THE DESIGN
OF ARTIFICIAL METACARPOPHALANGEAL JOINTS

GUO Yisheng

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Faculty Of Engineering

Univrsity Of Glasgow

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ABSTRACT

Artificial finger joints have been developed for the past 30 years, and a number of these prostheses has been applied in medical practice.

The Swanson prosthesis has enjoyed extensive use over a number of years. However, the main disadvantage of this type of prosthesis is its lack of longterm fixation.

Experience has shown that a substantial number of the joints become ineffective within one year after surgery and consequently need to be replaced.

The shortcomings of the Swanson prosthesis are mainly attributable to the following factors:

1) Material selected for manufacture;
2) The geometrical design of the stems of the finger joints prostheses.

The present work investigates methods of improving the design of the Swanson joint by looking particularly into the factors outlined above.

An investigation into the materials used for artificial joint prostheses was carried out, and suggestions for the use of material in finger joint prostheses is made.

The design of artificial finger joints was also scrutinized, and in order to improve the geometrical aspects of the joint, the irregularities of the shape of the bone cavity were modelled. The work concentrated on the metacarpophalangeal joint and bones.

The set of tools employed in the modelling aspects of this work comprised a CT scanner, X-ray and photography equipment and two different software packages for geometry definition and manipulation.

It was found that data obtained by CT scanning were not sufficiently accurate for modelling, this technique, however, deserves further investigation.

Instead, the bones were sliced and X-rays and photographs were combined together and used to obtain data for modelling.

A number of possible methods for further modelling are recommended alongside considerations for improved artificial joint design.

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CHAPTER 1. INTRODUCTION

1.1 Introduction

This thesis details the preliminary investigation of the size and shape of the metacarpo-phalangeal bone of normal fingers in order that a range of near optimal artificial finger joints may be designed. Consequently, the work involves the application of mechanical engineering practice, computer modelling technology, in conjunction with medical science. This work covers:

(i) A review of previous designs of finger joint prostheses;

(ii)The selection of materials used in artificial finger joints;

(iii) Computer modelling of the available space within the cavity of the metacarpo-phalangeal bones of normal hands.

1.2 Purpose

There are a lot of people, at least 4% of the population of the world, suffering from rheumatoid arthritis or post-traumatic joint deformity who can not properly flex or extend their fingers. To ease the patients' problems by helping them reachieve a hand of reasonable functionality necessary for daily life, hand surgeons together with engineers have developed artificial joints to replace diseased or otherwise damaged joints.

The first artificial finger joint, invented by Flatt (1960), has gone through several stages of development, from single piece types (Swanson one), to integral hinge types. A wide range of materials have been used including; metals and their alloys, polymers and ceramics. Most patients benefitted from the implant of these joints and more or less regained the function of the hand. However, some earlier designs have fallen into disuse due to unforseen design faults but one which remains in common use today is the Swanson joint, Fig. 1.1.

The design of the Swanson joint, however, could still be improved upon. Firstly, the geometric design of the prosthesis is obviously unreasonable in that the stems of the joint have a tapering rectangular cross-section.Whereas in fact, the shape of the cavities of metacarpo-phalangeal bone are not rectangular but are irregular in cross-section,varying from circular to near triangular.

However, none of the joint implants to date, have been designed with respect to this phenomenon. Consequently, when the artificial joint is implanted, the stems of the prostheses do not fit the cavity of the bones correctly.

Another problem occurs because the material used for the implant can cause a reaction at the interface between the stem and bone. This leads to loosening of the stem within the cavity over a period of time, failure of the fixation of stem leading to failure of prosthesis.

In an attempt to solve these problems, the following measures are required:

(i) A study should be conducted to identify the available space within the metacarpo-phalangeal bones of both nornal and diseased hands;

(ii) The best materials for joint prosthesis should be determined;

(iii) The required structure of a minumium series of joint implants should be designed for different sizes of finger joint to reduce costs whilst maintaining maximum function.

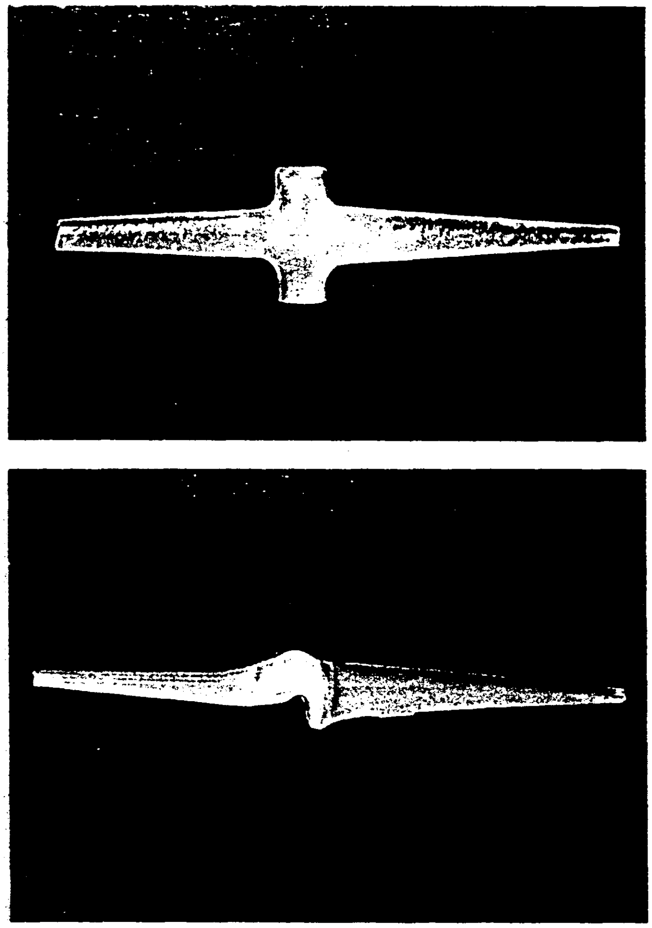


Fig. 1.1 Swanson prostheses

1.3 Plan

To perform this project, the following steps are required:

(i) The method most suitable for computer modelling of the metacarpo-phalangeal bone within available resources should be identified;

(ii) The available space within both normal and diseased hands for artificial joints should be established and a database created in a computer-aided design system to allow further design;

(iii) The basic geometric structure of the joint implant should be determined;

(iv) An analysis of available materials and the selection of the best according to predetermined design criteria, experience gained and experimental evidence;

(v) The detailed design and manufacture the joint.

During the whole procedure, the designer must bear the costs of the design in mind, including the design, manufacturing, etc. .

1.4 Techniques required

This is a bio-engineering project, covering several fields. However, during the early stages of the project, Computer-aided design is perhaps the most important part.

In order that a computer-aided design system can properly model the cavity of a bone, a set of data is required. This data can be obtained by several methods, such as a set of CT scanned images, or a set of photographs obtained from the slices of bone from the hand of a cadaver. This will involve medical instrumentation, X-ray and computer tomography technology, and photographing technology.

In this thesis, three kinds of data have been used to perform the computer modelling, tomography, X-rays, and photography, and two computer software packages have been used, GEOMOD, CATIA.

1.5 The structure of this thesis

Chapter 1. introduces the thesis, including the purpose , its plan, techniques required in this project and the structure of the dissertation.

Chapter 2. provides an outline of the anatomy of the hand in general and the metacarpo-phalangeal joint in more detail.

Chapter 3. reviews previous MCP joint prostheses to highlight design faults in order that these may be avoided.

Chapter 4. describes the criteria for the selection of materials used in joint implantation, then presents a choice of materials for further design and selects a suitable material.

Chapter 5. introduces techniques available for the modelling of bones and theory needed. This includes medical instrumentation, such as X-ray and computerized-tomography techniques, and computer-aided design methods such as computer solid modelling.

Chapter 6. presents the methods used to model bone cavities using different sources of data and software packages and presents and discusses the results.

Chapter 7 concludes all the review and work done and gives the conclusion and recommendation for the further work.

CHAPTER 2. HAND ANATOMY

2.1. *Introduction*

The hand is the most important human manipulator, being used in almost everything we do. A normal functioning hand is needed whether in earning a living, practising a hobby, or allowing independence in daily activities. Our hands grip and manipulate articles; they enable us to dress, eat, write, drive, manufacture, play musical instruments, and perform many more activities. The value of a strong and well co-ordinated hand is obvious . Less obvious, perhaps, is the extent to which the hand is a reflection of the personality and a vital organ of expression. Biomechanically, the hand has to be capable of applying large gripping forces between the fingers and thumb while maintaining precision of motion. In addition, the hand is capable of the most delicate touch, its rich and complex sensory innervation allows the finest judgement of texture, volume and temperature , and so acts as a sensory element to feed back information.

The hand consists of many bones, joints (Fig.2.1) and other tissue, which as a whole acts to perform complex functions. These joints and bones will not be considered individually but in groups, which it is hoped will indicate certain bio-mechanical functions [Unsworth, 1981]. Of these two divisions the one that supports the hand function is the joint, especially the metacarpo-phalangeal joint. If this joint does not work properly, the function of the hand will be reduced.

This chapter briefly introduces the anatomy of the hand, especially the metacarpho-phalangeal joint and discusses the effect of disease upon joints of the hand.

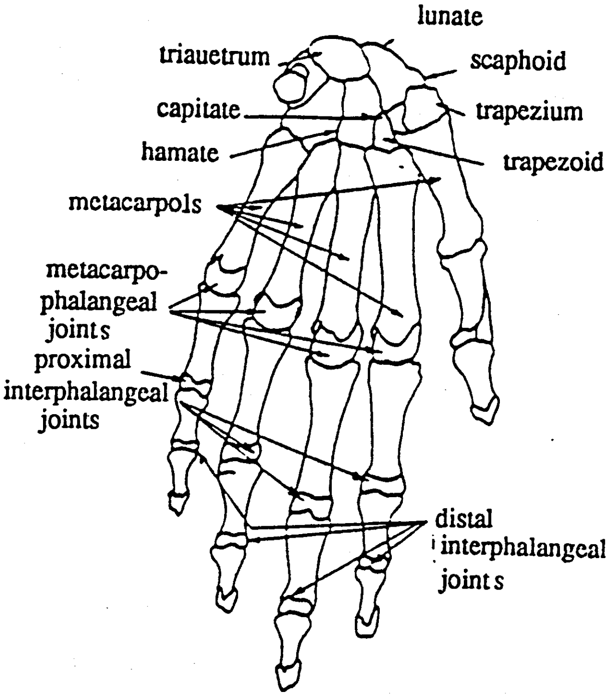


Fig. 2.1 Bones and joints of the hand

2.2 The joints and bones of the hand

There are several joint groups in the hand, wrist, metacarpo-phalangeal joints, interphalangeal joints, and thumb. Figure 2.1.

The wrist is the first combination of joints to be considered. It consists of the radiocarpal and intracarpal joints, both of which contribute to wrist flexion and extension as well as abduction, and ulnar-carpal joint. This joints also provide the stablity of the hand [Unsworth, 1981].

Interphalangeal joints allow only flexion and extension. There are strong collateral ligaments with both lateral fibres and oblique fibres inserted into the volar plate. These ligaments are similar to those in the metacarpo-phalangeal joint and have a strong attachment to the fibrous flexor sheath [Parry, 1973].

2.3 Metacarpo-phalangeal Joint of the hand

The joint which dominates the whole function of the fingers is the metacarpo-phalangeal joint. As the mechanism which links the phalanx to the metacarpus, the metacarpo-phalangeal (MCP) joint provides the finger with the mobility required to perform useful work. Any disturbances of this joint can lead to a functionally compromised hand.

The metacarpo-phalangeal joint consists of a partial ball and socket where the metacarpal head has an articular surface which extends over about 150 degree in the dorso-ventral direction. As a consequence of this approximately spherical geometry, the resulting motion encompasses flexion-extension, and abduction-adduction [Unsworth, 1981].

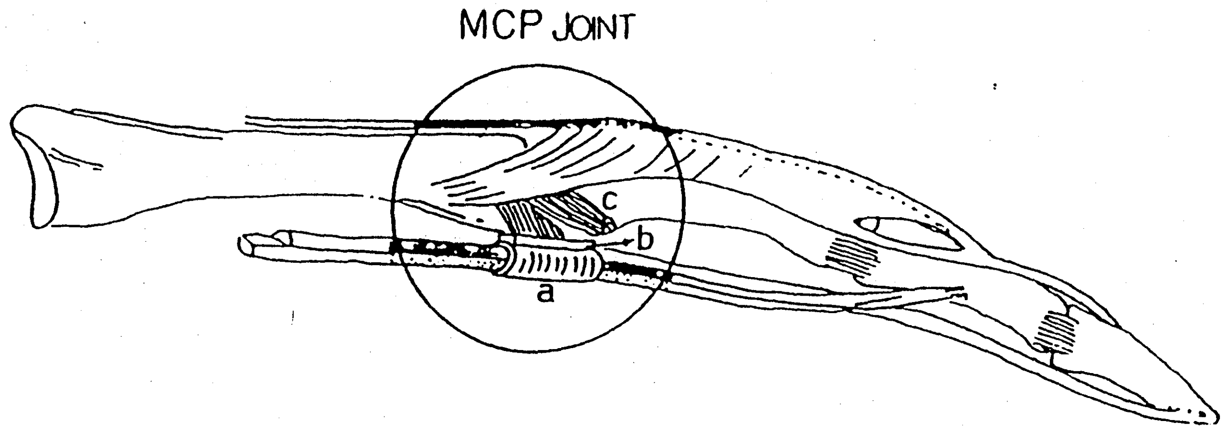
2.3.1 Features of the MCP joint and their kinematic function

The metacarpo-phalangeal joints are stabilized by the metacarpo-phalangeal (MCP) and metacarpo glenoidal (MG) ligaments, volar plate and capsule. The MG ligaments arise from the side of the metacarpal head and pass obliquely into the phalanx, thereby forming the primary link between the two bones. Also included in the MCP joint are the palmar plate and the flexor tendon sheath supported by the MG ligments [Parry, 1973]. (Fig. 2.3.2)

There are six muscles which actively control the finger. Three are extrinisic muscles, and three are intrinsic muscles. The extrinsic muscles (extensor digitorum communis, flexor digitorum superficialis and flexor digitorum profundus) are the primary movers of the MCP joint about a flexion-extension axis. The intrinsics (ulnar and radial interossei and lumbrical) act in the radial-ulnar plane about an abduction-adduction axis and contribute to MCP flexion [Wray, 1983].

The joint is enclosed by a fibrous capsule which contains a volar fibrocartilaginous plate which helps stabilize the joint against hyperextension and also forms the dorsal sliding surface for the flexor tendon sheath. The lateral directions from the plate contain the tranverse intermetacarpal ligament. Also, the capsule contains collateral ligaments which form in an interesting way across the joint. They travel volarly and distally, which enables the tension in the ligaments to vary with angle of flexion. In extension, this tension is small. In flexion, the ligaments tighten to provide greater stability for the joint. This is important when discussing the muscle force around joints.

The heads of the metacarpals are eccentric. On the radial side the condyle is larger than on the ulnar side and the ulnar condyle slopes proximally so that an extensor tendon is more liable to sublux towards the ulnar than towards the radius, as happens when the metacarpo-phalangeal joint becomes swollen in



(a) Flexor tendon sheath, (b) Volar plate, (c) Ligaments. MCP Joint

Fig. 2.3.2 Anatomy of the metacarpophalangeal joint.

rheumatoid disease which gives rise to an obvious symtom. The capsule of the joint has a special development in its volar part, known as the volar plate. Distally it is cartilaginous and is inserted into the palmar surface of the base of the proximal phalanx. Proximally it is lax, thin and attached to the palmar aspect of the neck of the metacarpal. Laterally the volar plate is inserted into the transverse ligament which connects the metacarpo-phalangeal joints anteriorly. Dubousset (1971) makes the ingenious suggestion that the volar plates are really a differentiation of the transverse intermetacarpal ligament, which is itself the thickened distal portion of the deep palmar aponeurosis. Anteriorly the volar plate is closely adherent to the fibrous flexor sheath.

The volar plate is responsible for strengthening the capsule and provides a stabilizing force for the joint and, indeed, is really part of the joint, broadening the articular surface of the phalanx. The articular surface of the base of the phalanx, the volar plate and the collateral ligaments, with which it is continous, act as a sort of cradle for the head of the metacarpal and increases its stability. The collateral ligaments are strong fibrous reinforcements to capsule which maintain lateral stability of the metacarpo-phalangeal joints. They originate from the tuberosities on the heads of the metacarpals and run obliquely to be attached to the base of the lateral tuberosities on the base of the proximal phalanx (Fig.2.3.3) [Parry, 1973].

Lateral movement of the metacarpo-phalangeal joints is virtually impossible in flexion, but free in metacarpo-phalangeal extension. Abduction is greatest for the index finger, usually more than 50 degrees, and least for the middle and ring fingers. In metacarpo-phalangeal extension, stability of the metacarpo-phalangeal joints is provided by the interossei. The accessory collateral ligaments or metacarpo-glenoid fibres also originate from the tuberosities on the metacarphal heads and are inserted in a fan-like manner into the volar plate

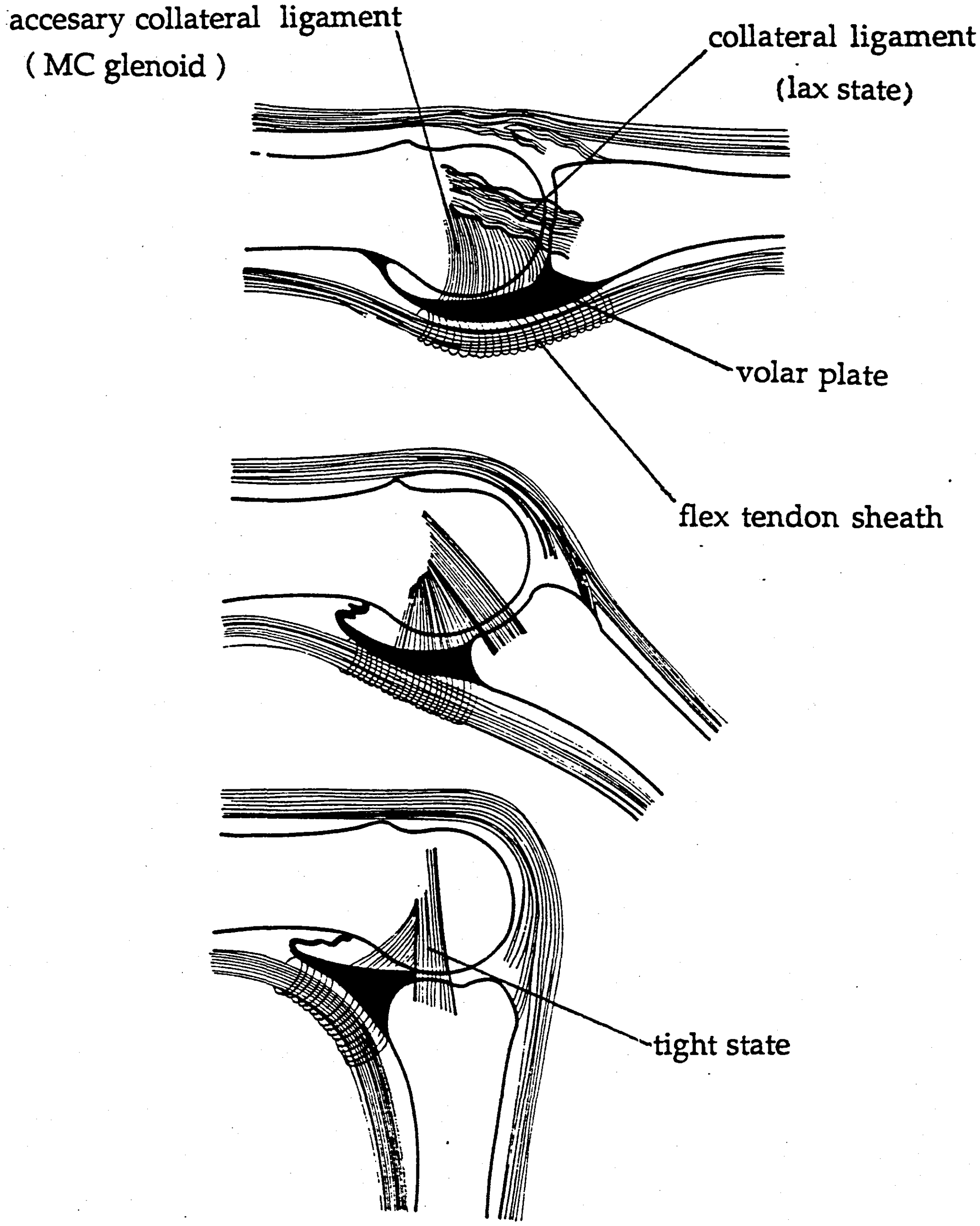


Fig 2.3.3 Lateral view of the metacarpo-phalangeal joint with the surrounding tissues.

and into the fibrous flexor sheath.

The accessory collateral ligaments lie volar to the axis of the joint and are therefore taut in extension and lax in flexion, and help to stabilize the flexor tendons in flexion.

There is a continuity between all the structures surrounding the metacarpo-phalangeal joint, as the extensor hood, extensor tendons, collateral ligaments, volar plate, and fibrous flexor sheath and capsule of the joint are all intimately interwoven. This continuity plays a valuable role in the stability of the joint. Also, each metacarpo-phalangeal joint is connected by the transverse metacarpal ligament and this, with the interconnection of the extensor tendons over dorsum of the wrist and that of the flexors in the forearm, allow for co-ordinated movement of the fingers [Parry, 1973].

2.3.2 *Anatomical structure of the metacarpo-phalangeal joint*

The work of Unsworth et al. (1971) based on studies of the middle finger shows that the radius of the metacarpal head is slightly smaller (6 percent) in the sagittal plane compared with the transverse plane. This was confirmed by Youm et al. (1978). Earlier work by Bartel et al. (1968) had already shown that in living MCP joints active motion of flexion and extension covered circular arcs [Jackson, 1981] .

In a further study of metacarpal heads from other fingers, Unsworth and Alexander(1979) , demonstrated that the metacarpal heads of the ring and little fingers are much nearer to a true sphere than those of the middle and index fingers. The difference in mean radius in the sagittal and transverse plane is 1.6 percent in the case of the little finger, while the mean differences of radii yield only 1.2 percent in men and zero in women. As expected the male metacarpal heads had a greater radius than the female ones (about 10 percent) and the radii varied from 6 mm in the little finger to 8 mm in the index finger.

The base of the proximal phalanx which articulates with the metacarpal head is also spherical (to within 1percent). The mean clearance between the ball and socket was seen to be 0.5 mm in the sagittal plane (Unsworth et al., 1971) while in the transverse plane the base of the proximal phalanx gripped the metacarpal head very slightly by 0.025 mm on radius. Figure 2.3.4 shows two different joints, one in which the proximal phalanx grips the metacarpal head, and one in which there is a transverse clearance [Unsworth, 1981].

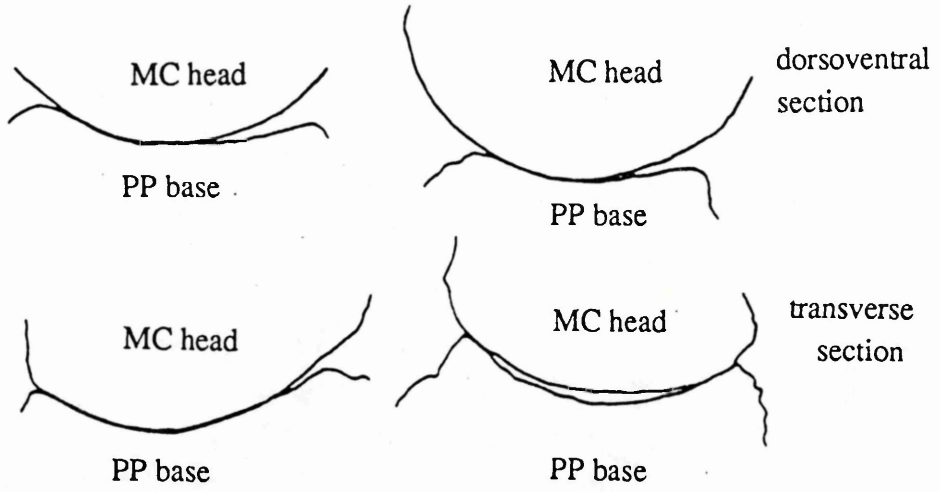
The geometry of the metacarpal and phalanx bones is irregular. Fig. 2.3.5 shows a cross-section through the bones. From this Figure, one can see that the section near the metacarpal head or the phalanx base is somewhat rectangular, but away from the MCP joint, the bone becomes smaller and the shape of the cortical bone and cavity become more triangular. The section at middle part of the bone is smallest. After this the bone increases in size again. X-rays of the bone also indicate this phenomenon. (Fig. 2.3.6).

2.4 Joint range

2.4.1 Normal range of movement.

The range of movement of the metacarpo-phalangeal joints is very much dependent on the patient's occupation and age. It is always advisable to note the range of movement in the equivalent unaffected joints when examining joints with a limited range of movement.

