MEASUREMENT OF SOFT TISSUE IMBALANCE IN TOTAL KNEE REPLACEMENT : SYSTEM DESIGN AND DEVELOPMENT.

BY

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ABSTRACT

The existence of soft tissue contractures in arthritis and the presence of soft tissue imbalance at the time of a total knee arthroplasty causing deformity in the coronal plane has been debated extensively. This discussion has been based on instrumentation which tensed the medial and lateral soft tissues maximally during the operation. Soft tissues are however viscoelastic structures with non-linear load elongation curves, without any distinct reference point to be used as a force datum point. Surgical instrumentation has been developed to estimate soft tissue imbalance independently of the compressive passive loads through the knee joint. A homeostatic datum point is assumed when constant force is applied to both the medial and lateral soft tissues structures.

In order to validate this assumption and redefine the datum point for measurement of soft tissue imbalance, an electronic measuring system was developed to record the soft tissue imbalance at 0.25mm distraction intervals of the knee.

This soft tissue measuring system consists of a surgical instrument containing electronic transducers, an analogue conditioning unit and a portable computer. The surgical instrument introduces a pivot to the centre of the knee in the coronal plane so that the clockwise and counterclockwise moments produced by the collateral soft tissues produce an angular deviation at the equilibrium position. Measurements of angular deviation and separation gap are recorded by the electronic transducers.

Ten patients were measured whilst undergoing total knee replacement at Bretby Hall Orthopaedic Hospital. The mean change in angular deviation over an average distraction of the knee of 7.15mm was 0.68° with a standard deviation of 0.8. It is concluded that this is an acceptable error band compared to current methods of measurement and soft tissue imbalance can be measured independently of the passive compressive loads through the knee.

The development of the instrumentation within this thesis has resulted in patent applications in both the U.K and the U.S.A.

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CONTENTS

TERMINOLOGY

Anterior	In front of.
Posterior	Behind or to the rear of.
Superior	Above.
Inferior	Below.
Lateral	Away from the midline or the median plane.
Medial	Towards the midline or the median plane.
Distal	Away from the trunk.
Proximal	Close to the trunk.
Superficial	Close to the surface of the body or skin.
Deep	Further away from the surface of the skin.
Flexion	The bending of adjacent body segments in a given plane so that their two anterior and posterior surfaces are brought together.
Extension	The moving apart of two opposing surfaces in a given plane.
Abduction	The movement of a body segment in a coronal plane such that it moves away from the midline of the body.
Adduction	The movement of a body segment in a coronal plane such that it moves towards the midline of the body.

ANATOMICAL PLANES

Sagittal	Any section parallel to a plane passing from front to back of the body, and dividing it into two symmetrical right and left halves.
Coronal	A plane passing from top to bottom of the body, at right angles to the sagittal plane.
Transverse	A plane at right angles to the two previous planes that divides the body into upper and lower portions.

INTRODUCTION

Bony alignment and soft tissue balance have been formulated as the important surgical principles for the replacement of the arthritic knee joint. The recent evolution of the surgical technique and the instrumentation associated with the family of the total condylar type of prosthesis have shifted the emphasis towards achieving the correct angles of the tibial and femoral bony osteotomies with great accuracy. Problems associated with soft tissue balance seem to have been largely neglected. This is probably due to the difficulty in objectively measuring balance during the operation, and the absence of an unambiguous post-operative test to illustrate its existence.

The problems of soft tissue balance arise from the pathology of arthritis which causes changes to both the hard and the soft tissues of the joint. The loss of cartilage and bone is usually associated with a contracture of the ligaments and tendons surrounding the knee although the existence of true contractures in the coronal plane has been debated. Furthermore, the issue of the extent of soft tissue releasing procedures required to obtain a "tolerable" amount of imbalance is still controversial. Research however, has concentrated on problems of fixation and prosthetic design rather than the fundamental questions associated with the deformity of the soft tissues that stabilise the joint.

A number of methods of assessing soft tissue imbalance have been described in some detail. These methods can be divided into three groups, the tensers, spacers and manual distraction. These methods of assessing soft tissue imbalance are subjective and rely on the assumption that the ligamentous structures of the knee are inelastic strings. They all basically tense the knee until the surgeon cannot physically separate the joint anymore both medially and laterally. If the resultant geometry of the separation gap is a trapezoid then imbalance is assumed.

This surgical approach directly contradicts early theory on the biorheology of soft tissues. These structures are composite materials which include the nodal patterns of the stiffer element collagen, the viscoelastic elastin and the ground substances of the supporting matrix. Living soft tissues are not elastic. The best approximation is to consider such structures as being nonlinearly viscoelastic. Consequently, soft tissues do not have any reference datum or a natural state like elastic structures, which they remember and return to after the removal of external loads that cause deformation. Soft tissues also retain some tension in vivo, so that rheological measurement should be considered as a steady state response, where a homeostatic condition is reached before a reference state can be considered. A mechanical analogy for viscoelastic soft tissues was first proposed by Vidiik and Magi in 1967 in terms of dashing, springs and frictional bodies and allowed for the mathematical analysis of soft tissue structures. Clearly the assumption that the trapezoidal geometry of the bony separation gap can be used to define imbalance without defining the homeostatic condition of the soft tissues involved is incorrect.

Extensive experimental rheological work has been carried out in-vitro, on individual ligamentous structures of the knee to validate such theoretical modelling and it is extensively reported that they exhibit viscoelastic characteristics with ultimate strain rates between 12% and 50%. In-vivo measurement has been restricted to a number of implantable strain gauge transducers but they suffer theoretically by disrupting and shortening the structure under test on insertion.

This individual project was conducted as part of a much broader research investigation into the clinical and biomechanical implications of soft tissue imbalance during total knee arthroplasty. The remainder of the research team were Orthopedic surgeons. The literature survey will give a general introduction into the knee joint, its soft tissues, replacement and biomechanics, whilst referring to other

texts from the research team for more detailed information. Soft tissue rheology will however, be dealt with in more depth as its understanding is fundamental to the development of any instrumentation.

Soft tissue imbalance is associated with all soft tissue structures around the knee and not only the ligaments. The continuous measurement and recording of imbalance at different separation gaps is required. Such instrumentation would allow the study of soft tissue imbalance and rheology at different tensions of the extension and flexion gaps, created by the bony osteotomies. It is hoped that such instruments will allow surgeons to quantify such imbalance to allow them to make clinical decisions on what is and what is not an acceptable level of soft tissue imbalance.

CHAPTER 1

LITERATURE REVIEW

1.1 Anatomy of the knee

The knee joint is situated in the middle of the articular chain of the lower limb. It is a complex hinge-like anatomical structure whose main function is to provide mobility and stability during ambulatory activities. The knee consists of three bones, the tibia, femur and the patella, figure (1.1). The knee is sub-divided into two condylar joints between femur and tibia and a sellar joint between patella and femur. The anatomical axis of the femur is situated at an average of 7° from the anatomical axis of the tibia in the frontal plane. The tibial and femoral articular surfaces are partly separated by the menisci which are semilunar fibro-cartilaginous structures. The ligaments of the knee provide its positional stability and reinforce the fibrous capsule of the joint, figures (1.2, 1.3). The muscles of the knee provide the dynamic forces required for activity, figure (1.4).

1.1.1 Menisici

The meniscal cartilages increase the congruency of the tibiofemoral joint and provide for considerable increase in the contact surface area for load transmission between the tibia and the femur (Kapandji 1987). They also provide some functional stability due to their intimate relationship with the ligaments. The lateral meniscus is small in diameter, thicker and wider in body, and more mobile than its medial counterpart. It is rather "O" shaped in contrast to the much larger "C" shaped medial meniscus. Both menisici are triangular in cross-section with concave surfaces directed towards the convex form of the femoral condyles and flat tibial surfaces.

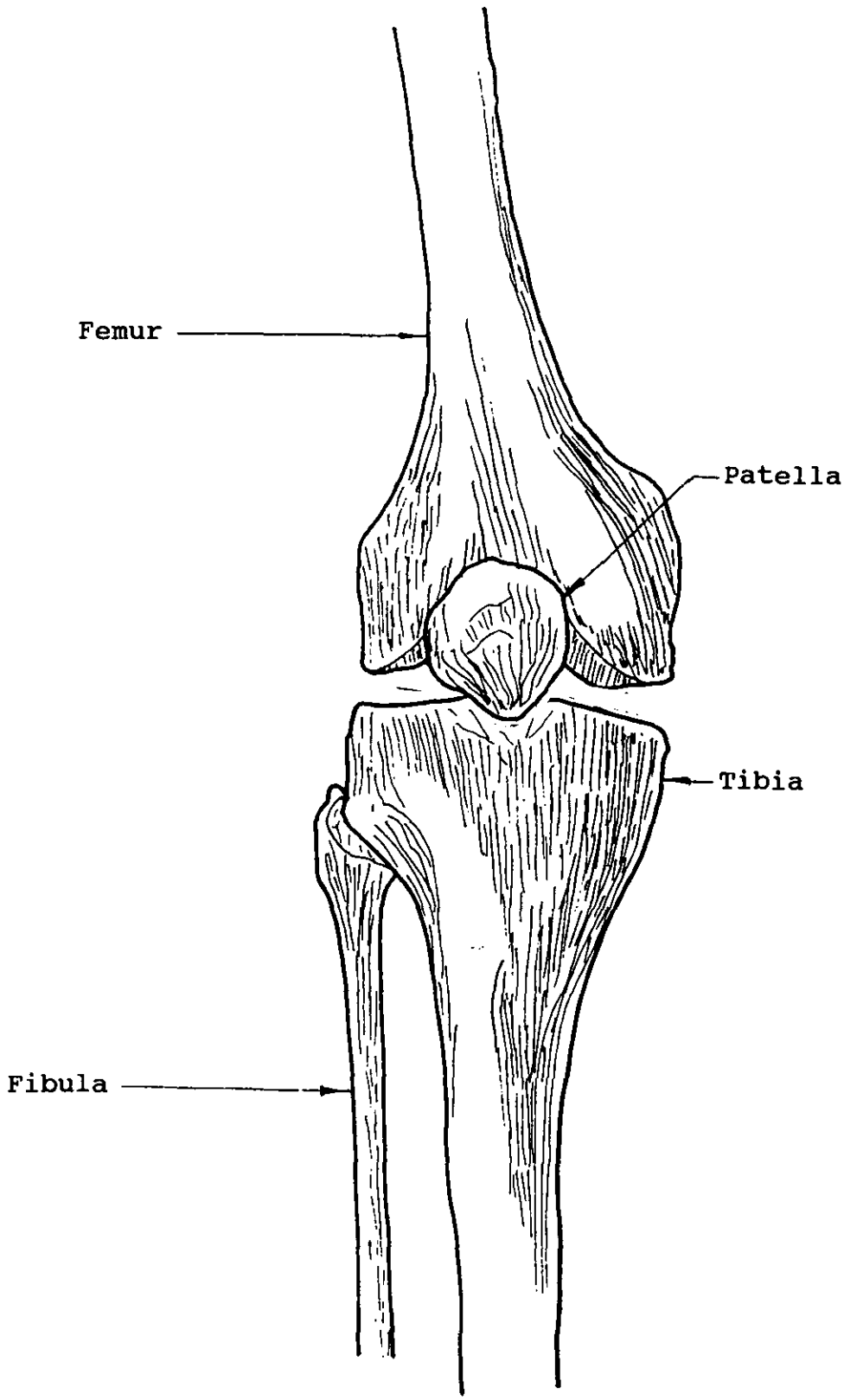


Figure 1.1. The bones of the knee joint.
(After Insall 1984)

1.1.2 Ligaments

The ligaments of the knee are viscoelastic structures that contribute to knee stability during ambulation. They achieve this by interacting with each other three dimensionally within the fibrous soft tissue capsule (Gray's Anatomy 1989).

1.1.2.1 The tibial collateral ligament

The tibial collateral ligament, figure (1.2) is a broad flat structure near the back of the joint. It is about 10 centimetres long and extends from the medial femoral epicondyle, immediately distal to the adductor tubercle, to the medial tibial condyle adjacent to the shaft. Its posterior margins are in continuity with the fibres of the posterior capsule, and its anterior margin blends with the quadriceps expansion of the patellar retinaculum.

The ligament prevents valgus displacement of the tibia relative to the femur. Other functions of the ligament include internal rotary stability. External rotational forces combined with abduction forces result in the tearing of the medial collateral ligament.

1.1.2.2 Fibular Collateral ligament

The fibular collateral ligament extends from the lateral epicondyle of the femur to the head of the fibula, where it overlaps with the tendon of the biceps. It spirals downwards and backwards from the femur to its attachment on the fibula, and therefore has little effect in preventing internal rotation of the tibia relative to the femur. Unlike the tibial collateral ligament, which partly attaches to the medial meniscus, there is no meniscal attachment of the fibular collateral ligament. The main function of this ligament is to provide lateral stability to

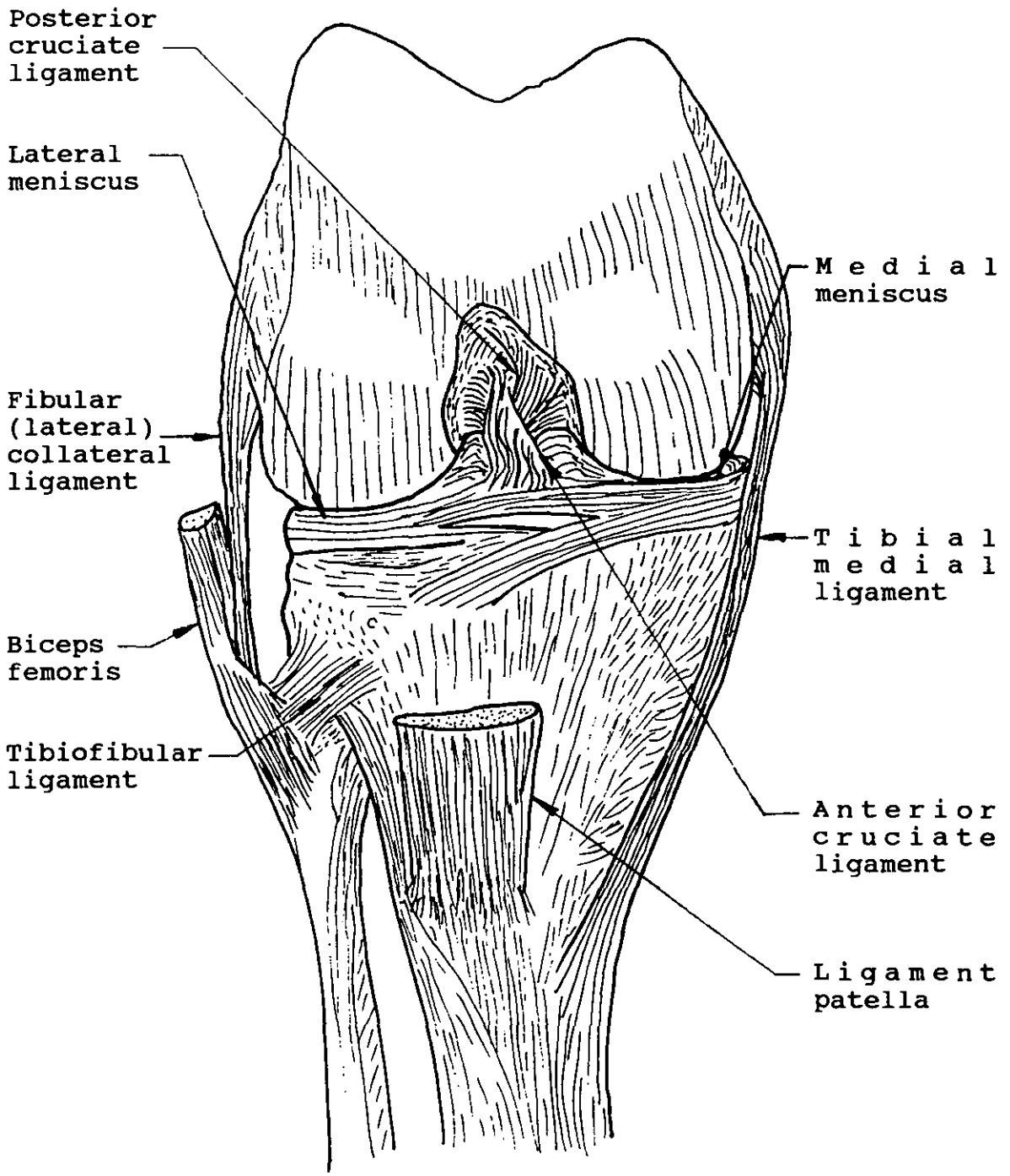


Figure 1.2. Anterior view of the ligamentous tissues of the knee.
(After Insall 1984)

the joint against varus displacements. Although anatomically small compared to the tibial collateral ligament it is one of the most important stabilising structures in the knee. It combines with other lateral soft tissue structures to provide a tension band which stabilises the knee against varus bending moments during the stance phase of the gait cycle.

Both the tibial and femoral collateral ligaments are taut when the knee is fully extended and slack when the joint is flexed. Maximum knee joint stability is therefore provided by these ligaments when the knee is extended.

1.1.2.3 Cruciate ligaments

The cruciate ligaments represent the internal ligaments of the knee and are considered together. They contribute a stabilizing function through the full range of flexion as some of the fibres of these ligaments are tight in every position of the joint.

The anterior cruciate ligament is attached medially to the tibial anterior intercondylar area, ascends posteriorly twisting on itself and fanning out to attach to the lateral femoral condyle. It resists forces that tend to displace the tibia anteriorly with respect to the femur.

The posterior cruciate ligament is much stronger than its counterpart. It is attached to the posterior intercondylar area of the tibia, and ascends anteromedialy to its attachment on the medial femoral condyle. Its main function is to prevent posterior displacement of the tibia with respect to the femur. Both cruciates together resist internal rotation of the tibia by twisting on each other.

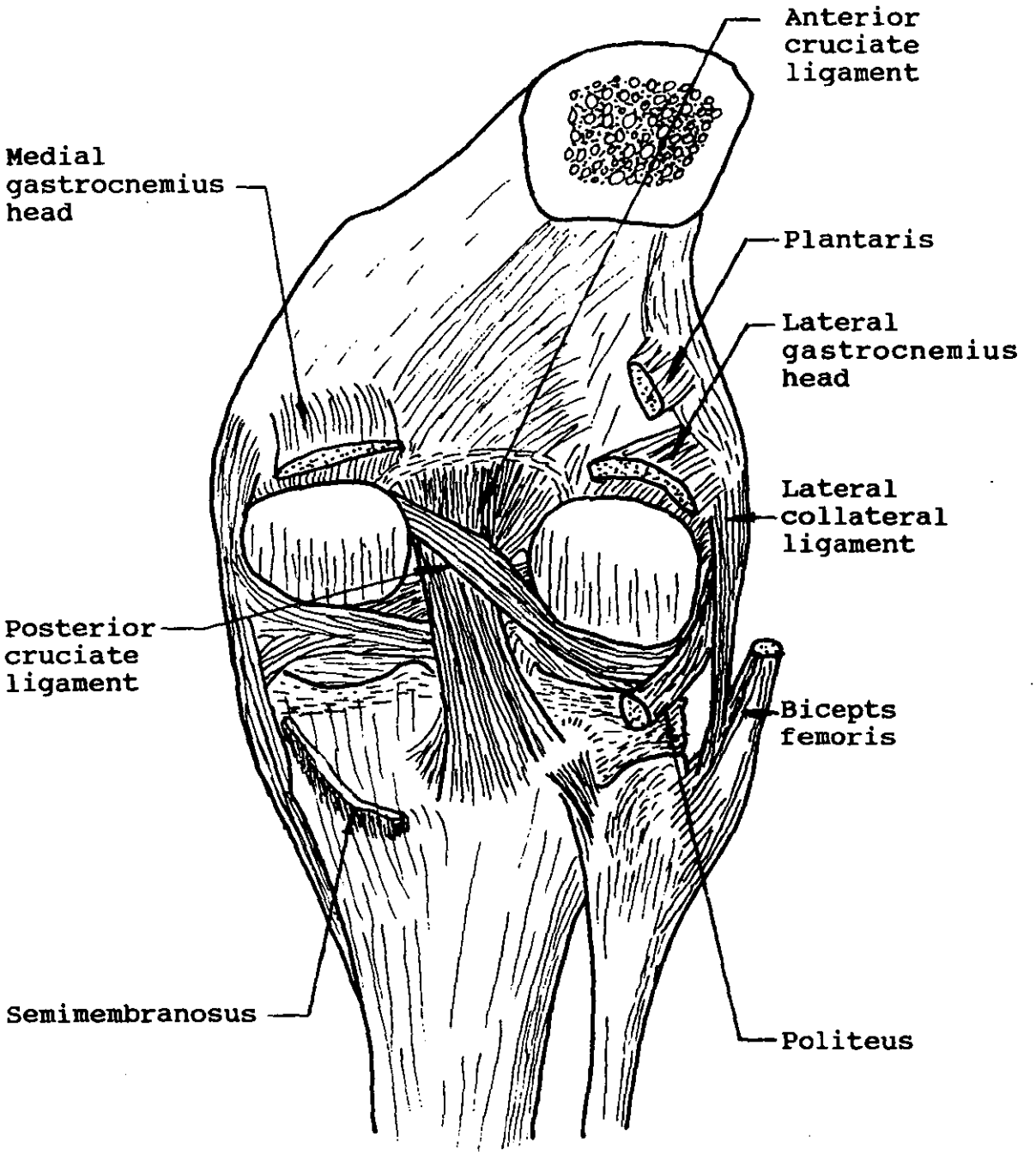


Figure 1.3. Posterior view of the ligamentous tissues of the knee.
(After Insall 1984)

1.1.2.4 Ligamentum patella

The ligamentum patellae is the continuation of the quadriceps mechanism connecting the distal pole of the patella with the tibial tuberosity. It is a strong and flat band, about 8 cm in length. The patellar retinacula flank the patella medially and laterally and represent direct connections between the quadriceps muscles and the tibia.

1.1.2.5 Oblique popliteal ligament

The oblique popliteal ligament represents one of the five expansions of the semimembranosus tendon. It blends partly with the capsule, and ascends in an oblique manner to the lateral femoral condyle.

1.1.3 Muscles

The main function of the muscles is to provide the forces required for ambulation. However, they do assist the ligaments in stabilizing the knee. The main muscle groups are the quadriceps anteriorly, the tensor fasciae latae and biceps femoris laterally, the pes anserinus group and semimembranosus medially and the gastrocnemius posteriorly.

1.1.3.1 Quadriceps

The quadriceps is the main anterior muscle group and occupies practically the whole anterior compartment of the thigh. The muscles act mainly through the patella and the ligamentum patellae providing the forces required to extend the tibia. It also stabilizes the knee anteriorly because of its interaction with the ligaments of the knee. This muscle group has the effect of moving the centre of gravity of the body mass forward and upward during ambulation.

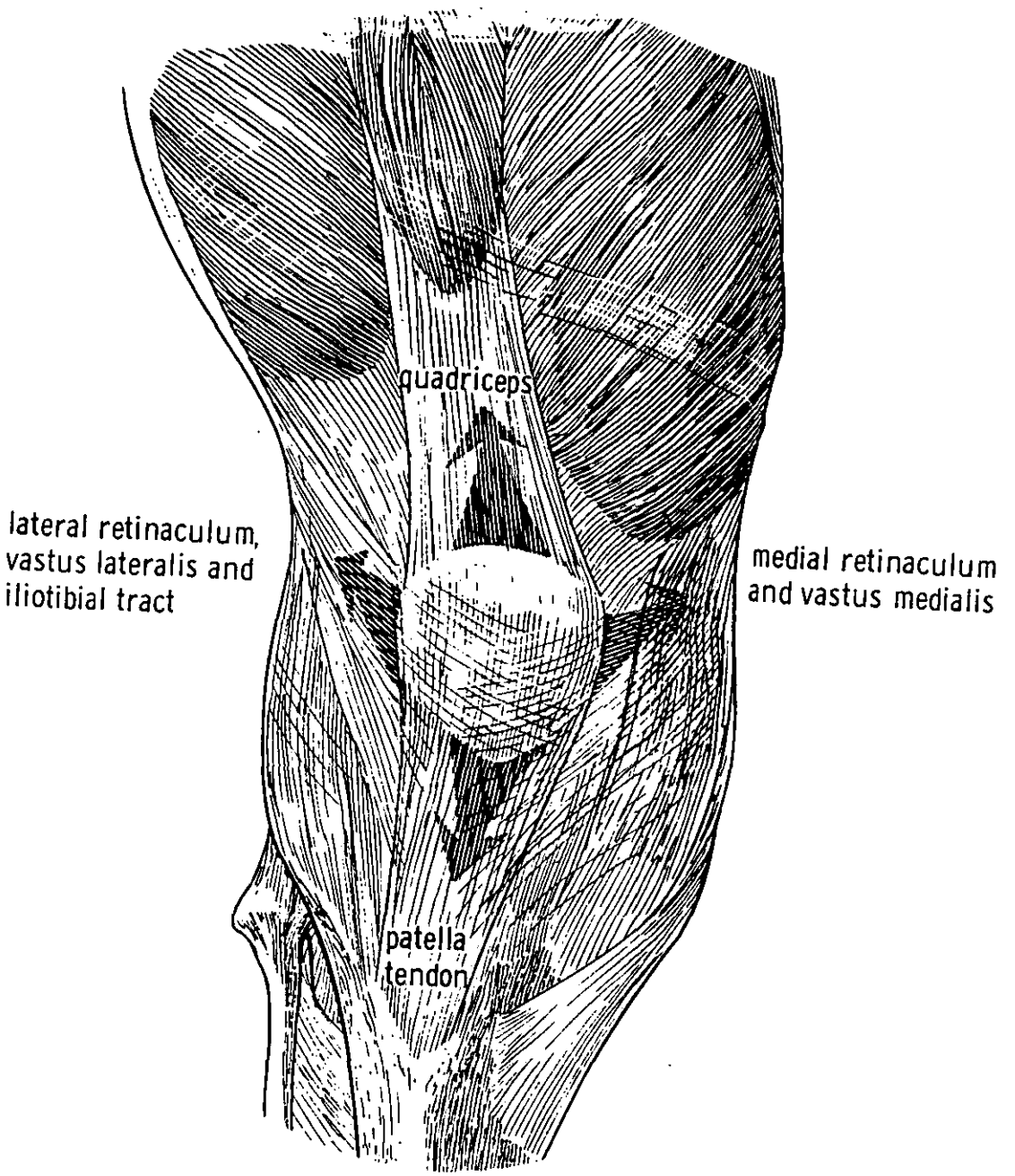


Figure 1.4. Anterior view of the muscles of the knee. (After Insall 1984)

1.1.3.2 Biceps femoris and tensor fasciae latae

The tensor fasiae and biceps femoris contribute to the lateral rotatory movement of the tibia on the femur when the knee is in the flexed position. They also provide some lateral stability to the joint. The biceps tendon together with the medial hamstrings and the gastrocnemius contributes to the flexion of the knee joint as its line of action passes behind the transverse axis of rotation.

1.1.3.3 Pes anserinus muscles

The medial pes anserinus group of muscles is made up of the sartorius, gracilis and semitendinosus muscles. They jointly provide a stabilizing force medially and rotate the tibia medially with the knee in the flexed position. They are also powerful flexors at the knee joint.

1.1.3.4. The semimembranosus muscle

This is the most powerful flexor of the knee joint. It inserts with five expansions to the medial and posterior part of the upper tibia. Together with the pes anserinus group they constitute the medial hamstrings.

1.1.3.5. Gastrocnemius and Popliteus

The medial and lateral gastrocnemius, popliteus and to some extent the medial and lateral hamstrings combine to form the posterior muscles. The popliteus retracts the posterior horn of the medial meniscus during flexion and the gastrocnemius aids in the flexion of the knee (McMinn 1990). They also combine with the posterior capsule to prevent hypertension of the joint.

1.2 Historical review of total knee arthroplasties

The total knee replacement has evolved from the 1950's and can be catagorized into families of knee replacements along its evolution process. They are the single pivot, polycentric and the total condylar groups. The surgical technique associated with the implantation of these prostheses underwent a number of radical changes.

1.2.1 History of total knee replacement

The evolution of the total knee replacement commenced with the development of the Walldius simply constrained hinged arthroplasty, (Engelbrecht et al 1976) figure (1.5). The prosthesis constrained the joint to one simple axis whilst ignoring the ligamentous structures which support the natural knee. This principle of a single pivot was repeated by a number of different researchers with differing detailed design modifications over the next two decades (McKee 1974, Shiers 1974, Wilson 1974, Engelbrecht 1974). Unfortunately the design had only limited success because the fixed linkage did not take into consideration the natural geometrical path of the knee. This resulted in the three dimensional soft tissue structures around the knee producing excessive stress at the cement / bone interfaces, leading to both the high rate of component loosening and particular metal debris generation (Arden and Kamdar 1974, Werner et al 1978)

In the early 1970's Gunston (1971) devised the polycentric knee arthroplasty which attempted to model the basic biomechanics of the natural joint. The diseased surfaces of the femoral condyles and tibial plateaus were replaced separately by the prosthetic implants and secured with cement. The exact position of the medial and lateral components could be adjusted to take into account any varus or valgus deformity. The collateral and cruciate ligaments were retained to give the joint its functional stability. This type of arthroplasty incorporated the polyethylene used by

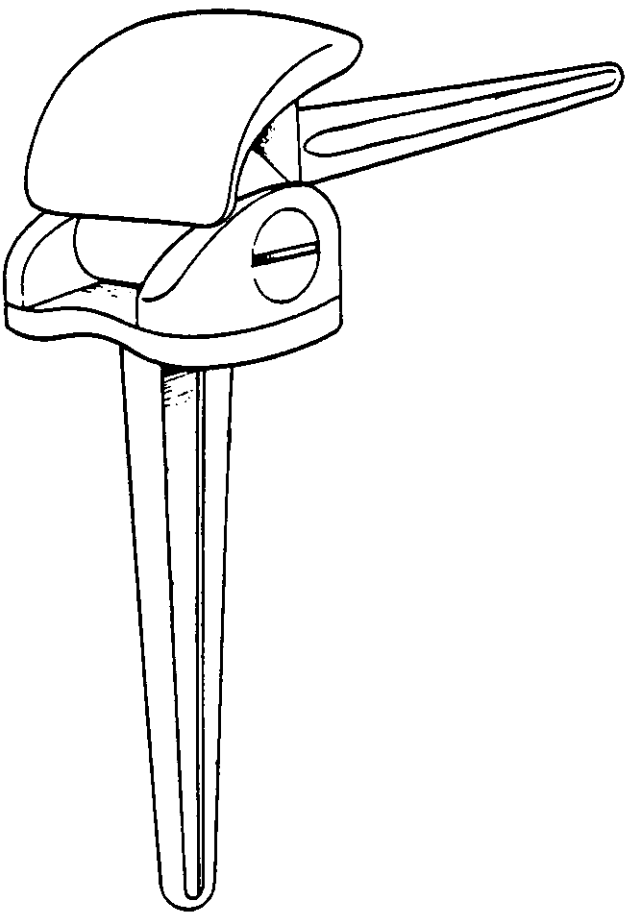


Figure 1.5. A simple pivot arthroplasty

Charnley (1955, 1959a&b, 1960) in hip arthroplasties, as a bearing surface to allow the joint to both rotate and slide. This step proved to be a decisive breakthrough in the development of knee arthroplasty because it allowed the soft tissues, along with the surface geometry of the prosthesis, to define the instantaneous centres of rotation of the knee and allowed the ligaments to absorb any applied torsional loads. The Marmor (1976) and the Manchester knee (Shaw et al, 1974) are further examples from this family of arthroplasties. They illustrated the natural problems of the bony alignment, ligament contracture and stability of the knee, figure (1.6).

The next family of arthroplasties to arrive was the total condylars, figure (1.7). This arthroplasty was also un-linked and allowed the instantaneous centres of the knee to be defined by the soft tissues and the surface geometry of the prosthesis, but removed the tibial intercondylar area to allow the tibial prostheses to be replaced in one piece. The polycentric nature of the articulating surfaces was compromised in order to increase the contact surface area between the tibial and femoral components and so reduce the compressive stresses and wear on the tibial component. Examples of prostheses from this family are the Freeman Swanson knee, (Freeman 1973 & 1974 & 1980, Freeman et al 1977 & 1978) and the Kinemax knee.

The basic principle of the total condylar family remains with us today despite going through some design and development phases which have subsequently generally been regarded as blind alleys. They are as follows.

1) The tibial and patella components were manufactured totally out of polyethelyne as well as being metal backed.

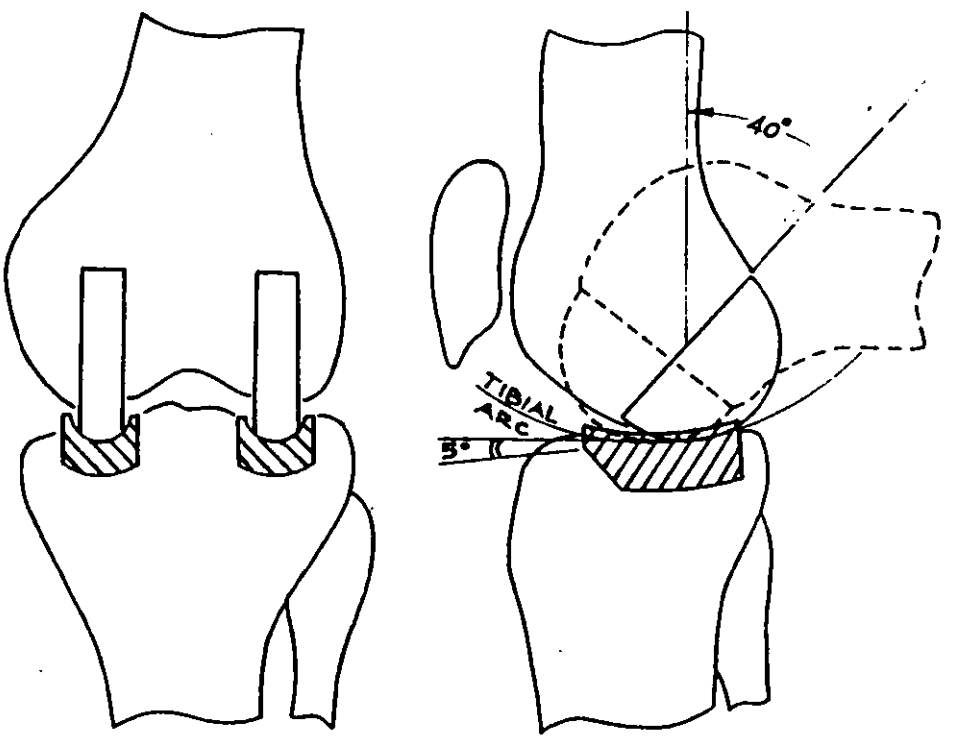


Figure 1.6. A polycentric knee arthroplasty
(After Gunston 1971)

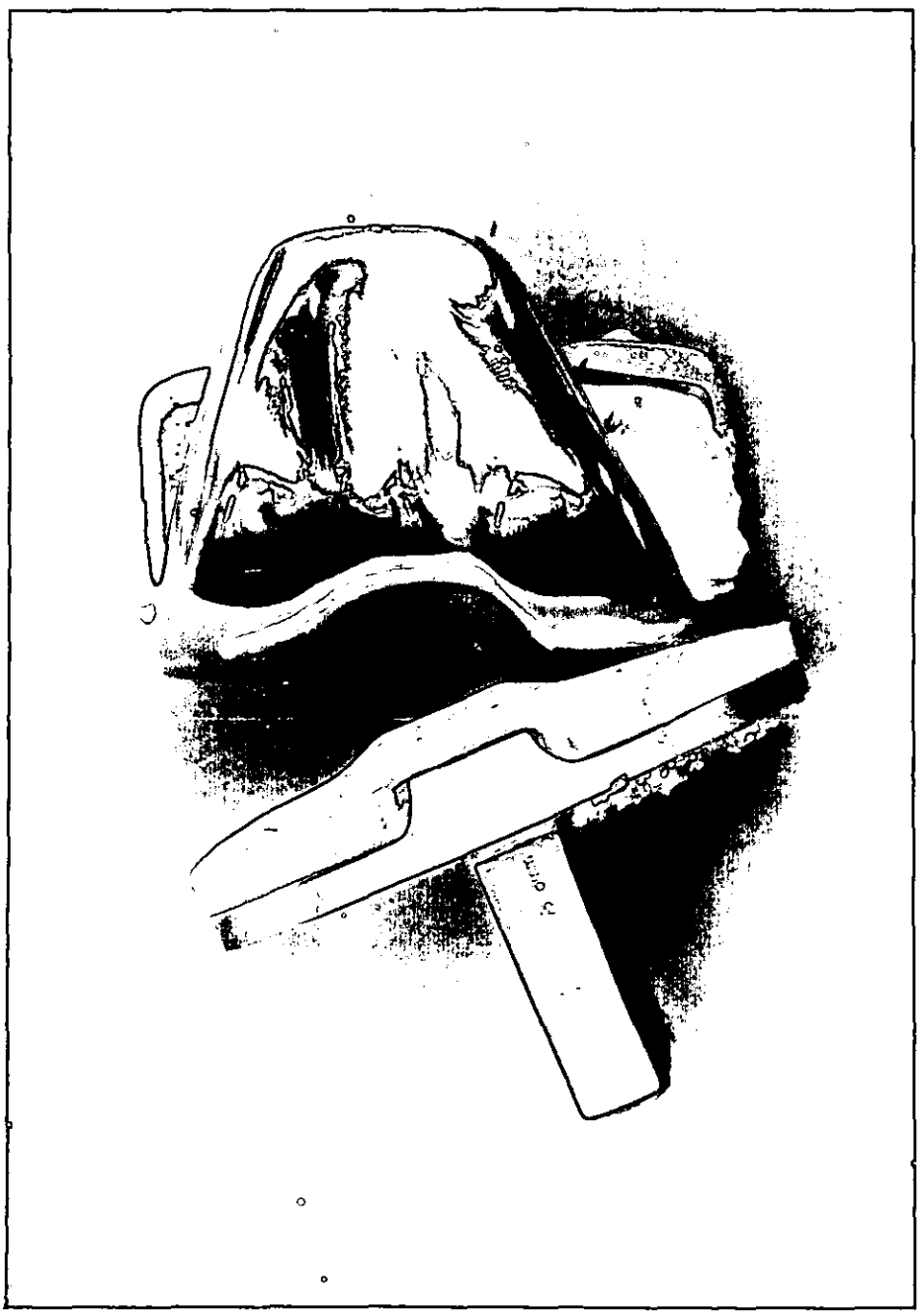


Figure 1.7. A total condylar arthroplasty

2) The tibial and patella components were produced for use without surgical cement. It was assumed that natural bone would grow into porous holes in the prosthesis and hence fixing it in position. (Homsy 1974, Pilliar 1983, Swanson 1977).

Research and numerous clinical studies had identified that the tibial component fixation was the most important source of fixation failure of this type of condylar arthroplasty. (Ducheyne et al 1978, Evanski et al, 1976, Freeman et al 1986, Walker et al 1981, Walker et al 1976) As a result, attention was directed towards implant design (Freeman et al 1986) fixation (Walker et al 1976) and the material quality (Wright and Bartel 1986, Wright et al 1981). In vitro biomechanical studies demonstrated that tibial component strength increased when the polyethylene bearing surface was reinforced with a metal tray between the bearing and the tibial bone. (Askew et al 1978, Bartel et al 1982, Murase et al 1983, Walker et al 1981). The trend towards metal backed components had been supported theoretically (Dorr 1985) as the first comparative study did not appear until 1991 (Apel et al 1991). This study was inconclusive clinically, and recommended the use of all plastic components on the basis that they are cheaper to produce. Failure of the all plastic components seems to be by deformation and subsidence of the plastic and failure of the metal backed implants by fracture of the tray.

The biomechanical implications of these changes in design will be discussed in depth in a later section.

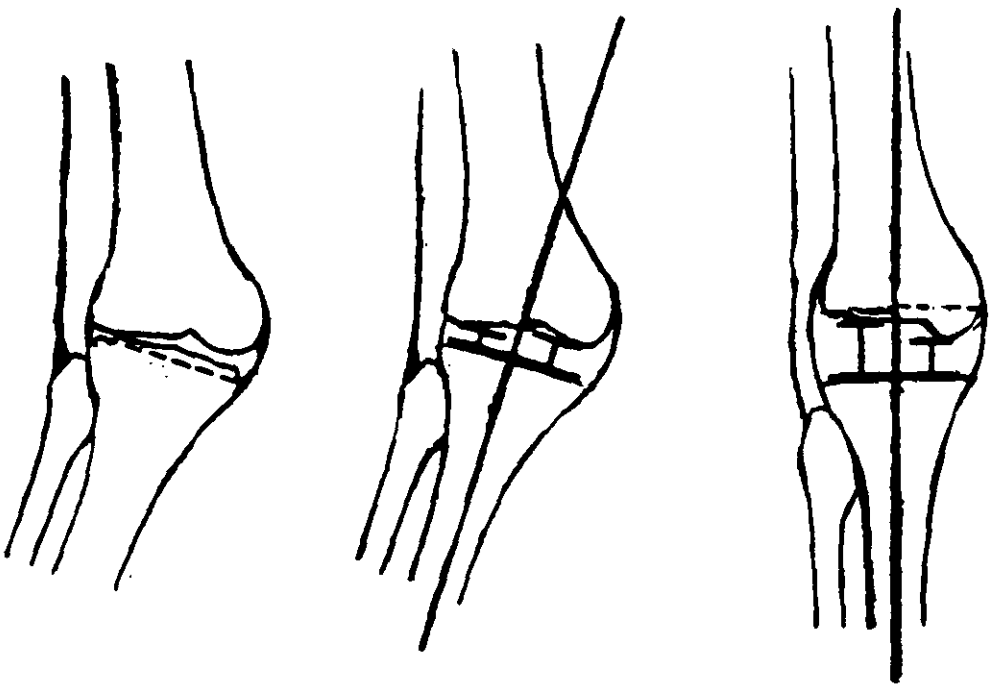
1.2.2 Clinical historical review

By 1977 Freeman had experimented with the ICLH (Imperial College London Hospital) prostheses for nine years, and realised that the bony alignment of the knee and control of instability could not be achieved accurately and reliably by eye (Freeman et al 1977, Freeman et al 1978). He suggested that the solution to the problems of alignment and stabilisation of the tibio- femoral joint could be predominantly in the field of morbid anatomy and surgical technique and less on prosthetic design. He suggested that a fixed varus or valgus deformity was due to bone loss over the years of disease, and that soft tissue contractures fix the malalignment. Freeman developed an operative sequence for the implantation of the prosthesis around the contracted length of the medial and lateral collateral ligaments. The main assumption that he made with this approach was that the ligaments were inextensible strings. The operative procedure that he developed is based on tensing the tibia on both of the medial and lateral condyles independently until no more force could be exerted. If the bony alignment was not acceptable at this position then soft tissue releasing procedures were carried out before the femoral bony cut was performed, figure (1.8) This operative technique is as follows:-

1) The tibial cut is made at 90° to the axis of the tibia, figure (1.8a).

2) The tensor is inserted into the knee and its medial and lateral blades are expanded as far as possible, figure (1.8b).

3) The structures on the tight side of the knee are then released, and the tensor blade on the corresponding condyle is opened until the knee is aligned, figure (1.8c). Correct alignment is assumed by a straight



1) 2) 3)

Figure 1.8. Freeman's early operative technique.
(After Freeman 1980)

bar running through the tensor and extending proximally to the centre of the hip and distally to the centre of the ankle.

4) The femoral cut is made parallel to the tibial cut.

5) Finally the patella osteotomy is performed.

With bony alignment and soft tissue balance now assumed, stability of the joint is then gained with the thickness of the tibial insert chosen.

By 1980 a number of reports of tibial prostheses loosening and failure began to surface, (Ducheyne et al 1978, Tew & Waugh 1982). Ducheyne reported, from a study of 100 knee replacements, from which seven had failed and required revision between seven and seventeen months postoperatively, that no single factor is to blame for these failures. He concluded that the events leading to the eventual mechanical loosening of the tibial prostheses were probably due to:-

1) The implantation of the tibial component with a medial or lateral tilt, resulting in the lack of firm skeletal stabilisation and the production of local stress concentrations.

2) Changes in the alignment at the extremities.

3) Degradation and fragmentation of the polymethylmethacrylate cement.

Finlay et al (1991) suspected that the fixation of the tibial component was the reason for the loosening and conducted a study of twelve different tibial components for fixation. He introduced a mechanical device to load the prostheses in cadaveric bone and then measured deflections in a number of directions whilst under load. He found that deflections of up to 0.5mm were obtainable across the range of prostheses during static loads of

three times that of body weight. This study had limited clinical use because firstly it was not conducted in living tissue, or even cadaveric knees with the soft tissues intact, and secondly it did not provide for a dynamic loading pattern to mimic natural gait forces. It did show that even at this early stage in the development of the tibial prostheses, there was little to choose between them in terms of mechanical function.

Tew and Waugh (1982) estimated the survival time of knee replacements. A study of failure rates from 365 operations encompassing the early and late Freeman, Sheehan and Manchester prostheses was performed. They concluded there was no statistically significant difference in the incidence of annual failure between the Sheehan and Manchester and the two Freeman prostheses. However, both the Freeman prostheses had better survival rates than the Sheeman and Manchester prostheses.

It can be surmised that there is little to choose between the different types of tibial prostheses at that time, but Freeman had basically a better understanding of the surgical techniques necessary to perform a total knee replacement. It was concluded that the survival rate of the prosthesis could be increased with better bony alignment to avoid asymmetric loading of the tibial condyles. Intra and extra medullary jigs were developed to enable accurate bony alignment (Manning et al 1988) and the operation devised by Freeman was altered to incorporate them. The operative sequence was changed to

1) An intra medullary guide is positioned inside the femur, figure (1.9a).

2) A distal resection block is positioned with reference to the intra medullary jig. This allows the distal cut to be made at 97° to the axis of the femur, figure (1.9b).

3) The femoral anterior - posterior cutting guide is then positioned on the flat surface previously prepared and the cuts made, the guide ensuring their correct position and angle, figure (1.9c).

4) The femoral chamfer cuts are made using another simple positioning jig, figure (1.9d).

5) The tibial osteotomy is performed using a extra medullary jig which is clamped around the ankle to ensure that the resection is perpendicular to the axis of the tibia and to prepare a flat surface for the tibial prosthesis, figure (1.9e).

6) Soft tissue imbalance is now assessed and corrected with soft tissue releases where necessary. A number of different ways of assessing this imbalance have been devised and will be considered later.

7) The patella osteotomy is now performed.

8) Components are then tried to ensure the stability of the joint and then implanted.

This basic procedure is the one that remains today and is mirrored in many different surgical instrument sets for total knee arthroplasty.

The introduction of this procedure standardised the operation and allowed the bony cuts to be made much more accurately and consistently than before. This accuracy was achieved, however, at the expense of soft tissue balance because the cuts were made with reference to the geometry of the tibia and the femur and not to the soft tissue imbalance. This technique therefore seemed to relegate the consideration of soft tissue contracture at the time of operation.

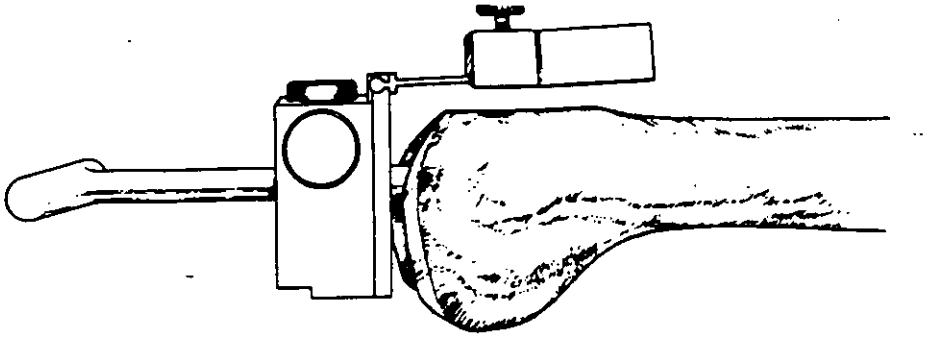


Figure 1.9a. Intra-medullary rod in position inside the femur.

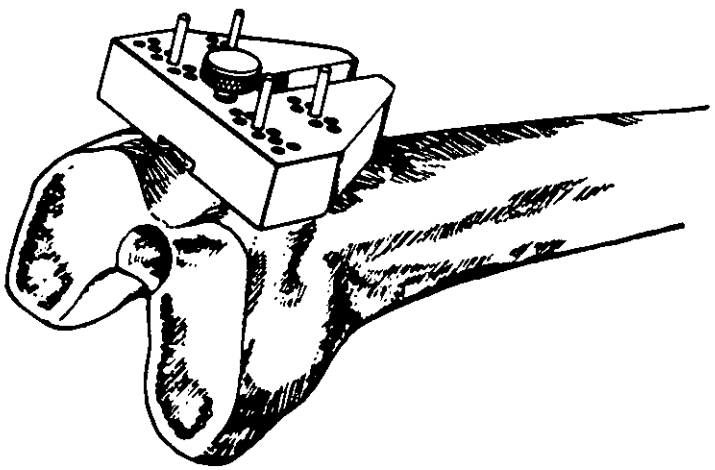


Figure 1.9b. Distal resection block position from the intra-medullary rod allowing the femoral cut to be made.

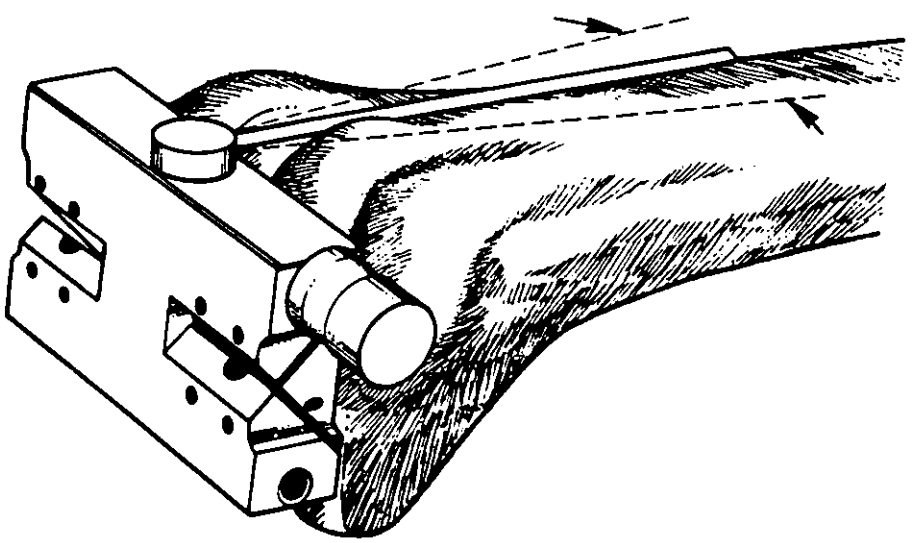


Figure 1.9c. The femoral anterior-posterior cutting guide is then positioned on the previously prepared surface.

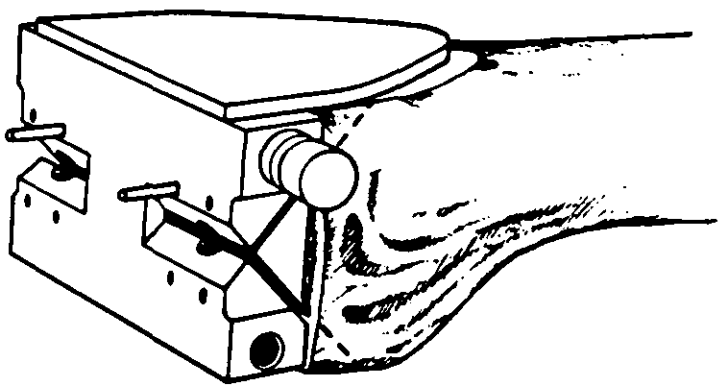


Figure 1.9d. The anterior, posterior and chamfer cuts are made.

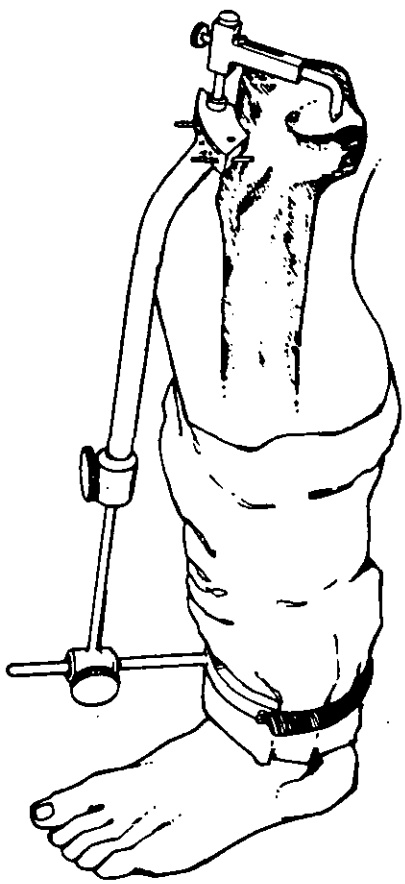


Figure 1.9e. Extra-medullary guide is used to position the tibial cutting block.

Figure 1.9. The operative sequence using a typical modern day instrument kit.

Insall (1984) continued the argument about soft tissue releases when he said that in the advanced stages of arthritis changes usually take place in the ligaments. For the usual deformity of osteoarthritis, the medial collateral ligament becomes shortened due to osteoarthritic overgrowth on the medial side of the knee and to actual contracture of the ligament as its physiologic length is not maintained because of the loss of medial bone. Also the lateral ligament becomes stretched by the stress of walking on a knee which is fixed in a varus position. Insall recommended that this asymmetric instability should be corrected by further femoral osteotomies at the expense of bony alignment and that some minor ligament asymmetry or laxity may be tolerated. Only in the case of major fixed deformities does he recommend ligamentous releases, but he does not define what he considers to be minor and major. Insall did, however, suggest for the first time the surgical procedures required for formal soft tissue releases.

By 1985 Tew had built up a database of some 428 knees and was beginning to build up a comprehensive picture of the failure of the total knee arthroplasty, (Tew & Waugh 1985). She found that the highest success rate was in those knees which had been aligned at the time of surgery and were more likely to remain stable. However, she found that half of all the failures occurred in knees correctly aligned at operation and two-fifths in knees which remained stable in this alignment. She also noticed a strange phenomeon for the first time. Some knees, well aligned at operation, deteriorated into severely varus or valgus positions. Their failure rate was significantly higher than for knees left severely malaligned in a varus or valgus position at the time of the operation. She further speculated that there are more potent factors at work than malalignment that cause deterioration. Such factors including ligamentous imbalance and loosening or wear of components, may also affect initial knee malalignment and be the principal cause of their failure while malaligned knees which are unaffected are more

likely to remain satisfactory. She concludes that malalignment in itself may not be the most important cause of failure though it probably does compound failure from other causes.

Goodfellow & O'Conner (1986), in discussing the clinical results of the Oxford knee, suggested that if the tensions in the collateral ligaments were allowed to define the thickness of the bicondylar tibial prostheses, most limbs would automatically return to their normal alignment when the ligaments are restored to their normal tension, suggesting that there is little or no soft tissue contracture. He goes on to add that in those instances, where true collateral ligament length discrepancy was present, a degree of misalignment in this plane was accepted rather than prejudice joint stability by performing any soft tissue releases. Goodfellow effectively claimed that the problems experienced with the tibial prostheses were not due to ligament imbalance because the contracture of these soft tissues only occurred in very rare cases, directly contradicting Insall and Tew. The problems of interpreting the difference between soft and hard tissue loss or contracture seemed to be compounded by the various qualitative methods of measuring imbalance at the time of the operation.

Moreland (1988) tried to resolve these controversial points. He acknowledged that there was some confusion between malalignment resulting from an inaccurate resection plane of the bony osteotomies and malalignment resulting from ligamentous instability. He advised that they should be differentiated on the operating table by:-

1) Placing the resected distal surface of the femur and the resected proximal end of the tibia together, and checking that the line from the centre of the femoral head to the centre of the ankle must lie over the centre of the knee. This assures bony alignment.

2) By placing the trial prostheses components into the knee, the tighter ligaments on one side of the knee pull the prosthesis apart on the looser side which indicates soft tissue ligament imbalance.

