows the prosthesis designed by Newton and a summary of the clinical results is given in Table 2.2.

Another recent ankle prosthesis has been designed by a group in Italy headed by Calderale (1983). This group looked at biomechanical aspects such as the stresses and temperatures that the implant has to withstand. The tibial component had an intramedullary stem which was designed by analysing the heat flow during the cement curing stage. It was hoped that by reducing the peak temperatures around the stem, there would be less bone necrosis and hence less chance of loosening.

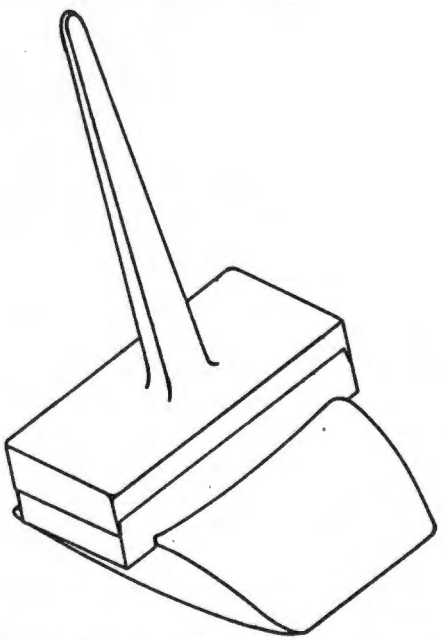


Fig.2.38Pipino Calderale Ankle Prosthesis (Calderale etal, 1983)

Other features of the design (see Figure 2.38) included;

(a) a method of fitting the talar component which did not significantly weaken the prosthesis (since very little bone resection was needed)

(b) using the tibial diaphyseal cortex to support the tibial component of the prosthesis

(c) using a HDPE insert as a bearing material

(d) having a trochlear groove on the talar component with the tibial part reciprocally shaped.

Unfortunately the authors did not mention the range of motion, overall dimensions nor the metal from which the implant was made.

Guidelines for post-operative physical therapy, for patients who have had total ankle replacements, have been described by C L Smith (1980). She suggested the following procedures be followed:

(a) Applying a bulky pressure dressing after surgery and elevating the foot for about three to five days.

(b) Removing the suction drain after a day or two.

(c) Physiotherapy commencing on the first day after surgery. This includes isotonic ankle exercises and toe flexion and extension.

(d) On the second day after surgery transfer activities from the bed to the chair begin. No weight-bearing on the involved extremity is allowed.

(e) On the fifth day, an Ace bandage is used to replace the bulky dressing. Active plantar- and dorsi-flexion exercises can begin, as well as weight-bearing to tolerance on the involved foot.

(f) Full weight-bearing is allowed when the therapist considers the time right and the sutures are removed. After twelve to fourteen days the patient can be discharged.

(g) Normal activities can be resumed after three to five weeks after surgery.

(h) Six weeks after discharge a follow-up appointment is advisable.

Another article on post-operative management (Opitz, 1979) dealt mainly with hip replacement, but the knee, ankle, shoulder,

elbow and wrist joints were also included. With reference to the ankle joint, Opitz suggested a routine similar to that above but emphasised the following:

(a) When gait training begins, dorsi-flexion during the swing phase must be encouraged.

(b) Isometric quadriceps strengthening exercises must be done regularly.

By following a carefully laid out plan (similar to these above) both Smith and Opitz considered the chances of successful ankle arthroplasty to be favourable when compared to ankle arthrodesis.

A summary of some of the features of the ankle prostheses which have been reviewed in this chapter is given in Table 2.3.

Name	Type	Materials	Range of Motion	Tibial Fixation
St. George	congruent cylindrical (c/c)	cobalt chrome & HDPE	?	six small ridges
Smith	domed	metal & UHMWPE	25° (post-operatively)	one large ridge
Waugh	toroidal	colbalt chrome & UHMWPE	three-dimensional	stem
Mayo	c/c	stainless steel (s/s) & UHMWPE	25°	two small ridges
New Jersey	c/c	cobalt chrome & UHMWPE	65° (pre-operatively)	two small ridges
Oregon	c/c	cobalt chrome & "Poly Two"	40°	one small ridge
Odland	c/c	cobalt chrome & "Poly Two"	45°	two small ridges
ICLH	c/c	Vitallium & UHMWPE	35° (pre-operatively) 14° (post-operatively)	one small
Newton	domed (non-congruent)	Vitallium & HDPE	three-dimensional	one large ridge
Calderale	trochlear	metal & UHMWPE	?	stem

Table 2.3 Summary of the Features of Ankle Prostheses

CHAPTER 3

ROLE OF GAIT ANALYSIS

Gait analysis is becoming increasingly important as the questions asked by biomedical engineers and orthopaedic surgeons become more and more specific. There are basically three areas where gait analysis plays a major role;

(a) Determining the biomechanics of normal and pathological joints

(b) Assessing results of joint replacement

(c) Choosing candidates for joint replacement

Before these areas are dealt with separately (and with particular emphasis on ankle arthroplasty), some methods of gait analysis will be discussed briefly.

3.1 Methods of Analysing Gait

(a) EMG Analysis. This technique involves the measurement of the electrical activity of muscles. (Before a muscle can contract it must receive an electrical impulse.) By either placing an electrode on the skin or a needle into the muscle and using suitable amplification and filtering, it is possible to record the phasic behaviour of a muscle. It is also possible to detect the onset of fatigue, but attempts to relate EMG to muscular tension have met with limited success.

(b) Cinematography. This involves recording a gait sequence on film and analysing it after it has been processed. If the frame rate is known together with the magnification between the image on the screen and reality then the following information can be derived;

* stride length
* stride time

* joint angles
* joint velocities and accelerations
* cadence
* velocity of walking

(c) Force Plate. This instrument comprises a rigid rectangular plate mounted on load transducers, and is positioned such that its surface is level with the floor. As a person steps on to the plate the load transducers convert the forces which are exerted on the surface to electrical signals. These can then be amplified and either displayed on a TV screen or recorded for later use.

(d) Goniometry. This is the recording of joint angles at different stages of the gait cycle. Usually two links which are hinged together using a potentiometer are placed across the joint of interest (e.g. the knee). As the subject walks, the potentiometer will record any changes of the angle between the distal and proximal body segments.

(e) Metabolic Consumption (VO_2). During a gait cycle, a certain amount of energy is consumed. In a normal gait cycle, this energy is minimal, but in pathological conditions it might not be so. By recording the oxygen consumption during gait it is possible to get an idea of the effectiveness of the locomotor system.

3.2 Relevant Biomechanics of the Ankle

In Chapter 2 the contributions of various authors who have studied the mechanics of the ankle complex were reviewed. In this Chapter an attempt will be made to answer the question, "What characteristics of the ankle are important to someone who

wishes to design an artificial replacement?"

Many studies of gait have concentrated exclusively on the events occuring in the sagittal plane. It is common to see graphs of hip, knee and ankle angles that have been measured from the lateral side of a person's limb and diagrams showing the vertical forces that are present at heel strike and toe-off. In the case of prosthesis design, these data are insufficient, since they inadequately describe the gait pattern. Some designs that have failed in vivo have done so because of the omission of certain relevant information which could have been obtained by observing gait in three dimensions.

With regard to biomechanics of the ankle complex it is thus felt that a knowledge of the following at all stages of the gait cycle is important;

(a) axes of rotation

(b) abduction/adduction

(c) inversion/eversion

(d) flexion/extension

(e) spatial orientation of muscles

(f) magnitude, direction and position of resultant joint force

(g) contributions of each of the muscles to the total joint torque. (This includes the phasic activity of each of the muscles.)

Besides these parameters, it is also necessary to know the anatomical proportions of the ankle and the mechanical strengths of the various joint tissues. This information however falls outside the realm of gait analysis.

The first four points in the list above are important since the collateral ligaments of the ankle have limited elasticity and

hence can only tolerate certain movements. They allow about 40^{o} of rotation in the sagittal plane but lesser amounts in the other planes. A prosthesis which allows too much motion to occur in these planes is liable to cause failure of either the ligaments or the malleoli (see Figure 3.1). On the other hand, a prosthesis which restricts motion is in danger of being forced loose (see Figure 3.2).

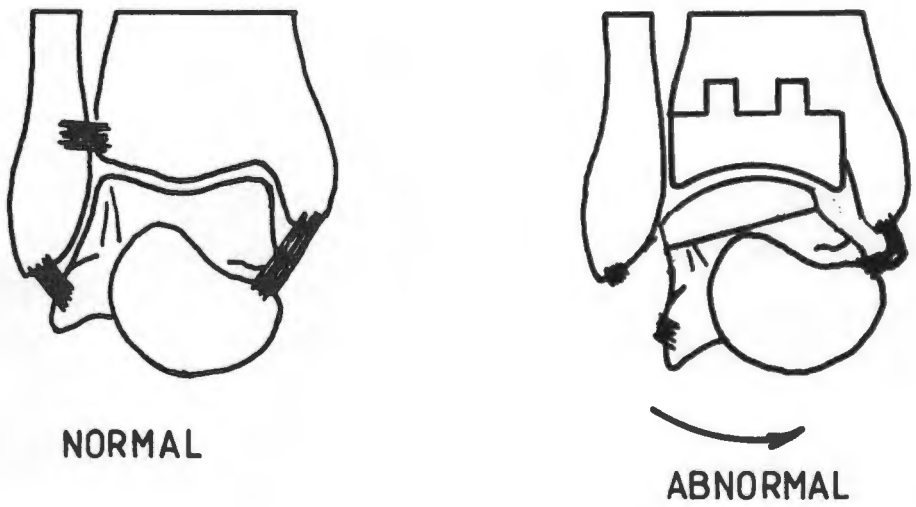


Fig. 3.1 Failure of Lateral Ligament due to Excessive Inversion

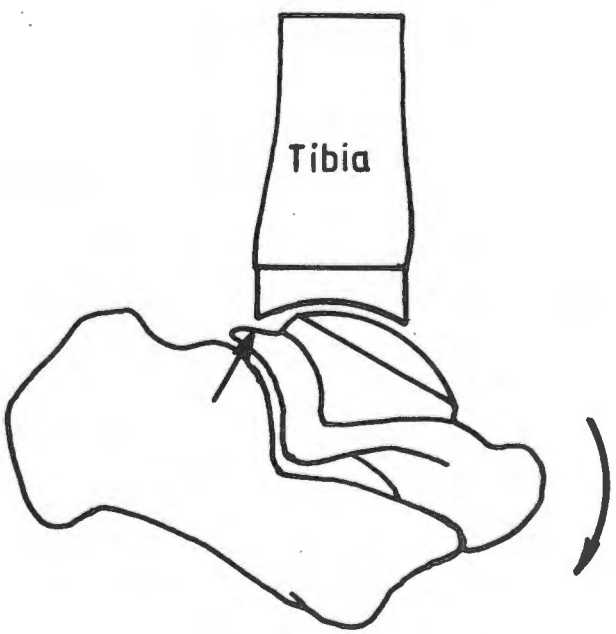


Fig. 3.2 Impingement Between Talus and Tibial Unit

Other factors which can cause loosening are shear and tensile stresses between the prosthesis and the bone. For these to be minimised, any design should take the last three points listed above into account. (By knowing the phasic behaviour and the position of each of the muscles crossing the ankle it is possible to deduce in which direction the joint would prefer to rotate. A prosthesis which allows this motion has less chance of working loose than one which constrains the movement.) Besides muscular forces, there are also impact forces as the foot strikes the ground. These forces combine to give a resultant joint reaction force which typically has components in three orthogonal planes. The method of fixation between prosthesis and bone should be capable of withstanding this force and any other which can be expected at other stages of the gait cycle.

3.3 Assessing Results of Joint Replacement

As was mentioned in Chapter 2, there are a variety of ankle prostheses which have been implanted in patients and therefore assessed clinically. Any new design should be contemplated only after careful consideration of post-operative results has shown some inherent defect in existing implant designs. Once it has been established that a new design is needed, all the post-operative results should again be scrutinised since it may be possible merely to combine features of two or more of the existing prostheses.

The problem with this philosophy is that the recording of post-operative results is often very subjective. Sometimes this is unavoidably so. The assessment of pain in the affected joint for instance is very difficult to quantify. In other cases it is possible to measure certain relevant parameters such as stride length, joint angles, limb velocities, etc. (It may happen that

pain can be indirectly measured by analysing its effect on joint motion. This however is very difficult at present.)

A comprehensive study on the results of ankle arthroplasty (Demottaz et al, 1979) was aimed at assessing the merits of the procedure. EMG, force plate, moving pictures and radiological data were used to compare one prosthesis with another in an objective manner. The main drawback of this investigation was that for each prosthesis the sample size was limited to about three or four patients. Some findings were;

(a) Walking speed, cadence, step length and single limb stance time were all reduced.

(b) The arcs of motion at the hip and knee appeared normal.

(c) The whole foot made initial contact with the ground and was in full plantar-flexion at this instant. (Normally the heel makes initial contact and the foot is in a neutral position.)

(d) There was no apparent ligament instability across the ankle.

(e) Proprioception at this joint was normal.

(f) There was noticeable muscle weakness about the ankle joint (especially in the plantar-flexors).

(g) Prostheses with a single axis were transversely rotated.

Demottaz et al were of the opinion that the body compensated for the muscle weakness of the calf group by

(h) creating abnormal patterns at the opposite ankle (having similar patterns helps to maintain a smooth symmetrical trunk motion)

(i) greater activity of the proximal ipsilateral limb muscles.

This last point is interesting since Brandell (1977) suggested that interdependence between the vasti and calf muscles

indicates a phenomenon of muscle substitution. He felt that the constant action of the calf muscles in lifting the heel and plantar flexing the ankle may be complemented by the tendency of the knee-extending action of the vasti to pull on the tendo-calcaneus via the heads of the gastrocnemius.

A method of evaluating knee replacement (Johnson, 1983) by looking at the everyday activity of patients seems to have some merit. He used a foot switch pedometer and a strain gauge goniometer on the anterior aspect of the knee (a 2mm rubber tube filled with mercury) to measure the amount of walking done each day and the use made of the knee during walking. The data was recorded on a tape recorder and analysed afterwards. By extending this technique it may be possible to assess the results of any joint replacement without incurring large financial costs.

Besides the seven points listed in section 3.2 another aspect which should be studied post-operatively is whether the replacement of the ankle has any affect on the other joints of the locomotor system. This is possible since the action of walking depends on a multitude of interrelated factors. If one is significantly altered, then the other components of the system will be affected as well. With regard to ankle replacement, it would be especially interesting to note the EMG activity of the Gastrocnemius muscle since this muscle spans three joints of the lower leg. Any change in the activity would thus likely affect motion at the knee and subtalar joints as well as the abkle joint.

An example of the inter-relation between the foot and knee mechanisms has been given by Morris (1977);

"At heel contact, an arc of rotation of the ankle occurs about a radius formed by the heel as the ankle plantar-flexes. An inter-

secting arc is subsequently made by rotation of the foot about a centre in the forepart of the foot as plantar-flexion occurs prior to toe-off. At this point the knee flexes more, and this combined action helps produce the smooth sinusoidal pathway of the centre of mass."

With regard to the hip joint, Brown et al (1981) showed how replacement could affect the knee of the opposite limb. They compared the design of two prostheses with specific emphasis on the lever arms of each of the devices (see Figure 3.3). They observed no difference in the moment opposed by the abductors between the Charnley and Muller patients and since the lever arm is reduced in the latter design, they deduced that the abductor force must be greater for this implant. On the unaffected limb, supra-normal adduction moments cause increased abductor forces at the hip and in addition the knee would carry a higher portion of its load on the medial side. In the case of rheumatoid arthritis this may cause rapid deterioration of the knee.

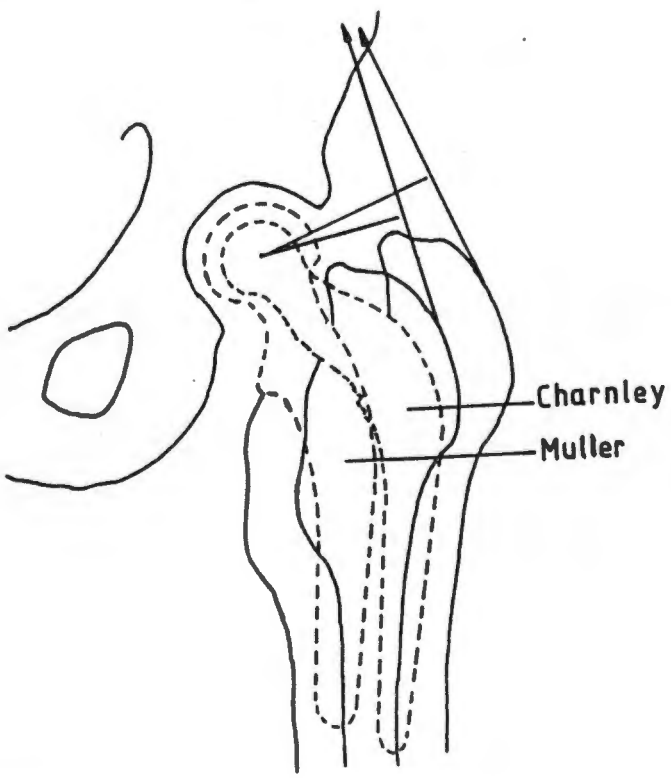


Fig. 3.3 Different Abductor Lever Arms (Brown et al, 1981)

By extending post-operative gait analysis to the locomotor system as a whole it would be possible to ascertain whether or not the other joints were being affected by the procedure, and steps could be taken to correct faults in either the design of the implant or the surgical rationale.

3.4 Candidates for Ankle Replacement

Joint replacements are examples of high cost treatment mainly confined to the elderly. This group of the population is on the increase - between 1969 and 1979 the British population increased by 1,2 percent whilst the number of people over sixty-five years increased by 13,8 percent (Johnson, 1983). In the United Kingdom the cost of a single hip replacement is of the order of 2000 pounds and about 25000 are performed annually. If it was possible to select patients such that the less severely afflicted had a simpler operation then there would be a greater economy in terms of effort and cost to the patient as well as the state.

Although the assessment of the degree of arthritis can usually be adequately performed using X-rays, gait analysis can play a role in measuring other parameters which affect the choice of patients and prostheses. One of these parameters is the mobility of the person prior to surgery.

According to Johnson (1983) it was found that if a person led an active life in spite of being afflicted by arthritis, then a prosthesis which depended on soft tissue support should not be implanted. (Simpler models which do not rely on the ligaments being intact usually last longer than the more complex versions.) As an example of a joint which has a variety of artificial substitutes, Johnson cited the knee. He also suggested that the method he used to assess patients post-operatively (discussed

earlier in this chapter) by measuring their activity could be used pre-operatively to choose a suitable prosthesis for each candidate.

If it so happened that a simpler implant was recommended for a particular patient then an additional saving would be that a later revision would be easier to accomplish. (Revisions are unavoidable if the implant has been subjected to wear over a long period of time.)

Another area in which gait analysis can play a role is in choosing between arthrodesis and arthroplasty. Mazur et al (1979) performed such a comparative study with regard to the ankle and concluded that fusion is a viable procedure provided the other joints of the foot and the opposite ankle are mobile. For patients with rheumatoid arthritis he suggested joint replacement would be a better alternative.

To determine whether or not the subtalar joint has involvement of rheumatoid arthritis can sometimes be difficult even with the aid of X-rays. Godfrey and Old (1982) demonstrated how gait analysis can assist the surgeon in this diagnosis, since rheumatoid arthritis in this joint causes the following abnormalities;

(a) there is late heel rise; and

(b) lack of plantar-flexion during ipsilateral heel-strike.

To conclude, it is apparent that gait analysis plays an essential part in the whole picture of joint replacement. It allows a sound judgement of both patient and prosthesis to be made as well as an objective assessment of the surgical procedure. It is important however to know which characteristics are relevant to the engineer and which are relevant to the orthopaedic surgeon. (In the next chapter the former will be used in the design of an artificial ankle joint.)

CHAPTER 4

THEORETICAL DESIGN OF AN ANKLE PROSTHESIS

Once a need has been expressed for a certain device (such as an ankle prosthesis) the classical method of proceeding with the design is first to specify the requirements and constraints pertaining to the design. Once such a list is compiled it often becomes clear that compromises are necessary so that a solution to the problem can be obtained. For this reason it is advantageous to separate the "absolute necessities" from the "desirable features".

Requirements. There are basically only two main requirements of a joint replacement procedure:

(a) Relief of pain

(b) Restoration of function

The first of these necessitates the removal of the articular surfaces and other diseased tissue whilst the second depends on the specific prosthesis design and the degree to which any deformity can be corrected.

As in virtually any design, there are a number of factors which limit possible solutions to the problem. These constraints are listed below.

Biological constraints. These are as follows:

(a) The materials used must be biocompatible. In addition, any wear debris must not be carcinogenic or cause extensive tissue reaction.

(b) If a filler-material (such as PMMA) is used it should be kept to a minimum to reduce bone necrosis (due to the heat dissipated during the curing stage).

Mechanical Constraints. These are as follows:

(a) Loads of about five times body weight must be tolerated, without danger of the implant fracturing. Even while being subjected to such loads in vivo, the wear rate must be such that the implant's strength does not markedly diminish with time. (It would seem reasonable to expect a lifetime of about fifteen years - Elloy, Wright, Cavendish, 1976.)

(b) The prosthesis should be able to cater for approximately 30^{o} of movement in the sagittal plane. The movement in other planes should not be absolutely restricted (as in a hinged prosthesis) since undesirable stresses would then be transmitted to the prosthesis/bone interface. If this were to occur then the fixation would gradually become less effective.

Surgical Constraints. These are as follows:

(a) The surgical approach should not be hazardous to the patient (i.e. there should be little chance of permanently disrupting the nerve or blood supply).

(b) It is desirable to keep bone resection to a minimum so that arthrodesis is still a viable technique post-operatively.

(c) A subcutaneous implant should be avoided since this may retard wound healing and increase risk of infection.

Design Criteria. Even though there may still be a number of solutions to the problem of designing an ankle prosthesis (all satisfying the above constraints) only one or two will meet certain additional criteria. These criteria are as follows:

(a) Operation time should be relatively short (less than one and a half hours).

(b) The instruments used to insert the prosthesis and align it correctly should be few in number and readily amenable to sterilisation. They should also be easy to manipulate.

(c) Post-operative treatment should be simple and not time consuming.

(d) If the prosthesis fails (e.g. develops a crack) then it should be possible to remove the device with little or no bone resection.

(e) Costs of the implant should be in the order of R200-R400.

Further Considerations. The two primary features of a joint prosthesis are, first, the articulating surfaces and, second, their fixation to bone. Secondary features include the choice of materials, method of insertion and method of manufacture. Naturally all these factors are inter-related; e.g. for rigid fixation of the implant the articulating surfaces must move in harmony with the action of the muscles; also, the choice of materials influences the size and shape of the fixating projections and if these are porous (to allow bone ingrowth) then suitable manufacturing techniques must be employed. As a last example, the directions of the fixation projections (e.g. antero-posterior) determines, to a large extent, the direction of insertion (see Figure 4.1). In some cases, the reverse occurs; anatomical constraints such as the presence of nerves determine which surgical approach may or may not be used. This, in turn, may constrain the shape of the fixating projections.

The ultimate aim of any joint arthroplasty should be to replace the joint with an artificial substitute without the need of screws, nails or filler cement. Unfortunately, the need to distribute bone/prosthesis forces over the largest possible area (and hence reduce the stresses on the interface) is most easily

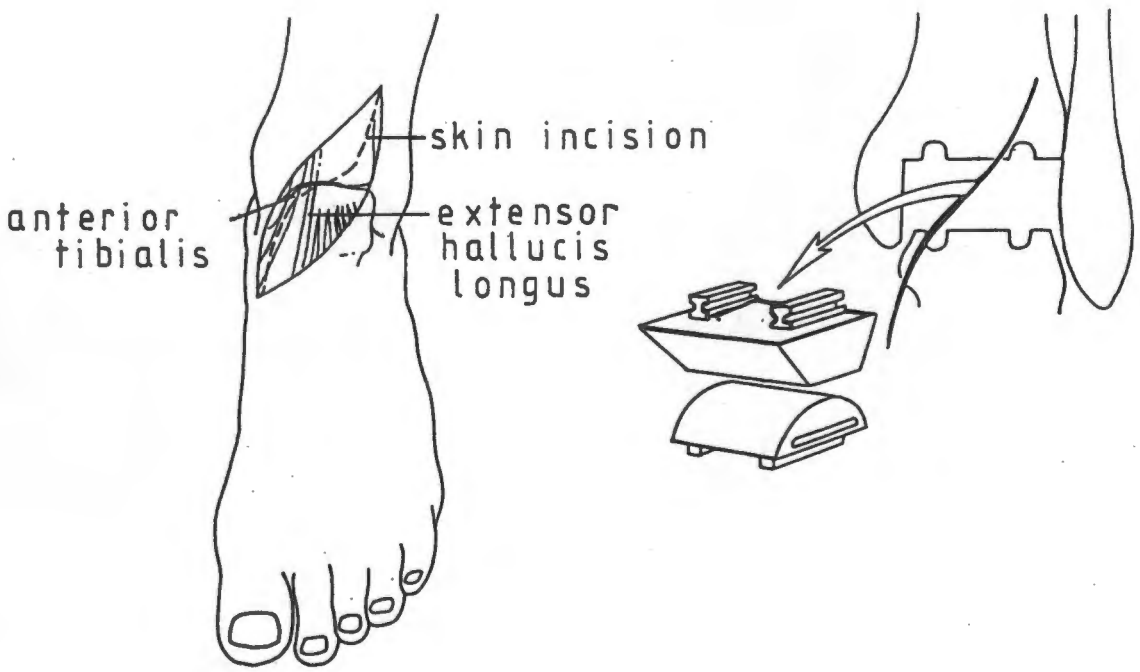


Fig. 4.1 Anterior Approach

fulfilled by using a cement to act as a filler material wherever there are small gaps. The ankle prosthesis which will be described in this chapter will nevertheless be designed to minimise the interface stresses so that if a suitable porous material can be coated on the areas in contact with bone, there will be the best chance of a firm bone/prosthesis union developing. (In such an event, there will be no need for filler cement.)

4.1 The Articulating Surfaces

4.1.1 Surface Shape

If one were to design an artificial ankle joint to strictly imitate normal anatomy, then an implant with conically-shaped surfaces would be called for (refer to Chapter 2).

It is felt, however, that a good design should take into account the function of the foot as a whole. A prosthesis which is designed for a "normal" foot is not necessarily the best for an arthritic foot and therefore the surfaces cannot simply be made from sections of cones.

In a disease such as Rheumatoid Arthritis (RA) it is very likely that, if the tibio-talar joint is involved, the subtalar joint will be affected as well. It is thus desirable to have an artificial ankle joint which relieves some of the duties of the subtalar joint. Inman (1976) in a comprehensive study on the joint of the ankle stated: ".... orthopaedic surgeons who are considering the design of a new ankle prosthesis or contemplating the insertion of such a device should carefully reflect upon the functional inter-relationship between the ankle and subtalar joints."

Wright **et al.** (1964) point out that as a result of the location of the ankle axis, dorsiflexion is combined with slight abduction of the foot (and plantar flexion with adduction). On the other hand, because of the position of the subtalar axis, motion at this joint combines dorsiflexion with abduction and eversion whilst plantarflextion is coupled with adduction and inversion. (These movements of the subtalar joint are referred to as pronation and supination, respectively.) It is important at this stage to note that abduction of the foot refers to the distal part of the foot moving laterally and the heel moving

medially.

Some authors (Frankel, Nordin 1980) have referred to motion at the subtalar joint as being similar to that of a screw (see Figure 4.2). Inman (1976) in his study, looked at this theory and concluded that this is true in about half of the population. He added that the actual pitch of the screw varied widely from individual to individual.

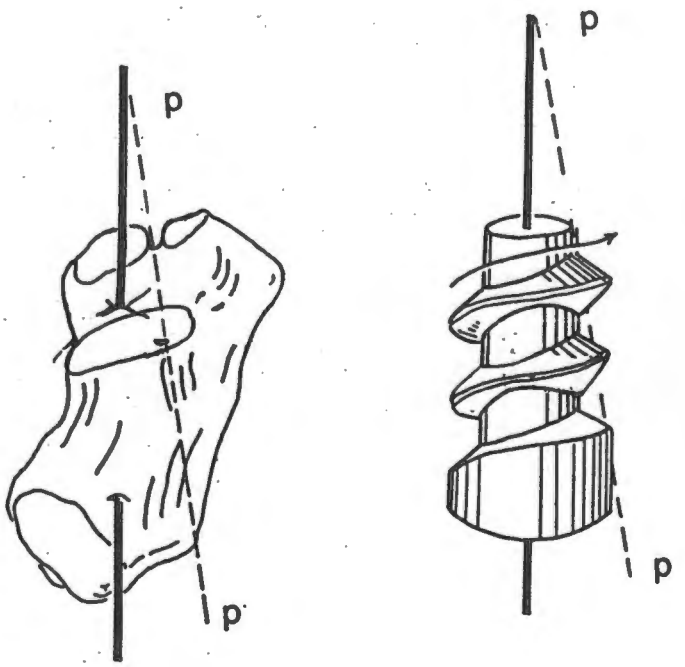


Fig. 4.2 Subtalar Joint (Frankel and Nordin, 1981)

An interesting hypothesis put forward by Helfet (1983) is that almost all the major joints of the body are screw-like in character. Helfet has used this theory, with success, in designing a knee and elbow prosthesis. It is well-known that the tibia rotates outward whilst the knee is extended and inward when the knee is flexed (Helfet 1974, Basmajian 1976). In the case of the elbow, as the ulna swings around the trochlea of the humerus from flexion to extension, it is forced gradually lateralward and

so out of line with the humerus. The difference in alignment of about 15^{o} is referred to as "the carrying angle" (Basmajian 1976).)

Goodsir (1868) was the first to suggest that the ankle had a "screwing-up mechanism". The clearest example of "screw joints" was given by Barnett et al. (1962) when they presented diagrams of a wallaby's talus and a horse's ankle. (See Figure 4.3) Whilst this is not indicative that the human ankle is part of a screw, it does suggest that a closer look be taken of a helical ankle prosthesis.

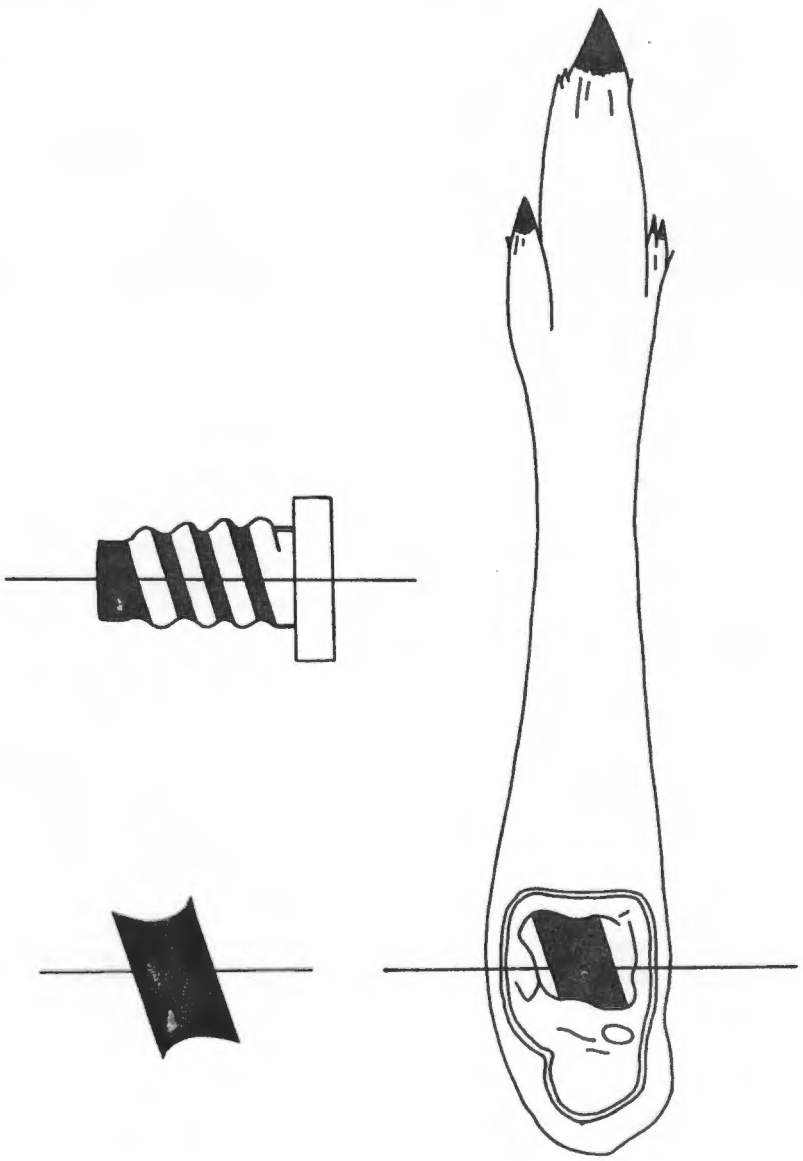


Fig. 4.3 The Trochlear Surface of a Wallaby's Talus Compared to a Portion of a Screw

In his book on knee disorders, Helfet (1974) explained how the medial vastus muscle which runs from without inward and is inserted mainly on the medial side of the tibia, can rotate the tibia outward while extending the knee. In a similar manner the medial hamstrings are used to rotate the tibia inward while flexing the knee. Helfet (1983) is of the opinion that the ankle operates in a similar (helicoid) manner.

As was shown in Chapter 2, the two most important muscles crossing the ankle are the Anterior Tibialis and Triceps Surae. It was also illustrated how these muscles act at different stages of the gait cycle. This phasic behaviour will be shown to be a very important factor that must be taken into account when designing an ankle prosthesis.