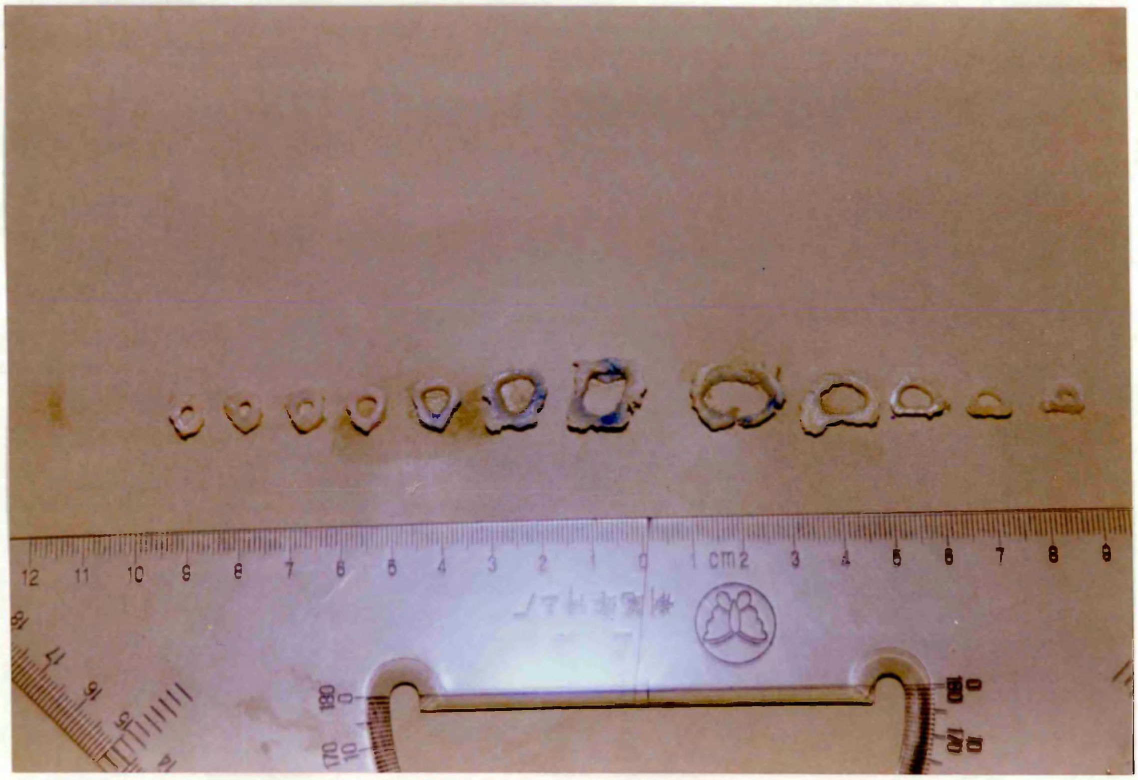
After examing 25 volunteers (50 hands), Y. Youm *et al* (1978) gave the normal range of movement of flexion and extension in the metacarpo-phalangeal joints of the finger. In the normal metacarpo-phalangeal joints, the normal total range of movement is within the region of 0-90 degrees of flexion



Metacarpol head smaller radius than proximal phalanx base

Metacarpol head being gripped by proximal phalanx base

Fig. 2.3.4 Two kinds of different joints



From 1st to 7th, slices of MC bone from smallest section to the MCP joint

From 8th to 12th, slices of PP bone from the MCP joint to the smallest section

Fig. 2.3.5 Photo of slices of Metacapo-phalangeal bone

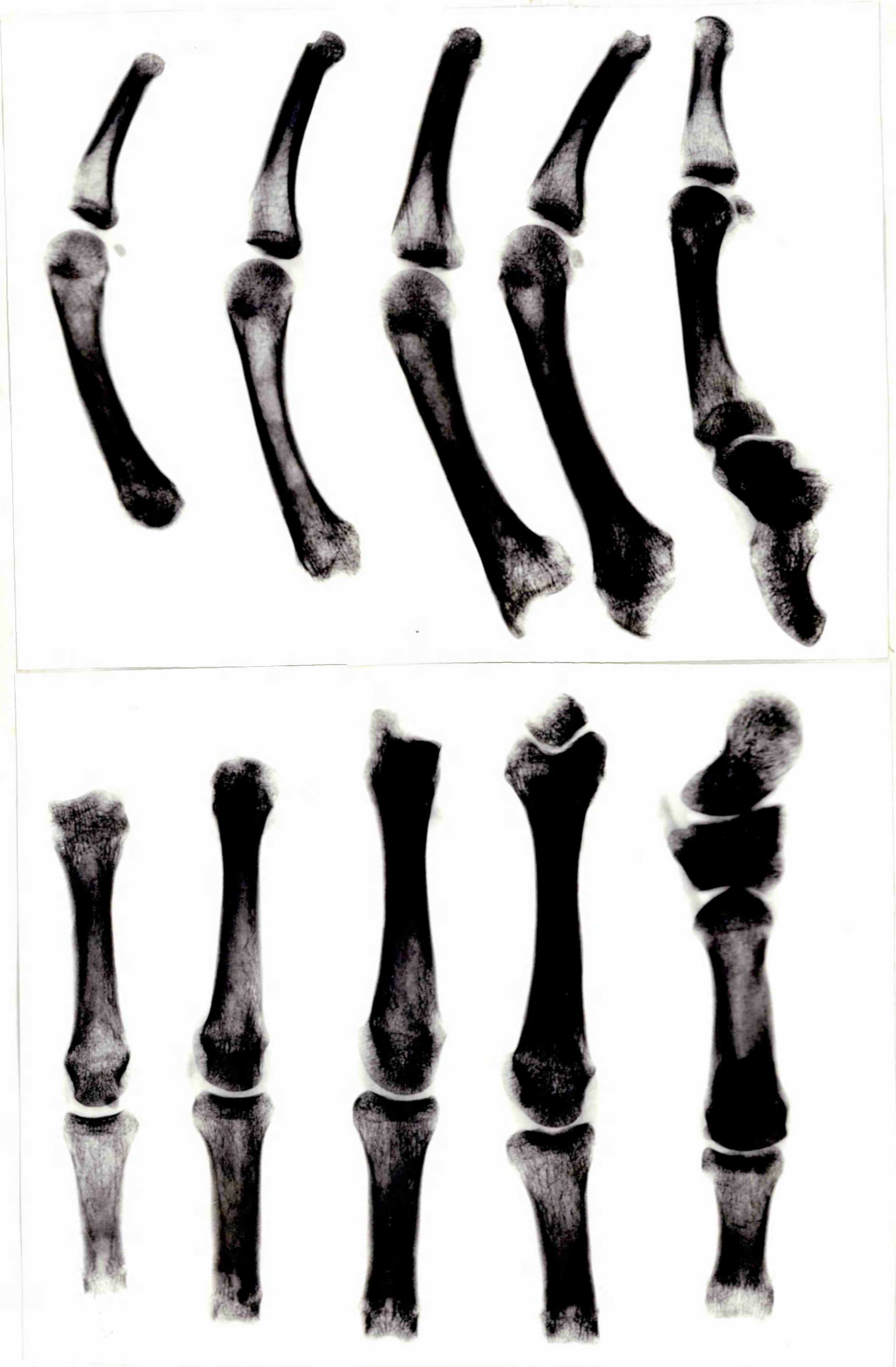


Fig. 2.3.6 X-ray of the bones

and extension, a greater range can be achieved by hyper extension.

2.4.2 *Functional range of movement*

However, it is important to realize that one rarely uses this full range even when making a fairly powerful fist; the index finger can flex through up to 90° and the other fingers progressively more until we reach the little which can flex to 105°. The great majority of metacarpo-phalangeal joint movements are within the 0-45° range. This range being called the functional range of movement. It is in the light of this range of function that the results of joint replacement by prosthesis, should be judged rather than the total range. In addition, the required range for the rheumatoid patient is probably less than in the normal individual, particularly in the patient with advanced disease elsewhere, e.g., shoulders and lower limb. If the proximal interphalangeal joints have a good range of movement then hand function, especially for the rheumatoid patient, can be extremely good even in the presence of little or no metacarpo-phalangeal joint movement [Parry, 1973].

2.5 *Diseases of the hand*

All types of disease affect the hand, infection, arthritis, neoplasms, and degeneration, but unfortunately, the hand is also subject to injury to an alarming degree. Rank and Wakefield (1953) pointed out that approximately one in three injuries requiring treament in a casualty department involve the hand. However, prosthesic replacement of the finger joint is usually performed to correct the deforming effects of rehumatoid arthritis.

Although the development of deformities has attracted the most interest, stiffness of the fingers due to permanent joint changes is the most important. When the joint deforms, the patient losses the function of flexion and extension and the hand becomes stiff and less useful.

1) Loss of extension

It is uncommon to see sufficient loss of passive extension of the fingers to interfere seriously with function, and loss of extension is usually less troublesome than an equivalent loss of flexion. Sometimes a patient is unable to grip a glass tumbler or other large object, but there is seldom any difficulty in handling small objects.

2) Loss of flexion

At the metacapo-phalangeal joints a few of degrees' loss of flexion may be important, particularly in the ring and little fingers. Some activities, such as picking up a small object, handling a hammer, or holding a knife, do not require the full flexion of the fingers, but flexion of the little and ring fingers is needed to steady the handle of a knife. In general the index and middle fingers work in opposition to the thumb and can function adequately with flexion limited to half of their normal ranges; whereas the ring and little fingers grip against the palm so that relatively small loss of flexion in these fingers causes greater disability.

The effect in the proximal interphalangeal joints varies greatly with the degree of flexion loss; if the restriction is slight so is the disability, but inability to flex beyond 45 degrees may be disastrous. Stiffness of the distal interphalangeal joint is seldom disabling.

3) Subluxation

Subluxation of the metacarpo-phalangeal joints is one of the most common and most characteristic deformities of the rheumatiod hand. In the early stage of the disease, the first evidence of impending deformity is the presence of joint instability. Once instability is clearly established subluxation is virtually inevitable. The final deformity is to an antero-medial dislocation and this leads to the improper function of the hand.

However, the main deformities affecting these joints are two in number, ulnar deviation and volar subluxation. The former may be severe and yet be compatible with a reasonable degree of hand function. The latter, even if moderate, greatly reduces the mechanical efficiency of the hand. It must be appreciated that both of these deformities are dynamic ongoing processes; thus one cannot expect the prosthesis alone to deal with these problems. Certain steps must be taken in the surgical procedure to correct the causal factors in the deformity, for example, using a splint to try to correct the deformity [Parry, 1973].

From the above discussion, it is clear that hand is one of the most important part of human body. The hand consists of joints and bones which can act as a whole mechanism. The structure and function of human joints are very complex and current understanding is limited. The metacarpo-phalangeal joint plays an important part in determining the function of the hand. A normal hand has a wide range of movements in the metacarpo-phalangeal joint, which is generally unused. The range that is adequate for hand function is called the functional range of movement.

When disease occurs in the metacarpo-phalangeal joint, it may become deformed resulting in some loss of movement in flexion and extension. This affects patients in both social activities and daily use of hand.

In order to reduce hand deformities, research has been carried out by hand surgeons together with engineers, and the advance of medical science and engineering technology eventually led to joint replacement in the early 1960's.

CHAPTER 3.

METACARPOPHALANGEAL JOINT REPLACEMENT

3 .1 *Introduction*

Due to primary osteoarthrosis or accidental injury, a finger joint may be destroyed or damaged. Thousands of people suffer from arthritis or post-traumatic joint deformity at present. This means that they cannot properly flex or extend their fingers, nor abduct or adduct them. To relieve patients from this damage and disability, surgeons regularly employ finger joint replacement.

The development of internal orthopaedic prosthesis has a history of more than 100 years of successful collaboration between orthopaedic surgeons and design engineers. Cast iron bone plates were first used in Germany in 1886 [The Times, 1988], for internally splinting broken bones. However, it has only been in the past two decades that advents in materials science have provided the missing link needed to progress towards finger joint replacement.

The replacement of finger joints started in 1960 by Flatt's introduction of the first finger joint prosthesis [Jackson, 1981]. Since then, a number of prostheses have been devised for replacement arthroplasty of the finger metacarpophalangeal joint. These designs have achieved varying degrees of success. Today's prosthetic replacements provide some degree of improvement in both appearance and function.

3.2 *The development of finger joint replacement*

Prosthetic replacement of finger joints may occasionally be performed for post-traumatic joint deformity or primary osteoarthrosis, but by far the most frequent pathology is that of rheumatoid arthritis. This is due to the fact that the disease only affects the joint and causes deformity whereas when a joint is damaged in a accident, the joint and the bones near it is usually destroyed and it is very difficult to use an ordinary prosthesis to replace it. Unless otherwise stated all further discussion will be related to hands affected by this disease.

In the hand, total joint replacement is performed on the metacarpo-phalangeal and proximal interphalangeal joints, and in the carpo-metacarpal joint of the thumb, where additionally the proximal bone, i.e., the trapezium, is replaced. In the last two decades, replacement of the metacarpo-phalangeal joint of the thumb has been advocated; but to date the only joint commercially available is prohibitively expensive.

The first prosthesis to be introduced [Flatt 1960] was an all metal (316 Stainless steel) prosthesis consisting of two parts linked by a hinge (Fig. 3.2.1). The function achieved was not as satisfactory as had been hoped. This was due to the axis of rotation of the hinge being wrongly situated and a redesigned prosthesis correcting this fault gave better results. Flatt (1971) reported removal of 26 prostheses for various reasons out of a total of 242 inserted [Jackson, 1981]. The main disadvantages of these prostheses are high cost and problems of instability due to erosion around the stems.

This was followed by the silicone integral hinge prosthesis designed by Swanson (1968) , which remains the most commonly used and will be reviewed in detail later.

In 1968 Calnan and Reis introduced an integral hinge polypropylene prosthesis which had the merit of being inexpensive, but with the problem that polypropylene is a substance which does not wear well. The main design fault was the lack of shoulders on the prosthesis, which enabled the raw bone ends to

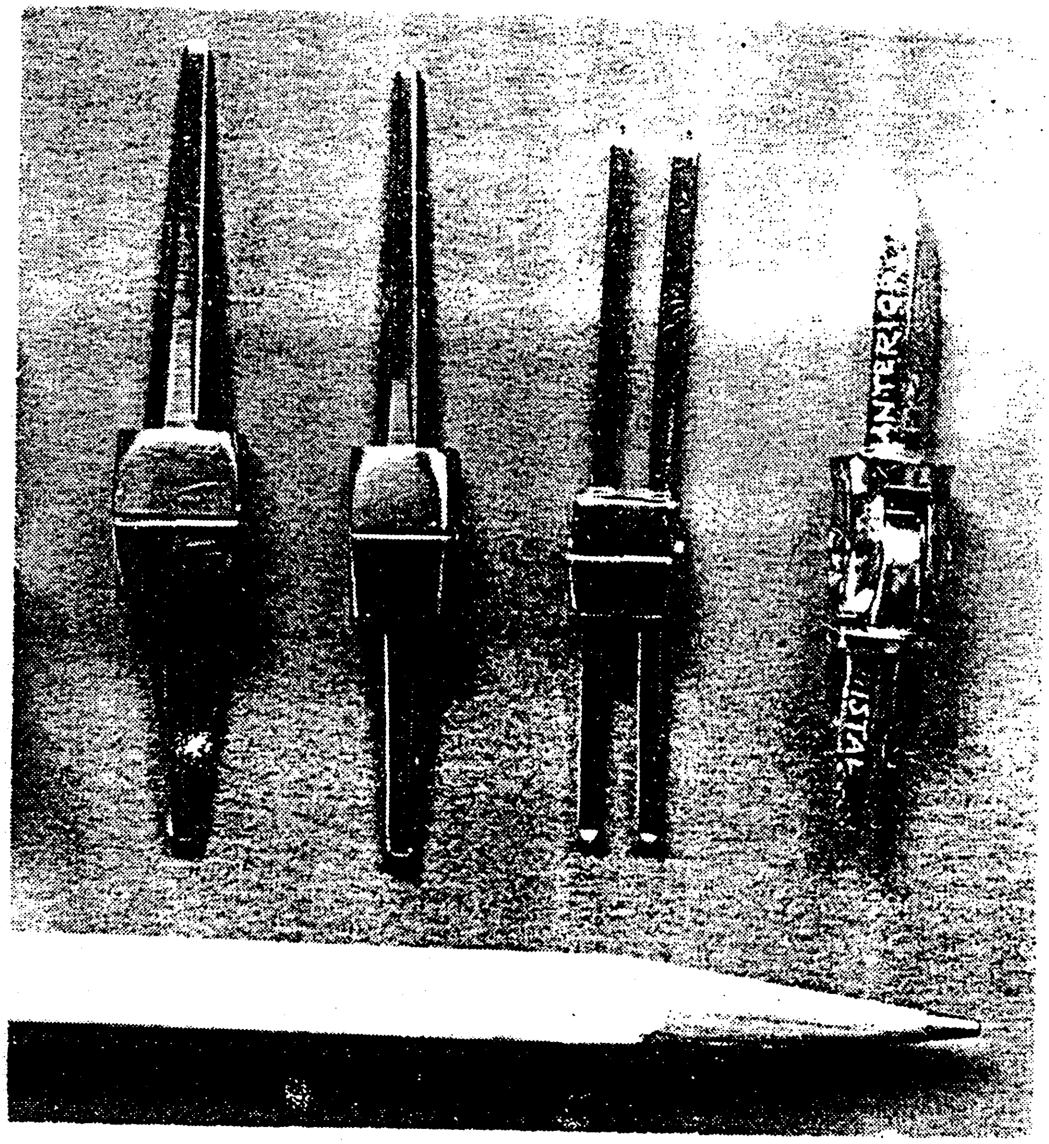


Fig. 3.2.1 The first finger joint prosthesis invented by Flatt in 1960

come together by simply telescoping over the implant, thus fixing the joint in extension, giving the prosthesis a short lifespan.

In order to eliminate the above problems, Nicolle and Calnan(1972) introduced a silicone and polypropylene prosthesis. In this the stems and hinge resembled the Calnan-Reis device and like it it was fashioned from polypropylene. To protect the hinge from ingrowth of fibrous tissue and to keep the bone ends apart, the hinge area was encased in a hollow silicone sphere. The stems passed through square holes on either side of the sphere and this could readily be removed, indicating free access between the outside and inside of the sphere around the polypropylene shafts. In addition to this two small holes midway between the cavity entrances on either side of the sphere allow fluid into the sphere providing lubrication.

The Swanson and Calnan-Nicolle prostheses are not fixed within the bone cavity. Niebauer felt that better function would be achieved by a prosthesis which obtained adherence and fixation within the cavity of the metacarpals and phalanges. To this end in 1968 he introduced a silicone prosthesis, having a central integral hinge; the stems of which were wrapped in dacron velour which continues into the substance of the hinge in an attempt to provide durability since the silicone in this area is very thin[Jackson, 1981].

Stellbrink (1971) took this design a stage further in his St. George prosthesis. This is essentially a two-part design, the proximal portion being made of high density plastic and the distal of stainless steel; between them is a central hinge. The stems of the prosthesis are ridged and fixation is obtained by methylmethacrylate cement being introduced into the medullary canal prior to insertion of the prosthesis . There is a slight variation in the designs of the respective prostheses for the metacarpophalangeal and proximal interphalangeal joints.

In 1975, Schetrumpf presented another metacarpo-phalangeal prosthesis design which depended on stem fixation within the bone shafts. This two-part prosthesis uses a proximal polypropylene socket and a distal polyacetal roller; the stems have three fins to allow stabilization and particularly to prevent rotation.

Kessler(1974) presented a slightly different concept in that the metacarpal head alone is replaced by a silicone rubber implant having a 'Dacron' covered stem inserted into the metacarpal shaft.

In recent years, orthopaedic surgeons and engineers have researched new artificial materials and improved the structure of artificial joints to improve joint implantation and to reduce cost. However, no particular breakthrough in the design and manufacture of artificial joints has been observed.

3.3 *The assessment and requirements of the joint prosthesis*

1) *Assessment*

The structure and function of the metacarpo-phalangeal joints are so complex and currently so poorly understood that it is unwise to attempt to copy nature too closely when replacing a natural joint by an artificial one. Any joint replacement must be assessed in relation to correction of deformity, return of function, and functional adequacy. From chapter 2, it was seen that although the normal finger has a wide range of movement, a functional range which is usually near half of the total is sufficient. This must be born in mind when evaluating the result of joint replacement rather than the normal range of movement.

2) *Requirement*

The requirements of joint prostheses were clearly stated by Flatt (1971) and then added to by Jackson (1981) and a joint prosthesis should:

(1) restore a functional range of motion;

(2) provide appropriate stability;

(3) provide a mechanical advantage equivalent to normal;

(4) seat firmly and resist rotation;

(5) be easily implanted;

(6) accommodate anatomical variation in size;

(7) not damage surrounding structures, e.g., bone ;

(8) have long term durability (and consequently good fixation).

3.4 The summary of the typical joint prosthesis

The development of the MC joint prosthesis now can be regarded to have included two generations of design. The first generation prosthesis were rigid, single- axis, hinged metal implants fixed to bone with staples or by their inherent design. The second generation design is the 'spacer' concept, which provides an MC joint arthroplasty that maintains length and provides some degree of initial stability, with long-term stability dependent on the development of a suitable soft-tissue capsule. Second generation implants are flexible, one-piece devices that may be fixed (Niebauer) or freely moveable within the medullary canal (Swanson, Calnan, and Calnan-Nicolle). The third generation implants are articulated joints made of dissimilar materials which provide more initial stability than the second generation implants and require cement for fixation (Stellbrink's St. George prosthesis).

Fouth generation implants can be regarded to be under research and are predicted to use porous material for the stems which allows bone ingrowth into

Taable 3.4.1 (1) Some Typical types of finger joint prostheses

Designer	Date	Materials	Structure	Advantages	Disadvantages
Flatt	1960	316 stainless steel	two parts linked by a hinge		1) axis of rotation of the hinge wrongly situated 2) poor fixation
Flatt	1971	316 stainless steel	two parts linked by a hinge (redesigned)	corrects the above fault	1) removal of 26 out of 242 prostheses inserted; 2) high cost; 3) instability due to erosion around stems 4) poor fixation
Swanson	1968	Sillicone rubber	one piece model integral hinge	1) fulfils the required criteria of stability 2) has a range of movement which approximates to the functional range of movement; 3) remains the most common used	1) long term breakage; 2) bone errosion at the bone stem interface; 3) not fixed within the bone cavity (when the joint moves, the stem of the joint glides within the medullary canal.)
Calnan & Reis	1968	polypropylene	one piece type with integral hinge	inexpensive	1) not fixed within the bone cavity; 2) short lifespan; 3) the lack of shoulders on the prosthesis, which enables the raw bone ends to come together by telescoping over the implant.

Taable 3.4.1 (2) Some Typical types of finger joint prostheses

Designer	Date	Materials	Structure	Advantages	Disadvantages
Calnan & Nicolle	1972	sil icone and polypropylene	The stem and hinge resembled the'Calnan and Reis', hinge area encased in a hollow sillicone sphere, stems pass through square holes.	Solve the Calnan and Reis problems, no fibrous tissue ingrowth into the hinge at the early stage of implantation	1) fibrous tissue still jammed the hinge a period after operation; 2) stems of prostheses is cut by the bone.
Niebauer	1968	Silicone rubber	One piece type, having a central integral hinge stems wrapped in dacron velour	Stems fix when later ingrowth of tissue into the dacron mesh	
St. George	1971	High density plasty and stainless steel	Two pieces, articulated type. Two stems use different materials, proximal portion being made of plastic, distal of stainless steel	Good fixation obtained by methylmethacrylate cement. The cement is introduced into the bone cavity prior to insertion of prosthesis	1) Use of cement increase the operation time; 2) Expensive; 3) The result is inferior to that of Swanson; 4) Poor lateral stability; 5) Difficult to insert; 6) Ingrowth of tissue produces a frozen joint;
Sche-trumpf	1975	Polypropylene & polyacetal	Two pieces, articulated type, a proximal polypropylene socket, a distal polyacetal roller.	Pay attention to the fixation of the stems with bonecavity	Hasn't been widely used

Taable 3.4.1 (3) *Some Typical types of finger joint prostheses*

Designer	Date	Materials	Structure	Advantages	Disadvantages
Kessler	1974	Silicone rubber	One piece type with Dacron covered stem		Experimental only

the pores to obtain a natural fixation. Different materials are used for different components.

The relative merits of the MC joint implants available today are usually discussed in terms of their clinical evaluation, i.e., range of motion, and postoperative function. However, the biomechanical evaluation of these designs has not been described fully. In fact, there is little or no similarity in design among the existing prostheses. For example, Flatt, Stellbrink used a fixed center for rotation, whilst Swanson ultilizes a changing center for rotation. The inherent range of motion which these implants allow also varies considerably.

From table 3.4.1, one can see that there are several typical finger joints prothesis, Swanson, Calnan-Nicolle, Niebauer, and St. George. These are discussed in detail.

1) Swanson prothesis

The Swanson prosthesis is a one-piece, moulded silicone rubber implant with a preformed hinge. It resists flexion and maintains an attitude of neutral extension when there are no forces acting on it. The intramedullary stems are not fixed to bone and slide freely within the medullary canals during MC joint motion.

Swanson used this prothesis to good result. From the medical point of view, the surgery was performed with an average passive range of flexion of 60-70 degrees, but the radial ulnar deviation (R-U-D) was unpredictable. The results of the use of this prosthesis are summarised in Table 3.2. In this table one can see that pain relief was good, as was functional improvement; complications were few but the active range of movement was small.