He recommends that malalignment caused by bony resection plane angulation should be corrected by changing the angle of the resection plane with further bony osteotomies. Malalignment caused by ligamentous imbalance should be corrected by ligament balancing procedures and not further bony resection. He argues that some mild degrees of ligament imbalance are tolerable if the overall alignment is correct because when the patient bears weight on the knee the side that has slight condylar lift off will close. However, the method of distinguishing between "tolerable" and "intolerable" degrees of imbalance was left again to surgical feel and opinion.

Despite these surgical guide lines, the problems associated with tibial loosening remained. Argenson & O'Connor (1992) in discussing the polyethylene wear in the Oxford knee replacement, listed 23 arthroplasties retrieved between 10 and 112 months post operatively, mostly revised due to tibial loosening. This gives a clear indication that the continual up date in the finer points of the prostheses design has done little to increase the survival rate of the arthroplasty.

1.3 Biomechanics of the Knee

The mechanical function of the knee joint is to allow the desired movement between the tibia and femur to permit the ambulatory process of running, walking, ascending descending stairs etc, and to transfer the functional loads. The geometry and kinematics of the knee needs to be considered in its "natural" and diseased state before any changes in the functional loads due to body weight dynamic activity and the passive loads of the joint.

1.3.1 Geometry and Kinematics of the "natural knee"

The geometry of the tibial and femoral condyles along with the cruciate ligaments control the major influences on the kinematics of the normal knee in the sagittal plane. (O'Conner 1989). The average sizes of the tibia and femur can be seen in figure (1.10). The function of the cruciate ligaments in the sagittal plane has been described at some length by Müller (1983) in terms as a four bar linkage. This accurately describes the rotary motion of the knee assuming that the ligaments are fixed members or solid strings, figure (1.11). However, this is not strictly correct. The ligaments of the knee are not strings with small, constant cross-sections which insert into the bone at well defined points but are irregular in crossection becoming quite broad in places and insert into the bone over a large undefined area. Many studies have been carried out on cadaveric bones to estimate the true kinematic path of the knee (Gunston 1971) but the results given should only be considered as an estimation of the actual loci. The living meniscus of the knee acts as a moving bearing surface. It changes shape under external load to increase congruency and a large bearing surface for the transfer of loads at varying knee positions.

The forces and stress through the knee have been estimated by movements in the centre of gravity of the person or by gait analysis. Maquet (1984) suggested that

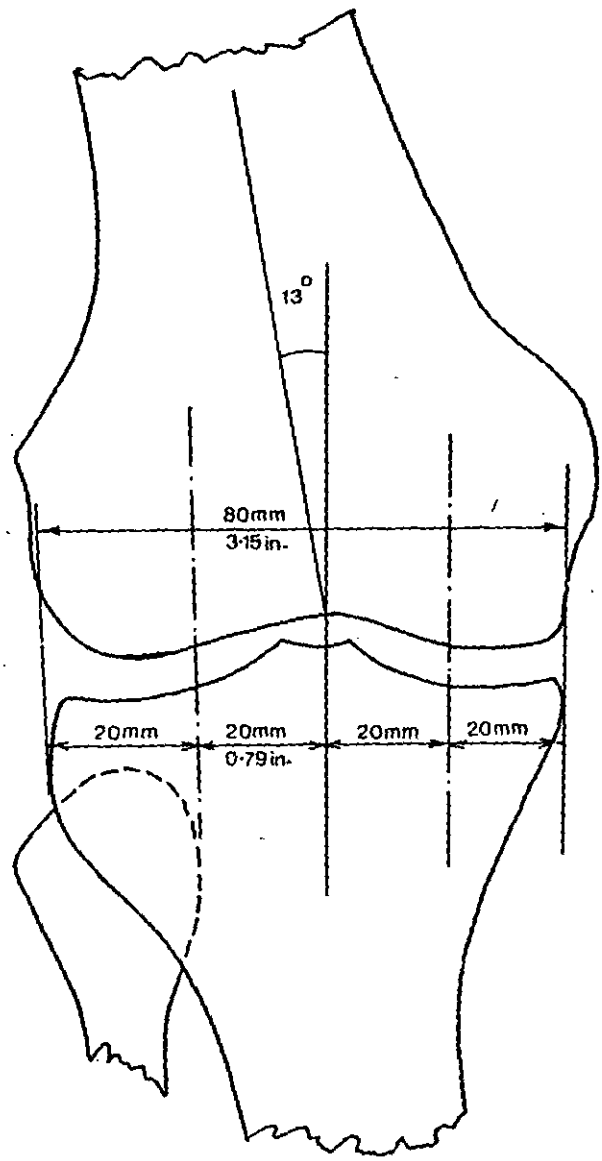


Figure 1.10. The mean sizes of the tibial and femoral condyles.
(After Harrington 1974)

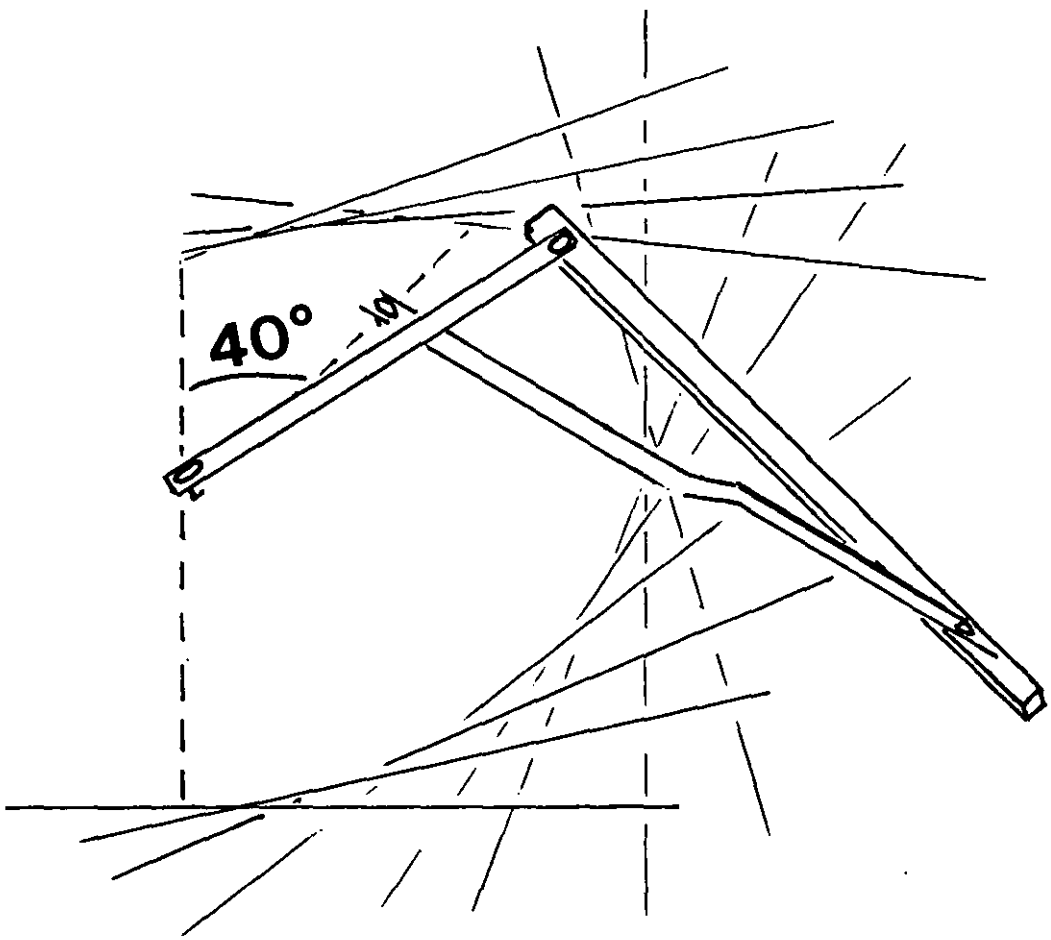


Figure 1.11. The four bar mechanism for modelling the function of the cruciate ligaments.
(After Müller 1983)

"the stress in the knee is generated only by muscular forces and cannot be determined in the state of our present knowleadge". This argument is extended so that during standing, the knee must support some of the body weight. If the line of action of this part does not pass through the knee then muscular forces must intervene to keep balance, figure (1.12). So the forces due to partial body wieght can be calculated if, the body weight, the weight of its several parts, the position of the centre of gravity and the displacements during walking of all the parts of the body are known.

Paul (1966,1967,1974) developed an alternative form of analysis by measuring the forces transmitted to the ground during walking using a force plate. Points on the body are logged using video cameras, so that the force at these points can be calculated by taking the relevant moment arms, figure (1.13). Such calculated values only give the resultant force through the joint. Many soft tissue structures apply forces in an equal and opposite direction, thus cancelling each other out and producing an underestimation of the actual loads being transmitted by the joint. Paul (1974) suggested the principle force actions of the soft tissue structures acting around the knee, figure (1.14). It is clear that these structures act in a multidirectional manner.

The basic assumption with these methods that the forces through the knee are soley due to muscular forces and the ligaments are stabilising strings is incorrect. Passive compressive forces, or forces generated from non-dynamic activity are present. The magnitude of these forces however, is unknown.

1.3.2 Geometry and Kinematics of the arthritic knee

A typical arthritic knee can be seen in figure (1.15). The arthritic disease process has eaten away at the bone stock causing a change of the bony alignment. Soft tissue contracture takes place over the years of arthritic

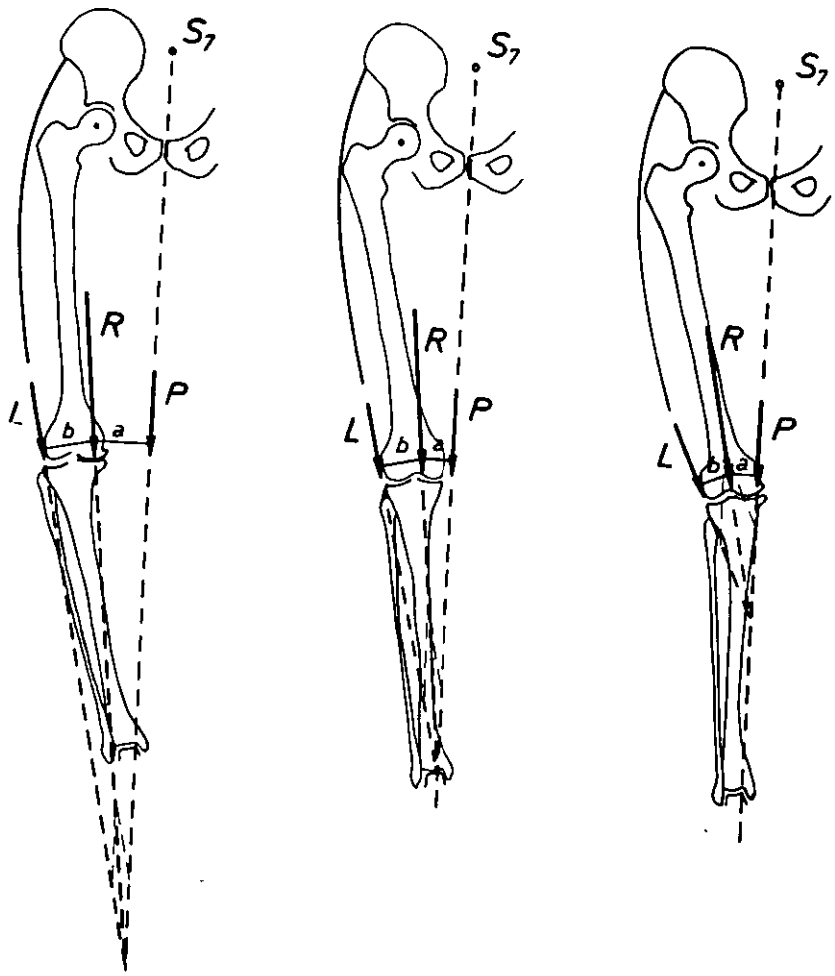


Figure 1.12. Changes in the position of the resultant force vector through the knee with changes in the bony alignment of the joint.
(After Maquet 1984)

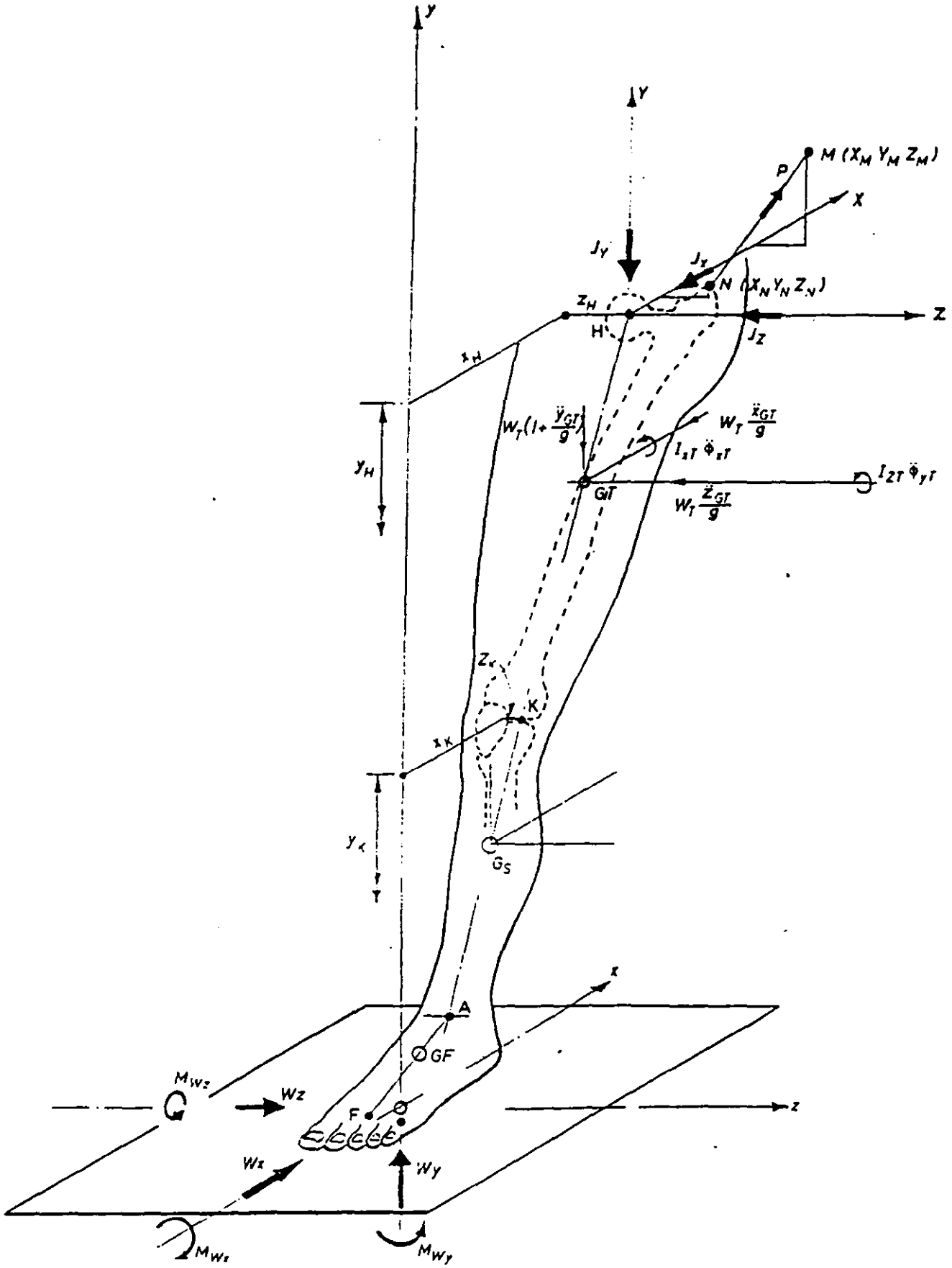


Figure 1.13. Calculation of the resultant force through the knee joint using gait analysis.

(After Paul 1966)

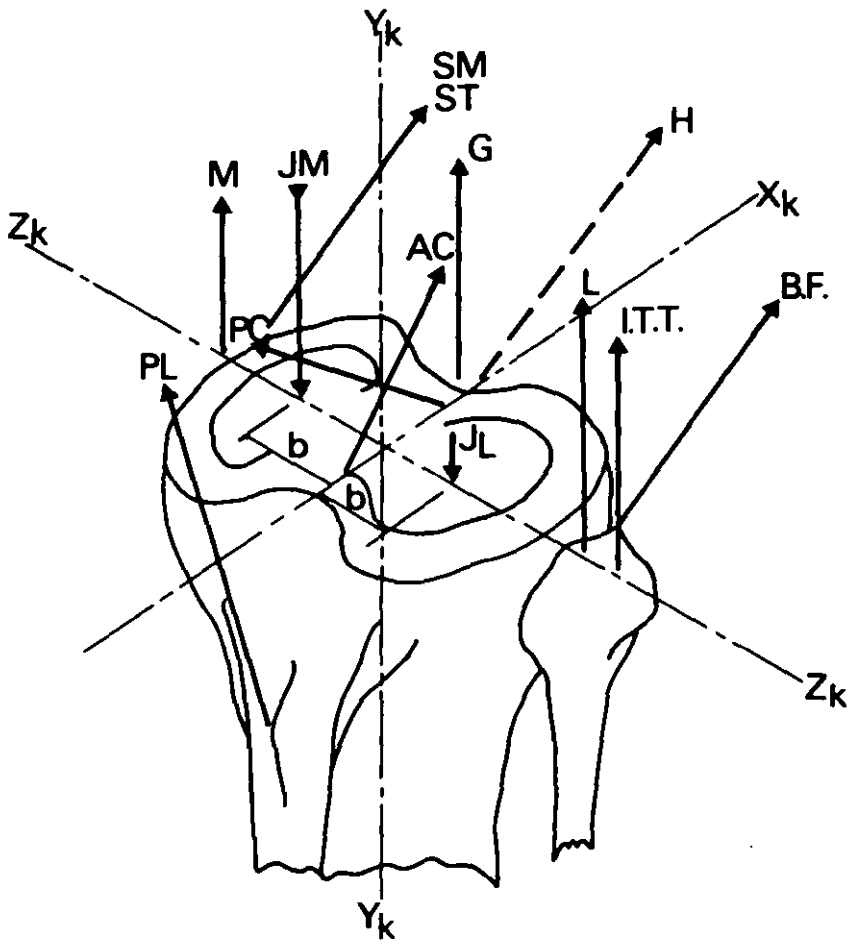


Figure 1.14. The principle force actions at the knee. (After Paul 1966)

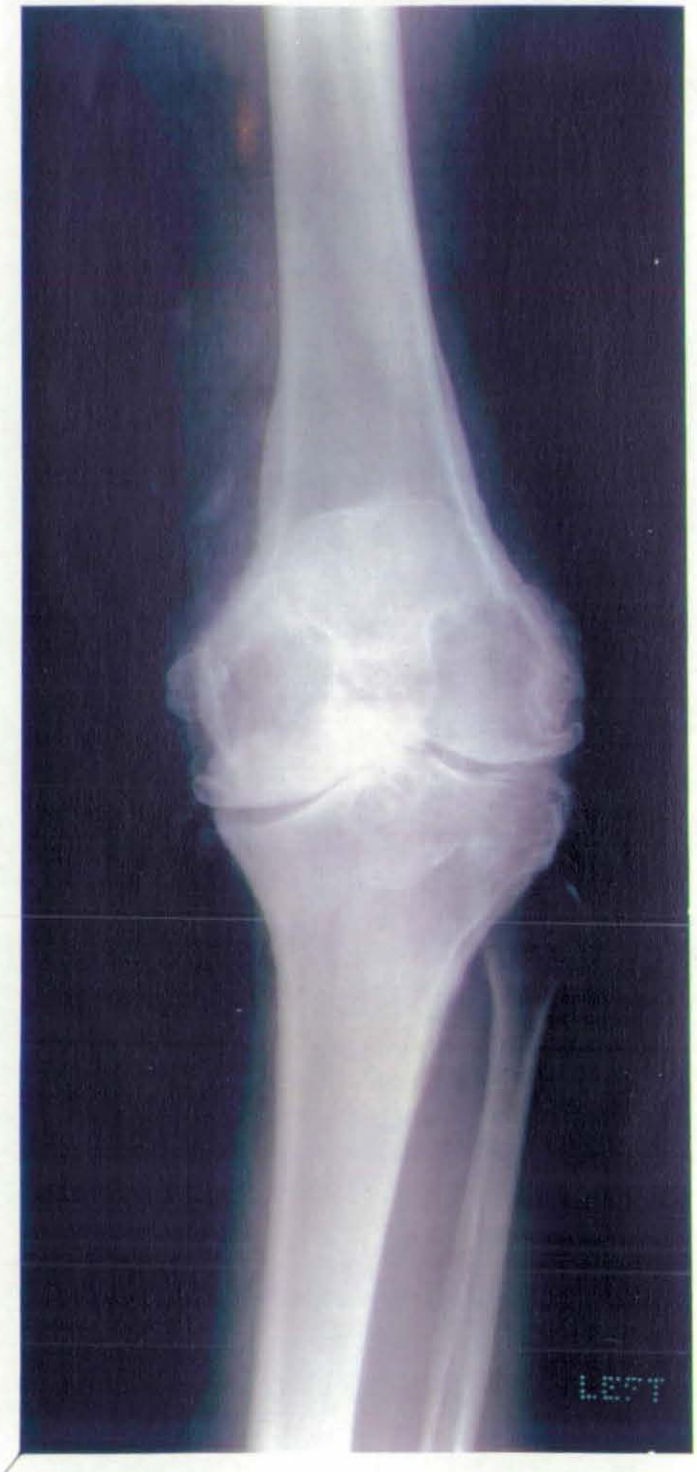


Figure 1.15. X-ray of a typical arthritic knee joint.

illness fixing the joint in its new position. In this new position the motion of the joint becomes altered as the soft tissues fix the joint in its new position the extremes of the natural swing of the leg may disappear as the collateral ligaments become over stretched.

1.3.3. Geometry and Kinematics of the total knee replacement.

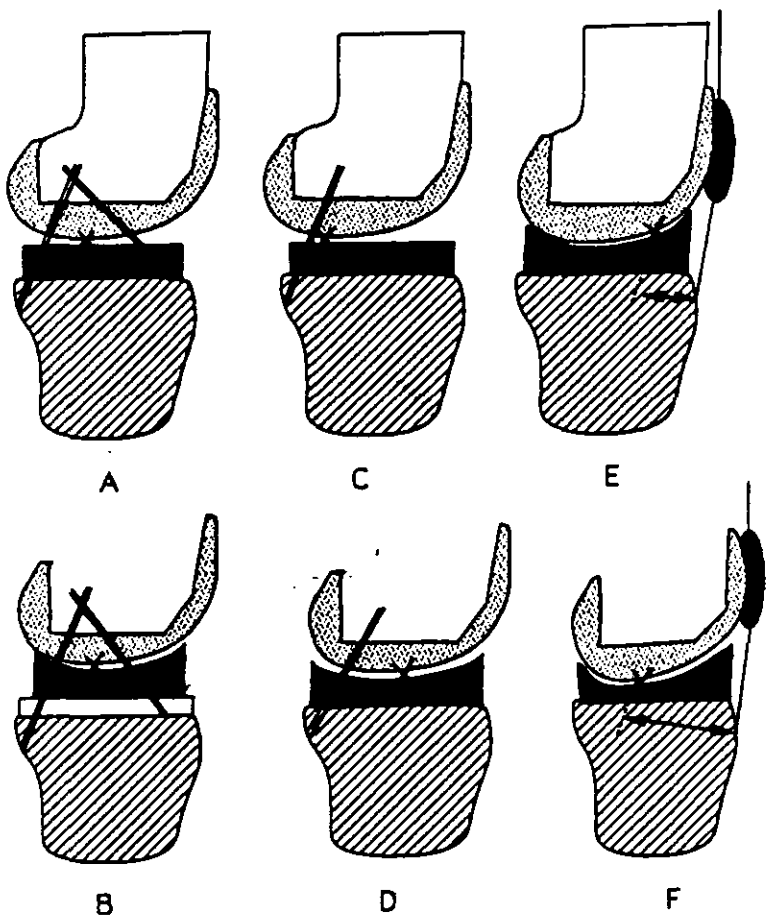
The total condylar type of replacement was developed to try to mimic the natural geometry of the knee. This is achieved by essentially correcting the bony alignment back to the "natural" state and reproducing the original shape of both the tibia and femur.

The bony osteotomies are performed on the tibia and femur during a total knee arthroplasty to a high degree of accuracy (Manning et al 1988). Any deviation of these accurate osteotomies from the "natural" mechanical axis of the leg, or the statistical mean for the tibio-femoral angle, will create an imbalance of the passive forces on the implantation of the prostheses when bicondylar contact is assumed. This natural physiological tibiol-femoral varus angle has been calculated independently by two research teams and found to be a mean of 6° with a standard deviation of 1° (Moreland et al 1987) and 7° and 2° respectively (Denham 1980). Therefore, it is possible to create surgically a small amount of soft tissue imbalance. The early surgical technique developed by Freeman accounted for this by attempting to balance the joint before the femoral bony osteotomy was performed and the latter instrumentation sets have allowed for accurate angular resection at the discretion of the surgeon.

The femoral component should profile the original geometry of the femur as closely as possible as any small deviations in the sagittal profiles of prosthetic components can expect to change the joint kinematics significantly, leading to either reduced motion or excess laxity. Hence at least five different sizes of femoral

component should be available at operation to enable accurate duplication of the "natural" femur. The best geometric arrangement of the replaced components is achieved when the cruciate ligaments are preserved and the plastic replacement of the tibia is flat. (Weinstein et al 1986, Whittle & Jefferson 1989). Figure (1.16). This arrangement allows for the the normal point contact locations depicted by the natural soft tissues of the knee with the muscles allowed to function at their correct moment arms (Walker 1992). The flat tibial surface can also allow near normal function when the cruciate ligaments are excised but such posterior point loading can cause excessive component wear. Therefore, the cruciate function is mimicked by a slight posterior upsweep of the tibial surface. Such dishing provides restriction to posterior displacements under weight bearing conditions by a potential energy mechanism called the "up hill principle" (Walker et al 1974). The ligament tensions could be unacceptably high however if this curvature was great resulting in joint restriction and loss of motion. Shear forces and torques can be transmitted to the components causing component failure. If the cruciates are not retained then posterior and anterior dishing is required for the stability of the joint, but when the posterior shear force acts on the tibia, the tibiol-femoral contact points can be too anterior, reducing the quadriceps lever arm. This problem was considered by Freeman & Railton (1988) who dished the tibial component posteriorly, to stabilise the design with intercondylar cams to guide the contact points throughout flexion.

All of the above design concepts assume that the soft tissues are in their original healthy state and not in any diseased or contracted form. In reality the cruciate ligaments are often sacrificed leaving the prostheses to define the kinetic motion and the collateral soft tissues to retain the stability of the joint. If however, one of the collateral structures is reduced in length, then



A. An ideal situation for normal kinematics.

B. An ideal situation with reduced bearing stresses (Sliding meniscus type).

C. A flat tibial surface and Absent ACL can result in posterior contact points.

D. A posterior upsweep mechanically substitutes for the ACL.

E. An Absent ACL and PCL can allow anterior contact points, reducing the quadriceps lever arm.

F. A posteriorly located cylindrical bearing restores the quadriceps lever arm.

Figure 1.16 Geometrical schemes for condylar replacement. The crosses show contact point locations.
(After Walker 1992)

bicondylar contact does not exist, and all forces are transmitted through one condyle. This will affect the kinetics of the replaced knee significantly.

1.3.4 Passive loads.

The passive compressive forces are the non-dynamic forces through the knee joint. Such forces are generated by the tension of the soft tissues crossing the knee, and cannot be estimated by any dynamic external measuring systems such as gait analysis. Estimation can only take place when muscular contractive forces are known to be zero and the compressive loads are measured directly to avoid the addition of body weight. Measurement therefore can only take place in cadaveric knees or when a patient is fully anesthetised at the time of operation.

An additional passive force has been suggested as the force generated in the imbalanced knee during dynamic activity generated by contracted soft tissues. Imbalance arising, when the bony alignment is within normal limits could be due to soft tissues exhibiting a difference in their "natural" lengths due to the contracture accompanying the arthritis disease process, or due to the positioning of the bone cuts. Post operative alignment of the imbalanced knee is indeterminate as it depends on the state of contraction of the muscles, so alignment in condylar knee arthroplasty can only be defined if the knee is known to be balanced at operation. Hence a balanced, normal knee, would produce a constant postoperative alignment. An imbalanced knee is a variable between the limits of bicondylar contact and a position where the muscles are completely relaxed, figure (1.17). (Sambatakakis 1993). Such additional imbalance has only recently been observed as a wedge of cement on post-operative standing x-rays. The tibial and femoral components have been allowed to rotate about two simultaneous centres of rotation upon cementing. This rotation produces pure condylar lift-off and has been considered as a two body system of the femur

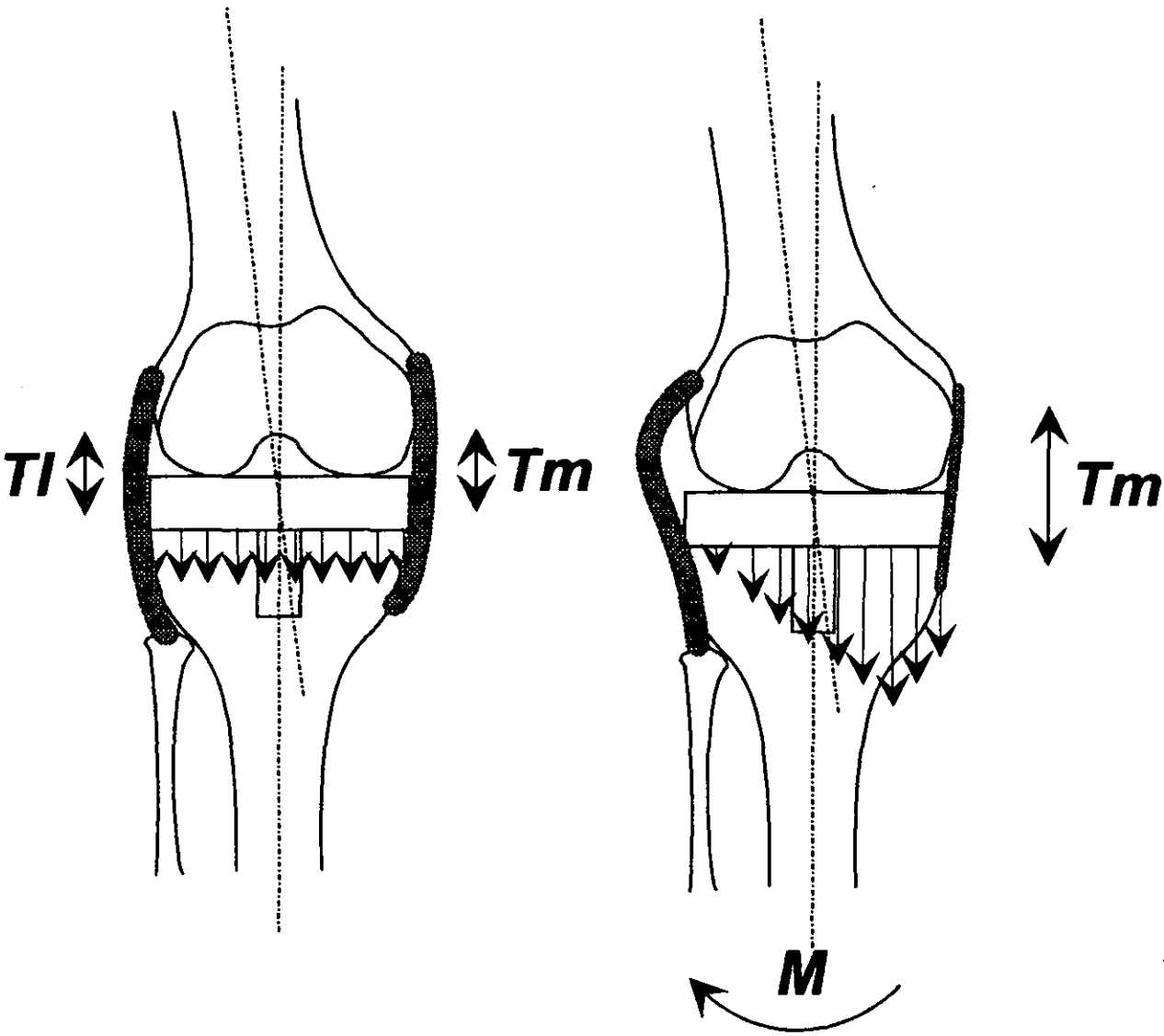


Figure 1.17. Additional passive force of imbalance, generated by contracted collateral soft tissue structures and an external moment.
(After Sambatakakis 1993)

plus the femoral component and the tibia plus tibial component. One instantaneous axis of rotation, which represents rotational-translational, varus-valgus movement (Grood et al 1981) is assumed to be situated at the centre of curvature of the femoral condyle of the tighter compartment. This is only true however, when the tight fit of the tibial component does not allow any relative movement between this component and the tibia, for example, when independent cementing of the components or press-fit fixation of the uncemented components are used. The simultaneous cementing of the tibial and femoral components has, however become popular (Sledge and Walker 1984). The preparation of the bony cuts and intra- medullary canal for the tibial component using past instrumentation were generous, allowing a very loose fit between the tibia and tibial component which was filled with cement. Relative movement of the tibial component with respect to the tibia was therefore possible on simultaneous cementing. The two body system described earlier (Grood et al 1981) has now become a three body system. Two instantaneous axes of rotation exist between the three bodies in the coronal plane, $I_{f,tc}$, at the centre of curvature of the femoral component of the tight compartment and $I_{t,tc}$ parallel to the tibia and tibial component on the tight side of the knee, figure (1.18).

When an imbalanced knee is extended on the operating table, the tension in the tight structures of an imbalanced knee produces two moments, each related to one of the two axes. One of the moments causes condylar lift-off and the other causes the rotation of the tibia with respect to the tibial component. These moments cease to cause movement as soon as they are balanced by the opposing moment from the increasing tension of the soft tissues of the looser compartment. The rotation about the instantaneous centre It,tc produces the cement wedge sign of imbalance. (Sambatakakis et al 1991).

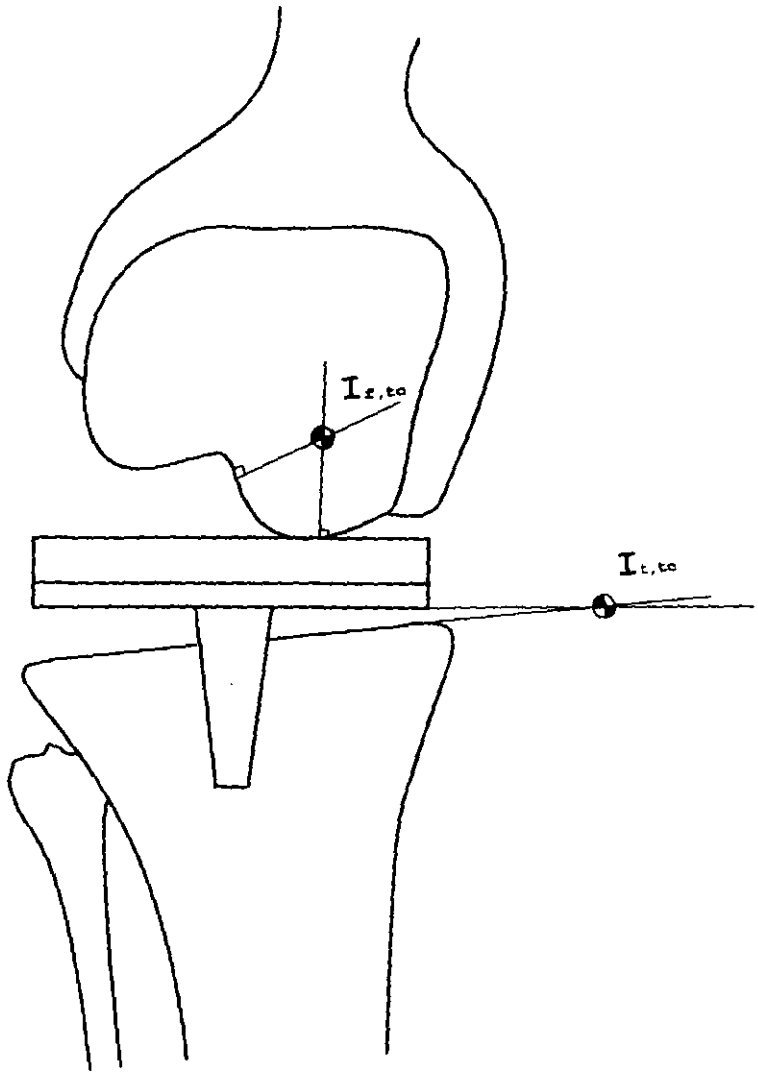


Figure 1.18. Definition of the centres of rotation of the tibial component.

1.3.5 Fracture of the metal backed tibial tray.

There have been a total of eight fractures of the metal backed tibial trays published. (Scott et al 1984, Mendes et al 1984, Ranawat et al 1986, Morrey et al 1988, Flivik et al 1990). The fractures do vary across different makes of prostheses and some have slightly different geometry but they are all from the total condylar family of arthroplasties and are all manufactured from cobalt-chromium-molybdenum cast alloy. All of the prostheses would have been implanted using a similar operative sequence as described in section 1.2.2 and would be subjected to similar loading patterns during ambulation.

The first two cases (Scott et al 1984, Mendes et al 1984) estimated the forces acting upon the tray by using the static and dynamic loading patterns derived by Harrington (1974). They concluded that the medial force developed was 1120N and 1800N in the two cases. Their explanation of the fracture was that the tray "was poorly fixed and supported by bone, would be cantilevered from the central stem and subjected to high bending forces. A fatigue fracture resulted, initiated at the corner of the cut-out due to stress-concentrating effect there". They did not, however, back this opinion up with a metrological study.

Mendes et al (1984) also reported a case of a cruciate sacrificing tibial tray and concluded that the fracture was due to "brittle cleavage". Electron microscopy images did show evidence of brittle fracture but also arguably showed the typical rings of fatigue failure. Therefore, this evidence is far from conclusive.

Ranawat et al (1986) reported on two Johnson and Johnson failed prostheses. They supported the view of the previous authors of the failure mechanism and backed their opinion up with a view of the fracture surface, viewed under an electron microscope. However, the images that they published do not show clear characteristics of

a fatigue or any other type of failure, nor do they indicate the position along the fracture surface from which the image originated.

The literature became even more confused when Morrey et al (1988) reported that their failure was probably due to fatigue failure. This is despite describing at length "what appeared to be cleavage (flat facets) on the fracture surfaces, which may signify a condition of low fracture toughness (brittleness)".

Flivik et al (1990) reported on a similar fracture in 1990 and again hypothesized the same cantilevered explanation for the failure first put forward by Scott et al (1984). However, they proceeded to discuss how relatively small changes in the design of the prosthesis have influenced the failure of this component. Such factors possibly did concentrate stresses in the previously discovered fracture regions but were not totally responsible for the failures. This view is vindicated by the complete range of prostheses that have failed, at similar fracture positions before and after this paper was produced.

The general opinion is that the failures are due to fatigue but nowhere in the literature are the typical rings of fatigue failure documented. Such rings would indicate the direction of crack propagation and indicate areas were future designs should concentrate. Signs of brittle cleavage have been reported which would be consistent with the final break of the prosthesis, but no indication is given of the position along the crack surface, from which the image was taken.

1.4 Mechanical properties of parallel fibred collagenous connective tissue

Connective soft tissue consists of collagen, a fibrous tissue, elastin and ground substances as well as water. Collagen provides the nucleus for salt deposition in the soft tissues and acts as the framework for resisting external forces. The molecular structure and chemistry of collagen as well as its synthesis and metabolism is well documented (Ramachandran 1967, Gould 1968). The collagen molecules form distinct fibrils which are between 2000-5000 Å long. These fibrils in turn collect as collagen fibres between 0.2 and 12 μm in diameter. Collagen in its natural state is only extendable by about 3% representing slight lengthening of the fibres but mostly rearrangement of the collagen network. The ground substances are responsible for the biomechanical functional properties of the tissue and consist mainly of the glycosaminoglycan acids which aid tissue nutrition.

The mechanical characteristics of soft tissues are dependant not only upon the varying proportions of these three constitutes but on all levels of its morphological structure from a macro to microscopic levels, (Vidiik 1979). The complexity of soft tissues increases when they are considered as functional structures because of their complex shape and their interaction with associate structures. When the collagen fibres are closely packed they represent a dense or regular connective tissue. The geometrical arrangement of these close packed collagen fibrils can be subdivided into structures that have essentially parallel fibred arrangements such as ligaments, two and three dimensional meshworks like skin and complicated patterns that interact with associated soft tissues (Vidiik 1973). This study will limit itself to the biomechanical properties of parallel fibred soft tissues associated with the ligamentous and tendinous structures of the knee joint.

1.4.1 Tensile strength of soft tissues

The mechanical properties of collagenous soft tissues has concentrated on recording the ultimate tensile strength of the structure. Such measurement is technically difficult because the failure point is well beyond the physiological range for soft tissues. Values for failures of fresh human tendons have been recorded as 45N/mm² (Stucke 1950) and 125 N/mm² (Cronkite 1936). Yamada (1970) summarised the results of extensive Japanese investigations with the failure rate within the range 50-100 N/mm² in the adult human. Yamada also observed that the ultimate failure rate was inversely proportional to the thickness of the specimen. The experimental data gathered by the authors above correlate well with the theoretically calculated values of Harkness (1961). He assumed that isolated fibres of purely collagenous soft tissues with a specific gravity of 1.4, would have an ultimate tensile strength in the range 100-500 N/mm².

1.4.2 Mechanical analogy

The stress strain relationship of collagen in the form of simple empirical mathematical formulae, was first proposed by King (1957), Morgan (1960), and Ridge and Wright (1964,1965,1966). Different functional states were compared by evaluating certain defined constants, but it has not been possible to show conclusively a link between these constants and any macro or micromorphological feature. Zarek and Edwards (1965) first applied elements such as elasticity, viscosity and dry friction to macromolecules which allowed for the early quantitative model of cortical bone. (Sedlin 1965). This method was first discussed and then developed as a model for ligamentous tissue. (Viidik 1966, Viidik and Magi 1967).

Viidik et al (1968) clearly explains elasticity, viscosity and plasticity of soft tissues in terms of Hooke, Newton and Coulomb elements. Elasticity is modelled in terms of the Hooke element or a simple spring, figure (1.19a) where

$$F = cX$$

Viscosity or the Newton element is represented by a dashpot or a viscous damper, figure (1.19b). It's behaviour is obviously dependant upon velocity

$$F = k\, dX/dt$$

Plasticity is represented by a Coulomb or a dry friction element where a stiff body is placed on a rough surface, figure (1.19c). This element is expressed in two terms

1) $|F| < Fs$, when $X=0$
2) $|F| = Fs$, when X is indeterminable

The simplest combination of these elements is the coupling of the elastic and viscous elements in series or parallel. The Kelvin unit combines the Newton and Hooke elements in parallel so that they are subjected to the same elongation with the force resulting from a summation of the force in each body, figure (1.20a).

$$X = Xc = Xk$$
$$F = Fc + Fk$$

$$F = cX + k\, dX/dt$$

If Fo is applied to the system at $t=0$ and $X=0$ a deformation results:

$$X = Fo[1-\exp(-ct/k)]/c$$

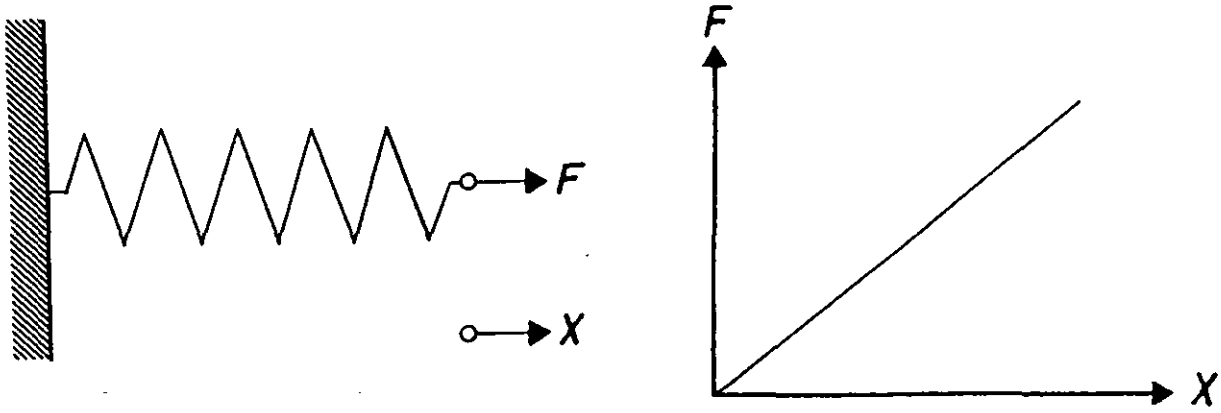


Figure 1.19a. The Hooke element.

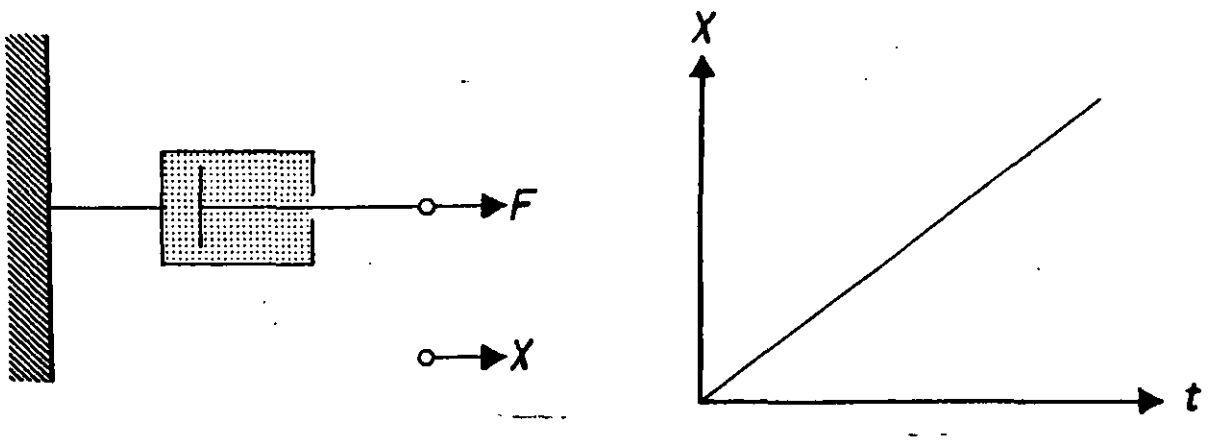


Figure 1.19b. The Newton element.

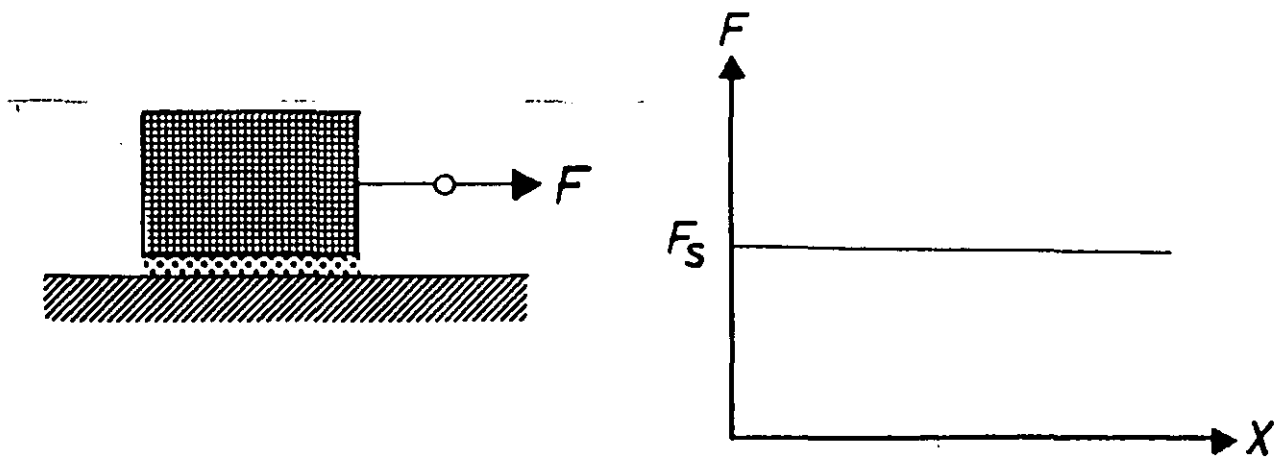


Figure 1.19c. The Coulomb element.

Figure 1.19. The basic rheological building blocks (After Viidik 1966)

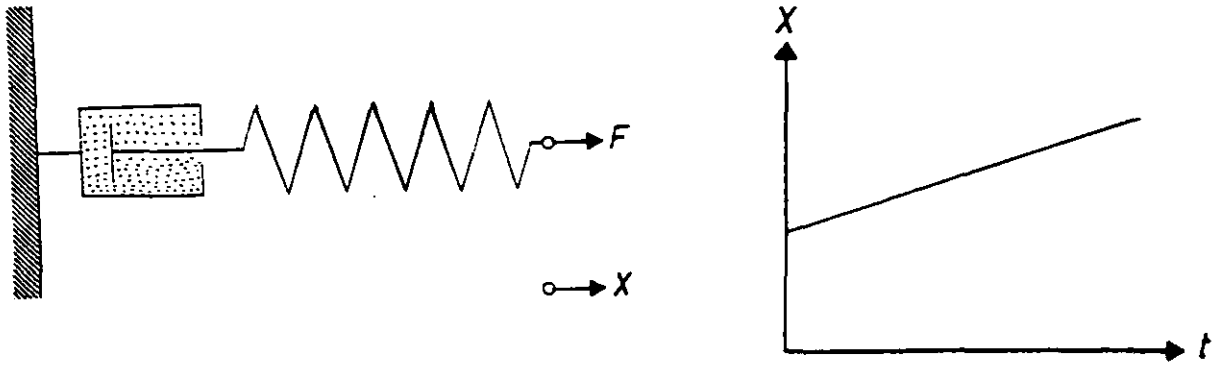


Figure 1.20a. The Kelvin element.

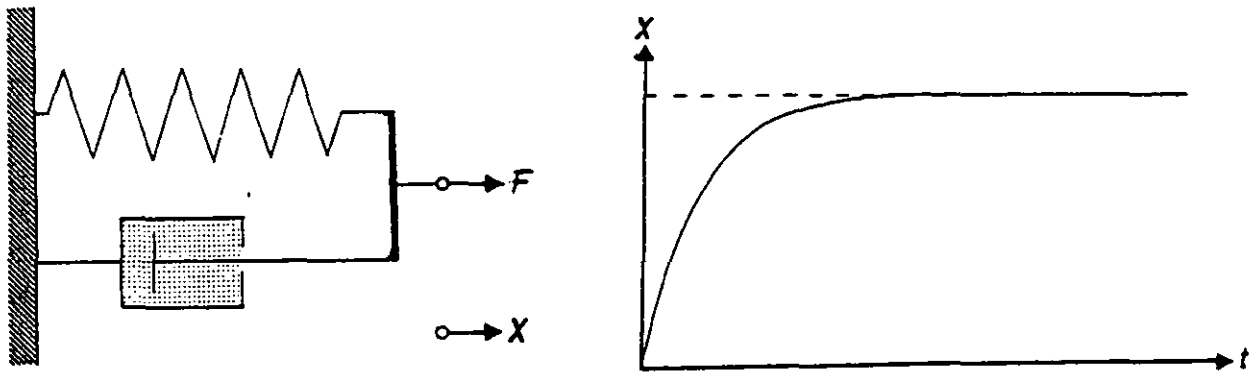


Figure 1.20b. The Maxwell element.

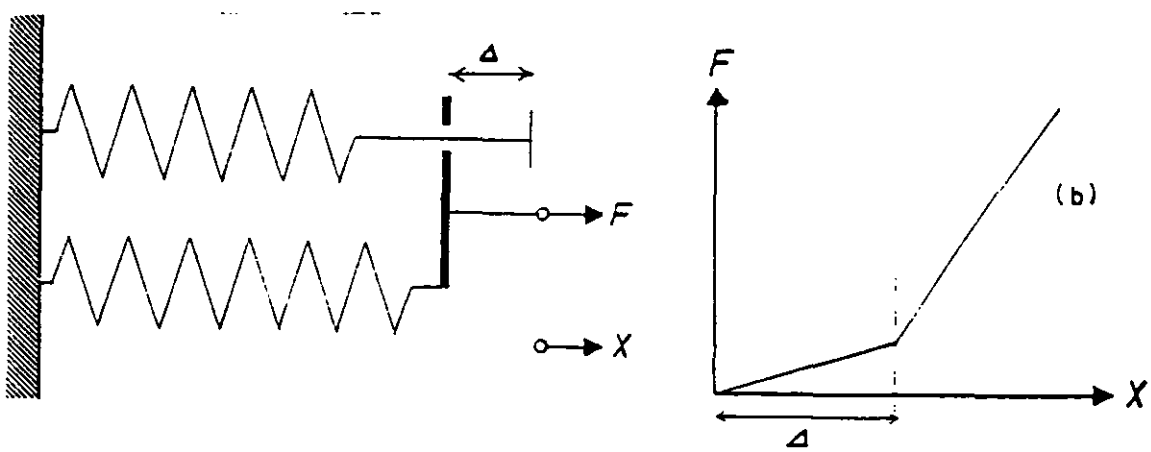


Figure 1.20c Non-linear spring action gained by a number of Hooke elements.

Figure 1.20 Combinations of the basic rheological building blocks.
(After Viidik 1966)

The Maxwell unit combines the Newton and Hooke elements in series so that they are subjected to the same external load with the total extension being the summation of the extension of each body, figure (1.20b).

$$X = Xk + Xc$$

and

$$F = Fc = Fk$$

This gives the equation

$$dX/dt = dF/dt\ /c + F/k$$

When a constant force Fo is applied at time t=0 and X=0, the following equation results

$$X = Fo/c + Fo\ t/k$$

The deformation of the Newton element remains at a maximum achieved value when the force Fo is removed from a Maxwell unit and the Hooke unit returns to its initial free length. In the Kelvin element however, the deformation decreases to zero when the applied force is removed, as the two elements are coupled in parallel, i.e. the two elements are equally deformed at any time.

A non-linear spring action can be created by coupling a number of Hooke elements in parallel as shown in figure (1.20c). In this example only two are coupled but any number can be joined to simulate a non-linear curve.

$$F=c1X + c2(X-\delta)u(X-\delta)$$

Where

if $\delta >= X$ $\quad u(X-\delta) = 0$

$\delta < X$ $\quad u(X-\delta) = 1$

Vidiik used these five basic building blocks to model the anterior cruciate ligament of the rabbit joint from experimental data. The complete model is shown in figure (1.21) although no estimations of the spring, dashpot and friction element constants are suggested. The model essentially breaks down into three sections.

1) A Newton and a Coulomb element in parallel to model force relaxation. This is at a maximum on the first cycle of any load - elongation testing and diminishes subsequently.

2) A Kelvin unit to represent the toe portion of the viscoelastic curve.

3) A number of parallel Hookean elements arranged in a non linear manner to represent the reversible main portion of the curve.

In vivo however, the ligaments are not isolated, independent bands of soft tissue. The tendons, muscles, ligaments and even the skin combine, into a meshwork of soft tissues. Investigation of individual structures in vitro is not realistic as the individual structures interact with each other, as they are performing their function. Wiederhorn (1953) proposed that such interaction should be represented by simple Hooke units. The individual structures can therefore be assumed to be continuously attached by a finite number of springs in parallel. This assumption has recently been proved. (Sambatakakis et al 1993). Where balance and stability of the knee joint were retained after the collateral ligament of the knee was totally released subperiosteally.

Studies have shown that the Kelvin elements correspond to the collagen molecules in this analogy and cross linking of the soft tissues is represented by the spring Ck.