Figure 4.4 shows the major ligamentous and tendonous attachments to the hindfoot. Of particular relevance are the insertions of Tibialis Anterior and Triceps Surae muscles. Figure 4.5 is a simplified sketch in which a line has been drawn through the centre of these insertions. It can be seen that the line passes through the centre of the ankle joint at an angle relative to the long axis of the foot. This angle is in the region of 12°.

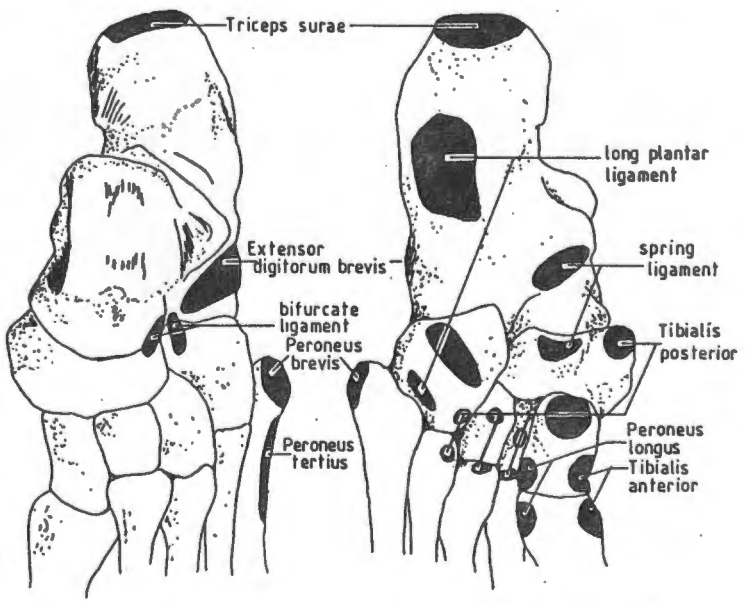


Fig. 4.4 Insertions into the Hindfoot

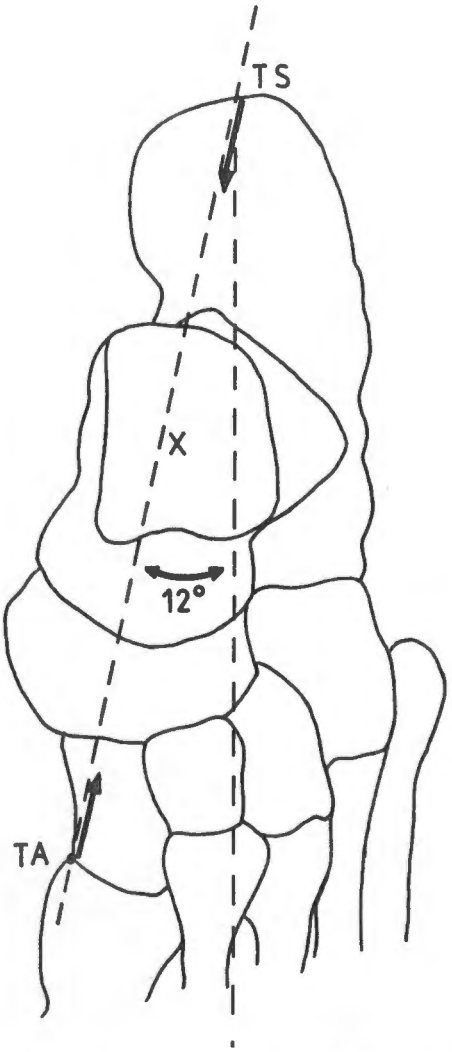


Fig. 4.5 Insertions of Tibialis Anterior and Triceps Surae

If the Triceps Surae muscles begin to plantarflex the foot it can now be seen that the insertion of the calf group will tend to move nearer to the centre of the joint (Point X). Similarly, when Tibialis Anterior contracts, its insertion will tend to move towards the same point though, in this case, it will move in the opposite direction. It is important to note that the motion that occurs more distally (e.g. at the forefoot) depends on the location of the axis of rotation.

As has been mentioned before, there is a phasic pattern to the behavour of Tibialis Anterior and the Triceps Surae muscles (see Figures 4.6a and b). If they acted simultaneously with equal force and leverage, the resultant reaction at the centre of the ankle joint would be directed vertically up the shaft of the tibia. In this hypothetical example, there would be no net force

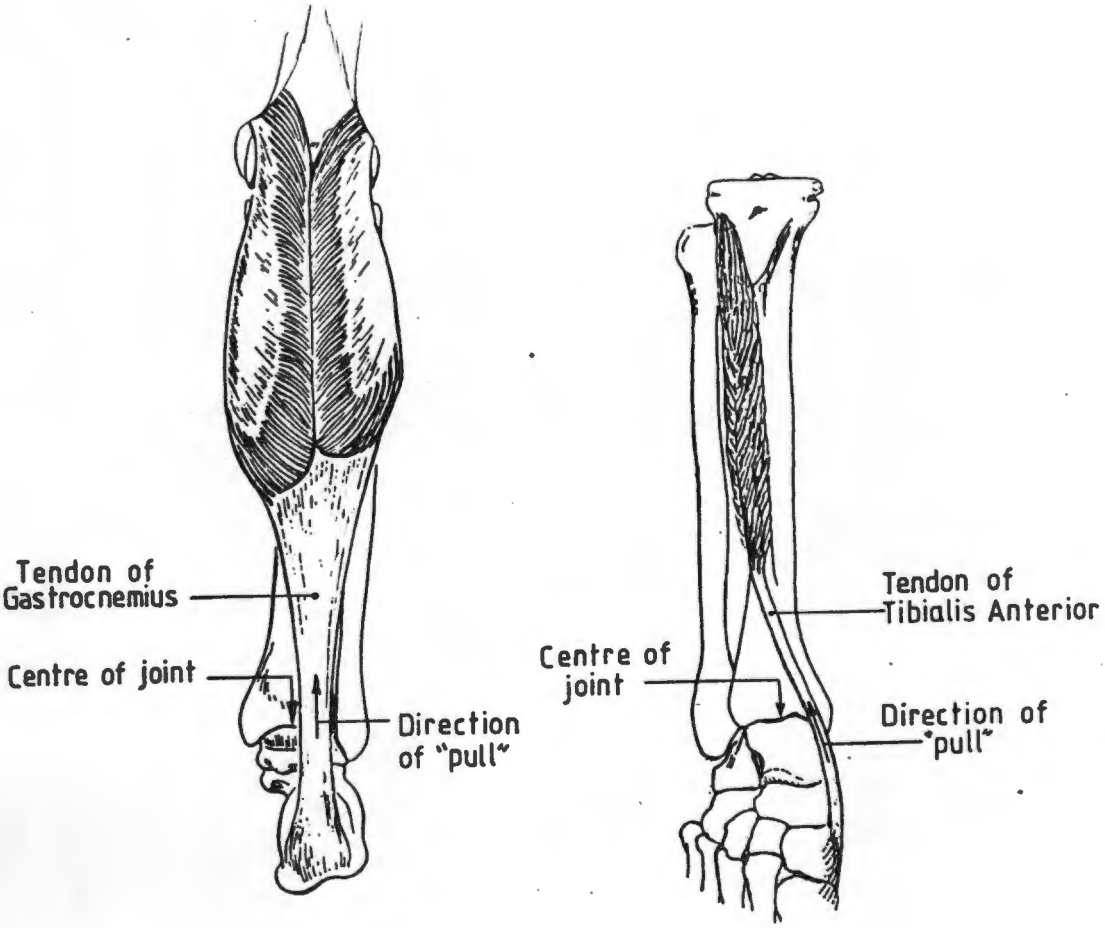


Fig. 4.6a Two Important Tendons Crossing the Ankle (Note Their Offset from the Joint Centre)

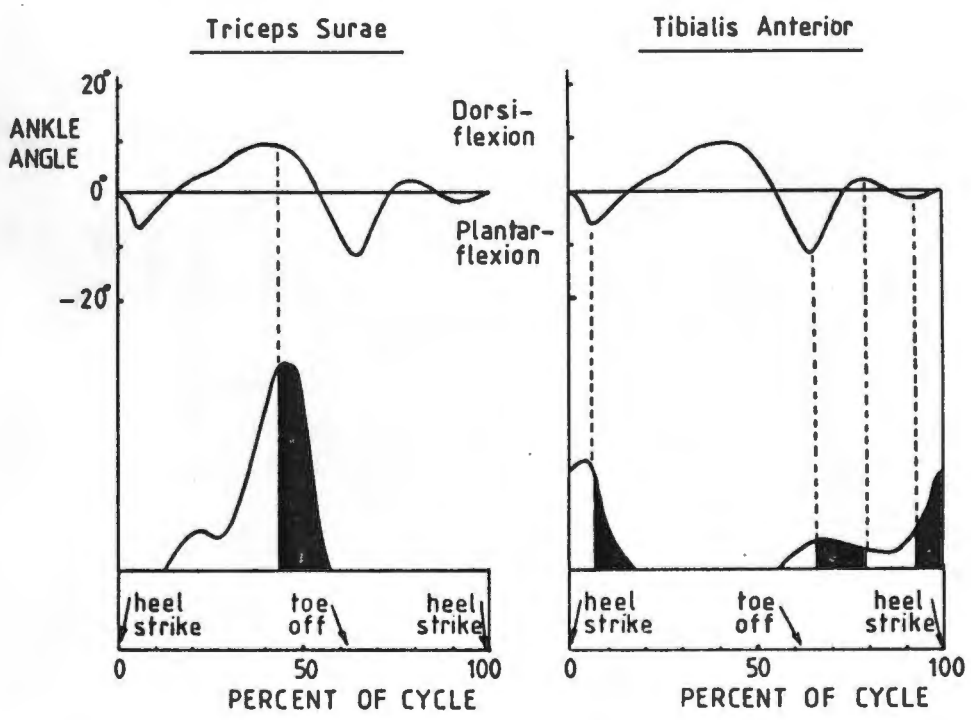


Fig. 4.6b Ankle Motion Related to EMG Data (Inman et al, 1981)

couple in the coronal plane since the contributions from each set of muscles would cancel each other. However in the real situation, their phasic behaviour during gait could cause force couples in the coronal plane. (At this point it must be noted that force couples in the sagittal plane are desirable since they cause the ankle to either plantar- or dorsiflex.)

It is the author's belief that force couples in the coronal plane are a prime cause of loosening of previous single-axis prostheses. These prostheses (e.g. Oregon, Mayo, ICLH, Odland) do not guide the ankle in such a manner that the insertion of the calf muscles, for instance, can move medially during plantar flexion and so reduce the force couple. In other words, these prostheses constrain the ankle to operate as a simple hinge joint whereas a helicoid type of motion is, anatomically, more correct.

To verify the above hypothesis of helicoid motion occurring at the ankle joint, the author referred to a study performed on twenty one cases of total ankle arthroplasty (Demottaz et al, 1979). One of the findings of this study was as follows:-

> "In all of the fourteen ankles containing a prosthesis with single-axis motion, the axis of flexion-extension of the prosthesis relative to the transverse axis of the ankle mortise (line between the tips of the lateral and medial malleoli) appeared to be slightly internally rotated in the horizontal plane."

This indicates that the alternative contractions of the main pre- and post-tibial muscles had caused the prosthesis to swivel around so that the plane of movement tended to coincide more with the line linking the insertions of these muscles (see Figure 4.5)

Naturally, once the prosthesis has shifted its position, there is no longer a rigid bond between it and the bone and

secondly, the axis of rotation is misplaced. This latter factor would cause stretching of the ligaments across the ankle and this would make the ankle still more unstable.

There are other advantages of using a helical ankle prosthesis. If one were to stand on tip-toes as is shown in Figure 4.7, then the prosthesis would fulfill some of the duties of the subtalar joint. A person with rheumatoid arthritis who has subtalar involvement would thus find it less painful to stand on tip-toes, and hence easier to climb stairs. The reason once again is that as they plantarflex their foot it would move medially and so reduce any bending moment in the coronal plane. This is different to the inversion that normally occurs as the subtalar joint supinates but the effect is similar.

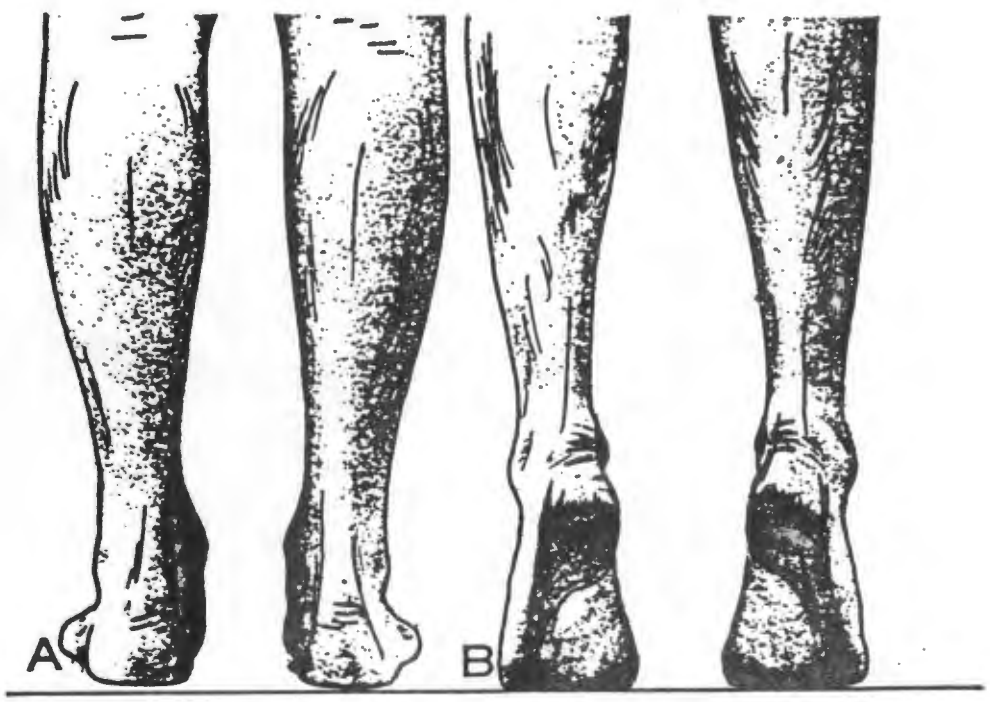


Fig. 4.7 Plantarflexion and Inversion of Heels (Inman, 1976)

It is important also to note that with any helix on the prosthesis, the relationship of the insertion of muscles (crossing the ankle) to the subtalar axis is not changed, since the helix causes the talus to move with the rest of the foot.

To summarise, it is hoped to minimise the peak loads (and fatigue) on the bone/prosthesis interface by having a helix which reduces the "peak force couples" that can reasonably be expected during everyday activities such as walking and ascending stairs. It is felt that a helical angle of about 12o (relative to the long axis of the foot) will help to reduce the chance of loosening.

4.1.2 Axis of Rotation

As was mentioned earlier, the axis of rotation plays a dominant role in determining the motion of the foot. For example, it is possible to get the forefoot to move either laterally or medially during dorsiflexion with any prosthesis simply by changing the axis of rotation. Morrey (1983) is of the opinion that the axis of rotation of a prosthesis should be as close as possible to that which occurs normally since this would lessen the chance of instability. According to Morrey, if the implanted device had an axis of rotation which differed to that which the patient had pre-operatively, then the ligaments would alternatively tighten and slacken depending on the amount of dorsi- or plantarflexion. The tightening could cause the prosthesis to cease moving and any further joint movement could only occur at the bone-cement interface.

In a study of the joints of the foot, Hicks (1953) found that there existed two axes of rotation of the ankle joint. One was for dorsiflexion and was directed laterally, posteriorly and downward. The other for plantarflexion was directed laterally

backward and upwards. Inman (1976) studied samples of ankles and concluded that 80% had a single axis that was directed laterally posteriorly and downwards. Clearly from a design point of view, it would simplify the manufacturing process to have a prosthesis with a single axis of rotation. It is important, however, that this axis is correctly orientated when the prosthesis is implanted.

If the desired helicoid motion is attained by cutting a helix on the surface of a cylinder, the axis of the prosthesis must be directed in a transverse plane. If it were not, then the tibial component would tend to slide laterally off the talar component. Besides this consideration, having an axis in a transverse plane would satisfy the findings of Hicks, since the average of the two axes he proposed would be approximately in the transverse plane.

To mimic the normal anatomy of the ankle still more closely, it is proposed that the axis of rotation be directed laterally and posteriorly. No previous design has specifically positioned the axis in such a manner, but it is felt this is important to prevent loosening of the implant.

If the desired helicoid motion is attained by cutting a helical groove on the surface of a cone, then it is possible to get an axis that is positioned downward as well as laterally and backward. Unfortunately as the tibial component moves over the talar component there will be varying degrees of contact between the two. The fit between the two surfaces will have to be very loose to accommodate the smaller curvatures near the apex of the cone as well as the larger ones nearer the base. For these reasons the option of using a cylindrical section with a helix is deemed more appropriate.

4.2 Method of Fixation : Introduction

It is vitally important that any joint prosthesis remain firmly in place for at least a decade. Naturally it would be ideal if an implant could remain fixed to bone for an entire lifetime, but at present this is unrealistic. The best that can be done is to try and eliminate those factors responsible for loosening of the prosthesis.

One such factor has been considered in the first part of this chapter. A cylindrical helical prosthesis with an oblique axis of rotation would seem to harmonise with the actions of both muscles and ligaments crossing the ankle. This feature would assist in reducing undesirable stresses at the bone/cement interface (or bone/prosthesis interface in the case of cementless fixation).

Lewis et al (1983) reports that loosening of the prosthesis at the bone/implant interface is a major cause of failure of total joint replacements, especially for the acetabular component of the hip and the tibial component of the knee. They outlined three mechanisms which play a role in loosening:

(a) failure of the interface due to excessive stresses

(b) inadequate strength of the interface bond

(c) biological reactions at the interface.

It has been a common finding of many artificial joint arthroplasties that after a period of time, there exists a fibrous layer between the bone and the cement (Hori et al, 1983). This fibrous layer is usually about 1 to 2mm thick, and unfortunately it has low tensile and shear strengths. A good prosthesis design should thus try and eliminate stresses at the bone/cement interface which are of a tensile, shear or torsional nature and in addition limit compressive stresses to an acceptable level.

The major direction of load transfer through the ankle is in the vertical direction. There should therefore be a large contact area between the prosthesis and the bone (in a transverse plane) so that compressive stresses on the interface can be reduced as much as possible. Naturally the largest possible contact area is limited by the cross-sectional area of the bone at the interface and is different in size and shape for each ankle specimen.

4.3 Method of Fixation : Tibial Component

In the case of the tibial component, Freeman **et al** (1979) arranged for the proximal surface to be made oversize in the antero-posterior direction. This could be trimmed to fit the bone at operation since it was made of high density polyethylene. One disadvantage with this prosthesis is that two skin incisions are needed (one anteriorly and one posteriorly) in order that trimming can be carried out. A better method might be to enter through the fibula and trim the component from the lateral side. This would only require one incision (although the fibula would be temporarily transected).

It is interesting to compare other designs of tibial components which do not provide an oversized upper surface. Demottaz et al (1979) looked at the clinical results of a number of ankle replacements, none of which featured an ICLH prosthesis. (The prostheses used were: Smith, Mayo, TPR, Buchholz, Oregon and Waugh.) The average position of these components after about fifteen months in vivo was 2,9 $\pm$ 4,4° inversion. This indicates that the tibial component was more supported by the cortical bone on the lateral side and less so by the cancellous bone nearer the medial side. (If the medial malleolus was replaced, then there would be cortical bone supported on both sides. However, since it

is imperative to keep the medial malleolus and its associated ligaments intact, there cannot be cortical support on the medial side.) In the case of the ICLH prosthesis, the tendency to invert will be less pronounced since there is cortical support on three sides of the bone/prosthesis interface. In addition, the tendency for anterior or posterior tilt will similarly be reduced.

Calderale et al (1983) are of the opinion that the ICLH method of distributing contact stresses at the tibia/prosthesis interface will cause the wall of cortical bone to open and buckle when loaded. This certainly seems a possibility, since the resection of the lower epiphysis of the tibia (to compensate for height of the prosthesis) could allow the cortical bone to 'open'. Calderale and his fellow researchers proposed an intramedullary stem on the tibial component to transfer loads to the strong tibial diaphysis. They felt this would substantially reduce the chance of loosening.

There are however problems associated with the use of intramedullary stems. First, they tend to increase the operative area which in turn increases the risk of infection. Second, the removal of stems can damage the surrounding cancellous bone which could make arthrodesis more difficult. Third, a very important function of cancellous bone is bypassed - that of shock absorption at heel strike. Another prosthesis which has an intramedullary stem on the tibial component is the "Irvine" ankle (Waugh et al, 1976). Since no thorough follow-up on the "Pipino-Calderale" prosthesis has been performed, it seems best to study the results obtained using the Irvine prosthesis. In one study, of twenty one ankle replacements, four used Waugh's prosthesis (Demottaz et al, 1979). These had an average of $2,8 \pm 4,7^{o}$ inversion of the tibial part, and although the sample size is small, it seems that inver-

sion is not prevented by using stems. (Other post-operative studies on the Irvine prosthesis (Evanski and Waugh, 1977) have not given roentgenographic details.)

In the absence of any other data it thus seems prudent to design the tibial component so that it is oversized and allows for trimming during the operation. In addition, the use of stems is not warranted at this stage. (In the case of hip replacement, the large bending loads that are encountered make the use of stems imperative. The ankle joint, however, is not subjected to such loads.)

Besides compressive loads, the ankle is also subjected to tangential loads in the transverse plane. Naturally, there must be some method of preventing the tibial component from sliding forwards or sideways. Many designs (ICLH, TPR, Mayo, etc.) use fixating projections made from high density polyethylene or some similar plastic. These protrude into the cancellous bone and are grouted into place. Although UHMWPE is an excellent bearing material, its structural properties are lacking when used as a peg or ridge for fixation. For this reason it is felt that a system similar to that employed in the "Oregon" ankle implant is an excellent idea. In the Oregon system, the plastic is moulded on a metal endoskeleton to form the top half of an ankle prosthesis. The metal which projects into the bone is less likely to become rounded and loosen under repeated loading. (The actual shape and size of the projection will be discussed later.)

4.3.1 Shape of Projections

There are various factors which constrain the shape and size of pegs or ridges which protrude into the cancellous bone of the tibia. The projection(s) should;

(a) be limited in volume and surface area (to reduce resection and exposed area of bone)

(b) distribute forces in the antero-posterior and medio-lateral directions such that no bone resorbtion occurs at the interface

(c) reduce shear, tension and torsion at the interface (i.e. only allow compressive stresses)

(d) withstand forces tending to tear them at their base

(e) be limited in height (so that they do not protrude past the epiphyseal line and in addition do not severely weaken the shaft by creating undesirable bending moments)

(f) be easy to insert from a surgical point of view.

These factors will be used to design a method of fixation for the tibial component. Initially a single ridge will be designed based on certain assumptions.

4.3.2 Assumptions

With reference to Figure 4.8, it is felt that a tangential force can cause the bone to fail in three ways:

(A) transverse fracture

(B) crushing failure

(C) spalling at the corner.

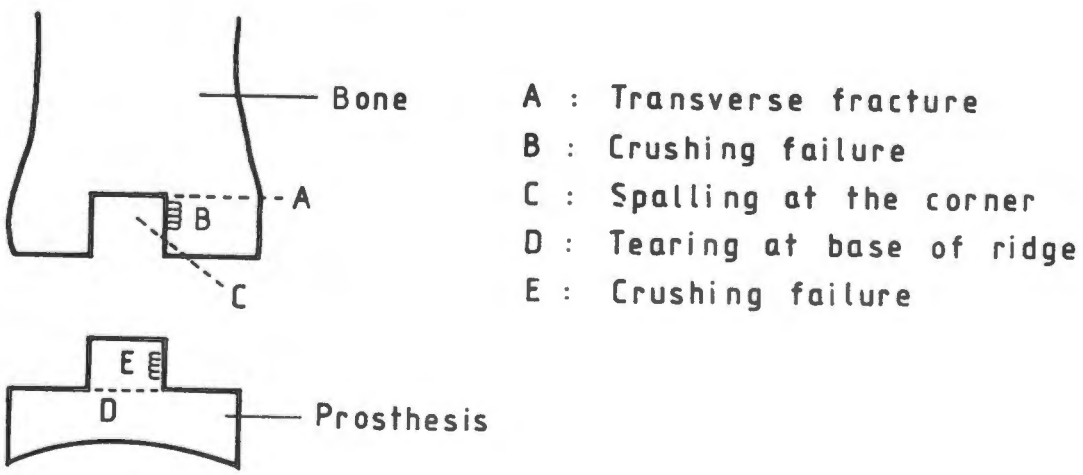


Fig. 4.8 Modes of Failure

In addition, the projection could fail as follows;

(D) tearing at its base

(E) crushing failure.

It is further assumed that the bone will not suffer fatigue failure as it is constantly being renewed at a faster rate than it is being damaged. This however does not apply in the case of the materials making up the artificial joint. Past experience has shown that prosthetic materials can and do fracture from fatigue stresses.

As can be seen from Figure 4.9, there are a variety of possible reactions caused by a single tangential force at the distal surface of the tibial component. For this reason it seems permissible to assume a stress distribution based on similar situations found in engineering practice.

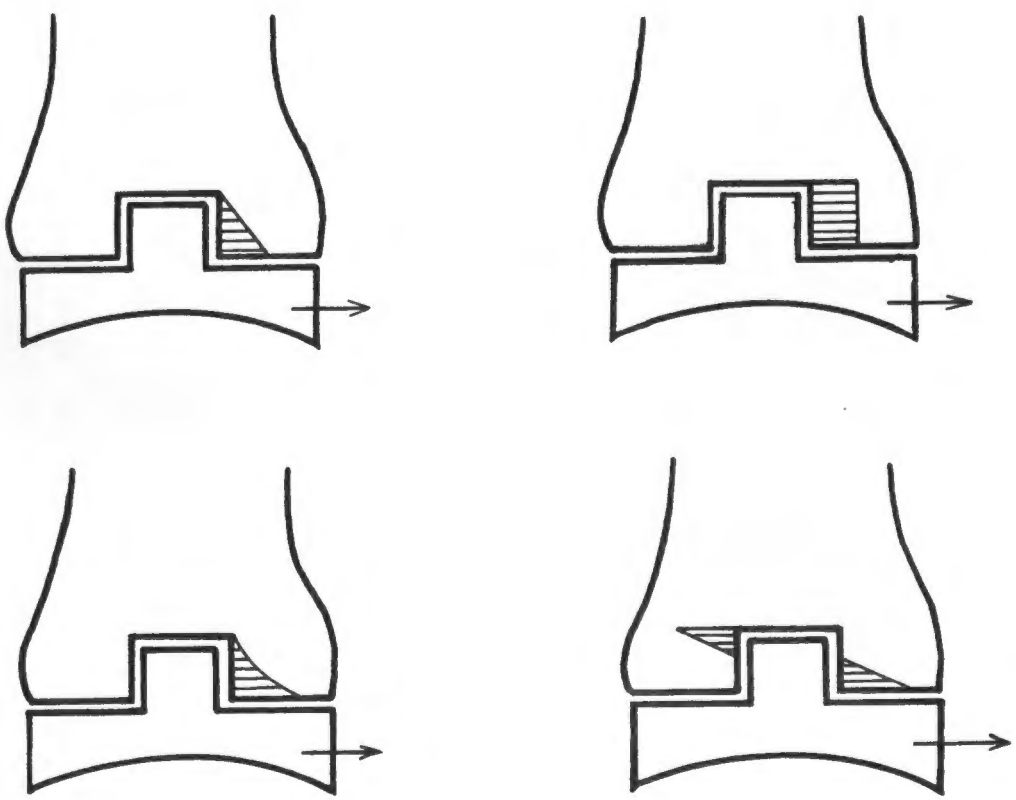


Fig. 4.9 Stress Distributions

If the projecting ridge is likened to a beam and the surrounding bone to cement, then possible stress distributions are shown in Figure 4.10 (Thorley, 1978). If the rotation of the end of the beam is restricted (as it is in the case of tibial fixation) by concrete on all sides of the beam, then the stress diagram is still more difficult to analyse. It seems practical to assume a triangular stress distribution since this is both conservative and simple to obtain. (It is conservative since it is more likely to cause bone failure than is the rectangular stress distribution shown in Figure 4.10.)

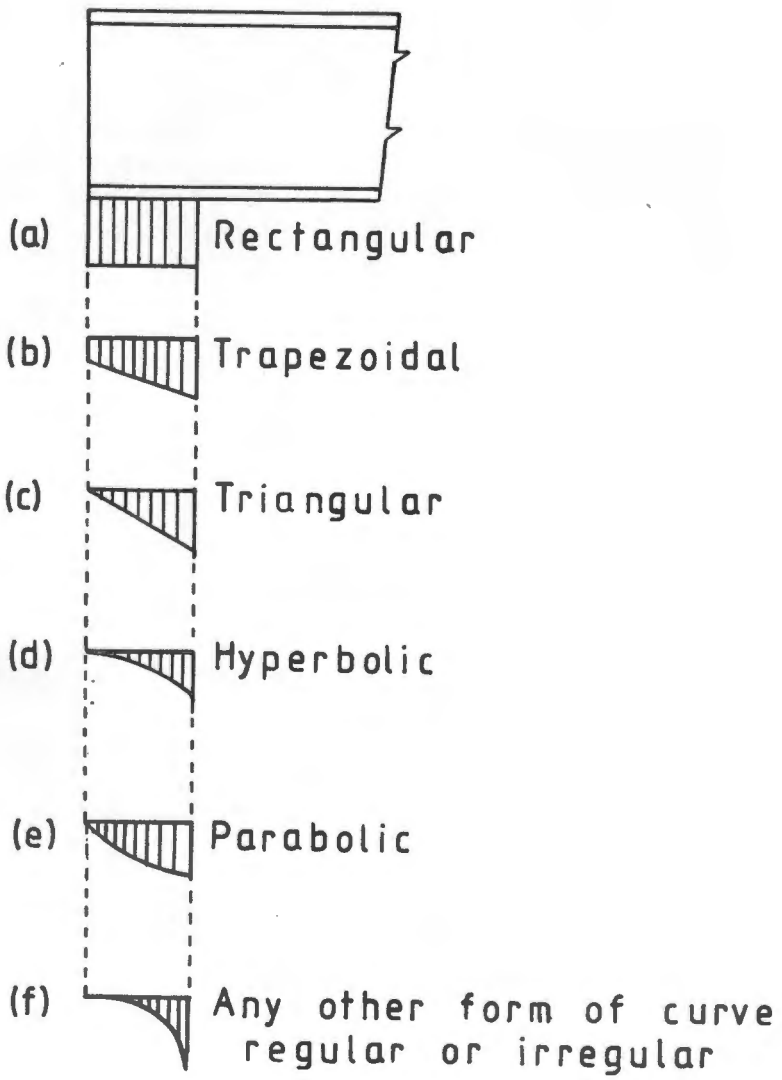


Fig. 4.10 Stresses Under an I-Beam (Thorley, 1978)

Two other factors pointed out by Thorley are that chamfers should be provided to prevent spalling and that an effective length of beam would approximately be equal to its depth (as shown in Figure 4.11. This latter factor would not apply if the cement was less stiff than the beam - or if stainless steel was grouted into cancellous bone. In this case the triangular stress distribtion would probably cover the entire interface.

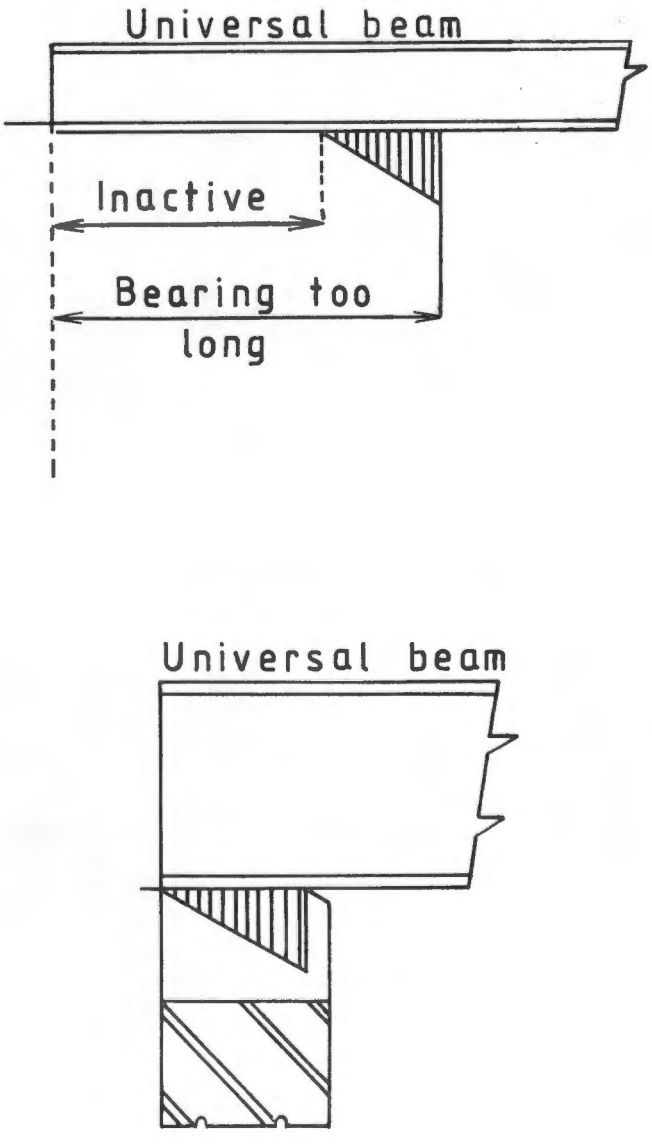


Fig. 4.11 Design of Beams (Thorley, 1978)

During normal walking the predominant load across the ankle is directed up the shaft of the tibia, and has been estimated by various authors (Procter and Paul, 1982; Patriarco et al, 1981; Seireg and Arvikar, 1975). However, besides this load, there are joint reactions perpendicular to the shaft of the tibia. Unfortunately these components of the total joint force have been subject to less scrutiny than the main compressive force.