The center of rotation was erratic and did not confine itself to any pattern. Maximum motion generally occurred at the bone and stems interface, most

Table 3.2 Results of metacarpo-phalangeal joint replacement using Swanson prosthesis

Total number inserted	680
pain relief	excellent
function	improved
deviation	good correction
range of movement	poor but in functional range
Patient acceptance good.	
complications	
wound infection	20 (2.9%)
prosthesis removed	9 (1.3%)
prosthesis fracture	10 (1.4%)
prosthesis displaced	1 (0.14%)
Total removed:	19 (2.8%)

Table 3.3 Results of metacarpo-phalangeal joint replacement using Calnan-Nicolle prosthesis

total number inserted 1971-2	79
pain relief	moderate
function	moderate improvement
deviation	moderate correction
range of movement	poor but in functional range
Patient acceptance poor.	
complications	
wound infection	5 (6%)
prosthesis removed	5 (6%)
prosthesis fracture	Estimated 100%
prosthesis removed for fracture and on patient request	34 (43%)
Total removed	39 (49%)

frequently at the proximal phalanx distal stem juntion, but motion also occurred at the 'joint' of the implant, particularly from 60 degrees to full flexion.

However, there seems little doubt that the Swanson joint is the best metacarpo-phalangeal joint prosthesis in that it fulfils the required criteria of stability and provides a range of movement which approximates to the required functional range. It can be thought of as a good internal splint with some mobility. Its disadvantages are those of long-term breakage, and bone erosion at the bone-silicone interface, causing later instability. The former occurs very occasionally but may be less of a problem now that the prosthesis is being manufactured from a new elastomer with a greater shear strength. The extent of the latter problem is unknown at the moment, but should emerge with long-tern studies.The research on the biomaterial will improve the biocampatibility of the material finally to solve this problem.

2) *The Calnan-Nicolle prosthesis*

The Calnan-Nicolle prosthesis (Fig. 3.4.2.1) has exhibited disappointing results and because of this is rarely used. In 1972, Nicolle presented good results but this has not been the general experience (Eiken; Harrison; Semple, 1973). Major design faults and the complications which could have been predicted from these have come to light in practice. Jackson's results are presented in Table 3.3. The use of this prosthesis was stopped because of accumulating problems. In a trial group of eight patients who had all four joints in one hand replaced with Calnan-Nicolle and in the other with Swanson implants, i.e. , sixty-four joints in all, every patient preferred the Swanson joints for appearance, comfort, and function. Apart from one patient, all have asked to have the Calnan-Nicolle joints replaced with Swanson ones.

The complications of this prosthesis have been many. It was felt that replacing the metacarpal head with a sphere would give a good cosmetic result. This has not proved to be the case: the metacarpal head is not spherical (its su-

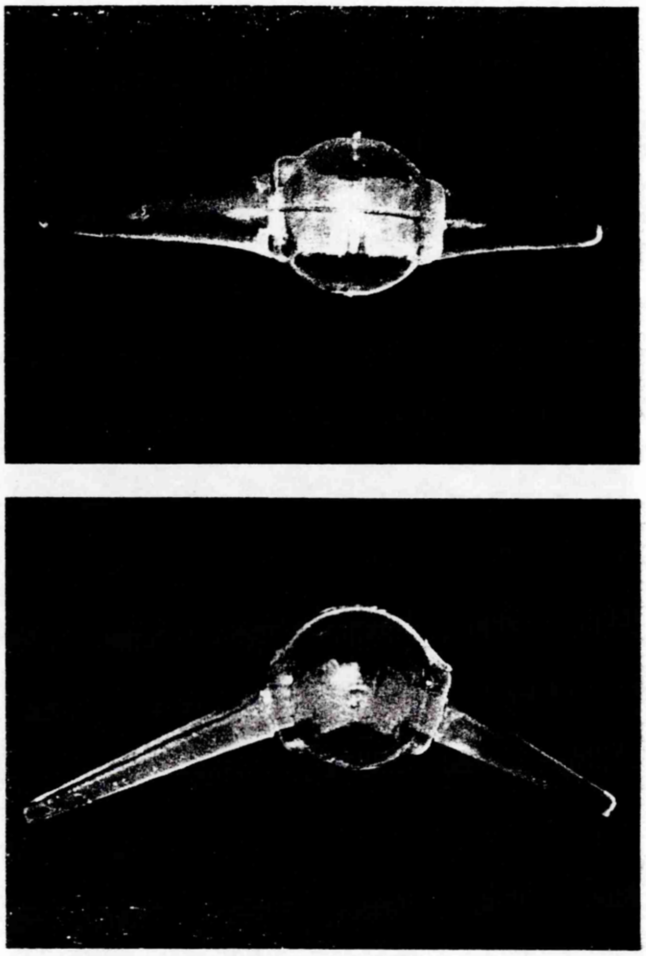


Fig. 3.4.2.1 Calnan-Nicolle Prosthesis

perior surface is flat), and the patients did not care for their prominent knuckles. Two further problems arose from this concept. Firstly, in elderly patients with thin skin, healing could be a problem, especially in the index and little fingers and could thus necessitate prosthesis removal. Secondly, it has consistently been found to be difficult to stablize the extensor tendon on top of the sphere (the tendon tended to always sublux to the ulnar side). Even with careful stabilization, exploration in the long term always revealed the tendon to be on the ulnar side of the ball, or, worse still, in two cases, the continuity of the tendon had been interrupted, presumably due to pressure.

Wound infection of any degree necessitated removal of the prosthesis; the fluid-filled ball underlying the wound provides an ideal culture medium, which contrasts strongly with the Swanson implant where antibiotics and elevation may settle the infection and removal is not necessary. The concept of the ball isolating the hinge was good; unfortunately the isolation is not total, connections are present where the stems go through the silicone and at the site of the two small holes used to inject saline and neomycin. Cells pass through these spaces and in all cases where removal was performed eighteen months or more after insertion the spheres contained white solid material. Initially this was thought to be fibrin but electron microscopy has confirmed the presence of collagen.

Breakage in the long term is also a problem. The breakage pattern ranged from tiny cracks on the volar part to total disruption of the silicone ball. Also, the microscopic fragnments of silicone and polypropylene were found within the tissue surrounding the articular surface.

However, the basic design was good and perhaps it may be of value in a different form and made of a different materials.

3) Niebauer prosthesis

Niebauer prosthesis (Fig. 3.4.3.1) is also a one-piece device with a Dacron reinforced silicone rubber implant [Thomas, 1979]. The proximal and distal stems are covered with Dacron mesh for fixation by later ingrowth of tissue. Immediate fixation is achieved by four Dacron ties affixed to the bone.

The ranges of motion in flexion-extension movement (F-E-M) and R-U-D is similar to that of Swanson, the center of rotation was erratic and half range of motion accurs at the bone and stem interface.

Another problem is buckling of the prosthesis. When the tendon is loaded, the implant buckles. The buckling can be reduced by notching the metacarpal and phalanx at far left and far right sides. The implant can then be inserted further into the bone, which provides better support at the base of the stem.

4) St. George prosthesis

Another typical finger prosthesis is the St. George one (Fig.3.4.4.1). This is a two-piece articulated prosthesis and requires cement for fixation. It has a fixed center for rotation. The stem of the joint is ridged as well so as to get a good fixation with the bone.

On the whole, the silicone rubber implants (Swanson, Niebauer) have an unpredictable center of rotation [Thomas, 1979]. When the finger flexes within the range of 45 to 60 degrees, the motion usually accurs at the bone and stem interface. The rotation center is also dependent on how much the bone is resected.

The biomechanical behaviour can not be divorced from the implant material property.

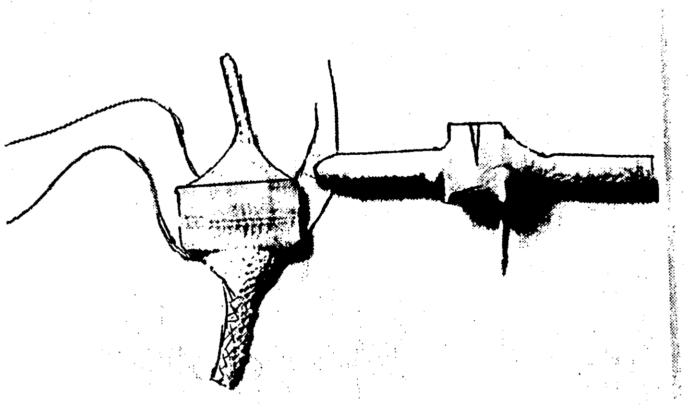


Fig. 3.4.3.1 Niebauer Prosthesis

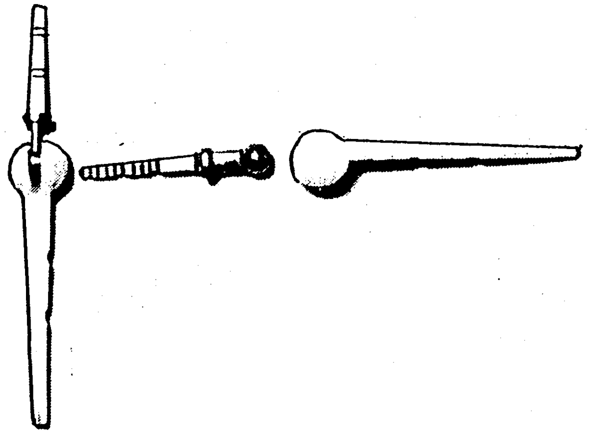


Fig. 3.4.4.1 St. Geoge Prosthesis

3.5 *Conclusions*

Since the first MC joint prosthesis invented by Flatt in 1960, the development of this prostheses have included three generations. The design of the prosthesis can also be classified into two caterories:

1) Moulded one piece type;

2) Two pieces and articulated type with different materials.

The biomechanical behaviour of these joints varies considerably, and none of them duplicates the normal MC joint.

One of the important factors influencing the implantation is the fixation. If the stem does not fit the medullary canal well, the load bearing ability is reduced.

However, none of the designs can be considered to be a success regarding their fixation with the bone. In most prostheses, the stems of the joint slides inside the bone cavities when the finger moves and this leads to the reduction in joint performance. The Niebauer prosthesis, however, is fixed within the bone immediately by four 'Dacron' ties.

The implant would be greatly improved if the fixation could be developed in an efficient way. Although Niebauer and Schetrumpf, and Kessler paid attention to stem fixation with their design, by wrapping textile on the stems. A study will be required to determine if they decompose or cause infection within the bone cavity.

One reasons for poor fixation is due to the geometric design of the prostheses. None of the designs of the stem shape is based on the geometry of the medullary canal. Therefore, in an attempt to solve the fixation problems, it is necessary to design a new type of implant where the shape of the stem is similar to the bone cavity into which it will fit. Apart from the geometry, certain materials can provide a good interface, without reaction, betweeen the bone and implant; and tissue ingrowth into the pore of the stem can achieve good fixation.

CHAPTER 4. MATERIALS USED FOR JOINT PROSTHESES

4.1 Introduction

One of the most important factors encountered in mechanical engineering design is the selection of materials. Materials affect the function, property and lifespan of a machine or a mechanism. In artificial finger joint design, the requirements for the materials are particularly demanding. The criteria for material selection are numerous, but may be classified into considerations of biocompatibility and mechanical and physical functionality, sometimes referred to as biofunctionality. In this section, the criteria for materials selection and the materials used for the finger joint replacement are discussed.

4.2 Materials requirements

The requirements for the materials can be divided into two sections:

1) Mechanical functionality;

2) Biocompatibility.

4.2.1 Mechanical functionality

There are many examples to show how design features and material characteristics combine to influence the clinical performance of implants. In simple mechanical terms, the load at which an implant itself would fracture is dependent upon the geometric design, as this controls the stress system within the implant when acted upon by external forces and also the material selection which governs its strength. Poor design or material selection may give high stress and low strength, predisposing to clinical failure. Furthermore, mechanical fracture of an orthopaedic implant is often due to fatigue failure; that is , the device fails under the influence of repeatedly applied cyclic loads which are , in magnitude, appreciably smaller than the ultimate tensile strength of the material. Each material displays its own fatigue characteristics, but fatigue cracks usually nucleate at surface irregularities. Fatigue failure can often, therefore, be attributable to design or handling-induced surface features rather than to inherent material weakness.

Considering friction and wear in total joint prostheses, the wear rate is dependent on both the sliding distance, related to the geometry of the interface and the wear characteristics of the material employed, while the frictional torque in ball and socket joints is again governed by the geometry and the material-dependent coefficient of friction. Therefore, it is easy to see that from a mechanical point of view, the most important aspect is the geometric design of the joint, which is discussed later. From the above, the mechanical requirements for the materials employed in the joint prosthesis are:

1) Good fatigue charateristics;

2) The ability to wear well (long term durability);

3) Formability in order that proper fixation of the stems into the bone is possible.

4.2.2 Biocompatibility

Biocompatibility is a loosely defined term. A material which is biocompatible is generally thought to be one which can exist in close harmony with the tissues of the body without the bodily environment adversely affecting the material or vice versa. Assessment of biocompatibility is clearly very subjective as there will always be some degree of interaction. Biocompatibility requires :

1) Materials that do not degenerate in the human body;

2) Materials that do not cause reaction or infection in the body.

It must be understood, however, that these two aspects are closely related; for example, it is frequently the products of material degradation that are responsible for the most significant tissue responses.

4.3 Materials employed in finger joint replacement

There is a large range of materials that have been used in the past. The first material used for finger joint replacement was metal(316 stainless steel) by Flatt in 1960 [Flatt, 1960]. Since then, stainless steel, cobalt chromium alloys, titanium, silicone, polypropylene, fibrous materials, ceramics, etc. have been employed in clinical practice [Black, 1988]. These materials can be classified into three categories:

1) Metals, such as: stainless steel, titanium and its alloys, vitallium, cobalt-chromiun steel;

2) Polymers: polymethylmethacrylate (perspex), polyethylene, silicone rubber, polypropylene, polyethylene terephthalate, polyacetal, polytetrafluoroethylene (teflon), proplast; and so on.

3) Ceramics and glasses, including alumina and bioglass.

4.3.1. Metals

Only a few metallic materials are in use today for the construction of orthopaedic implants. These are stainless steels, a small range of cobalt-chromium alloys, pure titanium and some dilute alloys of titanium.

4.3.1.1 Stainlesss steel

(a) Mechanical functionality. Stainless steels are alloys of iron and carbon combining with other elements. They traditionally possess great strength because of the hardening effect of the interstitial carbon atoms. Stainless steel always contains chromium and usually nickel. The 18-8-SMo (18%chromium and 8% nickel) stainless steel has been the basic implant material because the addition of 2-4% molybdenum to the 18-8 steel greatly increases the resistance to corrosion. The mechanical properties are adequate but not outstanding.

(b) Biocompatibility. The biocompatibility of stainless steel orthopaedic implants is dependent on the corrosion resistance of a particular specimen and the effects of the corrosive products in the systemic circulation. Two kinds of responses occur at the interface between stainless steel and bone:

(i) localized tissue response. When a smooth-surfaced steel implant is located in soft tissue, it will only induce a thin capsule of fibrous tissue around if there is no film breakdown and corrosion. If corrosion occurs, the corrosive products may induce more significant response, the extent of which depends on the volume of corrosion products released. Small corrosive products are usually phagocytosed without any obvious clinical significance when they are formed. However, in case of more severe corrosion, large extracellular particles may be found in the tissue, sometimes associated with marcophages and giant cells.

(ii) Systemic and hypersensitivity responses. There is always a release of ions from the alloy into the tissue, including those of iron, chromium and nickle. This will occur although there is no corrosion, but it is probably released from the film breakdown. It is not so clear what happens to these ions after they are release into the tissue, but it is reasonable to extrapolate from the animal experiments to predict that they will be distributed around the body. Also, hypersentitivity has been noted in some patients with stainless steel [Dumbleton, *el,* 1975].

The main disadvantage of stainless steel is that it is not totally compatible with the surrounding tissue. The implant tends to develop slight loosening after the surgery. Also, stainless steel may induce hypersensitivity, thought to be due to its nickel content. Several cases of sensitivity to nickel which was present as an alloying addition in steel implants have been reported in literature [Dumbleton, *el,* 1975].

4.3.1.2 Cobalt-chromium alloys

(a) Mechanical functionality. Alloys consisting predominantly of cobalt and chromium are often referred to as "Stellites", this being a proprietary name. A large number of these alloys are commercially available and several are used in implant surgery. Additional elements such as: molybdenum, carbon, tungsten and nickel are used to vary their mechanical and corrosion characteristics. For example, cobalt-chromium-molybdenum alloy work hardens so rapidly that it cannot be shaped by forging or machining and therefore has to be cast, while cobalt-nickel-chromium-molybdenum alloys can be wrought. The strength of this alloy is considerably improved by working. It should be noted that the strength of the cold-worked wrought alloys is similar to that of the Ti-6AL-4V alloy and, as such, these represent the strongest of the presently available materials.

The elastic modulus of this cobalt alloy is similar to that of stainless steel and hence about twice that of titanium. One further point of interest is that their hardness is the greatest of currently used alloys. Occasionally a small amount of corrosion may take place, usually at a point where local conditions become extremely unfavourable, such as areas of surface porosity.

(b) Biocompatibility. The tissue response to these alloys is the most favourable as there is rarely any corrosion and the problems encountered with stainless steel do not appear. Furthermore, no pigmentation occurs as in the case of titanium, which will be discussed later.

One disadvantage of these alloys is the potential hypersensitivity that may sometimes be developed in response to them by patients. This is largely due to the cobalt content this being the most prominent sensitizer [Dumbleton,*el*, 1975].

4.3.1.3. Titanium and its alloys

(a) Mechanical functionality. Titanium may be used in either the commercially pure form or as a dilute alloy. The metal titanium exists at room temperature as a close-packed hexagonal crystal structure, this form being known as α-titanium. Above 880ºC, β-titanium, of b.c.c.(body-centred cubic crystal structure) form, is stable. A commercially pure titanium is essentially a very dilute alloy of α-titanium and oxygen. The oxygen is in solution and the structure is single phase, the greater the oxygen content, the stronger the material due to the solute hardening effect.

Alloying additions to titanium can stabilize either the α or the β phase. Generally, aluminium and interstitial elements auch as oxygen and nitrogen stabilize α whilst the transition metals such as molybdenum and vanadium stabilize β. In order to get some combination of phase, 5-6% aluminium together with a small amount of a transition element is frequently used. The alloy currently used for surgical implants contains 6% aluminium and 4% vanadium. This alloy is amenable to heat treatment and a variety of microstructures, each with a different relationship between α and β phases, may be produced.

The strength of commercially pure grades of titanium depends on the amount of oxygen, as seen in Table 4.3.1. Also included are the values for the Ti-6%Al-4%V alloy. From this, it can be seen that a considerable improvement in the strength is obtained with this alloy (0.1% proof of yield stress from 160 to 1000 MN m-2). The Elastic modulus is changed very little by alloying and is only about 50% of that of stainless steel.

Titanium is a highly reactive metal which oxidies easily in the presence of both air and water. Paradoxically it is this very reactivity which makes the metal so resistant to attack since the oxide film that forms is so stable and hence protective. As soon as titanium is explosed to the air, it reacts with the oxygen and a layer of oxide film forms. This oxide film protects titanium from coming into contact with the other medium, for example, the water inside the human body. Experience with titanium has verified this immunity to corrosion under physiological conditions. Also, many of the dilute alloys, including Ti-6%Al-4%V, are equally corrosion resistant.

(b)Biocompatibility. The tissue reaction to a titanium implant is better than the reaction to a non-corroding stainless steel implant because the predominant observation is that of minimal fibrosis with little or no inflammatory response, whilst the stainless steel may react with the tissue and there exist a small clearance at the interface between the implant and tissue. Since the titanium does not corrode, the more severe responses sometimes seen with stainless steel do not occur.

Table 4.3.1 Mechanical properties of metallic implant materials

	Elastic modulus (GN m-2)	0.1% Proof or yield stress (MN m-2)	Ultimate Tensile Stress (MN m-2)	Elongation at failure (%)
316 Stainless steel (annealed)	200	240-300	600-700	35-55
316 Stainless steel (cold worked)	200	700-800	1000	7-10
CP titanium (low oxygen, annealed)	110	160	400	30
CP titanium (high oxygen, annealed)	110	470	700	15
Ti-6%Al-4%V (heat treated)	120	1000	1200	16
Cast Co-Cr-Mv (as cast)	210	480-500	680-700	4
Wrought C0-Cr-Ni (forged/annealed)	240	320-380	880-920	60
Wrought Co-Ni-Cr-Mo (hot forged)	230	110-1300	1300-1600	15-25

Nevertheless, there may be some morphology associated that is unique to titanium implants. It has been frequently noted that the tissue is pigmented and that dark particulate matter may be present in the tissue. This is due to the slow diffusion of titanium ions through the oxide film (which does not itself break down) and their release into the tissue. However, this does not usually appear to be clinically significant.

Titanium is released into the tissues and it is reasonable to assume that some of this (titanium) finds its way into the systemic circulation. However, there are no recorded case of hypersensitivity to titanium, in contrast to both stainless steel and cobalt-based alloys, so that this may be the material of choice when metal sensitivity is suspected.

The elastic modulus of titanium is only half that of stainless steel. Therefore, it is not rigid enough to be the bearing material because bearing material is required to wear well. If titanium is used as an articulating surface, it will be continually abraded causing the oxide film to be disrupted. The successive breakdown and reformation leading to accelerated wear. However, the situation may be improved by pairing with the plastics.

From the above discussions, it is clear that each of the major metallic materials have their own advantages and disadvantages. The choice of material, therefore, has to be made with reference to the specific orthopaedic application. With non-articulating surfaces the Ti-6Al-4V alloy appears to offer the best combination of properties. Until research proves as to whether this alloy can be used in joint prostheses successfully, the cobalt-chromium alloys and stainless steels have to be used for prostheses.

The titanium has not been widely used in implantation for the following reasons:

1) High cost;

2) The processes required to form titanium were only commercially developed in the last decade;

3) It is difficult to machine and form.

4.3.2 *Polymers*

Main mechanical properties of some implantable polymers are shown in Table 4.3.2.

1) Silicone rubber

In previous joint prostheses design, Swanson, Niebauer and St. George prostheses were made of, or partly made of, silicone rubber.

Silicone rubber is an elastomer based on polydimethylsiloxane. It has poor mechanical properties, being weak and having poor tear resistance and consequently can only be used in a low stress situations. Its use in the musculo-skeletal system are limited to situations such as tendon sheath reconstruction and finger joint prostheses. Its poor abrasion resistance prevents its use in weight-bearing applications, whether as a member of a prosthetic wear pair or against tissue. This deficiency has also produced premature failure where bony margins can abrade silicone rubber devices. The long term breakage of Swanson joint is mainly caused by this. However, the use of modern device designs that incorporate sheaths to separate the silicone from the surrounding bone, and the development of materials with higher tear (and thus abrasion) resistance, have reduced this problem. The

Table 4.3.2 Mechanical properties of some implantable polymers

	Elastic modulus (GN m-2)	Ultimate Tensile Stress (MN m-2)	Elongation at failure (%)
Nylon 6	2	80 - 150	300
Polymethylmethacrylate	3	20	5
High-density polyethylene	0.05	30	800
Polypropylene	1.5	40	500
Silicone rubber	0.01	5	600-800

low tensile strength of silicone rubbers also prevents their use in ligament and tendon prosthetic applications, although they have been used as components in some experimental composite designs.

Lipid absorption might degrade the properties of silicone rubber implants because silicone rubber is modestly lipophilic, as was the case with the early silicone rubber heart valve poppets [Bieber, 1986]. Although evidence for such absorption has been found, there is no convincing evidence that it has contributed to device failure. Commercial silicone contains other additives, so, all silicones used in biomedical applications must be custom made to assure purity and nontoxicity; all of these materials are of medical grade.

However, recent investigation showed that silastic has a lot of problems, for example, bone resorption around the implant causes persistent pain. Therefore, the use of silastic material must be further studied carefully.

2) Polyethylene

The introduction of high-performance polymers to replace metal-metal wear pairs with metal-polymer ones leads to markedly lower wear, and presumably reduces the risk of both local and systemic adversion response to metal implants involving articulating interfaces.

The original polymers were "slippery" and possessed very low coefficients of friction. Thus, they appeared ideal for bearing applications and were used widely in industrial and consumer product applications. However, the relatively rapid wear and, the consequent aggressive foreign body response to the wear debris have rendered them unusable in implant applications in which wear phenomena are possible. Long term experience and experiments has enabled material scientists to develop high density polymers which improves the situation. For the purpose of implantation, and especially for joint replacement prostheses, only the ultra-high molecular weight, high density polyethylene (UHMW HD polyethylene) can be considered. This type has little or no molecular branching, so that there is virtually 100% crystallinity , and a high molecular weight, in the region of 5 million. This causes the mechanical properties (elastic modulus, yield stress and UTS) to be suitable for implant applications.

3) Polypropylene

In the Calnan and Reis, Calnan and Nicolle and Schetrumpf prostheses, Polypropylene are used to form the full or part of the prostheses.

Polypropylene is of the same polyolefin family as polyethylene and possesses very similar properties. It appears to be equally compatible with tissues as polyethylene, but although the strength and tensile modulus are as high as high density polyethylene, its wear resistance is not as good. The principal advantage of polypropylene is its very high fatigue resistance which gives an almost infinite life for well designed components subjected to repeated flexing. The use of polypropylene was abandoned due to design failure and joint stems loosening in bone.

4) Polymethylmethacrylate

This is an extremely versatile polymer, being used in a number of different forms. Although its versatility is well demonstrated by its diverse surgical applications, its only major use is in orthopaedics as a bone cement.

It has the tremendous advantage of being amenable to be dough moulded. In the polymerization method used in the preparation of bone cement, powdered prepolymerized methylmethacrylate is mixed with the liquid monomer and an initiator to start the polymerization process. The reaction is exothermic and a mass of cement similar to that used for fixation of a femoral component may reach nearly 90°C.

The structure of the resulting mass is far more complicated than a simple polymethylmethacrylate polymer because it is mixed with other substances during the forming procedure and operation.