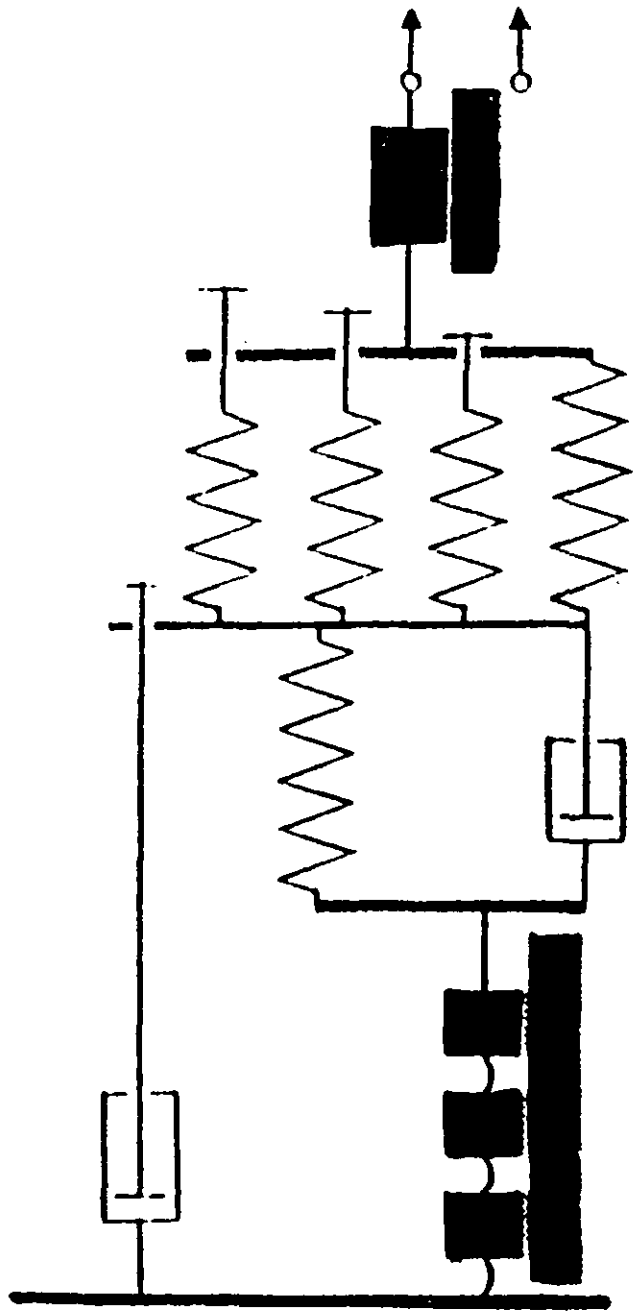


Figure 1.21. The complete rheological model for rabbit ligaments.

(After Vidiik 1966)

(Wiederhorn et al 1953) Alterations in the ground substance mainly affect the irreversible dashpot Kc. (Vidiik 1973)

1.4.3 In vivo Homeostatic condition

It has been clearly shown that living soft tissues are not elastic but at best non linearly viscoelastic. Fung (1971) argued that soft tissues could be treated practically as quasi-linear viscoelastic materials. i.e. the hypothetical stress depends nonlinearly on the instantaneous strain, and a linear relaxation law determines the current stress in terms of the history of the elastic stress by a convolution integral.

When living tissues are disturbed by an external load deformation occurs, when the load is removed the soft tissue structure will not return exactly to its original configuration. A "natural state" does not exist in soft tissues like in other truly elastic materials (Fung 1973). The absence of such a state is a vital consideration in the design and development of any instrumentation to quantify the passive soft tissues around the knee during TKA, and has been overlooked by most of the workers in the field.

As no natural state exists there is no unique datum point for the measurement of stress and strain in vivo. The free length with no external load applied is often used in vitro experimental procedures but such an assumption probably produces an over estimation of the toe portion to the viscoelastic curve. A standard engineering approach would be to examine a test specimen by measuring displacements and forces relative to the no-load situation as in the in-vitro condition. In-vivo however, a no-load condition doesn't exist. At best a steady state condition should be achieved where a particular response can be predicted because the loading and

unloading process has been repeated a large number of times. If this is achieved we have a homeostatic condition with a usable reference state.

1.5 Present methods of investigation

The measurement of the forces generated by soft tissues is notoriously difficult. The present methods of assessment can be broken down into two sections:

1) The analysis of individual structures in vitro and vivo developed primarily for rheological analysis and the estimation of the load / elongation curves of particular structures.

2) Instruments developed to assess soft tissue imbalance during total knee arthroplasty. These instruments were designed for surgeons to be used at a reasonable speed at the time of the operation.

1.5.1 Direct measurement of single structures

In vitro studies of the mechanical properties of ligamentous structures has been investigated extensively. (Fung 1982, Vidiik 1979, Woo et al 1990a). The problems of change in cadaveric specimens after death is well known. This is mainly due to the change in the water content. The problems of applying significant loads to specimens without reducing the original length of the structures is well known and many clamping devices have been suggested. All of these grippers reduced the length of the test structure and so they were generally discarded in favour of bone-ligament-bone preparations (Woo et al 1990a). These preparations retained their natural ligament bone insertions and were tensed directly by the bones. All other soft tissues were stripped away so that any inter tissue influences were not recorded, and assumed to be zero.

In vivo rheological measurement has been restricted to the individual measurement of individual ligamentous structures. These measurements have been achieved with implantable strain gauge type transducers (Barry & Ahmed 1986, Xu et al 1992). They suffer theoretically however,

by disrupting and shortening the structure under test on insertion and do not take into account the characteristics of the associated soft tissues of the knee to which they are continuously attached.

The next method estimated the three dimensional geometry of a particular soft tissue structure using a laser system. (Woo et al 1990b). The change in shape was recorded whilst an external load was applied. The change in volume was recorded and hence the load elongation curves could be plotted. Although this method was not directly invasive the particular structure required isolating in order for the instrumentation to differentiate it from others.

1.5.2 Assessment of whole system

This group of instruments were designed to give an indication of the imbalance of all the soft tissues around the knee at the time of operation. Imbalance was assessed after intra-medullary instrumentation was used to perform the 97° distal femoral osteotomy, followed by the anterior and posterior cuts, and the 90° tibial osteotomy using extra-medullary instrumentation. Osteophytes are generally removed before any balancing procedures are performed because they tend to lengthen and hence increase the tension in the soft tissues.

1.5.2.1 Rule measurement

This method of measurement by Rand, figure (1.22) is recommended by for use to balance the soft tissues with the Genesis total knee system. He suggests that the tibia should be distracted in both flexion and extension manually and the medial and lateral soft tissues spaces should be measured using a standard six inch rule. He assumes that the knee is balanced when the difference between the medial and lateral measurements was less than 2mm.

Practically this procedure is very difficult to achieve in the operating theatre. Unlike the illustrations provided by Rand showing just the bony hard tissues, the soft tissues around the knee provide a formidable obstacle to the flat rule. On the lateral side of the surgical wound the patella and its extensor mechanism is displaced. Measurement here in extension is very difficult. Physical reading of the rule can also prove difficult because the tibia and femur are rather eliptical in shape resulting in no natural reference points for measurement. Also metallic glare caused by the surgical lighting and the bloody environment can hinder reading.

Rand recommends that a medial or lateral difference of less than 2mm should be perceived as balanced. However, direct comparison with the load/elongation curves gained by Erkman and Walker (1974) shows that, depending on the position on the curve, an elongation of 2mm could induce a difference in tensions of up to 90 N. Clearly a more sensitive measure of imbalance is required for research purposes.

This method seems to be the simplest method of distinguishing between a rectangle and a trapezoid presently available. To enable the leg to be pulled in a direction that will apply equal forces to both the medial and lateral structures, the soft tissue imbalance needs to be known in the first instance.

1.5.2.2 Spacers

This method of assessing soft tissue imbalance was developed by Insall (1985), figure (1.23). A spacer is chosen from a series of spacers representing different tibial prostheses. It is then attached to an extra medullary bar extending proximally to the head of femur at the hip, and distally to the centre of the ankle, and inserted into the prepared knee. Imbalance is

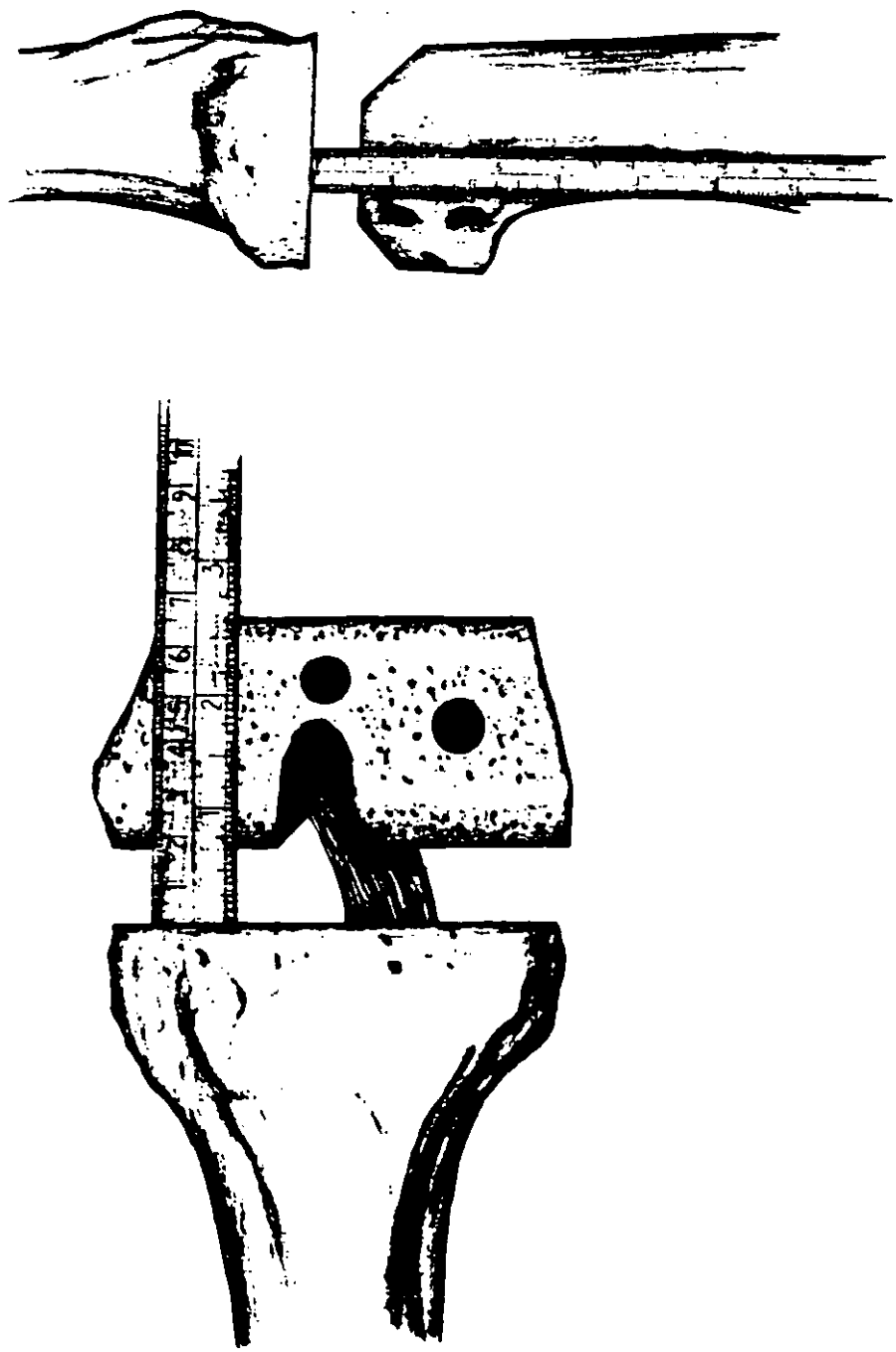


Figure 1.22. The Rule method of assessing soft tissue imbalance
(After Rand 1989)

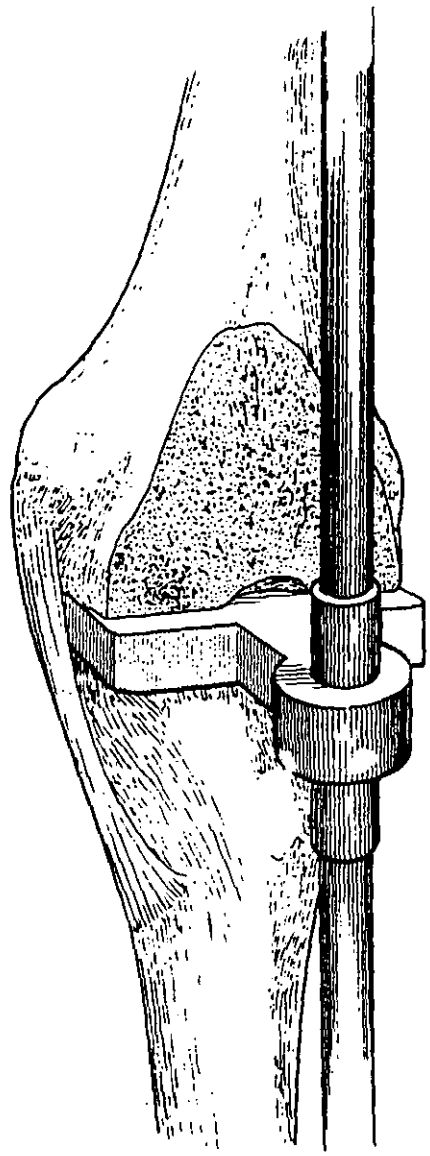


Figure 1.23. The spacer method of assessing soft tissue imbalance.
(After Insall 1984)

judged by the extent of condylar lift off of the femur from the spacer. Imbalance is also assessed in a similar manner at 90° of flexion.

This method is representative of the change in the surgical approach in the early eighties when soft tissue balance was relegated in importance compared to bony alignment. Correct alignment is guaranteed by this method and the stability of the joint can be assessed at different extension gaps in both extension and flexion but soft tissue balance is left to surgical feel as to the extent of any condylar lift off. It is very easy to exert differing forces to the collateral soft tissue structures using this method.

Practically the instrument is very difficult to use because the soft tissues of the knee tend to contract, closing the knee after the bony cuts have been made. Insertion of the device often requires much pulling on the tibia to create the extension gap. If the soft tissues are contracted, insertion can damage the freshly cut cancellous bone on the tight side of the knee. This can be a significant problem with some rheumatoid patients where the bone tends to be much more brittle.

1.5.2.3 Tensers

Many different adaptations of the design of the classical tensors have appeared from the tensor recommended by Freeman for use with the Proteck total knee system to the laminar spreaders adapted by Laskin (1989), figure (1.24). They all however, work on the same principle. After insertion into the knee the medial and lateral compartments of the knee are tensed independently until an acceptable bony alignment is achieved. If this is not achievable or the surgeon feels that he or she is applying unacceptably high forces on the corresponding soft tissues then ligamentous releases are indicated. Alignment is again

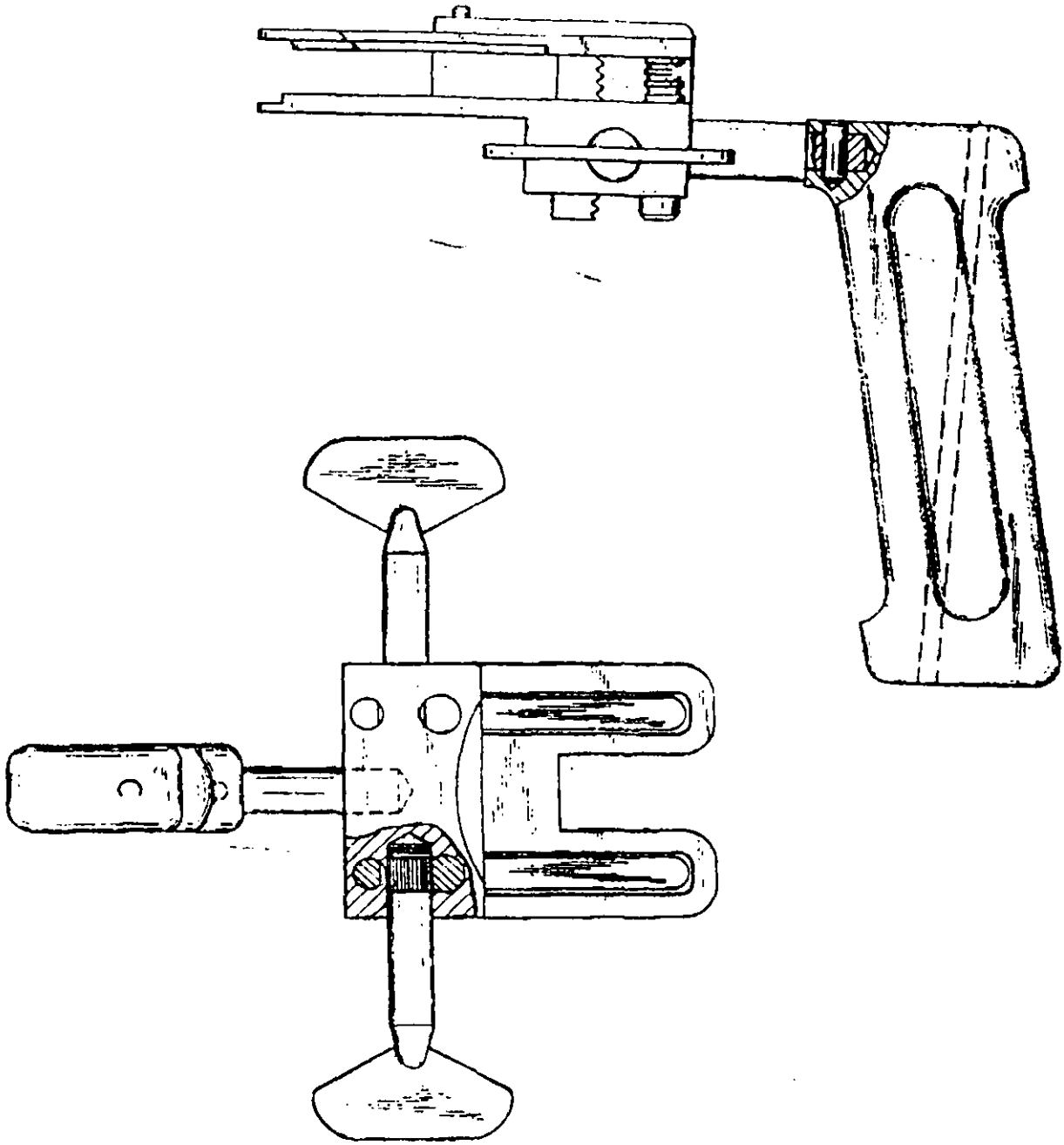


Figure 1.24. The tenser method of assessing soft tissue imbalance.

(U.S. Patent 5116338)

assessed by comparing an extra medullary bar extending through the instrument, to an imaginary line proximally to the head of femur at the hip, and distally to the centre of the ankle.

Practically these instruments are much easier to use than the previous methods because they collapse to allow easy insertion into the extension gap. However, the surfaces of these devices are rigid rectangles so they tend to exert edge loading and dig into the cancellous bone when forming the trapezoidal separation gap. The extreme forces exerted on the tight side of the knee also tend to crush the susceptible soft and brittle bones of rheumatoid patients. In order to evaluate the difference in tensions in both the medial or lateral soft tissues, independent measurement of the two tensing mechanisms would be required.

1.5.2.4 Biomet Knee Distractor

This instrument was a further development of the tensors. both the medial and lateral tensing means are attached to a sprung loaded tensing mechanism (US patent 4501266), figure (1.25). The instrument is used in the same way as the tensors and retains all its disadvantages. Practically this instrument requires the manual tensing of each of the condyles by the turning of the screws against the compression springs at the end of the two mechanisms. Later versions of this device incorporated two pneumatic cylinders, fed from a common regulated pressure source to ensure that equal pressure was applied to each of the condyles.

The main criticisms of this instrument are that it is very time consuming to use and that imbalance is quantified with reference to an imaginary line from the centre of the hip to the centre of the ankle.

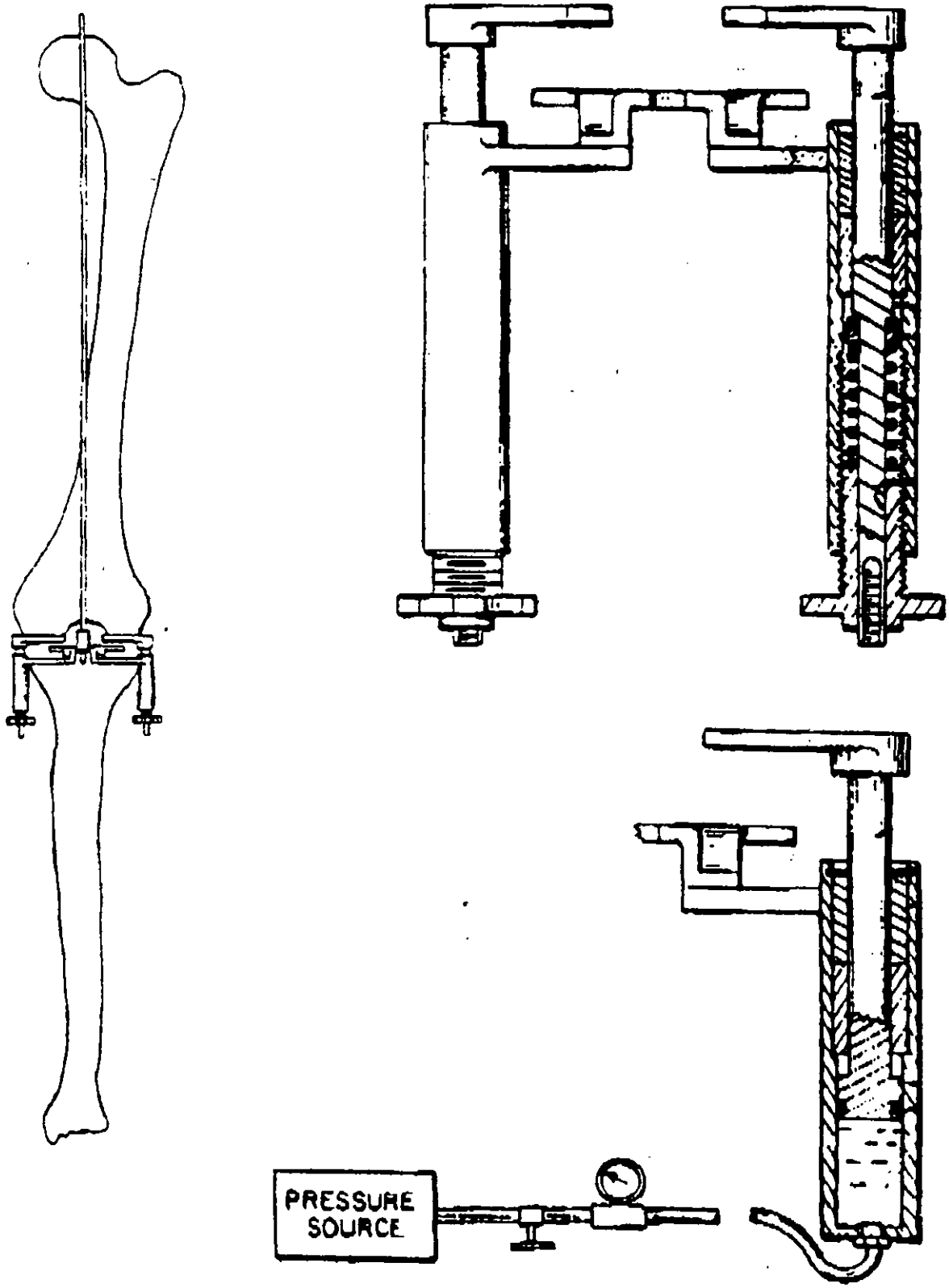


Figure 1.25. The Biomet method of assessing soft tissue imbalance.

(U.S. Patent 4501266)

1.5.2.5 Elastic Spacer

This method of assessing the soft tissue imbalance was devised by Sambatakakis (1993) to investigate the passive forces around the knee during total knee arthroplasty. The instrument was basically an elastic spacer. It consisted of two plates, ground parallel, and four standard compression springs. The springs are located in flat bottom holes, close to the corners in both the top and bottom plates. The plates had a cut out to allow the posterior cruciate ligaments to be maintained if required. The overall free height of the device with no compressive forces applied was 27 mm. The minimum height was 15.5 mm, obviously being dependant on the solid height of the springs.

After the device was assembled, it was compressed within the jaws of the applicator by a simple rack and pinion gearing system, figure (1.26). It was then placed within the bony gap of the knee. The applicator was then released and removed, leaving the instrument to find its equilibrium, trapezoidal position, figure (1.27a). Measurements were then taken to an accuracy of 0.1 mm, with a standard vernier caliper, between scribed marks on the two plates to ensure consistency. In the more contracted knees a considerable pull was required to displace the soft tissues on the tight side to allow for the device to be inserted. Otherwise the leg was left freely on the surgical table to find its own equilibrium position.

At the end of each measurement the applicator was reintroduced, the spacer was compressed and removed, allowing for any necessary releases to be performed. This was repeated until the difference between the medial and lateral measurements was 0.5 mm or less when the knee was perceived to be balanced, figure (1.27b).

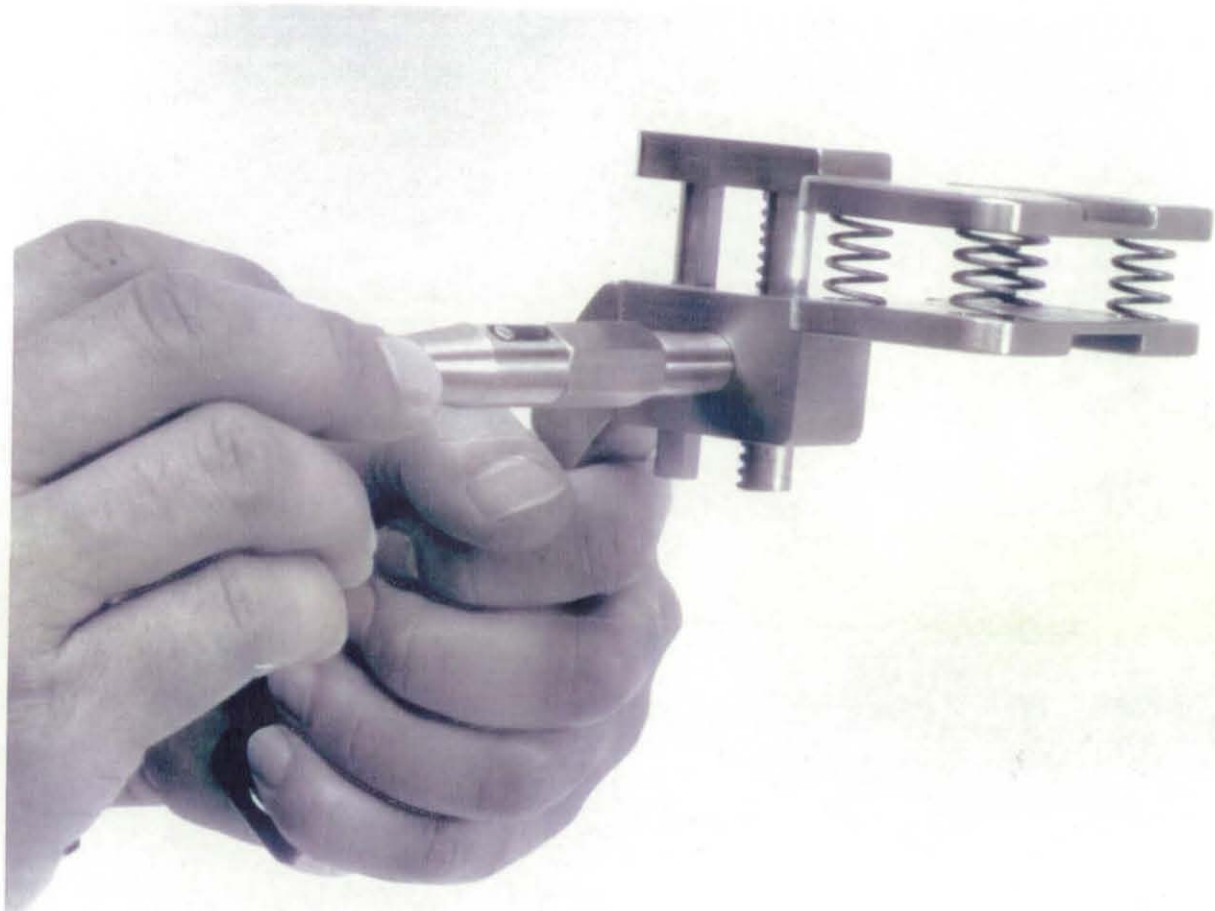


Figure 1.26. The spring device for assessing soft tissue imbalance.

(After Sambatakakis 1993)

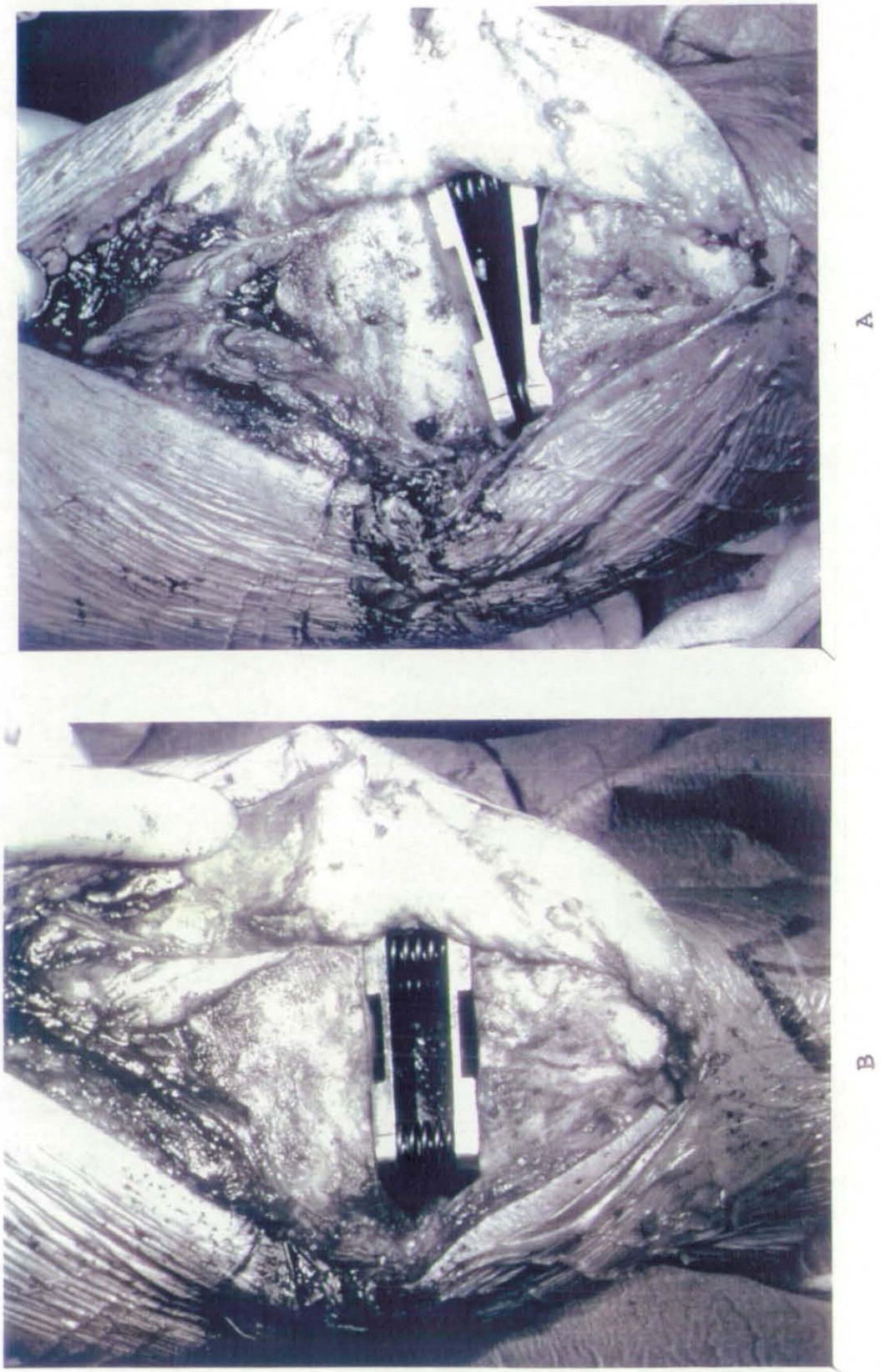


Figure 1.27. The spring device showing soft tissue imbalance of the knee before (A) and after soft tissue releases (B).

(After Sambatakakis et al 1993)

Theoretically the instrument only exerts equivalent forces medially and laterally when balance is achieved. At the equilibrium position in the knee, the compressed lengths of the springs were different, representing different applied forces. This force imbalance can be calculated from the medial and lateral lengths, and this known applied imbalance is significantly better than the unknown forces applied by the classical tensers. However, the trapezoidal equilibrium position gained by the instrument is purely arbitrary, and dependant on the spring rate of the springs used. It is also possible for the plates to move in a shearing direction distorting both the medial and lateral measurements. The instrument also suffers from the inability to measure the passive imbalance at different extension gaps, representing different thicknesses of tibial prostheses. The springs were also being compressed to their solid length, well beyond their maximum safe loads, resulting in the over stressing of the springs.

Practically a great deal of care needs to be taken by the surgeon to ensure that the device does not fall apart before it is compressed by the applicator and that the four springs are located properly within the two plates. Some difficulties have been observed in placing the device within the resultant trapezoid due to the contracture of the soft tissues on the tight side of the knee. The total thickness of the device could not be reduced because of the solid height of the compression springs. This resulted in the surgeon pulling on the leg and occasionally using a tibial pusher and hammer to insert the device before any ligament releases were made. Great care was needed not to damage the surface of the freshly cut soft cancellous bone. Once positioned in the knee it was practically very difficult to record the lateral measurement for the extension gap because of the protracted soft tissues and patella. The vernier

caliper also proved difficult to read in the theatre environment due to the metallic glare caused by the reflection of the surgical lights.

Despite all of these disadvantages this instrument did show true soft tissue imbalance in the arthritic knee for the first time. It was designed as a prototype, research instrument and proved to be a reliable qualitative measure of soft tissue imbalance.

CHAPTER 2

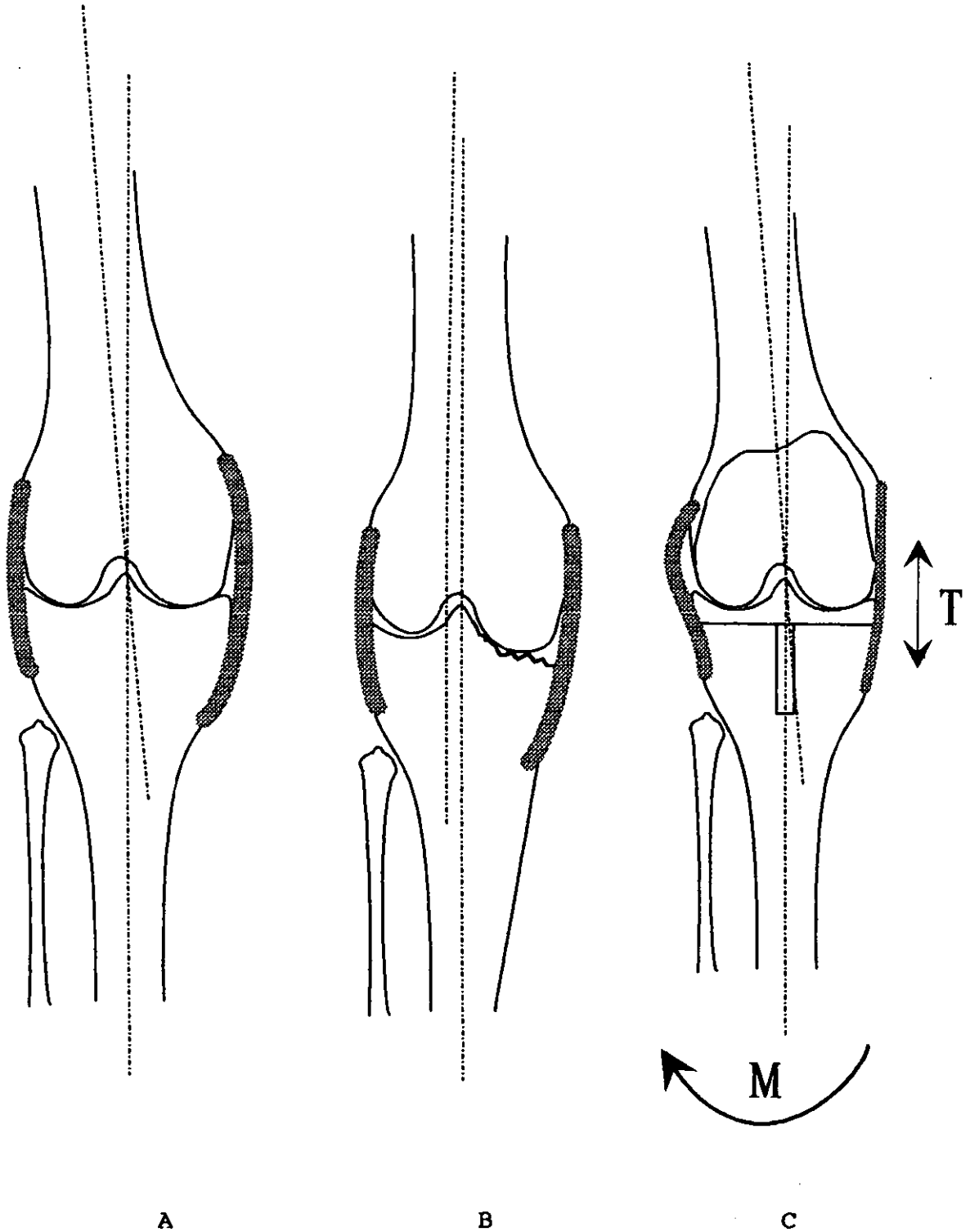
DESIGN AND DEVELOPMENT OF INSTRUMENTATION

2.1 Problem Evaluation

It is now generally accepted that soft tissue contracture in the coronal plane takes place during the years of arthritic illness. It is not clear however at what stage such material changes take place within these structures. It is possible that tightening of these structures in the first instance may cause the over loading of one of the compartments of the knee, resulting in the gradual eroding of the bone stock, or more likely the soft tissues might be reacting to a loss of the bone stock by other means, and just stabilizing the joint in its new position. Such arguments cannot be researched in any detail until the means to accurately and reliably quantify soft tissue balance, have been developed.

The mechanical design of most of the implants have attempted to mimic as closely as possible the natural movement of the knee joint. The operation is centred around returning the ends of the bones of the knee to their former profiles and geometries so that the alignment of the lower leg can return to within natural limits. The soft tissues have on the whole been overlooked. Gross soft tissue deformities have been corrected, but deformities that will allow bicondylar contact only when an external moment, such as body weight, is applied, have been generally accepted. Figure 2.1 shows the three stages of a "normal" knee, an arthritic knee with hard tissue loss and a replaced knee showing bicondylar contact only when an external moment is applied.

It is hypothesised that the remaining imbalance is a contributory factor to the failure the tibial component of total knee arthroplasties. Seven such failed tibial components were examined under an electron microscope to establish the cause of failure. All of these failures seemed to be the result of the overloading of one of the compartments of the joint, figure (2.2). Furthermore the failure is always on the side of the preoperative deformity.



A) A "normal" knee.

B) An arthritic knee with hard tissue loss and contracted soft tissues

C) A replaced knee showing bicondylar contact only when an external moment is applied.

Figure 2.1. The development of soft tissue imbalance.

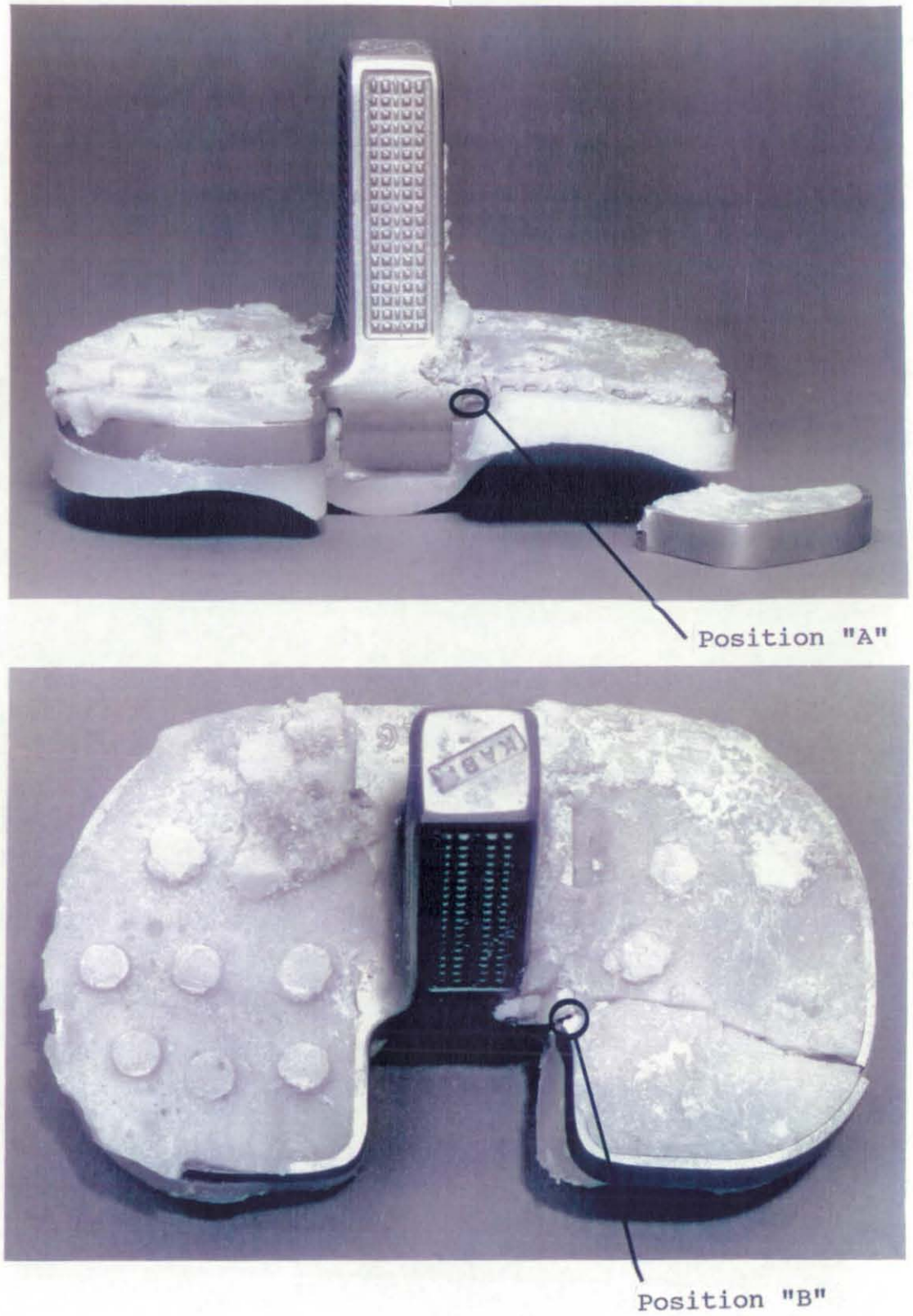


Figure 2.2. A typical failure of the examined arthroplasties.

The examination proved that the tibial tray failures observed in Derby were the result of fatigue failure. Figure 2.3 illustrates the typical fatigue rings radiating out from the posterior cruciate cut out of the component. Further evidence of the crack propagation direction was the observation of fibrous growth, growing along the crack from the posterior cut out, figure (2.4). The fatigue failure proves that the failures were due to a repeated cyclic loading and not due to a sudden load. The component manufacture companies have tried to prevent such failures by engineering the components to take greater loads. This however leads to the failure of the bone itself beneath the component, figure (2.5). The shift of the failure to the weakest point is not acceptable, and the forces of imbalance themselves need reducing.

The present surgical instruments available to quantify the soft tissue imbalance during a total knee replacement are numerous, but they all suffer from a number of theoretical and practical problems. The main problem was that they were designed around the assumption that the ligaments of the knee were inextendable strings and that the soft tissue structures should be distracted "maximally" before imbalance could be gauged. Such datum point is however ambiguous because a maximal tension could be described as rupture point of the soft tissues by one surgeon and low on the toe portion of the viscoelastic curve of the structures by another. The connection between surgery and soft tissue rheology was first made by McDaneil with his design of the Biomet tenser. He allowed for a known force to be exerted to both the collateral structures independently, before imbalance was assessed. His method was cumbersome to use practically and great care was required to ensure that equal forces were applied both medially and laterally, in an attempt to redefine the datum point.

Once any soft tissue imbalance has been quantified or has been assumed to be present, it can be elimininated by a series of soft tissue releasing procedures. Such intervention into the soft tissues has the effect of

Position "A"

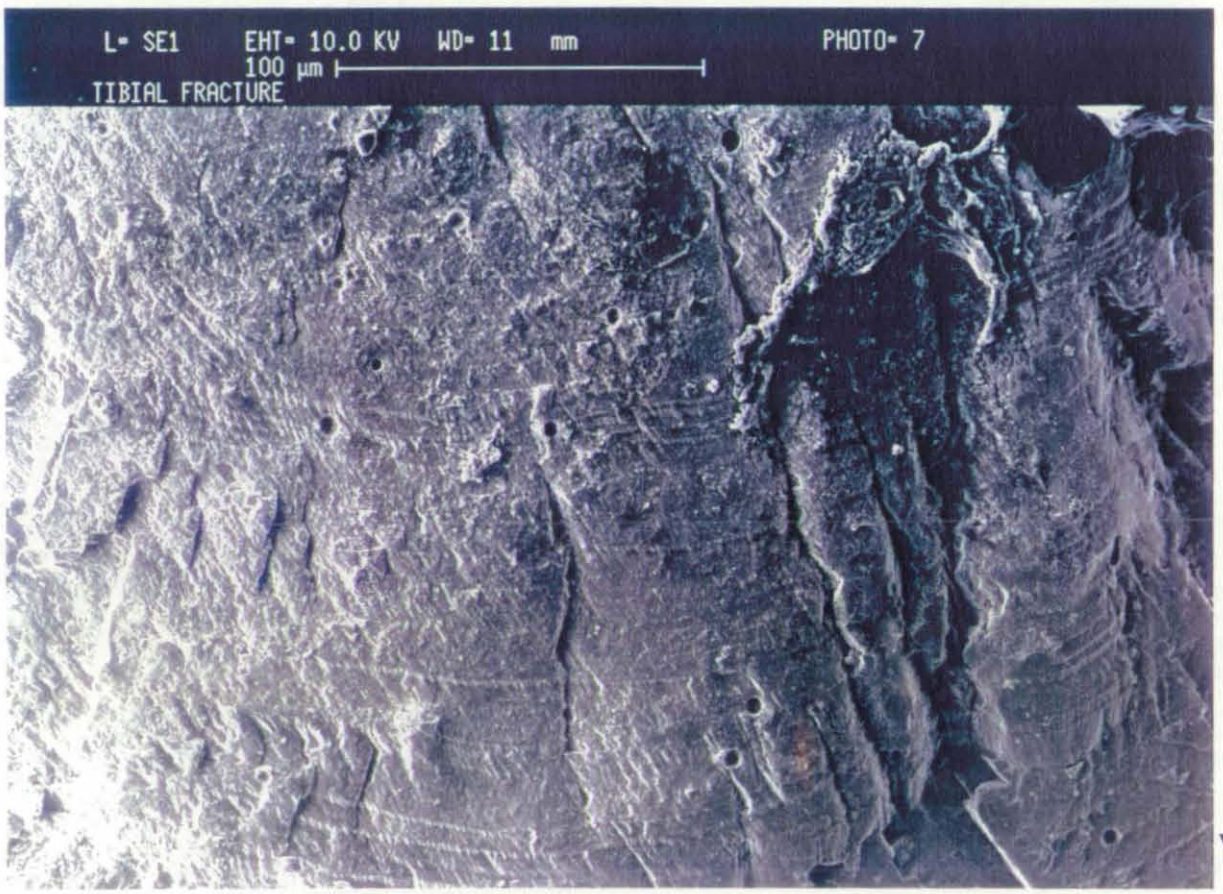


Figure 2.3. Fatigue rings visible close to the posterior cruciate cut out of the tibial component.

Position "B"

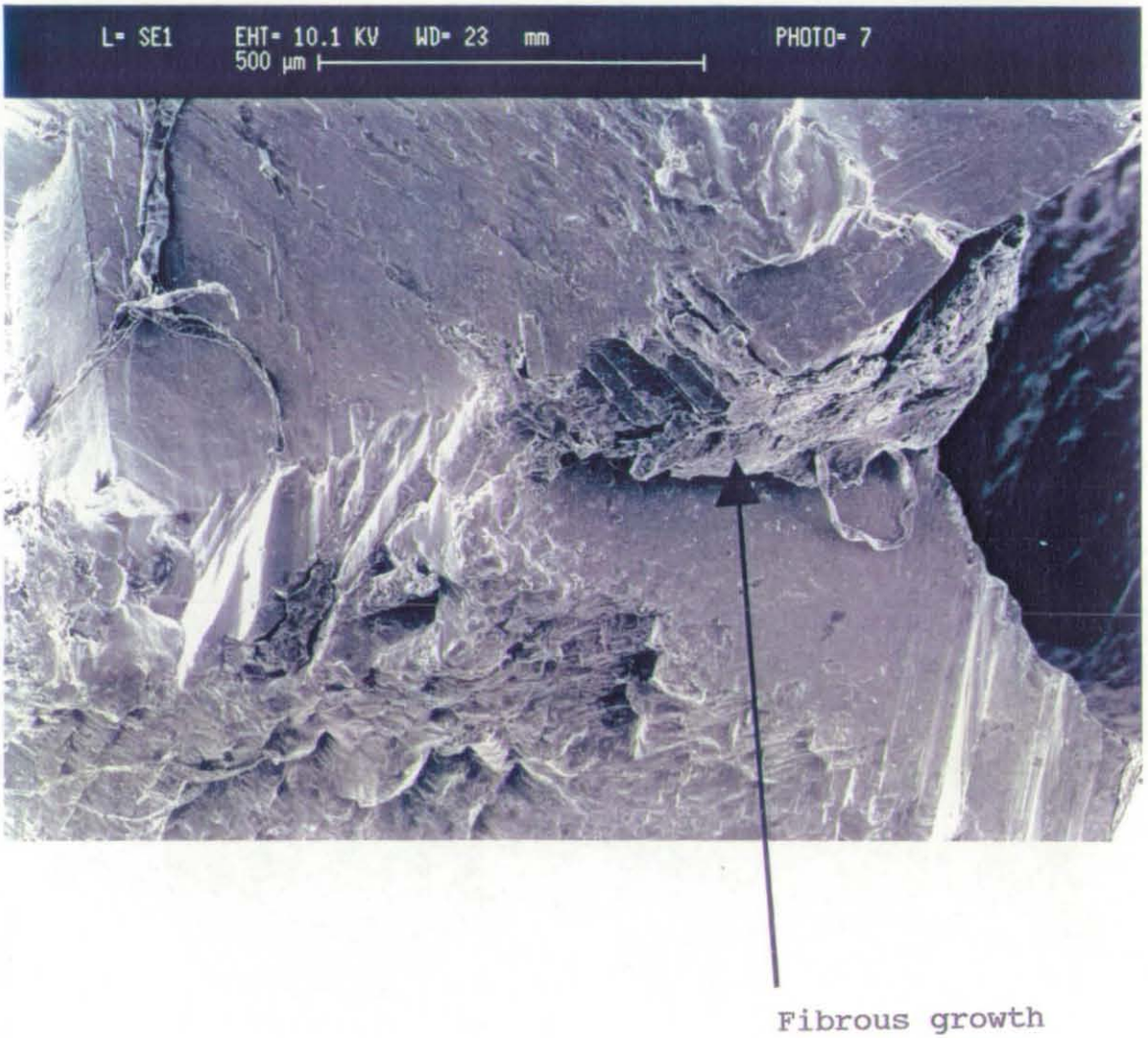


Figure 2.4. Fibrous growth along the direction of crack propagation.

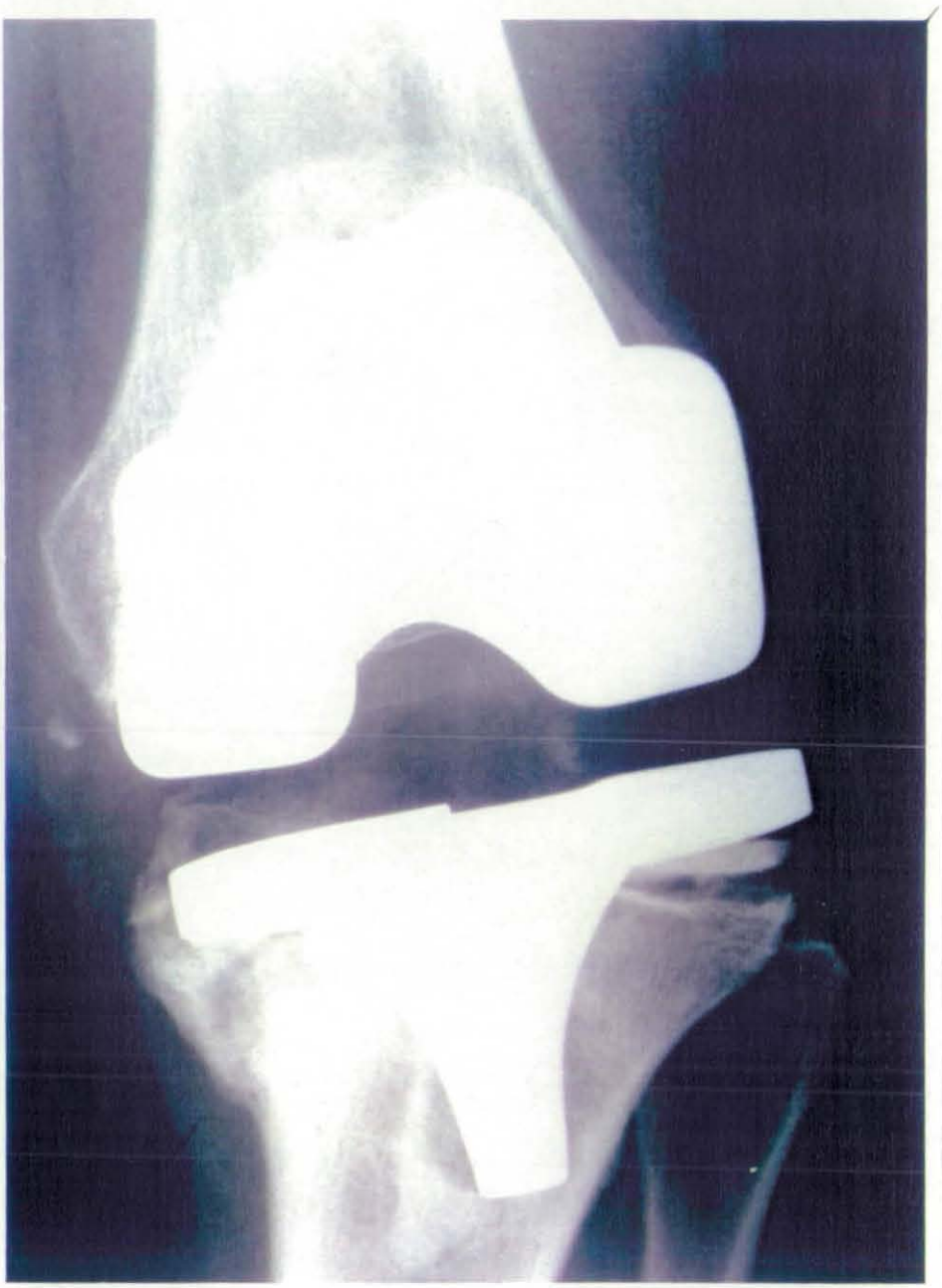


Figure 2.5. Failure of the bone beneath the tibial component when a thicker tibial tray is inserted.

lengthening the soft tissue structures whilst maintaining tension within the structures through inter-fibre and inter structure bonds, figure (2.6)

Any instrumentation to evaluate the soft tissue imbalance would have to be rheologically sound, with a known or homeostatic datum point. However, any direct measurement of forces in the theatre is practically difficult and time consuming and would not be tolerated at the time of operation by the surgeons. Any design would have to bridge this gap between a surgical tool and a rheological research instrument.