Procter and Paul, for instance, did not give the individual components that make up the total load across the ankle, nor the direction of the resultant force. Patriarco et al, however, estimated peak forces for a subject weighing about 560N as follows;

antero-posterior:	0,2BW	at 7% of cycle
	-0,2BW	at 50% of cycle
medio-lateral :	-0,09BW	at 12% of cycle
vertical :	1,2BW	at 50% of cycle

As can be seen, the ratio between the two tangential forces is $\pm$2,2. This ratio is very similar to that given by Seireg and Arvikar in their study on joint reactions. In this case the peak forces were:

antero-posterior:	+2,2BW	at 50% of cycle
medio-lateral :	-0,8BW	at 48% of cycle
	+0,8BW	at 50% of cycle
vertical :	5,2BW	at 50% of cycle

Although the ratio is similar, the timing is different as is the absolute magnitude of the individual components. The values of Patriarco et al. seem to be too small by a factor of at least four (since his peak compressive stress is just over body weight and other authors give values of about 4BW).

A simple two-dimensional study carried out by Stauffer et al (1977) on the ankle joint gave forces on the talus in the antero-posterior direction to be approximately 0,7 times body

weight (i.e. one third of that of Seireg and Arvikar). It should be noted that, unlike other recent studies, Stauffer et al. specified the joint surface on which the tangential forces acted. It thus seems likely that this simple model is more correct than the other, more complicated, models.

The peak tangential loads on the distal tibia during walking will therefore be assumed to be;

antero-posterior: -0,7BW

medio-lateral : -0,3BW

(i.e. directed anteriorly and medially).

During running it can be expected that the vertical and anterior forces will increase substantially since at heel-strike and toe-off the person is directed in the sagittal plane at an angle to the ground. In a study by Burdett, the maximum anterior shear force on the ankle was found to be between 3,3 and 5,5BW whereas the peak medio-lateral shear ranged between -0,8 and 0,5BW. For the purposes of this study it will be assumed that patients spend most of their time walking (and not running).

In order to design any device, it is imperative to know the properties of materials that are available. The device can then be designed to accommodate the assumed loads.

In the case of an ankle prosthesis it has already been stated that the fixating projections should be made from metal (and not UHMWPE). The most readily available material in this category is stainless steel (e.g. an austenitic grade such as 316L). If a filler cement is used, then the properties of interest to the designer are those of: stainless steel

filler cement

cortical and cancellous bone

UHHMWPE

The last mentioned in the list above has been included since fixating projections made from UHMWPE will be designed with the purpose of comparing other prostheses. The properties of the materials of interest are listed in Table 4.1

Material	Ultimate Tensile Strength (MN/m)	Tensile Yeild Stress (MN/m)	Young's Modulus (GN/m)	Compressive Strength (MN/m)	Fatigue Strength (10 cycles) (MN/m)	Source
Annealed s/s(316L)	520-620	250-330	200		245-300	Weightman (1981)
Filler cement	25		2	80	<14	"
Cortical Bone	80-160		20	130-280	30	"
HMWPE	43	22	0,5	20		"
UHMWPE			0,7 (flexural)	12 (yield)	15	Zimmer catalogue
Cancellous Bone			1-2	38		Carter (1982)

Table 4.1 Properties of Materials

It is important to know the geometric properties of the ankle joint as well as the material properties before the fixation for an artificial substitute can be designed. Since the author is of the opinion that finite element analyses of the ankle joint have severe limitations as well as being very time-consuming, it is felt that the shape of the joint will rather be simplified in some convenient and yet meaningful way.

On inspection of cross-sections of the tibia, three factors are apparent:

(a) As the cross-sections move proximally their respective areas decrease asymptotically to some value.

(b) These areas are bounded by hard cortical bone.

(c) The shape of the cross-sections lies somewhere between a circle and a square.

By considering the above factors it was decided to approximate the distal end of the tibia to that shape shown in Figure 4.12.

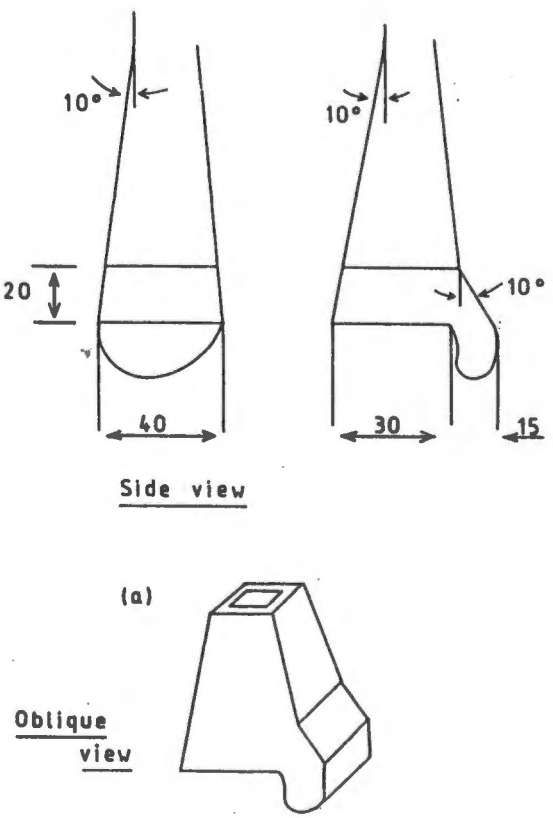


Fig. 4.12 Model of Tibia

4.3.3 Design of a Single Ridge.

The procedure for designing a single ridge to protrude into the distal end of the tibia will be as follows;

(a) The ratio of the lengths of the sides will be chosen as 7:3 since the peak compressive stresses on each side will then be equal. This means there will be two variables; the height (h) of the ridge and the width (x). (The length will be 2,3x.)

(b) Various volumes of the ridge will be chosen and for each volume a set of combinations of x and h will be calculated. This means that for a particular volume, h will be a function of x.

(c) For each combination of x and h the following stresses will be determined:

* compressive stress between bone and ridge
* principal stress on base of ridge
* resultant stress on bone adjacent to the anterior apex of the ridge
* maximum resultant stress on anterior aspect of the tibia

(d) By knowing the allowable stress limits, discussed earlier, a combination of x and h will be chosen which best satisfies the criteria listed in section 4.3.1.

Compressive Stresses Between Bone and Ridge. In Appendix E a relationship is derived between the maximum compressive stress and the height and width of the ridge. This relationship is depicted in Figure 4.13 for various volumes (200-2000ml).

If the yield strength of cancellous bone is 30 MPa and a factor of safety of 4 is used (see Appendix C) then the allowable

stress limit is reduced to 7,5 MPa. In Figure 4.13 values of x which will give stresses below this limit are shown for each volume.

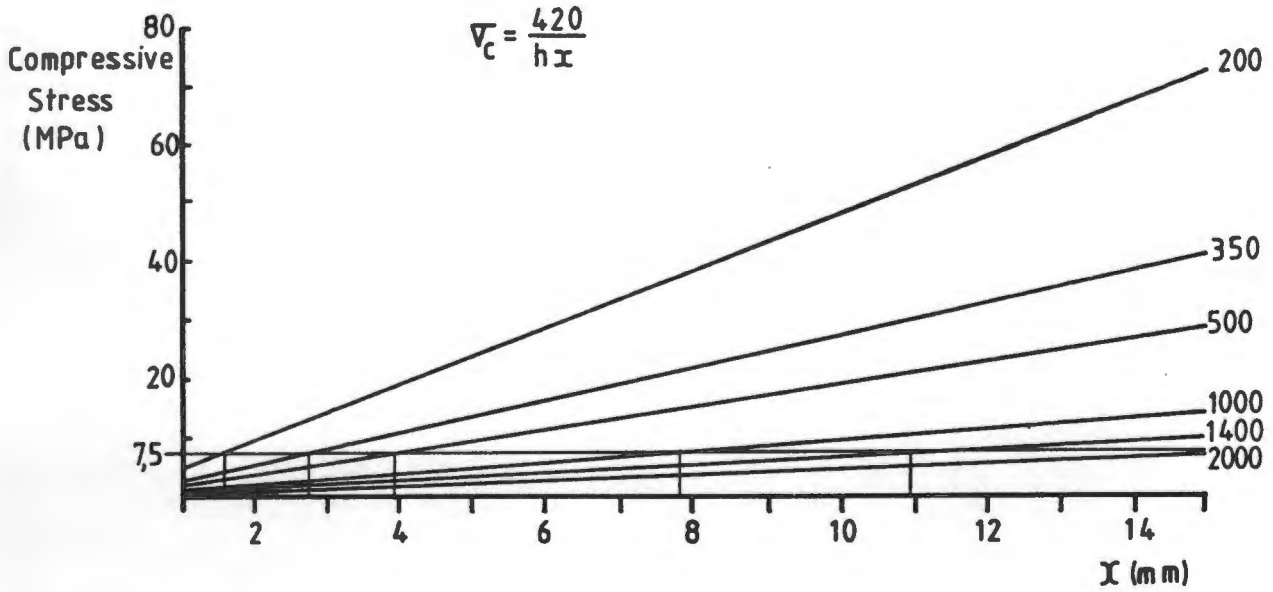


Fig. 4.13 Compressive Stresses Between Ridge and Bone for Various Volumes

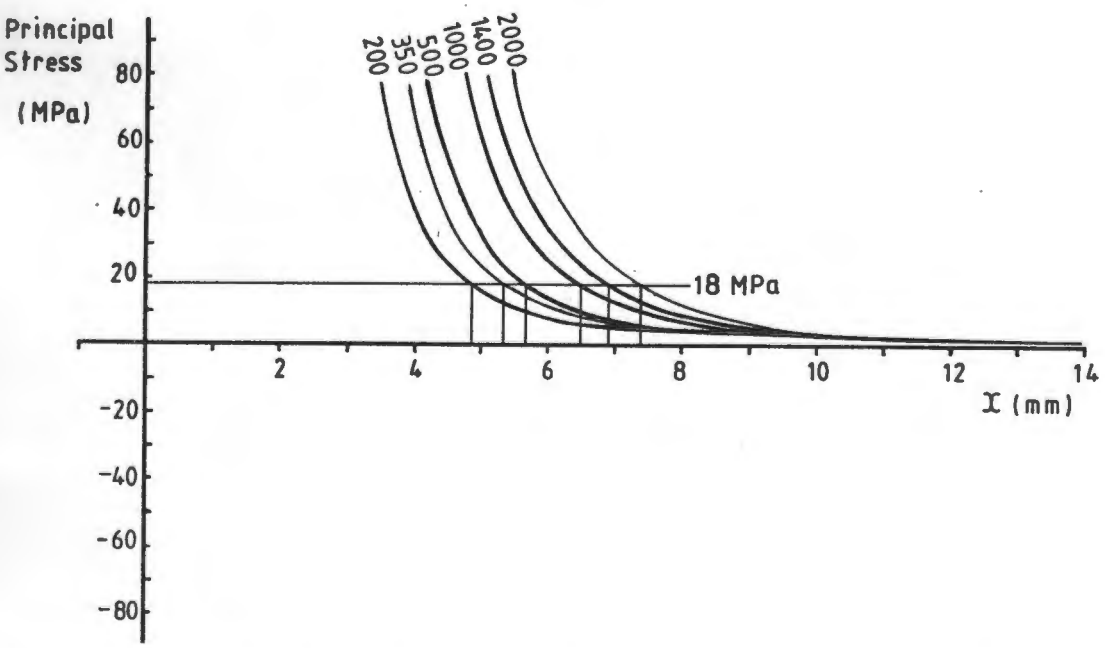


Fig. 4.14 Maximum Principal Stresses on Base of Fixating Ridge for Various Volumes

Principal Stress on Base of Ridge. The relationship between x and h and the principal stress (derived in Appendix F) is shown in Figure 4.14. If a stress of 18 MPa is permitted for stainless steel (see Appendix D) then another set of permissible values of x can be obtained.

A notable difference between Figures 4.13 and 4.14 is that in the former stress is proportional to x whereas in the latter it is inversely proportional to x. This means that for a particular volume (say 1000ml) there is a specific range of x values which satisfies both criteria. These ranges are shown in Table 4.2.

Volume (ml)	Range of x (mm)	Corresponding range of h (mm)
0,2	No range satisfies both conditions	
0,35	No range satisfies both conditions	
0,5	No range satisfies both conditions	
1	6,5-7,75	10,3-7,24
1,4	6,9-10,9	12,8-5,12
2	7,4-15,5	15,9-3,6

Table 4.2 Possible Dimensions of Fixating Ridge

Stress on anterior (or posterior) tibial wall. For a fracture to occur through the anterior (or posterior) cortex, either a crack must originate on the inside of the bone or the outer cortex must fail under compression. For a crack to start adjacent to the fixating ridge, there must be a nett tensile stress. (In other words, for such a failure the compressive stress caused by the

vertical loads must be less than the tensile stress caused by bending of the anterior tibial wall.)

In Appendix F a relationship is derived for an assumed tibial configuration which can allow one to choose h and x such that there is always compression on the anterior tibial wall (see Figure 4.15).

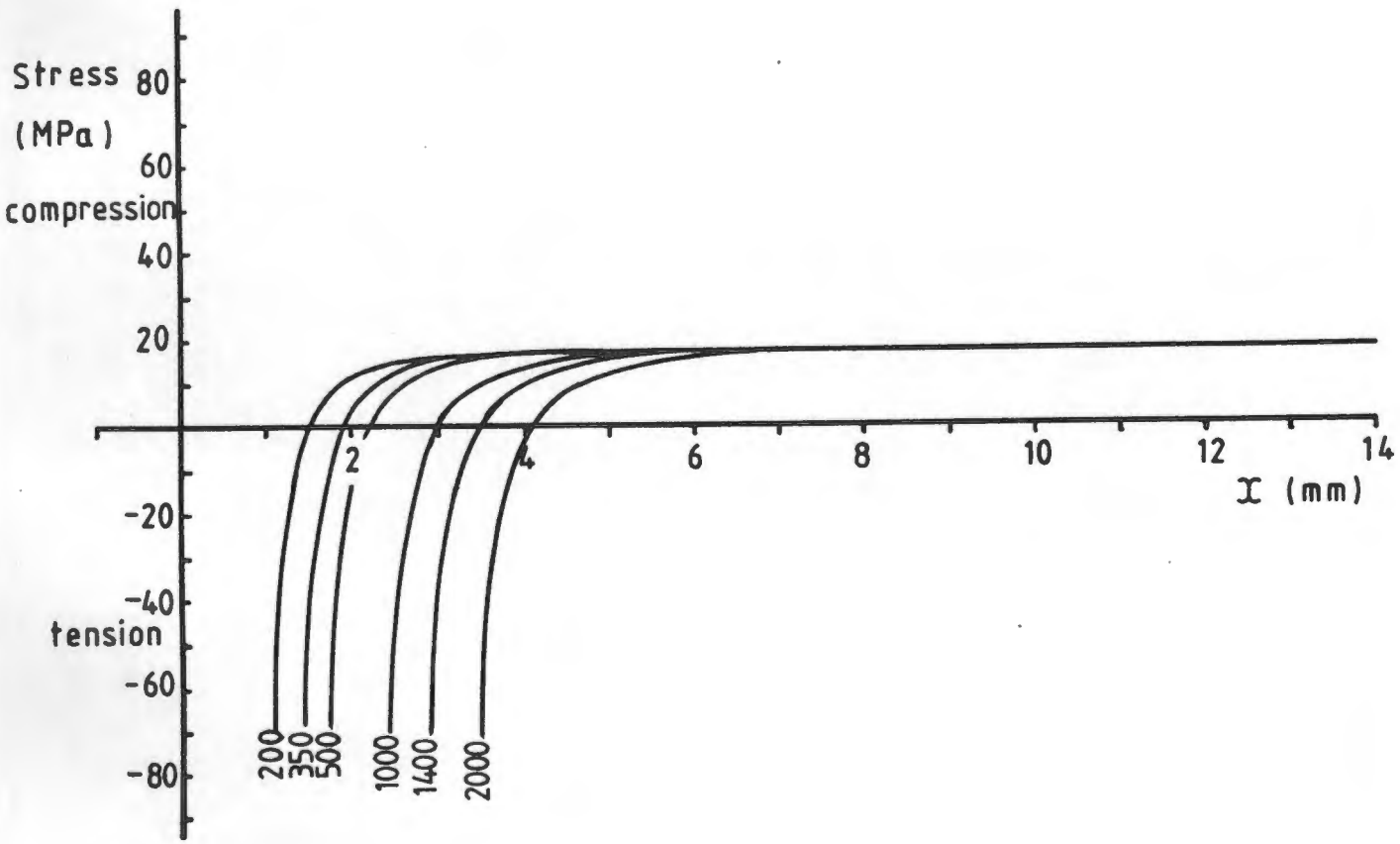


Fig. 4.15 Stresses on Anterior Tibial Bone Adjacent to Apex of Ridge (For Various Volumes of Ridge)

It will always occur that the compressive stresses on the outside of the anterior tibial cortex will be greater than those adjacent to the ridge of the prosthesis since the outer bone

cells are subjected to body weight and compressive bending stresses (see Appendix G). If the ridge is thus designed so that there is no chance of a tensile crack appearing inside the bone (by having substantial compressive stresses in this region) then there might be the danger of the outer cells failing under compression.

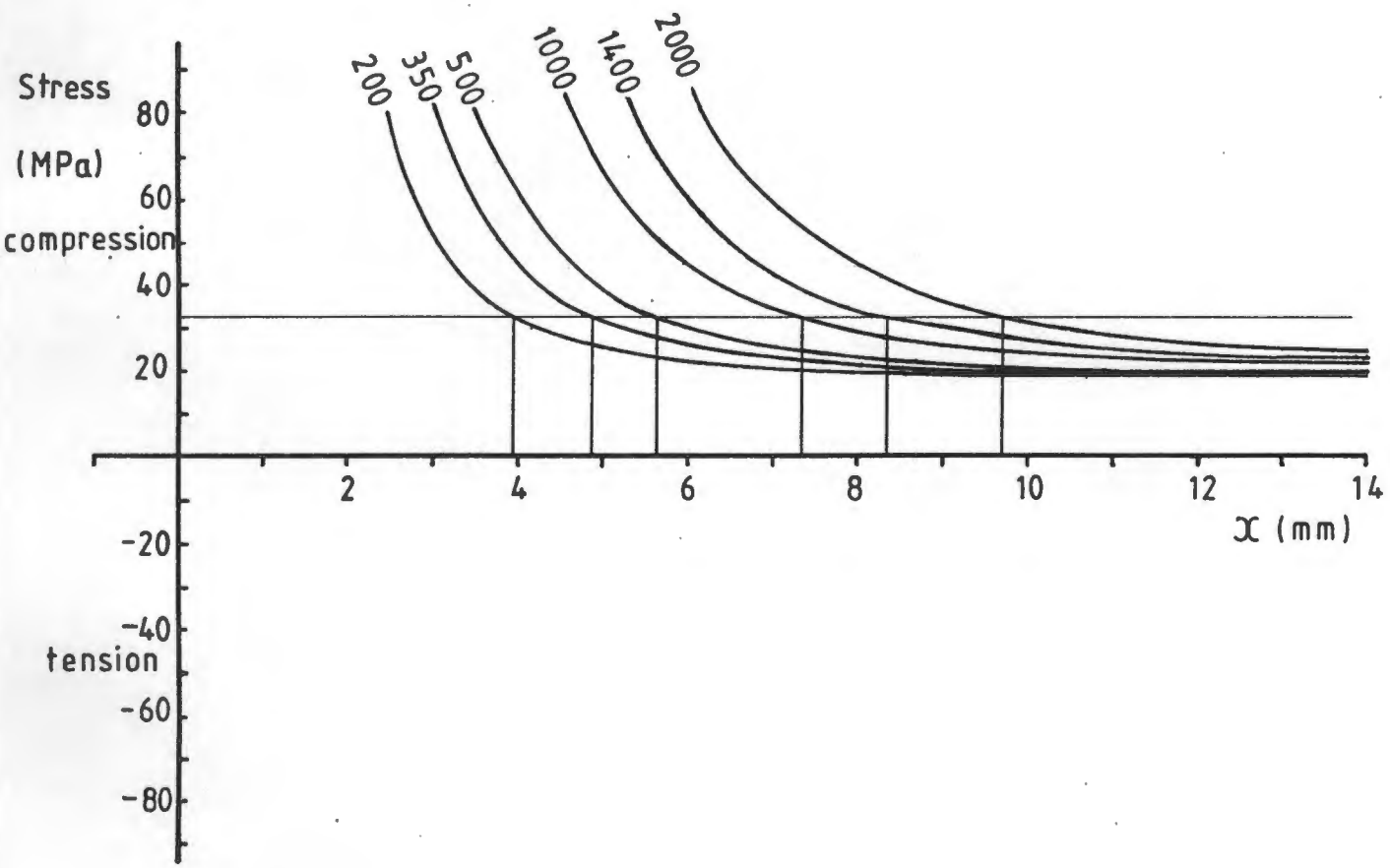


Fig. 4.16 Stress on Outer Aspect of Anterior Tibial Cortex (for Various Ridge Volumes)

By comparing Figures 4.15 and 4.16 it can be seen that if a compressive stress level of 33 MPa is permitted on the outer cortex (see Appendix G) then the stresses on the inner surface of the bone are automatically of a compressive nature. Figure 4.16

shows in addition that larger values of x are preferable.

In the light of these findings new ranges of x values can be chosen such that there is little chance of any failure occurring. From the theoretical model used in Appendices E to G, the following conclusions can be drawn;

(a) The upper limits of x are set by considerations of compressive stress between ridge and bone.

(b) The lower limits of x are set by considerations of compressive stress on the outer aspect of the anterior tibial cortex.

(c) Ridges with volumes substantially less than 1ml are liable to fail.

Suggested ranges are given in Table 4-3.

Volume (ml)	Range of x (mm)	Corresponding range of h (mm)
1	7,2-7,75	8,4-7,24
1,4	8,2-10,9	9,1-5,1
2	9,6-15,5	9,4-3,6

Table 4.3 Possible Dimensions of Fixating Ridge

4.3.4 Design of Two Fixating Ridges

The procedure for designing two ridges will be slightly simpler than that used to design a single ridge since dimensions will first be estimated and stress levels then checked. The reason for this approach is that once an idea of the size of a single ridge has been obtained, it is not too difficult to estimate the dimensions of dual fixating ridges.

From Table 4-3 it can be seen that the smallest suitable

volume for a ridge is approximately 1ml. If "x" is chosen as 7,2mm then "h" equals 8,4mm. This combination gives the ridge a cross-sectional area (in the sagittal plane) of 60,5mm^2, and a length of 16,6mm.

In the case of two ridges it was decided to give each ridge a cross-sectional area equal to half this and in addition, keep the ratio between h and x the same. This meant that the new values to be tested were;

h = 6mm

x = 5mm

It was also decided to keep the length of each ridge at 16mm so that the total volume remained approximately 1ml.

Stress Analysis. Since the total contact area between the ridges and the bone has not been diminished, the compressive stresses will not exceed the limit of 7,5 MPa. (In the coronal plane, the contact area has almost been doubled so the stresses will be considerably lower.)

In Appendix H, it is shown that for two ridges of the above dimensions, the principal stresses on the base of the ridge are well within the allowable value of 18 MPa. The last analysis (concerning compression on the anterior tibial cortex) is performed in Appendix I. In this instance the resultant compressive stress (due to bending and axial compression of the tibial wall) is much the same as that for the single ridge of volume 1ml and width 7,2mm. The stress of 32,3 MPa is still within the limit of 33 MPa, and can therefore be regarded as "safe". (It is interesting to note that once again the factors constraining the size of the ridges are first the compressive stresses between the ridges and the bone and second the compressive stresses on the outer anterior tibial cortex. This might not have been the case if

UHMWPE had been chosen as the material for the fixating projections.)

In summary, it has been calculated that two ridges 10mm apart, 6mm high, 5mm wide and 16mm long will give adequate fixation for the tibial prosthesis. In addition, this combination requires the least amount of bone resection and is simple to insert from a surgical point of view.

4.4 Method of Fixation : Talar Component

4.4.1 Shape of Projections

The factors which constrain the shape and size of the pegs or ridges which protrude into the talus are slightly different to those concerning the tibia.

(a) Since the height of the prosthesis is taken up by resecting the tibia, the talar dome can be preserved to a large extent.

(b) If the talar part of the prosthesis is made from a cylindrical tube, then anterior and posterior forces will be taken up by the dome of the talus (see Figure 4.17). The TPR ankle prosthesis uses this principle.

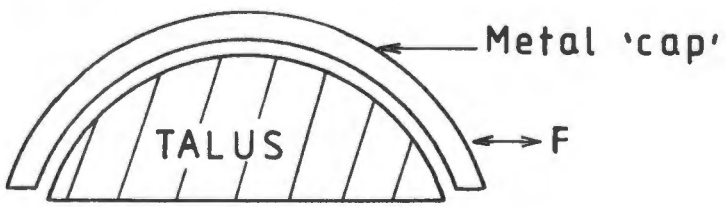


Fig. 4.17 Talar 'Cap'

(c) If side walls are added to the prosthesis then the talar unit would form a cap which could be fitted over the talar dome. In this way medio-lateral forces could be accommodated as well. (The Oregon ankle prosthesis uses this technique.) The main purpose of a fixating peg in a system such as this would be to prevent rotation in the sagittal plane.

(dd) Calderale et al (1983) simulated the structure of the talus on a computer and concluded that the cortical bone disperses localised loads over a wide area of cancellous bone. Resection of a part of this shell (such as with implantation of the ICLH prosthesis) causes abnormal stresses on the cancellous bone.

After considering these factors, it was felt that a system similar to that employed by the Oregon ankle prosthesis was the best solution. It was felt, however, that there should be less resection of bone (so that an arthrodesis salvage procedure coulld be performed). This could be achieved by making the medial and lateral sides of the talar component much steeper. In addition, if these sides were parallel, then implantation should be easier. (Since the instrumentation needed would be simpler to use.)

One problem that presented itself was that a lateral approach makes it difficult to gain access to the medial side of the talus. (In the Oregon system it is fairly easy to resect the bone on the medial and lateral side of the talus since an anterior approach is used.) Cadaver trials showed, however, that it is possible to get sufficient exposure for an oscillating saw to be used. (It must be remembered that about 8mm of the distal end of the tibia are removed and this provides further space for anoeuvering.)

Once it has been decided to use a "cap-like" talar compo-

nent, the only question remaining was how to prevent it rockinng on the talar dome. It was thought that the method used in the TPR and the Oregon system of a single central cylindrical peg was sufficient. The factors constraining the shape of this peg are as follows;

(a) It must not severely disrupt the blood supply of the talus

(b) It must not snap off from the undersurface of the prosthesis

(c) It must not severely weaken the talus

(d) It must be short for easy insertion

4.4.2 Assumptions

The assumptions regarding joint forces and strength of materials will be identical to those discussed previously (Section 4.3.2).

The tangential loads will be assumed to act solely on the peg, although in reality, the talar dome will bear a portion of these loads. It will also be assumed that the peak medio-lateral force acts at the same time as the peak antero-posterior force.

The gross shape of the proximal surface of the talus will be based on findings by Medley et al (1983). They obtained the following average dimensions (see Figure 4.18).

radius = 22mm

width = 26mm

a/p length = 35mm

The final assumption is that regarding stress distribution. If the ratio of the Young's Moduli of cortical and cancellous bone is assumed to be twenty then the stress on cortical bone will be twenty times that on the cancellous bone. In addition,

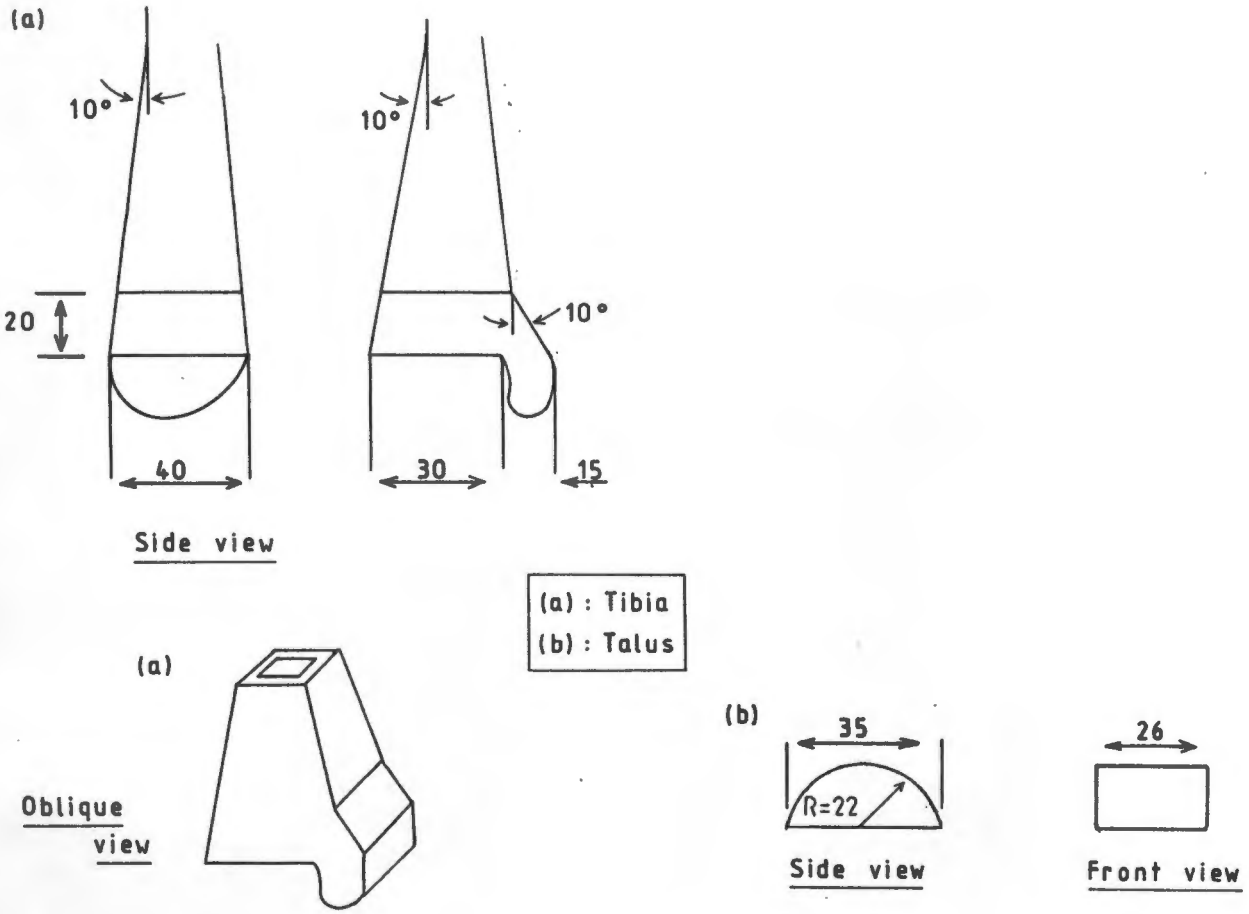


Fig. 4.18 Model of Talus

the actual distribution on each of the bone types will be assumed as shown in Figure 4.19.

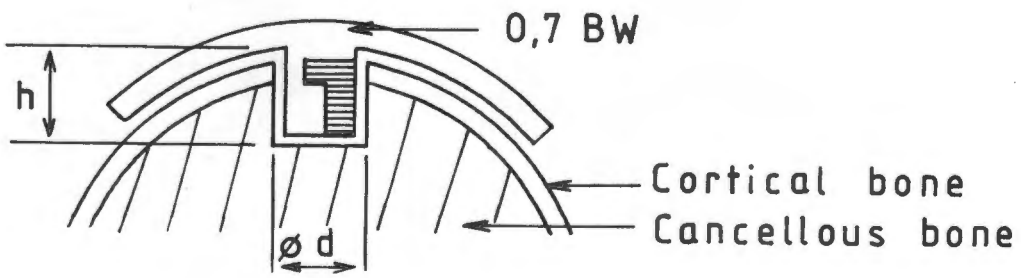


Fig. 4.19 Stresses on Central Peg

4.4.3 Procedure

The modes of failure of talar fixation will be limited to the cases of compressive failure between peg and bone. There is a possibility of the cylindrical peg fracturing, but since most of the stress will be adjacent to the cortical bone the bending moment tending to cause failure at the base of the peg will be negligible.

From Appendix J it can be seen that suitable dimensions of the projection are:

diameter = 4mm

height = 7mm

To drill the hole into the crest of the talar dome with a conventional drill and bit may be difficult due to the limited space between the talus and the tibia. (Even when the joint is prised open.) For this reason, the system of using an oscillating cutter such as in the ICLH procedure is preferred (see Figure 6.2).

4.5 Size of Prosthesis

In section 4.3 it was assumed that the width of the tibial component was 30mm and the height 10mm (i.e. 10mm of the distal end of the tibia would be resected in order that the prosthesis could be fitted).

By resecting the tibia in such a manner it is possible for a transverse fracture to occur through the medial malleolus. With regard to such a fracture, the following points are relevant:

(a) The malleolus is not subjected to a compressive load (as are the anterior and posterior apsects of the cortical wall).

(b) The outer aspect can be placed in tension as the powerful deltoid ligament is attached to it. (Eversion of

the foot could cause such tension.)

(c) The average force in the medial direction is about half that in the anterior direction.

(d) Besides the resection needed to accommodate the height of the prosthesis (previously assumed to be 10mm) the medial malleolus need not be weakened. (It is intended that the prosthesis be inserted from the lateral side.)

In the case of failure through the medial malleolus, the origin of bone fracture will not be at the apex of the fixating projection but rather on a plane through its base (see Figure 4.20).