Mechanically the acrylic cement is strong but relatively brittle, with a low impact strength. Some mechanical properties are shown in Table 4.3.2, but these must be regarded as a general guide because the mechanical behaviour varies considerably with the preparation and composition. The strength of the cement was often thought to be adequate, but it was clear that some fracturing of the cement did take place and caused the fracture or loosening of the stems.

Pure solid polymethylmethacrylate induces no significant tissue response. However, in common with plastic material, if abraded, the wear debris may provoke a fibrotic and cellular response. In addition, the high temperature generated during the polymerization process may result in some thermally induced effects including necrosis in the immediately adjacent tissue.

The metals discussed earlier are generally interchangeable in orthopaedic applications. In contrast, the use of plastics is more specialized, each material having its own use. Acrylic is suitable for bone cement, UHMN HD polyethylene for bearing material, whilst silicone rubber is used where a relatively soft elastomeric material is required.

4.3.3 *Ceramics and Glasses*

1) Alumina

There are numerous different types of ceramics which could be considered for surgical use. Among them, it is the single oxide, alumina, Al_2O_3 that has been chosen for widespread clinical evaluation and use. The main motivation for its use has been its potentially excellent wear resistance and biocompatibility. Ceramics, including alumina are very hard, which accounts for their wear resistance and experience has now confirmed that very little wear is evident in alumina joint prostheses. Ceramic structures represent the end stage in the corrosion process of metals. They are therefore of low energy, and do not normally corrode themselves. This stability in the physiological environment leads to the very good compatibility with tissues.

The disadvantage of ceramics is that they are notoriously brittle. However, techniques developed for the processing and shaping of materials such as alumina have resulted in materials which are very dense. This material has very little internal porosity and flaws, so that properties, such as impact and fatigue resistance, comparable to those of traditional metals are achieved.

2) Bioglass

To obtain good stabilization of implants within bone, a prosthetic material that will bond chemically to bone is needed. Bioglass was developed in the1970's. This is a glass-ceramic that is based on SiO_2 but also contains calcium, sodium and phosphate ions. Under normal physiological conditions, where the tissue is maintained at a pH of about 7.4, this glass ceramic is very stable. However, during periods of high metabolic activity, the pH may rise. Some calcium, sodium and phosphate ions are released from the surface in response to this pH change which influence the precipitation of hydroxyapatite in the surrounding tissue. This results in the formation of mineralized bone at the implant-tissue interface, the hydroxyapatite crystals nucleate within the orientated collagen matrix at this interface. The rate of mineralization is controlled by the rate of ion release, itself dependent on the composition of the bioglass.

Since the glass-ceramics have reasonable mechanical properties, it can be used as a coating on another (metal or ceramic) substrate.

4.4 Internal fixation

There are several methods for obtaining internal fixation, by impaction or direct mechanical fixation, by cements, by tissue ingrowth into porous surface, or by direct chemical bonding. Allowing tissue ingrowth into the porous surface of the stems is of interest because easy insertion of implants into the bone cavity, simplifies the operation, and good fixation after the operation is obtained. Therefore, material used for joint prostheses also plays an important role in the internal fixation.

It has been known for many years that soft tissue may grow into the interstices of a porous material that is implanted adjacent to it. Attempts have been made to utilize this phenomenon for the purpose of achieving long-term union between prostheses and tissue. Murray and Semple (1981) conducted a series of experiments to determine the anchorage of a prosthetic tendon in bone. The experiment confirmed tissue ingrowth into porous titanium and gave good fixation.

Ceramics have also been tested for the purpose of ingrowth of tissue into the pores. However, although ceramic has good biocompatibility, it has some poor mechanical properties including tensile brittle behaviour. Consequently, growth into porosity on the surface of the the ceramic is likely to nucleate and propagate a crack. For this reason, metal has proved to be more desirable. Titanium is chosen for its good biocompatibility and its porous shape can be fabricated by metallurgical techniques. Plastics can also be produced porously, but suffer from lack of strength and rigidity. Therefore, among the metals, plastics, and ceramics, titanium appears ideal for the stems of prostheses because of its good biocompatibility and mechanical properties.

Another advantage of the porous surface is that a more gradual stress transition between the implant and bone may be achieved.

The disadvantages of the porous system are:

1) The increased contact area between the implant and surrounding tissue. Any potential undesirable response to the material in solid form may be considerably aggravated.

2) If movement of the implant occurs during the healing process, a granulomatomous process may follow, leading to a failure of ingrowth and the formation of fibrous tissue around the prostheses.

3) Should any thing go wrong, the implant with tissue ingrowth is difficult to remove.

In load bearing prostheses, it would be a good idea to design a prosthesis with a strong, rigid base attached to a porous low modulus coating.

4.5 Conclusions

The materials used for prostheses demand a much higher specification than for ordinary mechanical devices. The criteria for selection of materials includes the consideration of both mechanical functionality and biocompatibility.

During the last two decade, several materials have been introduced to orthopaedics, especially joint replacement practice and have been accepted. Included in these materials are metals; 316 stainless steel, titanium and the titanium-6% aluminium-4% vanadium alloy and cobalt-chromium alloys, and plastics; UHMW HD polyethylene, polypropylene and silicone rubber. Generally, these materials are used interchangeably, but titanium alloy has marginally superior properties for non-bearing situations, especially when cast porously as a coating to the stems to enable good fixation; whilst wrought cobalt-nickel-chromium-molybdenum alloys are preferred for the wear surfaces of total joint prostheses. With plastics, each had its own area of superiority. UHMW HD polyethylene is used in metal-plastic articulating prostheses. Silicone rubber is ideal for many non-loaded or lightly loaded situations but polypropylene is preferred in some cases for its superior mechanical properties.

However, these materials should be used with some caution. For example, if bone cement is used, the high temperature caused by polymerization may damage surrounding tissue and the hypersensitivity of adjacent tissue to metal can lead to loosening of prostheses; but these look optimistic for further improvement.

Some advances have been made in certain areas and the next generation of implants might be based on quite different materials. The success of implantation will very much depend on the care and detail given to materials selection.

CHAPTER 5. TECHNIQUES REQUIRED

5.1 Introduction

The previous chapters present the review and discussion of the anatomy of the hand, previous joint prostheses design, and the criteria for selection of materials. From this, it is clear that a model which can represent the geometrical shape of the bone cavity is needed in an attempt to solve the fixation problem.

As discussed in Chapter 2., the geometry of bone cavity is irregular, and conventional manual design and representational methods are not suitable. However, computer software is now available to model the irregular objects, Additionally, medical instrumentation equipment can now be used to collect data for modelling.

X-rays have been used in medical practice to detect changes in a patient's body and mechanical components for a long time. An extension to this, known as computerized tomography (CT) was introduced in the early 70's with the ability to reconstruct cross-sectional representations of an object. These techniques give rise to the possibility of accurately modelling finger bones, and the following presents the details for the required technologies.

5.2 Medical instrumentation

5.2.1 X-ray

X-rays, are a type of penetrating electromagnetic radiation which is created when electrons, accelerated in a vacuum tube by very high voltages (20,000 to 1,000,000 volts), are suddenly arrested by impact on a target. Their extraordinary usefulness in diagnosis is due to the fact that their absorption varies from tissue to tissue, being least in structures containing air and greatest in bone. Thus the shadowgraph picture, produced by interposing part of the body between the X-ray tube and a photographic film (which is darkened by X-rays), can be used to show; fractures in bones, wear in joints or abnormalities in tissues. Because of this ability, X-rays outline the shape or contour of the bone, thus they can be used to obtain the contour or shape of the bone accurately.

The equipment for generating X-rays consists of a high-voltage generator connected to the X-ray tube by heavily insulated cables. In this vacuum tube, the electrons given off by a heated filament are accelerated towards a spot on a target, where some of their energy is converted into X-ray radiation. The tube is heavily shielded by lead cladding to confine the emission of X-rays to the required direction. Much of the bulk of modern machines is made up of equipment for adjusting the patient's position so that the beam is directed correctly and by equipment to hold the photographic plates or direct viewing devices.

However, X-ray shadowgraph can not display axial transverse tomographies of the specimen it examines. When a doctor wants to examine the body in detail, or an engineer wishes to inspect the detail of the cross-section of a component, general X-ray equipment is not satisfactory.

5.2.2 Computerized tomography (CT)

Computerized tomography (CT) is now used widely. (also known as CAT, computer aided tomography or computer axial tomography). CT is a special X-ray technique capable of imaging cross-sections of any part of a body and obtaining good contrast between tissues which cannot be visualized by conventional techniques.

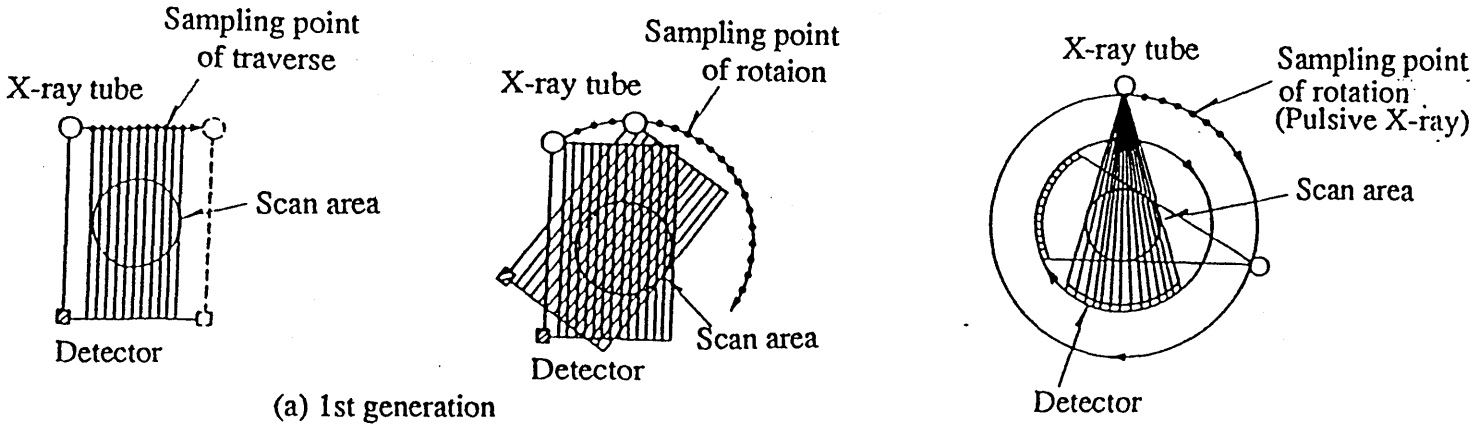
There are two types of CT scanner, one uses X-rays and another ultrasonic vibration as the penetrating sources. However, the CT scanner using X-ray is the most applicable for finger joint replacement, so we shall discuss X-ray CT scanning only.

1) Principles of X-ray CT

An X-ray CT scanner irradiates a specimen from a circumferential direction, collects the penetrated X-rays modulated by the X-ray absorption coefficient inside the sample, and then reconstructs the two dimensional X-ray absorption coefficient distribution within the cross-section using a computer. An X-ray CT image is expressed by means of a CT number, ranging from 0 for the X-ray absorption coefficient of water to -1,000 for that of air and +1,000 for bones. The X-ray absorption coefficient is approximately proportional to density, so that a CT image presents a two-dimensional distribution of density. An image is displayed in 64 grey levels (high quality devices now use 256) on a cathode ray tube (CRT), with black, white, and gray indicating low, high, and medium CT numbers respectively. As shown in Fig 5.1 , the scan mode of an X-ray CT scanner is classified into four generations, from first to fourth, in accordance with their usage. Among them, the second and third generations are for practical use in industry, whilst the fourth generation is generally applied in the medical field.

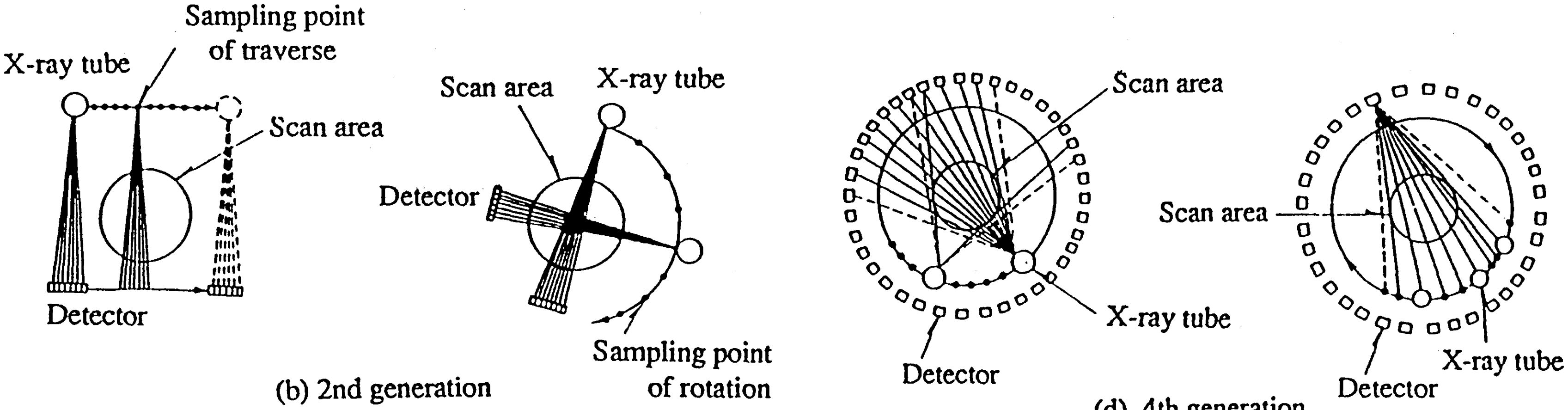
2) Image processing

In a CT scanner, the X-ray source and a radiation detector, which measures the intensity of a narrow beam of X-rays as it emerges after passage



(a) 1st generation

(c) 3rd generation



(b) 2nd generation

(d) 4th generation

Fig 5.1 Four generations of X-ray CT scanner. The second and third generations are for practical in industry. The forth generation is applied in medical pratice.

through the tissues, are moved in a compound pattern so that each part of the section is traversed by the beam in several directions.

Measurements of the absorption experienced by the ray in its various directions of transit are fed into a computer which forms part of the machine. This calculates, with great accuracy, how much of the beam was absorbed in each minute region. The local brightness of a cathode ray tube display is then modulated so as to map the pattern of absorption in the cross-section. Organs having slightly different X-ray absorptions can be visualized and abnormalities of blood content of different tissues noted.

All CT scanners include a half-tone screen. In relation to the object, the picture elements, usually being called PIXEL, are 1 mm x 1 mm, or 2 mm x 2 mm.

Two of the most important parameters are the scanning time and image resolution. These two parameters have been improved; the scanning time from 180 seconds on the first scanner (Watson, 1981) to a few seconds on the current machine, and the resolution has been improved from a pixel size of about 6 mm x 6 mm over a picture matrix of 80 x 80 pixels to a pixel size approaching 1 mm x 1mm (or even smaller) over a 320 x 320 matrix on current machines. However, pixel size is dependent upon the particular machine characteristics and the area under investigation.

Several forms of body image scanning are available for medical diagnosis as well as industrial inspection. The image reconstruction and display of the X-ray CT scanner has been developed from two dimensional images to three dimensional images. A three-dimensional image-reconstruction display system can build the structure of internal contours from input of multiple cross-section X-ray CT images.

Body profiles can be automatically intensified from scanned cross-sections and logically joined by a smoothing program that would draw the contour three-dimensional image on screen using computer graphic methods. Such a system makes it possible to view internal structures by modifying the three-dimensional image and rotating it into any desired position

This powerful technique has not only greatly extended the range of conditions in which X-rays can give diagnostic information, but also set up a new method in the industrial field for inspecting the internal structure and density distribution of important, heavy and valuable components.

5.3 Computer-aided design (CAD)

5.3.1 Introduction

5.3.1.1 The conventional procedure of mechanical design

Mechanical design is the fundamental technology of mechanical engineering. In general, Fig.5.3.1.1.1 shows the traditional procedure of mechanical design. From this diagram, we can see that the design procedure mainly contains the cycle indicated in Fig.5.3.1.2.

During the design process, the designer needs to establish the model first, this requires a lot of experimental data, and experiences of mechanical design. The solid modelling of the finger joint and bone in this project is for the purpose of collecting geometrical data for the further design of artificial finger joints. After setting up the model, an engineer must perform a large number of calculations, analyses, judgements, then modify the model again and again. The design cycle lasts a long time and uses a lot of manpower. So, the traditional design method is actually inefficient. As the specifications for the products becomes more and more stringent, the mathematical models set up become more and more complicated. Engineers must spend

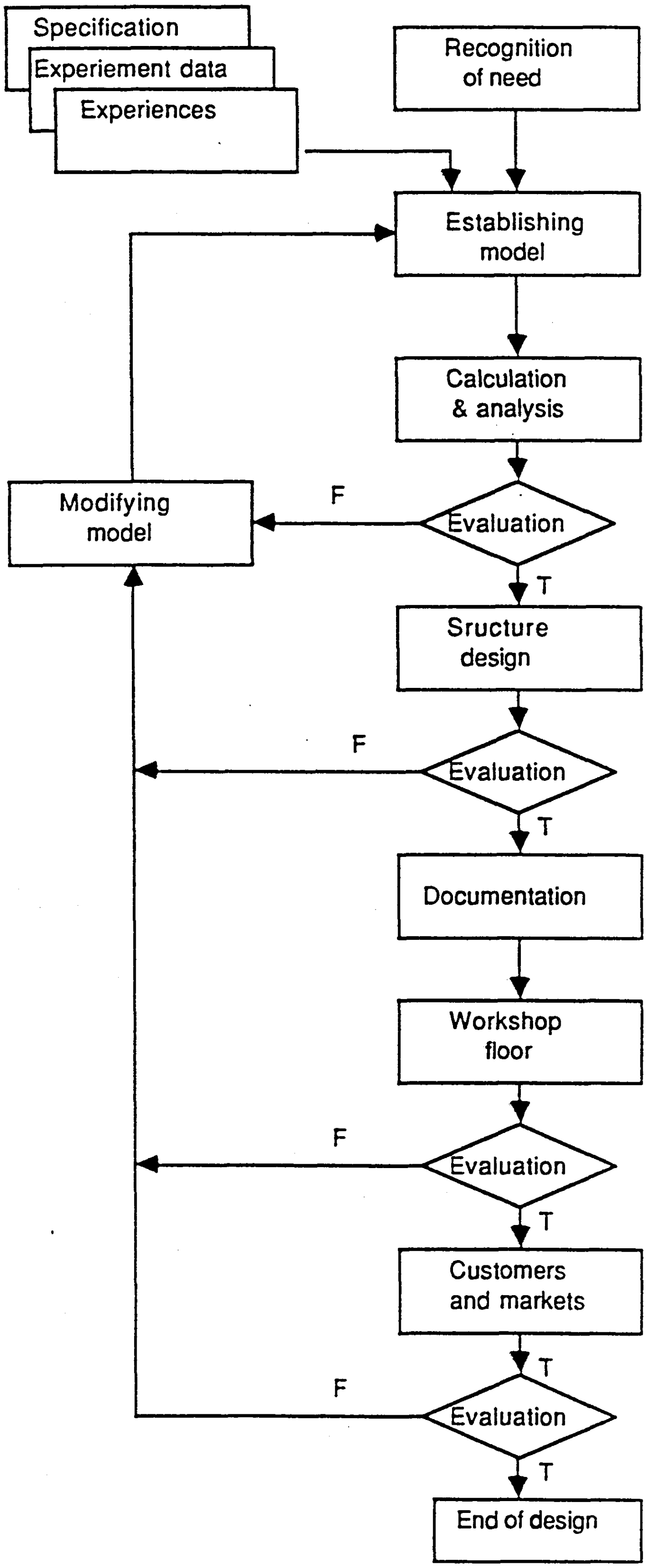


Fig. 5.3.1.1 The tradditional procedure of mechanical design

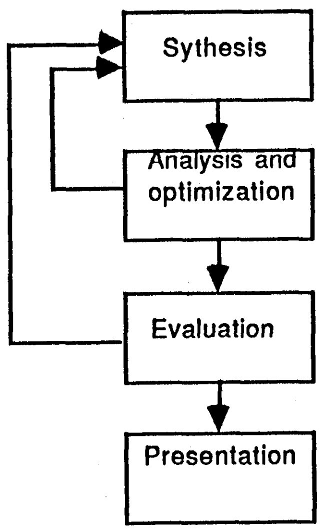


Fig.5.3.1.2 Main process of mechanical design

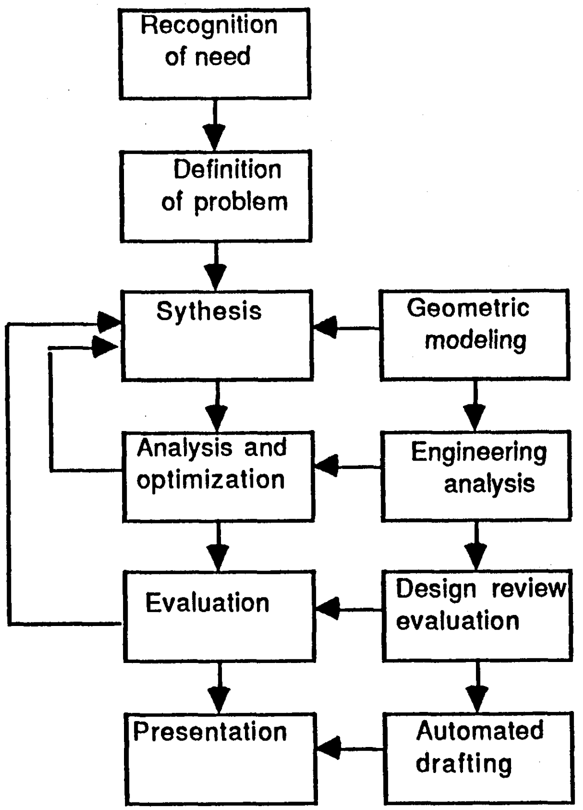


Fig.5.3.1.3 Application of computer to design process

much more time finishing the analysis work , etc., and have difficulty in finishing the estimated work when encountering a complex problem. It is impossible to design an artificial finger joint of which shape of stem is similar to the medullary canal of the bone, because of lack of graphic software for modelling to obtain the data for the design. In addition, as technology develops day by day, products change quickly. Customers often demand different kinds of products in small quantities, and require the supply quickly. Obviously, the traditional design method can not meet the requirements of technical advances.

5.3.1.2 The development of CAD

It is well known that digital computer technology has developed rapidly in recent years. The computer not only has the function for quick and accurate calculation ,but also has the store function and logical judgement. This means that the machine has the ability of memory and programmed thinking. As light pens, CRTs and plotting machines came into being, the possibility of carrying out user/computer dialogue is offered. Therefore, it is possible to combine computers with man to make good use of the advantages of both man and computer. This makes it possible to use computers to assist engineers with complicated design work, which is otherwise very time consuming or impossible to finish, like modelling and design of complex geometry. This is what CAD means. It frees an engineer from heavy calculation, and drafting, so that he/she can concentrate on solutions to real problems. It also enables the designer to carry out the modelling of complicated and irregular shapes, which are then be able to be designed and manufactured with the CAD/CAM system. For example, a component would take an engineer about 6 weeks to redesign if a customer required a different specification. If the engineer has access to a CAD system, the redesign work would only takes 10~15 minutes. Therefore, the manufacturing cycle of the product is shortened significantly. This helps a user company to beat the market competition. It also helps the user company to manufacture particular products which could not be designed and manufactured without the aid of a CAD/CAM system. Nowadays, CAD is widely used in industry and the interdisciplinary science, such as bioengineering, and is being improved continuously. Fig.5.3.1.3 indicates the application of the computer to the design process.

During the last few years, computer hardware and software have been improved significantly, especially in the area of graphic software. This enables solid modelling of any geometry. GEOMOD and CATIA are two types of powerful software used in this dissertation.

5.3.2 *Classificaiton of CAD System*

A CAD system contains hardware and software components, which are effectively integrated into one system. Typical hardware usually contains: 1) workstations, including alphanumerical display, console terminal and keyboard, graphic-interactive display digitizer and plotter; 2) Storage unit and processor with a magnetic tape unit.

However, the hardware would be useless without the software to support it. The CAD software consists of computer programs to implement computer graphics on the system plus application programs to facilitate the engineering functions of the user company.

Before further discussing the CAD system, it is necessary to have a rough idea about the user interface systems. User interface systems can be broadly classified as:

1. User-initiated interfaces,
2. Computer-initiated interfaces.

In the former case, the user is in charge, controlling the process of the user/computer dialogue. For example, the user issues a command to create a file in the computer, gives the command to compile the file to create an object file, and issues LINK commands to let the computer link the main program with other sub-programs and data in libraries. In this process, the user is in charge of the user/computer dialogue.

In the latter case the computer system originates the dialogue, the user replies and, on the basis of that reply, the computer selects the next stage in the interaction. The example given in section 5.3.3 basically indicates this procedure. When the program for a bearing housing design is running, the computer prompts the designer by some commands which ask for inputting parameters. When the parameters for the structural design are obtained, the computer asks the user to input commands to determine whether to draw an assembly drawing or a separated workpart drawing.

As a general rule, user-initiated interfaces are most suitable for experienced or regular computer users, whereas computer-initiated interfaces are best for inexperienced or casual users. Of course, situations exist where the most appropriate interface is made up of both interface classes. Also, in some cases, there is no apparent distinction between these two interfaces.