The above evaluation has therefore produced the following theoretical specifications.

1) The instrumentation must record measurements from a known or homeostatic reference datum.

2) The instrumentation must be able to record the passive imbalance at different extension gaps representing different tibial plate thickness.

3) The instrumentation must be able to relate the soft tissue imbalance to the bony hard tissue alignment.

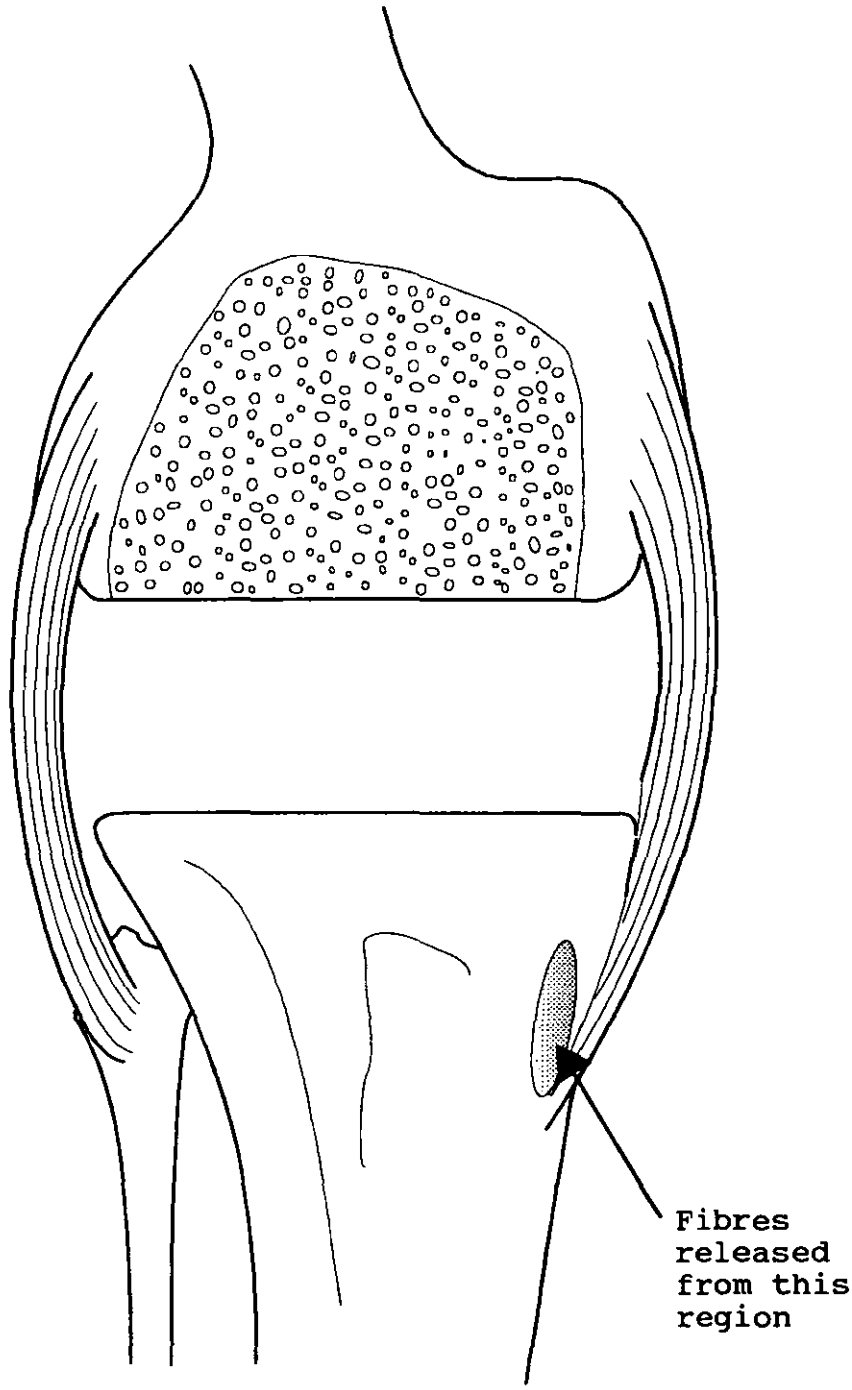


Figure 2.6. The retention of tension in the soft tissues after the surgical releases have been performed.

2.2 Conceptual Design

The complex system of soft tissues around the knee can be simplified, figure (2.7). Two standard linear viscoelastic models have replaced the medial and lateral structures. All of the anterior and posterior structures have been omitted as only the medial or lateral components of these structures are of concern in the coronal plane. Values for these springs, dashpots and free lengths are not estimated because they would differ greatly due to the extent of soft tissue contracture and the age and state of health of the patient. The model is only two dimensional, as this study is only concerned with changes in the varus/valgus directions. Therefore each of the collateral rheological models is intended to represent the resultant reactions of all of the soft tissues in the medial or lateral half of the knee. Therefore, any inter-structure rheological effects can be assumed to be equal and opposite.

Soft tissue imbalance has been defined in both extension and 90° of flexion as the geometry of the resultant trapezoid. This definition has, however, been recently modified as the resultant trapezoidal geometry, after the bony cuts have been made, and when the knee is tensed by equal forces both medially and laterally (Sambatakakis et al 1993). This reformulation was required because of the acknowledgement that the ligaments of the knee do not represent inextensible strings, but viscoelastic, extendable structures. Quantification of imbalance can be achieved in two ways, i.e. either as the difference in height between the medial and lateral sides of the trapezoid or as the angular deviation between the femoral and tibial bony osteotomies. Soft tissue balance quantified in these terms should be quoted in conjunction with the angle of the femoral osteotomy to allow the absolute comparison between patients.

If a central pivot is introduced into the centre of the knee in the coronal plane the resultant clockwise and counterclockwise moments of the soft tissues will produce an angular deviation θ. It can be assumed that this angle

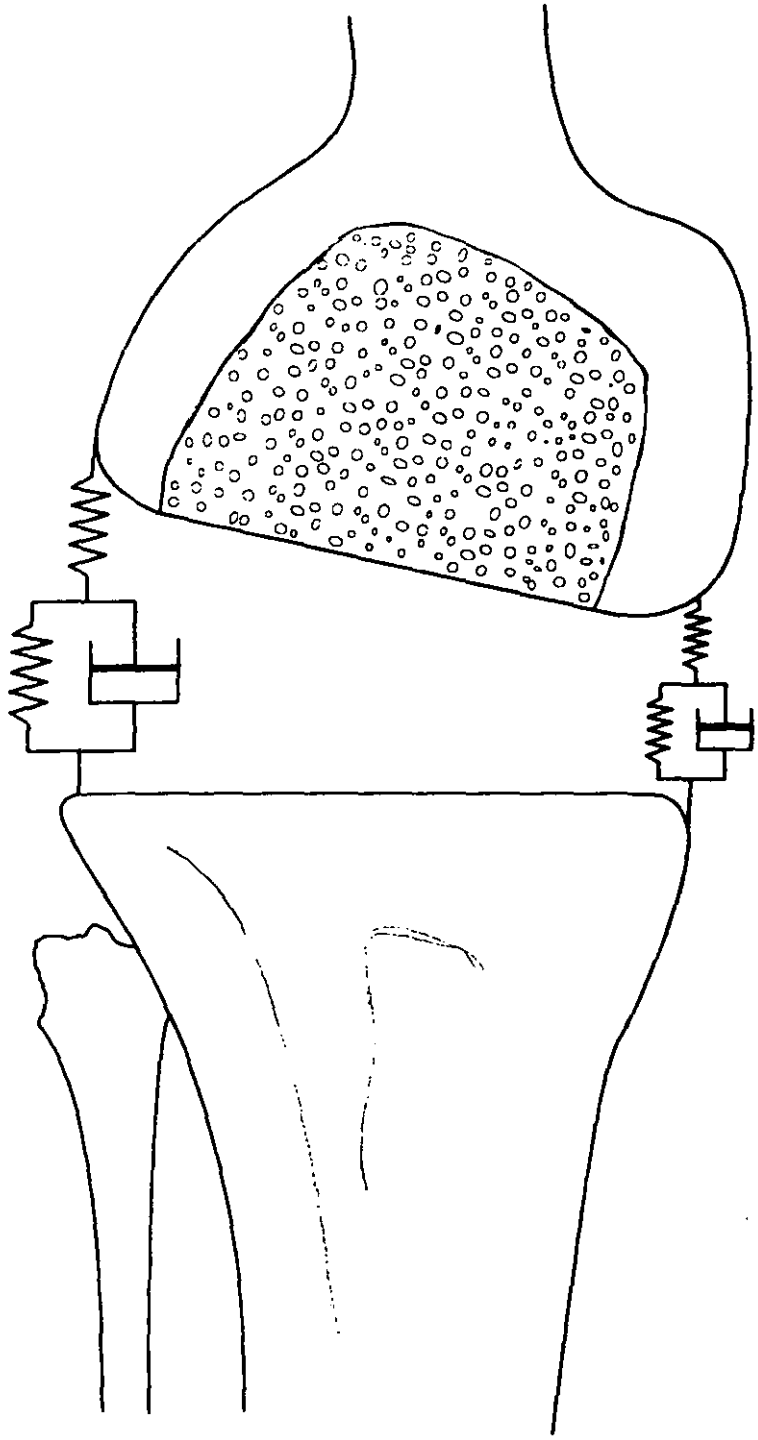


Figure 2.7. Simplified rheological model of the knee joint.

represents the position when equal forces are exerted onto both the medial and lateral structures of the knee as the pivot point is central and their moment arms are equal. The angular deviation θ can therefore be used as a unit of measurement for the quantification of soft tissue imbalance. This relationship assumes that the compressive forces acting through the medial and lateral compartments of the knee are always equal and opposite, figure (2.8).

Bone damage can occur when any instrumentation is being inserted into the knee. Observation in the theatre has shown that to avoid damaging cancellous bone on insertion, any device needs to be a maximum of 12mm thick. To protect the freshly cut cancellous bone during measurement, it is important to have the maximum possible surface area of the instrument in contact with the bone to keep the compressive stress acting on the bone down to a minimum. The elastic spacer (Sambatakakis et al 1993) proved that a plate covering the whole of the tibial or femoral plateau reduced any possible bone damage dramatically.

The conceptual design suggested in figure (2.8), will quantify the soft tissue imbalance as a function of the angular deviation from the parallel position. Assuming that the bony cuts have been made correctly with the intra and extra medullary jigs then any angular deviation is now due solely to soft tissue imbalance. Both are measured in degrees about the same reference axis so this conceptual design would only be as accurate as the initial tibial and femoral osteotomies. The resulting imbalance could therefore be as a result of both inaccurate bone cuts and true soft tissue contracture.

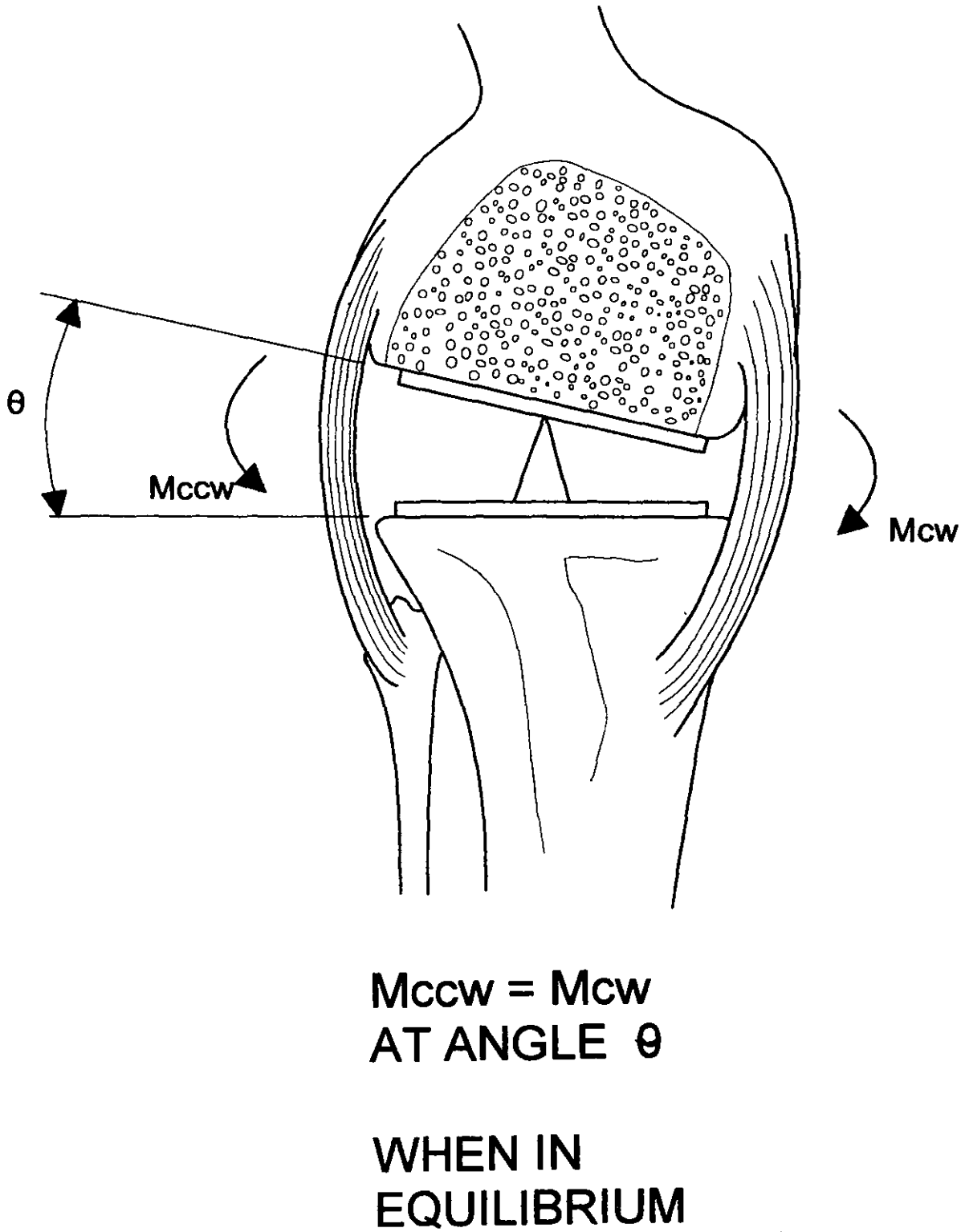


Figure 2.8. Conceptual design of the instrumentation.

2.2.1 Methods of obtaining required movement.

A number of methods of obtaining the conceptual plate movement were considered in the initial evaluation of the design possibilities.

2.2.1.1 Simple inserted pivot

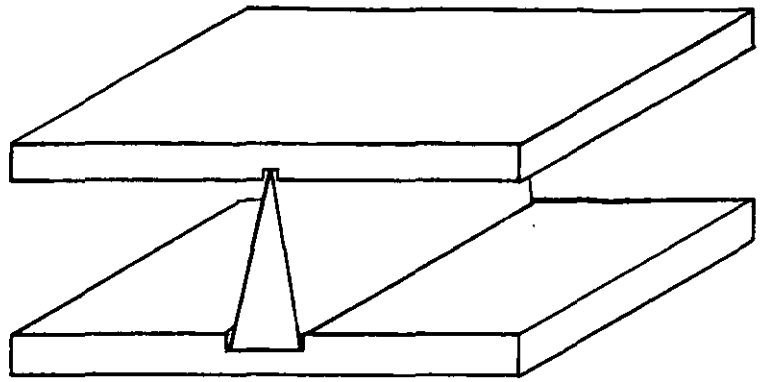
A number of triangular pivots representing different separation gaps could be inserted between the plates after insertion into the knee, figure (2.9a). This method is very simple but was rejected because it would be very cumbersome in the operating theatre and would be very unstable to shearing forces.

2.2.1.2 Internally expandable pivot

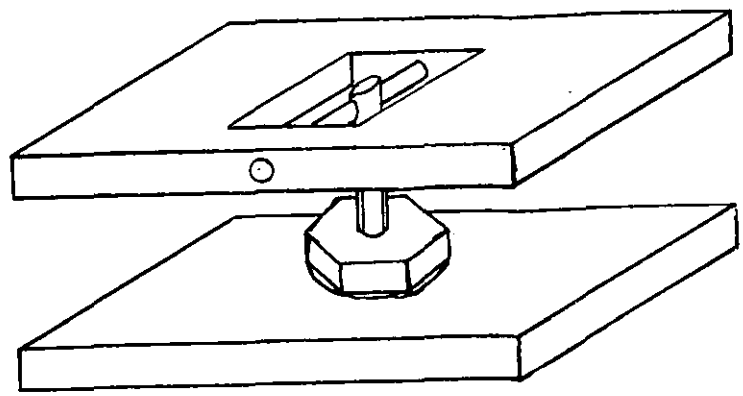
This method incorporates a bushed pivot at the end of an expandable central shaft, figure (2.9b). Once inserted into the knee the device would be expanded externally by a specially manufactured spanner. Stability of the instrument is much better than the previous example but the expanding central shaft would severely restrict the minimum solid height obtainable. Expanding and contracting the column by hand would be time consuming. Measurements would made by comparing the medial and lateral lengths with a standard vernier caliper.

2.2.1.3 External supporting column.

This method moves the tensing and supporting mechanism outside the knee to allow the plates to close fully, figure (2.9c). The top plate will pivot in relation to a central shaft inside the knee. The external tensing mechanism will allow for an ergonomically designed handle which will make the handling of the device much easier in the operating theatre.

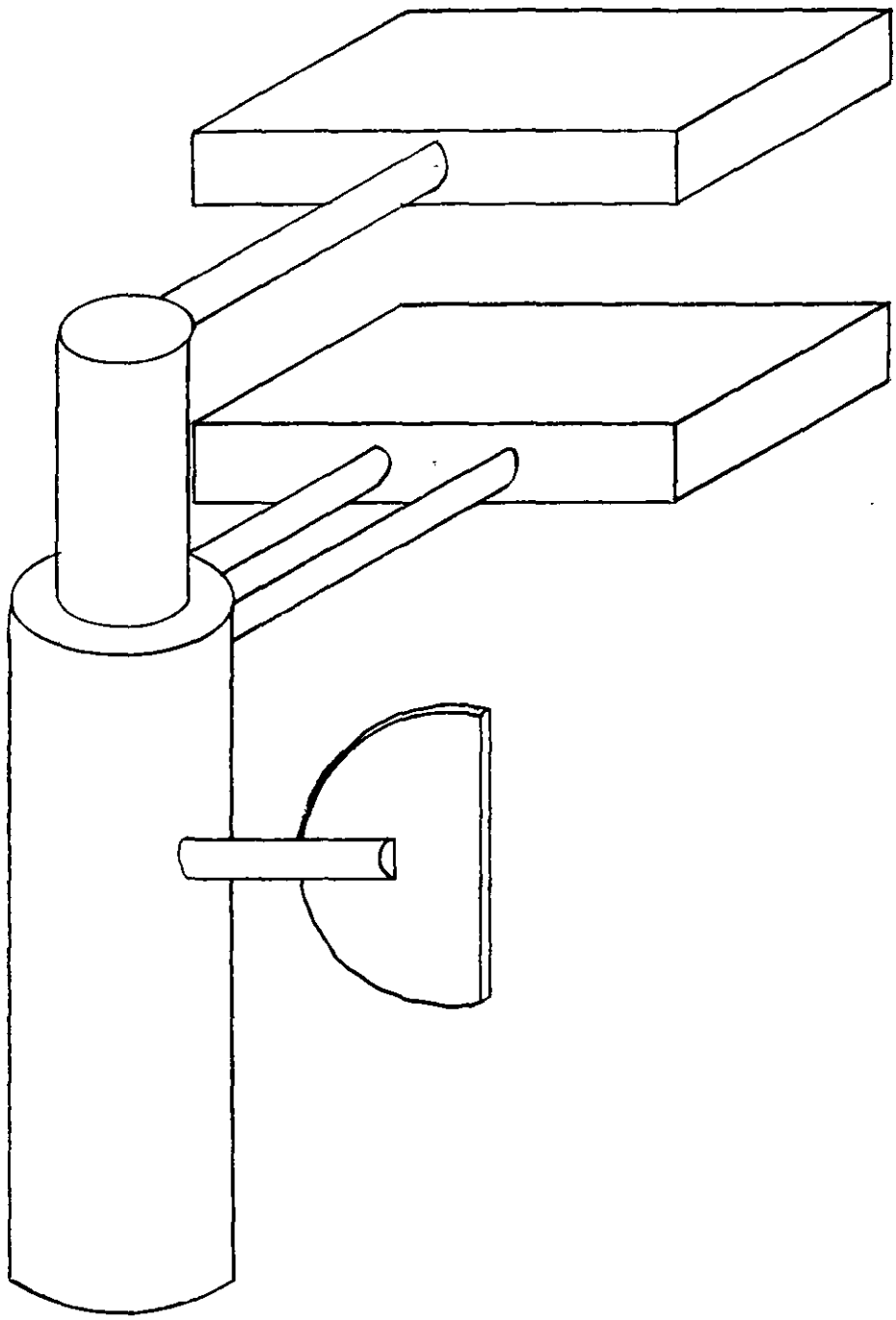


A) Simple triangular pivot.



B) Expandable pivot.

Figure 2.9. Conceptual design sketches.



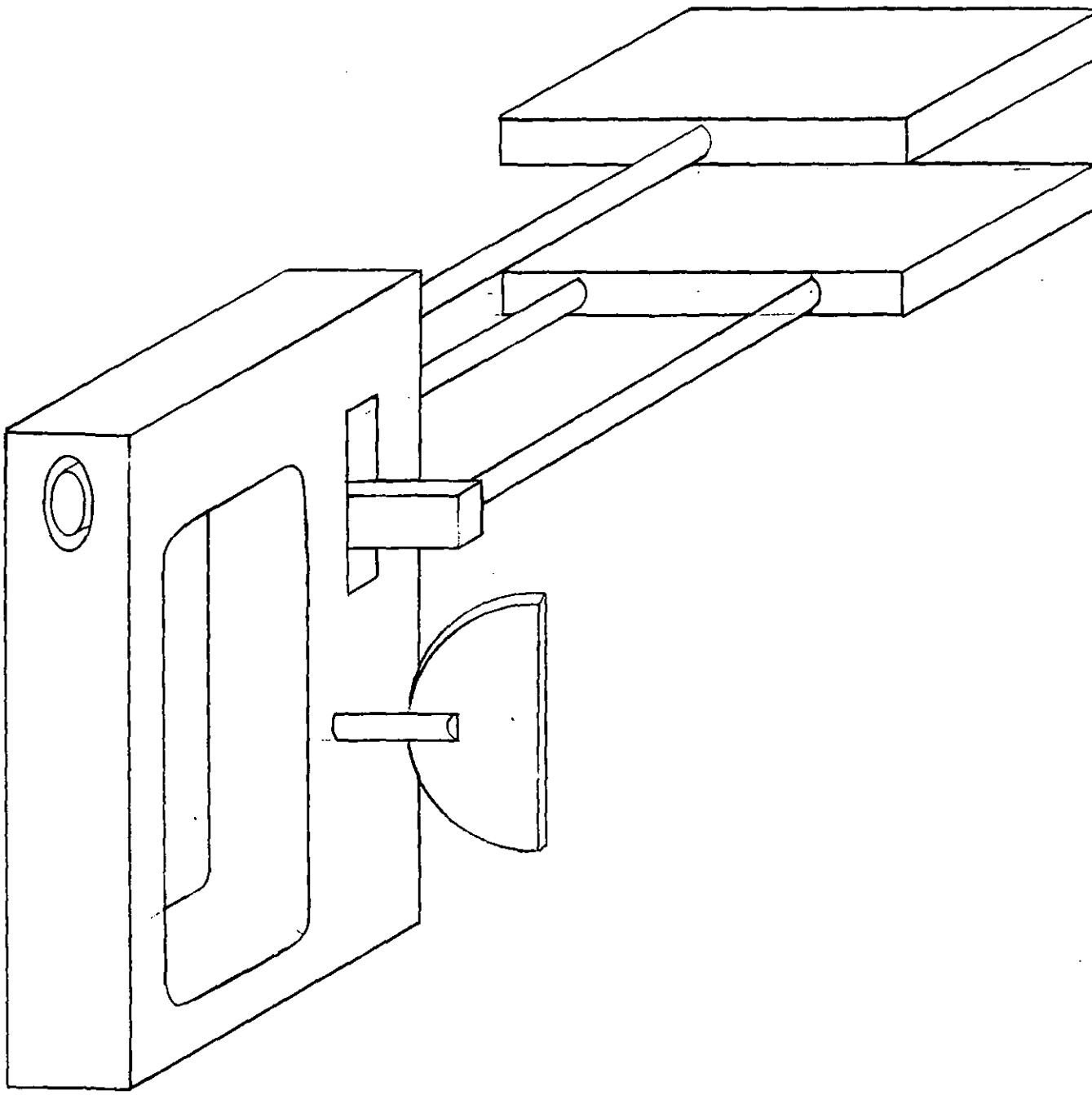
C) External supporting column

Figure 2.9. Conceptual design sketches.

This approach is an improvement on the previous methods. It does, however, create the problem of retaining the top plate in position whilst ensuring free movement in the varus or valgus directions. The introduction of small components in any such retaining assembly that would be inserted deep inside the knee should be avoided if possible. The angular deviation still requires calculating from measured lengths although it is possible to have an external scale to give the mean separation gap.

2.2.1.4 External pivot point

This method moves the pivot point to a position external to the knee, figure (2.9d). This allows all of the shaft retaining assemblies to be outside the knee and an angular measurement can be recorded directly with reference to the tensing assembly casing. Detailed design of the pivot assembly will allow close tolerance bushing which will increase stability further. Care will be needed to minimise any cantilever problems on the retaining bars.



D) External pivot point

Figure 2.9. Conceptual design sketches.

2.2.2 Conceptual design evaluation

The conceptual design discussed in section 2.2.1 clearly fulfills the design requirement of measuring the geometry of the resultant trapezoidal separation gap, at any mean separation gap whilst applying equal forces both medially and laterally. The design eliminates the need to physically measure and quantify the forces generated by the medial and lateral compartments of the knee by defining the centre of rotation of the knee and using the principle of moments about that known centre. Once at a position of equilibrium the moments about the knee in both the counter and clockwise directions are equal, so that the soft tissue imbalance can be quantified in terms of the angular displacement. Other factors such as the viscoelastic characteristics of the soft tissues could alter the soft tissue imbalance of a knee at different separation gaps. Past workers have not considered the possibility that imbalance could be dependant on the separation, or the thickness of component inserted at operation, figure (2.10). This assumption requires verification.

The size of the plates will dictate the magnitude of any possible errors in the location of the pivot point at the centre of the knee. Statistical data on the size of the tibia and femur from previous work will be used for these dimensions.

The accuracy with which the geometry of the separation gap should be measured, should be of the order of 1.25mm difference in the medial and lateral distances. This distance will produce an elongation of approximately .3 mm of the tight structures on the insertion of the prosthesis and pivoting about the condyle on the tight side of the knee. This will represent a force of approximately 15 N in the linear portion of published load / elongation curves, (Erkman & Walker 1974). A

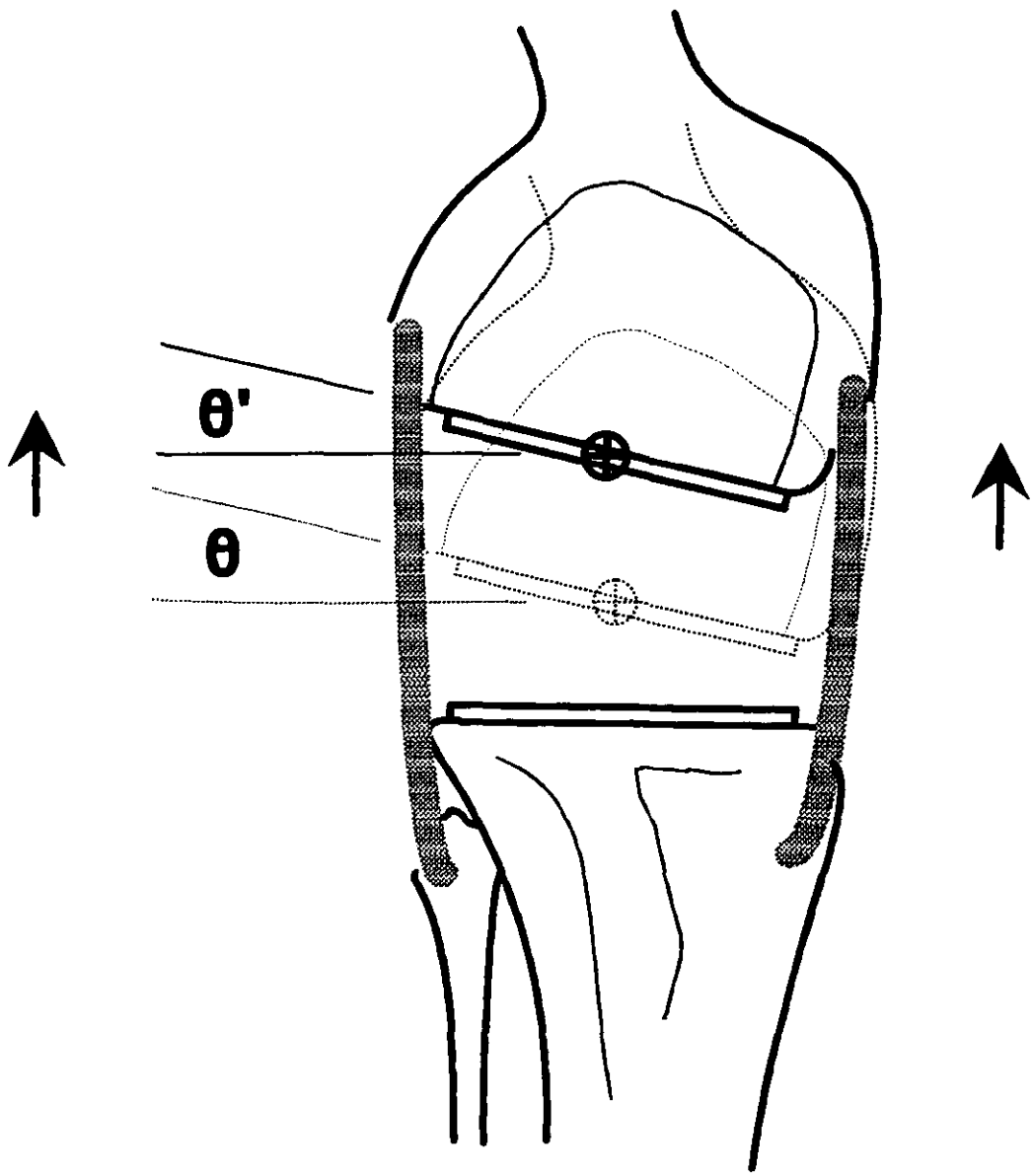


Figure 2.10. The assumption that the angular deviation remains constant during the tensing of the knee.

simple rotary engraved scale with divisions of one degree will therefore have a resolution that represents approximately 15 N of imbalance.

However, in order to investigate the assumption that the soft tissue imbalance will not change significantly at differing separation gaps a much greater accuracy would be required. This accuracy and the means to record the change in the angular deviation can only be achieved using electronic transducers. Such a system would allow data to be continuously down loaded into a portable computer in the operating theatre. The detailed design of this instrumentation will then be split into two sections.

1) An instrument using mechanical scales for the rotary deflection and separation gap to an accuracy of one degree and one millimetre respectively. This instrument will be used initially to research the extent of true soft tissue imbalance. It is also hoped to indicate the extent that individual structures play in the phenomenon.

2) An instrument using electronic transducers to measure the rotary deflection and separation gap to an accuracy of 0.1 degree and 0.25mm respectively. This instrument will be used to investigate the assumption that soft tissue imbalance does not differ significantly at different separation gaps. It is very unlikely that the angular deviation will be constant through the range of separation gaps and so an error band would have to be found to validate the definition of soft tissue imbalance. Such instrumentation will also allow for the rheological analysis of the complete soft tissue system around the knee.

Both instruments should be essentially the same with as many common components as possible. However, the body of the second instrument will be modified to allow for the installation of the electronic transducers.

2.2.3 Detailed Design specifications

The instrumentation should have the following detailed design specifications

1) The instrumentation should not damage any of the remaining cancellous bone.

2) The instrumentation should ensure that the medial and lateral structures are tensed with equal forces.

3) The instrumentation should relate the soft tissue imbalance to the bony alignment.

4) The instrumentation must be collapsible to allow easy entry into the closed trapezoid of the knee.

5) The instrumentation must have no loose components that will cause assembly problems in the theatre.

6) The instrumentation must produce a means of measurement that will not be hindered by the protracted soft tissues and patella.

7) The instrumentation must have a clear measurement indicator to avoid the need for vernier caliper measurements.

8) The instrumentation must be able to record measurements with out any human intervention.

9) The instrumentation must be able to record measurements in the minimum of time.

10) The instrumentation must be manufactured from standard surgical materials that will withstand standard sterilization techniques.

11) The instrumentation must not be too heavy.

12) The instrumentation must be able to accommodate both left and right handed surgeons.

13) The instrumentation must be able to withstand the harsh environment of the operating theatre.

14) The instrumentation must be able to be stripped down to it's component pieces to allow for extensive cleaning procedures.

2.3 MECHANICAL DETAILED DESIGN

The mechanical detailed design of the instrument will have both an external pivot and tensing mechanism as discussed in section 2.2.1.4. Although the mechanical instrument will be fitted with vernier type scales for the angular deviation and the separation gap, the instrument will be such that design changes will be kept to a minimum when the electronic transducers are fitted.

2.3.1 Material selection

The material used for the instrument should conform to a recognised standard for use within the operating theatre. Stainless steel to BS 5194 : Part 1 : 1985 : Stainless steel for surgical instruments. grade N table 1 was chosen for the instrument with the exception of the bearing material which will be discussed later.

2.3.2 Plate design

The surface of the plates that come into contact with the cancellous bone should be shaped to cover as much of the surface area as possible. The natural shape of both the tibia and femur are elliptical and so a rectangular plate with large corner radii would suffice. The plate dimensions can then be estimated from previous work which studied the average size of these plateaux. A posterior cut-out would also be required in case the posterior cruciate ligament were to be preserved.

The plate thickness, however, is one of the main design requirements of the instrumentation. The plates must be able to collapse to a minimium of 12mm whilst maintaining the required rigidity, and position to the retaining bars.

In order to allow such collapsibility and to have the retaining bars at the largest possible diameter it was necessary to cut away the plate thickness from the

plate/bar interfaces to allow the plates to mesh together. This can be clearly seen in the assembly drawing (B 1, appendix 1).

Drawing 1004 shows the top plate. The most important features are that the top and bottom surfaces are parallel so that when compressed with the bottom plate the two outermost surfaces are parallel. A geometrical tolerance of 0.02 has therefore been applied to these surfaces and a surface finish of N6. The plate will be attached to the top shaft by means of a taper pin. Although more expensive to produce than a threaded joint it was required because :-

1) Exact angular location is required because of the measurement of the angular deviation and the position of the top shaft locking pin.

2) To avoid any unwinding of threads if the attachment was by threaded means during the dynamic use of the instrument. Loctite adhesives would not be acceptable because of there toxic characteristics and the autoclaving temperature would weaken the bond strength.

The hole in the plate and mating section of the top shaft were dimensioned to H7 and g6 clearance fits to BS 4500A. The shear stress acting on the shaft at this interface can be calculated as

$$\text{Shear stress } \sigma = \frac{\text{Shearing force (F)}}{\text{x.sectional area (A)}}$$

The maximum shearing force acting will be the theoretical yield point of ligaments in aged humans and is estimated at 500 N from previous work.

$$\text{Therefore } \sigma = \frac{500}{3.142 \times (3 \times 10^{-3})^2}$$

$\approx 18 \times 10^6$ N/M^2

$\approx$ 18 MPa

Drawing 1005 shows the bottom plate. The design is very similar to the top plate except the two plate/shaft joints are threaded because there will be no rotary dynamic forces acting upon them.

Production of the two plates would be best achieved on a C.N.C. vertical miller out of 50x10 mm stock bar, prior to the drilling, reaming and tapping of the holes and the grinding.

2.3.4 Bar design

The function of the bars is to support the plates of the design within the knee and to restrict the degrees of freedom of the plates. The top shaft will be subjected to a cantilevered bending moment along its unsupported length. The maximum deforming force will again be the theoretical rupture point of the ligaments around the knee.

2.3.4.1 Cantilever calculations

The unsupported length of the top shaft is 50mm and the diameter of the shaft is 9mm. The maximum point load at 50mm will be 500 N.

Max.deflection $\delta = \frac{Fl^3}{3EI}$ ref pg 82 Stephens

Second moment of Inertia $I_{XX} = \frac{\pi d^4}{32}$

$= 644 \times 10^{-12}$ M^4

$$\delta = \frac{500 \times 0.05^3}{3 \times 210 \times 10^9 \times 644 \times 10^{-12}}$$

$\approx 1.5 \times 10^{-4}$ M

$\approx$ 0.15 mm

2.3.4.2 Shafts 1002&3

Drawing 1002 shows the top shaft. The ϕ15mm section of the shaft fulfills the following functions.

1) It acts as a retaining stop during the assembly of the device.

2) It provides a large bearing surface for the seating of the rotary scale 1015.

3) It provides additional material to allow for the female M5 thread which retains the rotary scale.

Three holes are also situated along the length of the shaft. The ϕ4.05/3.95 hole is for pin 1027 which retains the top shaft and plate in a parallel position with reference to the bottom plate. The ϕ3.35/3.25 hole is for the retaining collar 1012 and pin 1013 and the ϕ2.05/1.95 hole is for taper reaming at a later date to allow for the taper pin 1014. An N6 finish and tolerancing to f6 BS 4500A is required on the external diameter of the shaft where it is in contact with the bearings.

Drawing 1003 shows the bottom shaft. As the design incorporates two of these shafts and their diameters and cantilevered lengths are approximately equal to the top shaft, any shear or bending of the bars will be less than the top shaft. The component incorporates a male M6 thread for attaching to the bottom plate. Location on the arm is achieved by reducing the diameter of the shaft to ϕ7.95/7.85 and by the M5 female thread.

Manufacture of these two components would best be produced on a C.N.C. lathe out of ϕ15 & ϕ9mm stock bar respectively. The top shaft will then require grinding.

2.3.5 Tensing mechanism

The tensing mechanism of the bottom plate needs to be balanced between the ease of it's surgical use and a desire to protect the ligaments of the knee from overtensing leading to rupture. The mechanism should be such that the surgeon gets a clear indication of the separation tension through the instrument. This is to ensure that the surgeon cannot easily rupture the soft tissue structures without having an indication of the damage that could be caused. The maximum tibial plate thickness corresponds to a total separation gap of 32mm and so the instrument should not be capable of distracting further than this. If balance cannot be achieved at 32mm and the surgeon feels that stability of the joint cannot be guaranteed at this extreme then some ligament shortening techniques should be employed. The minimum height of the plates has already been fixed at 12mm so the total travel required for the instrument will be 20mm. This movement should also be achieved quickly. For instance the time taken for the surgeon to turn a key a number of times against the compressive forces of the knee,is too time consuming when the patient is under anesthetic. Therefore, a movement of half a turn (180°) should produce the required 20mm tensing displacement.

2.3.5.1 Gear calculations

A simple rack and pinion gear mechanism is required where the circumference of the pinion is approximately equal to twice the required movement i.e. 40mm, and the maximum gear tooth size that can be accommodated in the remaining material of the quill is 2 mm.

The gear calculation is as follows:-

$$\text{approximate dia. of pinion} = \frac{40}{\pi}$$

$$= 12.73 \text{ mm}$$

$$A + D \leq 2 \text{ mm}$$

Using a standard gear form, from BS 4582 (1970) part 1 figure 1, the following gear profile was chosen.

Module	0.8
Circular pitch	2.513
Addendum	0.8
Dedendum	1.12
Working depth	1.6
Whole depth	1.92

The number of teeth on the pinion can now be calculated.

$$\frac{12.73}{n} = 15.91$$

Therefore, 16 teeth are required on pinion with a pitch diameter of 12.8 mm.

With 16 teeth on the pinion a standard pressure angle of 20° is acceptable to ensure that undercutting of the gear profile doesn't occur.

The contact ratio between the rack and pinion can be calculated as follows.

$$\text{Contact ratio} = \frac{\text{arc of contact}}{\text{circular pitch}}, \text{ (Ryder \& Bennett 1975)}$$

arc of contact = angle turned through x pitch circle radius

$$= C \times 1/\cos\Phi$$

$$C = \frac{A + \sqrt{((\frac{1}{2}PD+A)^2-(\frac{1}{2}PD\cos\Phi)^2)} - \frac{1}{2}DA\sin\Phi}{\sin\Phi}$$

$$= \frac{0.8 + \sqrt{((\frac{1}{2}\times 13.6)^2-(\frac{1}{2}\times 0.94)^2)} - (\frac{1}{2} \times 12.03)}{\cos\Phi}$$

$= 3.1$

arc of contact$=3.1/\cos 20 = 3.3$

contact ratio$= \dfrac{3.3}{2.513} \approx 1.3$

This contact ratio is at the lower acceptable limit of gear design but this gear profile will be chosen in order to maintain the surface area of the gear teeth.

The maximum force transmitted from the quill to the pinion is again 500N.

The cross sectional area of each tooth of the rack A_X

$$A_X = 2 \times \sqrt{((\tfrac{1}{2}P.D+A)^2-(\tfrac{1}{2}P.D-D)^2)} \times C.P.$$

$$= 2 \times \sqrt{((\tfrac{1}{2}\times 12.8+0.8)^2-(\tfrac{1}{2}\times 12.8-1.12)^2)} \times 2.513$$
$$= 12.3 \text{ mm}^2$$

Therefore maximum shear stress $= \dfrac{500}{12.3\times10^{-6}} \approx 40$ MPa

<u>2.3.5.2 Central quill 1010</u>

Drawing 1010 shows the central quill of the device which will traverse up and down to give the required tensing action and will contain the rack of the gear mechanism. The quill also contains a key way which accommodates the locking key of the device. This feature has the following function.

1) To restrict any rotary motion of the quill within its bushes.

2) To restrict any longitudinal play between the two bushes.

3) To lock the quill at any given separation gap.

An N6 finish and tolerancing to f6 BS 4500A is required on the external diameter of the quill where it is in contact with the bearings. The central ϕ10.20/10.10 x 58.30mm bore is essentially a weight reducing feature in the mechanical balancer but will be used to house the L.V.D.T. (Linear voltage and displacement transducer) in the electro-mechanical balancer. These close tolerances have been maintained so that the quill will be a common part between the two devices. The ϕ9.987/9.702 f7 and the ϕ4.238/4.200 H8 holes are for location and attachment to the arm 1022.

Manufacture of this component will best be achieved on a C.N.C. lathe, the rack will be milled using a standard gear form cutter before the final ground surface finish.

2.3.6 Arm 1022

The function of the arm is to connect the quill to the two bottom shafts whilst allowing the shafts to be held such that the plates of the instrument will close fully. The shafts are retained with standard M5 pan head screws (1024). Location on the quill is maintained using a threaded pin 1021 so that the device can easily be disassembled.

Manufacture is again suited to C.N.C. vertical milling prior to drilling and tapping of the threaded pin hole.

2.3.7 Bushes 1006,8&9

These bushes are manufactured out of P.T.F.E. to BS 4480. P.T.F.E. is preferred over a sintered bronze bush because the lubricant with which metallic bearings are impregnated, will oxidise under the autoclaving temperature. Also P.T.F.E has excellent resistance to

corrosion, chemicals and is good in damp situations. Additional lubrication of the bearings is possible using light silicone oil.

2.3.8 Key assemblies

Both the locking key and pinion key assembies are positioned at an equal distance from the top shaft so that an external moment would not be applied to the device by the surgeon if he was holding the device by both keys when in use.

2.3.8.1 Pinion key assembly 1025

The pinion containing sixteen teeth is shown in drawing 1017. The external diameter of ϕ12.73 of this component is derived from the gear calculations and the M5 thread is to allow for fixing of the pinion into the main body assembly 1023 by a standard pan head screw 1024. Simple fluid film bearings were selected for the pinion in order to reduce the number of components and close tolerancing because positional stability of the pinion was not a high priority. Any slight backlash created within the gearing mechanism because of the bearing type can be tolerated. Production of the gears will be achieved by using a standard gear form cutter.

A flat key was chosen for the end of the pinion in favour of a knurled wheel because a wheel would tend to slip in the hands of a surgeon wearing surgical gloves in a bloody environment. The size of the key was determined by trial and error to ensure the correct level of feedback of the soft tissue tensions, (drawing 1018). Parts 1017 & 1018 are then welded together to form the pinion key assembly, 1025. It is cleaned using Metinox 71E paste.

2.3.8.2 Locking key assembly 1019

The locking key assembly is formed in a similar manner to the pinion key out of key 1018 and the locking screw 1016. The function of this assembly is to lock the tensing mechanism of the device at any given separation gap.

2.3.9 Body 1001

The main body is designed to support the two plate/shaft assemblies whilst maintaining their required degrees of freedom. It also provides a handle during use and reference points for the two linear scales.

The maximum number of this prototype body that is likely to be produced is five, so the most cost effective way of producing it would be to machine it out of a solid block. Volume production methods such as injection moulding with suitable alloys and/or plastics should be reserved for any further development work with a view to commercial exploitation.

The three main functions of the design are considered below:-

1) The ϕ12.018/12.000 bore (H7 transition BS 4500A) at the top of the component is designed to accommodate the P.T.F.E. bearings to support the top shaft assembly. The two recesses are to allow for the bushes to be flanged so that the retaining shoulder and collar of the top shaft assembly has got a bearing surface to run against.

2) The multiple diameter bore is designed to accommodate the tensing mechanism. The ϕ18.018/18.000 and ϕ20.281/20.260 sections of the bore are dimensioned to give a positive location to the two bushes. It is not possible to use a single bush here because of the production of burrs from drilling the cross holes

during production, which would foul the bushes upon use. The bore has a 7/8 inch -14 UNF thread to enable the bottom plug 1011 to be fitted to the device to protect the tensing mechanism from the bloody environment in the operating theatre. A metric thread would have been preferred here if the remaining material thickness would have permitted it. The flat bottom hole 120mm into the body is an undesirable manufacturing feature, but is unavoidable because if the hole broke through the top bore it would produce burrs that would foul the bushes on assembly. If the bore was reduced in length to incorporate a standard drill point the length, and hence the mass and amount of machining of the device would increase.

3) A 106 x 34mm section of the body has been cut away. This provides a convenient handle for the instrument whilst in use as well as reducing the mass of the device considerably.

Manufacture of the body is best achieved with a C.N.C vertical miller to remove material to produce the handle, the slot to situate the arm and the cross holes. The two bores will require drilling / reaming on a lathe.

2.3.10 Order of assembly

The instrument has been designed so that it can be periodically stripped down to its component parts for cleaning and sterilizing. The only exception to this is that the bushes should remain within the body. Assembly of the instrument is the exact opposite of the dismantling procedure.

1) Insert bushes 1006 (2 off),1008 & 9 into body 1001.

2) Screw the bottom shaft 1003 (2 off) into the bottom plate 1005.

3) Insert the arm 1022 through the slots in the body assembly 1023 fit the quill 1010. Insert the retaining pin 1021 through the arm and quill and torque to 4±.5 NM. Lubricate with silicone oil.

4) Insert the pinion key assembly 1025, and retain with screw 1024 and washer 1026. Torque to 4±.5 NM. Lubricate with silicone oil and ensure that the quill moves freely.

5) Insert the bottom shaft/plate assembly into the arm and retain with screw 1024 (2 off). Torque to 4±.5 NM.

6) Remove taper pin from the top plate assembly 1020 and insert shaft 1002 through the body assembly. Retain using collar 1012 and pin 1013. Lubricate using silicone oil. Replace the top plate 1004 and reinsert taper pin 1014.

7) Insert the locking screw 1019 and the bottom plug 1011.

8) Insure that the top shaft assembly rotates freely and that plates close to 12mm.

The assembled manual instrument is illustrated in figure (2.11).

2.3.11 Recommended operational procedure

Two P.T.F.E. sheets have also been added to the device to be placed under the patients leg during the balancing procedures. This is to lower the coefficient of friction between the leg and the operating table to avoid any underestimation of imbalance. The recommended operational procedure is as follows.

1) Close the plates and lock in position.

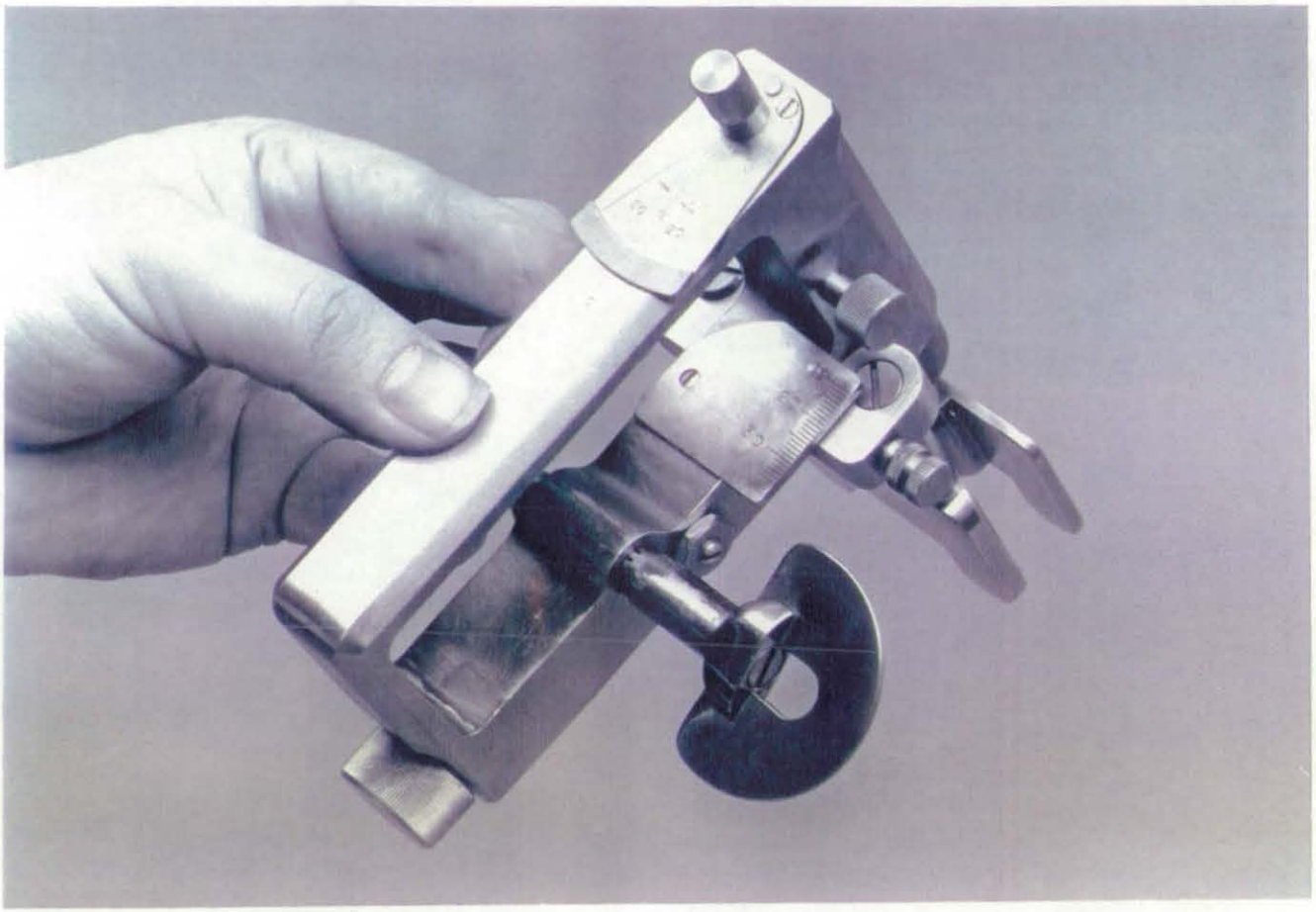


Figure 2.11.The manual balancer.

2) Insert into the knee.

3) Unlock and tense the knee to take up any ligamentous laxity.

4) Read any rotary deflection of the top plate to assess soft tissue imbalance. This can be repeated at 90° of flexion.

5) Unlock device, close the plates and remove from the knee.

6) Ligamentous balancing procedures are now performed if indicated.

7) Sequence (1-6) is repeated until balance is achieved in extension.

8) Soft tissue imbalance is then assessed at 90°of flexion.

9) The locking pin can be used to lock the top plate in a parallel position relative to the bottom plate, so that the device can be used as an adjustable spacer in a similar way to previous techniques.

2.3 ELECTRICAL DETAILED DESIGN

The Electronic Balancer is required to allow for real time data logging of the separation and angular deviation of the the remaining trapezoid gap of the knee after the bony cuts have been made. In order to do this two transducers were selected so that they could be incorporated into a second balancer with relatively few mechanical design changes. The new balancer will be connected to a conditioning unit to show the separation and rotary deflection data electronically and then to an analogue to digital converter for logging on a PC, figure (2.12). The instrument, along with its cable and connections, will have to be autoclaved. The conditioning unit and all subsequent instrumentation will be positioned beyond the sterile region of the operating theatre to avoid any possible contamination.

2.3.1 Transducer selection

The selection of the two transducers was challenging because they not only had to meet the functional requirements of the device but had to be able to withstand the autoclaving sterilization procedures and be acceptable for use in the operating theatre. The standard autoclaving technique is to heat the equipment to 134°C in a humid atmosphere. This will require the transducers to be both resistant to the temperature and the humidity.

2.3.2 Potentiometer

Functionally the potentiometer is required to give an indication of the rotary movement of the top plate between ±20°of the parallel position to an accuracy of 0.1 degree.

The potentiometer chosen was a 20k single turn screened conductive plastic element (RS 173-596). This type of transducer is designed as a position transducer for d.c. motor systems, with multifingered wipers providing a high degree of output smoothness with virtually infinite

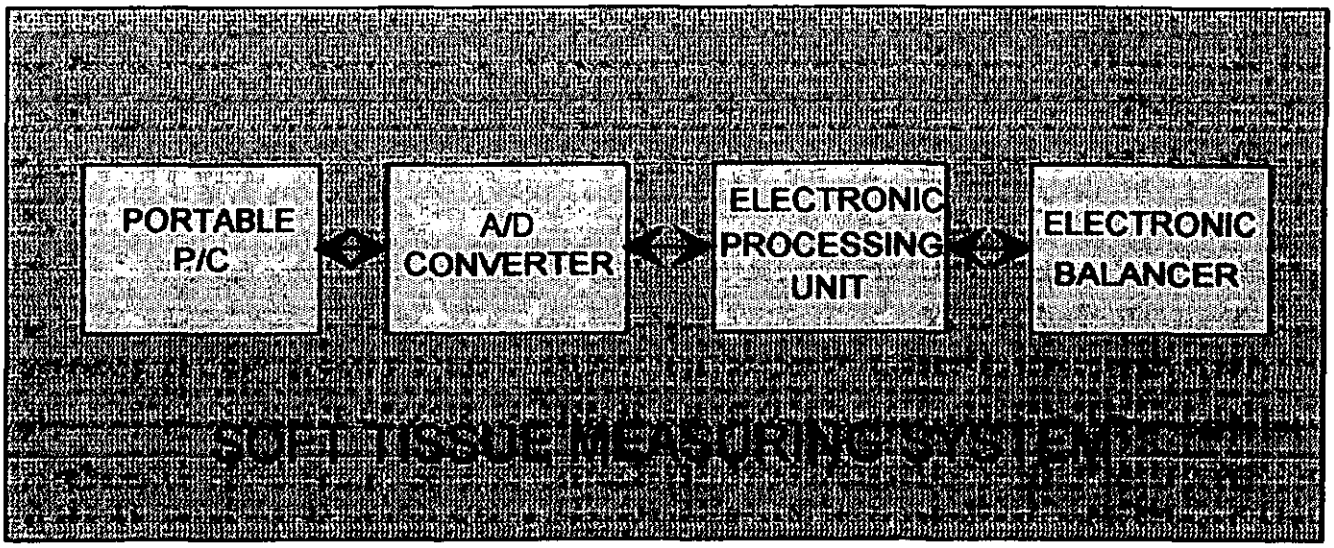


Figure 2.12. The basic structure of the soft tissue measuring system.

resolution. This device was chosen with as large as possible resistance to ensure that the change in the voltage at ±20° was at its maximum. The full technical specifications are listed below.