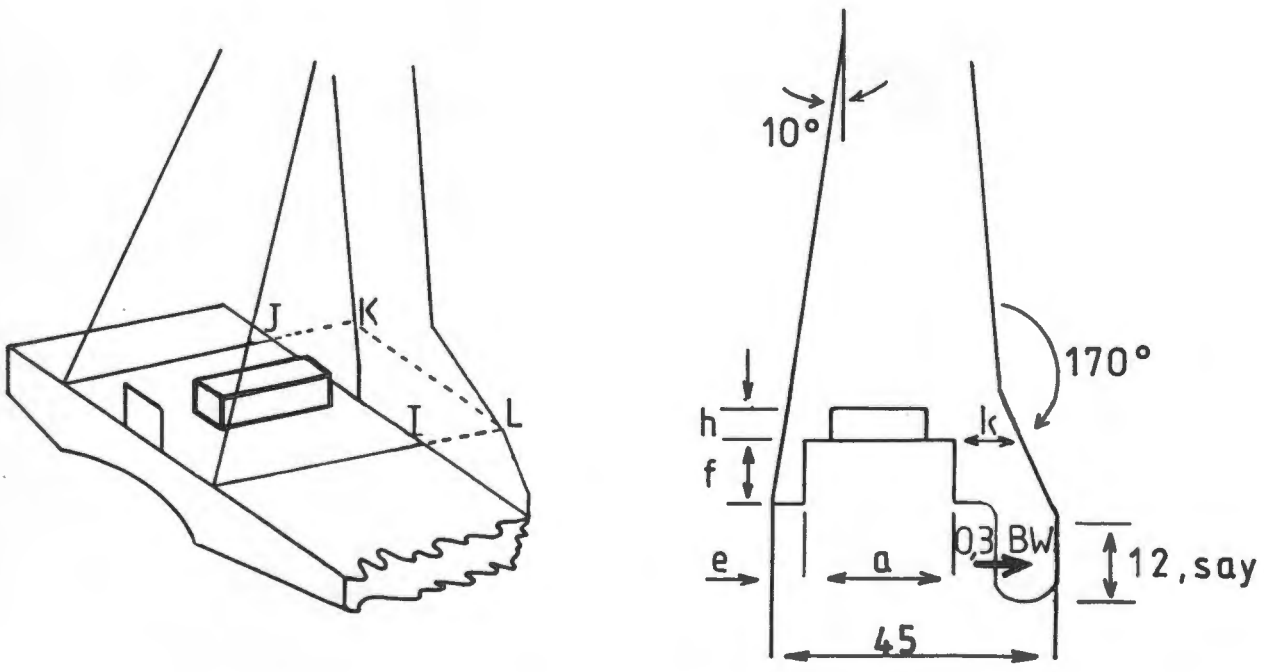


Fig. 4.20 Modelling Fracture Through Medial Malleolus

In Appendix K the equations relating height and width of the prosthesis to the compressive stresses on the outer aspect of the malleolus are derived for a load of 0,3 BW in the medial direction. From Figures 4.21 and 4.22 it can be seen that the height and width are constrained by the tensile rather than the compressive stress limit.

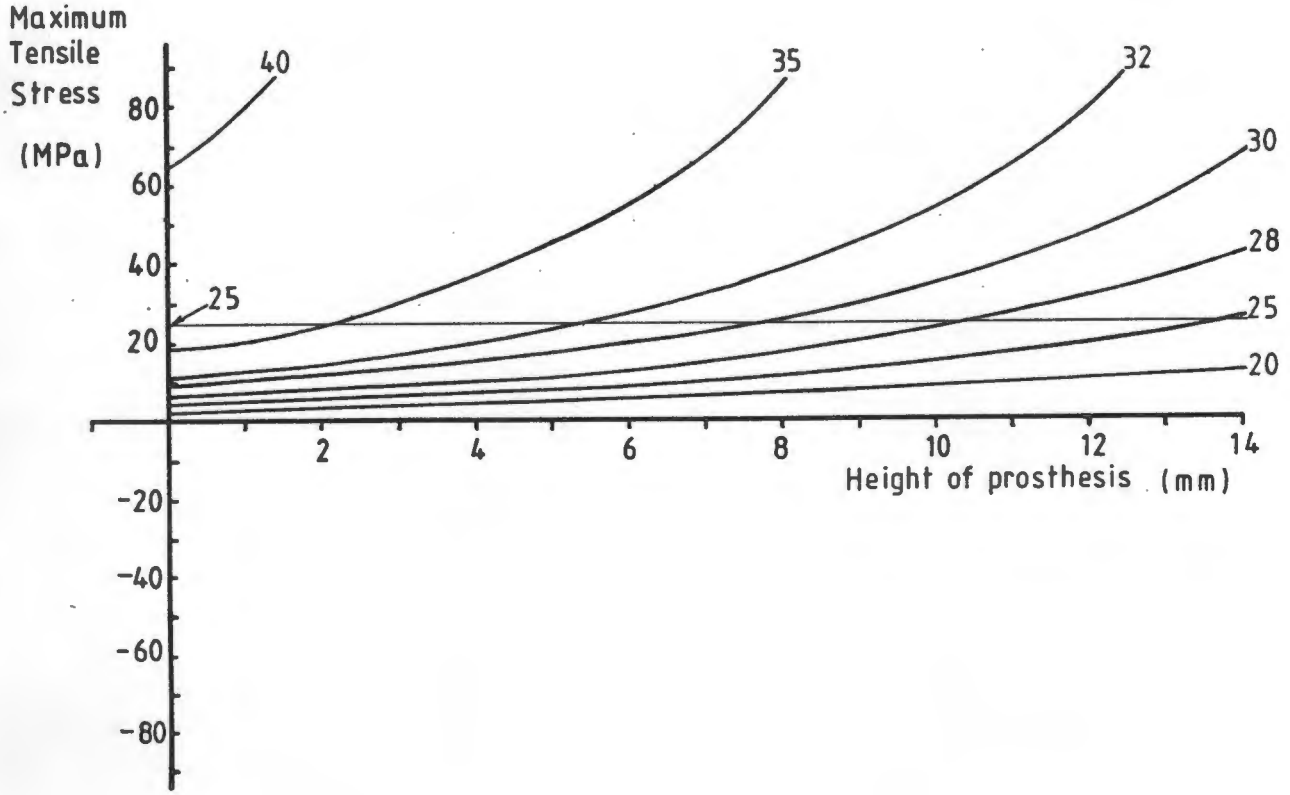


Fig. 4.21 Stress on Inner Surface of Medial Malleolus for Various Widths of Prosthesis

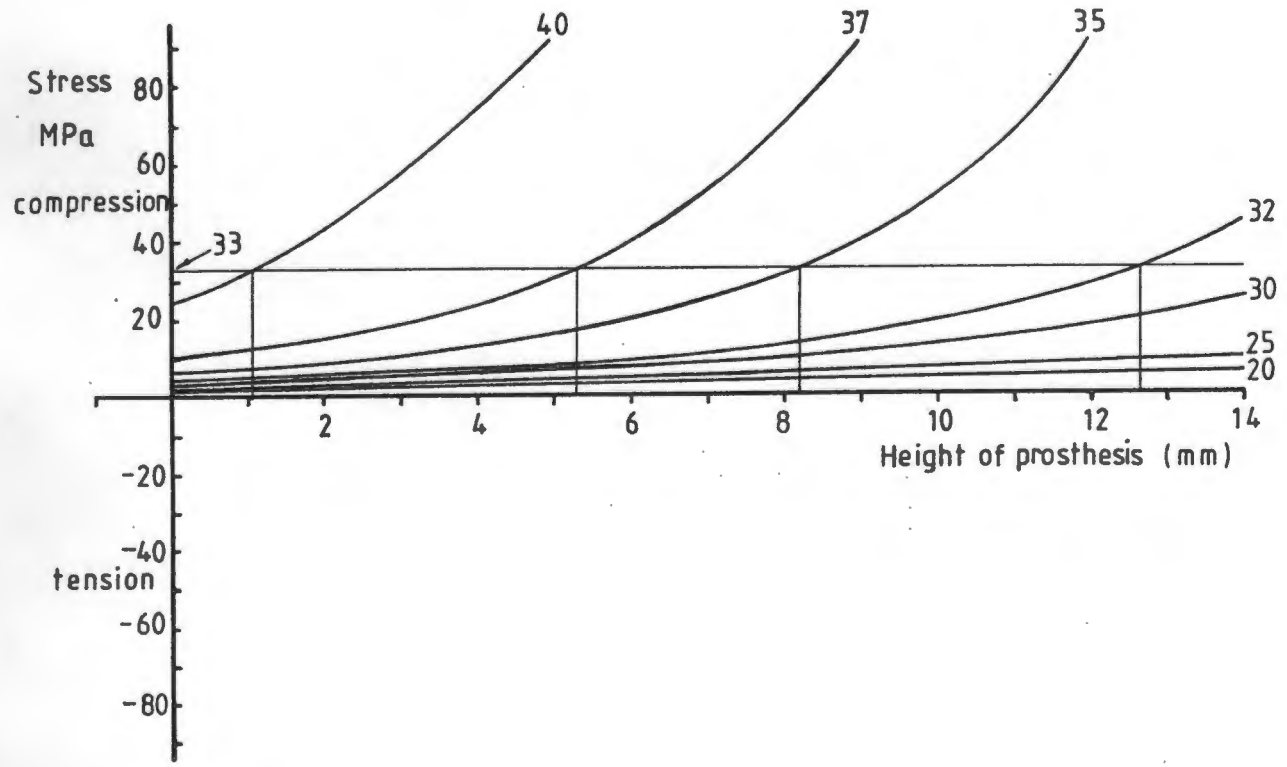


Fig. 4.22 Stress on Outer Surface of Medial Malleolus for Various Widths of Prosthesis

of 30mm and 10mm (for the width and height respectively) was a conservative assumption since the actual dimensions which will be used will either be

(a) 28mm and 10mm; or

(bi) 30mm and 8,8mm

(Both of these combinations give stresses lower than the previously assumed ones.)

In conclusion, the design of the prosthesis shown in Figure 4.23 is based on:

(a) reducing any force coupled in the coronal plane by allowing the ankle joint to move in harmony with the action of the muscles

(b) minimising the chances of loosening of the implant

(c) minimising the possibility of fracture of the distal tibial cortex, fixating ridges, and talar dome

(d) allowing the plastic tibial unit to be replaced without further damaging the distal tibia

(e) providing adequate bone support for the talar and tibial components

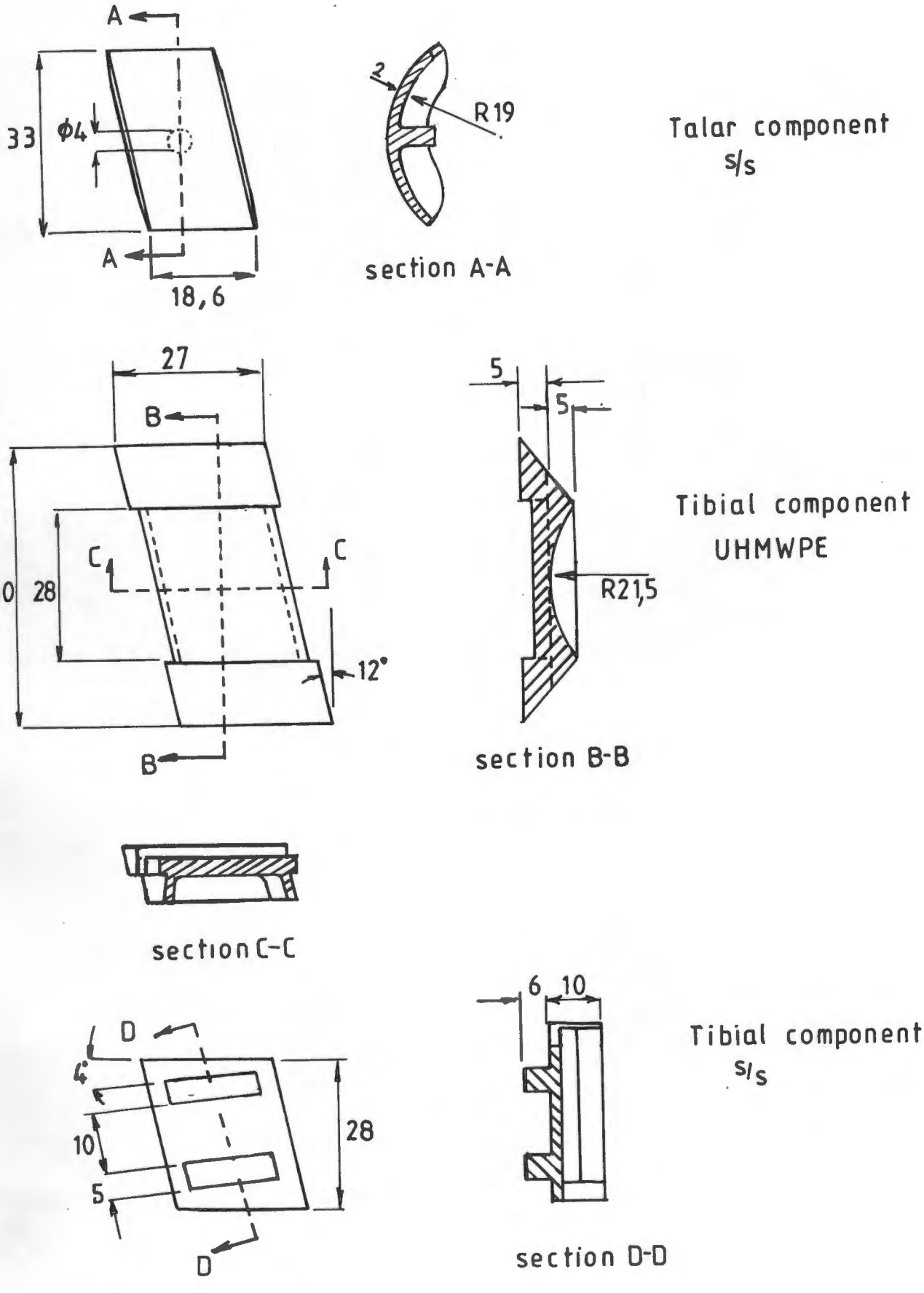


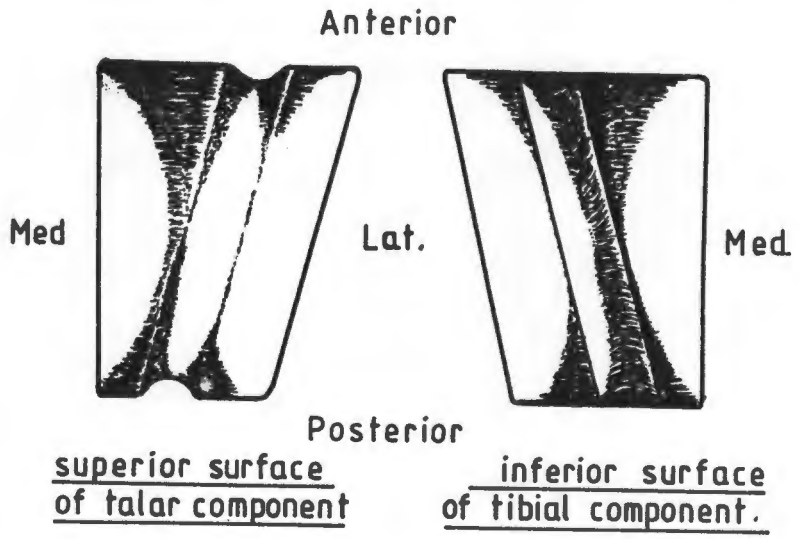
Fig. 4.23 Details of the Second Helical Prosthesis

CHAPTER 5

CADAVER TRIALS AND LABORATORY TESTING

5.1 Introduction

In 1981, a prototype artificial ankle joint was constructed at the Department of Biomedical Engineering (UCT) out of resins. This was then taken further by making a second version from stainless steel and UHMWPE. This prosthesis which is shown in Figure 5.1 was based on dimensions of existing prostheses but had, in addition, a helical trochlear groove and was wider anteriorly.



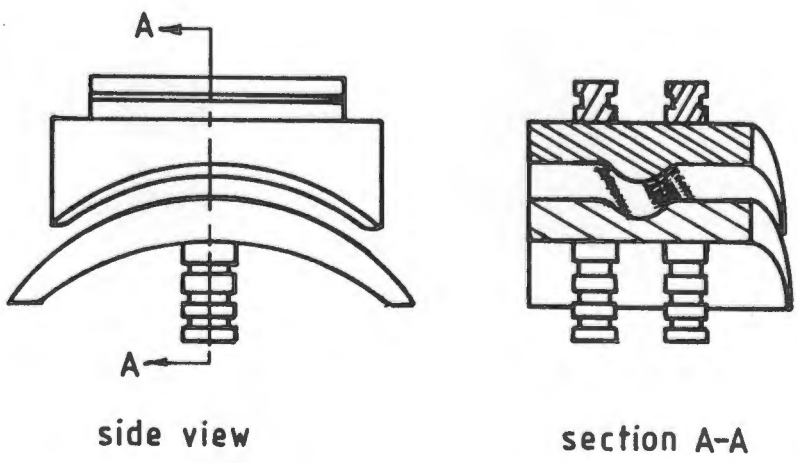


Fig. 5.1 First Prototype Helical Prosthesis

Initially it was thought that from the results of suitable tests, this prosthesis could be modified until the stage was reached where the model was ready for implantation. The tests which were envisaged were ones of a comparative nature whereby commercially available prostheses would be evaluated in conjunction with the prototype.

The problems with this strategy were as follows:

(a) It was very difficult to get samples of other prostheses.

(b) It was felt that all the existing prostheses suffered from serious design faults.

In the light of this, it was felt prudent to first carry out a detailed design of an artificial ankle joint (see Chapter 4) and then compare this with other designs.

In this chapter the following aspects will be covered:

(a) Measurements of the structure of the tibia

(b) Measurements of the shape of the articular surfaces

(c) Tests performed by other authors

(d) Method of testing the Prototype

(e) Cadaver trials

(f) Laboratory tests

5.2 Measurements of the Structure of the Tibia

In Chapter 4 the analyses of the stresses on the anterior tibial wall and the medial malleolus were based on an assumed tibial structure. This model was formulated after measurements were taken of the actual bone structure.

5.2.1 Shape of the Tibia

Figure 5.2 shows typical cross-sections of the distal end of the tibia. (In this specimen the distance between the tip of the medial malleolus and the tibial tubercle was 330mm.) Altogether

three tibiae were transected to obtain an idea of their shapes. (Two were from males and one from a female.)

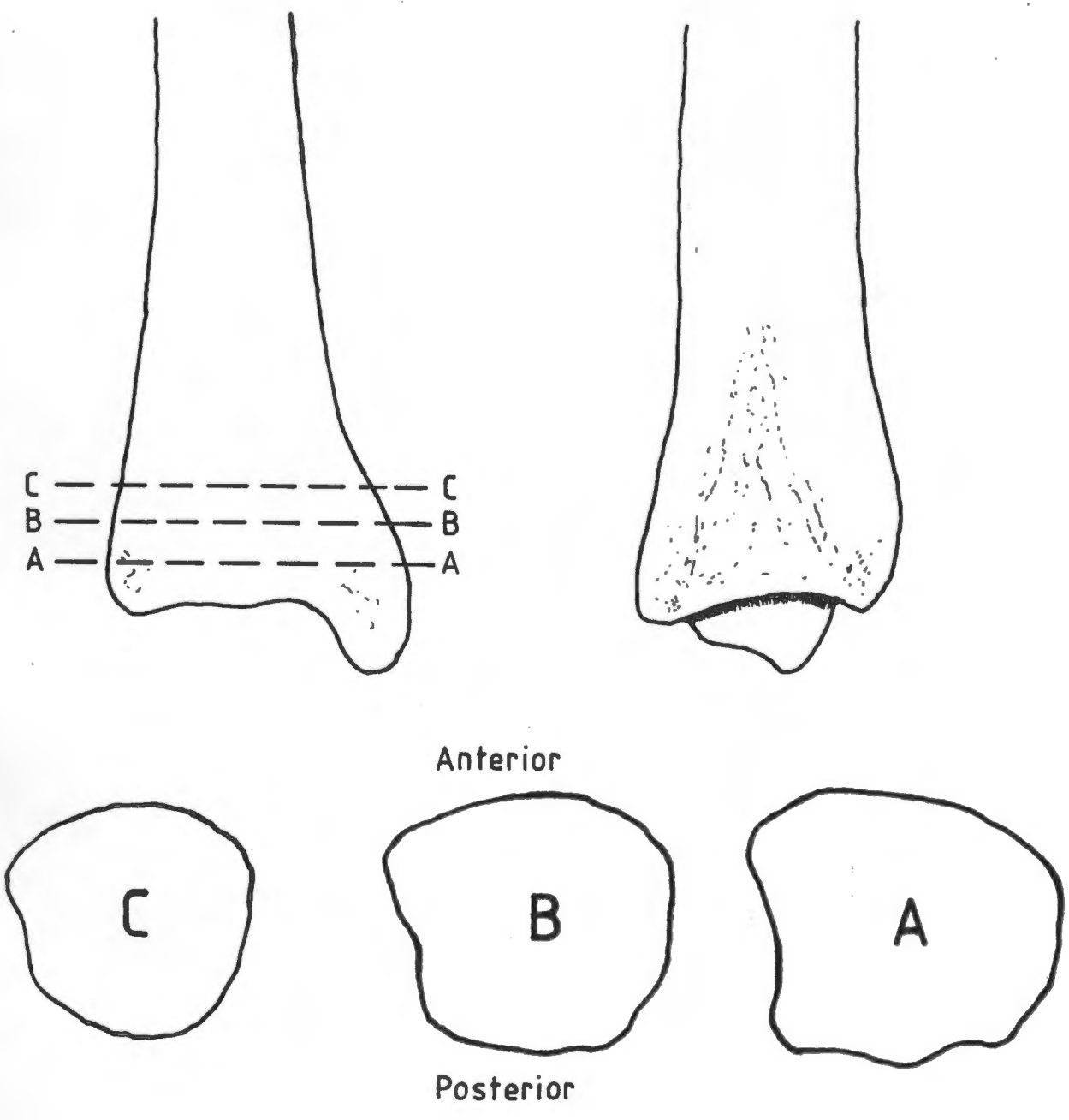


Fig. 5.2 Shape of Distal End of Right Tibia

In general the findings were that the distal cross-sectionns weere almost rectangular whereas more proximal ones were nearly circular. The areas of these sections also decreased asymptotically as they became more proximal. On the medial side the malleolus was the main cause of asymmetry of the end of the tibia.

5.2.2 Trabecular arrangement

Since it is important to know the bone stresses that will bbe caused by different fixating projections, measurements were taken of the cortical wall thickness and of the internal arrangement oof cancellous bone.

A problem encountered was that distally it was difficult to distinguish the precise boundary between hard and soft bone (especially in the specimens from the Anatomy Department at UCT Medical School which were from aged people and were preserved in formalin). The only fresh specimens that were obtained were from younger adults and in these the distinction was much clearer. In both types an estimation was made of the cortical wall thickness at about the level of the base of the fixating projections (i.e. about 12mm above the surface of the articular cartilage of the tibia). It was felt that a thickness of 2mm was a reasonable approximation.

Another observation was that the last 30-40mm of the distal end of the tibia had no appreciable changes in the gross internal structure. The orientation of individual trabeculae was not studied since this has been described by Takechi et al (1982).

Further up the centre of the tibial shaft the cancellous bonne became much weaker than that on the boundary. This change of structure was not incorporated into the model though, since thhe height of tibial resection would be considerably less than 30mm.

5.3 Measurements of the Shape of the Articular Surfaces

A study was performed with the aid of the Department of Surveying (University of Cape Town) on the shape of the articular surfaces of the ankle joint. The procedure involved in obtaining contour maps of the ankle joint was as follows:

(a) a fresh ankle specimen was dissected to the stage where only the distal tibia and fibula, supporting collateral ligaments and the talus were left.

(b) the undersurface of the talus was mounted in resin which was then allowed to harden. (The position of the talus was such that the crest of the talar dome was parallel to the surface of the resin).

(c) the specimen was then inverted with the ankle in a neutral position and the cut ends of the tibia and fibula were set in resin such that the two resin surfaces were parallel (see Figure 5.3).

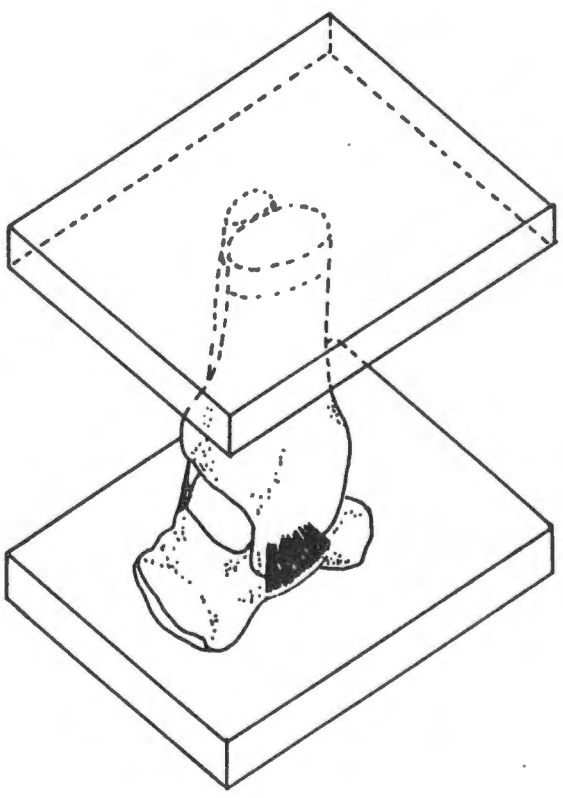


Fig. 5.3 Ankle Joint Mounted in Resin Blocks

(d) the ligaments were then removed and the joint was dislocated.

(e) the cartilage of the talus was inked and the two joint surfaces were then placed together again in the same position as previously.

(f) on re-opening the joint it was noted where the ink had stained the tibial cartilage (i.e. points of intimate contact were established).

(g) Four points of intimate contact on each articular surface were demarcated using pins with flat heads (of diameter 1,5mm). Each of the eight pins were driven into the joint surface until the heads were flush with the cartilage. This now meant that a common reference plane could be created for each of the distal and proximal joint surfaces.

(h) Stereophotographs were then taken according to the procedure described by Adams (1978). (Height pole control as advised by Adams was used so that errors of convergence could be corrected at a later stage).

(i) The negatives were then inserted into a stereoplotter and contours of each articular surface were plotted to an accuracy of $\pm$ 0,3mm. (This involves a high level of expertise and was performed by a suitably qualified member of the staff of the Department of Surveying.) Figures 5.4 and 5.5 show the contour maps that were obtained

(j) Along lines A-A, B-B, C-C and D-D (see Figure 5.4 and 5.5) altitudes were taken every 2mm. This enabled accurate cross-sections of the joint to be drawn (Figures 5.6 and 5.7)

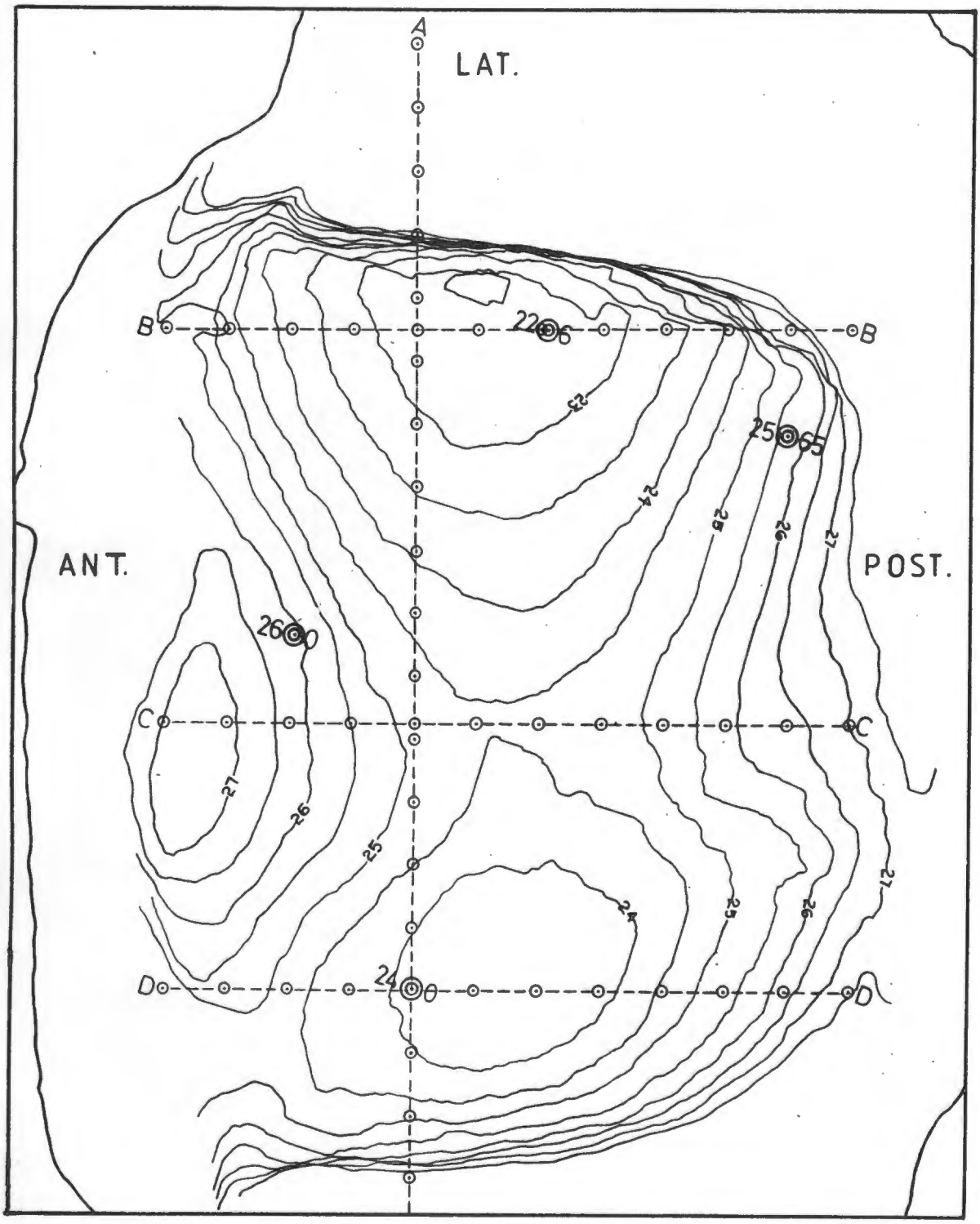


Fig. 5.4 Contour Map of Distal Tibial Surface

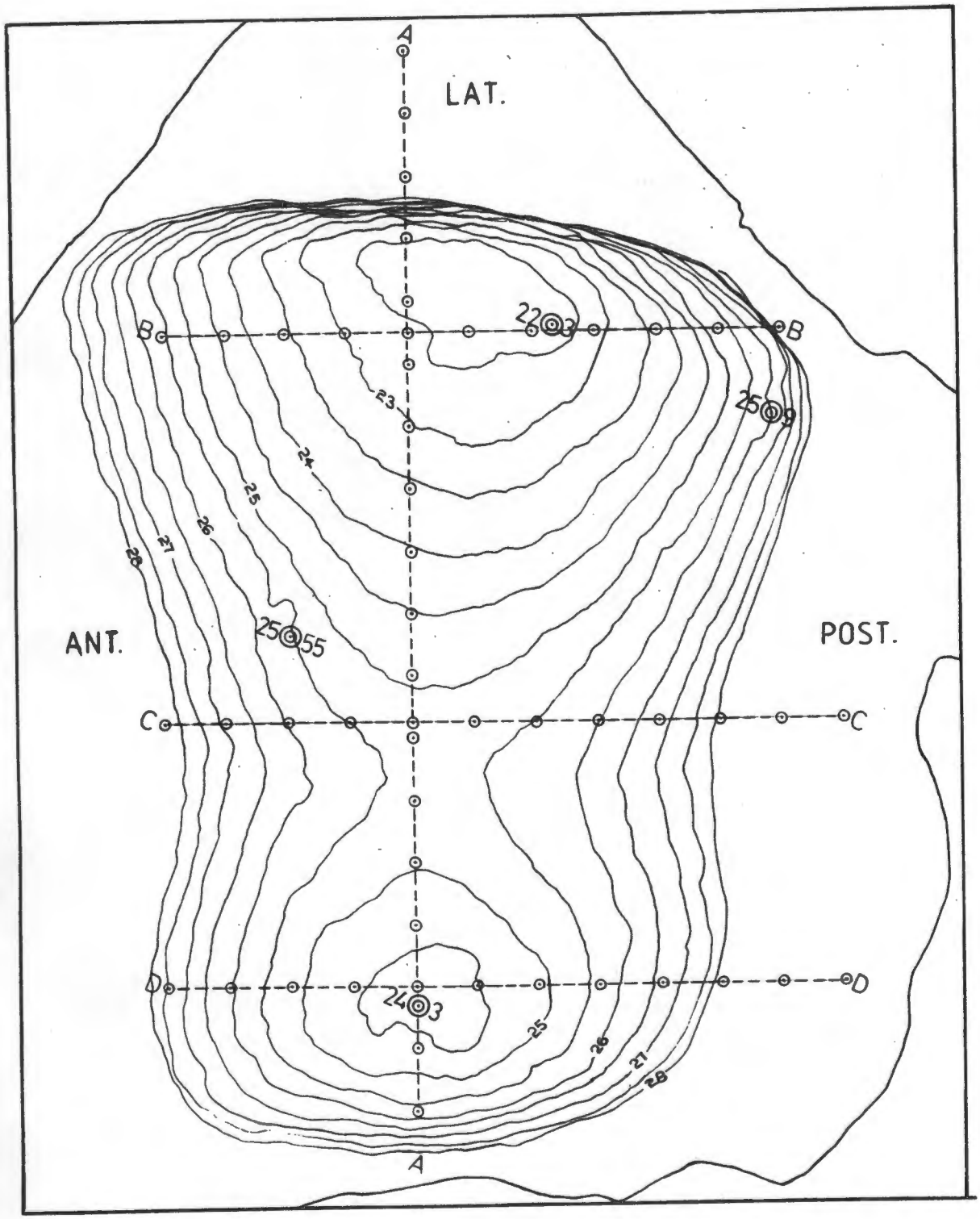


Fig. 5.5 Contour Map of the Talar Dome

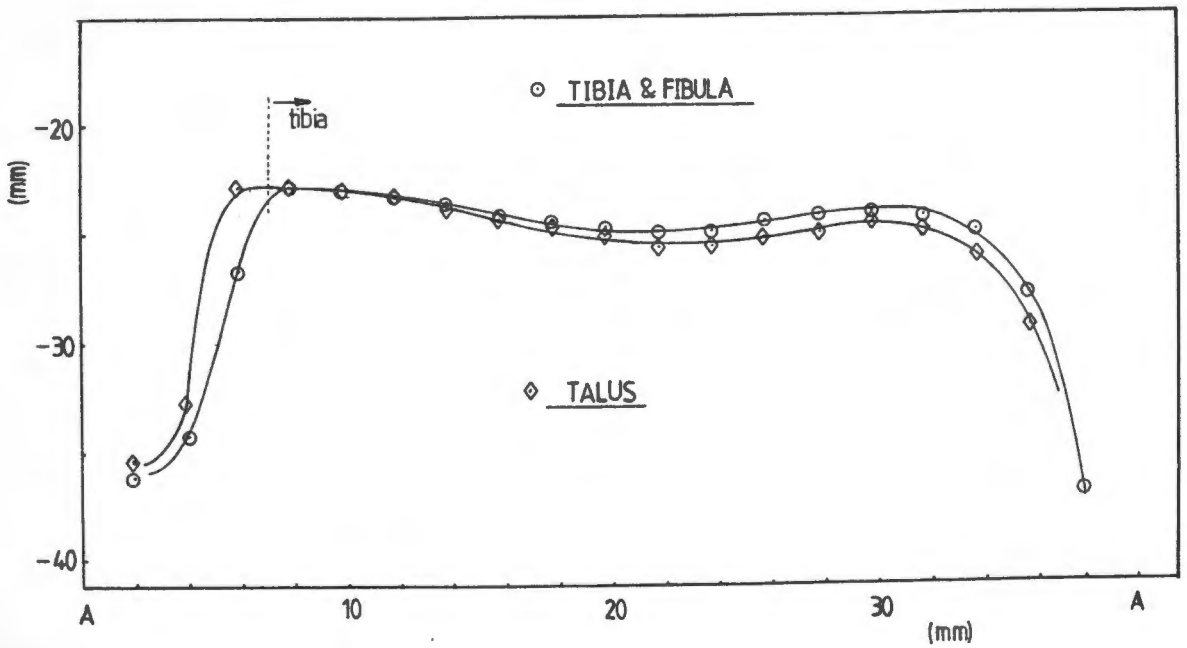


Fig. 5.6 Coronal Section Through Ankle Joint (on a Plane that Bisects the Malleoli)