In the case of application of CAD in engineering, computer-initiated interfaces are more suitable for CAD system design. However, some of the engineering problems can be described by some object function, and the computer can implement the design to get the best results without involving the designer. Nevertheless, some engineering problems are difficult or impossible to be described by an object function, especially the structural design, and the modelling and design of a workpart with an irregular shape. In this case, the designer is required to communicate with the computer and modify the design in time when using the computer to aid modelling or design. Therefore, within the computer-initiated interface, according to the extent of how much communication there is between the user and computer during the design process, the CAD system can be classified as either :

1) User/computer dialogue system.
or 2) Non-user/computer dialogue system.

5.3.2.1 User/computer dialogue system

User/computer dialogue systems fall into two classes:

1. Menu system where the user is presented with a list of alternatives and chooses one of these alternatives.
2. Question-answer systems where the computer asks a question and takes action on the basis of user's reply.

When running a program in this system, the designer is required to input information into the computer, thus the design is carried out by both the designer and the computer. A good example of this is the performance of structural construction in mechanical design. While the design is being implemented, some decisions should be made by the designer according to his or her experience.

The software GEOMOD and CATIA, which are used in this thesis have Menu type user/computer dialogue systems, whilst the example given in section 5.3.3, the bearing housing design program, partly uses the question-answer system.

In this system, the designer can correct and improve the design immediately according to his or her experience which is impossible to put into the database for the computer itself to judge.

5.3.2.2 *Non-user/computer dialogue system*

In this system, a design is carried out by a computer without inputting or by just inputting a little information from the designer to get the best result. Such a system is suitable for those problems which can be described by an object function, such as strength and stress analysis, heat-transfer calculation, and dynamic response of mechanisms. During the design process, the computer can automatically search for the necessary information, such as the restraint and optimization condition and so on, from the data base to compare with so as to get the best result.

The advantages of the system:

Finishing the design more quickly because the computer need not stop to wait for the designer's command.

Disadvantages are:

1) A designer who does not have a good background of computer knowledge will have difficulty or spend a lot of time modifying the design, especially the structural design in mechanical engineering. The reason is that the structure of most products can not be described by a proper function.

2) The designer can not interface with the computer while the design is being carried out. If the designer is not satisfied with the result, he or she can not correct the design at a certain stage. Nevertheless, such a situation often happens in the field of mechanical engineering.

In this case, it is better to apply a user/computer dialogue system so that the designer can evaluate the design and improve the design immediately according to his or her experience.

In conclusion, in the field of mechanical engineering, a good way to carry out CAD is to use a system that combines the two systems into one, using the non-user/computer dialogue system to execute stress-strain analysis and optimazition, using the user/computer dialogue system to perform the structural design or some sort of solid modelling. In this way, the advantages of both man and machine are well used. Several systems possessing this function have been developed. CAM-X system is one of these systems. The following presents a bearing housing design in this system as example.

5.3.3 Application example

1. The system

The CAM-X system is loaded on a VAX 11/750 computer and runs under the VMS operating system. A designer can write a program for non-user/computer dialogue and run it in the system. A designer can also use a command to enter the 'CAD' stage. This is a menu system for graphics design. When a user enters the system, it presents a list of alternatives for a user to choose from. A designer can sit at the terminal, carrying out the structural design. It is remarkably easy to change the shape of a part or a whole design. For example, if a customer requires a particular specification of product which does not exist at that time, the engineer can just call out the standard drawing, and scale the drawing to get a rough design. According to the specification required, he can then modify the design to get a better result. With a CAM-X system, an engineer can create a design at the terminal. When an assembly drawing is drawn on the screen, different parts can be put onto different levels. After the design is finished, the graphics stored on different levels can be called out together to form an assembly drawing for a component or part. They can be called out separately to print a drawing for a component or a part. To use computer assisted design, a parametric program, shown in Fig.5.3.3.1 is necessary.

2. Procedure

A bearing housing design can show how the computer system assists a designer to execute a mechanical design:

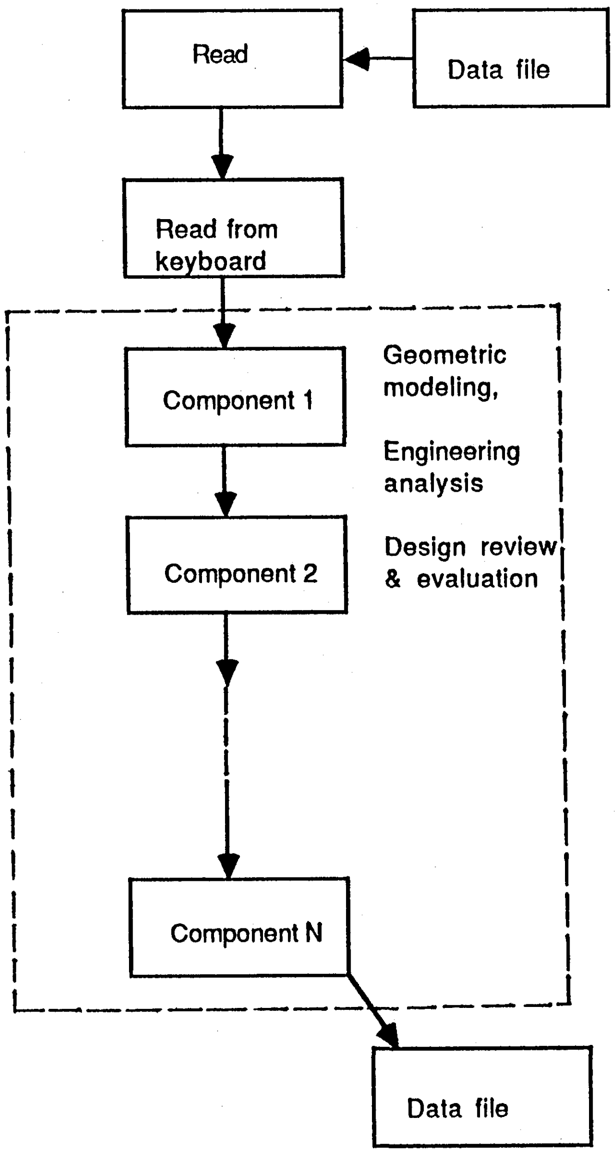


Fig 5.3.3.2 Structure of a parametric program

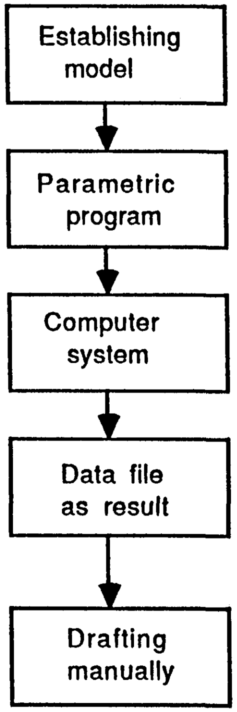


Fig.5.3.3.1 General way of CAD

(i) The designer must establish a standard structural model, and set up all necessary variables for writing a program.

(ii) The designer must translate all necessary design rules into a language which can be understood by a machine, i.e. write the parametric program. It can contain analysis, optimization and evaluation of the design.

(iii) The program is run in the CAM-X system to get the best result for structural design. After the program has been run, the result is output.

(iv) The designer can carry out the structural design according to the result, i.e. draw the bearing housing assembly on the screen, then print the result on the plotter. Note, here, after the computer outputs the result, the designer still needs to spend some time plotting the drawing. This procedure is showed in diagram Fig.5.3.3.2. However, the designer has to spend some time doing the structural design as mentioned above. Most of them think that computer aided drafting is computer aided design. This is a complete misunderstanding. In fact, a lot of graphic software has been produced. It is definitely possible to use computers to plot automatically. This would save more time based on the previous stage.

Since the CAM-X system is equipped with a graphic software GLUE-2, the idea becomes possible.

(v) A designer can use the data obtained from first part of the program to write a program as a pre-processor for drawing results. However, not all the designs require a program like this. Some particular parts of a component are just ordered in small quantities, it is not worthwhile to write a program to draw it. For those components or products which are often required in large amounts and different specifications by customers, this system would be a great advantage.

5.3.4. Discussion

1. Advantages

Compared with using pencils, scales, sheets and drawing boards to do engineering design, this method can save at least 70% of time. From this example, it can be seen that such a system has the following advantages:

1) Save time. After having spent some time learning how to operate the system, designers can be free from pencils, drawing board, etc.. The redesign cycle is significantly reduced.

2) Easy to learn . Such a system does not require users to have a good foundation of computer knowledge.

The design of a bearing housing would take a skilled engineer about 4 ~5 hours to carry out a structural design when a customer orders a different specification. Since a pre-processor has been programmed, all the essential parameters can be input to the pre-processor, and run by the computer then interface with the geometric data to form the representation of the design on the terminal. Input of the geometric data to the output of the result on the CAM-X terminal takes approximately 4 minutes. It is a hundred times faster than drawing it manually. This is how a user company can benefit from CAD.

The above example is only a component. If a complicated product is designed in this system, the designers would gain considerable benefit by using CAD.

All mechanical products are formed by many basic parts, such as bearings, shafts and so on. So, it is a good idea to standardize some of the shapes and programs for the basic parts and components, then create a library to store the subroutines. This offers designers more flexibility.

The advantages of a library is:

1) To save effort on design. The designers need not to go through the procedure which has been done before. He or she can simply call the subroutine needed in the main program.

2) Simplify the program, shortening the time for running a program.

2. Disadvantages of a computer-initiated interface CAD systems;

1) The system can not cope with a new product.

2) The system costs a large amount to finance. For small companies, it will not be widely used until the price of CAD systems are greatly reduced. This will be realized in about 5~10 years.

However, the system can carry out about 90% of design work for a designer, and shorten a design period by up to 70%.

In mechanical design, simple changes in components and size can be effected by one or two parameter alteration. Standard componenets can also be built into a system and used. When designing a product, an engineer often chooses the most suitable parameters and particular shapes to fit into the design. In this case, to set up a data base is obviously necessary.

3. Data base

A data base is a collection of varied information. Nearly all of the functions of a CAD system depend on its data base. The computer-aided design data base contains the application models, designs, drawing, assemblies, geometric data, process planning, bill of materials, parts lists, material specification, as well as additional data needed for manufacturing, much of which is based on the products design. So, it can not only be used in CAD, but also be used in CAM. In fact, a data base is a connecting link between design and manufacturing.

After a suitable method for the solid modelling of the finger bones is determined, a variety of solid models of the MCP joint and bones can be stored in a data base as the basic material for the joint prostheses design.

4. Benefits of CAD

There are many benefits of CAD, but only some of them can be easily measured. Some of the benefits are intangible, reflected in work quality and so on, others are tangible, but they show up in every stage of the production process, and it is difficult to assign a financial figure to them in the design phase. However, they can be summed up as follows:

1) Increasing the productivity of the design department of the user company. Produce those new products which can not be designed and manufactured without the assistance of a computer.

2) Shorten lead time.

3) Better design analysis. Since the time is saved, it allows the designer more time to repeat analyses so as to improve the quality of the design. In the preliminary stage, the designer can have a lot of alternatives, so it is possible to get a better design result.

4) Fewer design errors.

5) Greater accuracy in design calculations.

6) Standardizing of design, drafting and documentation procedures.

7) Improving procedure for engineering changes.

8) Benefit in manufacturing. The benefits of CAD carry over into manufacturing because the same data base is used for manufacturing planning and control.

From the bearing housing example, one can see the basic application of a CAD system in mechanical design. However, the bearing housing is a component in which each part has a regular geometric shape, whereas the bone cavity, which will be modelled for the design of the artificial joint, is irregular in shape. In addition, although the CAM-X system is mainly for 2D design, it can generate regular 3D models, but takes a long time and is unable to generate complex irregular models. Obviously, this system is not suitable for modelling the bone.

In order to use a CAD system to model the bone, a further understanding of the graphic software and solid modelling of an object is required. Following is the discussion concerning computer aided modelling.

5.4 *Computer aided solid modelling*

Compter-aided solid modelling is an important part of CAD, and modern CAD systems (also often called CAD/CAM systems) are based on the interactive computer graphics (ICG). A graphic modelling system is one which attempts to manipulate and display information about three-dimensional solid objects.

The graphics software is the collection of programs written to make it convenient for a user to operate the computer graphics system. It includes programs to generate images on the CRT screen, to manipulate the images, and to accomplish various types of interaction between the user and the system. Also, there may be additional programs for implementing certain specialized functions related to CAD/CAM, including design analysis programs, such as finite-element analysis and kinematic simulation; and manufacturing planning programs, such as automated process planning and numerical control part programming.

The modellers (i.e., graphic systems with the capability for modelling) hold information about the object being modelled. For some applications it is not necessary to have a complete description of the part, it is sufficient to use a simpler (and hence less expensive) modelling system. When a precise complete description of the component is needed, a full solid modeller is used. In this dissertation, the finger bones being modelled have a complicated geometry, so, a full solid modeller is required.

Geometric modelling is usually divided into three types. However, these types are broad and the distinction between them is by no means clear cut. These three types are:

1. Wire-frame modeller. This is the simplest type of modeller to develop. This system only stores and displays the edge of a component. It does not represent a complete description of an object. In addition, it is usually claimed that there is ambiguity inherent in a wire-frame model.
2. Surface modeller. This type of modeller can store and display the object with surface patches together with the wire-frame so that the image is displayed unambiguously. Normally, a surface modeller allows more complicated surface forms, and contains more information than the wire-frame one.
3. Solid modeller. An improvement over wire-frame models, both in terms of realism to the user and definition to the computer, is the solid modelling approach. In this approach, the models are displayed as solid objects to the viewer, with very little risk of misinterpretation. In addition, when colour is added to the image, the resulting picture becomes strikingly realistic. It holds sufficient data to be able to tell where the object is solid and

where it is not.

There are several approaches to solid modelling, (i) constructive solid geometry (CSG or C-rep); (ii) boundary representation (B-rep). The detail of these will be discussed in next chapter when the software for solid modelling is introduced.

5.5 Conclusions

With the advance of the modern instrumentation and CAD systems, there are several ways of solid modelling the metacarpo-phalangeal bones: First, the CT scanner can be used to obtain a set of cross-sectional images from live hands. Secondly, the sets of cross-sectional images can be obtained from X-rays, when the cadaveric bone is sliced. Then, the data obtained by CT scanner or X-rays can be input into the computer to perform the solid modelling, using B-rep approach method in the graphic software.

The following chapter presents the attempt at modelling using these available methods.

CHAPTER 6.

METHODS FOR SOLID MODELLING OF METACARPAL PHALANGEAL JOINT AND BONES OF THE HAND

6.1 Introduction

As reviewed in chapter 3, artificial finger joint prostheses have developed over the last 30 years. This has brought recipients a lot of convenience in their daily life as they more or less reachieve some degree of hand function. However, the design of the joints used to date have not fully taken account of the anatomical structure of the bone. This causes the stem of the artificial joint to poorly fit the cavity of the bone. This leads to a series of problems and finally to the failure of the joint implantation.

To attempt to solve this problem, it is necessary to design the stems of the joint prosthesis according to the space available within the bone cavity. Consequently, any model which represents the real geometric structure of the bone would provide a method to identify the available space within the bone.

The anatomical structure of the hand is irregular. The science and technology of the past limited the possibility of modelling complex bone structures. However, the advent of the digital computer, and three dimensional systems computer-aided design makes it possible to create the models needed in this project.

Computer-aided design is the only valid method to perform the modelling aspect of this model. As reviewed before, the computer-aided design system has been developed and has reached such a stage, that it can create any shape of solid model according to the data and parameters the designer possesses.

Recent technology has also offered a wide range of methods with the possibility of creating models, such as X-ray, and computer tomography. The modelling of the metacarpo-phalangeal, proximal-phalangeal bone and their joints has not yet been reported.

Among the several possibilities available, it is still difficult to decide which method provides the most suitable raw data for the modelling of the internal bone strutures.

However, in this chapter, computer-tomography, X-ray, and so on are used to perform data collection for the joint modelling.

6.2 Solid modelling using computer tomography in GEOMOD

6.2.1 Introduction.

Computer tomography has been widely used in medical practice and is becoming important in industry [Tanimoto *el*, 1985]. This is a non-contact method of examination which has the ability to generate an image of a slice within the human body or workpiece without physically disecting the object examined. So it is used to examine the human body or large workpieces or componets which can not be cut to be examined [Tanimoto *el*, 1985]. The software for computer modelling available today makes computer tomography a suitable method to acquire the data for computer modelling because it is clearly impossible to physically cut a living hand to get the data to model the bone and cavity. The computer tomographic scanner can be used to scan any part of the body, or to be more exact, any part of the metacarpo-phalangeal joint to get an image of the cross-section of bone and joints.

In addition, the GEOMOD software can be used to create a model using a set of cross-sections, gained from the images obtained by computer tomographic scanner.

Therefore, the computer-tomographic scanner is suitable for both data aquisition and computer modelling. The section following reports on the method using computer tomographic data for computer modelling.

6.2.2 Data for solid modelling

The method of obtaining data

The data for computer modelling is obtained from a CT scanner. A hand is placed inside the CT scanner so that the part of the hand, i.e., the MCP joint for which the data is required may be scanned. When the hand is scanned, the off-set between each cross-section can be adjusted according to requirements. The data is obtained in the form of a set of negatives of the sections throughout the hand. Positives can then be printed (Fig. 6.2.2.2).

From the positives, the edges (profile) of each cross-section can be easily seen, then a number of points along the edges can be digitized as data to form the profile for solid modelling.

6.2.3. Hardware and software

6.2.3.1 Hardware

The facility employed for solid modeling is an IBM 6150 micro computer system (engineering workstation) (Fig. 6.2.3.1), it consists of:

1) IBM 6150 computer system;

2) An alphanumeric keyboard;

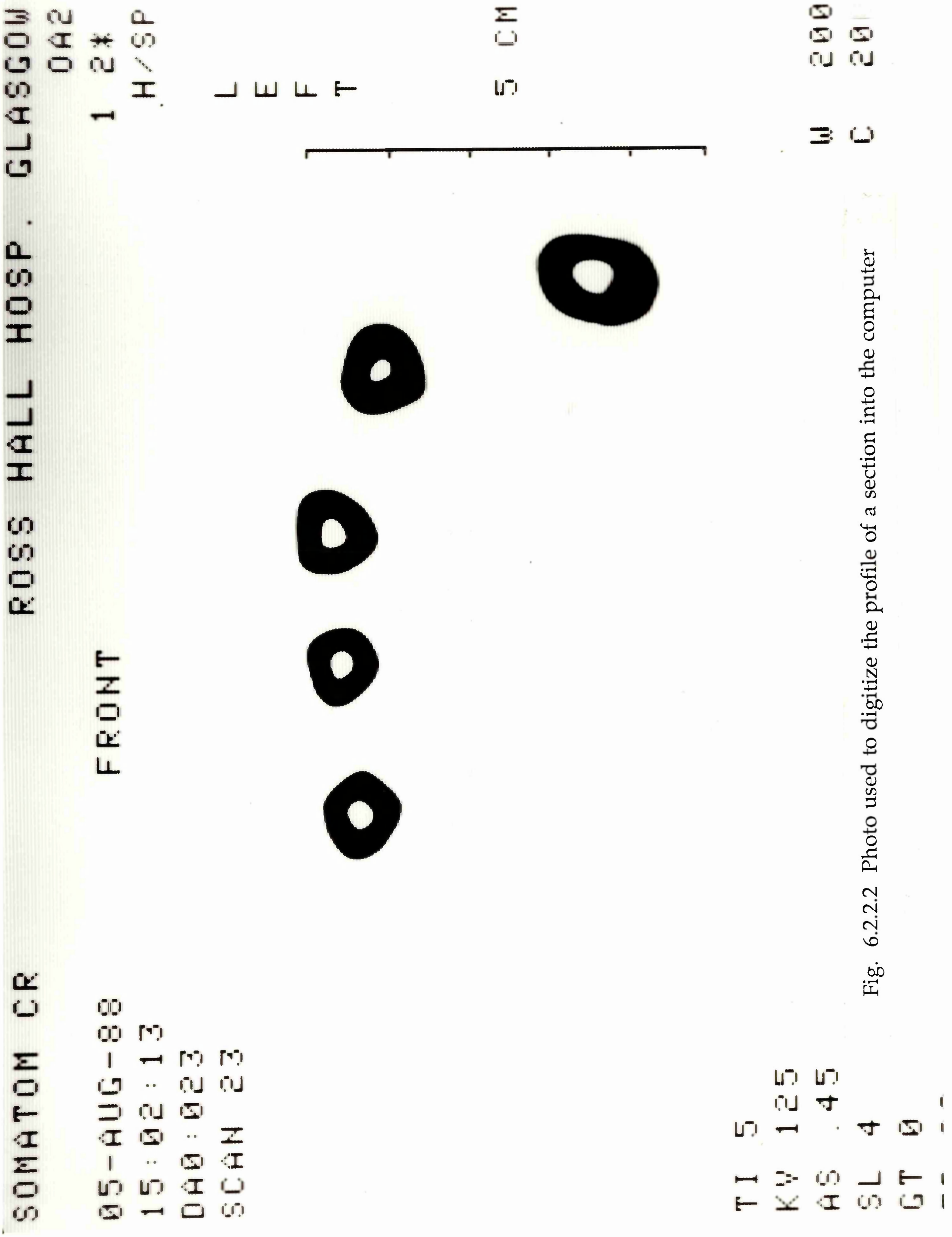


Fig. 6.2.2.2 Photo used to digitize the profile of a section into the computer

3) A monitor for alphanumeric display;

4) A monitor for graphic display;

5) A tablet with graphic cursor and 4 function button (mouse) to select commands and input data;

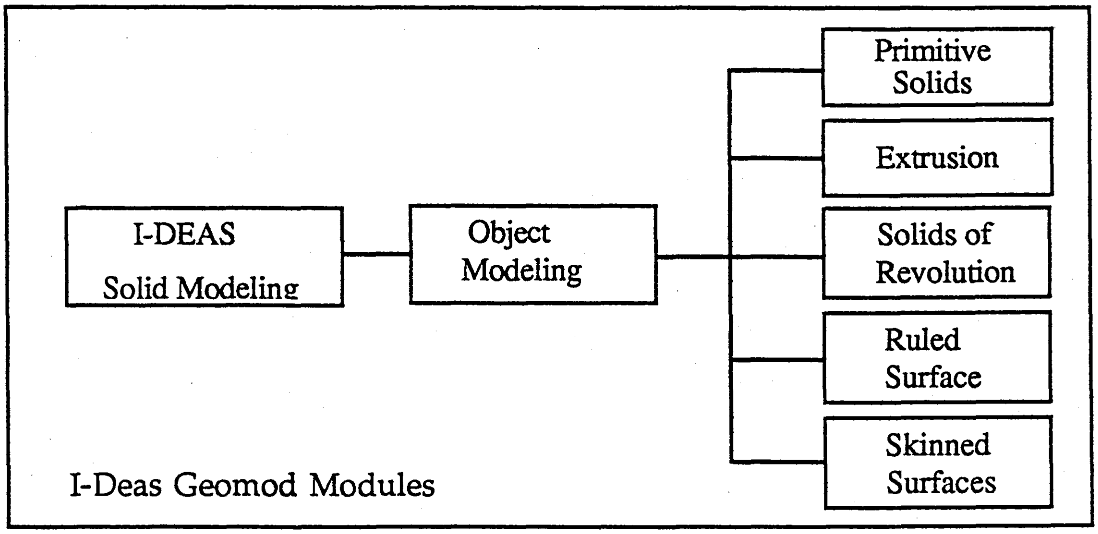
6) A lighted program function keypad;

7) A device with dials consisting of 8 potentiometers for controlling the graphic display.

6.2.3.2 Software

The software package used in this report is 'CAEDS', also known as I-DEAS GEOMOD. It is an interactive solid modelling tool for developing the concepts and initial designs of mechanical components and systems. It offers the capabilities the designer needs for defining and evaluating a product's geometry. Geomod is a modular family of software tools that allows the product designers to design solid geometry and use the geometry to model a system of components. This family consists of the modules shown inFig. 6.2.3.0:

Fig. 6.2.3.0 Modular family of GEOMOD



A designer can model geometry as solid objects by using Object Modeling. To create a solid object, Object Modelling allows the designer to use familiar 3D geometric shapes (primitives), 2D outlines, or sets of cross-sections. Manipulation of the geometry by Object Modeling lets the designer combine, cut, and deform objects. As the designer works with the solid geometry, Object Modeling offers the ability to display the geometry. Display parameters allow the designer to control the viewport, the optical characteristics of the displayed geometry, and other factors that affect the display.

The software package can be used to create:

1) A solid model which has a regular shape;

2) A solid model which does not have a regular shape but each cross section is the same: (a prism)

3) A solid model of irrregular shape.

The following will show how to use Object Modeling to create and manipulate solid geometry.

Object Modeling offers five ways to create a solid object:

1) Primitives — familiar solid shapes, eg. cuboid, cone, sphere.

2) Boolean operations —use of two or more objects to create a new object

3) Profiles — extrude or revolve a 2D outline

4) Skinning — use a set of cross-sections to define a solid

5) Elemental parts — assembling an object from points, facets, surfaces and bodies.

The type of data obtained from the CT scanner makes *Skinning* the best method of building a solid model of the finger joint.

SKINNING allows the designer to model a solid by defining its cross-sectional shape. The designer models one or more cross-sections of the solid as the profile. As the shape of the solid varies, the profiles are created to represent the solid shape at several planar locations. To generate a 3D solid from the profiles, Object Modeling lets the designer position a group of profiles in 3D space. The group of profiles is called a skin group. Object Modeling generates the solid model from the skin group. See Fig. 6.6.6.1 (1).