Linearity	±0.5%
Power rating	1W at 40°C
Electrical rotation	340°± 4°
Temp. range	-55°C to +150°C
Mechanical rotation	360° continuous

The potentiometer has a stainless steel shaft and an aluminium body which will be housed inside the instrument during use. The device was autoclaved fifty times prior to use to ensure that the electronic characteristics were not affected by the sterilizing procedure.

2.3.3 L.V.D.T.

The L.V.D.T. was required to give a measurement of the separation gap from the initial plate thickness of 12 mm to the maximum possible thickness of the total knee replacement prosthesis of 32mm. Following negotiations with RDP ELECTRONICS LTD, Wolverhampton, special transducer D5\400W\146 was selected. It has the following characteristics.

Length	85mm
diameter	10mm Dia
Working Stroke	±10mm
Linearity	±0.5% Full scale
Excitation	1 to 5 volts RMS 5Khz
Working temperature	-50°C to +150°C
Construction	body and actuator made from stainless steel.
Armature	Free and fully sealed.
Wires	All wires to withstand 150°C and all external sleeving to meet BS6893 part 2 1987. P.T.F.E. sleeving.

A signal conditioning unit S7AC was also purchased to provide a.c. excitation of the transducer and synchronous demodulation to a d.c. voltage which can then be calibrated before displaying and logging. This excitation unit needs a supply voltage of ±15v. Therefore a stabilised power unit of ±15v and 200mA per rail was chosen (RS 591-124) to power the conditioning unit.

2.3.4 Mechanical redesign

In order to incorporate the two chosen transducers into the mechanical balancer the body of the design was redesigned. Drawings 1029 & 1030 show two components that form the new body. Assembly will be exactly the same as the previous model. All of the dimensions and tolerances remain the same as the mechanical version to guarantee that all of the other components are completely interchangeable between the two devices. The potentiometer body has an interference fit in the handle to allow it to be held firmly in position and the body of the L.V.D.T. is held in position by flange positioned on the L.V.D.T between the bottom bush and the bottom plug. The armature is screwed into an M2 threaded insert which is positioned at the bottom of the ϕ 10.20\10.10 hole in the quill 1010. The redesigned unit can be seen in figure (2.13).

2.3.5 Electronic circuit design

The electronic circuit design requires the two analogue voltages from the L.V.D.T. excitation unit and the potentiometer to be offset and calibrated. The circuit should display the results digitally and supply an analogue voltage to allow for data logging. A standard instrument box was purchased and the L.V.D.T. demodulator, power supply, conditioning board and the L.C.D.S (Liquid crystal displays) were positioned within

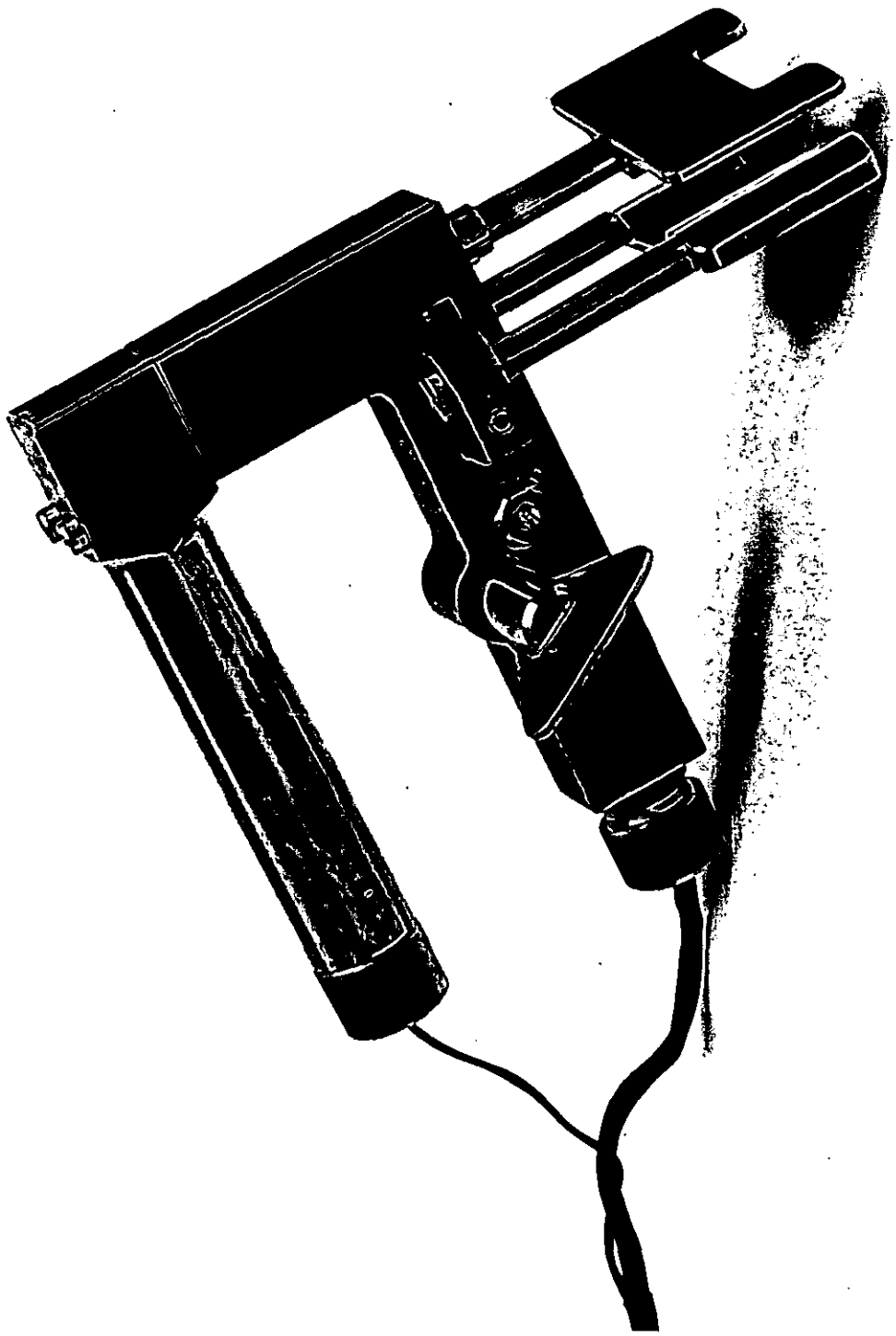


Figure 2.13. The Electronic Balancer.

it. The A\C power and transducer inputs, A\C fuse, on\off switch and the analogue output were added to the sides of the conditioning unit.

2.3.5.1 Deflection angle

The circuit design for the potentiometer for the rotary positional data is shown in figure (2.14). The circuit is made up of four separate electronic building blocks which process the analogue signals ready for input into the L.C.D.s. They are as follows.

1) A half Wheatstone bridge arrangement.

2) An amplifier of the input signal.

3) A fixed voltage divider for use with (4).

4) A summing amplifier for fine setting the L.C.D.

2.3.5.2 Half Wheatstone bridge arrangement.

The potentiometer in the device is duplicated with a similar device in the half wheatstone bridge arrangement. This will allow all other electronic and temperature dependant characteristics of the transducer in the instrument to be eliminated, (section A). Rotary movement of the top plate of the instrument will produce a detectable voltage drop at the mid-point of the Wheatstone bridge. The highest available resistance in the range of the chosen transducer, needs to be chosen, so that the maximum change of resistance per degree of rotation could be achieved. This will enable the gain of any further amplification to be kept down to a minimum, and reduce any possible instability and flickering of the L.C.D. displays.

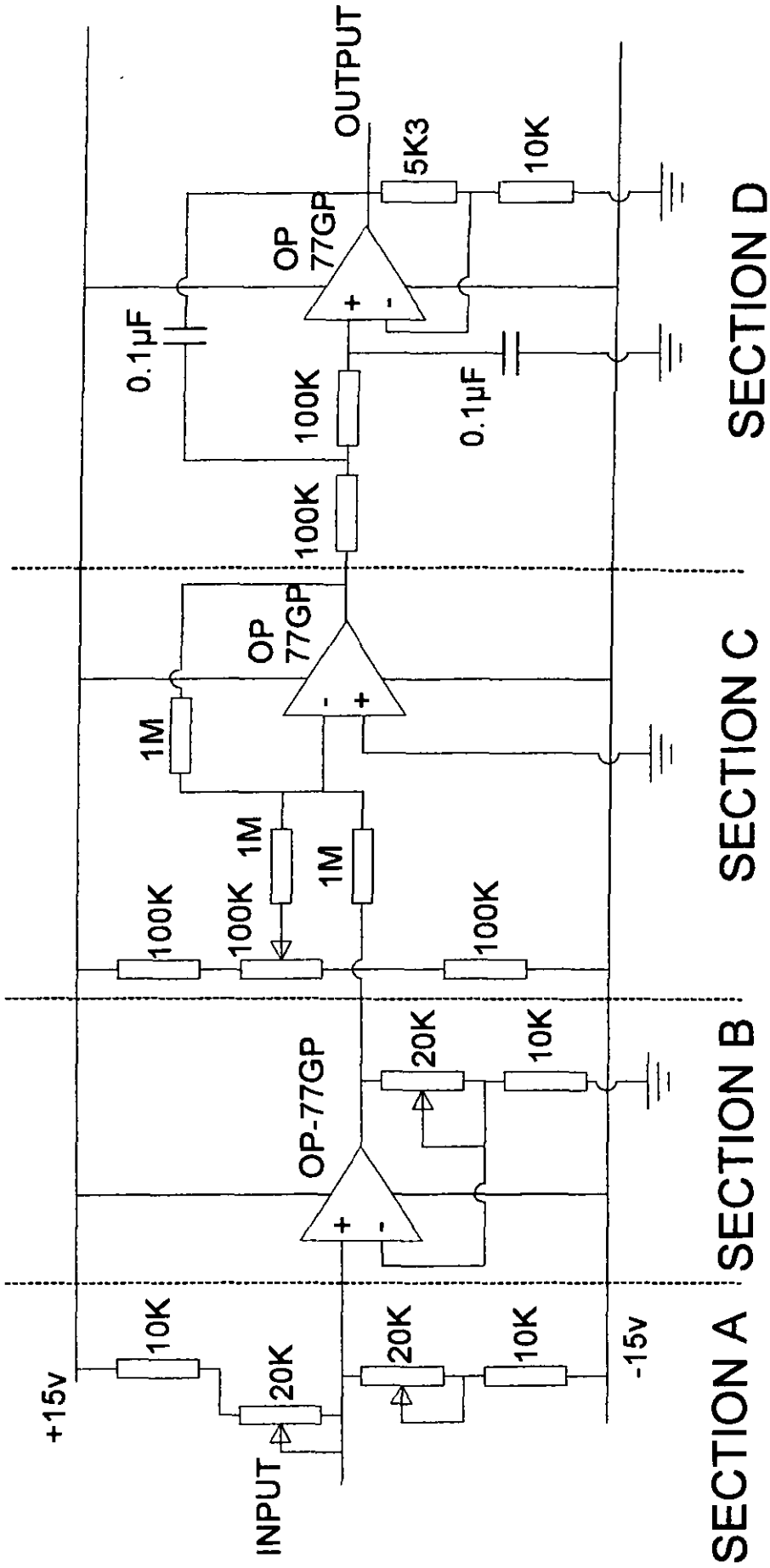


Figure 2.14. The circuit diagram for the deflection angle.

Rotation required ± 20°
Resistance of potentiometers. 20 kΩ over 340°

Therefore the resistance per degree will be

R=20000/340
=58.82 Ω

change in resistance at full scale deflection will be

=20 x 58.82
= 1176.4 ohms .....(1)

The power supply produces a standard ±15v, with 200mA of current.

Assuming that both of the potentiometers will be set at 10k then the total resistance across ±15v will be 20k.

Therefore total current flowing through potentiometers is

I=V\R
=30\20000
=1.5 mA

The L.V.D.T. demodulator requires 1.2 mA and so the draw of current by this section of the circuit will exceed the 2 mA supply so resistors need to be added to reduce the demand. The addition of such resistors will also protect the circuit against a current surge if the potentiometers are set to a low resistance during bench testing but will reduce the voltage drop across the transducer at full scale deflection. This will result in the greater amplification of the signal and any errors that it might contain. Two 10K resistors were placed in series with the

potentiometers to limit the maximum possible current through this route to 1.5 mA and to reduce the operational current to 0.75 mA.

It is now possible to calculate the change in voltage across the potentiometer at full scale deflection.

$$V=IR$$
$$=0.75x10^{-3}x1176.4$$
$$=.88 \text{ volts}$$

2.3.5.3 Amplification of the signal

This voltage now requires amplification to allow the calibration of the signal to represent angular displacement. This is achieved in section B of the circuit diagram using a standard operational amplifier configured as a non-inverting amp. The op-amp chosen (OP-77GP) has exceptional gain linearity suitable for high resolution instrumentation.

The open loop gain for A or the amplification of the amplifier can be written as

$$A= 1+R_f/R_i$$

The full scale voltage of .88 volts needs to be calibrated to read 20 degrees. The 0 to 2v input range of the L.C.D.s was selected in order to avoid electronic saturation of the op-amp. So this input needs to be amplified to somewhere in the region of 2 volts.

Required amplification $A= 2/0.88 = 2.27$

This amplification will be rounded up to 3 and a variable resistor used to allow for fine adjustment. If R_i is set at a standard 10K then the value of R_f can know be calculated.

$R_f = R_i(A-1)$

$=10000(3-1)$

$=20K\Omega$

Therefore a variable resistor of 20KΩ is required for the calibration.

2.3.5.4 Voltage Divider

This part of the circuit (section C) provides an adjustable constant voltage to section D where it is added to the calibrated input voltage. This will allow the full scale calibrated voltage to be adjustable as a fixed voltage band within the ±15v supply rails. This will enable the system to be adjusted to eliminate any electronic saturation problems and to set the zero position on the L.V.D.T.

The section was designed to allow for adjustment over the middle third of the ±15v voltage band with three equally valued resistors. The value of these resistors was chosen as 100KΩ to limit the current passing down this route.

2.3.5.5 Summing amplifier

Section D consists of an op-amp (op-77g) and three 1MΩ resistors configured in a standard summing amplifier arrangement. The output from this amplifier is fed directly to the L.C.D. and to the analogue output ready for the data logging.

2.3.6 Separation gap

A standard L.V.D.T demodulating unit was purchased for processing the separation gap signals and is located within the conditioning unit. Calibration of the output from the demodulating unit is then achieved using the electronic blocks B,C and D from figure (2.14). The

circuit is duplicated to allow for the display of the required plastic tibial insert required. The full circuit diagram is shown in figure (2.15).

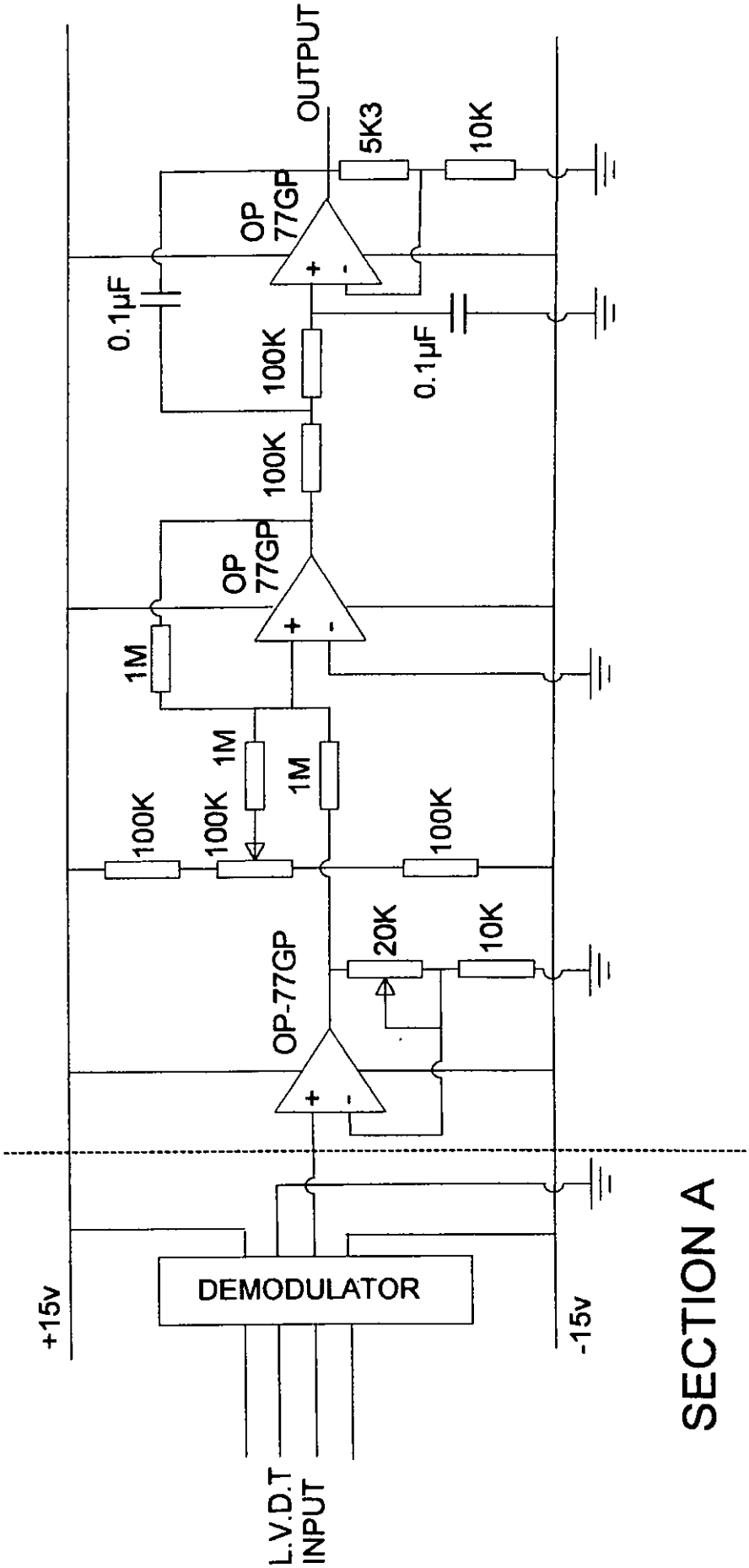


Figure 2.15. The circuit diagram for the separation gap.

2.4 SOFTWARE DEVELOPMENT

The software was required to input the data recorded in the operating theatre and store them for later analysis. The analogue signal from the processing unit is passed through the A/D converter (Amplicon PC26AT) into a digital form for data manipulation. Turbo Pascal programming language was used.

The main function of the software is to record values of imbalance at every 0.25 mm increment of the separation gap. This measurement is required after any of the anatomical structures of the knee have been released to gauge their effects on imbalance. After these readings have been recorded a graphical plot of the data are required immediately in the operating theatre, for the use of the surgeon during the operation. After the graphical plot the software should write the data to a data file so they can be analysed later at the laboratory. A real time screen is also required which will give other data such as the estimated tibial thickness required. It should also be possible to view an old data file.

2.4.1 Program Data

The flow chart for the program can be seen in figure (2.16a). The main section of the program sets the data array to zero and then calls upon a menu procedure to give a number of options. When a selection has been made then a further procedure would be called.

2.4.2 Procedure Menu

This procedure essentially formats and shows a text screen with the program options on it, figure (2.16b).

PROGRAM DATA

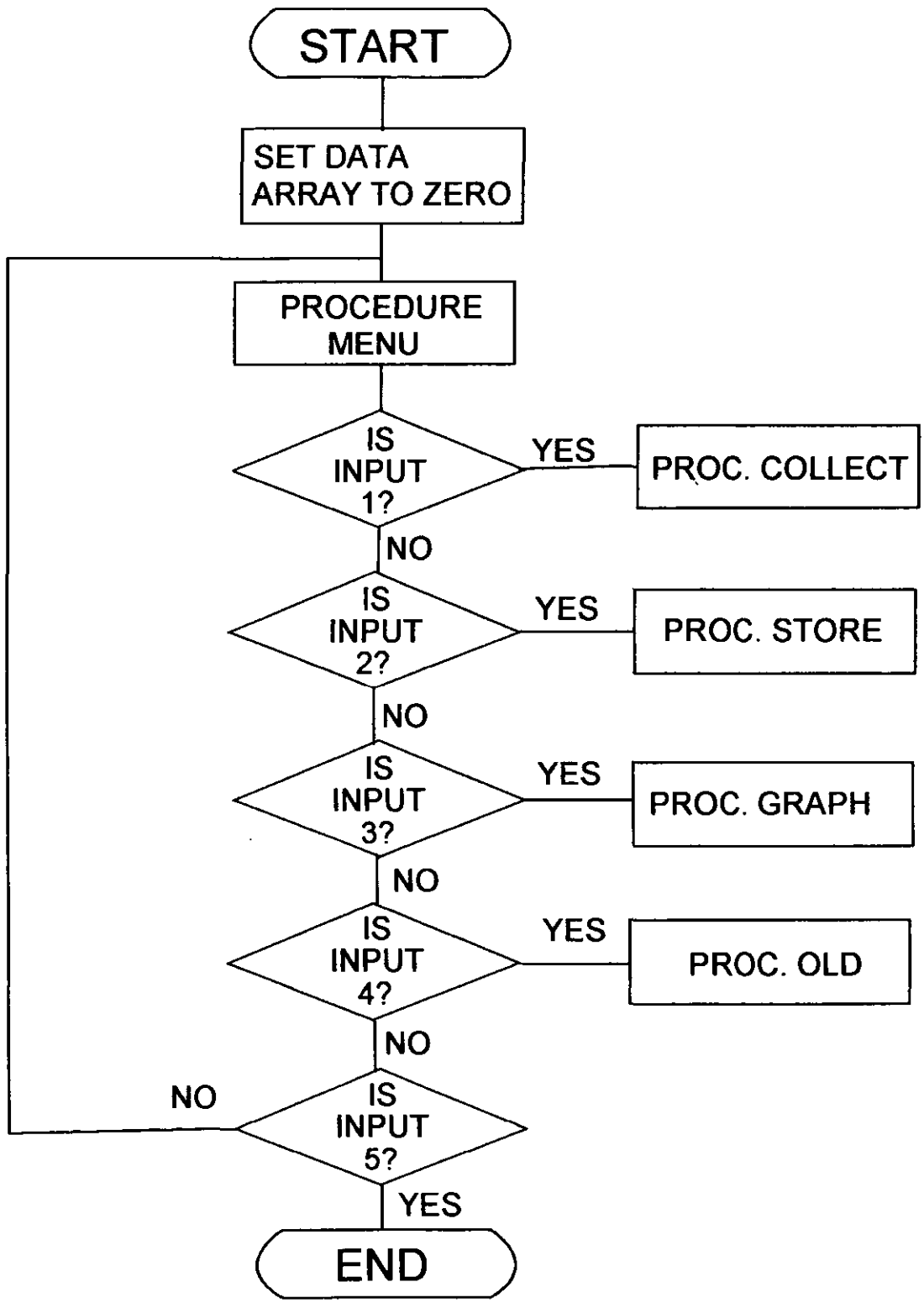


Figure 2.16a. Flow chart of program data.

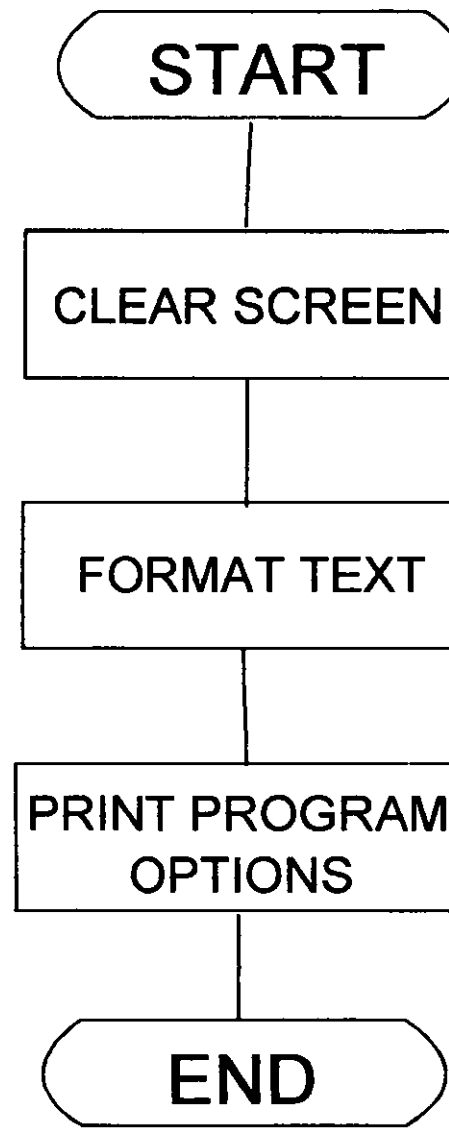


Figure 2.16b. Flow chart of procedure menu.

2.4.3 Procedure Collect

This procedure is responsible for collecting the data from the instrument and positioning the data within the the collection array. It also prompts the operator for a filename under which to store information and initialises the A/D card. Data for the imbalance are recorded at every 0.25mm increment of the separation gap. This format will allow easy transfer of the data into Harvard Graphics software package to allow for graphical analysis, figure (2.16c).

2.4.4 Procedure Store

This procedure creates a file under the filename given in the collect routine and stores the data to the specified drive, figure (2.16d).

2.4.5 Procedure Graph

This procedure produces a graphical plot of the data on the screen giving an indication of the imbalance and viscoelasticity of the soft tissues, figure (2.16e).

2.4.6 Procedure Old

This procedure reloads an old file back into the current data array so that it can be viewed using the graph procedure, figure (2.16f).

PROCEDURE COLLECT

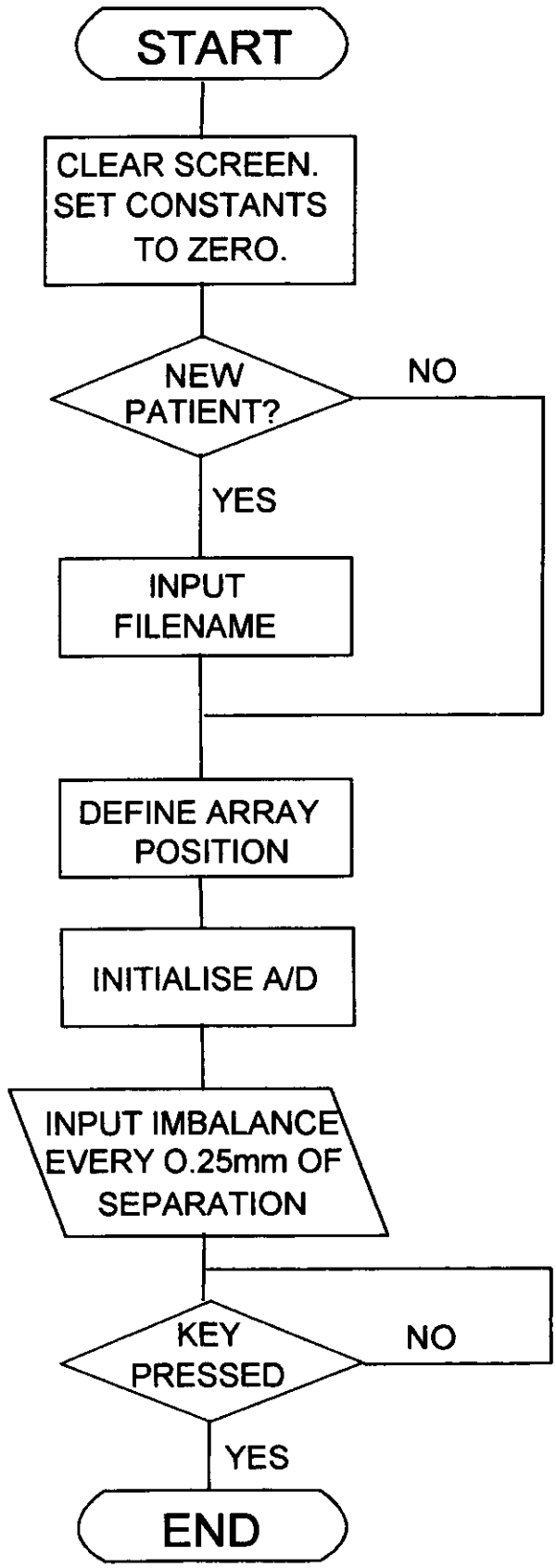


Figure 2.16c. Flow chart of procedure collect.

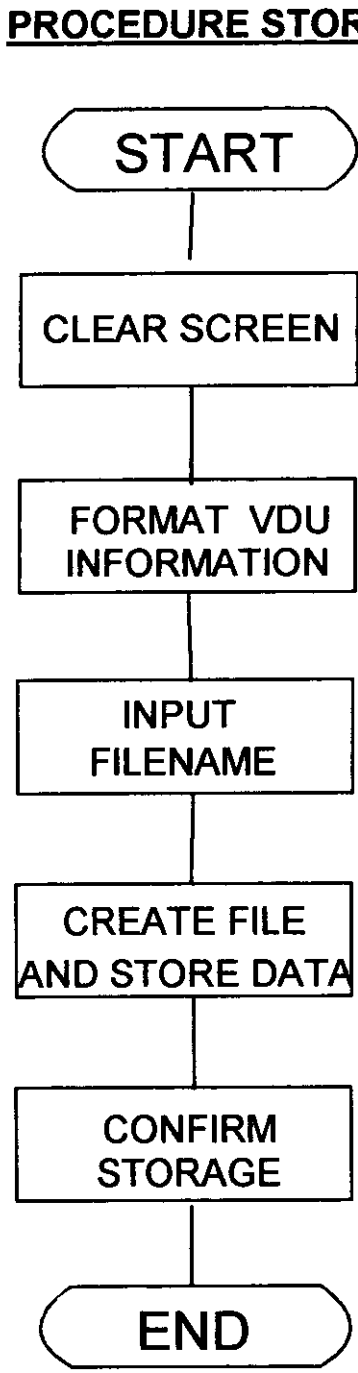


Figure 2.16d. Flow chart of procedure store.

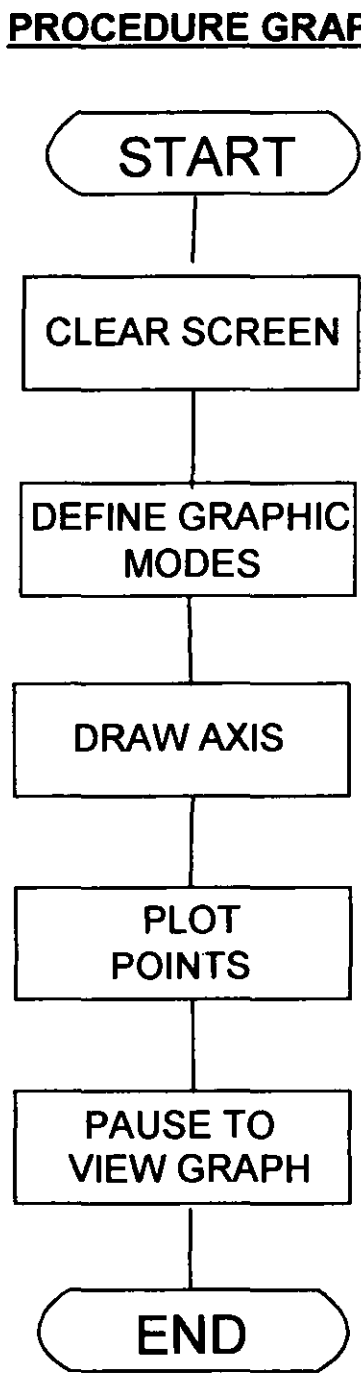


Figure 2.16e. Flow chart of procedure graph.

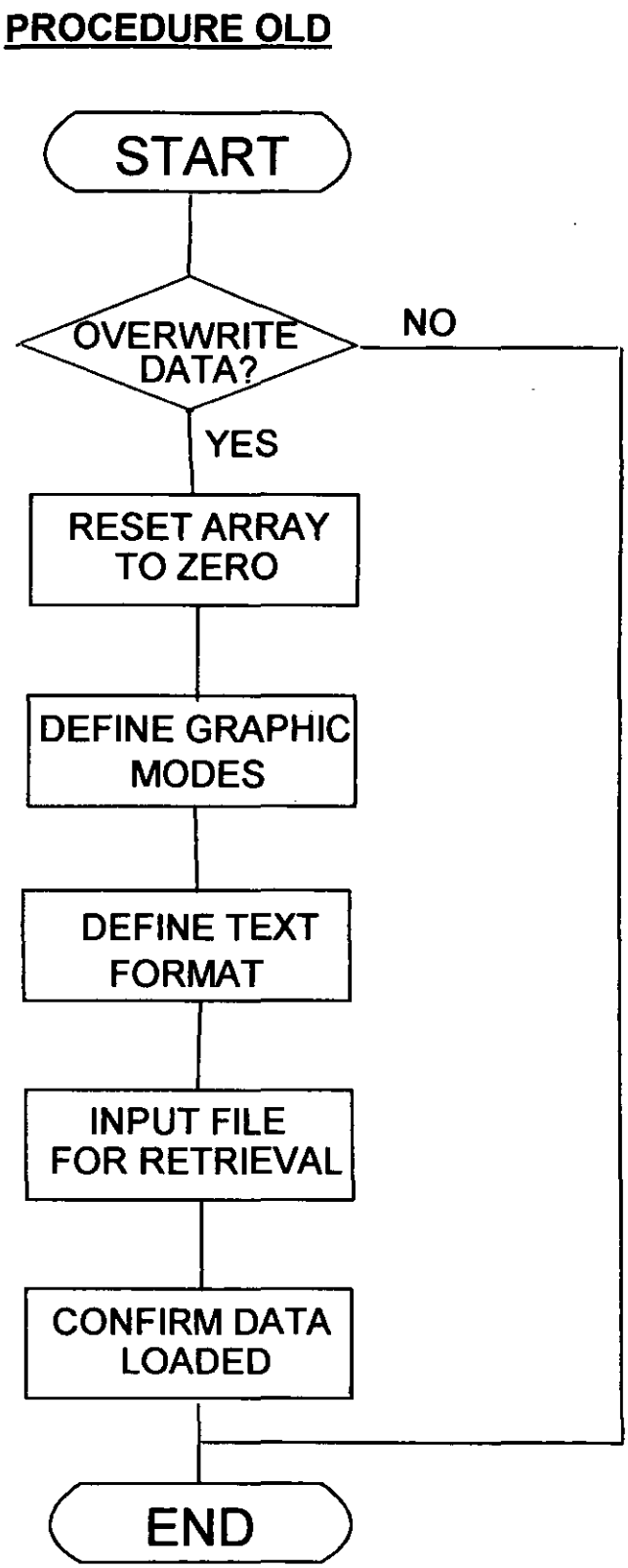


Figure 2.16f. Flow chart of procedure old.

2.5 CALIBRATION PROCEDURE

Before the new instrumentation could be used in theatre the electronics required testing and calibration.

2.5.1 Potentiometer testing and calibration

The potentiometer was tested by positioning angular slip gauges between the faces of the two plates before closing them. This will give the angular deviation of the internal surfaces of the plates but, as the plates surfaces were ground upon manufacture to within a geometrical parallel tolerance of 0.01, then the error in between the internal and value and external surfaces will be at least an order of magnitude lower than the resolution of the required readings.

A 15° degree angular slip gauge, figure (2.17), representing full scale deflection, was positioned between the plates and the calibration or amplifier gain potentiometer was adjusted to give a corresponding reading on the readouts (P.C. screen and the L.C.D.) The slip gauge was then removed and the zero position was checked. This was then adjusted using the zero offset potentiometer. This iterative sequence was then repeated until the readouts showed their correct values for both calibration and zero position.

The calibrated P.C. readout was then checked against the actual deviation at 5° steps from -20° to +20° degrees and then back to -20° using the manufactured slip gauges. The actual and system readings were then plotted against the recorded readings. This sequence was repeated five times so that the system repeatability and/or any hysteresis in the system could be assessed. A slight hysteresis curve was observed. The curve was directly proportional at all stages of the graph and there was

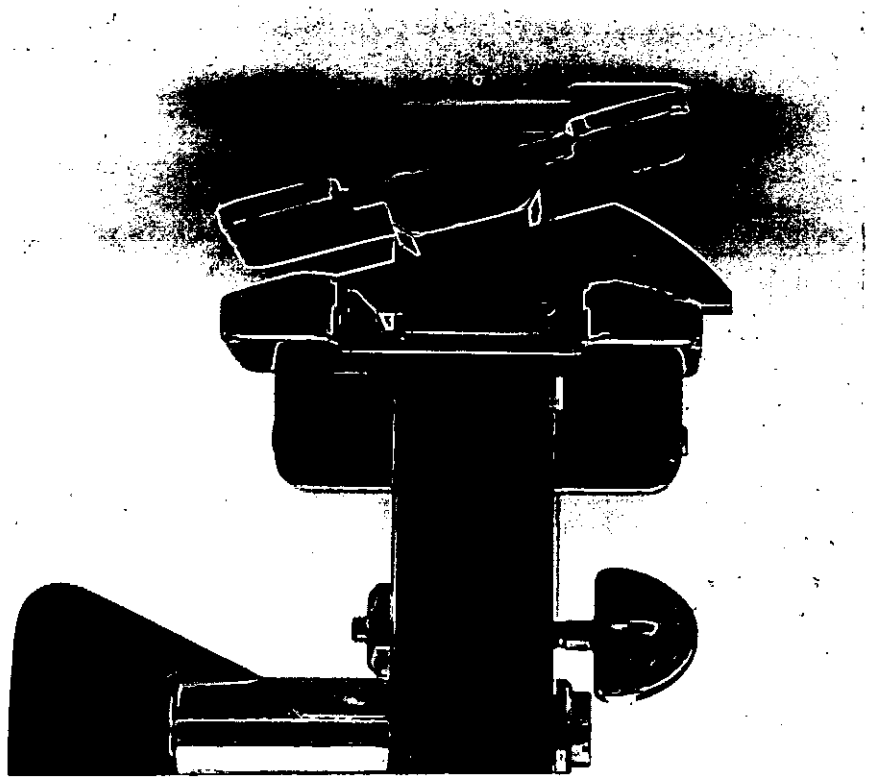


Figure 2.17. Calibration of the angular deviation.

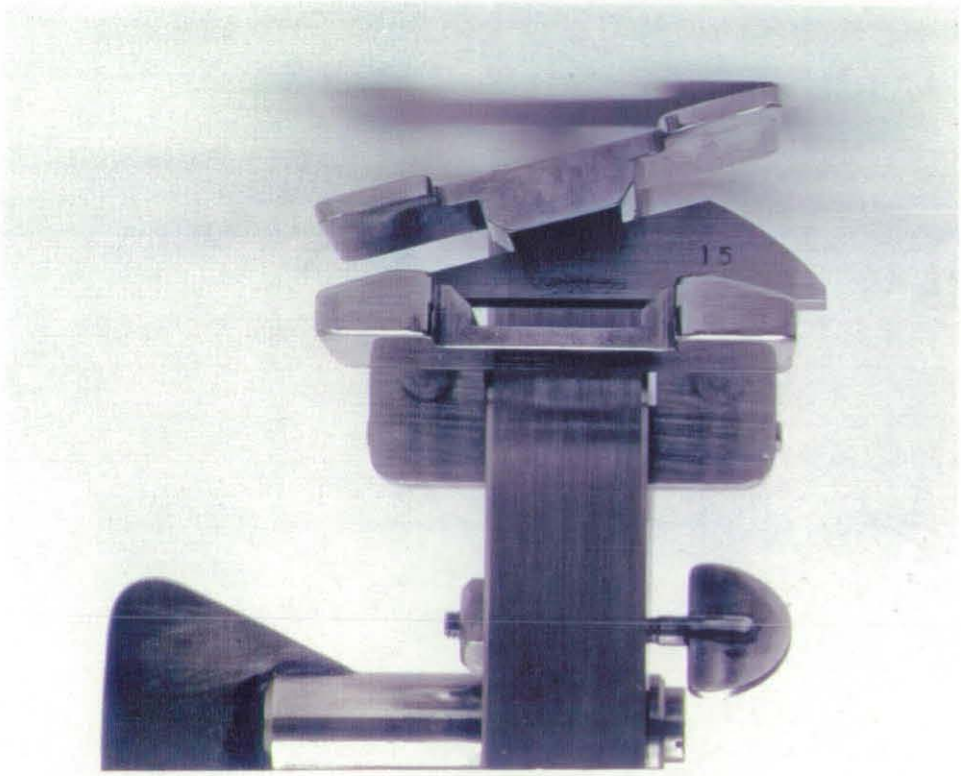


Figure 2.17. Calibration of the angular deviation.

no evidence of any tail off characteristic of operational amplifier saturation. It was concluded that the observed hysteresis was mechanical representing an error band of 0.01mm. Taper pins were used in the construction of the instrument to minimise this effect but the cumulative error of two joints plus the potentiometer have resulted in this error. The accuracy required from the instrument was 0.1° and so this error was considered acceptable.

2.5.2 L.V.D.T. testing and calibration

The L.V.D.T. was tested and calibrated in a similar way to the rotary potentiometer only parallel slip gauges were used. The range of the separation gap was from 12mm (the closed plate thickness) to 32mm, the full stroke of the L.V.D.T.

The testing produced a straight line when actual values were plotted against recorded values within an acuraccy of 0.001 mm.

The whole unit was also observed over a twelve hour period to ensure that the readings would not drift dramatically with time or with a temperature change. All of the above tests were repeated after the unit had been autoclaved.

The whole electronic system is ilustrated in figure (2.18).

Figure 2.18. The complete soft tissue balancing system.

CHAPTER 3

DESIGN EVALUATION AND OPERATIONAL TESTING

The practical surgical evaluation of the system was split into two sections. The first section will consider the experimental data gained with the manual balancer and its theoretical importance, the second will present graphical data in order to support the assumption in section 2.2.2 that soft tissue imbalance does not vary significantly at different separation gaps. Verification of this will allow the definition of soft tissue imbalance in terms of angular deviation independently of the separation gap, suggested in the conceptual design of the instrumentation.

3.1 The Manual Balancer

The manual balancer was used on 66 patients to assess soft tissue imbalance undergoing total knee replacement at the Derbyshire Royal infirmary and Bretby Hall Orthopaedic hospital by a co-worker (Sambatakakis 1993). The results of this study have been published (Sambatakakis et al 1993) and can be seen in appendix 3.

Following this clinical trial, UK and U.S.A. Patent applications were made based on the manual balancer. The full patent document can be seen in appendix 4.

3.2 Electronic Balancer

The calibration procedure of the electronic balancer showed that the angular measurement was repeatable and linear within a bandwidth of 0.01°. An accuracy of 0.1° is probably more realistic because of the cumulative effects of the errors of positioning the device in the centre of the knee and of any residual friction between the joint being operated upon and the P.T.F.E plates. The L.V.D.T. proved to be repeatable and linear to within 0.001mm but was subject to a total cantilever error of the supporting stainless steel bars of ±0.0075mm at a load of 500N across the plates. The accuracy of the separation measurement was therefore assumed to be within 0.1mm.

The system was used on eight patients undergoing total knee replacement at Bretby Hall Orthopaedic Hospital. Seven of the patients had a varus preoperative deformity as measured on standing x-rays. A standard operative sequence was performed using intra- and extra- medullary guides. A 7° valgus femoral and a 90° tibial osteotomy were performed on all patients. After these cuts had been made the electronic balancer was positioned within the knee. A P.T.F.E plate was positioned beneath the joint in order to reduce friction to a minimum, and the balancer was expanded until both plates were making full contact with the ends of the tibia and femur and tension of the soft tissues was felt. The system was then activated and the soft tissues were tensed considerably. These data were stored within a data file and imported into Harvard Graphics software for graphical analysis back at the laboratory.

3.2.1 Results

The plotted graphs of the patients with a varus pre-operative deformity can be seen in figure (3.1) and the patient with a valgus deformity can be seen in figure (3.2). A S curve is visible in some of the cases. The imbalance seems to plateau at a maximum before decreasing to a lower level of imbalance with further distraction of the joint. The error bandwidth of the measurement was taken to be the difference between the minimum and the maximum values of imbalance in each case, as defined by the minimum and maximum plateaus or measured points. The minimum varus error bandwidth was 0.1° (patient 6) and the maximum was 1.1° (patient 1), the mean value was 0.4° with a standard deviation of 0.40. The mean distraction of the knee measured perpendicular from the central pivot was 7.15mm with a standard deviation of 1.46. The valgus knee measured had an error bandwidth of 0.8° with a maximum value of 10.5° across a distraction of 10mm.

3.2.2 Discussion

The Derby balancer measures the geometry of the separation gap after both bony osteotomies have been performed. The exact angles of the bony osteotomies can be selected and performed at surgery with the accurate intra- and extra-medullary guides of the modern instrument sets. The actual angle of the femoral osteotomy performed with the instrument sets is variable and subjective to surgical opinion. It is therefore possible that the measured imbalance will include any errors in assessing the natural pre-diseased bony alignment of the joint as well as true soft tissue contracture. The surgical goal is to eliminate this combined imbalance by releasing procedures at the chosen bony alignment.

The balancer gives a continuous measure of soft tissue imbalance using deviation in degrees as its unit of measurement. Inter-patient analysis is possible when

SOFT TISSUE IMBALANCE
VARUS KNEES

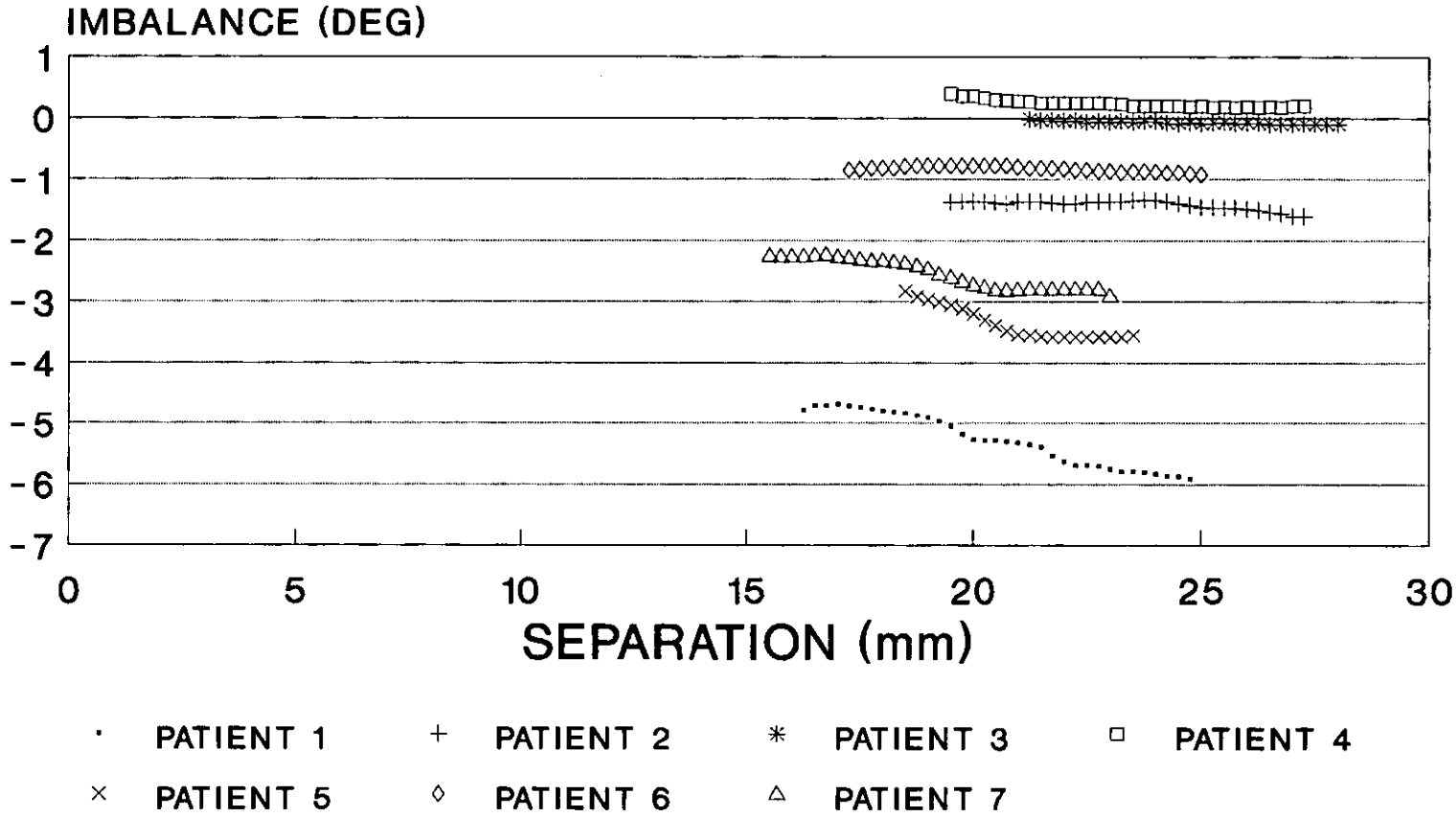


Figure 3.1

SOFT TISSUE IMBALANCE
VALGUS KNEE

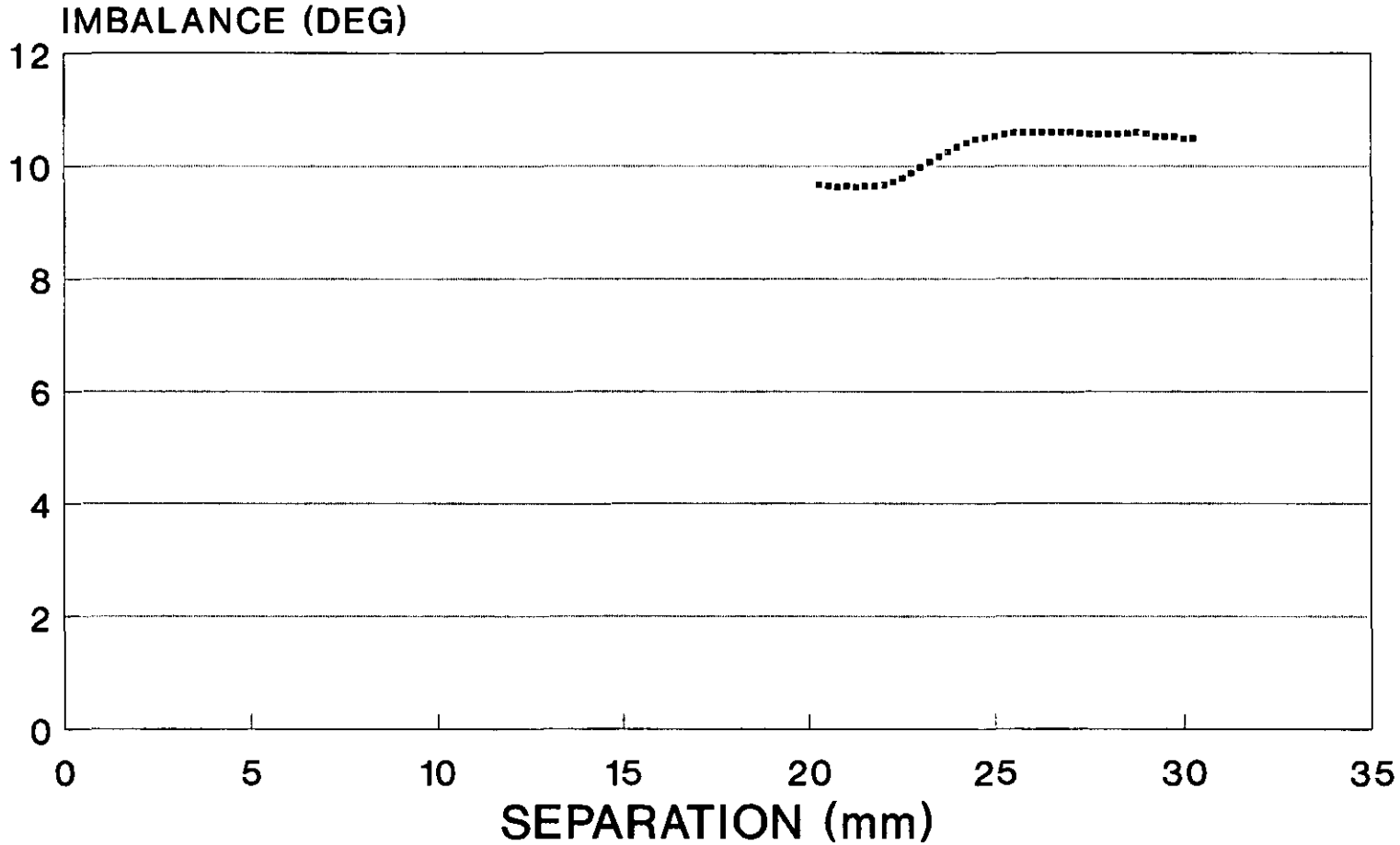


Figure 3.2

either the angle of the femoral osteotomy remains constant through out the trial, or the angle is quoted in conjunction with soft tissue imbalance.

This instrumentation has clearly demonstrated that soft tissue imbalance can be assessed at any distraction of the joint, or under any compressive tension. Varus soft tissue imbalance varies within an error bandwidth of 0.4° with a standard deviation of 0.4. The minimum deviation of 0.1° was observed (patients 3 & 6) in patients that were considered to have no soft tissue imbalance at the time of operation.

This study has experimentally tested the assumption that soft tissue imbalance can be measured independently of the compressive load through the knee. The change in angular deviation during the separation of the knee joint is an acceptable error for clinical measurement, and that the definition of angular deviation as a measure of imbalance in knee arthroplasty is valid.

3.3 DISCUSSION

Historically the tensor was the first soft tissue tensing device used during total knee replacement surgery. It was instrumental in the description of the pathological anatomy of arthritis of the knee which is a combination of hard tissue loss and soft tissue contracture. Many modern instrument sets for knee arthroplasty however, do not incorporate any tensing devices and those which do are often not used in practice. Many factors may have contributed to this apparently backward step. It is probable that surgeons had been reluctant to use them because they have failed to give the quantitative information required by the surgeon at the time of the operation. Tensers did improve the "feel" of imbalance, but they did not deal with the essential material property of living soft tissues, viscoelasticity.

The requirement to achieve an objective method of assessment by applying equal forces to the soft tissues in knee arthroplasty surgery was first recognised by M^{C}Daniel. He attempted with his redesign of the classical tensor to "equally tension both collateral ligaments" by introducing spring loading or a pneumatic system. Practically, however, this design retained the separate distraction of the medial and lateral structures. Furthermore, imbalance was estimated by the comparison of a proximal/distal bar running through the instrument to an imaginary straight line running from the estimated centre of the patients hip distally to the centre of the ankle. The tensor, and all the surgical instruments derived from it could not give a quantitative indication of imbalance. They were designed to give an all or nothing estimation.

This study has shown that soft tissue imbalance can be considered as the angular deviation of the tibia with respect to the femur when equal forces have been applied to both collateral structures. The measurement of soft tissue imbalance is therefore measured independently to the compressive force applied across the joint and the separation distance. Experimentally, this study has showed

that imbalance does not vary significantly at differing separation gaps, of the same knee, when an increasing force is loaded both medially and laterally at a constant rate. Therefore imbalance can be measured at any arbitrary tension or separation gap of the joint.

Soft tissue imbalance can be a function of two possible mechanisms, true soft tissue contracture during the disease process, or manufactured imbalance by the variation of the bony osteotomies from the natural bony alignment. The balancer uses both of the bone cuts as its reference datum so it is possible that both of these factors may add to or subtract from the final imbalance. The modern instrument sets maintain a constant 90° tibial cut with reference to the extra-medullary alignment jigs and the femoral cut varies between 5° and 9° depending on surgical opinion. If the surgeon is happy with the new bony alignment of the joint then the balancer will measure the cumulative affects of soft tissue imbalance. It is argued that both types of imbalance should be treated with soft tissue releasing procedures to ensure that over loading of one compartment of the knee does not occur. All of the patients measured within this study and previous studies of co-workers referred to have been 7° valgus and remained as a reference datum. However in situations where the angle of the femoral osteotomy is variant, this figure should be quoted along with the soft tissue imbalance to allow for an absolute inter patient comparison.