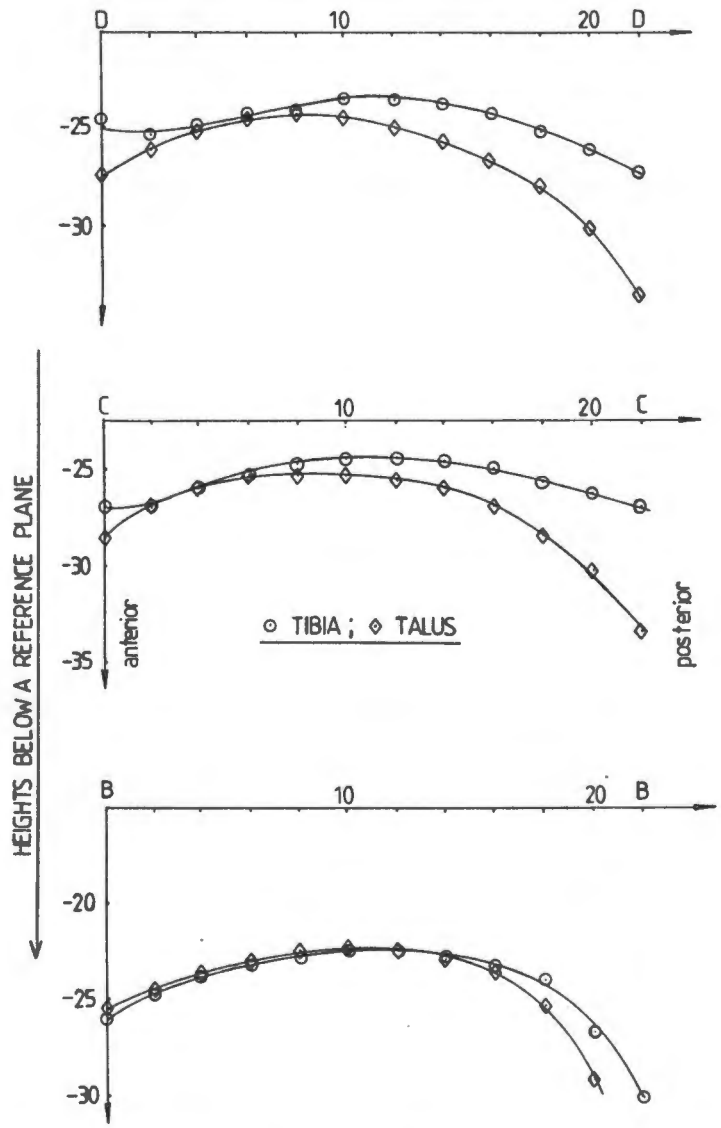


Fig. 5.7 Sagittal Sections Through Ankle Joint (all distances in millimetres)

If Figures 5.4 to 5.7 are studied, two factors point to malalignment of the two halves of the joint:

(a) Profiles B-B, C-C and D-D all need to be shifted in order for the best fit to be obtained (Figure 5.8)

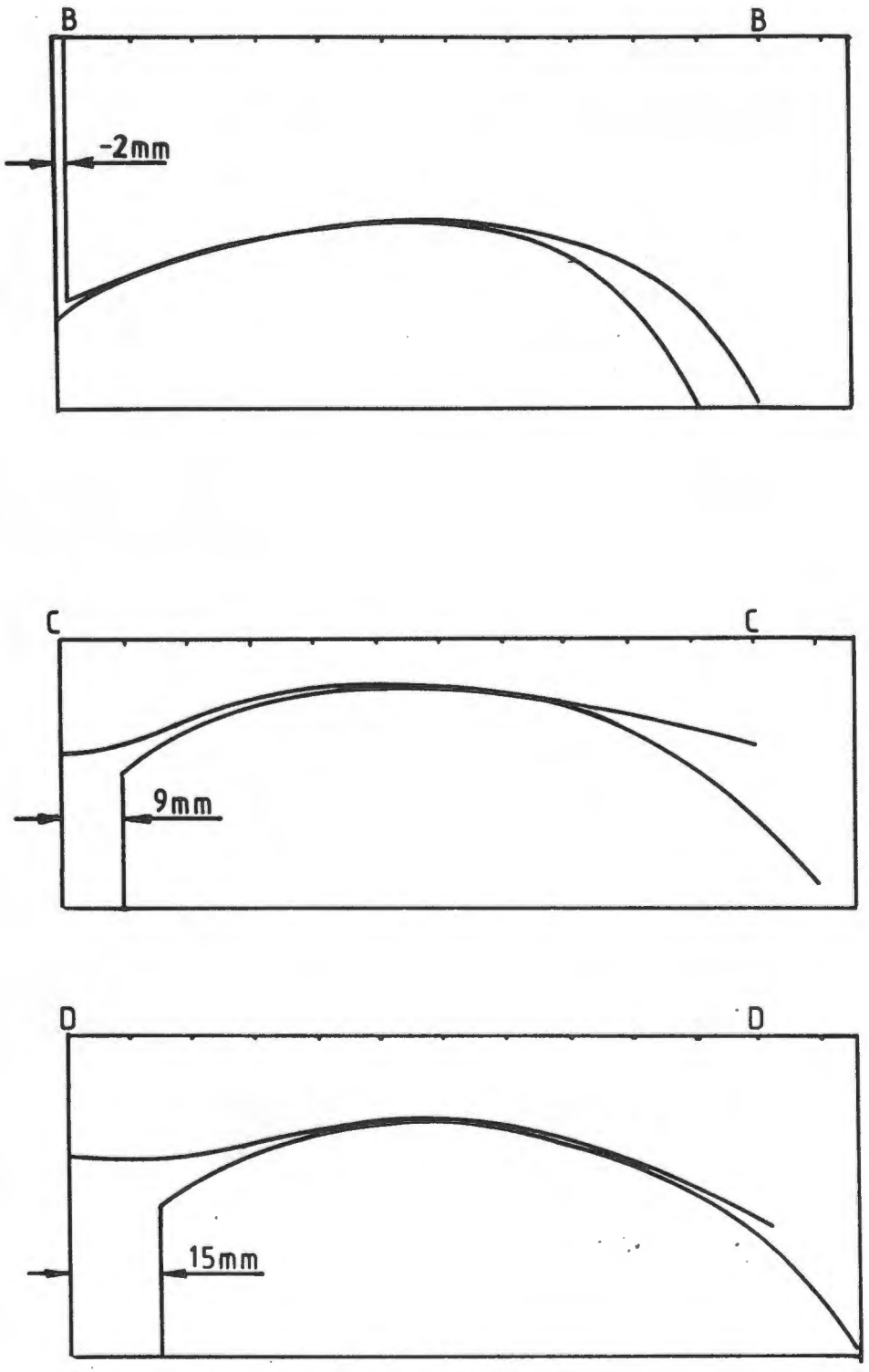


Fig. 5.8 More Congruent Profiles Obtained by Relative Shifting of Talar and Tibial Sections

(b) When superimposed the contours seemed to fit better when the A-A (tibia) and A-A (talar) lines were placed at about 10^{o} to each other. In this position the profiles mentioned above were far more congruent (as shown in Figure 5.8).

It is thus thought that in stage (e) of the procedure the joint surfaces were repositioned incorrectly. Although this means the profiles are not in the exact same plane, it can still be observed that the ankle has surfaces which closely approximate one another.

Earlier it was noted that the trochlear of the ankle has a groove. It was thought that by examining the contour maps the direction of this groove could be measured relative to the axis of rotation. In Figure 5.4 the line A-A which joins the centres of the articulating surfaces of each of the malleoli was considered a good approximation of the axis of rotation (seen from above). The line A-A on the talus, however, cannot be regarded in the same manner since it seems likely the talus was shifted before the alignment pins were inserted. For this reason only the ridge of the tibia will be investigated.

Figure 5.9 shows a line tracing the ridge of the cartilage on the tibial surface and its orientation to A-A. From this initial survey it would appear that the ridge lies at an oblique angle to the axis of rotation but many more specimens will need to be surveyed before any definite conclusions can be drawn.

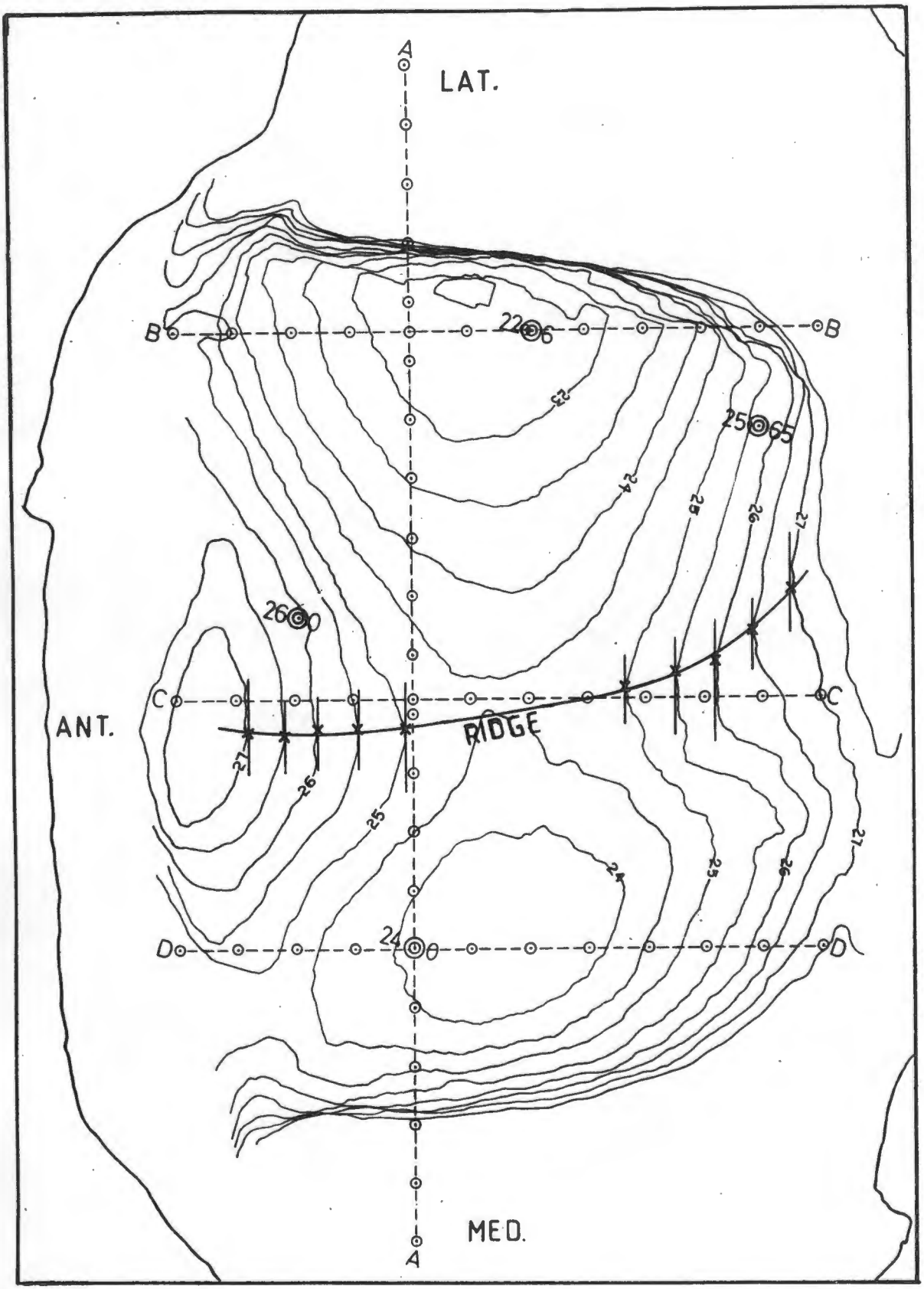


Fig. 5.9 Approximate Position of Trochlear Ridge

5.4 Tests Performed by Other Authors

Since the main problem with ankle arthroplasty is the loosening which occurs after a period of about one year in vivo, most tests have been directed at ascertaining the strength of fixation. The following are examples of such tests:

(a) Determining the tensile strengths of the prosthesis-cement and cement-bone interfaces (Walker, 1977). These simple tests are carried out on an Instron machine by simply exerting an extraction force on the cement and the corresponding material. A measurement is made of the force needed to cause separation at the interface.

(b) Groth, Fagan and Shen (1977) performed equally simple tests in designing the Oregon ankle prosthesis. They installed tibial components in two cadaver tibiae and mounted them on two tali which in turn were rigidly clamped. They then applied vertical compressive loads of 1800N and simultaneously rotated each tibia about its long axis. The results were that the bone fractured in one case and the cement in the other. The torque needed to cause these failures was greater than that encountered during walking, so the fixation was regarded as being satisfactory.

(c) In a test similar to that described in (a), Walker (1977) tested the pull-out forces for different shapes of fixating pegs or ridges. He cut slots in some tibial plateaus and inserted rectangular bars into them. Other plateaus had holes drilled in them and in these, round pegs were cemented into place. As in (a), the forces needed to cause loosening were measured, and hence an idea of the optimum shape and position of the fixating protruberance could be ascertained.

(d) Before any clinical trials are initiated, attempts are often

made at simulating the conditions found *in vivo*. (This enables surgeons to evaluate a design prior to actual insertion into a patient.) Unfortunately there is a direct relationship between the cost of the simulator and the closeness to which it matches the body. Even with expensive equipment, though, it is often difficult to assess laboratory results and the most one can hope for is to eliminate the poorer designs.

There have been recent developments in the design of hip and knee simulators (Walker, 1977; Swanson, 1977; Dumbelton, 1981) but to date there have been no ankle simulators that have been built.

The closest which investigators have come to using an ankle simulator was during the testing of the ICLH ankle prosthesis (Freeman *et al*, 1979). This implant was oscillated through an arc of 35° at a frequency of 2Hz in Ringer's solution. A wear rate of 0,016mm per million cycles was found (at a load of 1800N). The fixation was not tested during these "in service" conditions.

(e) A laboratory evaluation of various total ankle designs was attempted by Matejczyk *et al* (1979). They tested the intrinsic stability of each implant in three directions: horizontal rotation, anterior-posterior and medial-lateral.

Rotational testing. Articulated ankle joints in a neutral position were loaded in compression to 2670N. A horizontal torque of 8,5Nm was applied and the resulting angular displacements were measured see Figure 5.10). The authors concluded that multi-axial designs freely permit rotation with low torques being transmitted to the bone-cement interfaces whereas the more

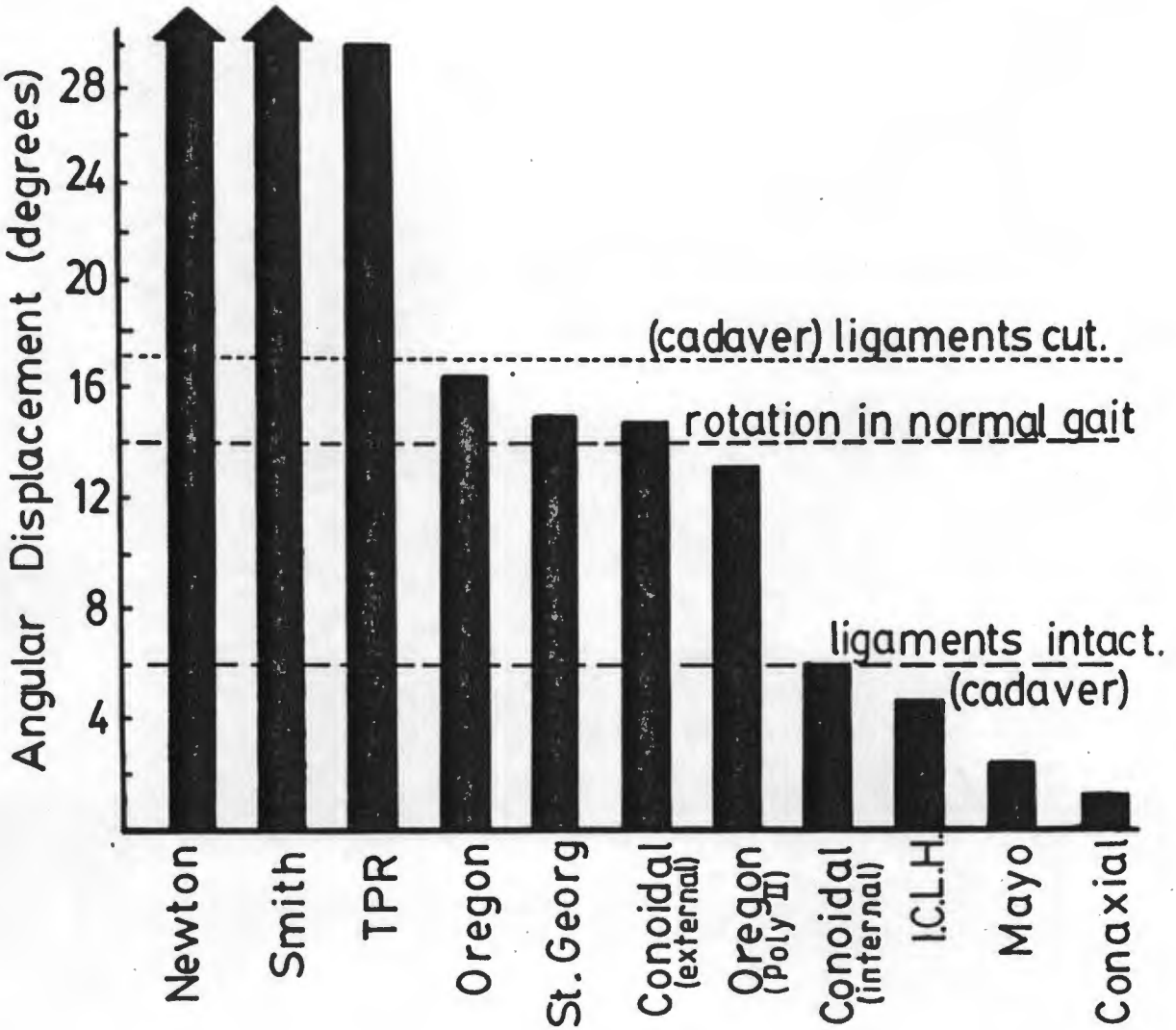


Fig. 5.10 Rotation of Ankle Implants under 600 lbs Compressive Load and Torque of 75 in-lbs (Matejczyk et al, 1979)

hiighly constrained prostheses transmit large torques to the interface.

Antero-posterior and medio-lateral testing. Once again arrticulated ankle joints were loaded in compression to 2670N. In this case shear forces in the above two orthogonal directions were applied until the prostheses either dislocated or loosened. Figure 5.11 shows the results of the antero-posterior tests and a similar graph was obtained for the medio-lateral tests.

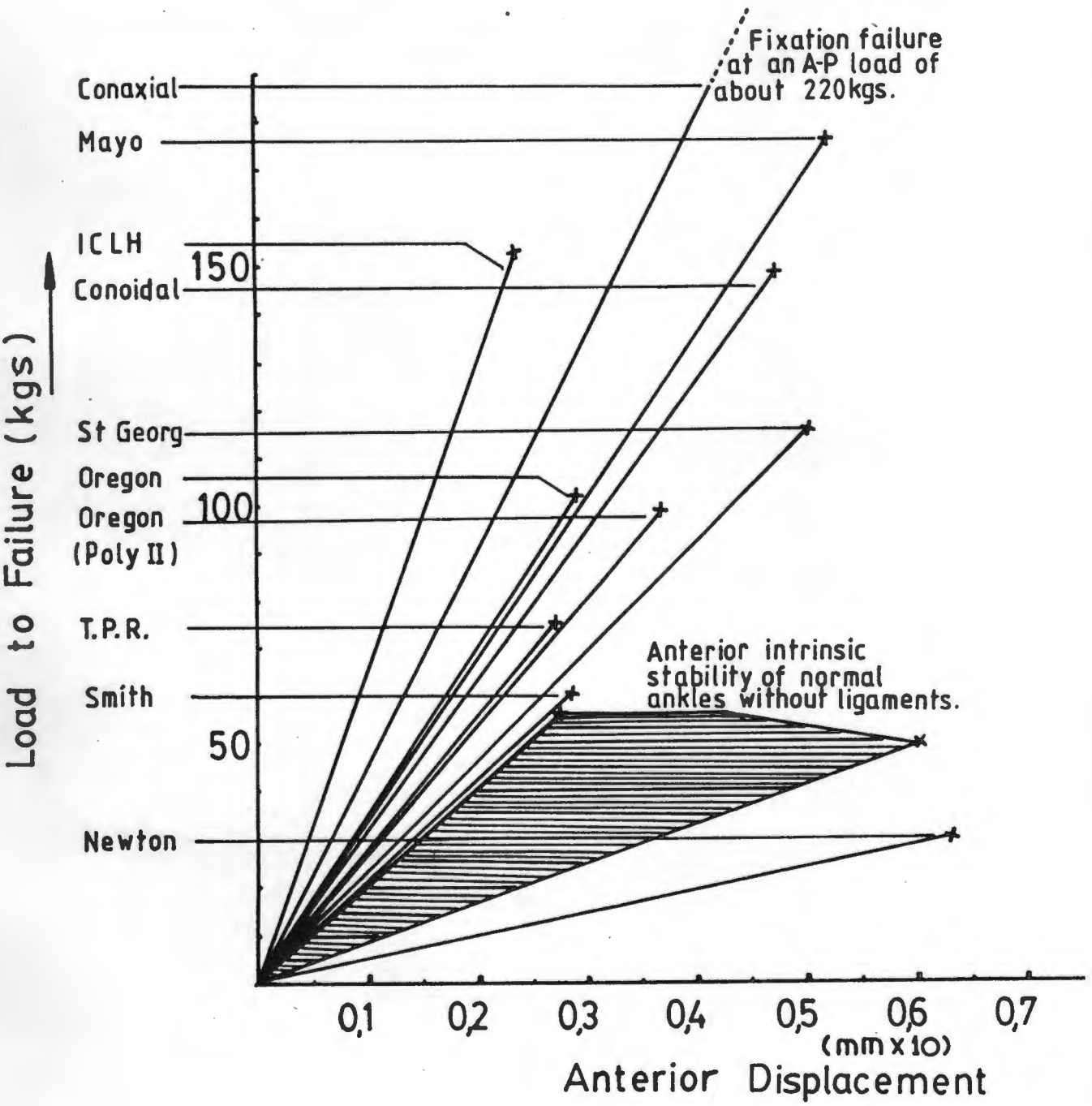


Fig. 5.11 A-P Stability of Ankle Implants Under 270 kg Compressive Load (Matejczyk et al, 1979)

The authors concluded that with the exception of the two minimally constrained designs (Newton and Smith), all the systems offered greater intrinsic stability than the normal ankle.

5.5 Method for Testing the Prototype

It was felt that the tests described in the previous section had certain drawbacks;

(a) if human bone is used then a large number of experiments must be performed (to minimise the effect of biological variability).

(b) the loads which are used to test fixation should be physiologically compatible (i.e. testing fixation by pulling the prosthesis out of the tibia in a caudal direction is not appropriate since, during gait, this type of force is never applied to the tibial surface).

(c) some of the conclusions drawn after fairly extensive tests could have been made by simple inspection of the prosthesis (e.g. noting the degree of constraint between the articular surfaces). A prosthesis which is uni-axial can be expected to transmit higher torques to the bone whereas multi-axial designs transmit the torques to the ligaments. In a similar manner if the ratio between the forces in the anterior and medial directions is 2,3:1 then it can be deduced that for a square fixating ridge the shear stresses will be in the same ratio. (The ICLH prostheses each have a square fixating ridge.) Experiments could be devised to test the effectiveness of using cement lugs to improve fixation, since this is difficult to estimate.

(d) Besides measuring the results of shear and tensile

forces on the various interfaces (i.e. loosening) it would seem just as appropriate to measure the actual tensile and shear forces at these interfaces during simulated trials. By this it is meant that instead of subjecting a prosthesis to one million cycles and then looking at the gap which develops between it and the bone, one could shorten the procedure if one knew the cause of the loosening (in a quantitative manner). This may be possible if an arrangement of strain gauges could be placed between the protuberances of the implant and a "rigid" reference such as cortical bone. In this way different designs could be directly compared with each other.

After considering these factors it was felt that the wide variations in composition and behaviour of human tissue would be bypassed by using plastic models of the ankle joint. This technique has been used extensively by Miles (1983) in experiments on the load transfer between bone and hip prostheses. It was envisaged that the plastic models would be used to determine aspects such as:

(a) amount of bone resection

(b) range of motion

(c) stability of the prosthesis

(d) bone stresses caused by the implant

It was also decided that physiological loads would be used to test each configuration and that the surgical procedure would be evaluated during cadaver trials.

5.6 Cadaver Trials

In all of these trials staff of the Department of Orthopaedic Surgery at the University of Cape Town performed the opera-

tion of inserting prostheses into ankle joints. On the first of these trials, the initial prototype (Figure 5.1) was tested, and in this case, no special instruments were used to check the alignment. The only tools used were:

two osteotomes

mallet

bone nibbler

scalpel

skin retractors

forceps

periosteal elevator

hand drill

The method of implantation was as follows; an anterior incision was made approximately 130mm in length and the retinacula were cut. The extensor hallucis longus and vascular bundle were retracted laterally and the anterior tibial tendon, medially. After stripping the periosteum and joint capsule the bone was prepared to accommodate the prosthesis.

Problems encountered were:

(a) The two fixating ridges on the tibial component were too close and consequently the intervening bone fractured whilst using the osteotome.

(b) An excessive amount of tibial resection was required.

(c) The pegs on the talar component severely weakened the trochlea of the talus.

(d) The talar component was far too large: the radius of curvature was such that there was a gap between the dome of the talus and the undersurface of the prosthesis.

(e) Both parts of the prosthesis were too wide and

consequently the medial malleolus was severely weakened by the resection to fit the implant in place.

Besides these factors, two further design faults were noted:

(f) The helix was in the wrong direction.

(g) Since the helix and the medial side of the implant were at an angle to each other, on dorsi-flexion the medial side of the tibial component moved laterally with respect to the talar component. On plantar-flexion the reverse occurred. This meant there was the possibility of wear on the plastic being greater in those areas which were in constant contact and less on the medial side of the tibial part which, in certain positions, made no contact with the talar part. Another possibility was that on dorsi-flexion the medial malleolus could impinge on the exposed medial side of the talar component.

After considering the above seven points it was felt that the prosthesis should be redesigned with more attention being paid to surgical approach, size of prosthesis, fixation and direction of helix. With regard to the direction of the tibial fixating ridges, it was felt that by placing them medio-laterally, there would be less tendency for them to loosen. This, in turn, implied that a lateral approach (as used in the St. George system) would be preferable.

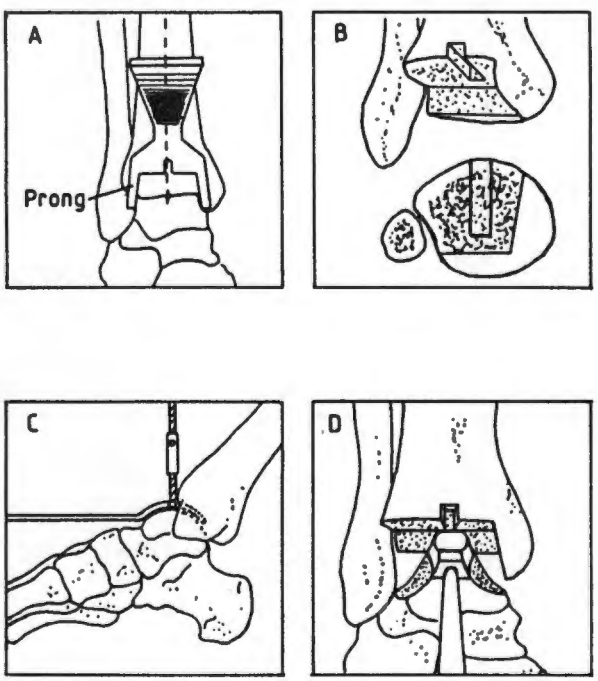
An articulated cadaver ankle joint was obtained and a lateral approach was attempted by performing a transverse osteotomy through the fibula (about 10mm above the level of the tibio-talar joint). It was found that such an approach gave excellent exposure to the ankle joint and trimming of the dome of the talus was relatively easy. This was due to: the talus being viewed from the side, and the posterior margin being accessible.

Implantation of the Oregon Total Ankle. After the implantation of the first prototype two commercial ankle implants were inserted into cadavers to evaluate the surgical procedure. In both cases the correct instrumentation was used.

The first prosthesis to be tested in this manner was the Oregon Total Ankle. The procedure used was that described by Groth et al (1977) with the only exception being the notch in the tibia was made slightly deeper to accommodate the longer ridge in the latest Oregon designn.

The problems encountered which were not related to the use of a cadaver were:

(a) The prongs of the tibial resection guide (see Figure 5.12) were too short since the bone demarcated by the guide was less than the actual amount needed to be resected.)



A: Using 'Tibial Resection Guide'
B: Distal tibia after resection
C: Drilling hole into dome of talus
D: Using Talar Resection Guide

Fig. 5.12 Oregon Instrumentation

(b) The talar resection guide was difficult to use and did not clearly indicate those areas which were to be removed.

(c) The amount of resection of both the talus and the tibia were excessive.

(d) It was difficult to gain sufficient access to drill the hole into the crest of the talus.

The good features of the procedure were;

(a) The talar component formed a "cap" over the remainder of the dome of the talus.

(b) The tibial component had posterior and medial bony support.

(c) There was no possibility of the malleoli impinging on the talus since the tibial component had "walls" on the sides.

Implantation of the TPR Total Ankle. In a similar manner to the previous trial, a TPR prosthesis was implanted into an adult male cadaver (approximately 30 years of age). Regular sized components were used, the tibial one additionally being specified as "thin", instead of being "regular" or "thick".

The main difference between the Oregon system and the TPR system was that very little talar resection was required by the latter. Other differences were that the TPR system;

(a) required less tibial resection

(b) required holes to be drilled into both the tibia and the talus. These holes were relatively easy to drill since they sloped posteriorly. It was felt, however, that the tibial peg was dangerously close to the anterior cortex of the tibia.

The main similarity between the two systems was that ante-

rior approaches were used and hence it was extremely difficult to trim the posterior margins of the tibia and talus. It was felt, however, that the ICLH method of using both anterior and posterior incisions, with the temporary removal of the Achilles tendon, was not the best method of resolving the problem.

5.7 Laboratory Tests

As was mentioned in section 5.5 it is advantageous to use plastic models of bones for comparative tests since the repeatability of the tests is far greater. In a similar manner to that described by Miles (1983), replicas of the tibia and fibula were thus made in silicone rubber moulds, using methalene di-isocyanate (polyurethane) as a casting material. In addition, artificial tali were obtained using a mixture of fibre-glass resin and armospheres. (The latter serves as a heat-sink during the curing process and can be used to decrease the density of the casting.)