The designer uses Object Modeling's solid geometry to solve design problems. Object Modeling offers several ways to manipulate the solid geometry. A task is a set of commands that relate to a specific activity. To create and manipulate solid geometry, a designer can use the following operations:

1) Object 3D-- to create annd manipulate 3D geometry.
2) Working Set 2D-- to create and manipulate 2D geometry.
3) Profile 2D-- to create and manipulate 2D geometry.
4) Skin group-- to model a solid using cross-sections of the solid [36].

6.2.4. Procedure used to create the solid model

6.2.4.1 Input data

Photographs of the cross-section are sequentially fixed to the tablet. A number of points along the edges of both the outside cortical bone and cavity of the bone are then manually digitized into the computer to define the profiles for skin grouping of the bone model.

All the sections need to be related to an axis in 3D space whilst cross-sections in the CT scanner are being obtained and also whilst the solid model on the computer is being created. Consequently, all the sections must align (be relative to the same axis set) properly when digitizing the data into the computer, otherwise the model built of the finger will be meaningless.Therefore, it is important to carefully align every picture with the datum so that each section is in the correct position in 3D space.

There are two ways to implement this procedure:

Method 1 Make a mark, such as a line and a point, or a cartesian coordinate system on the tablet, see Fig 6.2.4.1. Every time the points are input into the computer, use this as the datum to locate the picture and secure it to the tablet. Use the 'puck' to digitize the points into the computer to form the boundary of each cross-section. This is a quick way to input the data.

However, the datum mark is on the tablet, and when the operator aligns the photographs on it , a small error in positioning the photographs away from the axis set on the tablet would cause a large error on the computer because the scale between the tablet and the computer, in this case, is increased. See 3.1 5).

Method 2 Mark 3 coordinates on each photo first. Each time the WORKING SET is set, key in the coordinate of the datum to display the datum on the screen, then display the datum of the photographs on the screen as well, move the photograph untill the two datums fit together on the screen. If the photo is not in the correct position, it will be easy to see because a small error on the tablet will be enlarged on the screen display. See Fig. 6.2. 4.2. After aligning the photo, proceed as in method one.

This method takes more time than the previous one, but is more accurate. A small error of 0.2 mm on the tablet, however, would became 1mm on the screen, if S2=5:1, and this error is easy to see so that the operator can align the pictures again.

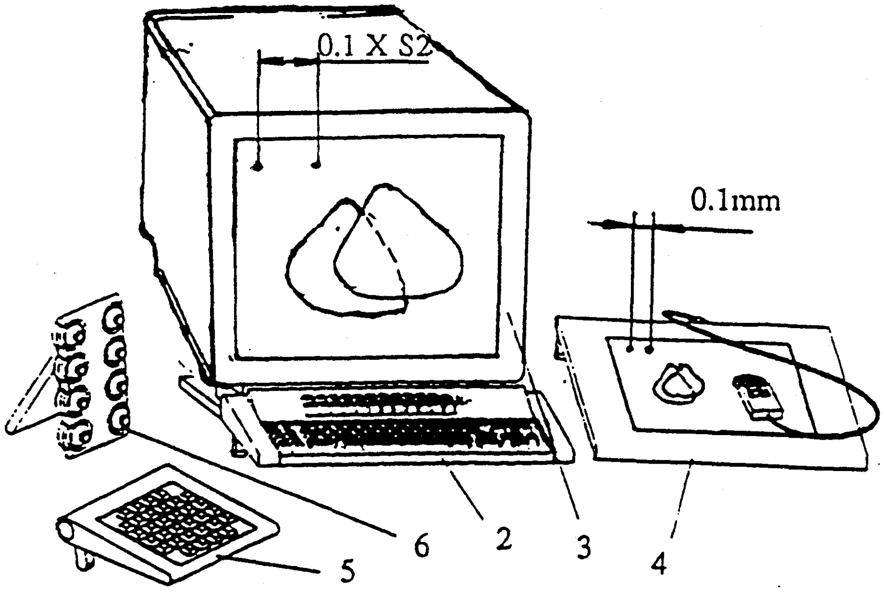


Fig. 6.2.3.1 IBM 5080/5085 Graphics Workstation

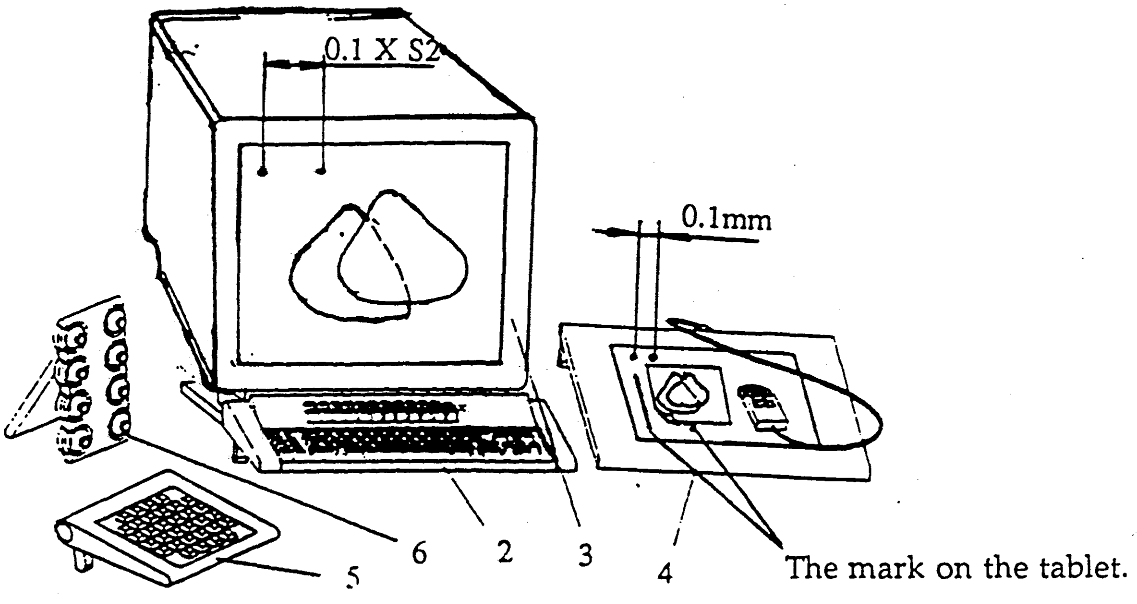


Fig. 6.2.4.1 The relationship between the tablet and workplane(screen)

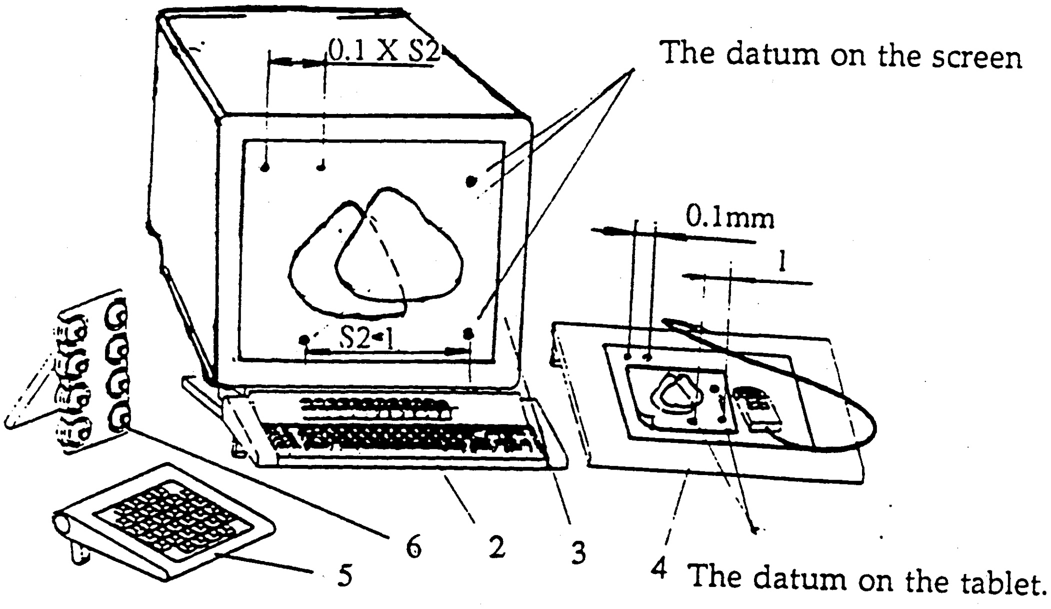


Fig. 6.2.4.2 The second method to input the data.

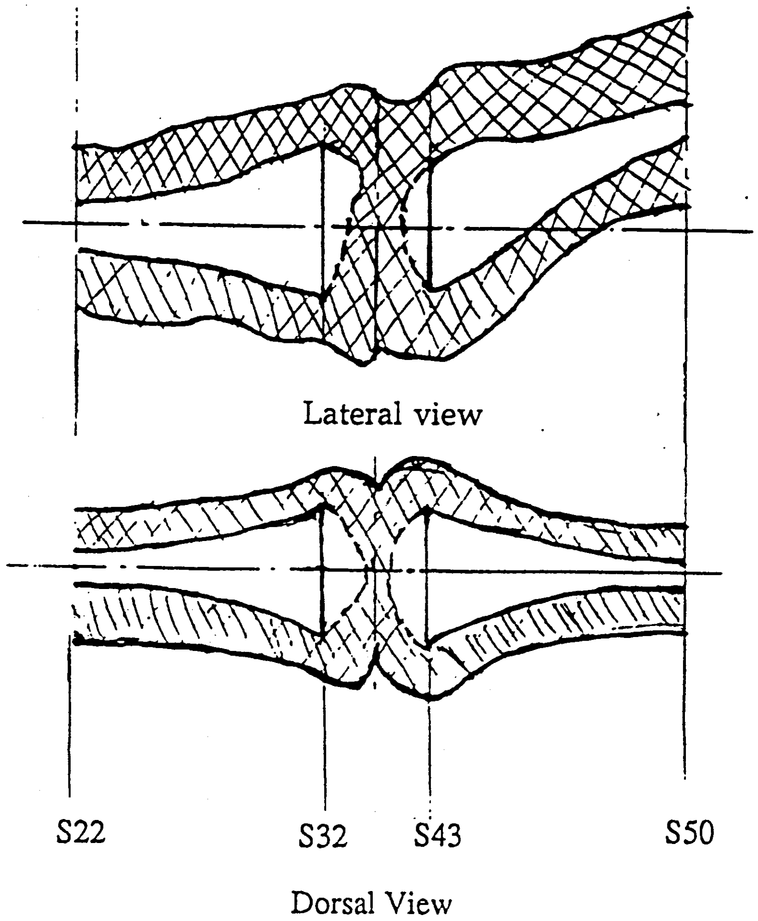
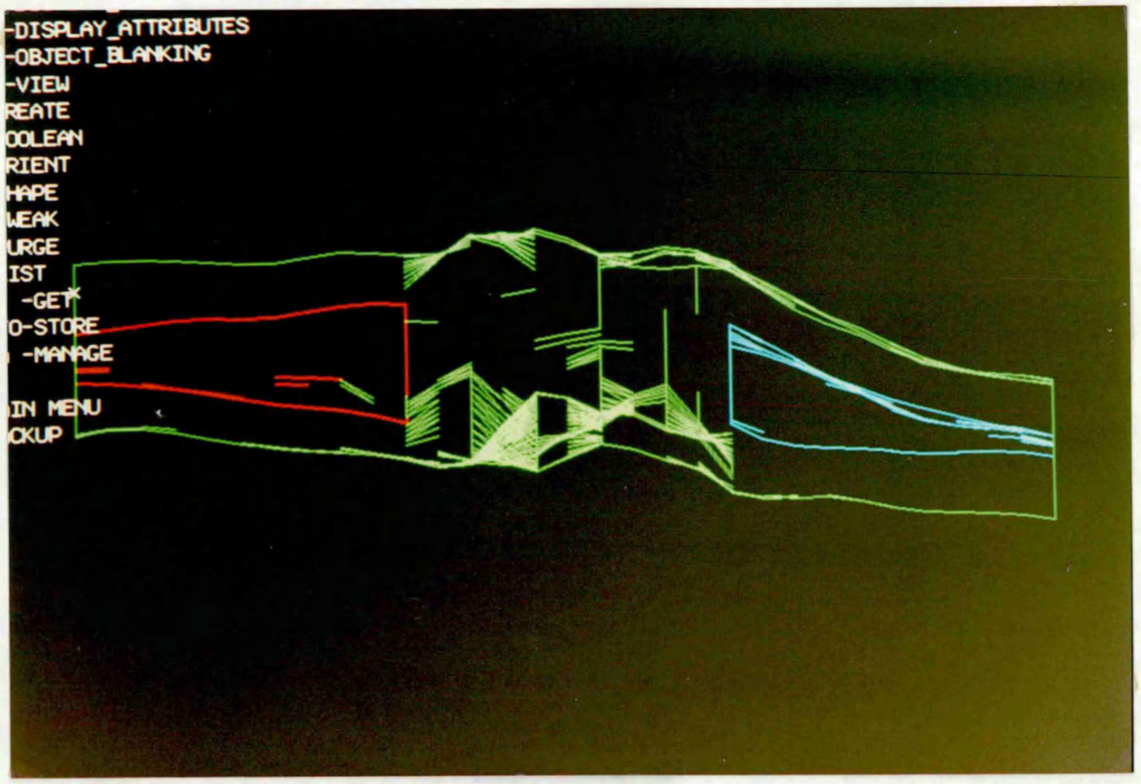
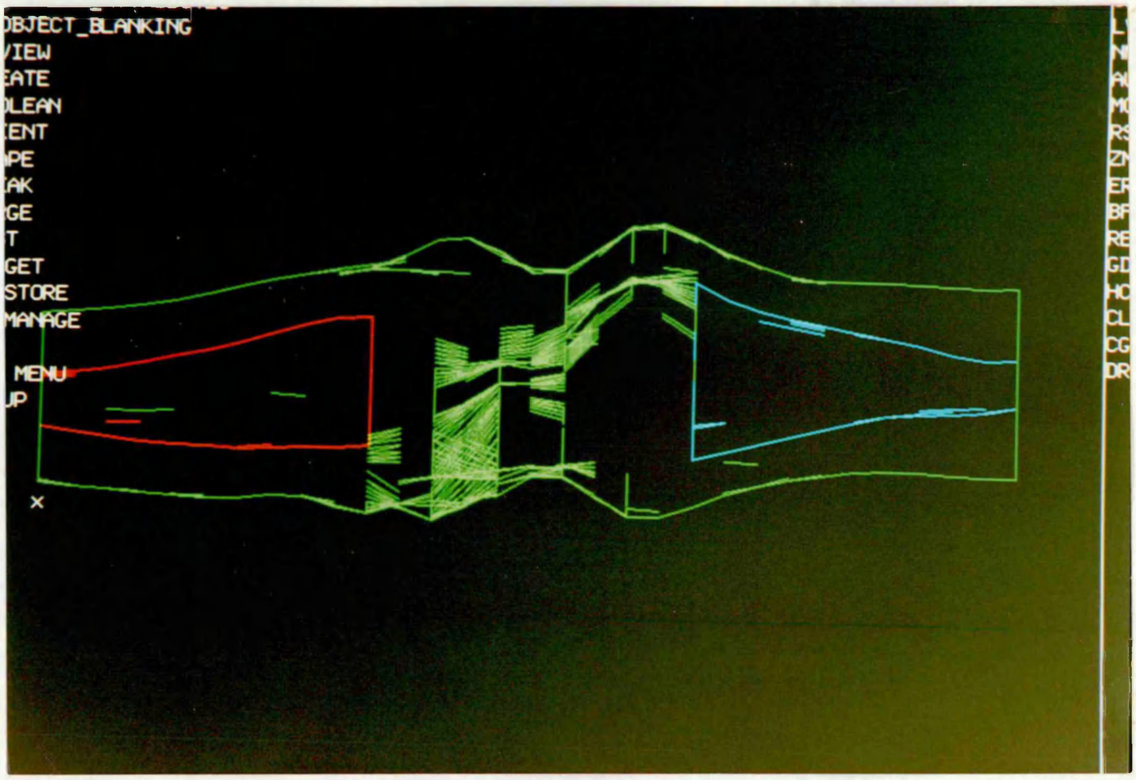


Fig. 6.2.5.1 (2) The model created by the second method



Lateral View



Dorsal View

Fig. 6.2.5.1 (1) The model created by the second method

6.2.4.2 Creating the solid model

Use the data input(points) to create the profiles, then use the set of profiles to create a skin group, and finally create the solid object.

6.2.5. Results

The solid model of the metacarpo-phalangeal joint is displayed with outer cortical bone and the cavity together. The solid model created by the two methods are slightly different. The main differences between them is due to the accuracy of the methods used to input data for modelling. See section 6.2.4.1.:

The one created by the first method is seriously kinked, whilst the one created by the second method is smoother in shape. Here, the one created by the second method is recorded (Fig. 6.2.5.1 (1)).

After the model has been built, the designer can use a plane to cut the model in any direction to obtain a cross-section. It is easy to visualise the bone and the cavity. The space for the artificial joint can also be obtained. Choose a plane, and cut the solid where the largest section is located on both the metacarpol and proximal phalangeal bones. The space between the two largest sections, S32 and S43 in this case, is the space allowable for the hinge of the artificial joint. See Fig. 6.2.5.1 (2).

6.3 Solid modelling using Computer Tomographic data in CATIA

6.3.1 Introduction

Modelling of the middle finger bones using GEOMOD was carried out on the IBM 6150 engineering workstation. However, to implement solid modelling, a large amount of memory as well as high computational speed is required, in order to operate the model. IBM 6150 is not amenable to this performance due to its small memory and slow computational speed. One of the ways of estimating how closely the model represents the real geometry of the bone, is by using the casts of the bone cavity and comparing by eye. This requires the model to be shown as a shaded image and rotated in any direction. Because of slow data processing, GEOMOD and the IBM 6150 can not meet this requirement.

Since another powerful graphic software CATIA is available and loaded on the IBM 3090 mainframe, it can improve the above situation, so the modelling was transfered to CATIA. This section shows the modelling carried out on CATIA. The data used in this section is the same as that used in GEOMOD.

6.3.2 Hardware and software

6.3.2.1 Hardware

The hardware on which CATIA is loaded is almost the same as that of GEOMOD, see section 6.2.3.1. The only difference is , when CATIA is used, it is read into the IBM 3090 from the local station first. All the data processing during the modelling is performed on the IBM 3090.

6.3.2.2 Software

CATIA is a Computer Aided Design and Computer Aided Manufacturing (CAD/CAM) interactive software package. It possesses fully integrated advanced drawing functions and three-dimensional creation, manipulation and display of objects. The main dialogue device in this CAD/CAM system is an IBM 5080 graphic screen. The best use of the screen is with all capabilities of this screen, including local graphical processing, polyhedral shapes shading, colors, adjustable brightness and blinking, mainly taking human factors into account.

CATIA is divided into several modules. Those which are relevant to the modelling of MCP joint are:

1) *Base* module, which is mandatory for the CATIA software modules. It includes all the necessary common resources, such as alphanumerical screen management;

2) *Three Dimensional Design* Module: This module is used to define, analyse and manipulate various wireframe, three dimensional geometric entities; and define and manipulate simple surfaces accessible through their canonical equation;

3) *Advanced Surface* Module: This module is used to define complex surfaces generated through variations of planar curves (such as, segments, circles, conics or unspecified curves) meeting certain conditions (e.g. laws of tangency to other surfaces); create developable surfaces (surfaces that can be flattened); develop ruled surfaces.

4) *Solid* Geometry Module: This can be used to design and use three-dimensional objects by combining simple volumes.

In GEOMOD, the solid model of an object with an irregular geometrical shape can be created by defining the profiles of each section. A skin group is created and it is changed into a solid model, see section 6.2.3.2. However, it is quite different to perform solid modelling of such an object in CATIA.

In CATIA, a solid model with regular geometry may be created by the following procedure:

i) Create faces. To create a face in three dimensional space, one must use points and lines in either 3D space or a defined 2D plane to define them.

ii) When all the necessary faces are created, create 'corner surfaces' based on the above faces.

iii) Transfer the corner surfaces into curved faces. All these faces are created for joining the different elements (faces).

iv) Create connecting surfaces between each base face.

v) Join all the faces to create a volume, and finally transfer them into a solid.

For an object with regular surfaces, the designer can also use the primitives, such as cubic, cylinder, sphere, etc., to form the solid model by using the functions join, subtract, union, etc..

The procedures for the creation of a solid with an irregular shape is complicated. When we use CATIA to create the solid model of the MCP joint and bones, it can hardly be done due to the complex surfaces of the bones. First, a designer needs to create the complicated surface, then divide the surface into several faces and create two faces at each end of the model, connect them to get a volume and finally turn them into solid.

A designer can also use another command to define a solid model using multi-section and two end points. Fig. 6.6.6.1 (3).

However, the surface model, or a very thin skin surface solid, can also represent the geometry of the bones. Therefore, we can carry out the surface modelling of the bones and joints instead of solid modelling.

There are two methods of modelling complex surfaces using multiple sections in CATIA:

1) Use multiple sections, spine and seam as the basic elements to generate surface:

To model a complex surface in CATIA, a designer can use a number of sections described by open or closed composite curves, such as circles, arcs, splines, etc., to define a complex 'skinned' surface as in GEOMOD. The difference from GEOMOD is, in CATIA, apart from defining each sections, one must define a 'spine' or 'path' for the section placement. Each section has to pass through a point along this 'spine' and lie entirely on the plane normal to the 'spine' at that point. A 'seam' for the resulting surface must also be defined and this can use any three sections to define a twisting duct. Nevertheless, the surface model can not be cut by a plane as the solid model can.

2) Use multiple sections and the NET command to generate the surface:

A designer can also declare all the sections, either open or closed composite, to create a net, and turn the net into a polyhedron and finally transfer to a curved surface.

6.3.3 Procedure used to create the model

1) Input data.

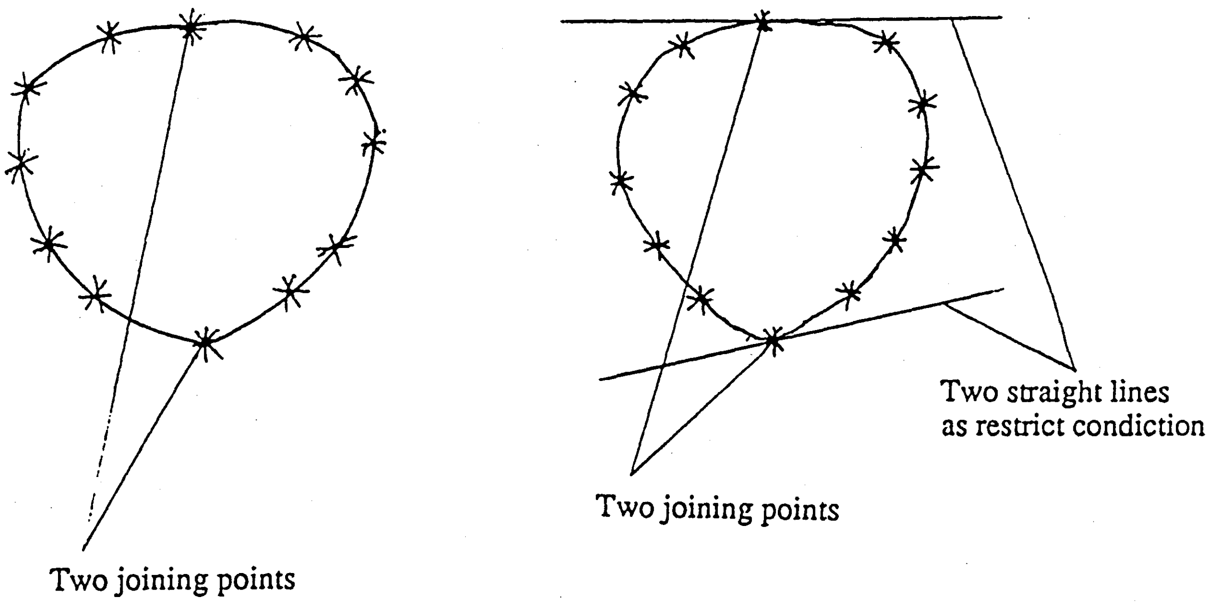
Data used in this section is the same as that used in GEOMOD. When the model is created in GEOMOD, the data form for modelling is a set of pictures. Then the pictures are digitized into the computer to form the profiles for each of the sections. When the pictures are digitized, the computer also judges the position of the points, and stores the coordinates of each point. Therefore, the coordinates are printed out and input into CATIA to define the multiple sections for the modelling of the surfaces of the bones. The data accuracy is the same as that used in GEOMOD.

Since the data is from GEOMOD, the problem of data accuracy exists in this model. One of the problems is, again, the number of points to form the profile. If too many points are used, it will take a lot of memory, which is unncessary, in the computer and increase the computational time.

2) Creating the models

To create the model, first, the profiles for each sections should be defined. Unlike GEOMOD, in CATIA, it is impossible to define all the points and then declare the spline as a closed one to create a closed profile. To create a closed spline, a designer has to define two open splines first, then join them into a closed one. A problem exists here, if the opened spline is created without any restriction, the closed spline formed by these two parts is not smooth where they join (Fig6.3.3.1 (1)). These closed composite curve can not reflect the real geometry of the bones in that cross-section. Therefore, when the opened splines are created for the first time, two straight lines which pass through the points and along a certain direction should be created as a restrictive condition, each open spline must be created tangentially to these lines at both ends, Fig 6.3.3.1 (2). Therefore, when these two open curves are joined together, they connect smoothly.

Each profile is created in a different plane, by defining different planes which are parallel to each other, similar to GEOMOD.



(1) Since no any restricting condiction, curve at joining points does not smooth

(2) curve at joining points is smooth.