The time taken, to insert the instrumentation into the separation gap of the knee, tense and record data over the whole range of the separation gaps takes no longer than thirty seconds and can be consider negligible, compared to the over all length of the operation. However the soft tissue releasing procedures performed on a badly deformed knee can take as long as fifteen minutes to reach soft tissue balance.

The plates of the instrumentation were manufactured as large as possible, from known data on the mean size of the femoral condyles so that the pivot would be located close to the centre of the knee. Deviation from this position would change the lengths of the moment arms of the medial and lateral soft tissue structures, resulting in unequal forces being applied by these structures at the equilibrium position. In practice however negligible differences in readings are obtained for imbalance as long as the centre of rotation remains between the insertion points of both the anterior and posterior cruciate ligaments in the coronal plane. Currently any knee that has achieved a soft tissue imbalance of 2 degrees or less is perceived to be balanced, so any deviation from the between the absolute and visibly aligned centre of the knee will be negligible, compared to the acceptable error in the system.

After soft tissue procedures have been performed the separation gap observed is larger than before the releasing procedures had been performed, at any constant applied load. However, the homeostatic datum point of measurement of soft tissue imbalance remains constant. Equal forces are still applied medially and laterally resulting in the datum point being independent of both applied load, and the separation of the joint. Errors accumulating from the repeatability of measurements can only come from the slight misplacement of the device away from the absolute centre of the knee.

This instrumentation will provide an absolute measurement of soft tissue imbalance through the complete range of the separation gaps. The thickness of the components selected represents the tension of the soft tissues which the surgeon considered to reflect their homeostatic condition. As measurements are continuous this unique datum can postoperatively be related to the recorded data of angular deviation and separation gap. The effects of the surgical release of each tight structure can be examined with respect to both extension and the flexion gaps. This will lead to quantitative recommendations on the releasing procedures which are necessary to obtain soft tissue balance.

3.4 CONCLUSIONS

1) The current tensers using the "maximal" tension approach do not provide a quantitative measurement of imbalance.

2) Soft tissue imbalance can be redefined as the angular deviation of the tibia with respect to the femur when equal forces are applied to the collateral soft tissues.

3) A homeostatic reference datum can be assumed for the measurement of soft tissue imbalance when equal forces are applied to both medial and lateral soft tissue structures.

4) Soft tissue imbalance can be measured independently of the passive compressive forces through the knee within an error band of 0.4° with a standard deviation of 0.4.

5) The soft tissues of the knee can be tensed through a average range of 7.15mm with a standard deviation of 1.36.

3.5 FURTHER WORK

The design and development of the instrumentation within this thesis has already allowed significant research work to be carried out. This work, published elsewhere has been used to partly evaluate the design and illustrate the large proportion of knees on which the system has been used. The simplistic approach of the central pivot has solved the problem of the measurement of soft tissue imbalance. However, the system has opened up further medical and neurophysiology questions which are worthy of investigation.

1) It has been postulated that a hypothetical neurophysiological mechanism for the failure of knee arthroplasties exists. This has lead to a possible mechanism for the pathogenesis of primary osteoarthritis being developed, based upon the joint mechanoreceptors sending "imbalanced" information to reinforce a destructive feedback loop. It is thought that restoration of soft tissue balance in the knee improves conscious proprioception. As this is assumed to be correlated to unconscious proprioception, thought to be responsible for the failure mechanism described above, measurement of the expected return of conscious proprioception after balanced knee arthroplasties would be an important result.

   The instrumentation developed within this thesis has given a quantitative measurement of soft tissue imbalance for the first time, so such questions can be asked a) Does balancing of knees restore proprioception? b) Have patients whos knees did not require balancing better proproiception than others? and c) Are soft tissues the only decisive factor for proproiception?

2) Presently soft tissue balance is being measured at a any separation gap. If soft tissue imbalance, or the additional passive force of imbalance is detected it is eliminated surgically. The passive force of imbalance,

or the constant compressive force at which the prostheses are implanted is not measured. Such tension is again left to surgical feel and opinion. The stability of the knee through the full range of flexion is dependant upon such tension and could be an important area for research.

This work has not been done because of the difficulty in distinguishing between the passive and the additional passive forces through the knee. The balancer distinguishes between these two parameters and a load cell could be incorporated within the main column of the device, with the data being sent via the existing routes to the PC. Such data would be very valuable in the design and development of arthroplasties as this compressive force is unknown, it is often neglected, and at best estimated.

3) The ultimate clinical question is, do the arthroplasties have a lower failure rate if the soft tissue structures are balanced? The only possible way to prove this conclusively is to conduct a retrospective follow up study after ten years. Such a follow up would provide the ultimate measure of success of the soft tissue balancing system.

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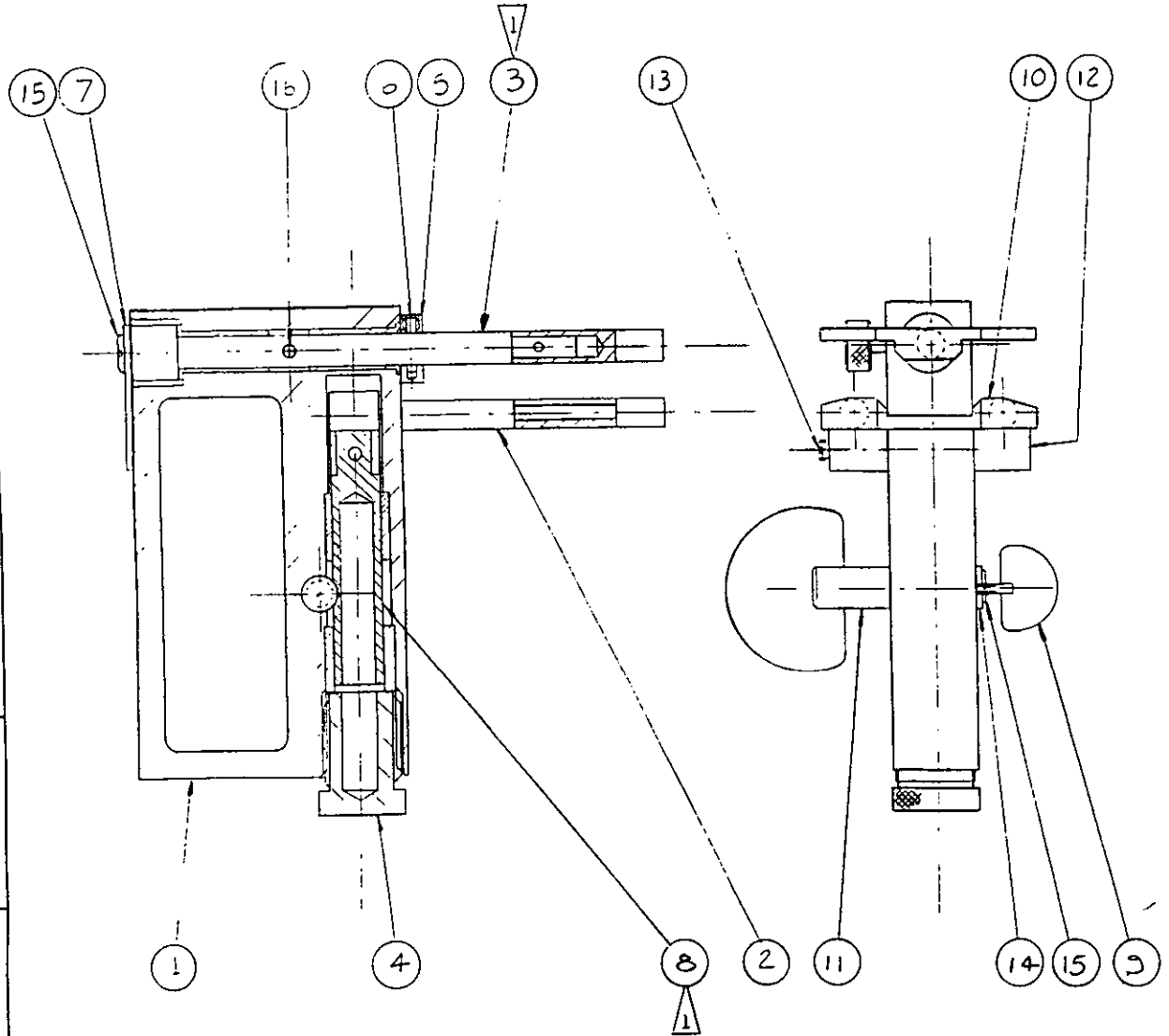
APPENDIX 1

DETAIL DESIGN DRAWINGS.

PART OF



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3	1020	SHAFT ASSY	1
4	1011	BOTTOM PLUG	1
5	1012	COLLAR	1
6	1013	PIN	1
7	1015	SCALE	1
8	1010	QUILL	1
9	1019	KEY ASSY	1
10	1005	BOTTOM PLATE	1
11	1025	PINNION KEY ASSY	1
12	1022	ARM	1
13	1021	PIN	1
14	1026	WASHER	1
15	1024	SCREW	4
16	1027	PIN	1

NOTES

1 LUBRICATE THE TOP SHAFT, ITEM 3 AND THE QUILL, ITEM 8 WITH SILICON OIL.

DRG.No.

ISSUE	DESCRIPTION	APPD.	DATE

TITLE THE BALANCER

DRAWN	TRACED	CHECKED	APPROVED	DATE
SFA				09/06/02

DRAWING No. B 1

BS 361-397

420 x 594mm A2

PART OF

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SHEET 1 OF 1

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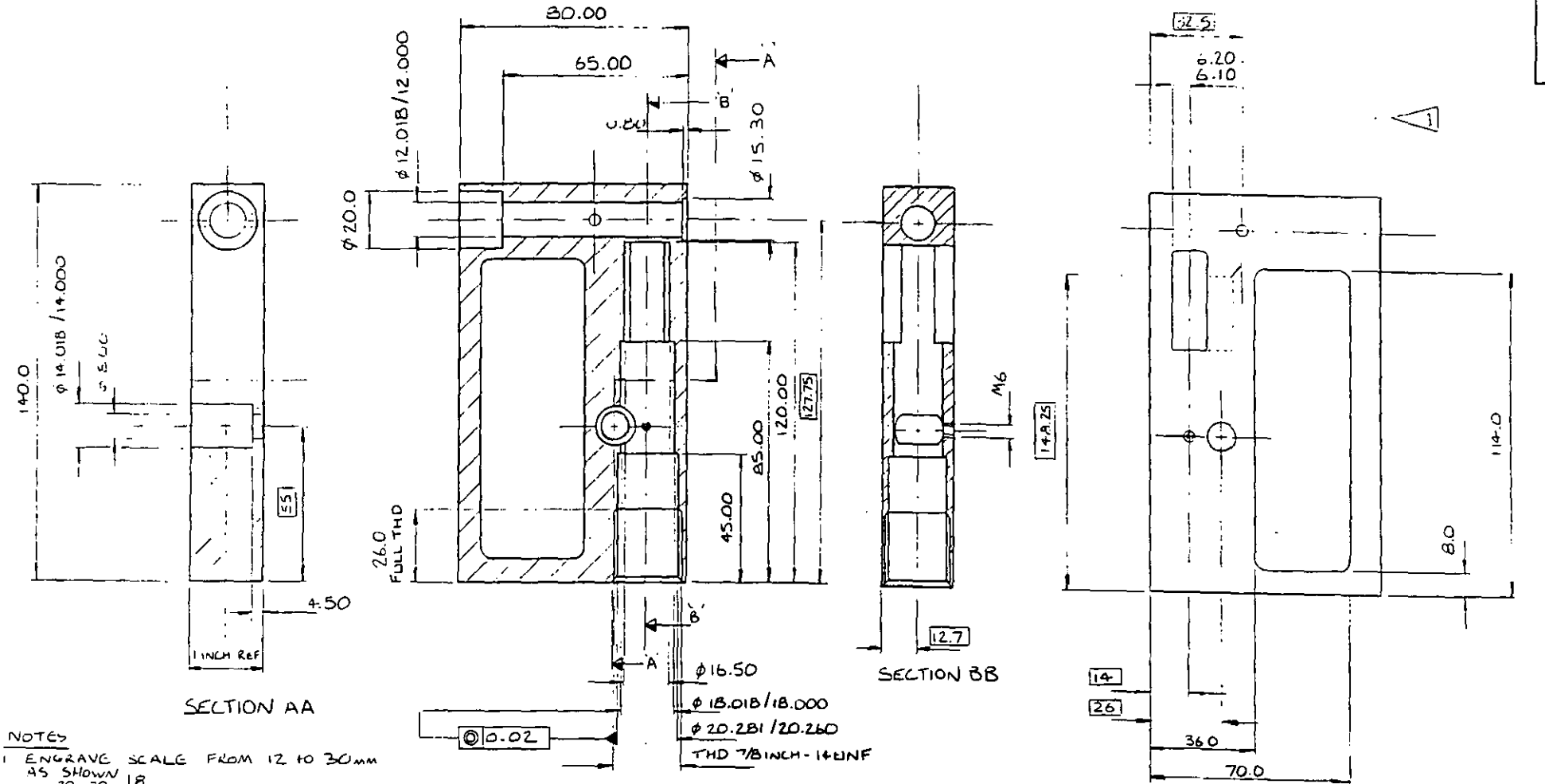

NOTES

1 ENGRAVE SCALE FROM 12 TO 30mm AS SHOWN

UNSPECIFIED TOLS X.X ±0.25 X.XX ±0.15 ANGLES ∠ ±1° REMOVE ALL BURRS AND SHARP EDGES. CHAM / RAD TO 0.5 MAX PERMISSIBLE ⌖ 0.02 TYP

ISSUE	DESCRIPTION	APPD.	DATE

MATL :- STAINLESS STEEL TO BS 5154 GRADE N

SCALE 1:1

TITLE: BODY

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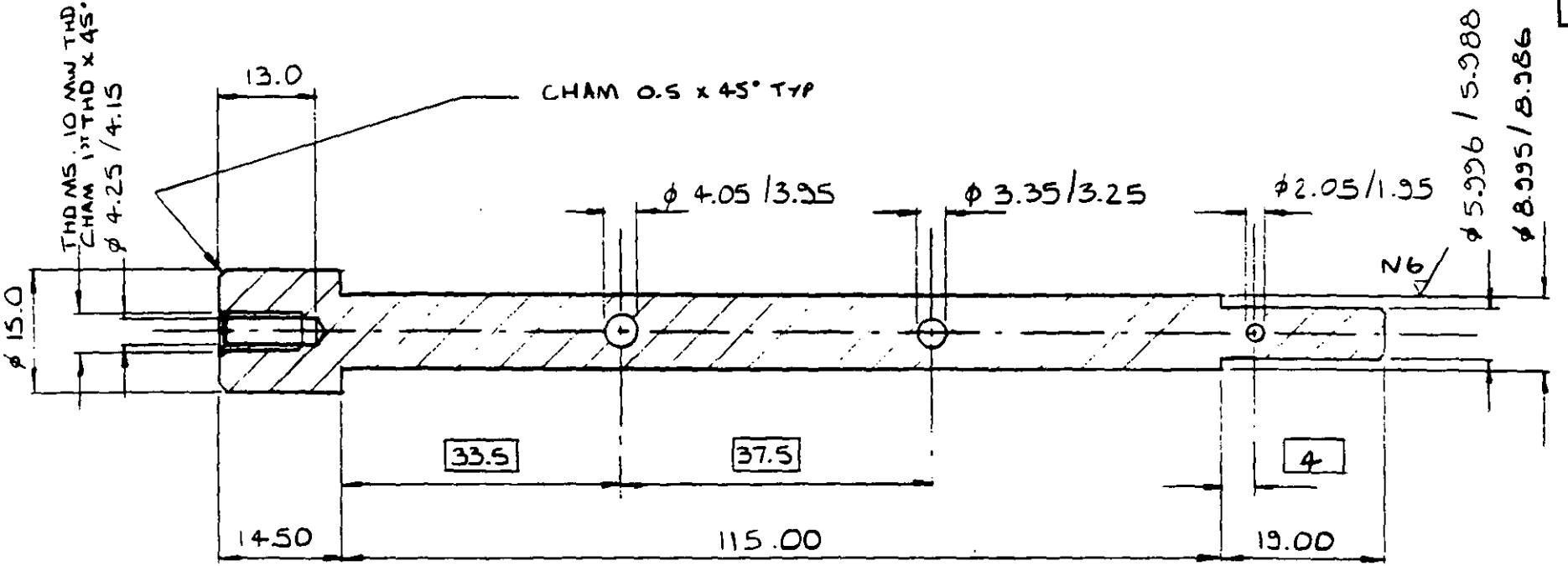

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ISSUE	DESCRIPTION	APPD	DATE

MATL :- STAINLESS STEEL TO BS 5194 GRADE N

SCALE 2:1

TITLE: SHAFT

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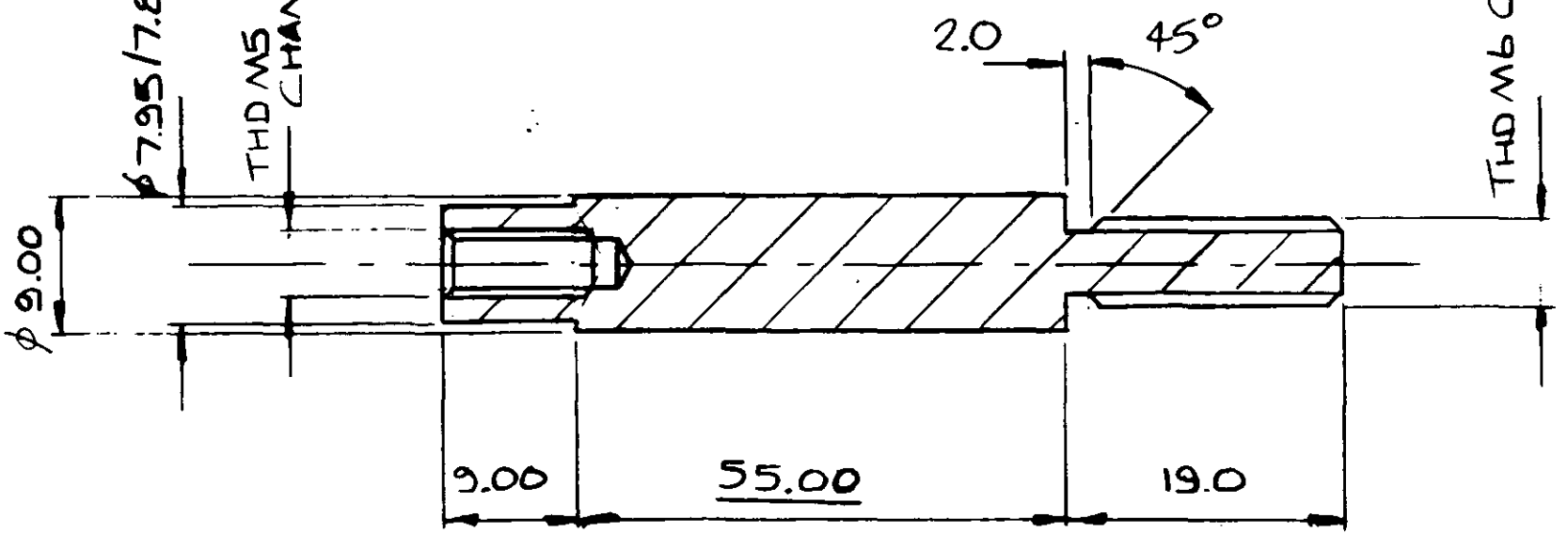

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UNSPECIFIED TOLS :- x.x ±0.25 x.xx ±0.15 ∠ ±1° REMOVE ALL BURRS AND SHARP EDGES.

ISSUE	DESCRIPTION	APPD	DATE

MATL:- STAINLESS STEEL TO BS 5194 GRADE 1

SCALE 2:1

TITLE: SHAFT

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RS 561-375

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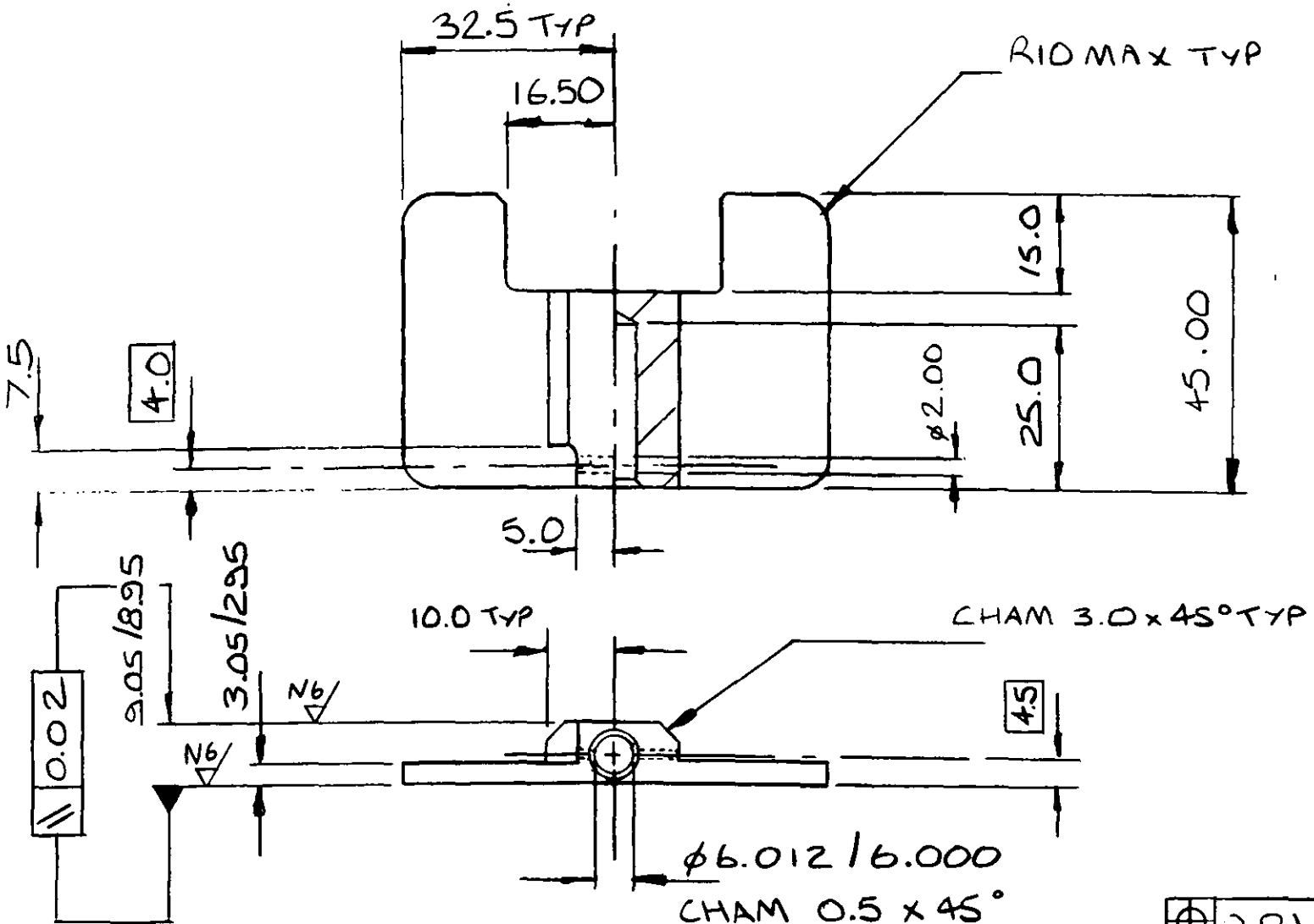

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ISSUE	DESCRIPTION	APPD	DATE

MATL :- S.STEEL
TO B.S 5194 GRADE N

SCALE 1:1

TITLE: PLATE

DRAWN	TRACED	CHECKED	APPROVED	DATE

DRAWING No. 1004

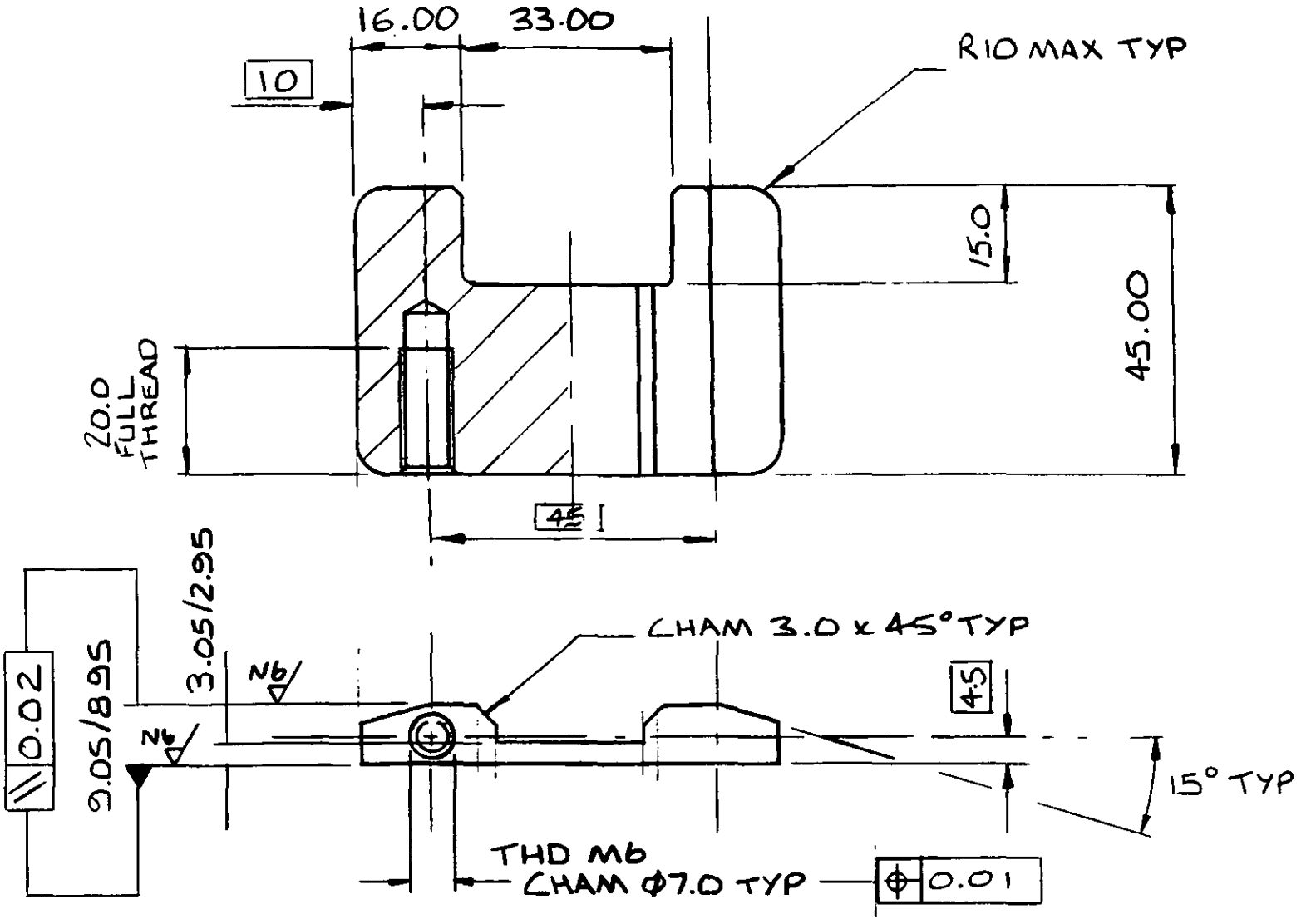
RS 581-375

210 x 297mm A

PART OF

DO NOT SCALE

DRG. No.



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ISSUE	DESCRIPTION	APPD	DATE

MATL :-
STAINLESS STEEL
TO BS 5194 GRADE N

SCALE 1:1

TITLE
PLATE

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RS 561-375

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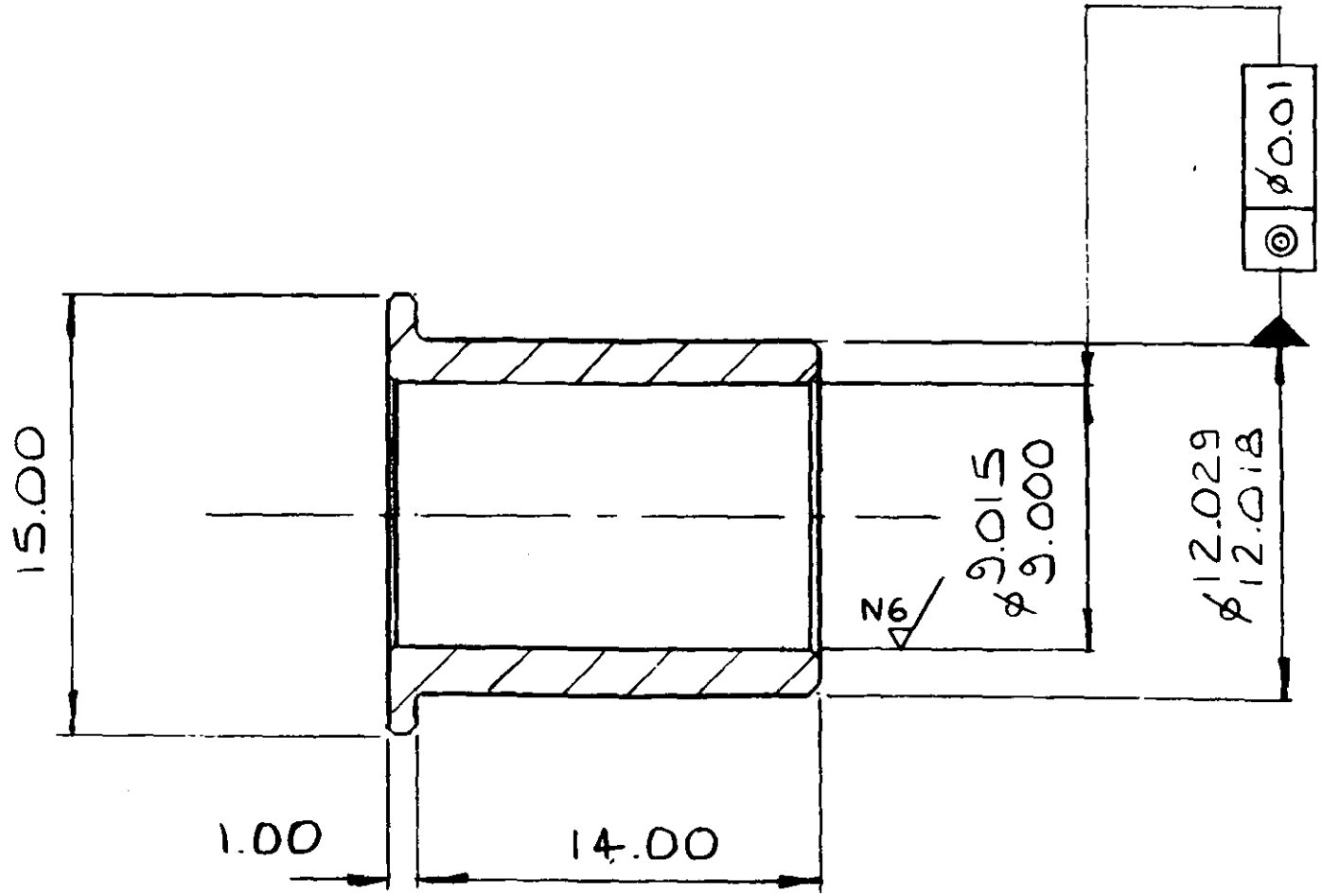

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ISSUE	DESCRIPTION	APPD	DATE

MATL :- P.T.F.E

SCALE 4:1

TITLE BUSH

DRAWN	TRACED	CHECKED	APPROVED	DATE
S.F.A				

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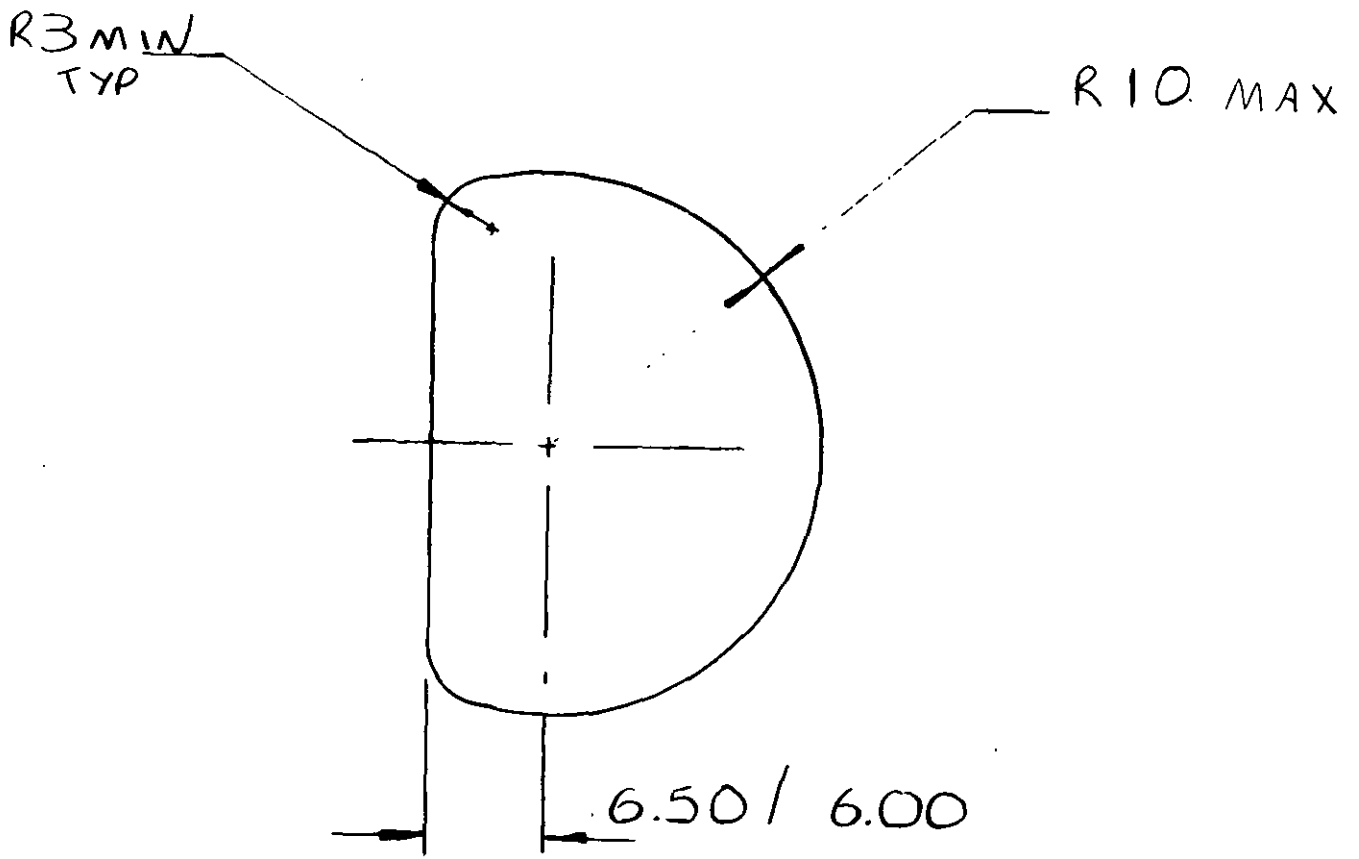

REMOVE ALL BURRS AND SHARP EDGES

ISSUE	DESCRIPTION	APPD	DATE

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TITLE: KEY

SCALE 4:1

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S.F.A				

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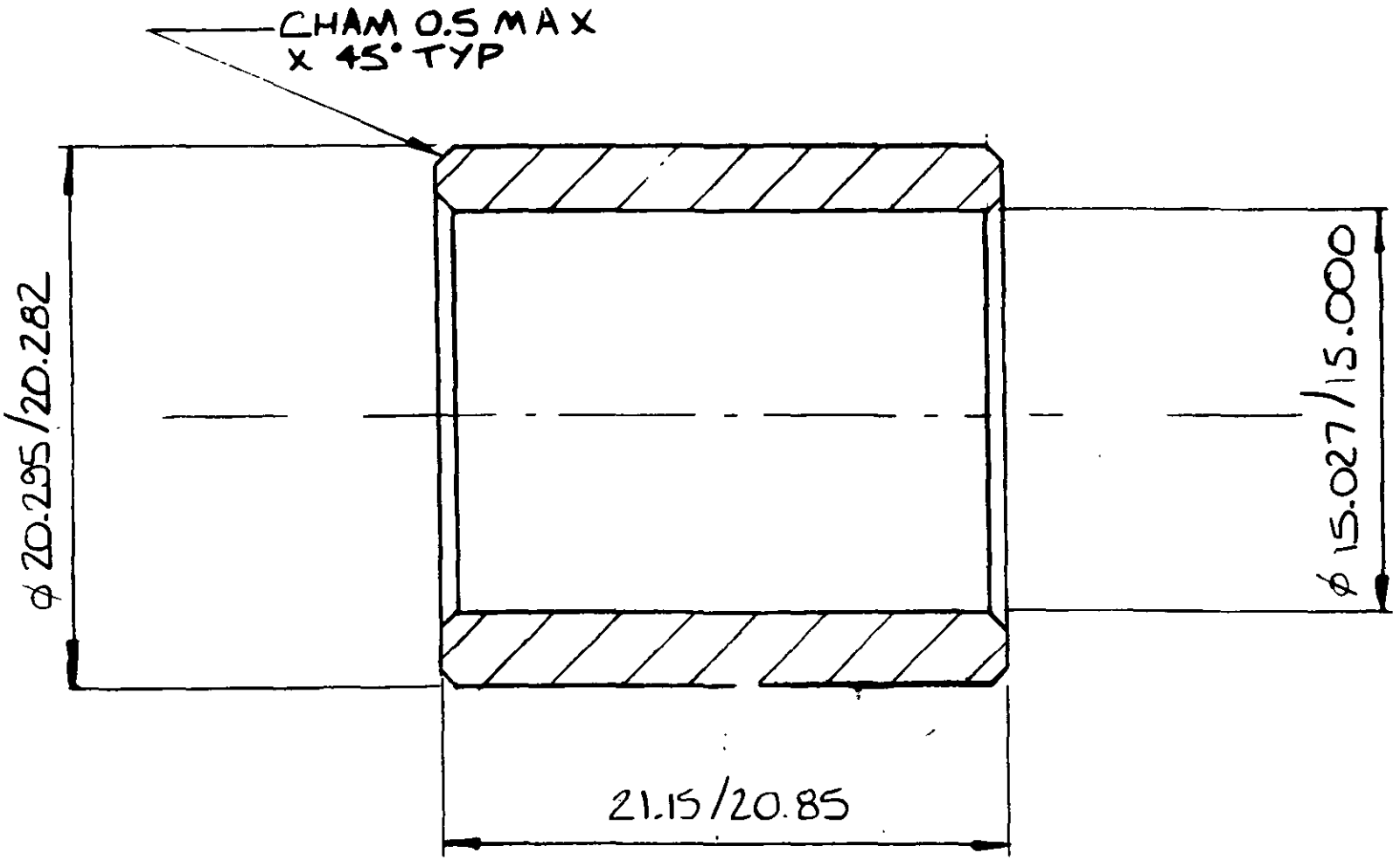

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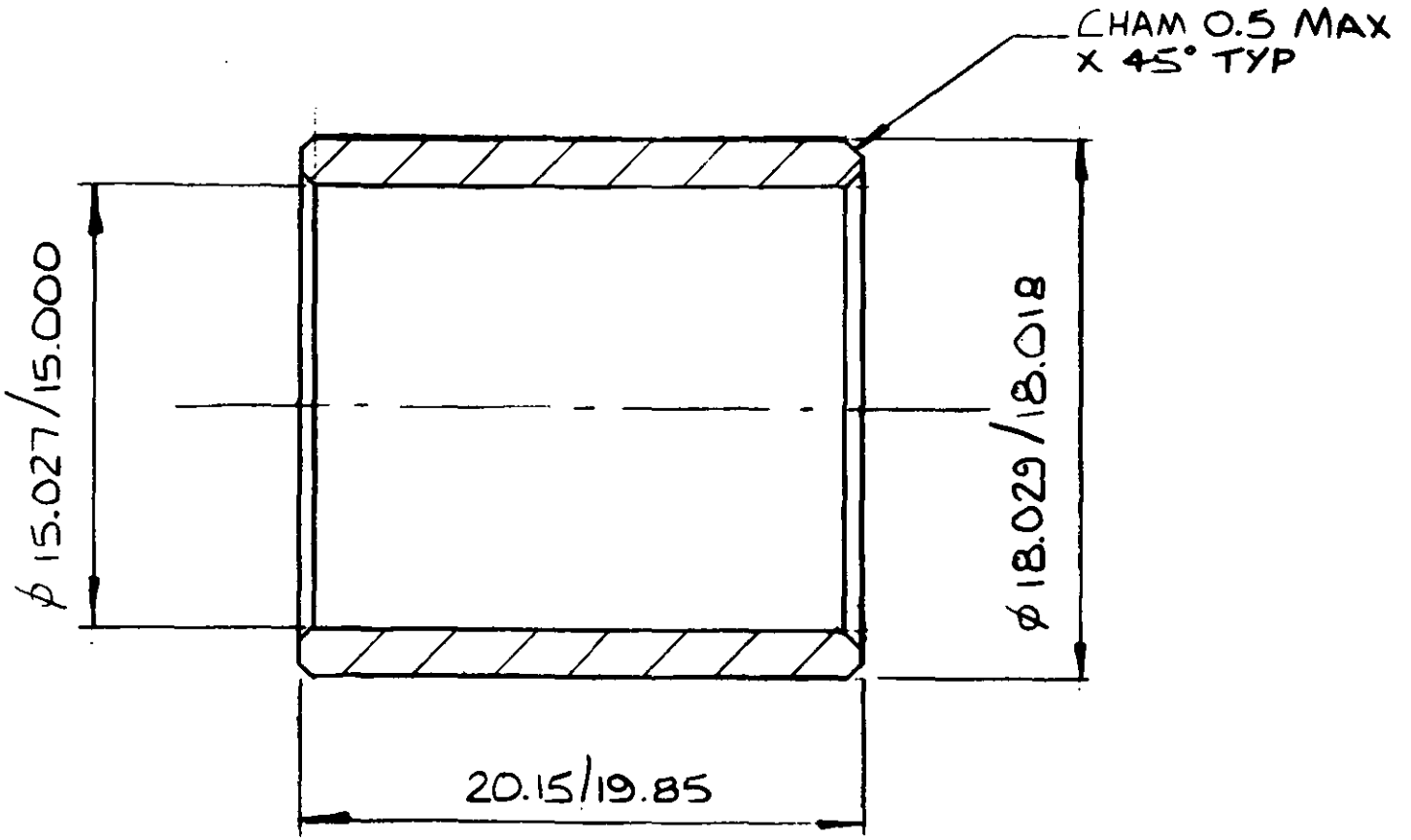

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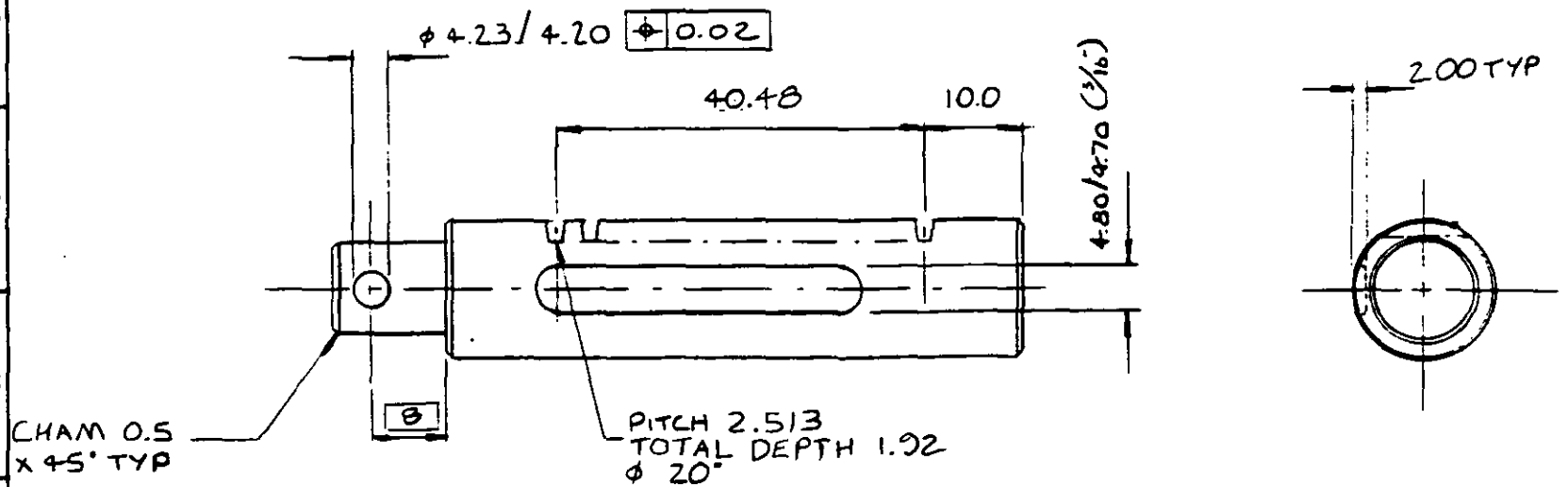

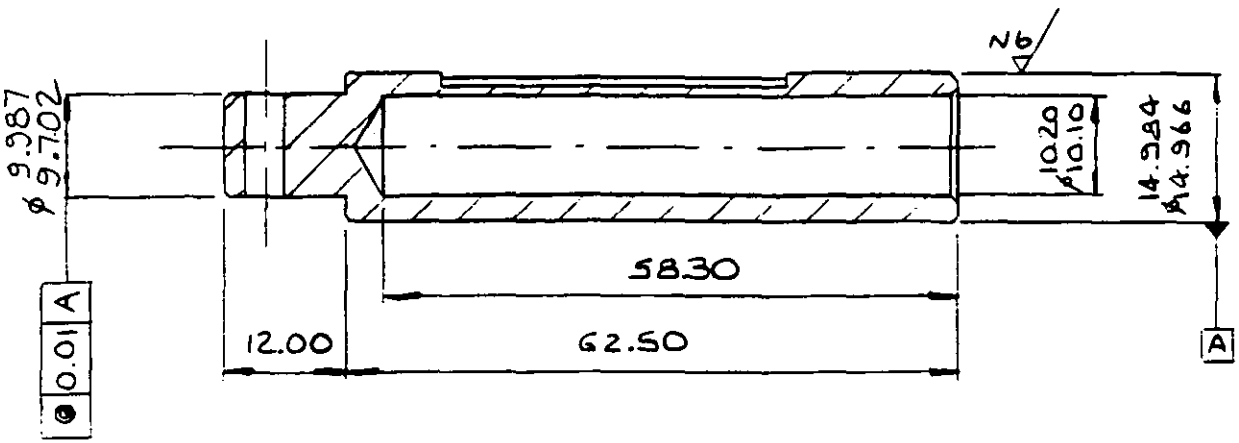

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ISSUE	DESCRIPTION	APPD.	DATE

MATL :- STAINLESS STEEL TO BS 5194 GRADE N

SCALE 2:1

TITLE: QUILL

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SFA				

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BS 5611-3B1 | 297 x 420mm A3

PART OF

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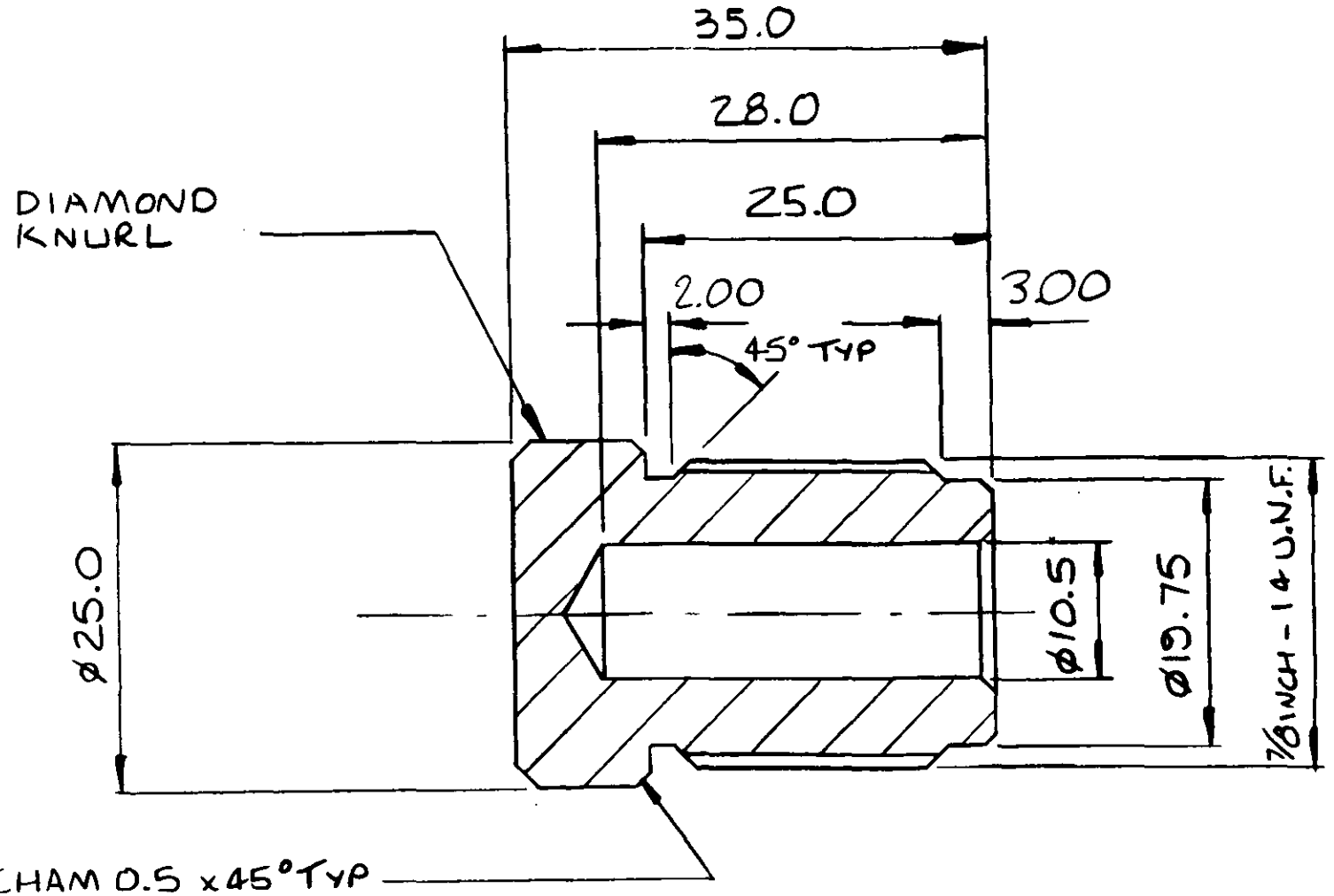

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ISSUE	DESCRIPTION	APPD	DATE

MATL :-
STAINLESS STEEL TO BS 5194 GRADE N

SCALE 2:1

TITLE
BOTTOM PLUG

DRAWN	TRACED	CHECKED	APPROVED	DATE
SFA				

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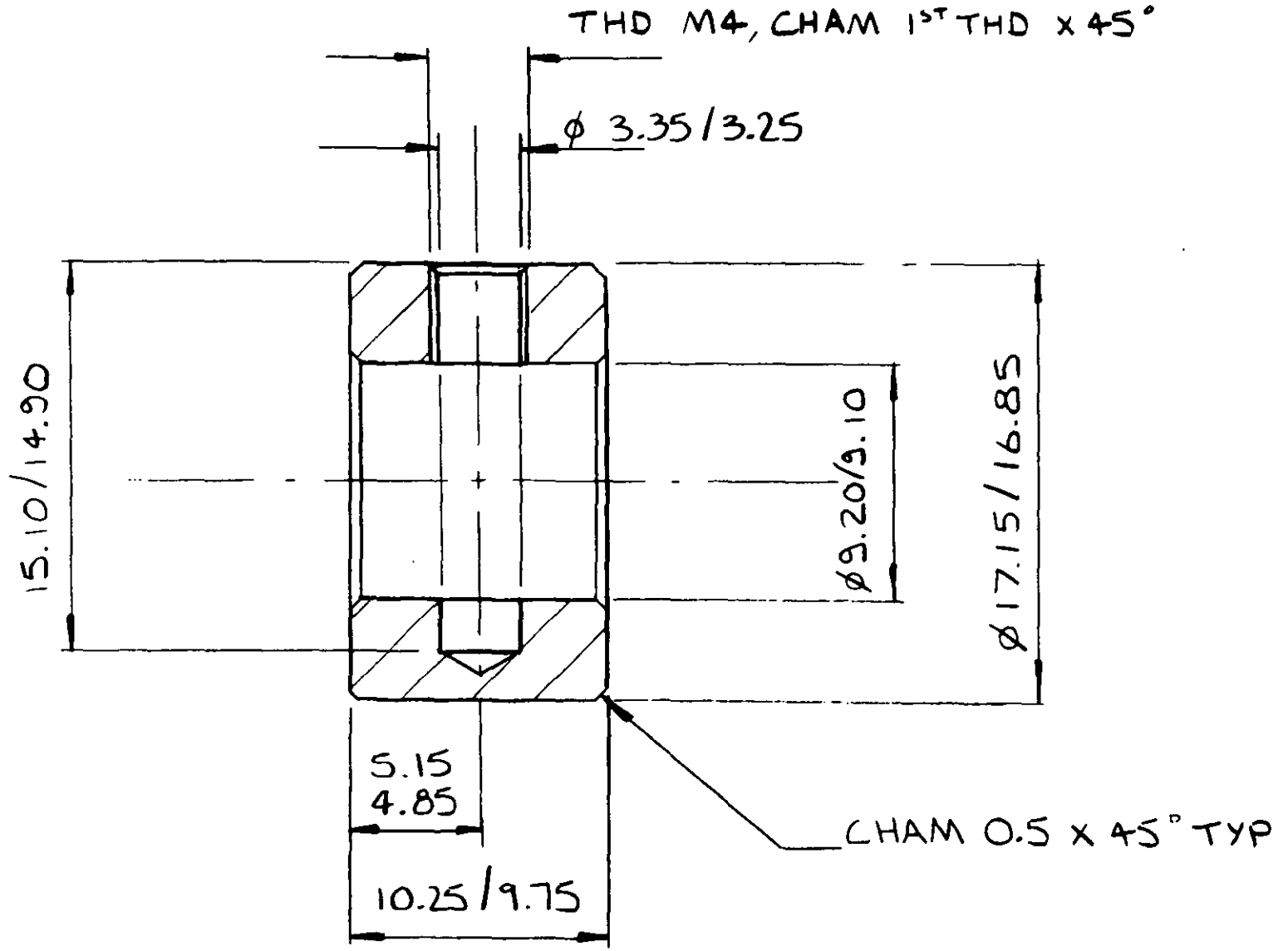

DRG. No.

ISSUE	DESCRIPTION	APPD	DATE

MATL :-
STAINLESS STEEL TO BS 5194 GRADE N

SCALE 4:1

TITLE
COLLAR

DRAWN	TRACED	CHECKED	APPROVED	DATE
S.F.A.				