In this study it was important to know the density of each casting for two reasons;

(a) amount of bone resection could later be determined

(b) castings of similar composition could be chosen for stress testing

The method of determining the density of each bone model was simply to weigh the specimen and then find its volume by immersing it in water in a measuring flask. By dividing the weight by the displaced volume the density could be ascertained.

5.7.1 Measuring Amount of Bone Resection

One method of evaluating an ankle prosthesis is to determine the amount of bone which must be resected during its implantation into a joint. (The less resection that is required, the greater

are the chances of a successful salvage operation should the prosthesis fail.)

Once ten plastic models of the ankle bones had been cast and their densities determined, three commercial ankle prostheses were inserted (according to the methods described in the literature) as well as the first and second prototype. The latter was a model of the prosthesis designed in Chapter 4. After the postions of the implanted devices had been checked by an orthopaedic surgeon, the prostheses were removed and the bones were weighed. The procedure was then repeated for each implant. By dividing the weight loss for each bone by its density, the average resected volume could be calculated and the results are shown in Table 5.1.

Bone	Prosthesis	Average Resected Volume (ml)
Tibia	TPR	8,6 ± 0,5
	ICLH	11,0 ± 0,5
	Oregon	11,7 ± 0,5
	1st prototype	18,0 ± 0,5
	New design	10,3 ± 0,5
Talus	TPR	1,4 ± 0,2
	ICLH	3,3 ± 0,2
	Oregon	4,4 ± 0,2
	1st prototype	1,7 ± 0,2
	New design	1,7 ± 0,2

Table 5.1 Resected Volumes

The results of this test showed the TPR implant required the least resection of both tibia and talus. This is understandable since both the dome of the talus and the posterior cortex of the tibia are preserved. In the case of the ICLH procedure both these structures are removed so even though the height of tibial resection is minimal (about 6mm) the amount of bone removal is increased. Two other interesting results were that there was substantial bone loss of the talus during the Oregon implantation and that the first helical prototype needed excessive tibial resection. An additional drawback with the Oregon system is that whilst the volume of tibial bone removal is reasonably low, the height of resection is significantly greater than for either of the other commercial prostheses. Although the posterior cortex is preserved -- which would tend to indicate an acceptable amount of resection -- there is, in reality, little chance of a successful arthrodesis at a later stage.

With regard to the design of the new helical prosthesis it appeared that the volumes of resection of both tibia and talus were within acceptable limits. This applied particularly to the talus where only the TPR component needed less bone removal. It was felt that the additional stability which the side walls of the talar component afforded (in the case of the helical design) outweighed the advantage of the slightly smaller amount of bone removed during the implantation of the TPR prosthesis.

5.7.2 Range of Movement

Another method of evaluating artificial ankle joints is to measure the range of movement (R.O.M.) which each one allows. There are two difficulties which present themselves in this regard:

(a) R.O.M. in vivo is reduced by soft tissue resistance

(b) The definition of R.O.M. of a prosthesis has not been standardised.

In this study it was decided to measure the degree of rotation in the sagittal plane using two concepts of R.O.M.;

(a) Designed R.O.M. - The amount of rotation that occurs as the surface of the tibial component slides either backwards or forwards over the talar component with the area of contact remaining constant.

(b) Total R.O.M. - The amount of rotation that occurs between maximum plantar- and dorsi-flexion. (This implies that the tibial component can slide off the talar dome.)

The actual method of measuring these rotations was to mount the various prostheses into models of the ankle joint with no soft tissue support and to oscillate the tibia and fibula over the talus. The degree of oscillation was ascertained using a clinometer mounted on the shaft of the tibia (see Figure 5.13).

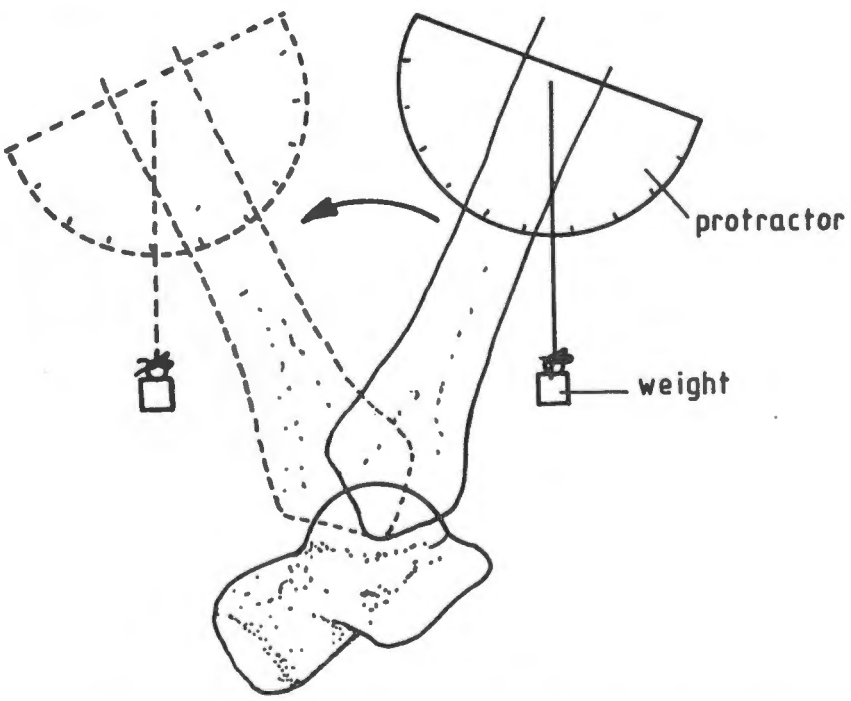


Fig. 5.13 Measuring Range of Movement

The results of these tests are summarised in Table 5.2.

Prosthesis	Designed R.O.M. (degrees)	Total R.O.M. (degrees)	R.O.M. in the literature (degrees)
TPR	50	>70	?
ICLH	40	45	35
Oregon	40	>80	40
New Helical Design	30	60	-

Table 5.2 Range of Movement in Sagittal Plane

From this table the following points emerge:

(a) There was good agreement between the R.O.M. as given in the literature and that measured for the ICLH and Oregon prostheses.

(b) There was little difference between the total and the designed R.O.M. for the ICLH prosthesis. This means that there is a possibility of the tibial component actually coming into contact with the talus in some patients who have this device implanted. This, in turn, means that additional loads could be applied to the bone-cement interface (see Figure 3.2).

(c) The total R.O.M. for the Oregon implant was about 80^{o}. This means that it is very unlikely the tibial component would ever impinge on the talus. In addition, of all the prostheses tested, the Oregon was the least constrained in the coronal plane. Both these factors indicate that the Oregon Total Ankle needs sound ligaments for its support.

(d) The difference of 20^{o} between the total and the designed

R.O.M. for the TPR component was due to extra plantar-flexion. This indicates that contact between the tibial component and the neck of the talus is possible on full dorsi-flexion. Another feature of the movements permitted by the TPR prosthesis was that on full plantar-flexion about 15° of transverse rotation was possible. This means that in a position such as standing on tip-toes, the ligaments and muscles would have to stabilise the joint.

(e) The designed R.O.M. of the second helical prototype was less than that of the other prostheses. In addition the medial wall of the tibial component was found to impinge on the talus on full plantar-flexion. However, by decreasing the height of the walls of the tibial component both these problems were solved at the slight expense of some articulating surface (see Figure 5.14).

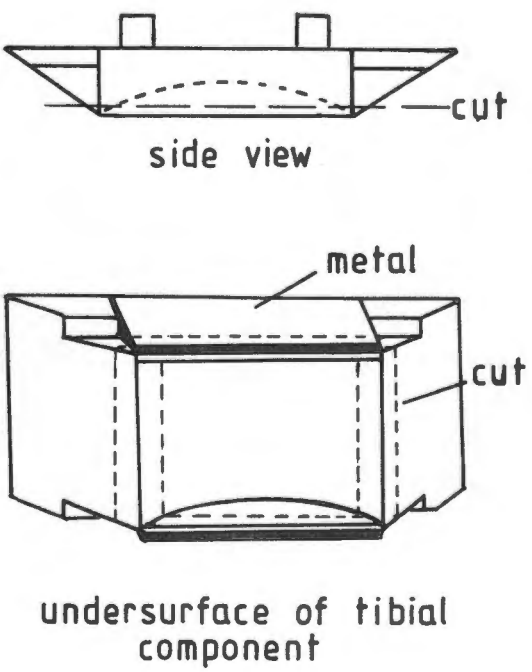


Fig. 5.14 Increasing Range of Motion (by reducing the height of the "walls")

5.7.3 Stress Testing

One of the important features of an ankle prosthesis is its fixation to bone. In section 5.4 some tests which other researchers have performed to evaluate fixation were mentioned and in section 5.5 some drawbacks of these tests were discussed. It was also suggested that the cause of loosening (i.e. shear and tensile stresses on the bone-cement interface) should be measured instead of the end result (i.e. a gap between bone and implant).

Originally it was thought that by placing an arrangement of strain gauges (mounted on strips of spring steel) between the prosthesis and the bone, the stresses for various loads could be determined. (Each strip of metal would have one end connected rigidly to the implant and the other to the adjacent bone surface as shown in Figure 5.15.) It was found that this was impractical since:

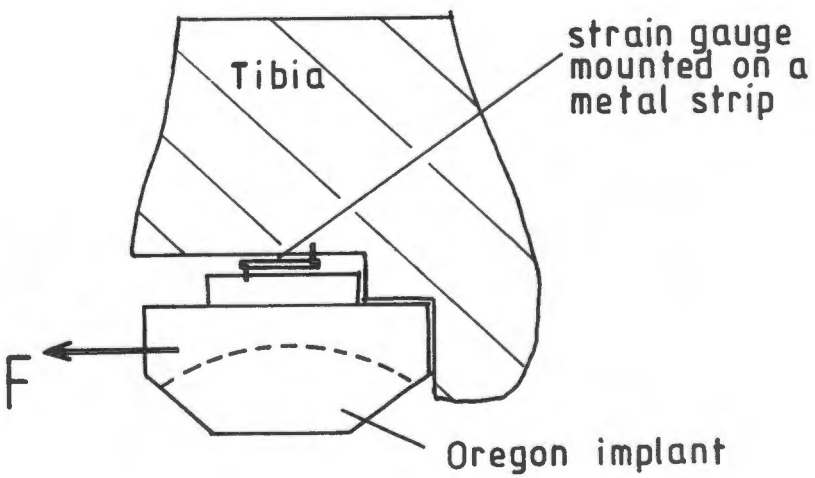


Fig. 5.15 Measuring Shear Stresses on the Interface Between Bone and Implant

(a) The strips of metal could not be attached across the interface since this was not easily accessible.

(b) The size of the strain gauges prohibits one from measuring localised shear stresses between a fixation peg and the adjacent bone.

It was then thought that by using a strip of spring steel as a deflection gauge (see Figure 5.16) it would be possible to compare the fixation of one prosthesis with another. If the gauge was mounted on the anterior aspect of the tibia, and the lower end made contact with the front of the tibial component, then slight movements of this unit would be detected as physiological loads were applied to it. The problem with this test procedure is that the results can be anticipated by visual inspection of each prosthesis - e.g. since the Oregon implant is inserted from the front of the tibia and has a single a/p ridge, it can be expected that anterior forces will cause the prosthesis to move in that direction. On the other hand the projection on the tibial surface of the ICLH prosthesis would largely prevent anterior displacement of this component.

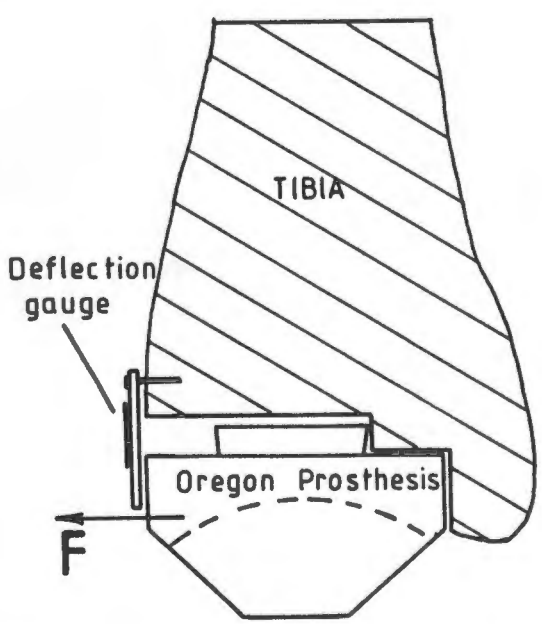


Fig. 5.16 Position of a Deflection Gauge for Anterior Loading

The eventual solution to the problem of evaluating each method of fixation was to perform the following test:

(a) Four tibiae were cast with approximately equal densities (within 4% of each other)

(b) The TPR, ICLH, Oregon and Helical (second prototype) prostheses were carefully fitted in position

(c) Two strain gauges were bonded on the outer surface of each tibia - one on the medial malleolus and one on the posterior cortex

(d) The positions of these strain gauges were such that for each implant an estimate of the greatest stress on the medial and posterior surfaces could be obtained (see Figure 5.17).

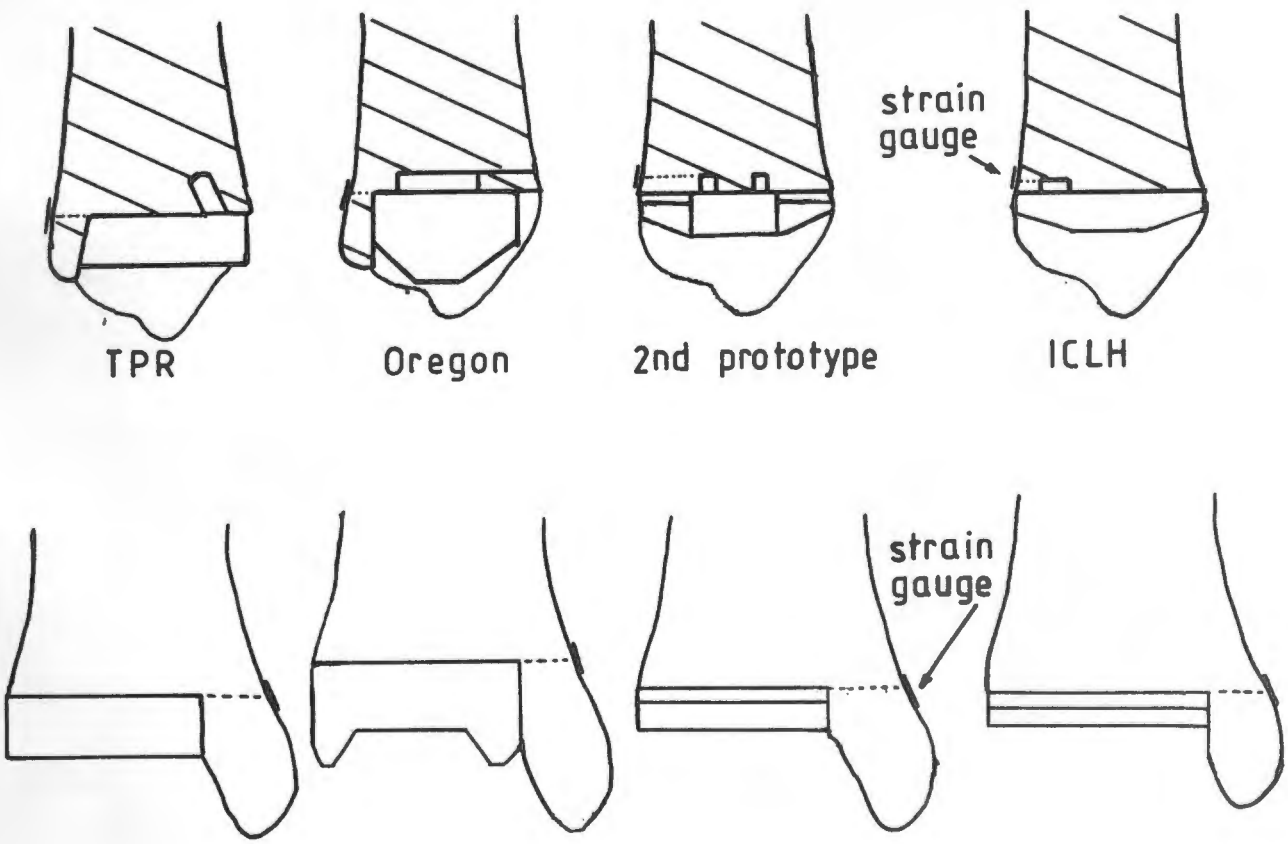


Fig. 5.17 Positions of Strain Gauges

(e) Each tibia was placed in a loading rig (see Figure 5.18) and one of the two strain gauges was connected to a power supply, amplifier (see Appendix B) and voltmeter.

(f) Depending on which strain gauge was wired to the circuit, either antero-posterior or medio-lateral forces were applied to the tibial implant.

(g) Each load was applied three times and the average strain was measured via a change in the voltage (from the inital offset). To check there was little or no creep, this offset voltage was closely monitored by removing the load after a reading had been taken.

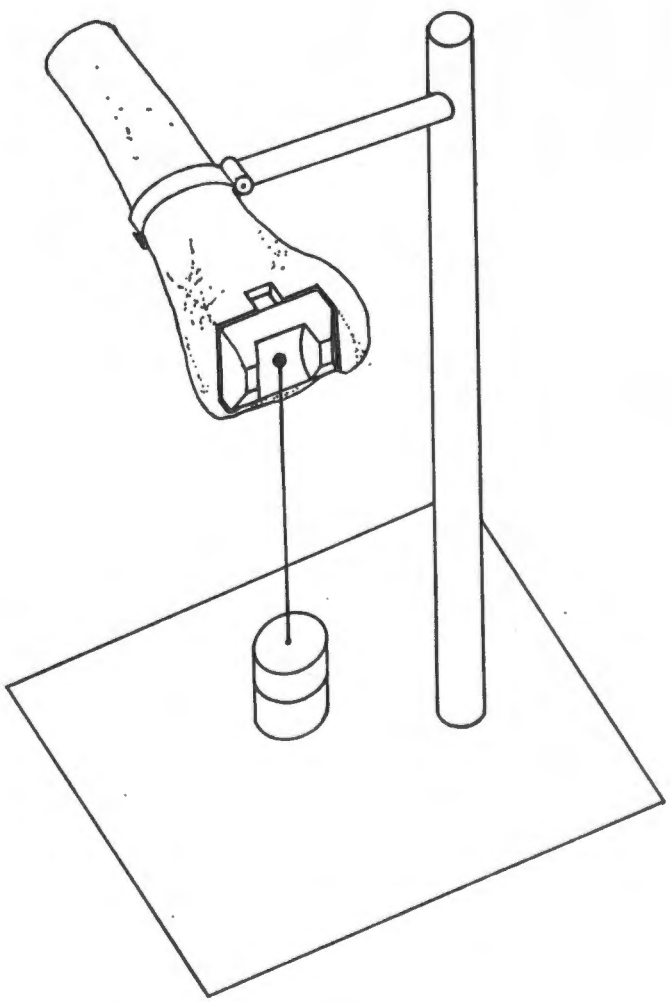


Fig. 5.18 Loading Rig (schematic) for Antero-Posterior Testing

The advantages with this test are two-fold:

(a) Since there is always posterior and medial bone support, these structures can serve as "deflection gauges".

(b) An idea of the weakening of the distal end of the tibia can be obtained. In other words an estimate can be made of the fixation system as a whole, since high strains on the outer cortex either indicate the fixating protrusions are not shielding the cortex from stress or that the cortical wall has been weakened by excessive resection.

At this stage three further points should be noted:

(a) No cement (or any adhesive) was used to bond the prosthesis to the bone since this would have increased the shear strength of the interface. (Usually after about a year **in vivo** there is a fibrous layer between the cement and bone which has low shear strengths.)

(b) No mechanical interlocking was provided by cement lugs since it is hoped to dispose of bone cement eventually in favour of biological fixation.

(c) Only the tibia was tested since it was felt that as the method of fitting a "cap" to the talar dome did not require significant resection, the problems of talar fixation are far less.

Results of Medio-lateral Loading. Figure 5.19 shows the strains on the outer cortex of the medial malleolus for different prostheses and loads. It is noteworthy that although the new helical prototype has ridges in the medial-lateral direction, the strains were less than those for any of the other implants. The author is of the opinion that this is due to the limited resection that

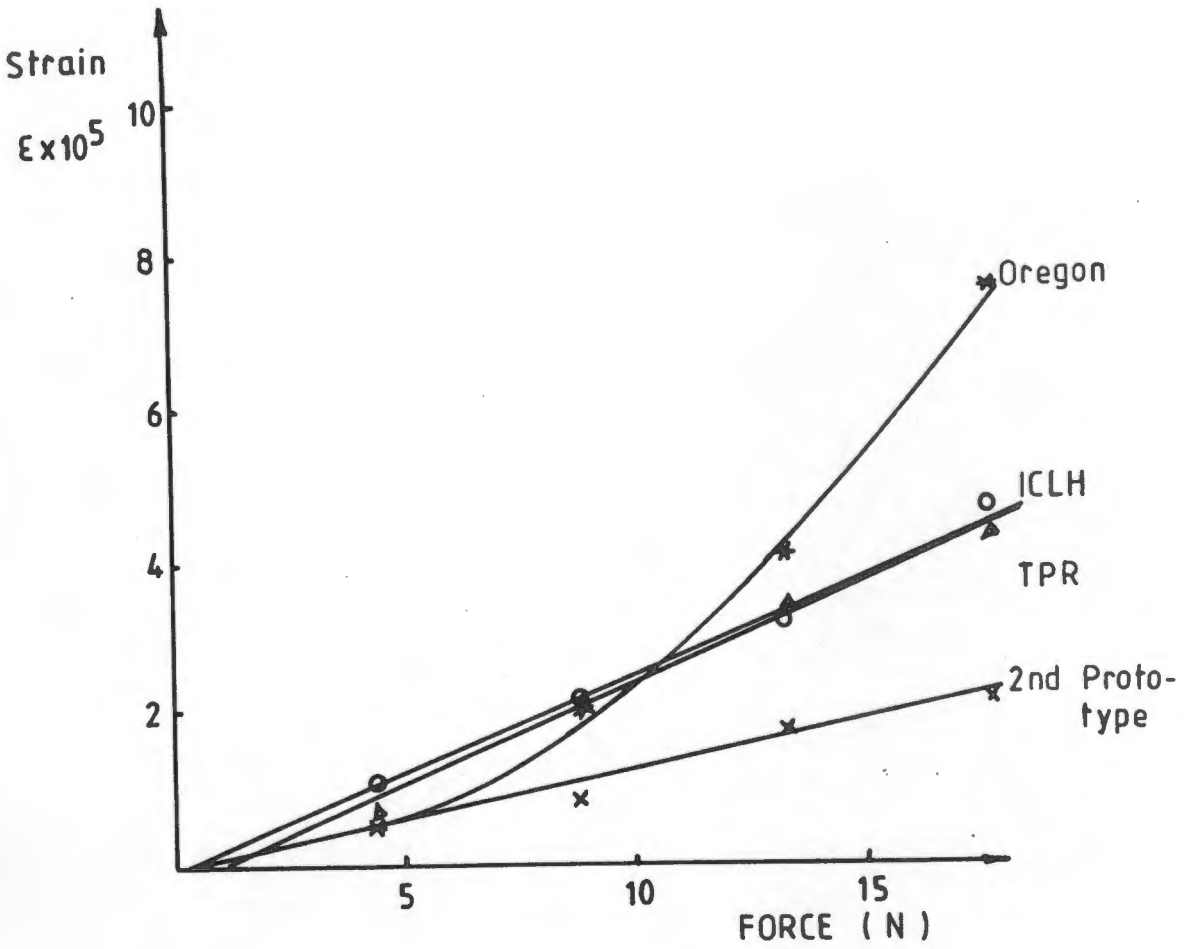


Fig. 5.19 Results of Medio-Lateral Testing

is required on the medial side of the joint. Other interesting points are:

(a) The malleolar strains caused by medial loads on the TPR and ICLH prostheses were virtually identical.

(b) The strains caused by medial loads on the Oregon prosthesis did not increase linearly and in addition started by being lower than the strains for the other implants, but soon became greater. It is felt that this non-linear behaviour was due to the stress distribution on the inside of the malleolus changing as the force increased (i.e. it is likely two factors were changing - the lever arm and the force as shown in Figure 5.20).

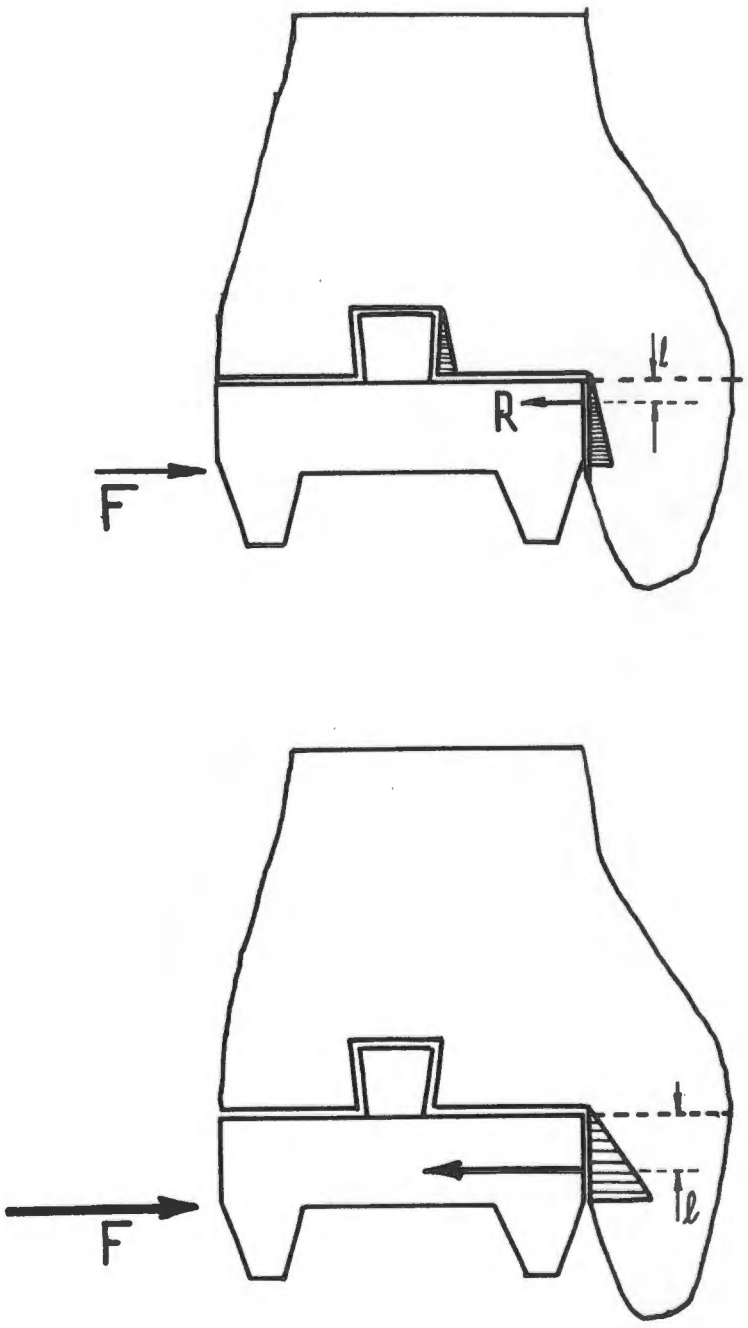


Fig. 5.20 Possible Relationship Between Force and Lever Arm

(c) The highest strain recorded for a load of 18N (about 0,03 BW) was $7,6 \times 10^{-5}$ (for the Oregon prosthesis). This corresponds to a stress of approximately 0,07 MPa. Although one is tempted to estimate the corresponding stress in vivo as 0,7 MPa for a medial force of 0,3 BW, this is inadvisable since the internal structure of bone and model is not comparable.

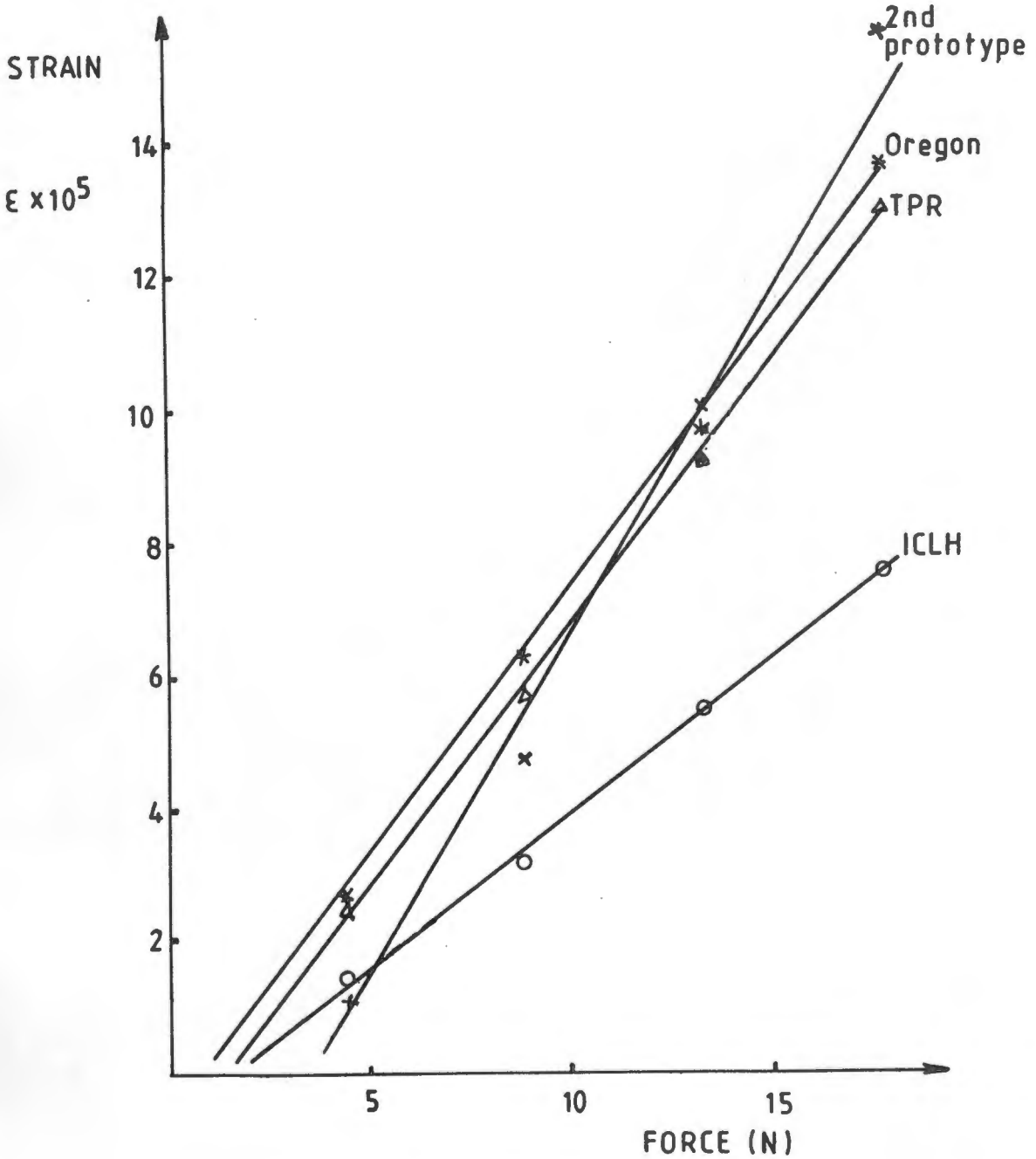


Fig. 5.21 Results of Antero-Posterior Testing

Results of Antero-posterior Loading. Figure 5.21 shows the strains on the posterior cortex of the tibia for different prostheses and loads. In the case of the new prototype and the ICLH prostheses the posterior strain gauge was positioned across a point in line with the apex of the fixating ridges, whereas for the TPR and the Oregon implants, it was slightly lower. The

reason for this difference was that in the latter two designs the posterior cortical wall acted to support the prosthesis and would therefore be subjected to higher stresses than more proximal regions. (Figure 5.17 gives the positions of the gauges.)

From Figure 5.21 it can be seen that the strains on the posterior wall for the TPR and Oregon prostheses are directly proportional to load and, in addition, are almost identical. Since there is more bone resection in the case of the Oregon system, the fixating ridge itself must shield the posterior cortex to a greater degree than the TPR projection. This is probably due to the latter protrusion being made from UHMWPE and therefore being less rigid than the metal ridge on the Oregon prosthesis.

Other interesting points are;

(a) The ICLH prosthesis has the lowest stresses on the posterior wall. This does not mean it has the best method of fixation since it is felt the small contact area between prosthesis and bone will cause high compressive stresses between the ridge and surrounding bone. In addition any torque in the transverse plane will tend to cause the implant to swivel around.

(b) The curve relating strain on the posterior cortex to the applied force for the new prototype has a gradient steeper than any of the other three implants that were tested. This could be due to the fact that the implant was inserted from the lateral side and hence some cortical bone support was removed. (This would make it easier for the posterior margin to deflect).

(c) Although the new helical prosthesis seemed to cause higher strains (for a force of 18N) on the posterior aspect of the tibia, it is felt its ability to resist anterior loosening

would be superior to that of either the TPR or Oregon implants. This would be advantageous since the peak tangential force on the distal end of the tibia during gait is in the anterior direction.

To summarise, it would appear that the method of testing the overall performance of the fixating system is valid and gives results which are not immediately obvious. In addition, it indicates that due caution must be exercised in fitting a prosthesis such as the new helical prototype since there must be adequate bone on the anterior and posterior margins of the tibia. This suggests that it may be advisable to provide the surgeon with a choice of sizes, so that for a smaller patient a component with fixating ridges slightly closer could be selected for implantation.