Fig. 6.3.3.1 The method of creating a close profile on CATIA

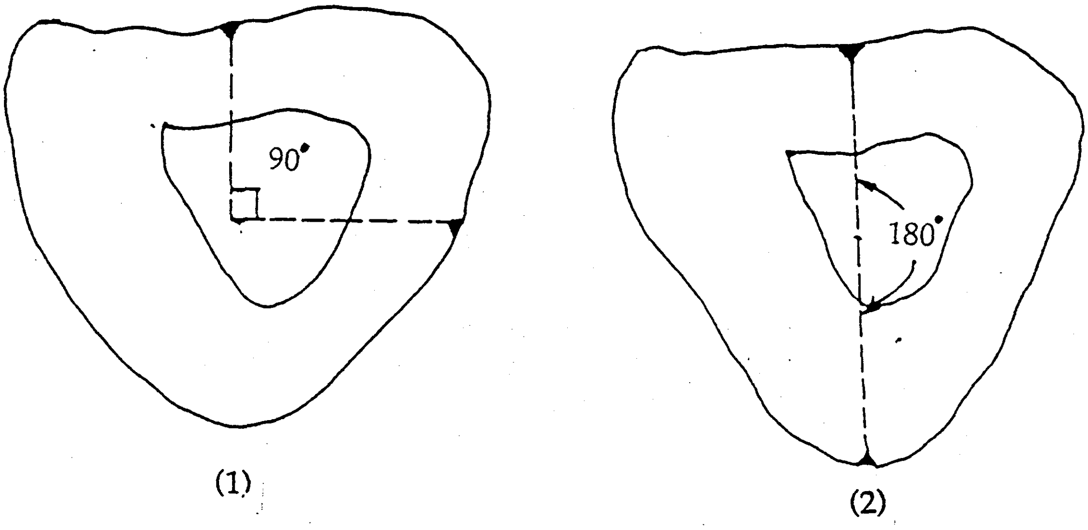


Fig. 6.4.4.1 Two possible sets of positions for aligning each section

When each profile is created, the spines and seams are created to define the surface finally.

6.3.4 *Results:*

As is the case in GEOMOD, we have a problem with creating a reasonable number of points to generate the profile and a reasonable number of sections for the model.

The data obtained by CT has an offset of 2 mm, so we used this offset to create the model, that is, the distance between each section is 2 mm. Each profile is defined by 40 points, then the model is created.

However, it is not necessary to create the model exactly, different hands have the different sizes, what is important is its general shape. Therefore, if we can use a smaller number of points and sections then we can save the computer running time and memory storage.

Using the above idea, another model was created. In this model, the number of points for each section was reduced from 40 to 10, and the offset between each section for the model was increased from 2 mm to 4 mm, that is to say, the number of section was reduced by a half. A problem exists with the number of points used for each section. When the data was originally input into computer, in order to reflect the real shape of each section, we picked about 40 points from each section to digitize into the computer. In the second model, the number was reduced to 10. Is this number enough to represent the shape of model? The answer to this is positive. The detail of this will be discussed in section 6.6.5. The resulting model is shown in Fig. 6.3.4.1. There is little difference between the two models, ie the more complicated one and the simplified one. They were compared by putting them into one file checking the profiles. Therefore, we can use a smaller number of points and less sections to perform the modelling.

Nevertheless, the model created is far too different from the real bone. As mentioned in chapter 2, the anatomical characteristic is: near the joint, the cavity becomes the largest section and then smaller and disappears quickly; at the place where the largest section exists, the bone is very thin with a range of 1.5 mm around. However, the model is not coincident to this. In the model, the thickness at where the largest cavity lies, is much greater (Fig. 6.3.4.1). This means that the model created in both GEOMOD and CATIA using data obtained by CT does not reflect the real geometry of the bone and joint. There may be a number of reasons for this:

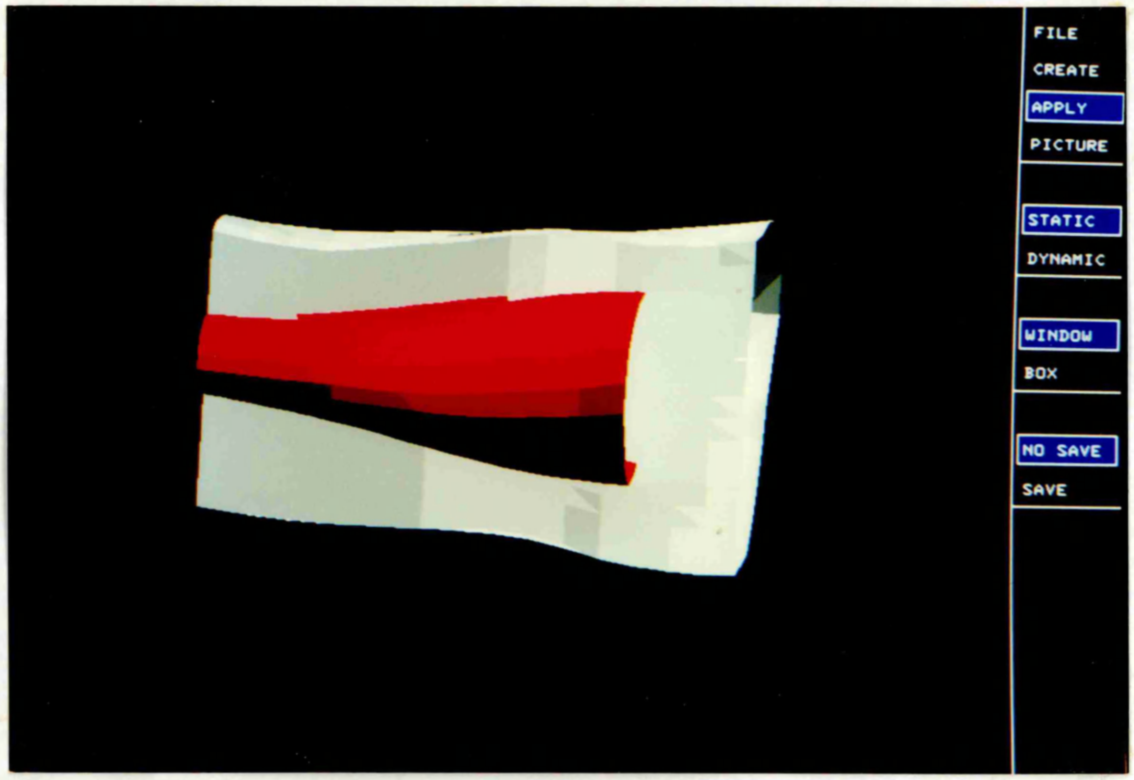
1) The data for the modelling is not satisfactory;
2) The software for the modelling is not well chosen;
3) Method may be not correct.

All these possibilities will be discussed in next chapter. However, to identify the problem, another kind of data is used to implement the modelling. In the following section, data obtained from a cadaveric hand was used.

6.4 Modelling using cadaveric data from X-ray

6.4.1 Introduction

In section 6.3., the modelling is performed by using the data obtained by a 2 dimensional CT scanner. However, the results of modelling are not satisfactory. This might be caused by the accuracy of data. The CT scanner might have some systematic error in producing the image for each section of the tomography of the bone. To identify this, the method of data



portion of the model of MCP joint and bones.

Fig. 6.3.4.1 Resulting model using CT data on catia acquisition is changed to using a cadaveric hand. In this section, the cadaveric hand is sliced, then the image of each slice is obtained by X-rays.

This section provides the method for data acquisition and the model of the results using this data.

6.4.2 *Method of data acquisition*

The material used is a cadaveric hand. A frozen hand is defrosted and all tissues surrounding the bone removed. A saw used in dental practice is used to slice the bone.

Before the hand is processed and sliced, it is first X-rayed. The X-ray is shown in Fig. 2.3.6. The reasons for this are:

1) to keep the original information about all the structure and geometrical position of the whole hand;

2) since the X-ray (pictures) are gained by the X-rays directly penetrating through the bones, they can reflect the real geometry and contours of the bone;

3) The X-rays can be used as the datum.

After taking the X-rays, the bone of middle finger was sliced. Because the machine used was not accurate enough, each slice of the bone is not quite the same length and each end of a slice are not completely parallel to each other. This may again effect the results of the model. In addition, the circular saw of the machine is 0.90 mm in thickness. This must also be taken into account when the position for each cross-section is defined.

Because of the uncertainty of the validity of this method, only one bone is sliced.

About 40mm length of the bone was sliced which is sufficient for the insertion of the stem of the joint prosthesis. All the slices of the bone, about 7 slices, are X-rayed, then the X-ray images are used to print the positives.

The X-ray images (negatives) are produced on a 1:1 scale, they are used to print positives for data input, as with the CT images. In order to reduce the data input error, the positives are enlarged to a scale of 3:1, then the contour of each picture is digitized into computer.

6.4.3 Procedure to input data

Although the model is created using CATIA, the method of inputting data is similar to using GEOMOD.

In CATIA, a designer can also create a plane which is parallel to the screen, then the 'puck' is used to digitize the profile of the picture into the computer, as was the case in GEOMOD.

In section 6.2.4.1, when the photos were used for digitizing the profile into the computer, there was a datum problem, that is how to align all the sections in space. A fixed scale on each photo, obtained when the hand is scanned is used as the datum when the data is input. However, in this section in which the cadaveric data is used for the modelling, a problem occurs. Before slicing the bone, a mark, which can be used as the datum, is made, so, when the bone is sliced, the orientation of each slice is not lost. When, however, the picture is put on the table and used for digitizing into the computer, it is difficult for the designer to judge the correct position of each profile.

To attempt to solve this problem, tracing paper is used: The contour for each slice is traced first, then the traced contour is used to align each profile according to the designer's judgement. It is obvious that the designer can not be sure that all the sections are in the right orientation using this method. Therefore, the resulting model is no doubt the wrong one which can not represent the real bone. See Fig. 6.4.3.1. The model is twisted and kinked seriously.

To improve the situation, a second mark for datum should be made before the bone is sliced, or some other measure should be taken.

6.4.4 Improved method for data acquisition

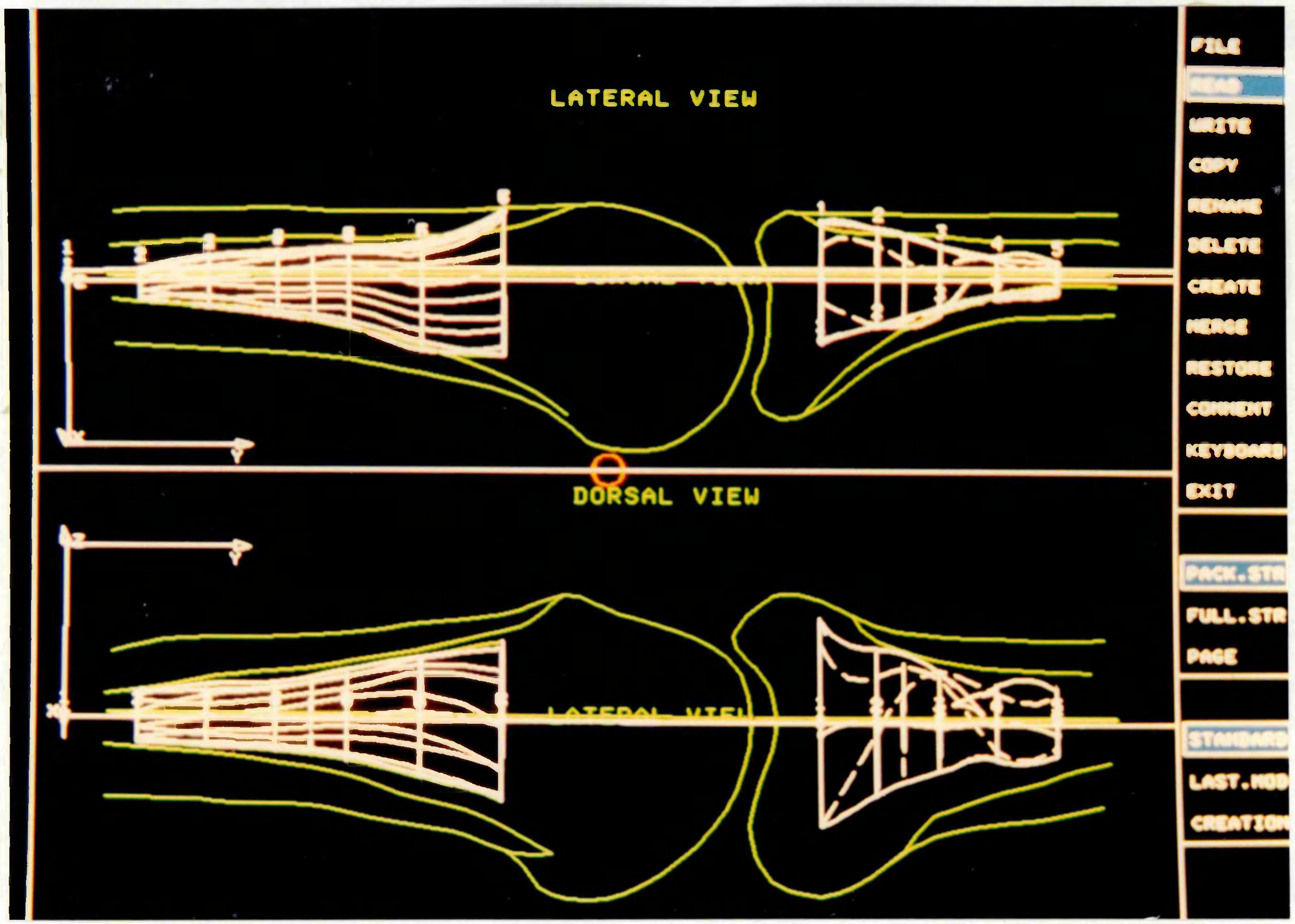
In section 6.4.2, the data obtained was not satisfactory for the modelling due to lack of a datum for orientation. To create a datum for the orientation, it is necessary to have a mark on the bone. The requirements for the mark is:

1) it must not be damaged after the bone is sliced;

2) it can be seen in the X-rays picture.

To satisfy these requirements, slots are marked on the bone. However, how many slots are needed and where they must lie remains to be solved. To determine a plane on an object in a 3 dimensional space, three points are required. In this case, a profile has already been obtained, and its plane has been already determined. Therefore, only two points are required. Next step is to determine the positions of the two points.

There are two possible set of positions for locating the slots (Fig. 6.4.4.1): 1) each slot together form a 90° angle; 2) each one together form a 180° angle. The first method was chosen since it is more convenient to



The model is twisted and kinked

Fig. 6.4.3.1 Model created using X-ray data and tracing paper mark the bone and more important, there will be no confusim when aligning the profiles (see Fig. 6.4.4.2).

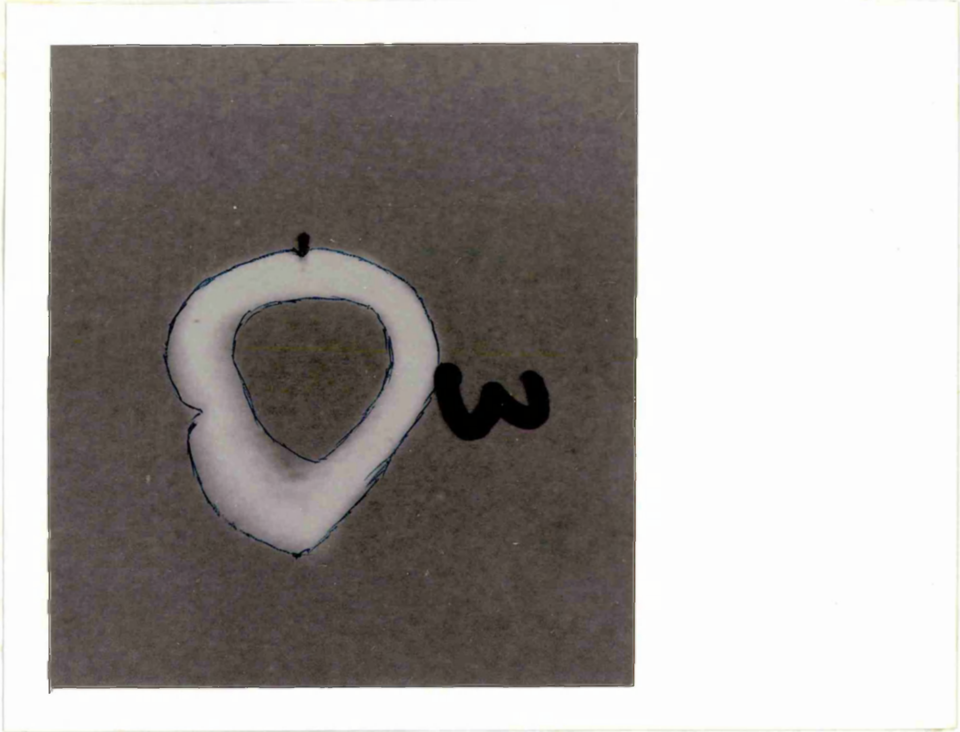
Two slots are carved on the bone, then coloured. When the slots are cut, they are made to be as straight as possible so as to keep the accuracy for later alignment. However, it is difficult to keep the grove as a straight line. The MC and PP of index bones are then sliced into several slices.

After the above process, all the slices are X-rayed. On each X-ray image, each slice of bone leaves only two contours, they represent the largest and smallest sections of the bone (Fig. 6.4.4.2). The X-ray images are then used to print the positive with a scale of 3:1.

Again, the tracing paper is used to obtain the contours for each slice from the enlarged positive, the tracing papers with the contours on it are fixed to the tablet and digitized. Considering the alignment of the pictures, the largest section which is near the joint is digitized first, then the others are placed on it one after another.

Each picture has the marks on it, thus enabling the designer to align each profile. However, when the pieces of tracing paper are stacked one on top of the other, the marks do not exactly correspond due to the different size of each section, and the different levels in space that they represent. Therefore, the designer still has to use his judgement to position the bones.

The model of the cortical bone has been created in the previous section. However, it is not very important for the design of the joint prosthesis. Therefore, we must concentrate on the modelling of the medullary cannal.



Photograph printed from X-ray

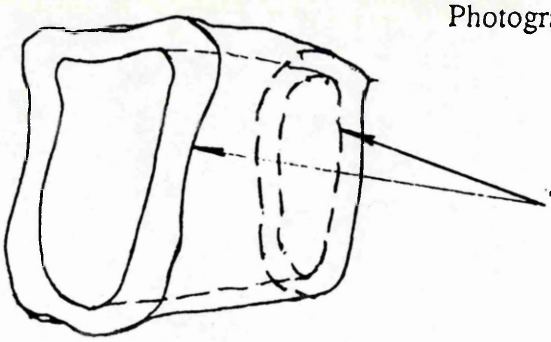


Fig. 6.4.4.2 X-ray can only shows two profiles of a slice

The resulting model is shown in Fig. 6.4.4.3. The lateral appears to be kinked. This is obviously caused by the manual alignment.

When the marks are used to align each profile, they can define the orientation on the X-Y plane, but they can not ensure the correct positions of each section on the X-Y planes (Fig. 6.4.4.4). To improve this shortcoming, the contours of the bones at dorsal and lateral views obtained by X-rays (see section 6.4.2) are introduced to be the datum for the further alignment (Fig. 6.4.4.5).

Fig. 6.4.4.6 demonstrates the space position of each section before being modified, together with the bone contours at dorsal and lateral views obtained by the X-rays. To use the X-rays contours as the datum, they must be used together. That is, the profiles for each section must align to both dorsal and lateral views. Every profile is moved gradually until it fits into the bone contour at both dorsal and lateral direction.

After all the sections are moved to the proper space position, the spine and seam needed for forming the model are created, as is the case in section 6.3.3.

The resulting model is shown in Fig. 6.4.4.7. There is a problem here. From the model, one can see that it is too short. Comparing with the X-ray contours, one part, which is the bigest section and near the joint, is missing. This is fatal because the missing part is the important part for the fixation of the stem within the bone cavity.

However, the previous method used is not sufficiently accurate. To improve this, a three view drawing was used - see Fig. 6.4.4.8.

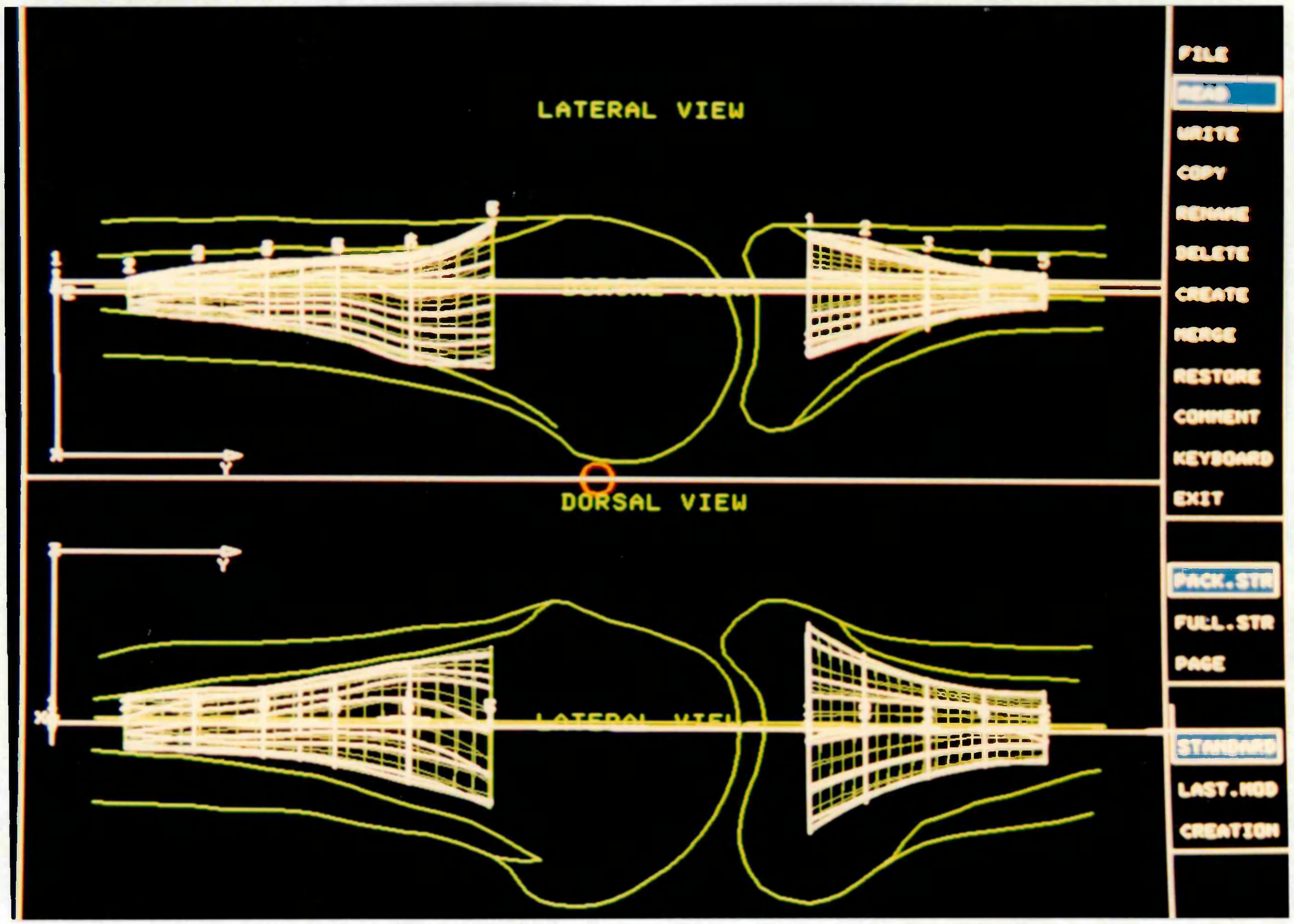
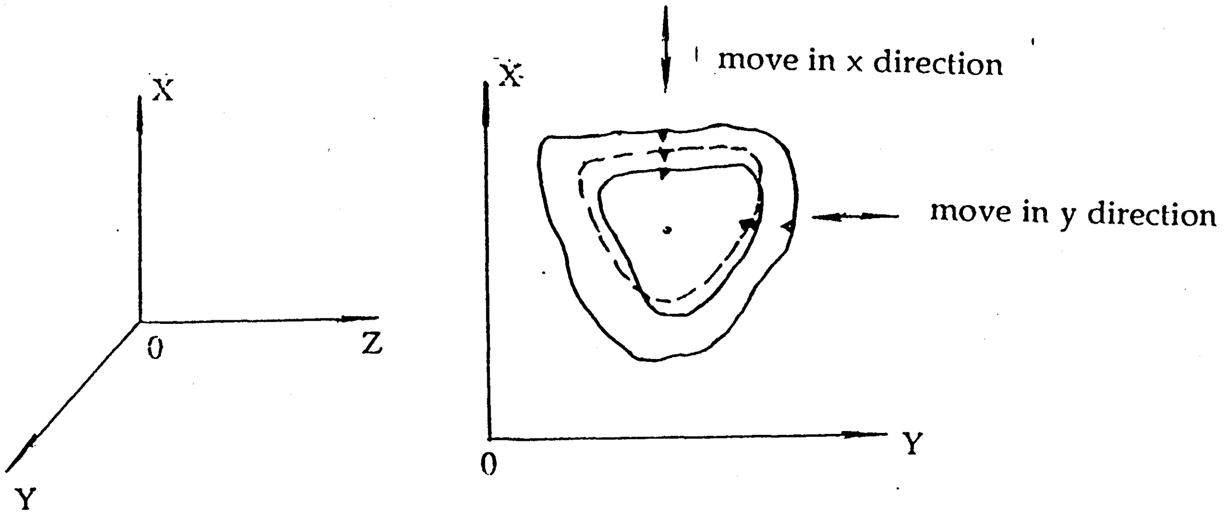