DRAWING No. 1012

RS 561-375

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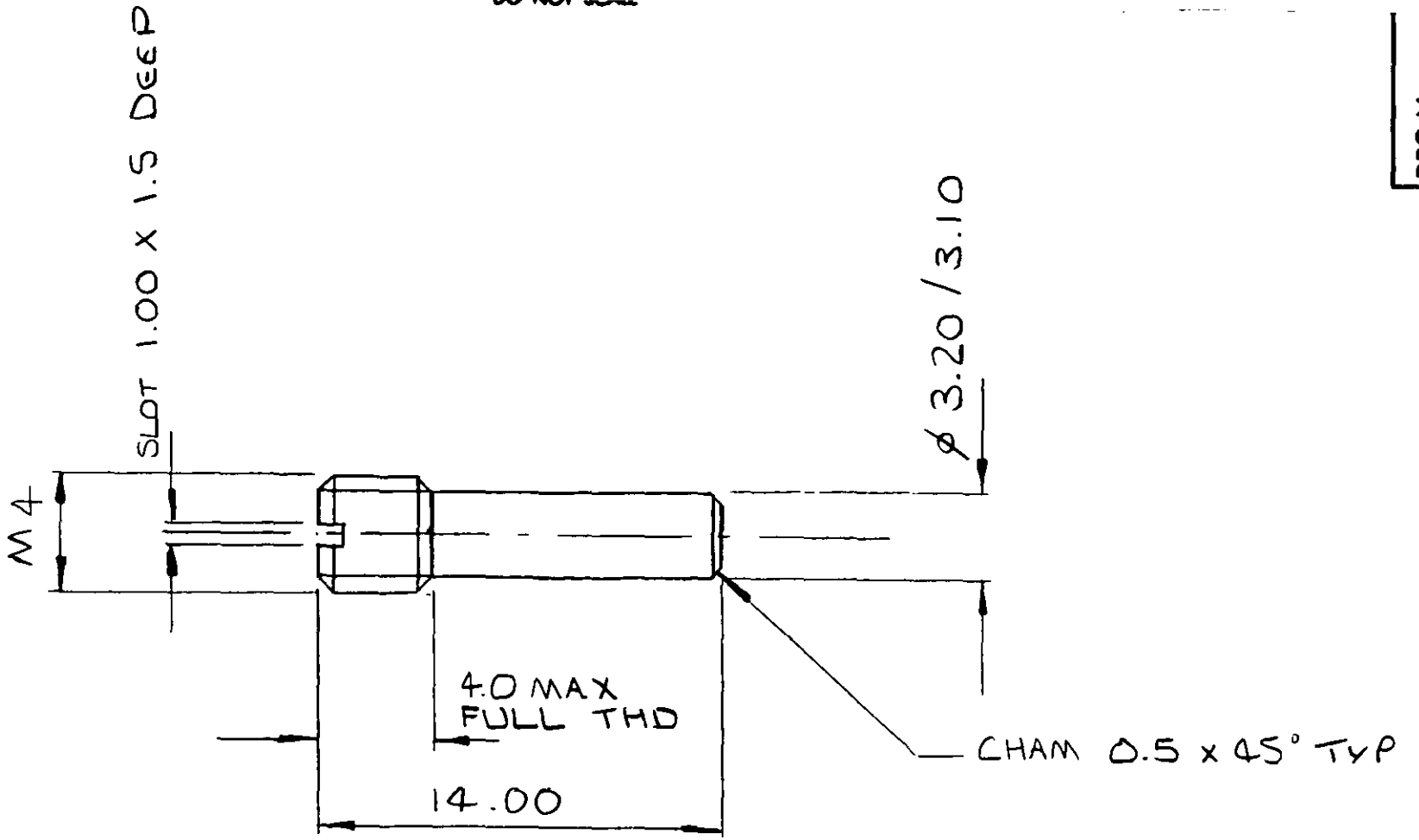


DRG. No.

ISSUE	DESCRIPTION	APPD	DATE

MATL :- STAINLESS STEEL TO BS 5194 GRADE N

SCALE 4:1

TITLE: PIN

DRAWN	TRACED	CHECKED	APPROVED	DATE
SFA				

DRAWING No. 1013

RS 561-375

210 x 297mm A4

DRG. No.

STANDARD Φ2 STAINLESS STEEL
TAPER PIN. 20 MAX LENGTH.

ISSUE	DESCRIPTION	APPD	DATE

TITLE: TAPER PIN

DRAWN	TRACED	CHECKED	APPROVED	DATE
S.F A				

DRAWING No. 1014

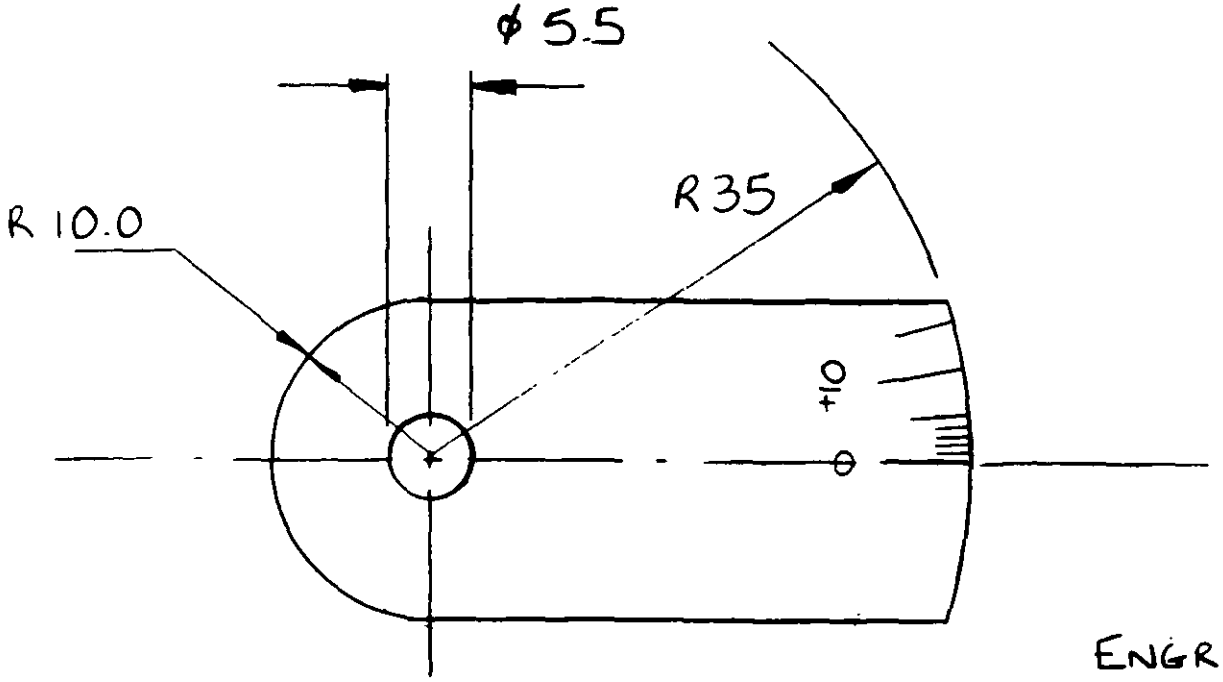
RS 561-375

210 x 297mm A4

PART OF

DO NOT SCALE

DRG. No.



ENGRAVE TO ±15°
AS SHOWN TO 8 HIGH

UNSPECIFIED TOLS :- X.X ±0.25 X.XX ±0.15 ∠ ±1° REMOVE ALL BURRS AND SHARP EDGES

ISSUE	DESCRIPTION	APPD	DATE

MATL :- 18 S.W.G STAINLESS STEEL TO BS 5194 GRADE N

TITLE SCALE

SCALE 2:1

DRAWN	TRACED	CHECKED	APPROVED	DATE
SFA				

DRAWING No. 1015

1 2 3 4 5 6 7 8 9 10

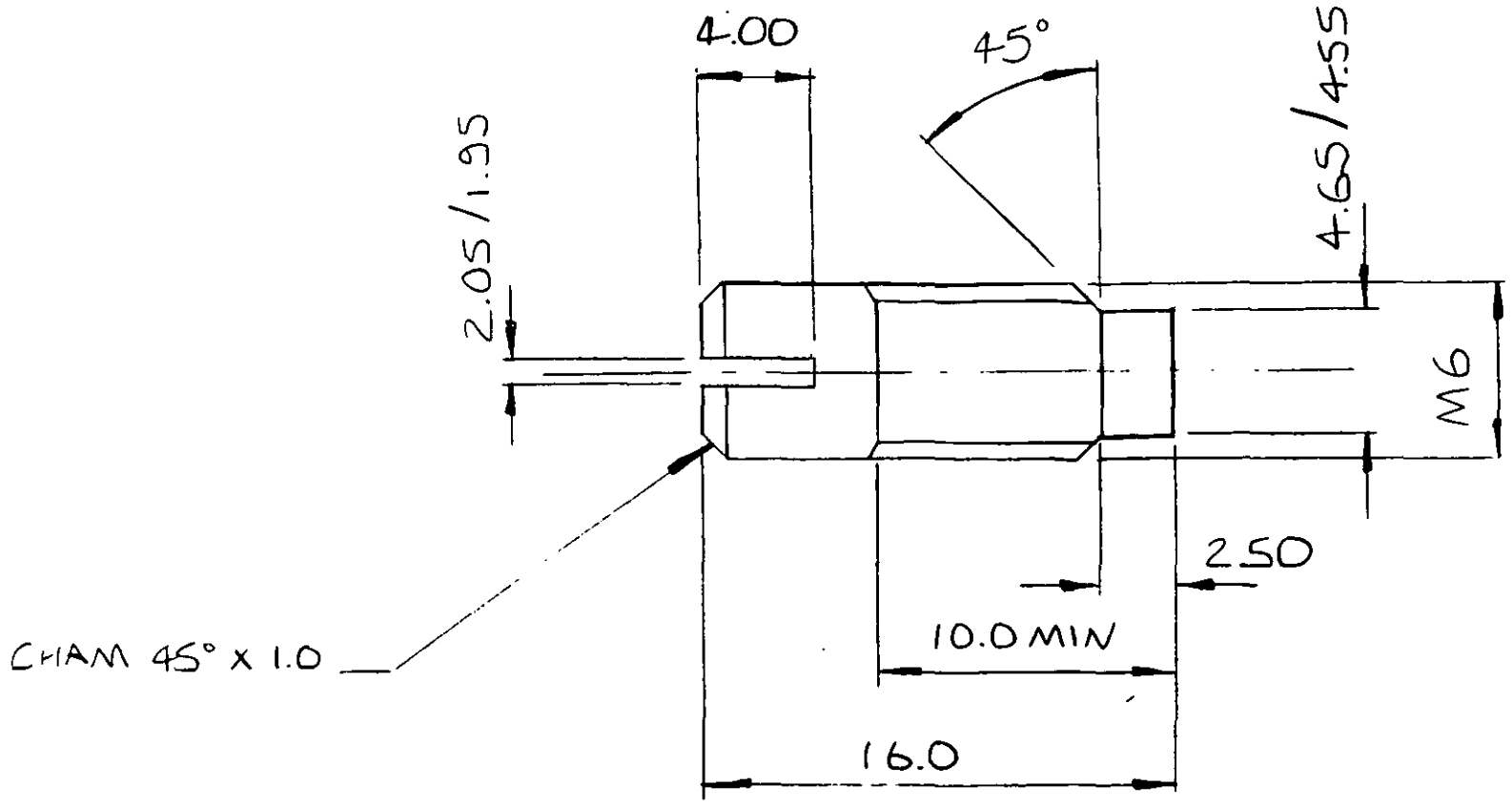
BS 5A1.375

210 x 297mm A4

PART OF

DO NOT SCALE

DRG. No.



UNSPECIFIED TOLS :- X.X ±0.25, X.XX ±0.15 ∠ ±1° REMOVE ALL BURRS AND SHARP EDGES

ISSUE	DESCRIPTION	APPD	DATE

MATL :- STAINLESS STEEL TO BS 5194 GRADE N

SCALE 4 : 1

TITLE: LOCKING SCREW

DRAWN	TRACED	CHECKED	APPROVED	DATE
SFA				

DRAWING No. 1016

RS 561 375

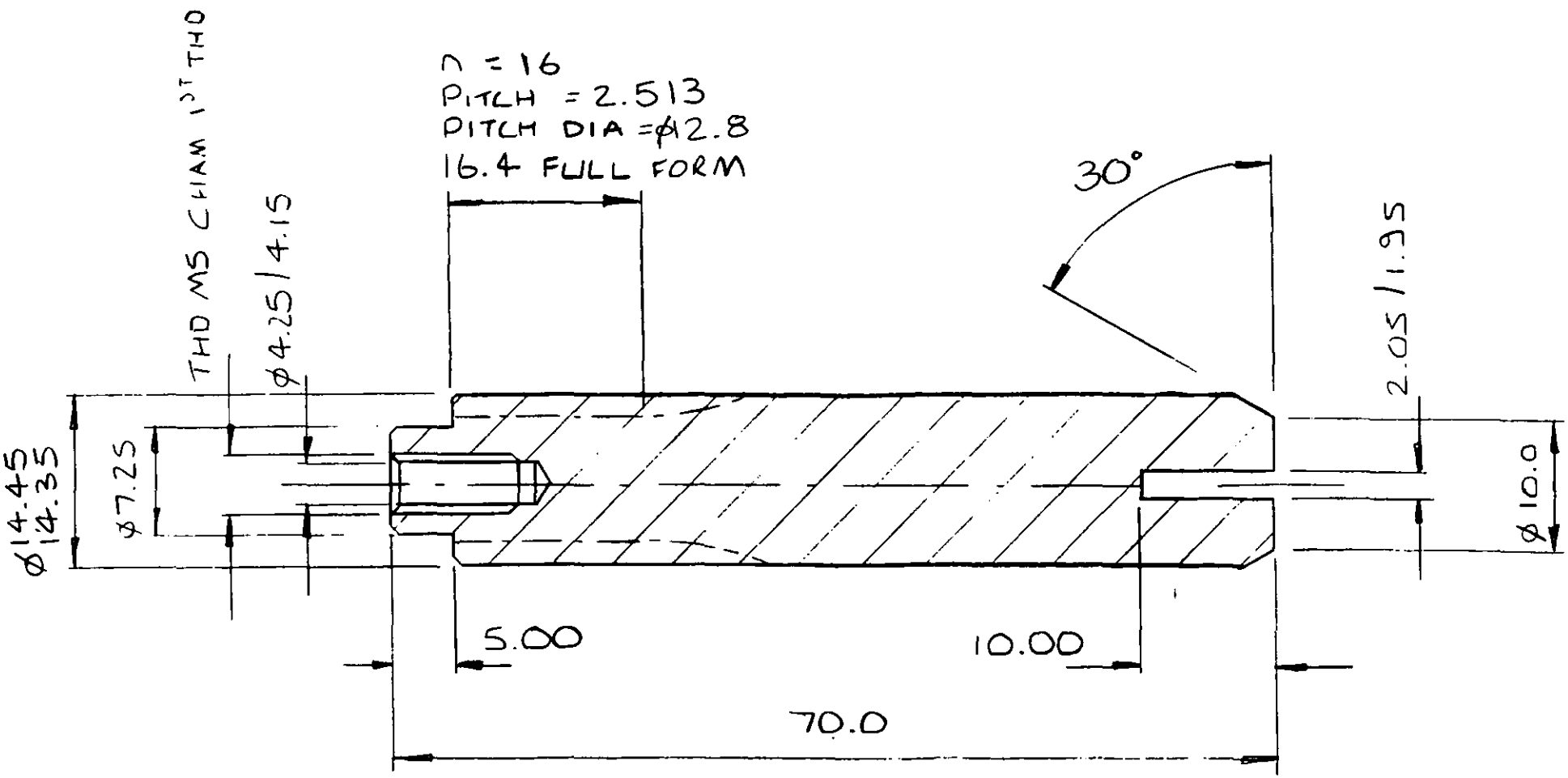
210 x 297mm A4

PART OF

DO NOT SCALE

SHEET 1 OF 1

DRG. No.



UNSPECIFIED TOLS :- X.X ±0.25 X.XX ±0.15 ∠ ±1° REMOVE ALL BURRS AND SHARP EDGES.

ISSUE	DESCRIPTION	APPD	DATE

MATL :- STAINLESS STEEL TO BS 5194 GRADE N

SCALE 2:1

TITLE: PINNION

DRAWN	TRACED	CHECKED	APPROVED	DATE
SFA				

DRAWING No. 1017

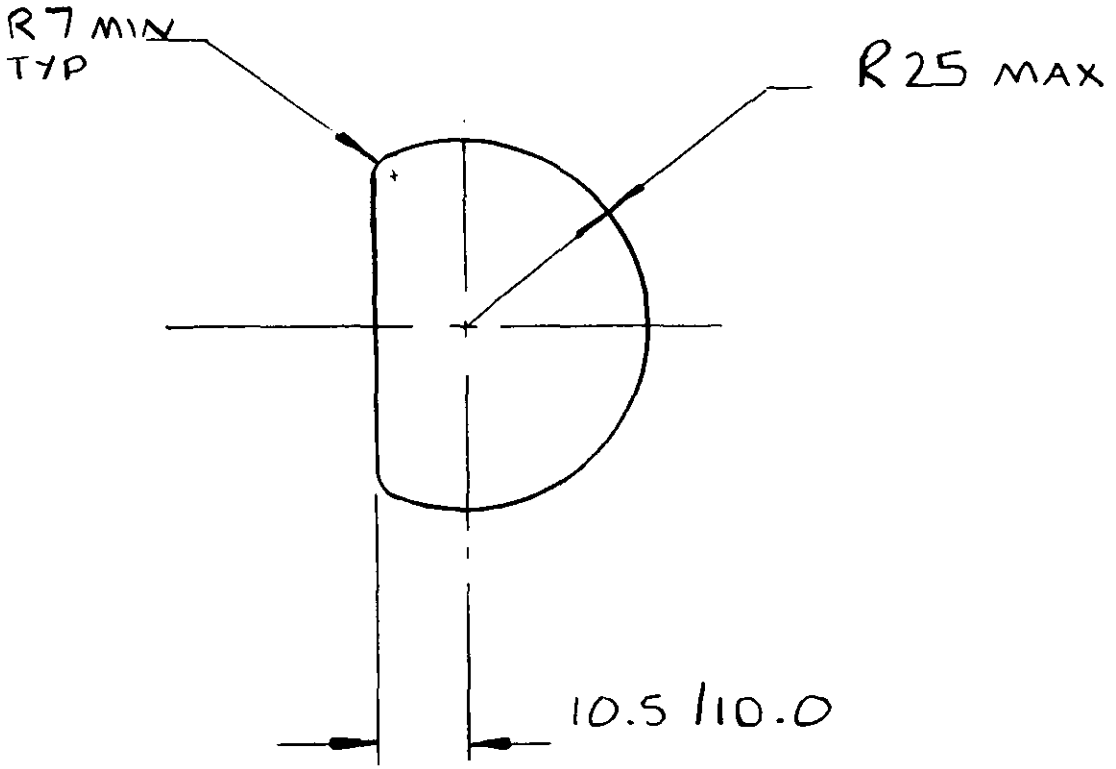
RS 561-375

210 x 297mm A4

PART OF

DO NOT SCALE

DRG. No.



REMOVE ALL BURRS AND SHARP EDGES

ISSUE	DESCRIPTION	APPD	DATE	MATL :- STAINLESS STEEL TO BS 5194 GRADE N. 14 S.W.G	TITLE	DRAWN	TRACED	CHECKED	APPROVED	DATE
				SCALE 1:1	KEY	SFA				
						DRAWING No.	1018			

RS 561-375

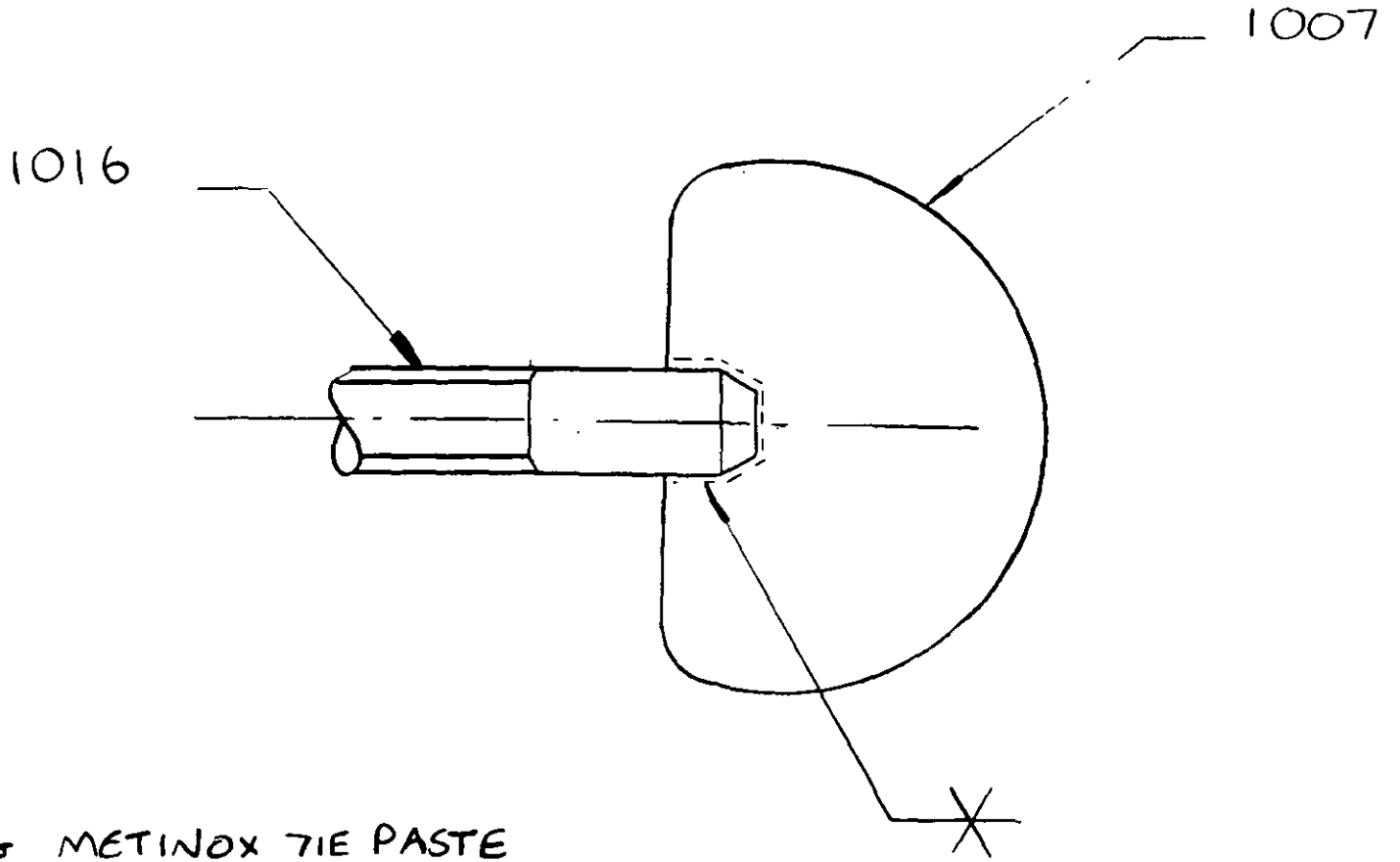
210 x 297mm A4

PART OF

DO NOT SCALE

SHEET OF

DRG. No.



CLEAN USING METINOX TIE PASTE

ISSUE	DESCRIPTION	APPD	DATE

SCALE 4:1

TITLE: LOCKING KEY ASSY

DRAWN	TRACED	CHECKED	APPROVED	DATE
SFA				

DRAWING No. 1019

RS 561-375

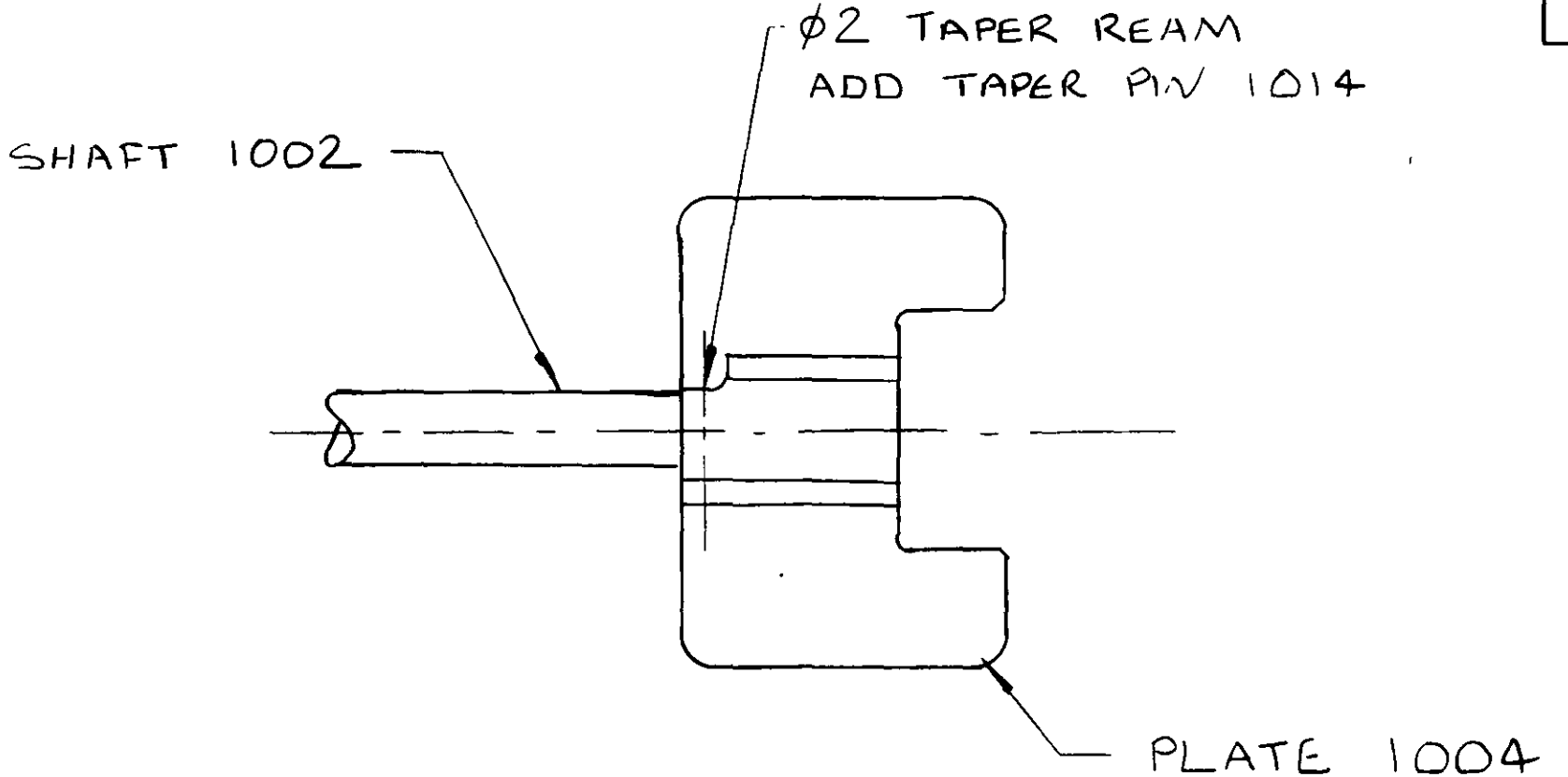
210 x 297mm A4

PART OF

DO NOT SCALE

SHEET

DRG. No.



ISSUE	DESCRIPTION	APPD	DATE

TITLE: TOP SHAFT ASSY

DRAWN	TRACED	CHECKED	APPROVED	DATE
SFA				

DRAWING No. 1020

RS 561-375

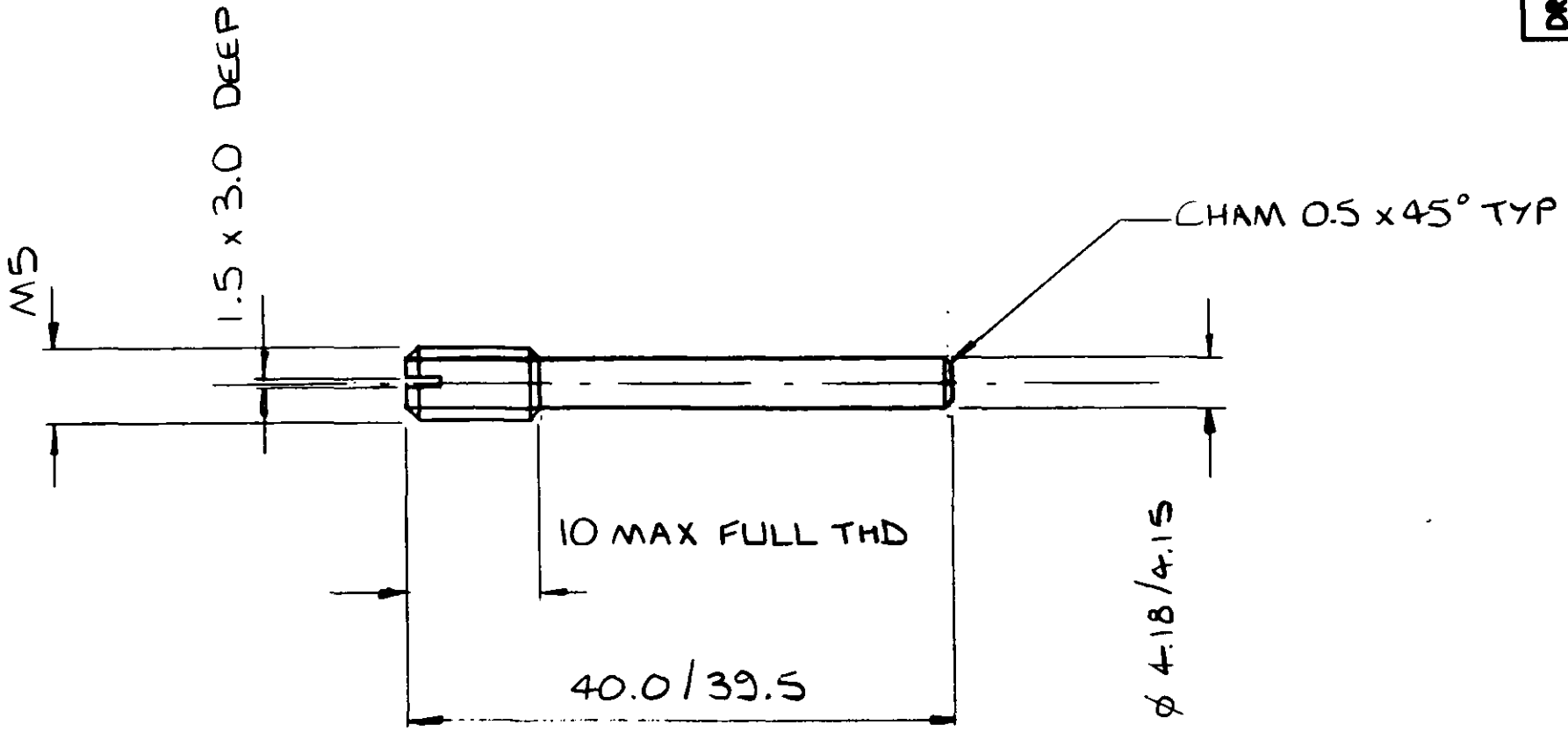
210 x 297mm A4

PART OF

DO NOT SCALE

SHEET OF

DRG. No.



ISSUE	DESCRIPTION	APPD	DATE

MATL:- STAINLESS STEEL
TO B.S 5194 GRADE N
SCALE 2:1

TITLE
RETAINING PIN

DRAWN	TRACED	CHECKED	APPROVED	DATE

DRAWING No. 1021

RS 561-375

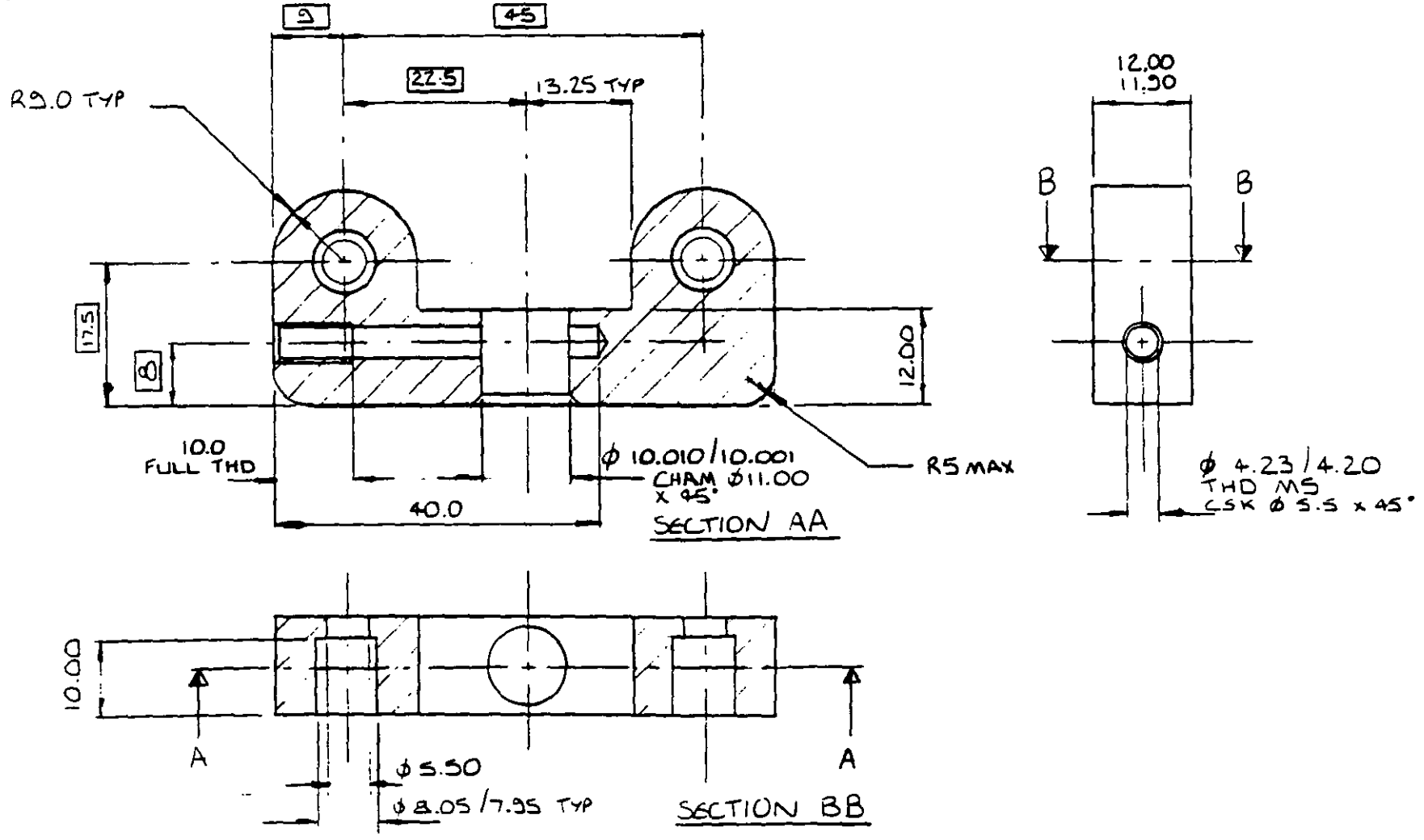
210 x 297mm A4

PART OF

DO NOT SCALE

SHEET 1 OF 1

DRG. No.



UNSPECIFIED TOLS :- X.X ±0.25 X.XX ±0.15 ANGLES ∠±1° NJ ⌖ 0.05 REMOVE ALL BURRS AND SHARP EDGES.

ISSUE	DESCRIPTION	APPD	DATE

MATL:- STAINLESS S. GL TO B.S. 5194 GRADE J

SCALE 2 : 1

TITLE

ARM

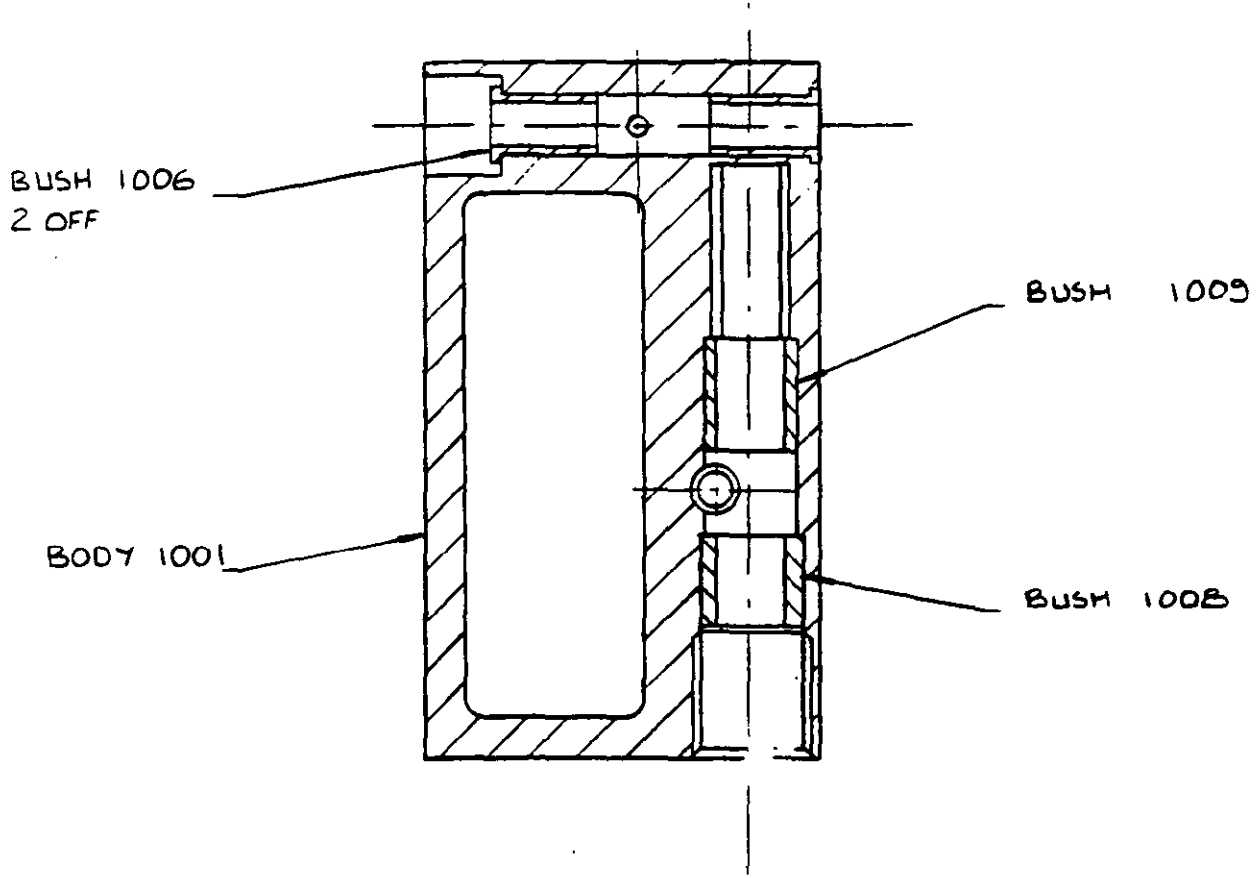
DRAWN	TRACED	CHECKED	APPROVED	DATE
SFA				

DRAWING No. 1022

RS 561-381

297 x 420mm A3

PART OF | DO NOT SCALE | SHEET OF | DRG. No.



ISSUE	DESCRIPTION	APPD	DATE

SCALE 1:1

TITLE: BODY ASSLY

DRAWN	TRACED	CHECKED	APPROVED	DATE
S.F.A.				

DRAWING No. 1023

PART OF

DO NOT SCALE

SHEET 1 OF 1

DRG. No.

STANDARD M5 x 8mm PAN HEAD SCREW.

MATL STAINLESS STEEL.

ISSUE	DESCRIPTION	APPD	DATE

TITLE: SCREW

DRAWN	TRACED	CHECKED	APPROVED	DATE

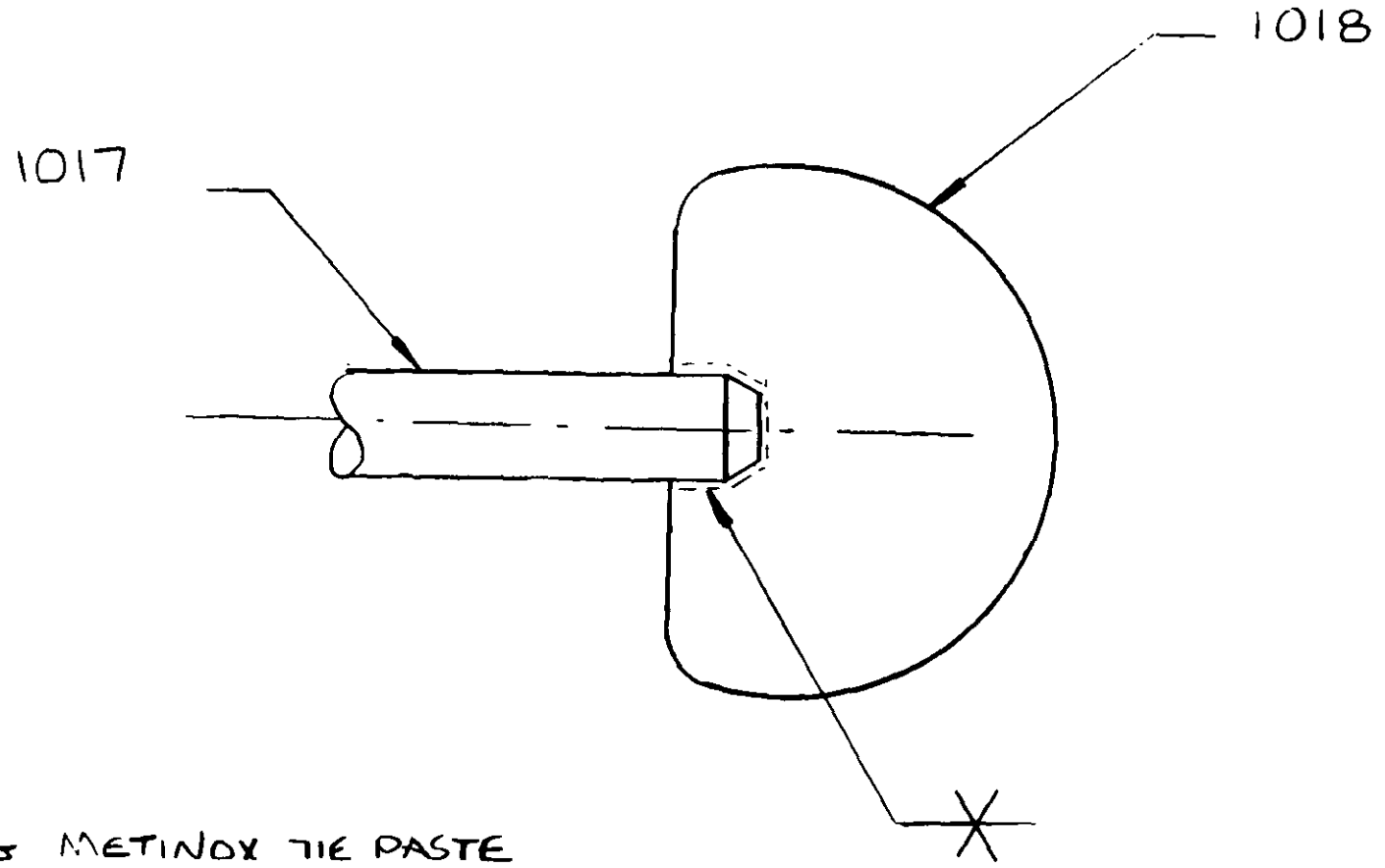
DRAWING No. 1024

RS 561-375

210 x 297mm A4

DO NOT SCALE

DRG. No.



CLEAN USING METINOX TIE PASTE

ISSUE	DESCRIPTION	APPD	DATE

TITLE
PINNION
KEY ASSY

DRAWN	TRACED	CHECKED	APPROVED	DATE
SFA				

DRAWING No. 1025

RS 561-375

210 x 297mm A4

PART OF

DO NOT SCALE

DRG. No.

STANDARD M5 STAINLESS STEEL WASHER

I.D 5.5/5.3

O.D 12.6/12.4

T 1.0

ISSUE	DESCRIPTION	APPD	DATE

TITLE: WASHER

DRAWN	TRACED	CHECKED	APPROVED	DATE
SFA				

DRAWING No. 1026

RS 561-375

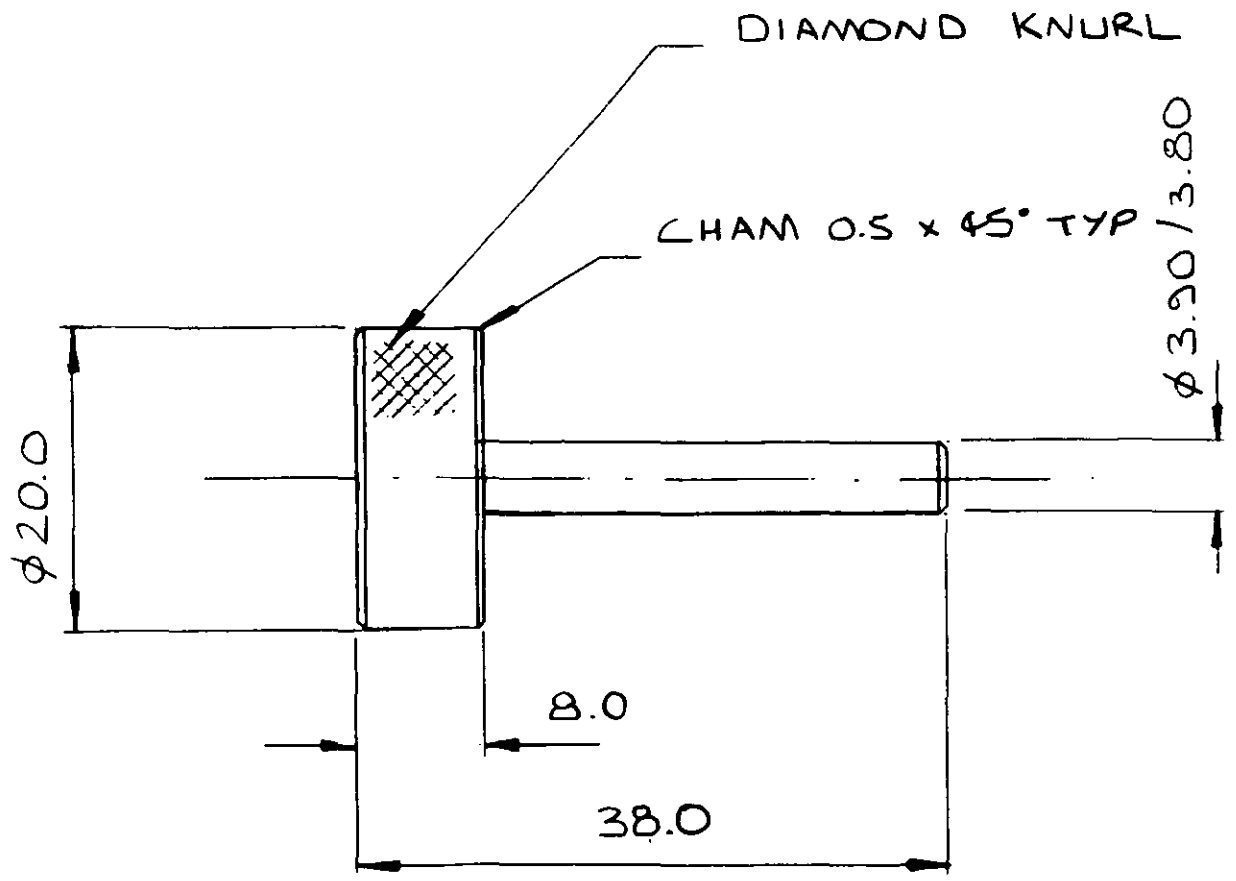
210 x 297mm A4

PART OF

DO NOT SCALE

SHEET

DRG. No.



UNSPECIFIED TOLS :- X.X ±0.25. X.XX ±0.15. ∠ 1°. REMOVE ALL BURRS AND SHARP EDGES

ISSUE	DESCRIPTION	APPD	DATE

MATL :- STAINLESS STEEL TO BS 5154 GRADE N

SCALE 2:1

TITLE

PIN

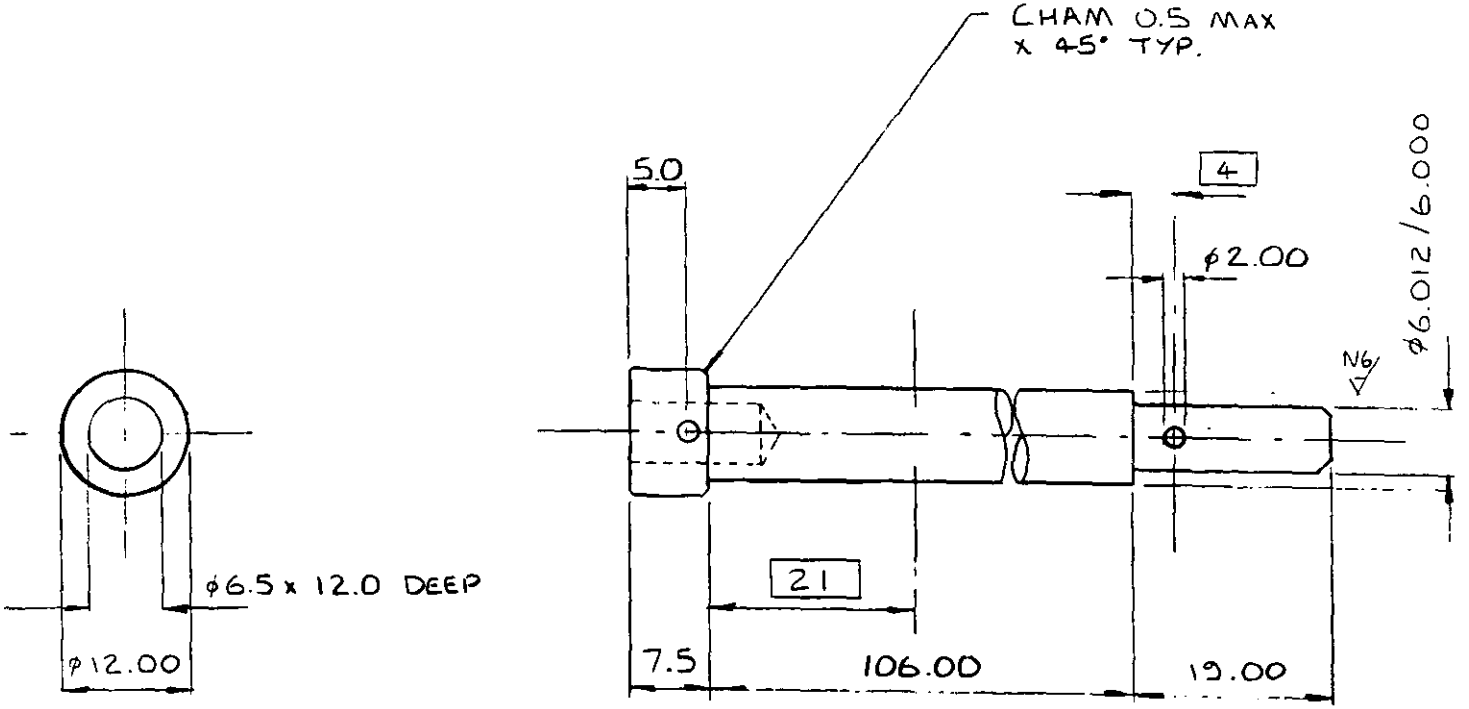
DRAWN	TRACED	CHECKED	APPROVED	DATE
SFA				

DRAWING No. 1027

RS 561-375

210 x 297mm A4

PART OF | DO NOT SCALE | SHEET OF | DRG. No.



UNSPECIFIED TOLS :- X.X ±0.25. X.XX ±0.15. ∠ 1°. REMOVE ALL BURRS AND SHARP EDGES. N7 | ⌖ | ϕ 0.5

ISSUE	DESCRIPTION	APPD	DATE

MATL :- STAINLESS STEEL TO BS 5134 PART 2

SCALE - 2 : 1

TITLE: SHAFT

DRAWN	TRACED	CHECKED	APPROVED	DATE
S. Ashfield				

DRAWING No. 1028

BS 561-3B

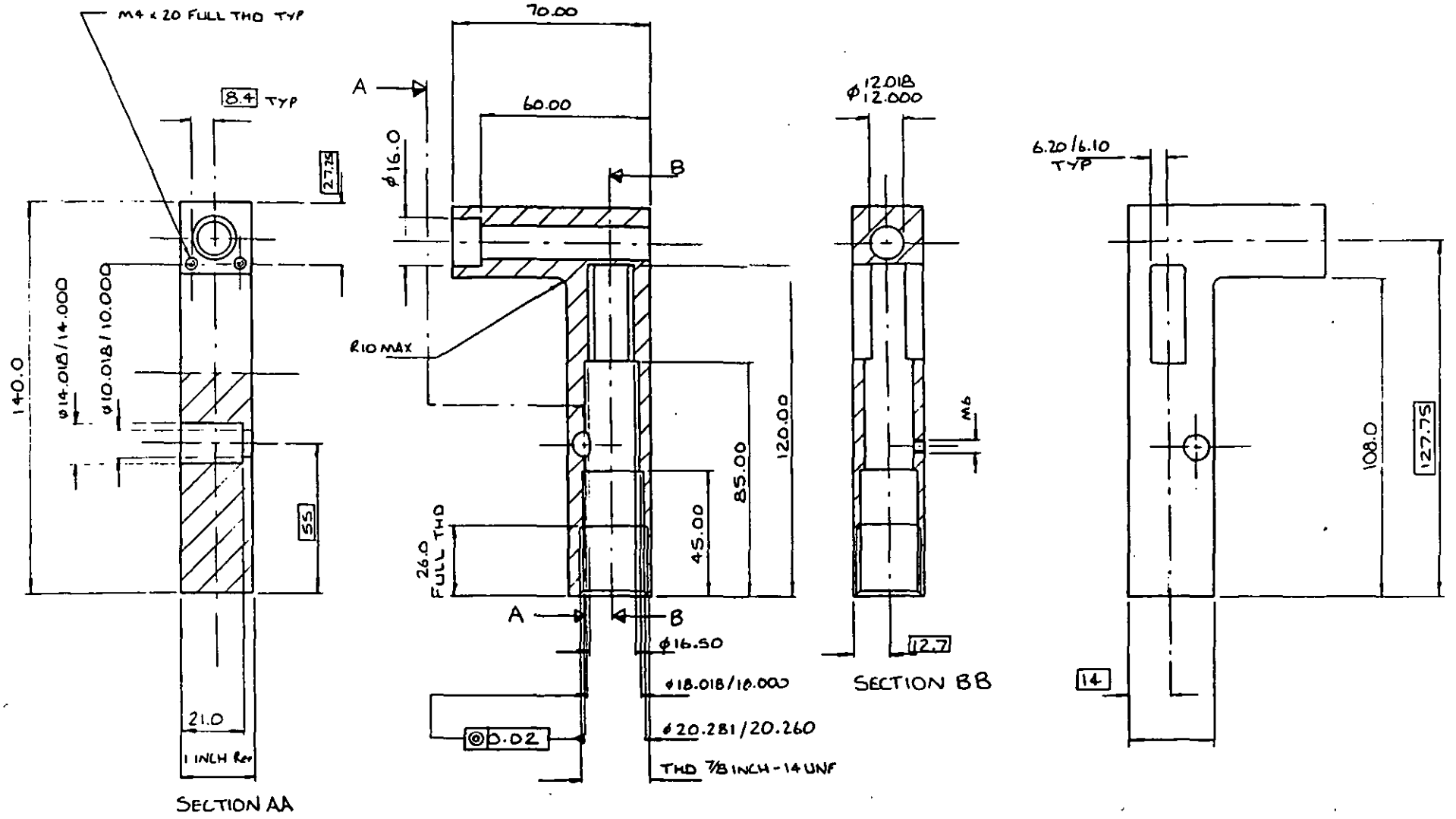
297 x 420mm A3

PART. OF

DO NOT SCALE

SHEET OF

DRG.No.