With regard to withstanding peak tangential loads of 0,7 BW (anteriorly) and 0,3 BW (medially) the new prototype compares favourably with the other three commercial prostheses that were tested.

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With regard to withstanding peak tangential loads of 0,7 BW (anteriorly) and 0,3 BW (medially) the new prototype compares favourably with the other three commercial prostheses that were tested.

CHAPTER 6

CONCLUSIONS AND RECOMMENDATIONS

6.1 The Design of the Prosthesis

The artificial ankle joint that has been designed in this study is based both on known biomechanics and on various assumptions which, at present, seem feasible. It may happen though that in the future these assumptions will have to be modified when new information becomes available (especially with regard to ankle forces). If alterations to the design are needed then it is hoped that by following the same procedure outlined in Chapter 4, the design will be relatively simple to change. It should be remembered that throughout the design of the fixating ridges, a "factor of safety" was used which incorporated an "uncertainty factor" of at least two (see Appendix C). This means that even if the actual loads at the ankle are twice as great as those assumed, the design presented in this study will still be valid.

Whilst it is acknowledged that further refinements to the design may be required, it is felt that the present version is superior to other implants for the following reasons:

(a) It does not restrict the ankle to operate as a simple hinge but rather allows the foot to move in harmony with the major muscles as they cause it to dorsi- or plantar-flex.

(b) No extra loads are placed on the collateral ligaments since the axis of rotation is maintained as closely as possible. (This is not the case with multi-axial prostheses.)

(c) Very little resection, especially of the talus, is required (**i.e.** arthrodesis is still a viable alternative should the prosthesis fail).

(d) If, after a number of years **in vivo**, the plastic component wears thin, then it could be replaced without the need for

the removal of the entire prostheses (since the plastic articulating surface can be unclipped from the metal component which is fitted to the distal end of the tibia).

(e) The fixating projections can be made porous to allow bone ingrowth. This implies that the surgeon would have the choice of using filler cement or encouraging biological fixation.

(f) The metallic backing to the side walls affords these structures added stability.

(g) It is unlikely that the prosthesis will "sink" into the tibia since anterior and posterior cortical support is provided. In addition, since the fixating projections are metallic, they are structurally more robust.

(h) Since the lateral approach is intended, the preparation of the bone surfaces to receive the implant will be easier from a surgical point of view. (With an anterior approach it is difficult, first to gain access to the posterior part of the joint, and second to trim the talus such that the dome has a constant radius of curvature.)

Modifications to the Design. After the second prototype had been made and tested as described in Chapter 5, it became apparent that:

(a) the method of unclipping the plastic unit from the metallic tibia component might cause difficulties during a repeat procedure. (By prising them apart, the integrity of the tibial fixation could be damaged by tensile stresses on the interface.) If this problem did arise, then a slightly different system of attachment between the two parts may be required.

(b) In order that more patients could benefit from the design presented in this study, it is felt that different size prostheses should be made.

(c) Since the anterior forces on the ankle during gait are approximately 2,3 times greater than the posterior forces, it may be advisable to place the fixating ridges slightly further back (relative to the axis of rotation) so that the anterior cortical wall is thicker than that posteriorly. (This principle is used in the design of the ICLH prosthesis.) At the moment, however, it seems that stresses on the outer aspect of the cortical wall will be well within acceptable limits so this change may not be necessary.

6.2 The Testing of the Prosthesis

Just as it is convenient for future researchers to have a definite design procedure to follow, so is it in their interests to have a series of objective tests by which any new design can be evaluated.

As was mentioned in Chapter 5, most of the previous tests which have been performed by other authors suffered from being either statistically unsound (i.e. biological variability was ignored) or were inappropriate. Although the tests on fixation which were described in Section 5.7.3 can still be improved, it is felt they were more informative than those described in the literature.

In general the tests on the new helical prosthesis showed:

(a) From a surgical point of view, the alignment and positioning of the device is easier if a lateral approach is used.

(b) It is far more convenient to use plastic replicas of the ankle rather than actual human joints in determining as-

pects such as bone resection, range of motion, adequacy of fixation.

(c) The new prototype required very little resection of the inner aspect of the medial malleolus and the dome of the talus (when compared to other prostheses).

(d) It is unlikely the tibial component will come into contact with the talus in either of the extreme dorsi- or plantar-flexion positions.

(e) The range of motion of 30^{o} in the sagittal plane could be improved by decreasing the "overlap" between the tibial and talar components.

(f) Care must be taken by the surgeon when fitting the tibial unit that there is adequate anterior and posterior bone support for the fixating ridges.

Modifications to the Tests. With regard to testing fixation, extreme care had to be taken when implanting the prostheses into the polyurethane models since malpositioning would have affected the results. It is thus felt the prosthesis should be coated with a release agent and the bone then cast around the component. This would ensure good contact between the fixating projections and the "bone", as well as allowing the implant to be removed for other tests.

It is also thought that both cancellous and cortical bone should be modelled. This may be possible by casting a more dense plastic shell around a less dense polyurethane "core".

6.3 Selection of Patients

The prosthesis which has been designed and tested in this study is intended for initial use only in patients who:

(a) Have not had a fracture of the ankle

(b) Have sound collateral ligaments

(c) Have no severe deformity of the foot

(d) Are relatively inactive (e.g. in the case of aged people), but are not obese

(e) Suffer from rheumatoid arthritis (patients with osteoarthritis can undergo arthrodesis of the ankle)

(f) Are willing to cooperate during post-operative management. (In this regard it is felt that if the patient is willing to wear soft-heeled shoes, the chances of the prosthesis loosening will be substantially reduced.)

6.4 Future Work

It is hoped that research into artificial ankle joints will be continued at the University of Cape Town since there are aspects which must still be covered. As these were not intended for inclusion in the initial study.

The main area which needs further work is that of instrumentation. It is vitally important that the surgeon has at his disposal, instruments that are simple to use, and yet ensure correct alignment of the prosthesis. The purpose of these tools would be as follows:

(a) Locate the axis of rotation of the ankle joint

(b) Indicate the level at which the fibula should be transected

(c) Demarcate those areas of bone which need removal

(d) Facilitate the gross resection of bone

(e) Allow accurate slots to be cut into the tibia for the reception of the fixating ridges

(f) Allow accurate drilling of the central hole into the dome of the talus

(g) Provide a means of checking the new axis of rotation

of the implant

Although an in-depth study on the instrumentation for the new prosthesis has yet to be performed, initial indications are that it may be advantageous to:

(a) first prepare the bone surface on the distal end of the tibia so that there is more room for manoeuvering

(b) trim the medial and lateral sides of the dome of the talus simultaneously, using an oscillating saw with a special blade attachment (see Figure 6.1)

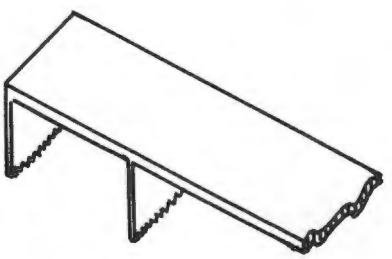


Fig. 6.1 Special Blade (schematic)

(c) use a "Tuke" saw as in the ICLH procedure (see Figure 6.2) for cutting a hole in the talar dome (a drill is difficult to operate in the narrow confines of the ankle joint cavity)

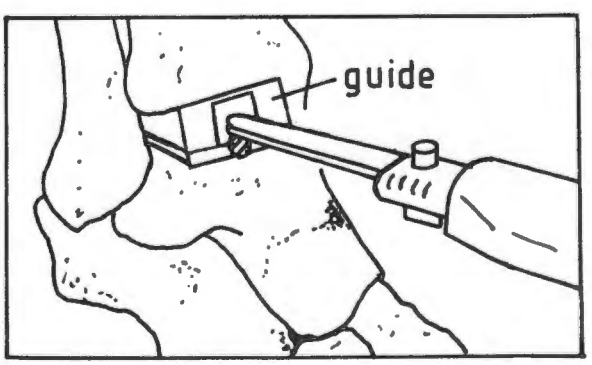


Fig. 6.2 Drilling a Hole with a Tuke Saw

Besides evaluating the modifications mentioned in sections 6.1 and 6.2, other areas in which research can still play a role are:

(a) determining the effect of helical motion on the wear rate of UHMWPE

(b) evaluating the use of cement lugs or porous projections as a means of improving fixation

(c) evaluating different metals (e.g. titanium, cobalt chrome alloy) for use in ankle arthroplasty

With regard to biomechanics of the ankle, it would be interesting to perform an optimisation study to look at the motion that is desirable at the joint (given the phasic behaviour and positions of the muscles). This is opposite to the usual procedure of estimating muscular torques by knowing the motion at the joint.

6.5 Conclusions

After initial tests had shown the first helical prototype was inferior to existing prostheses, a second prototype was designed by considering the ankle complex as a whole. This second implant was then tested along with three other commercial ankle prostheses and the results were very promising.

It is interesting to compare this procedure of developing an implant to that suggested by Dowson and Wright (1981). Their procedure which is shown in Figure 6.3, and which is very similar to the one adopted in the case of the second prototype, shows the interdisciplinary nature of the design process. In the case of the latest design, engineers, orthopaedic surgeons, surveyors, and technicians all made substantial contributions. It is anticipated that further dissiplines will become involved when the manufacturers are approached with the task of making a prosthesis

for actual implantation and when post-operative gait analysis studies are undertaken.

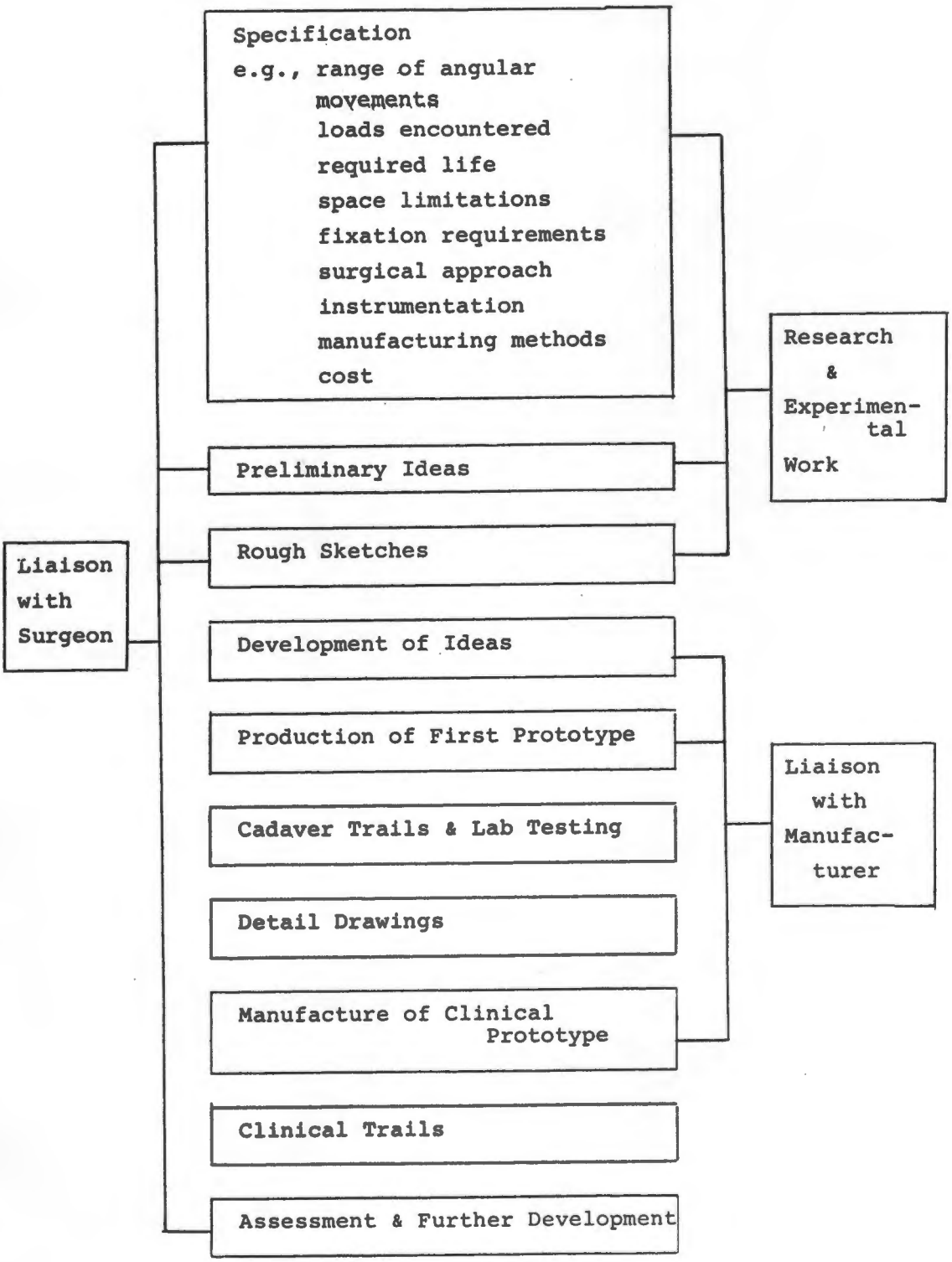
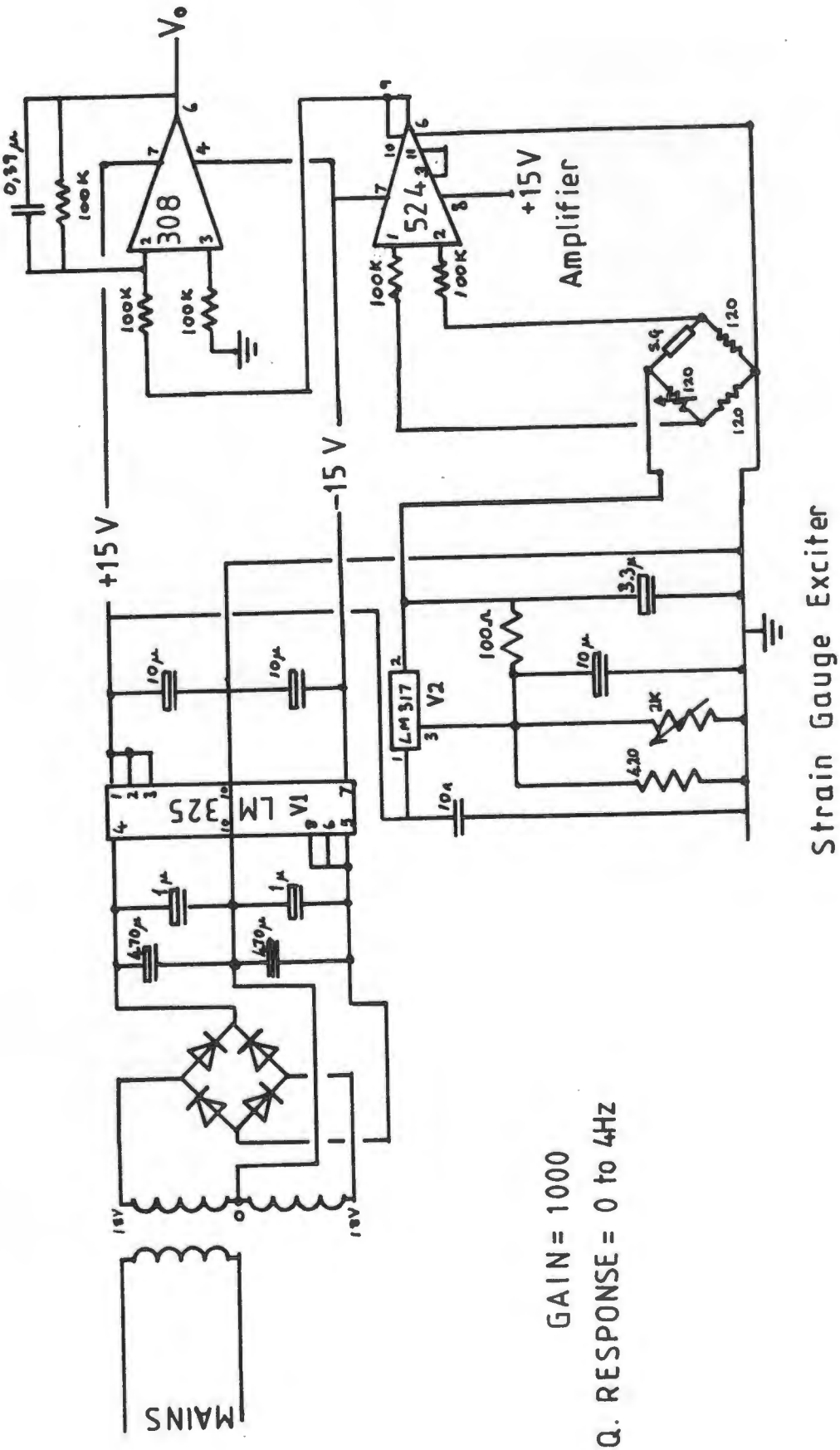


Fig. 6.3 An Idealised Rational Design Procedure (Dowson and Wright, 1981)

SURVEY	NO. Of Patnts	Avr. Yrs of follow up	REASONS FOR ARTHRODESIS	TECHNIQUE (SURGICAL)	COMPLICATIONS	RESULTS
Mazur et al 1979	12	8 (3-13)	Traumatic Arthritis	Charnley Compression-9 Fib. graft - 2 Hatt Fusion - 1	None (but 9 could not run).	A weighted point system based on pain & functional activities was used. Aver.pre-operative score - 40,3% Aver.post-operative score- 80%
Lance et al 1979	168	4 yrs (7 mths 11yrs)	60% - Ant.Poliomyelitis 25% - Post Traum Arthritis 6% - Neurological disorder 3% - R A 6% - Other	Transfibular 44 Anterior Arthrodesis 36 Distraction / Compression 50 Compression 18	Non-union - 11% " " 22% " " 36% " " 6%	Unsatisfactory - 13% " 31% " 45% " 33%
Morrey, Weiderman 1980	60	7	Post-Traumatic Arthritis	Charnley Anterolateral (20) Lateral (12) Medial & lateral (11) Transverse (3) Blair (8) Other (3)	48% had either infection, non union malalignment or delayed union. 25% 92% 36% 67% 50% 50% Aver 48%	Subjective assessment by patients showed that 83% were satisfied.
Scranton et al 1980	50	15 mths	Post-traumatic degenerative arthritis - 80% other - 20%	Charnley (16) R.A.F. (18) Hoffman (8) other (8)	Non union 37.5% 22.2% 31.2% 42.8% Aver. 30%	The most complications occurred in patients with deformed ankles.
Boobbyer 1981	37	8 1 - 17	Post traumatic OA (23) RA (6) Secondary OA (2) Neurological Disorders (6)	Charnley Classical Xverse Section (6) Longitudinal ant incision (11) Roger Anderson (9) Cambpell & Rinehart (7) Brian Thomas (3) R A F (1)	5 poor results (2 (non union)) 2 non unions Good result " " 2 non unions 1 non union Overall 20% of Pseud-Arthrosis.	Objective Assessment, Excellent 32.5% Good 32.5% Fair 5% Poor 30%
Ahlberg & Henricson 1981	44	12,3	Post traumatic OA 55% Arthritis after infection 9% R A 7% Ankle fracture 7% Other 22%	Charnley Compression (14) Transfibular (16) Hatt (7) Ant tibial sliding graft (5)	Deep infection - 14% Superficial infection - 11% Overall non-union - 18%	68% had pain 74% walked with limp 23% severe limp

APPENDIX B

CIRCUIT DIAGRAM FOR STRAIN GAUGE AMPLIFIER



APPENDIX C

FACTOR OF SAFETY

Allowable stress = yield strength/f.o.s

f.o.s = b x c x d x k

where b = fatigue factor

= 1 for load between zero and maximum

= 1,5 for load causing alternate tension and compression

c = shock factor

= 1 for load gradually applied

= 2 for load suddenly applied

= 2,5 for impact load

d = uncertainty factor

= 1,2 - 1,5 for ductile steels

= 2 - 4 for materials in uncertain environment

k = stress concentration factor

= 1,5 - 2 (usually)

For annealed stainless steel fixating projection;

f.o.s = 1,5 x 1,1 x 3 x 1,6

= 8

For cancellous bone;

f.o.s = 1 x 1,1 x 2 x 1,6

= 3,5 (say 4)

For UHMWPE;

f.o.s = 1 x 1,1 x 1,5 x 1,6

= 2,7

APPENDIX D

FATIGUE STRESSES

In most engineering materials, a stress that fluctuates between two levels is more likely to cause failure than a steady stress equal to the greater of the two. However, in the case of steels, below a certain reversed stress no failure will occur. This limit is the fatigue endurance limit (f_{el}).

In order to avoid fatigue failure, the so-called "Soderberg criterion" is usually used. (see Figure D.1)

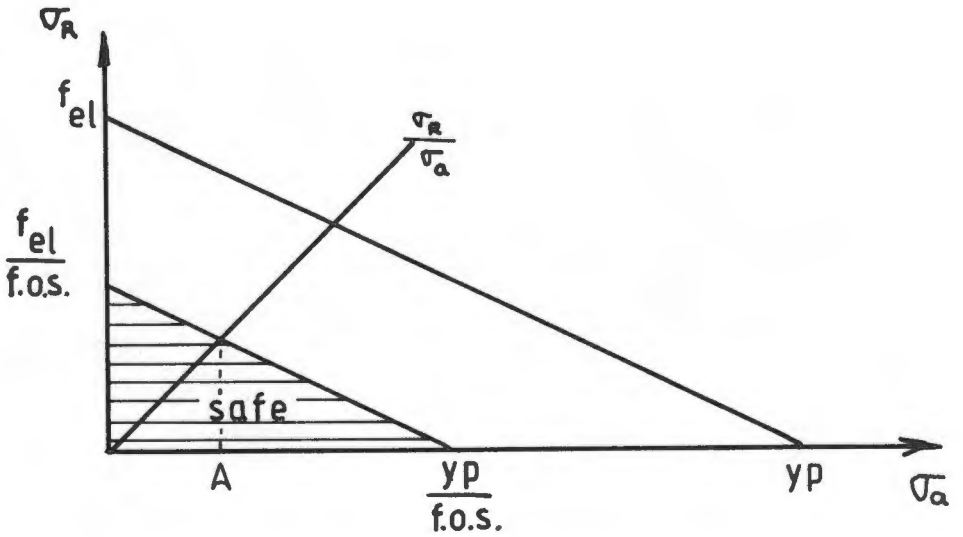


Fig. D.1 Soderberg Line

Average stress, $\tau_a = \frac{1}{2}(\tau_{max} + \tau_{min})$

Range stress, $\tau_R = \frac{1}{2}(\tau_{max} - \tau_{min})$

(if $\tau_{min} = 0$ then $\tau_R/\tau_a = 1$)

The sketch above shows a line drawn through the yield point and the endurance limit on average stress - range stress coordinates. Parallel to this line is the "safe line" which takes a factor of safety into account. Any combination of average stress and range stress to the left of this line will be regarded as "safe". If the ratio of these stresses is unity then the average permissable stress is given by point "A" shown in the sketch.

Annealed stainless steel. Figure D.2 shows the Soderberg criterion applying to annealed stainless steel (316L). The data used were:

f_{el} = 270 MPa
y.s = 290 MPa
f.o.s = 8 (from Appendix C)

The average permissible stress is seen to be 18 MPa.

UHMWPE. Figure D.3 shows the Soderberg criterion applying to UHMWPE. The data used were:

f_{el} = 15 MPa
y.s = 12 MPa
f.o.s = 2,7 (from Appendix C)

The average permissible stress is seen to be 3 MPa.

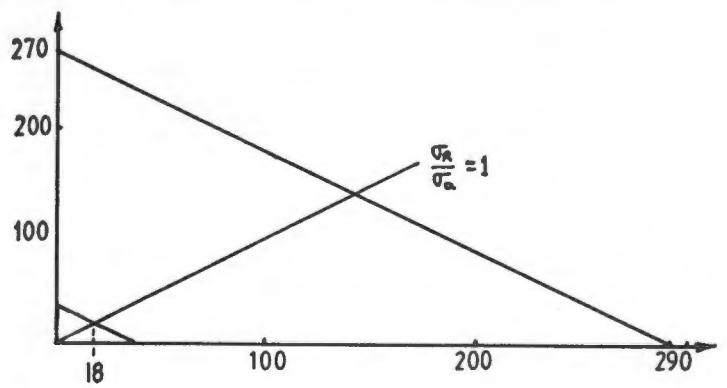


Fig. D.2 Soderberg Line for Stainless Steel

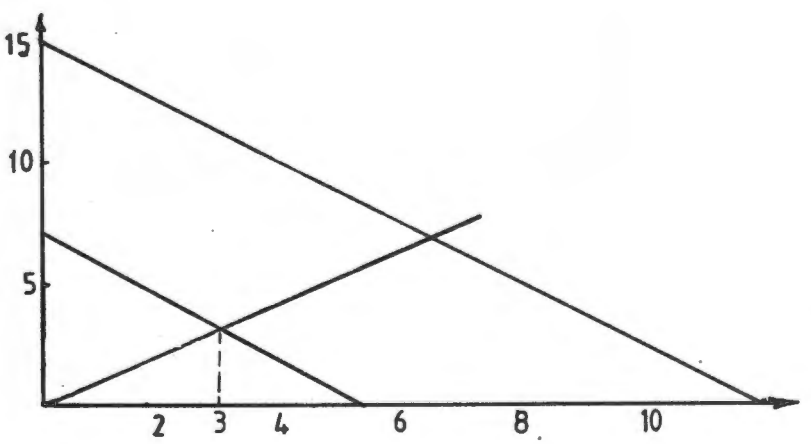


Fig. D.3 Soderberg Line for UHMWPE

APPENDIX E

COMPRESSIVE STRESS ON BONE

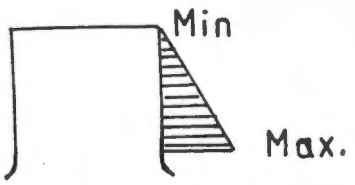


Fig. E.1 Stress Distribution

If the stress distribution on the bone/cement interface is as shown in Figure E.1 then the peak compressive stress will be twice the average stress.

Average compressive stress, σ_c = Force/Area

= F/A

= 0,3BW/Area

= 0,3 x 700/hx

= 210/hx

Maximum stress, $\hat{\sigma}_c$ = 2 x 0,3 x 700/hx

= 420/hx for a 70kg person (1)

Minimum stress, = 0 MPa

For a factor of safety of 4 (see Appendix C)

$\hat{\sigma}_c \leq 30/4$ MPa (if yield strength is 30 MPa)

$\leq 7,5$ MPa (2)

Combining equations (1) and (2) gives

$$7,5 \leq 420/hx$$

or $$hx \geq 420/7,5$$

$$\geq 56mm^2$$

APPENDIX F

PRINCIPAL STRESS ON FIXATING RIDGE

In Figure F.1, failure is most likely to originate either at points B or C. The resultant force F fluctuates between -0,7BW and +0,7BW and is situated 1/3h above the base of the ridge. It causes both shear and direct stresses at B and C.

Shear stress, $\tau = F/2,3x^2$ (1)

Direct stress, $\sigma_d = Mt/I$ (2)

where M = Bending Moment

= Fh/3

y = variable between 0 and x/2

I = second moment of area section

$= 2,3x(x)^3/12$

Substituting into equation (2) gives

$$\text{Maximum } \sigma_d = \frac{12Fhx}{3 \times 2 \times 2,3x^4} = \frac{Fh}{1,15x^3} \quad (3)$$

According to Rankine's theory of maximum principal stress,

$$\sigma_{MAX} = \frac{1}{2}(\sigma_d + \sqrt{\sigma^2 + 4\tau^2}) \quad (4)$$

Using equations (1), (3) and (4) and F = 0,7BW, for a 700N person the maximum stress is:

$$\tau_{MAX} = \frac{1}{2}\left(\frac{0,7 \times 700h}{1,15x^3} + \sqrt{\left(\frac{0,7 \times 700h}{1,15x^3}\right)^2 + 4\left(\frac{0,7 \times 700}{2,3x^2}\right)^2}\right)$$

$$= \frac{1}{2}\left(\frac{426h}{x^3} + \sqrt{\left(\frac{426h}{x^3}\right)^2 + \left(\frac{426}{x^2}\right)^2}\right)$$

$\leq$ 18 (from Appendix D)

$$36 \geq \frac{426h}{x^3} + \sqrt{\left(\frac{426h}{x^3}\right)^2 + \left(\frac{426}{x^2}\right)^2} \quad (5)$$

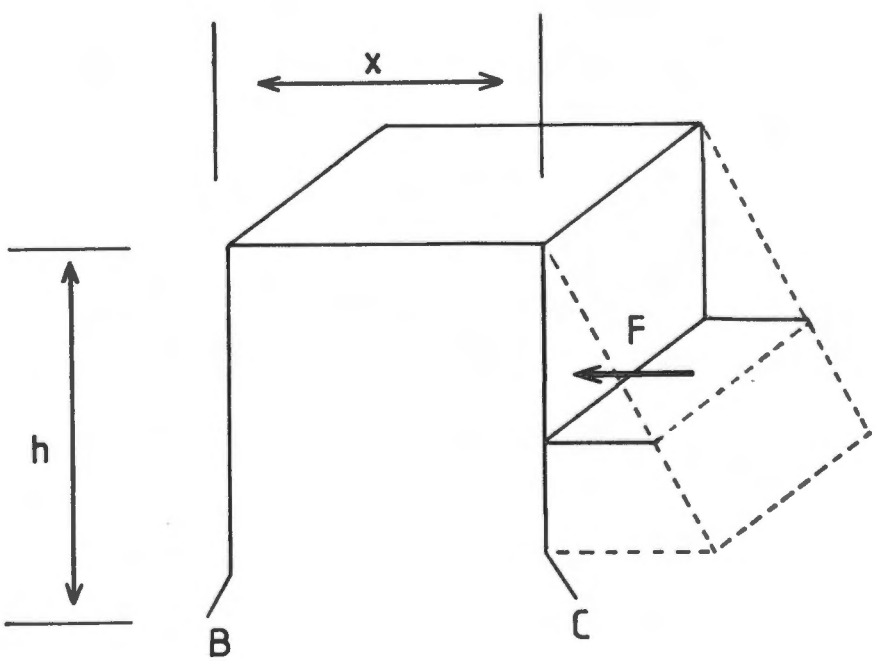


Fig. F.1 Cross Section of Fixating Ridge

APPENDIX G

FRACTURE THROUGH ANTERIOR CORTICAL BONE

As we assumed earlier, a third mode of failure is transversely through the tibia. This necessitates failure of cancellous as well as cortical bone.

Fracture through the anterior part of the tibia:

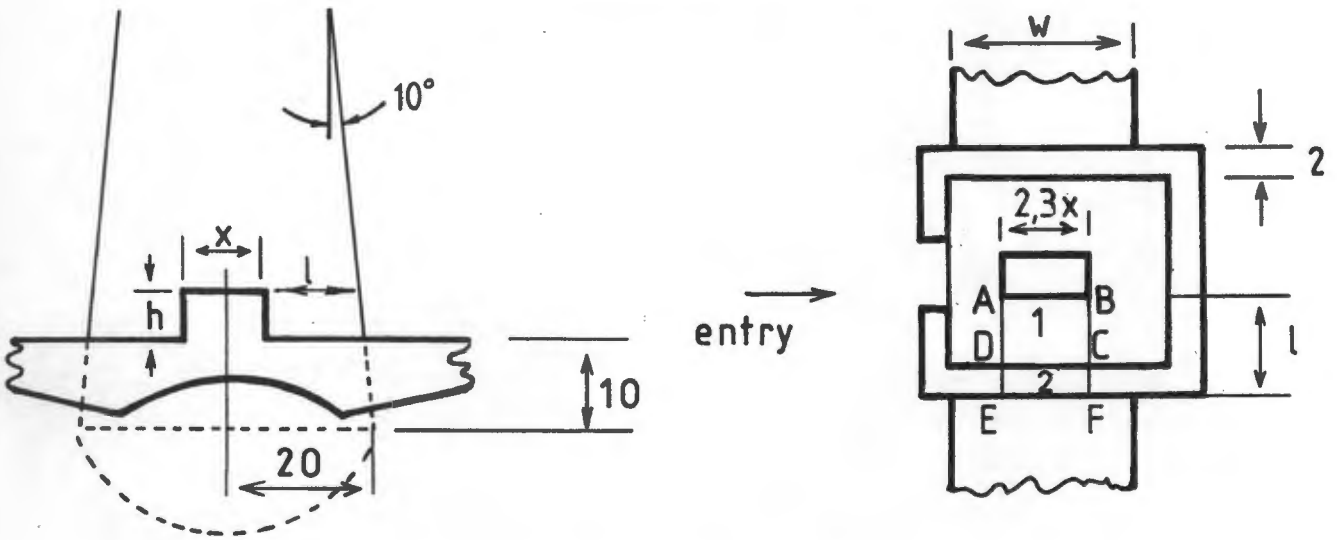


Figure G.1 Modelling Fracture through Anterior Cortex

If the height of the prosthesis (excluding fixating projections) is estimated at 10mm (see Figure 4.14(a)), then the dimension designated as 'ℓ' will be

$$\ell = 20 - (h + 10)\tan 10^{o} - x/2 \qquad (1)$$

The area is then;

$$A = \text{length} \times \text{breadth}$$

$$= \ell \times 2{,}3x \qquad (2)$$

The area of bone above the prosthesis is approximately given by;

$$A_T = \text{length} \times \text{breadth}$$

$$= (2\ell + x)(w) \qquad (3)$$

$$= (2(20 - (h + 10)\tan 10^{o} - x/2)w$$

$$= (40 - 2(h + 10)\tan 10^{o} - x + x)w$$

$$= (40 - 2(h + 10)\tan 10^{o})w \qquad (4)$$

This can be subdivided into area of hard cortical bone (A_H) and area of spongy cancellous bone (A_S).

$$A_H = 2(w \times 2mm)$$
$$= 4w \quad (5)$$

$$A_S = A_T - A_H \quad (6)$$

At the moment when the maximum a/p force is acting, so is the maximum compressive force. (Stauffer 1977)

The compressive load is shared between A_H and A_S as follows;

$$\frac{N_H}{A_H \times E_H} = \frac{N_S}{A_S \times E_S} \quad (7)$$

where $E_H = 20\ 000\ N/mm^2$

$E_S = 1\ 000\ N/mm^2$

N_H = Axial force on cortical bone

N_S = Axial force on spongy bone

$$N_H = \frac{(N_S)\ (A_H)\ 20}{A_S} \quad (8)$$

$(N_S = N_T - N_H)$

but $N_S = 4BW - N_H$

$$= 2800 - N_H \quad (9)$$

$$N_H = \frac{(2800 - N_H)\ A_H \times 20}{A_S}$$

$$= \frac{2800\ A_H \times 20}{A_S} - \frac{N_H \times A_H \times 20}{A_S}$$

$$N_H = \frac{56000\ A_H}{A_S + 20A_H} \quad (10)$$

Compressive axial stress on cortical bone is

$$\sigma_{ACOMP} = \frac{N_H}{A_H}$$

$$= \frac{(N_S)\ (A_H)\ 20}{A_S\ \ A_H}$$

$$= \frac{20N_S}{A_S} \quad (11)$$

(i.e. twenty times the stress on the cancellous bone)

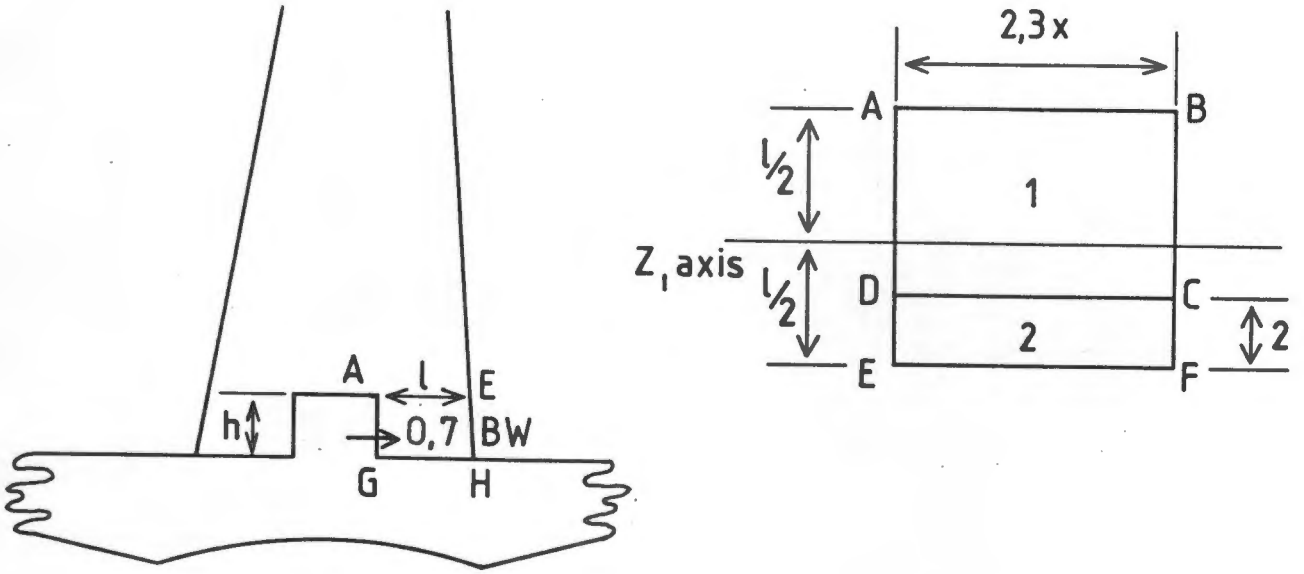


Figure G.2 Section of Anterior Cortex

As a very conservative estimate the shear strengths of the planes perpendicular to ABFE (AEGH) will be considered as zero.

The bending moment on plane ABFE is

$$M = 0,7BW \times 2/3h$$

$$= 0,7 \times 700 \times 2/3h$$

$$= 326h \qquad (12)$$

and $$M = M_1 + M_2 \qquad (13)$$

For a complete section (such as ABFE) the curvature due to a bending moment is the same for each material.

$$\frac{M_2}{E_H \times I_2} = \frac{M_1}{E_S \times I_1} \qquad (14)$$

where E_H and E_S are as before.

$$M_2 = \frac{M_1 \times E_H \times I_2}{E_S \times I_1} = \frac{(326h - M_2)\, E_H \times I_2}{E_S \times I_1}$$

$$M_2 = \frac{326h\, E_H\, I_2}{E_S\, I_1 + E_H\, I_2} \qquad (15)$$

About Z_1 axis (see Figure G.2), the second moments of area are:

$$I_1 = \frac{bd^3}{12} + \text{Area} \times (\text{shift})^2$$

$$= \frac{2,3x\ (\ell - 2)^3}{12} + 2,3x\ (\ell - 2)\ X1$$

$$= (2,3x\ (\ell - 2))\ (\frac{(\ell - 2)^2}{12} + 1) \qquad (16)$$

$$I_2 = \frac{bd^3}{12} + \text{Area} \times (\text{shift})^2$$

$$= \frac{2,3x\ (2^3)}{12} + ,3x(2)\ (\ell/2 - 1)^2$$

$$= 2,3x\ (2/3 + \frac{\ell^2}{2} - 2\ell + 2) \qquad (17)$$

The tensile stress along AB due to bending

$$\sigma_{BTEN} = \frac{(M_1)\ (\ell/_2)}{I_1} \qquad (18)$$

Compressive stress along EF due to bending

$$\sigma_{BCOMP} = \frac{(M_2)\ (\ell/_2)}{I_2} \qquad (19)$$

Combined compression along EF (due to bending and axial load)

$$\sigma_{TCOMP} = \sigma_{ACOMP} + \sigma_{BCOMP}$$

$$= \frac{20N_S}{A_S} + \frac{(M_2)\ (\ell/_2)}{I_2} \qquad (20)$$

If compressive strength of cortical bone is 130MPa and a factor of safety of 4 is allowed, then

$$33 \geq \frac{20N_s}{A_S} + \frac{M_2\ell}{2I_2}$$

Resultant on AB;

$$\sigma_{RES} = \sigma_{ACOMP} - \sigma_{BTEN} \qquad (21)$$

Since cancellous bone should not be placed in tension, σ_{RES} should be greater than zero.

APPENDIX H

PRINCIPAL STRESSES ON BASES OF TWO RIDGES

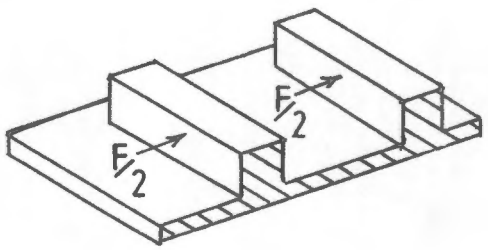


Figure H.1 Section Through Two Fixating Ridges

According to Rankin's theory of maximum principal stress,

$$\sigma_{max} = \frac{1}{2}(\sigma + \sqrt{\sigma^2 + 4\tau^2}) \quad \text{(see Appendix F)}$$

In this case, for h = 6 and x = 5 and length, 16mm.

$$= \frac{F}{5 \times 16}$$

$$= \frac{0,7 \times 700}{2 \times 80} \quad \text{(for 700N person)}$$

$$= 3,1 \text{ MPa}$$

$$\sigma = \frac{My}{I}$$

$$= \frac{(0,7 \times 700) \times (6/3) \times (5/2) \times 12}{2 \times 16 \times 5^3}$$

$$= 7,35$$

$$\sigma_{max} = 0,5(7,35 + \sqrt{7,35^2 + 4(3,1)^2})$$

$$= 8,5 \text{ MPa}$$

Compressive stress on front of tibia due to M_2 is:

$$\sigma_{BCOMP} = \frac{M_2 \ (\ell/2)}{I_2}$$

$$= \frac{924 \ (3,5)}{211}$$

$$= 15,3 \text{ MPa}$$

The expressions for compressive stress due to axial loads will be virtually the same as that derived in Appendix G (Equations 1 to 11) and hence for h = 6 and x = 5,

$$\sigma_{ACOMP} = 17 \text{ MPa}$$

Combining these two stresses gives

$$\sigma_{TCOMP} = (15,3 + 17) \text{ MPa}$$

$$= 32,3 \text{ MPa which is less than the allowable limit of 33 MPa.}$$

APPENDIX I

COMPRESSION ON ANTERIOR TIBIAL CORTEX FOR THE CASE OF TWO RIDGES

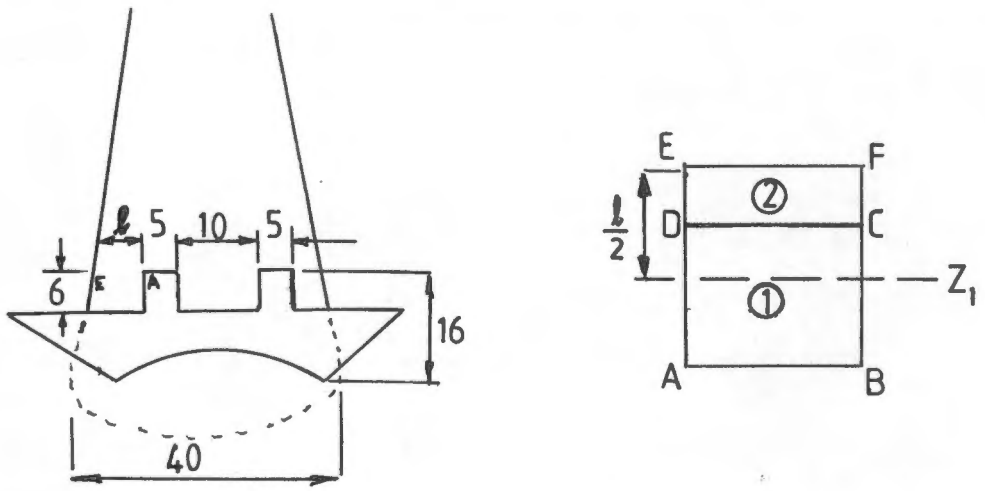


Figure I.1 Section of Anterior Cortex

From Figure I.1

$$\ell = 40 - 10 - 2(5) - 2(\tan 10°)$$
$$= 7\text{mm}$$

About Z_1 axis,

$$I_1 = \frac{bd^3}{12} + \text{Area X(shift)}^2$$

$$= \frac{16(5)^3}{12} + 16 \times 5 \times 1$$

$$= 247\text{mm}^4$$

and $$I_2 = \frac{16(2)^3}{12} + 16 \times 2 \times (2{,}5)^2$$

$$= 211\text{mm}^4$$

If bending moment is assumed to be half that used in Appendix G (since there are two ridges), then

$$M = 326h/2$$
$$= 163 \times 6$$
$$= 978\text{Nmm}$$

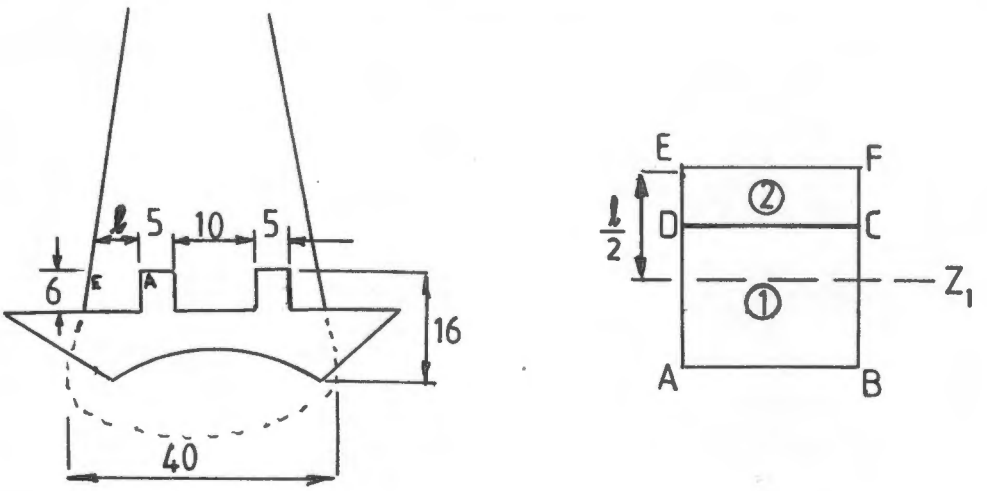
and $$M_2 = \frac{978 \times E_H I_2}{E_S I_1 + E_H I_2}$$

$$= \frac{978 \times 20 \times 211}{247 + 20 \times 211}$$

$$= 924\text{Nmm}$$

APPENDIX I

COMPRESSION ON ANTERIOR TIBIAL CORTEX FOR THE CASE OF TWO RIDGES



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$$= 7\text{mm}$$

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$$= \frac{16(5)^3}{12} + 16 \times 5 \times 1$$

$$= 247\text{mm}^4$$

and $$I_2 = \frac{16(2)^3}{12} + 16 \times 2 \times (2{,}5)^2$$

$$= 211\text{mm}^4$$

If bending moment is assumed to be half that used in Appendix G (since there are two ridges), then

$$M = 326h/2$$
$$= 163 \times 6$$
$$= 978\text{Nmm}$$

and $$M_2 = \frac{978 \times E_H I_2}{E_S I_1 + E_H I_2}$$

$$= \frac{978 \times 20 \times 211}{247 + 20 \times 211}$$

$$= 924\text{Nmm}$$

APPENDIX J

STRESS ANALYSIS ON TALAR FIXATING PEG

If the ratio of the Young's Moduli of cortical and cancellous bone is assumed to be twenty, then the stress on the former will be twenty times that on the cancellous bone.

$$\text{i.e. } \frac{21}{20}\sigma_{COR} = \frac{\sqrt{(0,7BW)^2 + (0,3BW)^2}}{hd} \qquad \text{(see Figure J.1)}$$

where σ_{COR} is the permissible stress on cortical bone.

$$\text{From this, } hd \geq 20 \times \frac{\sqrt{(0,7 \times 700)^2 + (0,3 \times 700)^2}}{21 \times 33}$$

(It was earlier assumed that $\sigma_{COR} \leq 33$ MPa)

$$hd \geq 15,4mm^2$$

In other words a cylindrical peg of diameter 4mm and height of 7mm will easily suffice.

In addition, since most of the stress is taken up by the top two millimetres of the peg, the bending moment tending to snap the peg off the undersurface of the prosthesis will be negligible.

To drill the hole into the crest of the talar dome with a conventional drill and bit may be difficult due to the limited space between the talus and the tibia. (Even when the joint is prised open.) For this reason, the system of using an oscillating cutter such as the ICLH procedure is preferred. (see Figure 6.3)

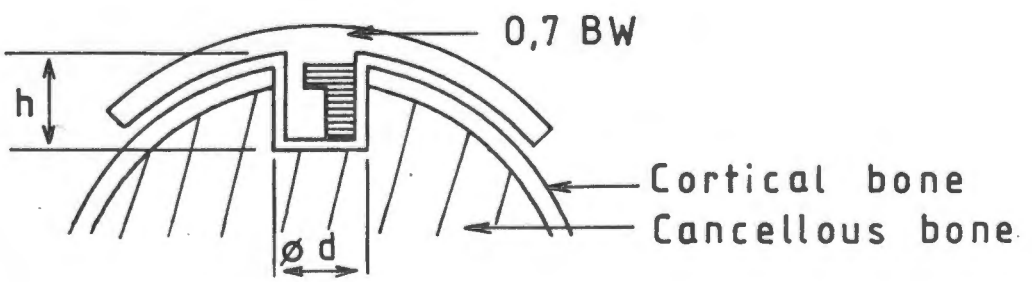


Fig. J.1 Cylindrical Peg

APPENDIX K

FRACTURE THROUGH MEDIAL MALLEOLUS

With regard to a transverse fracture through the medial malleolus the following points are relevant:

(a) The malleolus is not subjected to a compressive load (as are the anterior and posterior aspects of the cortical wall).

(b) It can be placed in tension as the powerful deltoid ligament is attached to it. (Eversion of the foot could cause such tension.)

(c) The average force in the medial direction is about half that in the anterior direction.

(d) Besides the resection needed to accommodate the height of the prosthesis (previously assumed to be 10mm) the medial malleolus need not be weakened. (It is intended that the prosthesis be inserted from the lateral side.)

In the case of failure through the medial malleolus, the origin of bone fracture will not be at the apex of the fixating projection but rather on a plane through its base. (see Figure K.1)

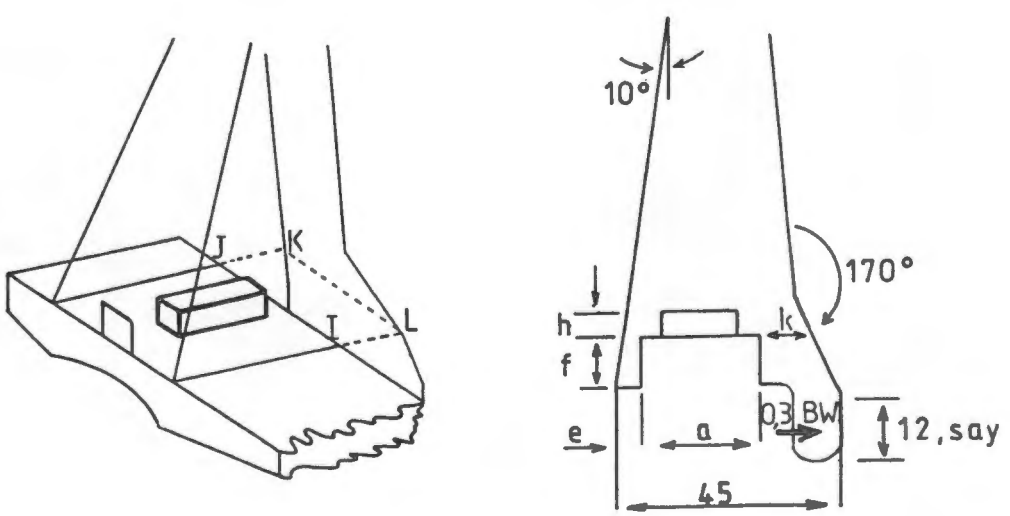


Figure K.1 Modelling Fracture through Medial Malleolus

Note: For previous calculations 'a' was estimated to be 30mm and 'f' to be 10mm

From Figure K.1 the following relationships apply:

$$e = f \tan 10^{o} \tag{1}$$

$$k = 45 - a - e - f \tan 20^{o}$$

$$= 45 - a - f (\tan 10^{o} + \tan 20^{o})$$

$$= 45 - a - 0{,}54\ f \tag{2}$$

$$c = 40 - 2f \tan 10^{o}$$

$$= 40 - 0{,}35\ f \tag{3}$$

As a conservative estimate, the bending moment on plane IJKL will be

$$M = (0{,}3BW) \times 2/3(12 + f)$$

$$= 140\ (12 + f)\ \text{Nmm (for a 70 kg person)} \tag{4}$$

For simplicity, this bending moment will be considered to act only on the cortical bone.

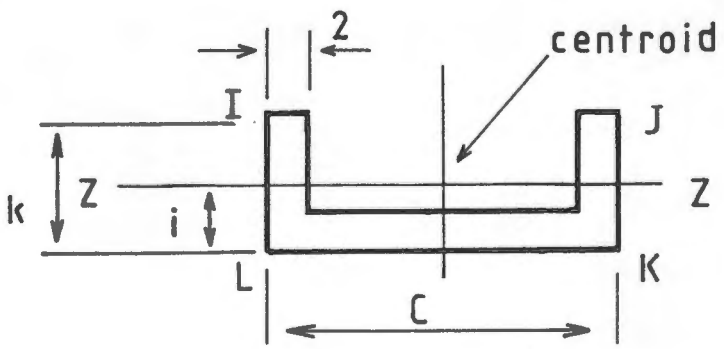


Fig. K.2 Segment of Cortical Bone

From Figure K.2

$$(4k + 2(c - 4))i = 4K(K/2) + 2(c - 4)(1)$$

$$i = \frac{2K^{2} + 2(c - 4)}{4K + 2(c - 4)} \tag{5}$$

About X axis, second moment of area is

$$I_3 = 2\left(\frac{2K^3}{12} + \left(\frac{K}{2} - i\right)^2 (2K)\right) + \frac{(c - 4)2^3}{12} + (i - 1)^2 (2(c-4))$$

$$= K^3/_3 + 4K\left(\frac{K}{2} - i\right)^2 + (c-4)(2/3 + 2(i-1)^2) \tag{6}$$

Now, tension along IJ due to bending moment is

$$\sigma_{BTEN} = \left(\frac{My}{I}\right)$$

$$= \frac{M(k - i)}{I_3} \qquad (7)$$

If tensile strength of cortical bone is 100 MPa and factor of safety of 4 is allowed,

$$25 \geq \frac{M(k - i)}{I_3} \qquad (8)$$

Compression along LK due to this moment is:

$$\sigma_{BCOMP} = \frac{M(i)}{I_3} \qquad (9)$$

As before, $\sigma_{BCOMP} \leq 33$

$$\text{i.e. } 33 \geq {}^{M_i}/_{I_3} \qquad (10)$$

APPENDIX L

ALTITUDE READINGS FROM PHTOGRAMMETRIC STUDY

In chapter 5, profiles were drawn through the ankle joint, using altitude readings taken by the Department of Surveying (UCT). These profiles (B-B, C-C, D-D) were in an antero-posterior direction whilst A-A was directed between the medial and lateral malleolus.

The readings are tabulated below.

TALUS

A-A	B-B	C-C	D-D
39,65	25,6	28,45	27,4
35,1	24,45	27,05	26,1
32,6	23,6	26,05	25,15
22,55	23,0	25,5	24,65
22,55	22,7	25,35	24,2
22,85	22,45	25,35	24,5
23,15	22,45	25,65	24,95
23,7	23,05	26,1	25,7
24,15	23,6	26,95	26,7
24,65	25,4	28,1	28,05
25,05	29,25	30,2	30,25
25,45		33,4	33,65
25,45			
25,05			
24,7			
24,2			
24,7			
25,95			

TIBIA

A	B	C	D
37,0	25,95	26,9	24,5
36,0	24,75	27,0	25,3
33,9	23,8	26,15	24,75
26,5	23,2	25,3	24,2
22,65	22,8	24,8	24,0
22,85	22,5	24,5	23,55
23,05	22,5	24,5	23,5
23,5	22,75	24,65	23,7
23,95	23,15	25,0	24,3
24,4	23,95	25,8	25,15
24,65	26,75	26,3	26,1
24,8	30,0	27,0	27,35
24,8			
24,8			
24,3			
23,95			
24,0			
24,05			
24,8			
27,6			
36,7			
37,5			

APPENDIX M

DETERMINING MODULUS OF ELASTICITY FOR METHYLENE DI-ISOCYANATE

Since the positions of the strain gauges on the distal end of the tibia were such that they detected compressive strains only, it was felt unnecessary to test the polyurethane in tension.

To test the Modulus of elasticity (E) for compressive loads, the following procedure was adopted;

(a) A strain gauge was attached to the undersurface of a polyurethane beam

(b) Four point loading was then applied to the beam (see Figure M.1a and M.1b.)

(c) For each load, the strain was recorded via a voltage signal

(d) By knowing the theoretical stress on the undersurface of the beam and the measured strain, the modulus of elasticity can be found by obtaining the ratio

$$E = \frac{\text{Stress}}{\text{Stress}} = \frac{\sigma}{\varepsilon}$$

and $\sigma = \frac{My}{I}$

from figure M.1, $M = \frac{Fx}{2}$ (x=17mm)

$I = \frac{bd^3}{12}$ (b=16,3mm, d=14,8mm)

$y = \frac{d}{2}$

Therefore $\sigma = \frac{51F}{bd^2}$

and $E = \frac{51}{bd^2} \times \frac{F}{\varepsilon}$ (F is the applied load)

$$= 0{,}0143 \times \frac{F}{\varepsilon} \qquad (1)$$

To determine F/ε :

$$\varepsilon = \frac{2\,\frac{Vo}{F}\,F}{A\ Ve\ G}$$

where A = amplification = 1000
Ve= excitation voltage = 2,58Volts
G = Gauge Factor = 2,15
Vo= Output Voltage
F = Applied load

From Figure M.2,

$$\frac{Vo}{F} = 0{,}0416$$

$$\varepsilon = \frac{2(0{,}0416)F}{1000x2{,}58x2{,}15}$$

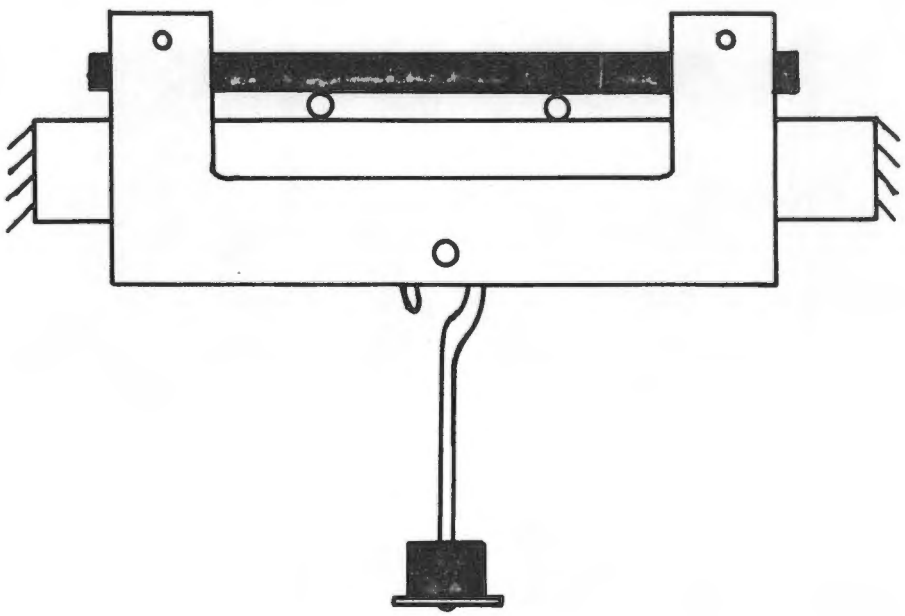
$$= 1{,}5 \times 10^{-5}F \qquad (2)$$

Combining equations 1 and 2 gives

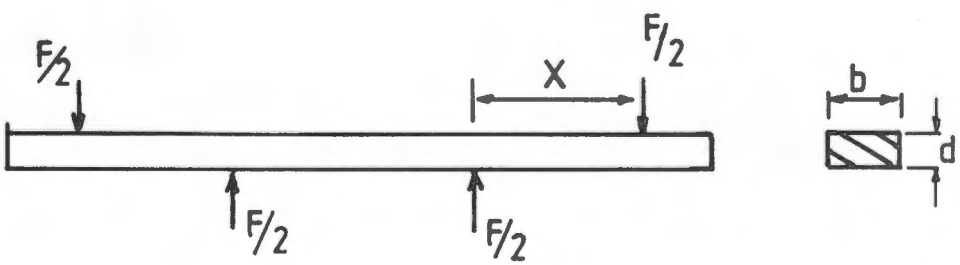
$$E = \frac{0,0143}{1,5 \times 10^{-5}}$$

$$= 950 \text{ MPa}$$

$$= 0,95 \text{ GPa}$$



(a)



(b)

Fig. M.1 Four Point Loading

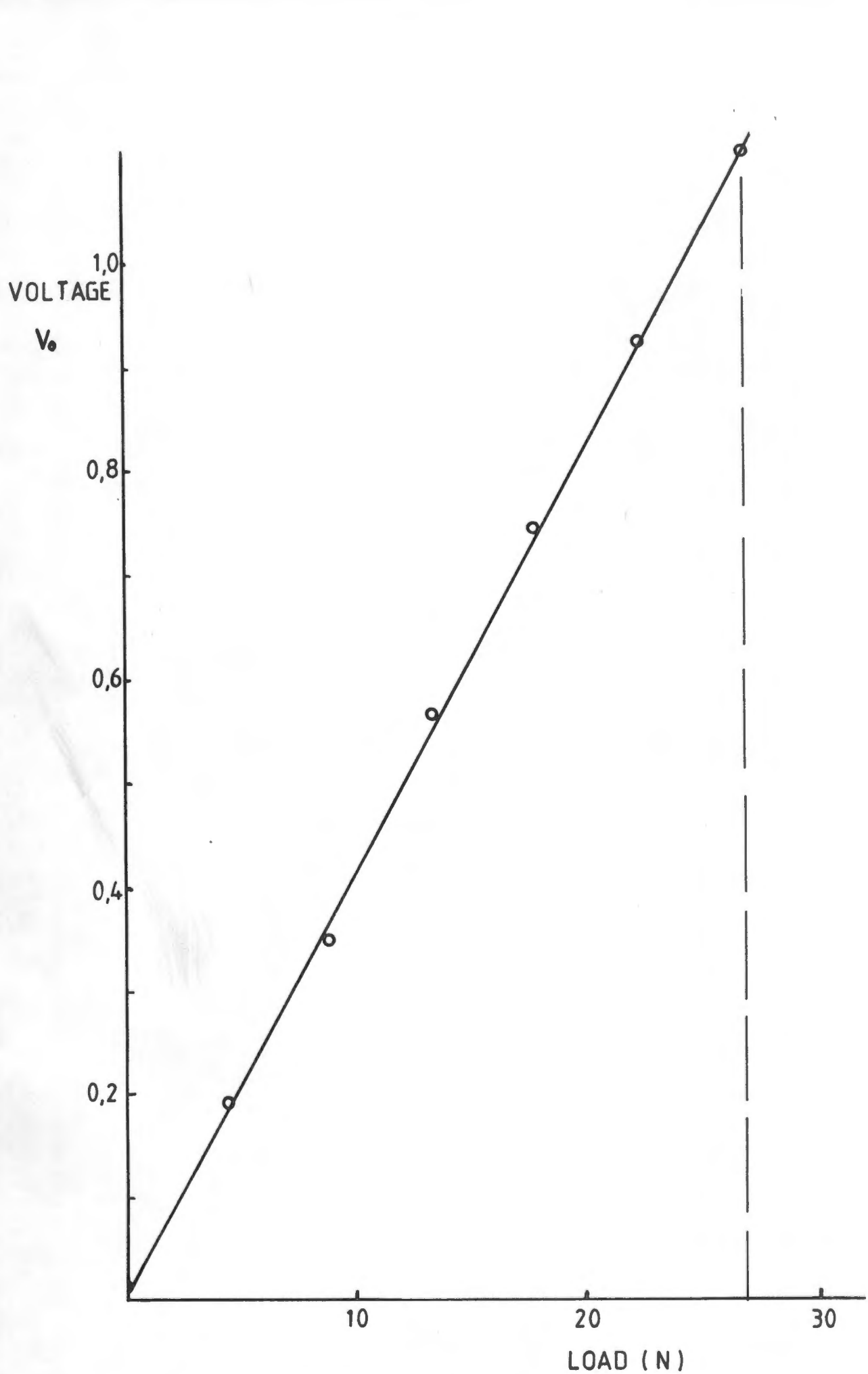


Fig. M.2 Curve Used to Determine Stiffness of Polyurethane

APPENDIX N

EXAMPLE OF STRESS CALCULATION

From Appendix M,

$$\text{Strain } (\varepsilon) = \frac{2\ Vo}{A\ Ve\ G}$$

For the Oregon implant, the maximum measured voltage signal (for a load of 18N) was 0,21 Volts

$$\varepsilon \text{ (for this load)} = \frac{2 \times 0{,}21}{1000 \times 2{,}58 \times 2{,}15}$$

$$= 7{,}57 \times 10^{-5}$$

$$\text{Also, Stress } (\sigma) = E\varepsilon \text{ (where E = 950 MPa)}$$

$$= 950 \times 7{,}57 \times 10^{-5}$$

$$= 7{,}2 \times 10^{-2} \text{ MPa}$$

APPENDIX O

RAW DATA FOR RESECTED VOLUMES

BONE	DENSITY (g/ml)	IMPLANT	ORIGINAL MASS (g)	NEW MASS (g)	RESECTED VOLUME (ml)
Tibia	0,42	Oregon	53,6	48,9	11,3
	0,43	ICLH	55,3	50,7	10,8
	0,44	TPR	56,6	53,0	8,1
	0,40	New Helical	51,4	47,5	9,7
	0,48	ICLH	61,8	56,4	11,2
	0,495	TPR	63,6	59,1	9,1
	0,46	Oregon	58,4	52,9	12,1
	0,52	1st Prototype	66,1	56,7	18,0
	0,46	New Helical	52,4	47,4	10,9
Talus	1,15	ICLH	49,8	46,0	3,3
	1,09	TPR	46,9	45,4	1,4
	1,15	Oregon	50,0	45,0	4,3
	1,12	1st Prototype	48,4	46,5	1,7
	1,15	New Helical	50,0	48,0	1,7

APPENDIX P

RESULTS OF STRAIN GAUGE TESTS

1) CALIBRATION.

Load (lbs)	Vo. (Average of three
1	0,19
2	0,35
3	0.57
4	0.75
5	0.93
6	1,10

2) LOADING POSTERIOR CORTEX.

	Load (lbs)	Vo.
ICLH	1	0,04
	2	0,09
	3	0.15
	4	0,21
NEW HELICAL	1	0,03
	2	0,13
	3	0,28
	4	0,43
TPR	1	0,07
	2	0,16
	3	0,26
	4	0,36
OREGON	1	0,08
	2	0,18
	3	0,27
	4	0.38

3) LOADING MEDIAL MALLEOLUS.

	Load (lbs)	Vo
ICLH	1	0,03
	2	0,06
	3	0,09
	4	0,13
NEW HELICAL	1	0,015
	2	0,025
	3	0.05
	4	0,06
TPR	1	0,02
	2	0,06
	3	0,095
	4	0,12
OREGON	1	0,015
	2	0,06
	3	0,115
	4	0,21

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