UNSPECIFIED TOLS, X·X ±0.25 X·XX ±0.15 ANGLES ±1° ∇. REMOVE ALL BURRS AND SHARPE EDGES. CHAM/RAD TO 0.5 MAX PERMISSIBLE ⌖ 0.02 TYP

ISSUE	DESCRIPTION	APPD.	DATE

MATL :- STAINLESS STEEL TO BS 5194 PART 2

SCALE 1:1

TITLE

BODY

DRAWN	TRACED	CHECKED	APPROVED	DATE
S F A				

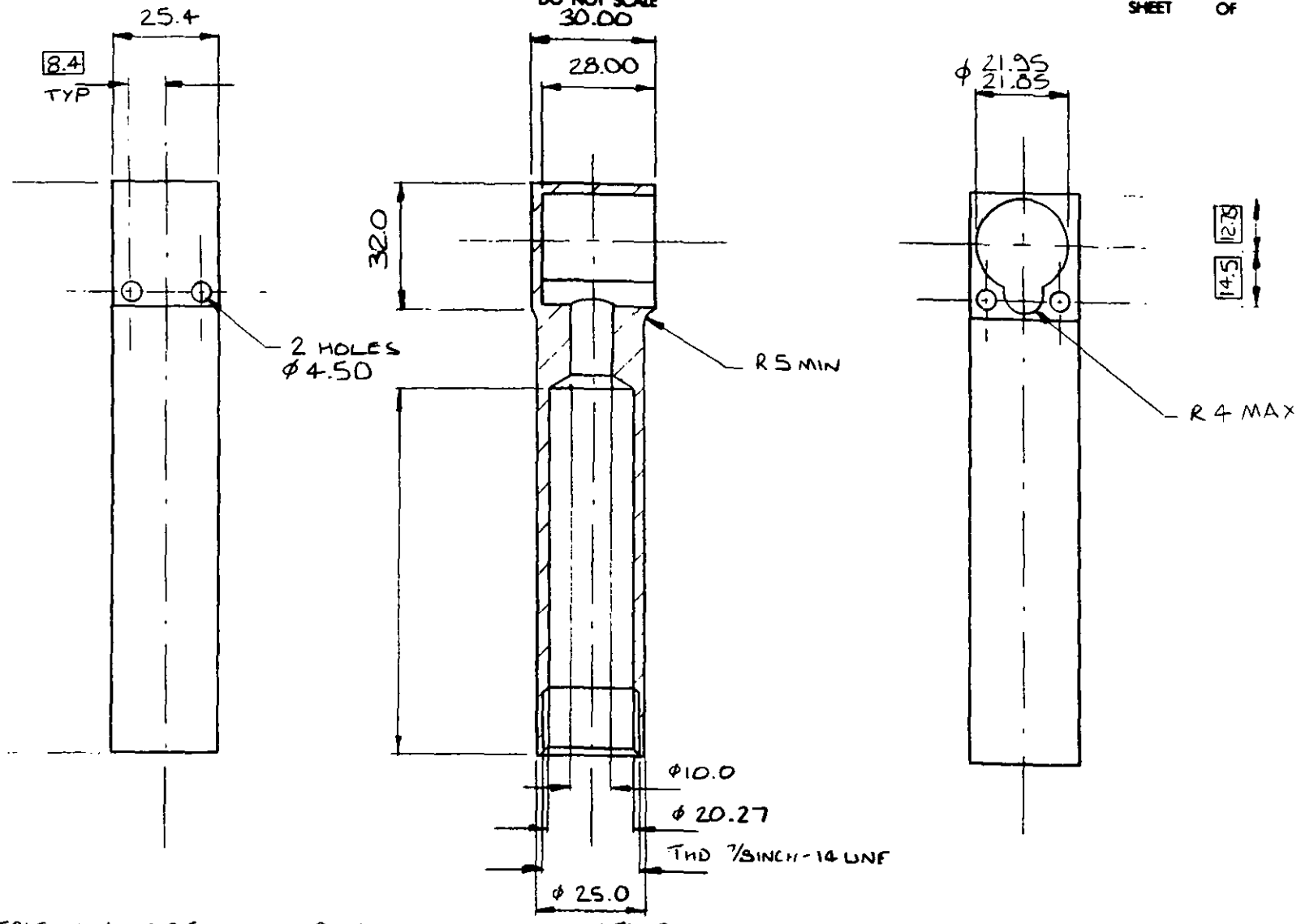
DRAWING No. 1029

PART OF

DO NOT SCALE

SHEET OF

DRG. No.



UNSPECIFIED TOLS X.X ±0.25 X.XX ±0.15 ANGLES ∠ ±1° ▽ REMOVE ALL BURRS AND SHARP EDGES

ISSUE	DESCRIPTION	APPD.	DATE

MATL :- STAINLESS STEEL

SCALE :- 1:1

TITLE

HANDLE

DRAWN	TRACED	CHECKED	APPROVED	DATE
SFA				

DRAWING No. 1030

BS 561-381

297 x 420mm A3

APPENDIX 2

TURBO PASCAL PROGRAMME

```
PROGRAM data;

VAR    n,sel,zero:integer;
       results:array[1..256,1..6]of real;
       row, error,col,p_col,c_col,error_a    : integer;
       FILENAME :STRING[13];
       inp   :string[1];
var
       store      : array[1..329]of integer;
       ch,
       t,y,
       ADPPI      : integer;

Const PORTA       : integer = 0;   { To address portA A0=0 A1=0.}
       PORTB      : integer = 1;   { To address portB A0=1 A1=0.}
       PORTC      : integer = 2;   { To address portC A0=0 A1=1.}
       CNTRL      : integer = 3;   { To address control A0=A1=1.}


Procedure InitAddr(NewAddr:integer);

begin
  ADPPI    := NewAddr;        { Base Address }
  port[ADPPI+CNTRL]:=$92      { Puts A/D in appropriate mode}
end;

Function  AdConv(chan:byte):integer;

  { This performs a single A/D conversion on the channel 'chan'}

var busy,
    SampleHI,
    SampleLO :byte;
    binary   :integer;
    scale    :real;

begin
   scale:=500/2048;


   port[ADPPI+PORTC]:= chan*16 + 2;     { selects the channel on the MUX }
   port[ADPPI+PORTC]:= chan*16 + 3;     { starts conversion by READ -> high}
   repeat
     busy:=port[ADPPI+PORTB] AND $20   { loop while conversion in progress }
   until busy<>0;
   sampleLO:=port[ADPPI+PORTA];        { get low byte}
   sampleHI:=port[ADPPI+PORTB] AND $0f; { get hi byte (4 bits only)}

   adconv  :=sampleHI*$100 + sampleLO -2048; { calcs digital voltage}
{   AdConv  :=round(binary*scale);  }         { scales for screen = +/- 10V}

end;
```

```
PROCEDURE menu(var option : integer);

var
  inp:string[1];
num_a,error_a    :integer;

 begin
    textbackground(8);
    clrscr;
    gotoxy(10,10);
    textcolor(3);
    writeln('OPTIONS:-');
    writeln('1)  COLLECT DATA.');
    writeln('2)  STORE DATA. ');
    writeln('3)  PRODUCE GRAPH OF DATA. ');
    writeln('4)  VIEW OLD DATA.');
    writeln('5)  REAL TIME READINGS');
    writeln('6)  END PROGRAM.');
    error_a:=0;
    repeat

      write('ENTER THE NUMBER OF THE REQUIRED PROGRAM: ');
      readln(inp);
      val(inp,option,error_a);
      if error_a <> 0 then
        begin
          writeln;
          writeln('Error, input NUMBER of required item');
        end;

    until error_a = 0
  end;


PROCEDURE graph;

VAR
 g_col,
 x1,x2,
 y1,y2,readings    :integer;
g_results  :array[1..180,1..6]of real;

begin
  clrscr;
  graphcolormode;
  graphbackground(0);
  textcolor(2);
  draw(1,1,1,200,1);
  draw(1,100,340,100,1);
  draw(1,39,340,39,1);
  draw(1,59,340,59,1);
  draw(1,80,340,80,1);
  draw(1,120,340,120,1);
  draw(1,141,340,141,1);
```

```
  draw(1,161,340,161,1);
  draw(36,1,36,220,1);
  draw(98,1,98,220,1);
  draw(160,1,160,220,1);
  draw(221,1,221,220,1);
  gotoxy(3,1);
  writeln('15mm');
  gotoxy(11,1);
  writeln('20mm');
  gotoxy(20,1);
  writeln('25mm');
  gotoxy(27,1);
  writeln('30mm');
  gotoxy(35,4);
  writeln('15ø');
  gotoxy(35,7);
  write('10ø');
  gotoxy(35,10);
  write('5ø');
  gotoxy(35,13);
  write('0ø');
  gotoxy(35,15);
  write('5ø');
  gotoxy(35,17);
  write('10ø');
  gotoxy(35,20);
  write('15ø');
  g_col:=1;
   for readings:=1 to 3 do
     begin
       for row:=1 to 179 do
        begin
          g_results[row,g_col]:=results[row,g_col];
          g_results[row,g_col+1]:=results[row,g_col+1];
          g_results[row+1,g_col]:=results[row+1,g_col];
          g_results[row+1,g_col+1]:=results[row+1,g_col+1];
          x1:=round(((g_results[row,g_col]-492)*0.3));
          y1:=100-round((g_results[row,g_col+1])*0.1);
          x2:=round(((g_results[row+1,g_col]-492)*0.3));
          y2:=100-round((g_results[row+1,g_col+1])*0.1);
           if x2 > 0 then
             begin
               draw(x1,y1,x2,y2,15);
             end;
        end;
      g_col:=g_col+2
     end;

  readln;
end;

PROCEDURE check_files;

var
```

```
 x  :byte;
 d_file    :text;

begin
   clrscr;
   ASSIGN(D_FILE,FILENAME);
   {$I-}
   reset(d_file);
   {$I+}
   x:=IOresult;
    if x=0 then
     begin
       writeln('FILE ALREADY EXISTS');
       readln;
       menu(sel);
     end;
  end;

PROCEDURE collect;
  var
  ans,row,prev_sep,sep :integer;
  gap,angle,q      :real;

begin
   clrscr;
   q:=0;
   ans:=0;
   clrscr;
   gotoxy(10,10);
   writeln('1)  NEW PATIENT.');
   writeln('2)  CONTINUE WITH PRESENT PATIENT.');
   writeln('3)  RETURN TO MENU.');

   error_a:=0;
   repeat
    writeln('ENTER SELECTION');
    readln(inp);
    val(inp,q,error_a);
     if error_a <> 0 then
       begin
         writeln;
         writeln('Error, input NUMBER of required item');
       end;
   until error_a = 0;


    if q=2  then
      begin
       c_col:=c_col+2;
      end;

    if q=1  then
      begin
        clrscr;
```

```
          gotoxy(10,5);
          textcolor(2);
          writeln('CURRENT FILE IS "',FILENAME,'".');
          gotoxy(10,10);
          textcolor(3);
          write('FILENAME FOR DATA STORING:');
          readln(filename);
          CHECK_FILES;
        for row:=1 to 180 do
           begin
             for c_col:=1 to 6 do
               begin
                 results[row,c_col]:=0;
               end;
           end;
         c_col:=1;
       end;

   if ((q = 1) or (q = 2)) then
     begin
       InitAddr($0300);
       clrscr;
       row:=1;
       gotoxy(23,14);
       writeln('START READINGS');
       prev_sep:=adconv(9);
       repeat
         sep:=adconv(9);
         if  ( prev_sep < (sep-4)) then
           begin
             prev_sep:=sep;
             results[row,c_col]:=adconv(9);
             results[row,c_col+1]:=adconv(0);
             writeln(results[row,c_col]:4:2,'   ',results[row,c_col+1]:4:2);
             row:=row+1;
             if row >180 then
               row :=180;
           end;
        until keypressed;
      col :=c_col;
    end;
end;

PROCEDURE log;

var
  c,h,l_col      : integer;
  d_file    : text;

begin
    assign(d_file,filename+'.dat');
    rewrite(d_file);
     for row:=1 to 179 do
       begin
```

```
      for l_col:=1 to 6 do
        begin
          write(d_file,results[row,l_col]* 0.0244:4:4,'  ');
        end;
        writeln(d_file);
    end;
  close(d_file);
end;


PROCEDURE old;
{show directory of data files in load chosen one}
 var
   A,t,o_col,num_b,error_b:integer;
   d_file:text;

 begin
  a:=1;
  if (col>0) then
    begin
      clrscr;
      gotoxy(10,10);
      writeln('CANCELL PRESENT DATA?');
      writeln('1   YES');
      writeln('2   NO');
  error_a:=0;
  repeat
   writeln('ENTER SELECTION');
   readln(inp);
   val(inp,a,error_a);
    if error_a <> 0 then
      begin
        writeln;
        writeln('Error, input NUMBER of required item');
      end;
    until error_a = 0;
    end;
 if (a=1) then
 begin
  for row:=1 to 180 do
   begin
    for o_col:=1 to 6 do
     begin
       results[row,o_col]:=0;
     end;
   end;

  clrscr;
  gotoxy(10,10);
  textcolor(4);

  write('FILENAME FOR DATA RETREVAL:');
  readln(filename);
  val(filename,num_b,error_b);
```

```
   assign(d_file,filename+'.dat');
   reset(d_file);
    for row:=1 to 180 do
     begin
       for o_col:=1 to 6 do
        begin
          read(d_file,results[row,o_col]);
          results[row,o_col]:=results[row,o_col]*40.96;
        end;
     end;
   close(d_file);
   clrscr;
   graph;
   end;
 end;

PROCEDURE time;

Var
  thick,ang,ext : real;

Begin
      InitAddr($0300);
       clrscr;
       graphcolormode;
       graphbackground(15);
           repeat
             ang:=adconv(0)/40.96;  {2048/50}
             ext:=adconv(9)/40.96;
             thick:=ext-10;
             gotoxy(1,1);
             write('ANGULAR DEVIATION IS   ',ang:2:1, ' DEGREES');
             gotoxy(1,5);
             write('EXTENSION GAP IS   ',ext:2:1, 'mm');
             gotoxy(1,10);
             write('TIBIAL THICKNESS REQUIRED  ',thick:2:1, 'mm');
             delay(30);
           until keypressed;
end;


BEGIN
 for p_col:=1 to 6 do
  begin
   for row:=1 to 180 do
    begin
      results[row,p_col]:=0;
    end;
  end;
   sel:=7;
   while (sel<>6) do
    begin
       menu(sel);
```

```
        case sel of
          1 : begin
                collect;
                graph;
                log;
              end;
          2 : log;
          3 : graph;
          4 : old;
          5 : time;
        end;
      end;
end.
□
```

APPENDIX 3

QUANTIFICATION OF SOFT TISSUE IMBALANCE. A.Sambatakakis, S.F.Attfield, G. Newton, J.Biomed. Eng. 1993, Vol 15, pp339-343.

Quantification of soft-tissue imbalance in condylar knee arthroplasty

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ABSTRACT

Soft-tissue balance has been debated in recent publications in connection with the long-term survival of the 'condylar-type' knee prostheses. Present methods of assessment have all assumed that the soft tissues around the knee are inelastic strings. The authors have developed two instruments to quantify soft-tissue imbalance, at the time of the operation, with the assumption that the soft tissues are viscoelastic structures. These two soft-tissue balancing devices were consequently used on 121 patients undergoing condylar knee arthroplasties at the Derbyshire Royal Infirmary and Bretby Hall Orthopaedic Hospital. The first instrument consisted of two flat plates separated by four standard compression springs and provided a qualitative measure of imbalance assuming that the soft tissues were viscoelastic. It was used on 55 patients before being replaced by the quantitative measure of the second instrument. The authors have redefined soft-tissue imbalance, to take into account the viscoelastic nature of the soft tissues, as the resultant trapezoidal geometry of the knee after the bony cuts have been made and when the knee is tensed by equal forces both medially and laterally. The second balancer eliminates the requirement to quantify the individual tensions in the medial and lateral structures by introducing to the system a low-friction, central pivot in the coronal plane. Once the pivot is situated at the centre of the knee, an equilibrium position is achieved where the clockwise and counter-clockwise moments are equal. The tensions exerted by soft tissues can be assumed to be equal and opposite as their moment arms are the same. Imbalance is quantified by the angular displacement of the top plate of the instrument in finding its equilibrium position. This instrument was subsequently used on 66 knees at the Bretby Hall Orthopaedic Hospital.

Keywords: Balancer, imbalance, knee, arthroplasty, arthritis

INTRODUCTION

Pioneering work on condylar knee arthroplasty defined correct bony alignment and soft-tissue balance as the important principles necessary for the replacement of the arthritic knee joint[1–3]. As surgical instrumentation evolved, the order in which the bony cuts and soft-tissue balancing procedures were performed reversed. This fundamental change influenced the actual relationship between bony alignment and soft-tissue balance. Currently, most surgeons prefer to perform the bony cuts first, followed by sequential soft-tissue releases where necessary.

Modern instrument sets allow for the angles of the bony osteotomies to be performed more accurately, but because the bony cuts are made independently of the soft tissues, the possibility increased of leaving the arthroplasty imbalanced.

Some authors have suggested that releases should be performed until acceptable balance has been achieved[4]. Some have said that a small amount of imbalance is tolerable, but a large amount is not[5,6]. Others have stressed the long-term detrimental effects of imbalance without attempting to distinguish between large and small degrees of imbalance[7].

The limits of tolerance for imbalance can only be established by the long-term follow-up of balanced and imbalanced arthroplasties[8]. To discuss the problem quantitatively, a clear definition of imbalance and how to measure it needs to be developed.

Soft-tissue imbalance in both extension and flexion has been defined as having the geometry of a trapezoid[9]. As the soft tissues around the knee are not inextensible strings, but viscoelastic, extendable structures, this definition needs to be redetermined. Soft-tissue imbalance can be described as the resultant trapezoidal geometry, after the bony cuts have been made, and when the knee is tensed by equal medial and lateral forces.

Using this definition, imbalance can be quantified in terms of the difference in length between the medial and lateral sides of the trapezoid or as rotary deflection away from the parallel, or zero, position.

A number of methods and instruments for assessing soft-tissue imbalance have been described[6,10–12], all aiming to provide a measure of imbalance. These methods all assume that the soft tissues are inelastic strings and not viscoelastic structures[1]. Before any

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valuable discussion can take place on tolerable amounts of soft-tissue imbalance, a method of quantifying it with respect to bony osteotomies needs to be developed.

MATERIAL AND METHODS

Two surgical instruments have been developed to assess the soft-tissue imbalance during a condylar knee arthroplasty. The first instrument consists of two plates, ground parallel, and four standard compression springs of free length 25.4 mm and spring rate 6.48 N mm^{-1}, *Figure 1*. The springs are located in flat-bottomed holes, close to the corners in both top and bottom plates. The dimensions of the plates are 70 × 45 × 6 mm. The overall height of the device with no compressive forces applied is 27 mm and the minimum height is 15.5 mm when the springs reach their solid height. A vernier caliper was used to measure the lengths, between scribed marks positioned on the medial and lateral anterior surface of the instrument, to an accuracy of 0.1 mm. The plates were compressed before being inserted into the knee using an applicator, consisting of a rack-and-pinion tensing mechanism.

Theoretically, this device only applies equal forces to both medial and lateral structures after any necessary releases have been made and the springs have been compressed to equal lengths. Balance can be assumed at this point, but the extent of imbalance cannot be estimated when the instrument shows a trapezoidal geometry, as different forces are applied medially and laterally. Soft-tissue balance was assumed when the difference between the medial and lateral vernier measurements was less than 0.5 mm, see *Figure 2*.

Figure 1 The first surgical instrument placed inside the knee and showing the trapezoidal shape of soft-tissue imbalance

Figure 2 The first surgical instrument placed inside the knee and showing the parallel shape after the soft tissues have been released

The second instrument[13] introduces a low-friction central pivot in the coronal plane, and an integral rack-and-pinion tensing mechanism. All the springs common to the first instrument have been discarded, see *Figure 3*. The angular rotation of the top plate and the bony separation gap are quantified by clear engraved scales on the body of the instrument away

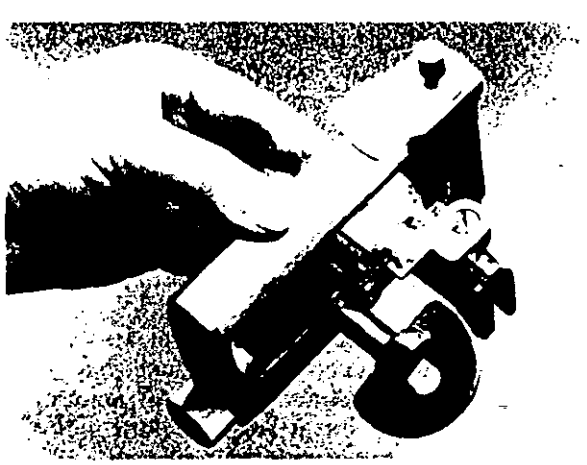

Figure 3 The second surgical instrument, shown with the top plate rotated to represent imbalance. This instrument is now used routinely at the Derby hospitals

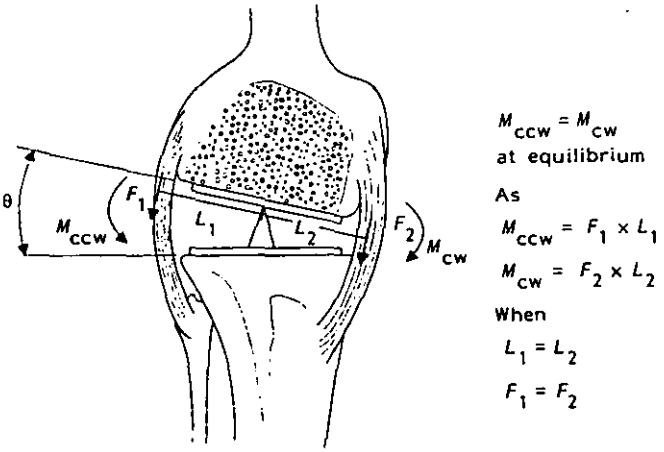

Figure 4 The definition of angular displacement as a unit to quantify soft-tissue imbalance

from the protracted soft tissues and patella, to an accuracy of one degree and one millimetre respectively. Equal forces exerted by the medial and lateral soft-tissue structures are guaranteed when the pivot is positioned at the centre of the knee, and the top plate reaches its equilibrium position, where the clockwise and counter-clockwise moments are equal, see *Figure 4*. This relationship allows the imbalance to be measured at any bony separation gap. Imbalance can therefore be quantified in terms of the angular displacement, θ, of the device's top plate relative to the bottom plate. The balancer assumes that the bony alignment has been correctly achieved with the intra- and extra-medullary jigs, allowing soft-tissue imbalance to be related to the angle of the bony cuts. The instrument has the additional feature of being an adjustable spacer. A locking pin can be placed through the top shaft after all balancing procedures have been performed, securing the two plates in a parallel position.

A preliminary investigation was performed on ten fresh cadaveric knees to test the compliance of these instruments. Seven of these exhibited macroscopic changes in the cartilage, consistent with arthritis. The remainder were normal. Four of the arthritic knees exhibited medial-tibial changes and three exhibited lateral ones. All the patients had died from unrelated causes and were over 78 years of age, with an average age, at death, of 81. Four of the five subjects (ten knees) had clinical symptoms consistent with arthritis of the knees.

The instruments were subsequently used on 121 patients as a routine surgical balancing instrument at the Derbyshire Royal Infirmary and Bretby Orthopaedic Hospital. The proportions of rheumatoid arthritis, osteoarthritis, varus and valgus knees that were encountered using each instrument are shown in *Table 1*.

The standard operative sequence was performed

Table 1 The proportion of rheumatoid arthritis and osteoarthritis, varus and valgus knees encountered by the two instruments

		Varus	Valgus
Instrument 1	Osteoarthritis	32	14
	Rheumatoid arthritis	3	6
Instrument 2	Osteoarthritis	57	3
	Rheumatoid arthritis	3	3

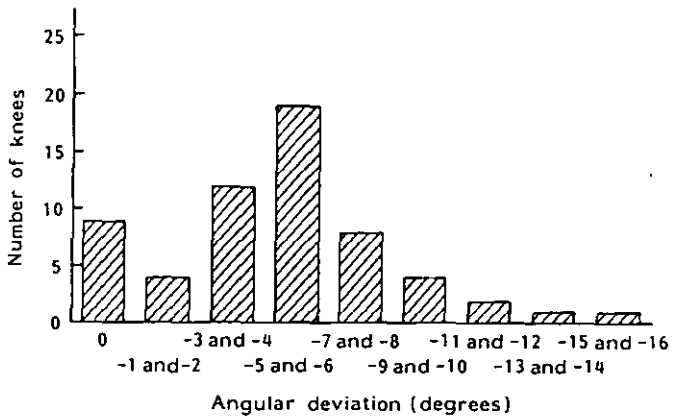

Figure 5 A histogram showing the angular displacement of 60 varus knees before any soft-tissue balancing procedures

in all cases. A 97° distal femoral osteotomy was performed using intramedullary instrumentation, followed by the anterior and posterior cuts, using standard jigs, and finally, the 90° tibial osteotomy was performed using extramedullary jigs. The soft-tissue imbalance was assessed, using either of the instruments, before any releases were made, with the exception of the removal of any osteophytes. Next, surgical releases were performed until balance was assumed. A polytetrafluoroethylene (PTFE) sheet was introduced to reduce the friction between the leg and the surgical drapes.

The soft tissue structures released and the final tibial insert thickness were both noted when either of the instruments was used, and the angular displacement and separation gap were noted with the second balancer.

RESULTS

The first instrument was used on 35 varus and 20 valgus knees. Out of the total population of 55 knees, 78% required formal soft tissue releases before balance was attained.

The second instrument was used on a population of 66 knees. The angular displacement of the predominant group of 60 varus knees ranged from 0–16° (*Figure 5*). As shown in *Figure 6*, 15% of the knees did

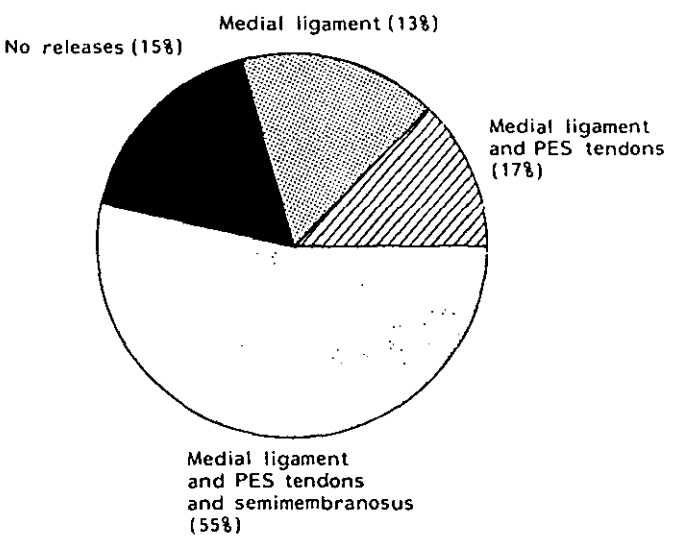

Figure 6 A pie chart showing the proportion of structures released to gain soft-tissue balance

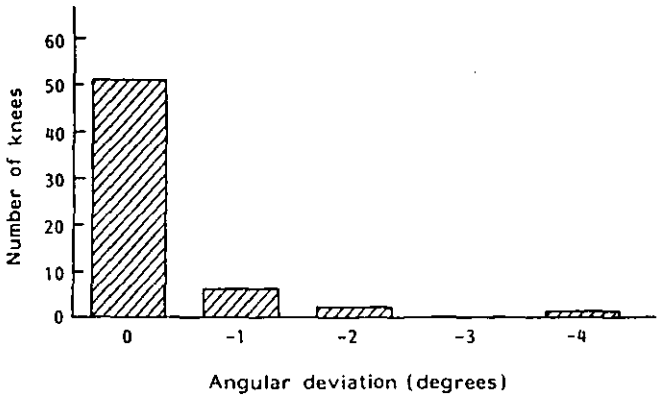

Figure 7 A histogram showing the angular displacement of 60 varus knees after soft-tissue balancing procedures

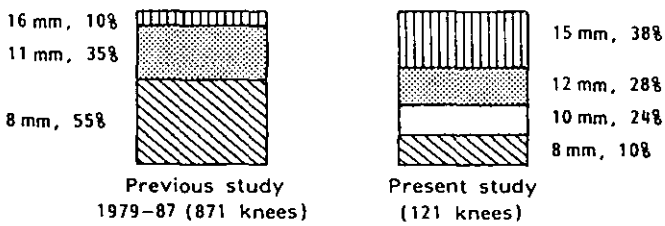

Figure 8 A comparison of the tibial component thickness inserted between the present and the previous study

not require any formal anatomical releases to achieve soft-tissue balance, 13% required the release of the medial collateral ligament, 17% required the release of the medial collateral ligament and all the pes tendons, 55% required the release of the medial collateral ligament, the pes tendons and the semimembranosus. The mean and standard deviation values of the 51 varus knees that were imbalanced were $-5.8°$ and 2.71, respectively. After all formal balancing procedures had been performed the range of imbalance decreased to between 0–4°, see *Figure 7*.

The comparison made between the tibial component thicknesses inserted in a previous study (1979–87) and the present study is shown in *Figure 8*. In 55% of the arthroplasties in the previous study, an 8 mm tibial component was used[14]. In this study of 121 arthroplasties only 1% used this thickness.

DISCUSSION

The traditional tensors and spacers contributed to the understanding of the surgical pathology of arthritis and the description of the fixed deformity of the knee[15]. However, the surgical technique associated with them could not always guarantee satisfactory bony alignment. The introduction of intra- and extramedullary jigs solved this problem, at the expense of soft-tissue balance[16].

The authors have demonstrated in the population of 60 varus knees using the second instrument, that 85% of the knees undergoing condylar knee arthroplasty required surgical releases to achieve soft-tissue balance. After the medial collateral ligament had been totally released, imbalance remained in 73% of the population. Previous methods of estimating imbalance have assumed that the ligamentous structures of the knee represent inelastic strings. This assumption is now clearly inaccurate as imbalance still remains in this large proportion of knees after this 'string' has been totally released. The passive imbalance of the knee needs to be considered in terms of the viscoelastic characteristics of all the soft tissues surrounding the knee.

The measurement of the individual tensions of the soft-tissue structures *in vivo* at the time of operation is notoriously difficult. The second instrument eliminates the requirement to measure the tensions directly by ensuring that the medial and lateral tensions are always the same with a simple balancing mechanism. Imbalance is then defined as the angular displacement θ. We have shown that soft-tissue imbalance can be quantified and diminished using surgical releasing procedures, whilst considering the soft-tissue structures to be viscoelastic. If the pivot is not positioned centrally in the coronal plane within the knee then there will be a difference in the medial and lateral soft-tissue tensions. We made the instrument's plates as large as possible using previously published data on the mean size of the femoral condyles. Further work is needed to estimate this error and to establish if a series of interchangeable plates of varying lengths would be beneficial to the instrument. Also friction between the lower leg and the surgical drapes was identified as a source of error. This underestimation of imbalance was eliminated by introducing the PTFE plate underneath the lower leg.

Compared to the authors' previous study[14] the proportion of thicker tibial component inserts used during this study has dramatically increased. The operative technique of the bony osteotomies has remained constant throughout both studies, suggesting that the magnitude of the soft-tissue releases used at present is responsible for this dramatic increase in component thickness. Consequently this technique indirectly addresses the current problems of plastic wear and tibial tray failure by inserting thicker components that distribute more evenly the compressive stresses throughout the two condyles.

The introduction of the second balancer has shown that soft-tissue balance can be quantified and eliminated using surgical releasing procedures. It is hoped that this instrumentation will contribute to a rational discussion on the imbalance tolerance limits, in relation to the long-term survival of total knee arthroplasties.

ACKNOWLEDGEMENTS

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APPENDIX 4

UK PATENT APPLICATION 9222720. The Derby Balancer.

(12) UK Patent Application (19) GB (11) 2 261 604 (13) A

(43) Date of A publication 26.05.1993

(21) Application No 9222720.6

(22) Date of filing 29.10.1992

(30) Priority data
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(51) INT CL[5]
A61B 17/56, A61F 2/46

(52) UK CL (Edition L)
A5R RAT

(56) Documents cited
EP 0327249 A2 US 4501266 A

(58) Field of search
UK CL (Edition L) A5K K6, A5R RAT, G1W WE6B
INT CL[5] A61B 5/103 5/107 5/11 17/00 17/56 19/00,
A61F 2/46
Online databases: WPI

(54) Surgical apparatus for use in knee surgery

(57) Surgical apparatus comprises first and second tissue engaging means 14, 16. The first tissue engaging means is displaceable towards and away from the second tissue engaging means. At least one of the first and second tissue engaging means 15 adapted to be oriented by the tissue engaged thereby. Measuring means such as a vernier scale or electronic means may be connected to the shaft 22 of the first tissue engaging means to measure displacement and similar measuring means may be attached to shaft 34 to measure rotation of the second tissue engaging means. The invention is particularly suitable for knee surgery where it can be important to determine the degree of imbalance between the medical and laterial soft tissue around the knee.

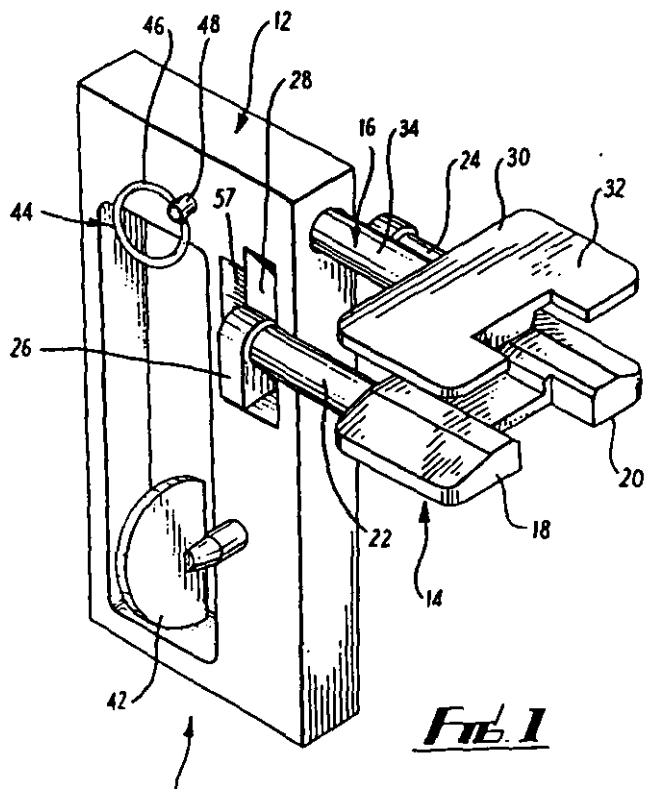

FIG. 1

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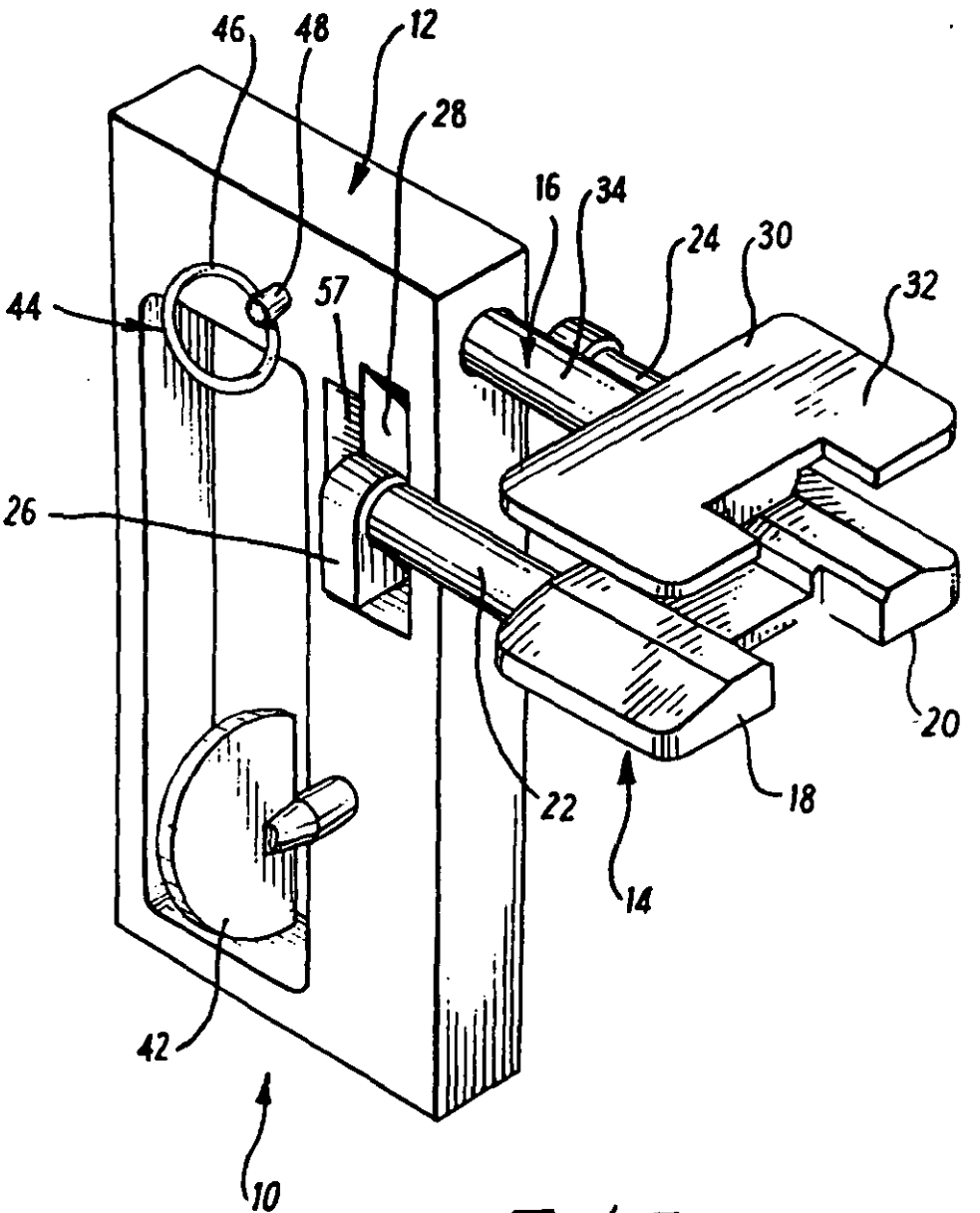
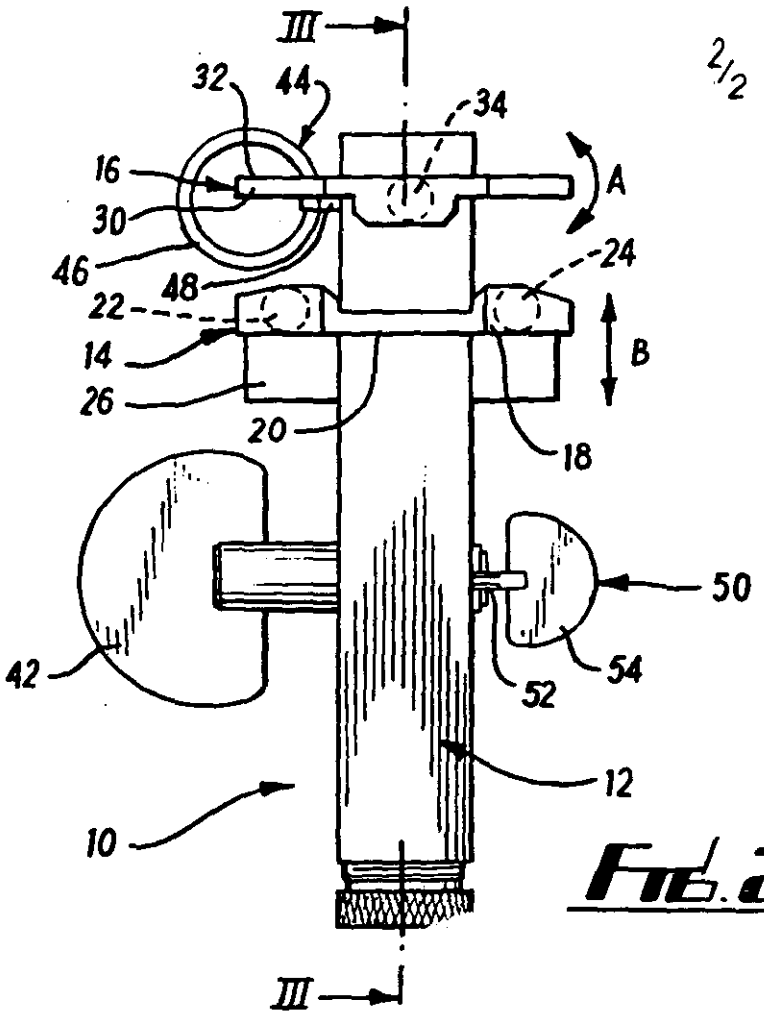


FIG. 1


III
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A
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B
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III

FIG. 2

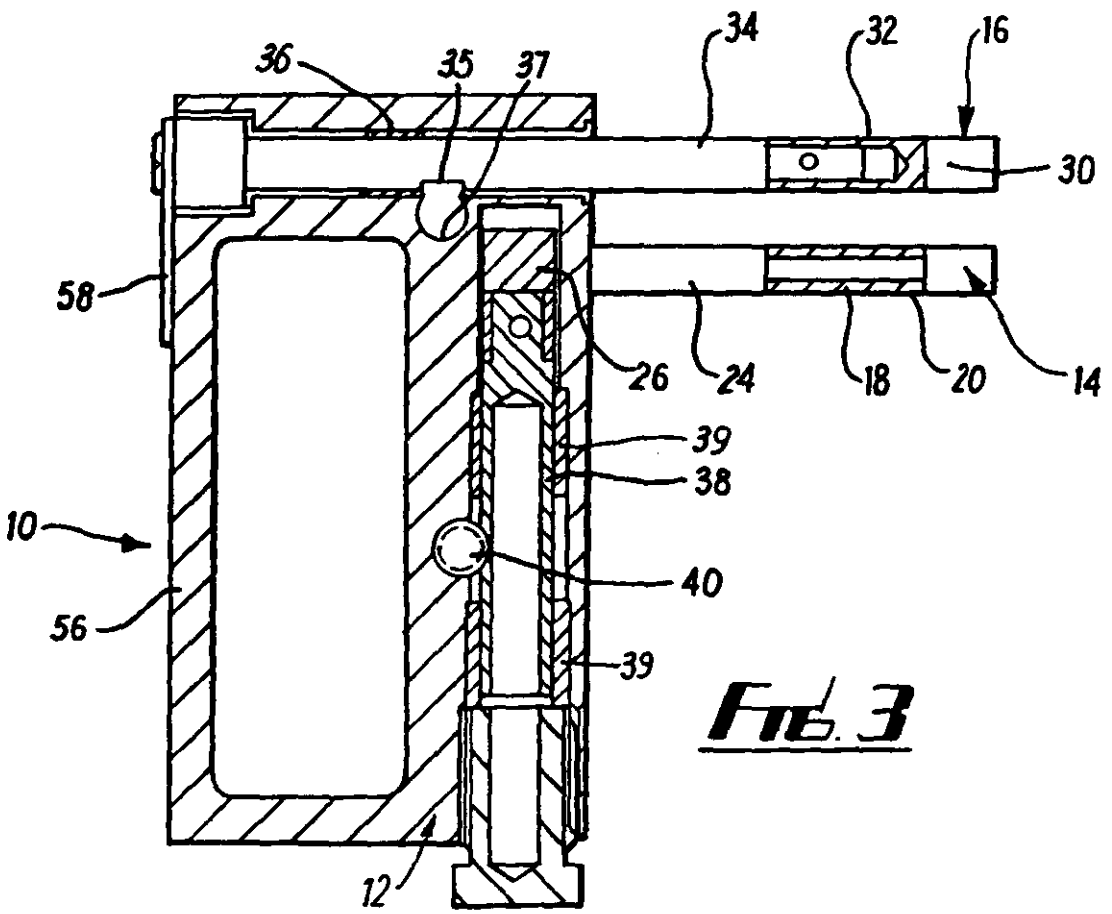
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FIG. 3

IMPROVEMENTS IN OR RELATING TO SURGICAL APPARATUS

This invention relates to surgical apparatus. Particularly, but not exclusively, this invention relates to surgical apparatus for use in knee surgery and especially total knee arthroplasty.

During total knee arthroplasty, it could be beneficial to eliminate the passive deforming forces around the knee associated with soft tissue imbalance at the time of surgery. Such elimination is achieved by gradual soft tissue releases of the contracted tissues around the knee. In order to carry out this technique successfully, the surgeon has to ensure that the tension of the medial and lateral soft tissue structures of the knee is symmetrically balanced. This is done solely by estimation, which is disadvantageous since if, after surgery, the knee is imbalanced, then failure of the prosthesis can result.

U.S. patent specification No. 4501266 discloses a device for use in knee arthroplasty. This device applies measured forces to both the medial and laterial compatments of the knee joint but has the disadvantage that it does not provide any means for determining whether the knee is symmetrically balanced. U.S. patent specification No. 5116338 also discloses a device for use in knee surgery. The device enables the surgeon

to apply unknown forces to the bones in the knee joint does not provide any means for determining whether the knee is symmetrically balanced.

It is an object of this invention to obviate and/or mitigate the disadvantages of these devices.

According to this invention there is provided surgical apparatus comprising first and second tissue engaging means, the first tissue engaging means being displaceable towards and away from the second tissue engaging means, wherein at least one of said first and second tissue engaging means is adapted to be oriented by the tissue engaged thereby.

The surgical apparatus is particularly suitable for use in joint replacement surgery, and in such cases the tissue engaged by the first and second tissue engaging means is bone tissue, for example bone tissue of the tibia and femur in a knee joint.

Preferably, the first and second tissue engaging means define respectively first and second tissue engaging surfaces, which may be substantially planar, and each of said tissue engaging means being desirably arranged such that said surfaces face away from each other.

In a preferred embodiment, only said second tissue engaging means is adapted to be oriented by the tissue engaged thereby. Preferably, said second tissue engaging means is adapted to be rotatably oriented by said tissue engaged thereby.

Measuring means may be provided to measure the degree of deflection of said second tissue engaging surface away from a position of parallelism with the first tissue engaging surface when said first and second tissue engaging means engage the tissue.

Locking means may be provided to lock the second tissue engaging means such that the first tissue engaging surface is parallel with the second tissue engaging surface. The locking means may comprises a pin adapted to engage said second tissue engaging means.

Preferably, the apparatus comprises displacement means to displace the first tissue engaging means towards or away from the second tissue engaging means. the displacement means may comprise a gearing arrangement. Preferably, the gearing arrangement comprises a rack and pinion assembly. Securing means may be provided to secure the first tissue engaging means at any desired separation from the second tissue engaging means. Preferably, the securing means

comprises a threaded member adapted to engage the displacement means.

The apparatus may comprise a main body part and each of the first and second tissue engaging means may comprises a shaft mounted on the main body part and a plate defining said tissue engaging surface. Preferably, the first tissue engaging means comprises two of said shafts mounted respectively on either side of the main body part and connected to each other by a connecting member. The connecting member is preferably mounted on the displacement means. Preferably the second tissue engaging means comprises only one of said shafts rotatably mounted in the main body part.

Preferably, the measuring means is connected to the shaft of the first tissue engaging means and may comprise a vernier scale. Alternatively, the measuring means may be electronic and may comprise a suitable transducer.

The main body part may include a handle to enable the apparatus to be manipulated manually.

An embodiment of the invention will now be described by way of example only with reference to the accompanying drawings in which:

Fig. 1 is a perspective view of a surgical apparatus;

Fig. 2 is a front view of the apparatus shown in Fig. 1; and

Fig. 3 is a sectional view along the lines III-III in Fig. 2.

Referring to the drawings, there is shown surgical apparatus 10 for use in knee surgery. The apparatus 10 comprises a main body 12, and first and second tissue engaging means 14,16. The first tissue engaging means 14 comprises a first plate 18 defining a first tissue engaging surface 20 which faces downwardly in the example shown in Fig. 1. The first tissue engaging means 14 also includes two shafts 22,24 which connect the first plate 18 to the main body 12 and extend on either side of the main body 12. A connecting means 26 extends through an aperture 28 in the main body 12 to connect the shafts 22,24 together.

The second tissue engaging means 16 comprises a second plate 30 defining a second tissue engaging surface 32. The second tissue engaging surface 32 faces in the opposite direction to the first tissue engaging surface 20, as shown in the drawings. The second tissue

engaging means 16 includes a shaft 34 extending from the plate 30 into the main body part 12 in which it is rotatably mounted in low friction bushes 36 such that it can rotate in the directions shown by the double headed arrow A (see Fig. 2).

The first tissue engaging means 14 is displaceable towards and away from the second tissue engaging means 16 in the directions shown by the double headed arrow B in Fig. 2. Displacement means in the form of a rack 38 and a pinion 40 are provided to displace the first tissue engaging means 14 in the directions shown by the arrow B. A key 42 is used to turn the pinion 40 to displace the first tissue engaging means 14. The rack 38 is mounted in low friction bushes 39.

Securing means 50 is provided to secure the first tissue engaging means 14, at any desired separation from the second tissue engaging means 16. Locking means 44 is provided to lock the second tissue engaging means 16 such that the second tissue engaging surface 32 is parallel to the first tissue engaging surface 20.

The locking means 44 comprises a pin 48 having a looped head 46 and can be received in the main body 12 through a bore 37. The pin 48 is substantially cylindrical in configuration and is provided with a

planar portion adapted to engage a correspondingly planar portion 35 on the shaft 34. When the pin 48 is inserted into the main body 12, the planar portion on the pin 48 and the planar portion on the shaft 34, engage each other to lock the second tissue engaging means 16 such that the second tissue engaging surface 32 is parallel to the first tissue engaging surface 20.

The securing means 50 comprises a threaded member 52 having a handle 54. The threaded member 52 is threadably received in the main body 12 and by screwing the threaded member 52 into the main body 12 by means of the key 54, the threaded member 52 can engage the rack and pinion 38,40 to secure the first tissue engaging means at any desired separation from the second tissue engaging means thereby preventing the first and second tissue engaging means 14,16 from being closed under the tension of the soft tissue surrounding the knee.

The main body 12 is provided with a handle 56 to enable the apparatus to be held by a surgeon for appropriate manipulation.

Measuring means in the form of a first vernier scale 57 is provided on the main body 12 (see Fig. 1) to measure the amount of displacement of the first tissue engaging means, and thereby measure the mean distance between the first and second tissue engaging surfaces 18,32.

A second vernier scale 58 is provided at the rear of the main body 12 connected to the second shaft 34. The vernier scale 58 measures the angle of rotation of the second tissue engaging means 16.

Alternatively, the second shaft 34 and the rack 38 can be connected to suitable electronic measuring means, for example a transducer, to measure the angle of deflection and the mean separation distance.

In knee replacement surgery, the end portions of the femur and tibia are removed, before the prosthesis knee joint is fitted. In order to fit the prosthesis correctly, it is necessary to ensure by surgery that there is no imbalance in the soft tissue around the joint.

In knee surgery, the end portions of the femur and tibia are removed to leave a planar end surface on the end of each of the bones. In order to determine whether there is any imbalance in the soft tissue, and if so, how much, the surgical apparatus 10 is used. The first and second plates 18,30 are inserted between the planar ends of the femur and tibia, and the first plate 18 is then adjusted towards the end of the tibia by turning the key 42. The key 42 is continued to be turned until both plates 18,30 engage respectively the tibia and the

femur, and further continued rotation of the key 42 will cause the femur and tibia to be moved apart to tension the soft tissue surrounding the knee joint. Any imbalance in the soft tissue will mean that the planar ends of the femur and tibia will not be parallel thus causing the second plate 30 to be rotated relative to the first plate 18. The amount of imbalance in the soft tissue can then be determined from the angle of deflection of the second plate 30. The device 10 is removed and the surgeon can then surgically release the tensions in the soft tissue thereby remove any imbalance. The device 10 is then inserted in the joint to measure the amount of imbalance and the process can be repeated until the imbalance has been completely removed.

The apparatus 10 has an alternative use in which the second tissue engaging means 16 is locked such that the first tissue engaging service 20 remains parallel with the second tissue engaging surface 32 on the second plate 26. With the second tissue engaging means 16 so locked, the apparatus 10 can be used as an adjustable spacer to assess joint stability. In order to do this, the first and second plates 18,26 are inserted into the place where the surgery is to be performed and by appropriate turning of the key 42 the soft tissue can be moved apart by the first and second plates 18,30.

Various modifications can be made to the apparatus without departing from the scope of the invention. For example, the second plate 30 could be fixed in position and the first plate 18, could be movable linearly as described above and also angularly to measure the amount of imbalance. Also a tension spring could be provided on the second tissue engaging means 16 to bias the second plate 30 to a position whereby the first and second tissue engaging surfaces are parallel.

A further modification of the invention is in the use of the apparatus 10 as a means for measuring the tension in the soft tissue around the joint in which it is used. In this modification, a suitable measuring device, such as a strain gauge could be fitted to the first measuring means 14 to determine the forces on the soft tissue around the joint. Also a suitable torque measuring device could be fitted to the second tissue engaging means to measure the torque stability of the knee. Also the second plate 30 could be adapted to rotate relative to the shaft 34, and measurements could be taken with a standard angular measuring means.

It will be appreciated that the use of the device 10 is not restricted to knee surgery but it can be used in surgery of other joints, for example, the hip and elbow.

Claims

1. Surgical apparatus comprising first and second tissue engaging means, the first tissue engaging means being displaceable towards and away from the second tissue engaging means, wherein at least one of said first and second tissue engaging means is adapted to be oriented by the tissue engaged thereby.

2. Surgical apparatus according to Claim 1, wherein the first and second tissue engaging means define respectively first and second substantially planar tissue engaging surfaces, each of said tissue engaging means being arranged such that said surfaces face away from each other.

3. Surgical apparatus according to Claim 2, wherein only said second tissue engaging means is adapted to be oriented by the tissue engaged thereby.

4. Surgical apparatus according to Claim 3, wherein said second tissue engaging means is adapted to be rotatably oriented by said tissue engaged thereby.

5. Surgical apparatus according to Claim 3,

comprising measuring means to measure the degree of deflection of said tissue engaging surface away from a position of parallelism with the first tissue engaging surface when said first and second tissue engaging means engage the tissue.

6. Surgical apparatus according to Claims 2,3,4 or 5 including locking means to lock the second tissue engaging means such that the second tissue engaging surface is parallel to the first tissue engaging surface.

7. Surgical apparatus according to Claim 6, wherein the locking means comprises a pin adapted to engage said second tissue engaging means.

8. Surgical apparatus according to any preceding claim, comprising displacement means to displace the first tissue engaging means towards or away from the second tissue engaging means, said displacement means may comprises a gearing arrangement.

9. Surgical apparatus according to Claim 8, wherein the gearing arrangement comprises a rack and pinion assembly.

10. Surgical apparatus according to Claim 8 or 9,

comprising securing means to secure the first tissue engaging means at any desired separation from the second tissue engaging means.

11. Surgical apparatus according to Claim 10, wherein the securing means comprises a threaded member adapted to engage the displacement means.

12. Surgical apparatus according to Claim 2, comprising a main body part, and each of the first and second tissue engaging means comprises at least one shaft mounted on the main body part and a plate defining said tissue engaging surface.

13. Surgical apparatus according to Claim 12, wherein the first tissue engaging means comprises two of said shafts mounted respectively on either side of the main body part and connected to each other by a connecting member, the connecting member being mounted on the displacement means.

14. Surgical apparatus according to Claim 12 or 13, wherein the second tissue engaging means comprises only one of said shafts rotatably mounted in the main body part.

15 Surgical apparatus according to Claims 12,13 or 14

wherein measuring means is connected to the shaft of the first tissue engaging means.

16. Surgical apparatus according to Claim 15, wherein the measuring means comprises a vernier scale.

17. Surgical apparatus according to Claim 15, wherein the measuring means is electronic and comprises a suitable transducer.

18. Surgical apparatus according to any of Claims 12 to 17 comprising further measuring means to measure the angle of rotation of the second tissue engaging means.

19. Surgical apparatus according to Claim 18, wherein the further measuring means comprises a vernier scale for measuring angles.

20. Surgical apparatus according to Claim 18, wherein the further measuring means is electronic and comprises a suitable transducer.

21. Surgical apparatus according to any of Claim 13 to 20, wherein the main body part includes a handle to enable the apparatus to be manipulated manually.

22. Surgical apparatus substantially as herein

described with reference to and as shown in the accompanying drawings.

23. Any novel subject matter or combination including novel subject matter herein disclosed, whether or not within the scope of or relating to the same invention as any of the preceding claims.

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Databases (see over)

(i) UK Patent Office

(ii) ONLINE DATABASES: WPI

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Documents considered relevant following a search in respect of claims 1-22

Category (see over)	Identity of document and relevant passages	Relevant to claim(s)
A	EP 0327249 A2 (PFIZER) - Figure 15 (corresponds to US 5116338)	
A	US 4501266 (MCDANIEL) - Figure 4	

Category	Identity of document and relevant passages	Relevant to claim(s)

Categories of documents

X: Document indicating lack of novelty or of inventive step.

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