Fig. 6.4.4.3 Model created using Xray, tracing paper from cadaveric hand



(1)

Fig. 6.4.4.4 Alignment of a section on X-Y plane

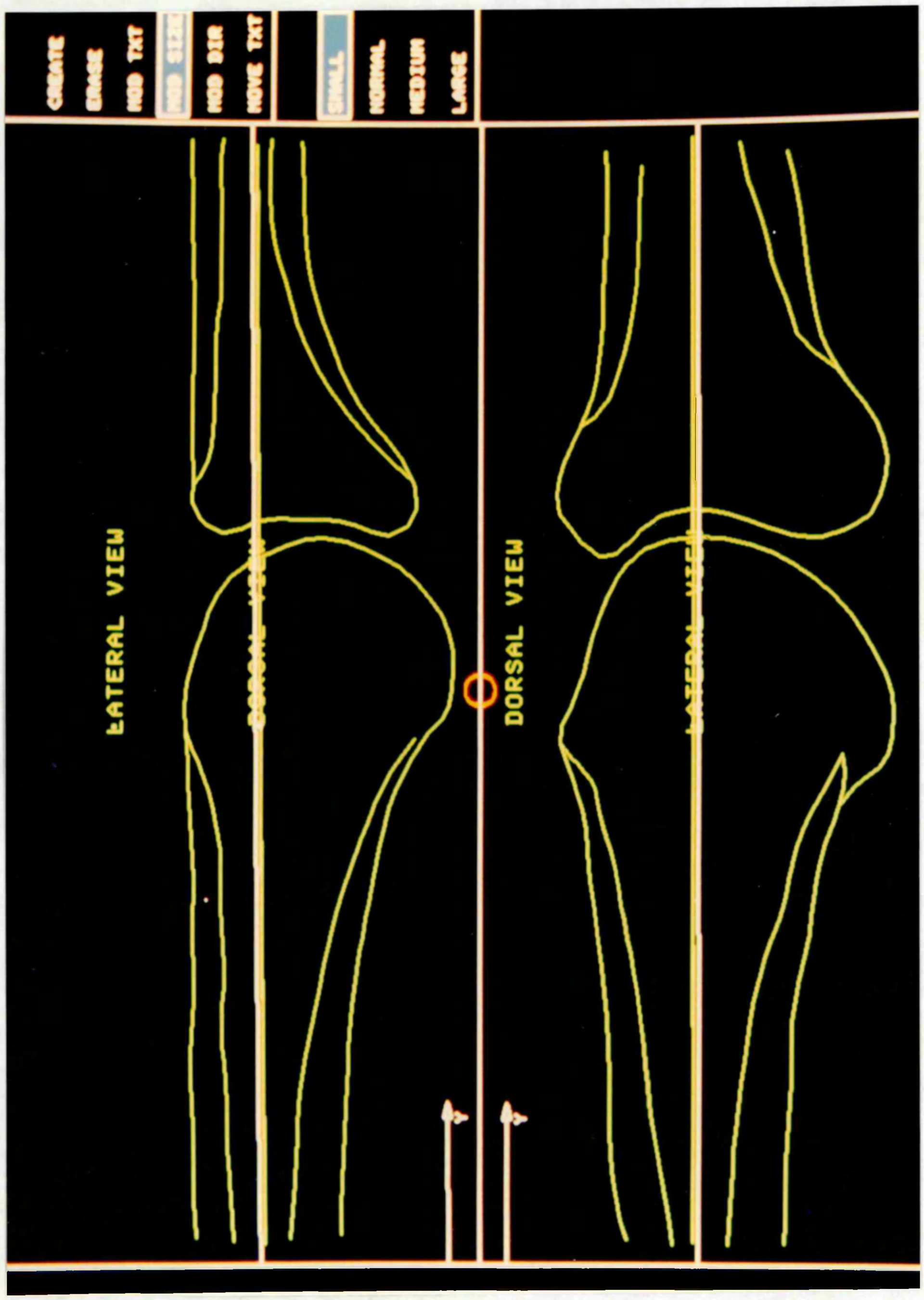


Fig. 6.4.4.5. X-ray contour of the bone used for aligning

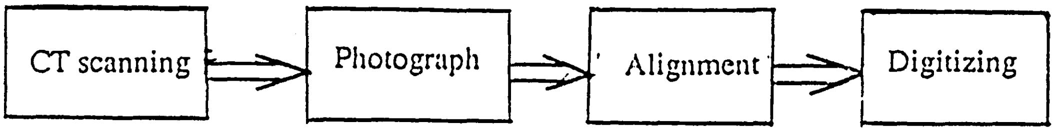


Fig. 6.2.2.1 The procedure of obtaining data for modelling

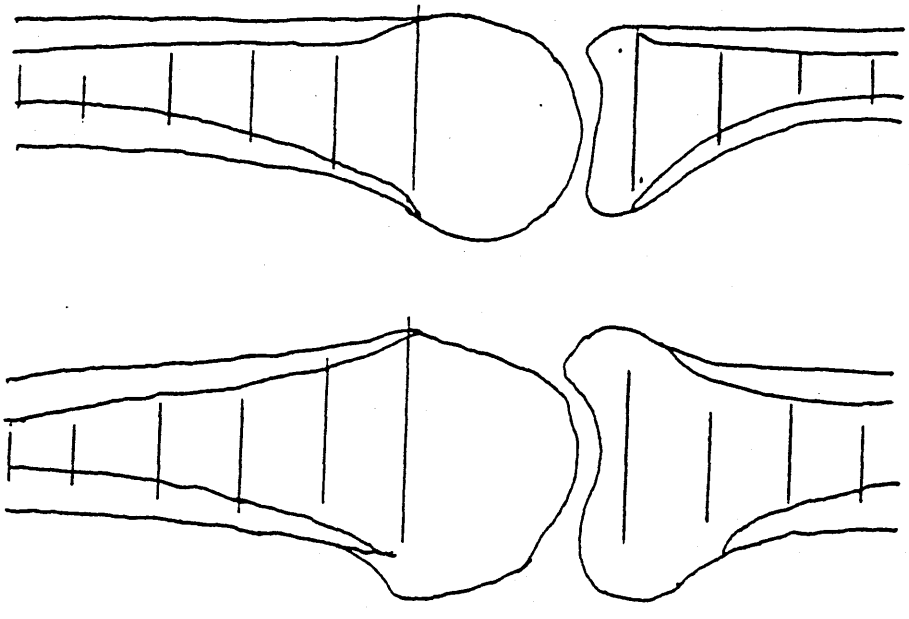
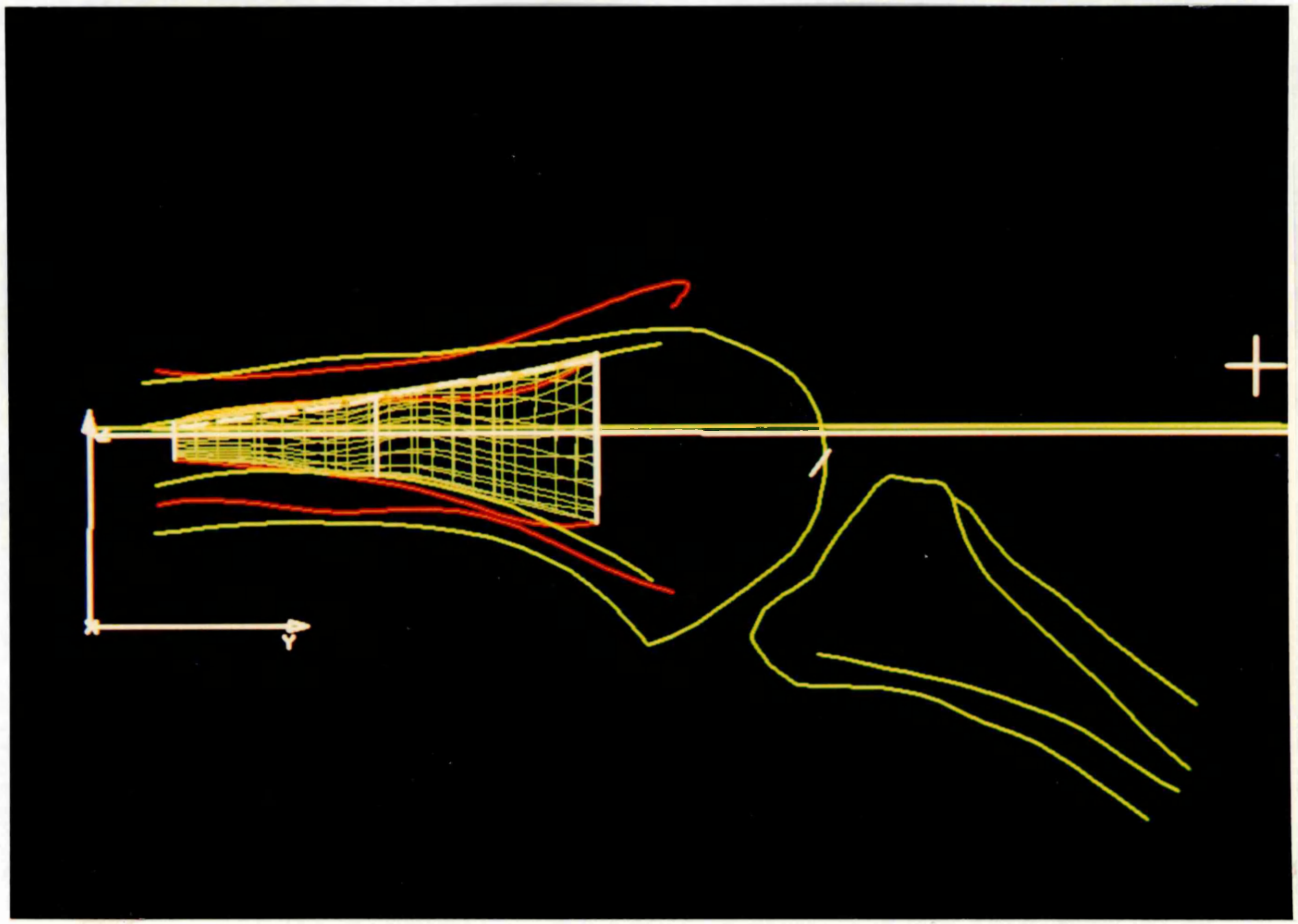


Fig. 6.4.4.6 X-ray contour and sections used for modelling before being modified



Model created is too short one part near the joint is missing

Fig. 6.4.4.7 Model created using modified sections

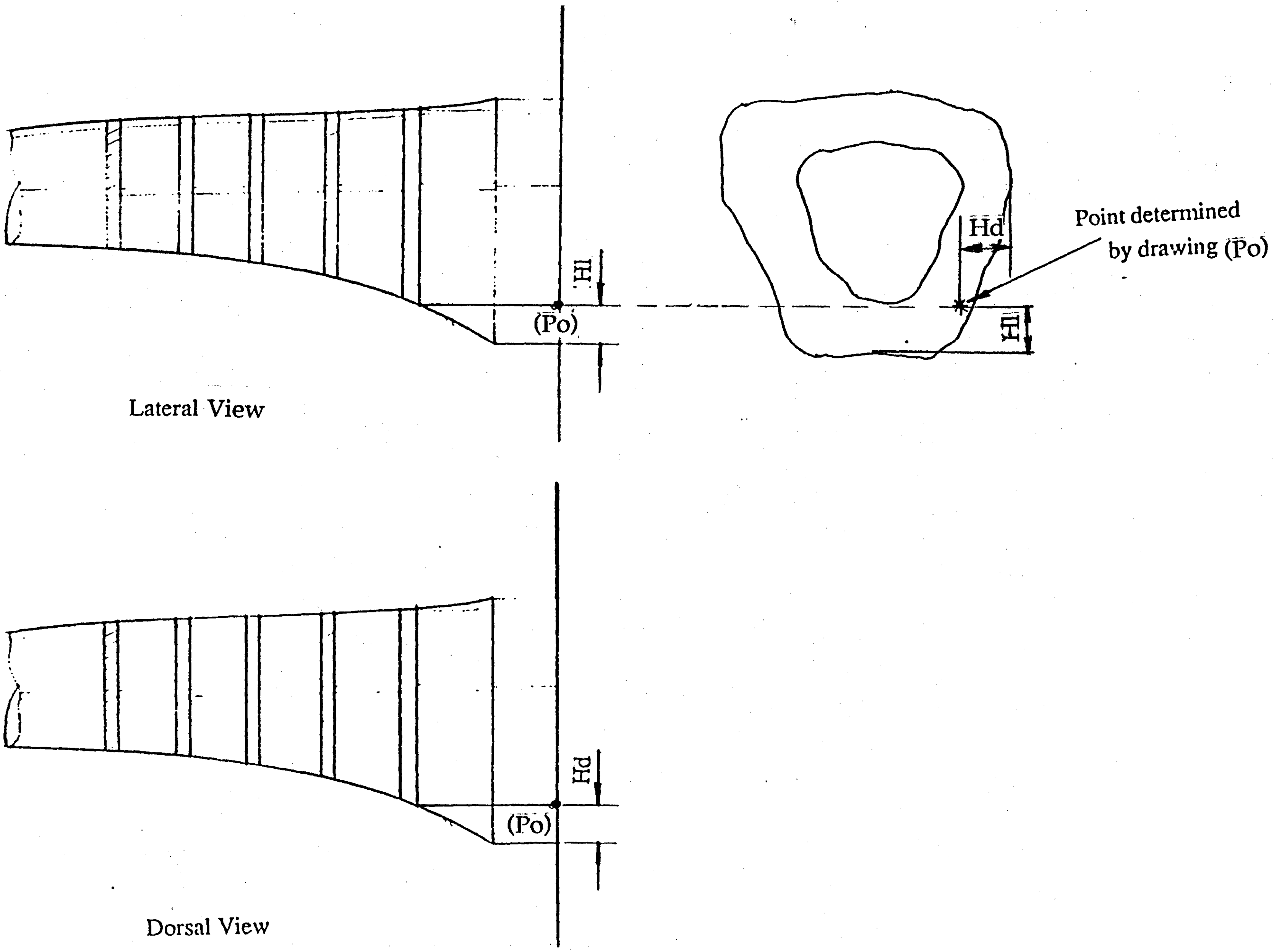


Fig. 6.4.4.8 Use drawing method to determine point for aligning

To determine the two points, 3 views of the bone are used. (Fig. 6.4.4.8). When the points on every section are determined on the paper, a ruler is used to obtain the rough coordinates of the points. These points were input into the computer as the datum to align each profile.

However, the model created using the method was almost the same as the one created above (Fig. 6.4.4.7). This is due to the method used , since it is impossible to obtain data with reasonable accuracy by drawing.

In order to improve the model, two aspects must be taken into account. 1) according to the geometrical principle, an image which can display the geometrical relationship of all sections is required. 2) to find a way to make up the missing part of the model. Two measures can adopted. One is to use the camera because the photo produced by the camera can reflect two contours of a section. The other is to revert to the CT image data, requiring a high quality CT scanner. In this thesis, the first measure is adopted. The following section presents the method using data obtained by camera.

6.5 Solid modelling using cadaveric data from photography

6.5.1 Introduction

Initially the slices were X-rayed to obtain an image which could be used for the input data for the model. A problem arose because the inner and outer profiles of the image referred to each end on the slice, due to the conical shape of the bone. In another words the two profiles did not lie on the same plane.

Therefore, the profiles were photographed because in a photograph both the profiles of the same end of the slice can be seen.

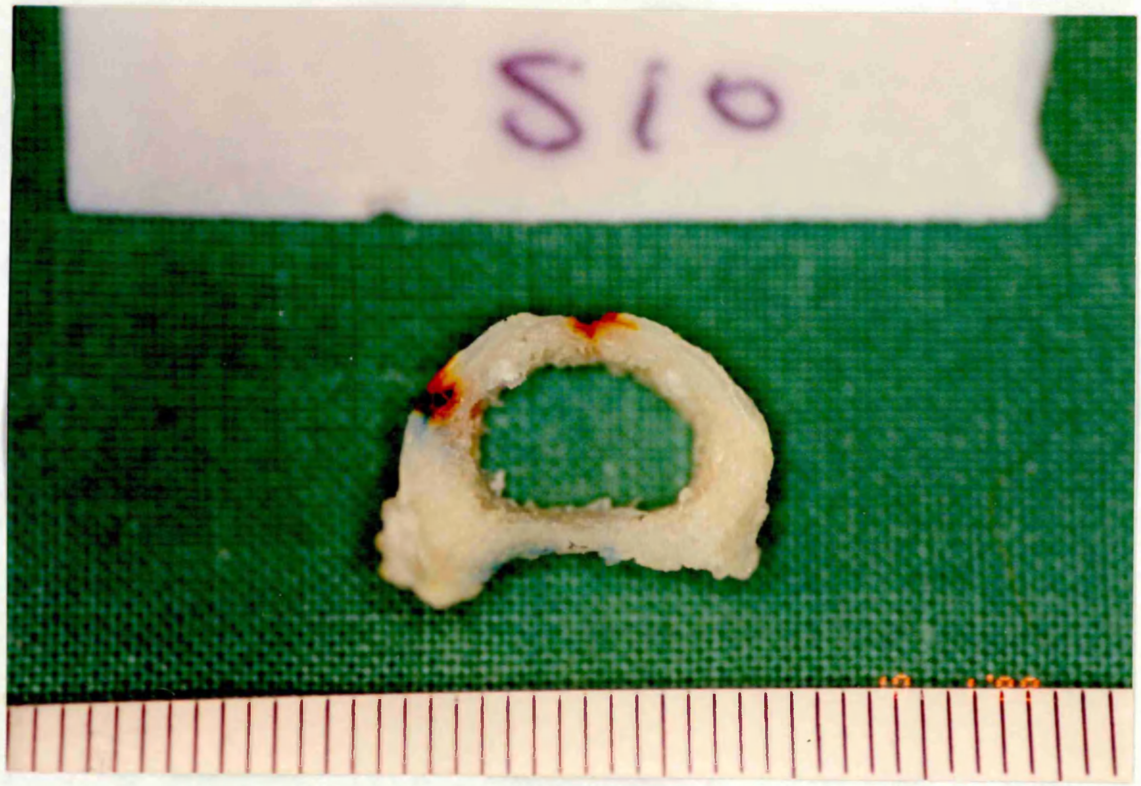
In this section, the slices of the bone used in section 6.4 are again used to produce the contours for each section from the photographs. The following sections present the method of data acquisition and modelling using the photographs.

6.5.2 *Method for data acquisition*

A camera is used to photographs each section of each slice. Each slice of bone is photographed individually. One photo for a slice can provide 3 profiles because of its visibility. See Fig.6.5.2.1. Since the photo for each slice is taken individually, there is a problem whether the image produced every time is at the same scale. The camera is set up at a constant distance from the slice, thus ensuring that the scale of each picture is the same.

A ruler is placed near each slice of the bone and both are photographed (Fig. 6.5.2.1) to enable the scale of the positive to be standardised.

When the photo of each slice is taken, special attention is paid not to mix the order of the slices. The geometrical shape of the bone is such that the closer to the joint, the larger section the bone has (Fig. 6.4.2.1). The section at middle of the bone has the smallest section. The MC and PP bones are sliced from the end to the middle. The two end sections of each slice are a different size, the one which is nearer the joint is larger than the other. In order not to mix the position of each section in later modelling, each slice is placed with the larger section upwards.



Three contours can be seen from one photo

Fig. 6.5.2.1 Photo of a single slice of the bone

Here, even a photo can shows 3 profiles and 2 marks of a slice, but when the photo is used to digitize, the same problem with determining the marks of each section will occur again, if no measure taken. Since photo can display a full image. the geometrical principle is applied here.

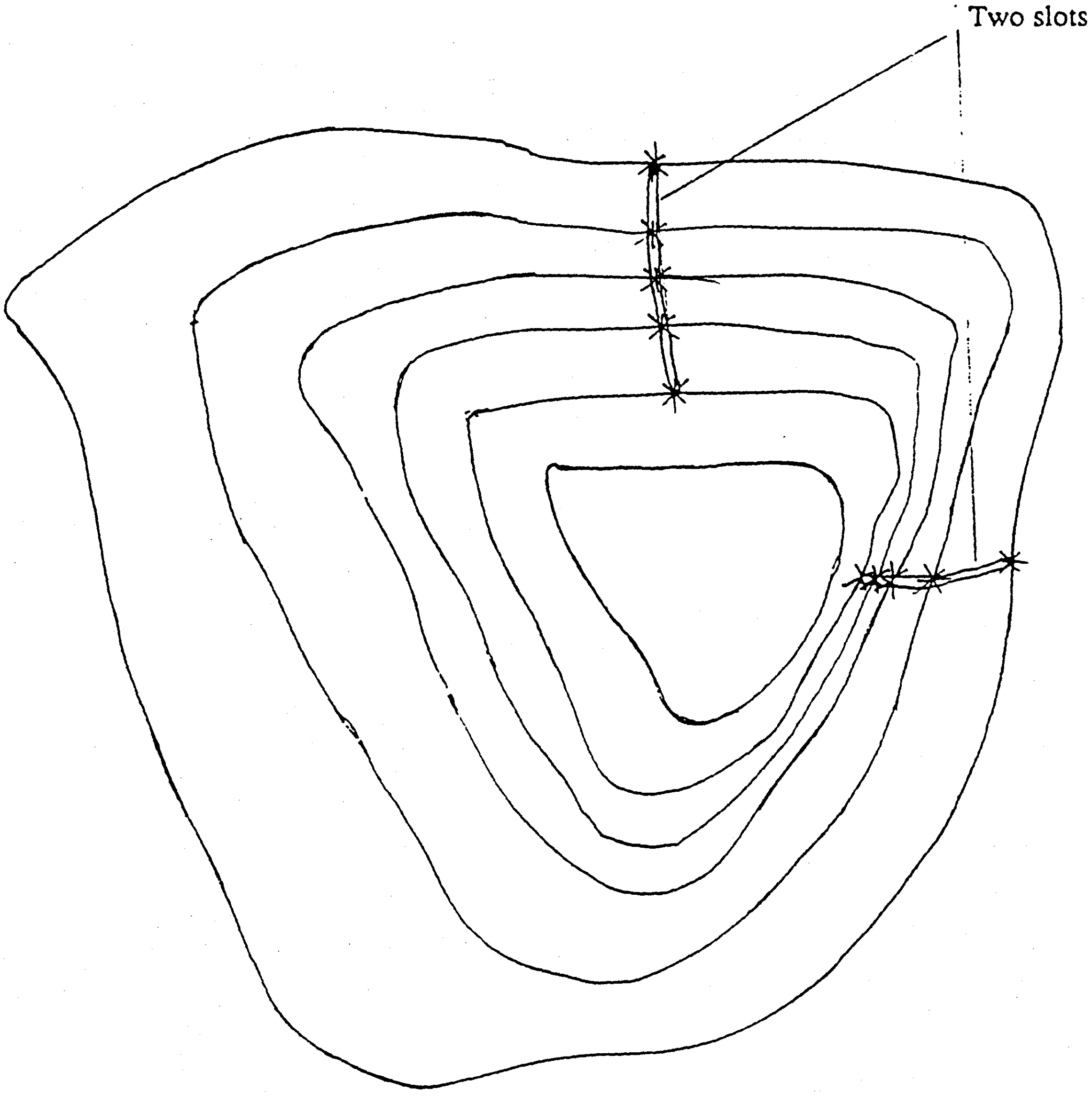
The bone was cut at the smallest diameter and, then two longitudinal and one circumferential marks on each section where it will be later cut, were carved. The bone with several contours on it was photographed with its small end towards the camera. The contour and the two marks of each section was then determined (Fig. 6.5.2.2).

When the photos are produced, as in the previous sections, the scale of the photos is calculated, and the scale between the tablet, screen and computer is also adjusted so that the computer can read the correct value.

Tracing paper is again used to obtain the profiles from the slices. The inner cavity profile can be built up by using the smallest profile on each section, i.e., the one facing away from the MCP joint, remembering again that the bone is conical in shape. The outer bone profile is formed using the largest profile of the section, i.e., the face closest to the MCP joint. This means that the two profiles are not in the same plane, but this does not affect the two surfaces being modelled.

The only problem that occurs is with the section nearest the joint, where both the inner profiles must be used so that the cavity near to the joint can be modelled , otherwise the last part of the cavity will be missing.

This means that the X-rays would be sufficient except for the bone slice nearest the joint.



*—Point as datum for aligning each section

Fig. 6.5.2.2 Contours and points from photo for aligning each section

6.5.3 Procedure to create model and results

The same procedure used to create models in the previous section is used again, including aligning each profile and modifying the model by modifying the space position of each section by using the X-ray contours as the datum, and, thus the model using the photographs is finally created. The resulting model is shown in Fig. 6.5.3.1. It is found that the model created here is the best one compared to all the models created before, although it does not fit well with the X-ray contours on the dorsal view.

From Fig. 6.5.3.1, it is clearly shown:

1) On the lateral view (front view), the model fits with the X-ray contour well;

2) On the dorsal view (top view), the model dose not fit with the X-ray contour very well, there is small gap between the model and the X-ray. There are some reasons for this and, they will be discussed in next chapter.

However, the models created in CATIA so far are actually surface models with a very thin surface solid. Unlike the solid model created by GEOMOD, after the model is created, it is impossible to slice the model by any direction of plane. If a cross-section at a certain part of the model is wanted, it is necessary to create the plane at the required location, and to make the plane intersect the model so as to obtain the contour of the cross-section.

When the model for MCP joint and bones are created, the available space for the artificial finger joint is obtained. Based on the model, one can start to make the simulation of the movement of the finger, model the

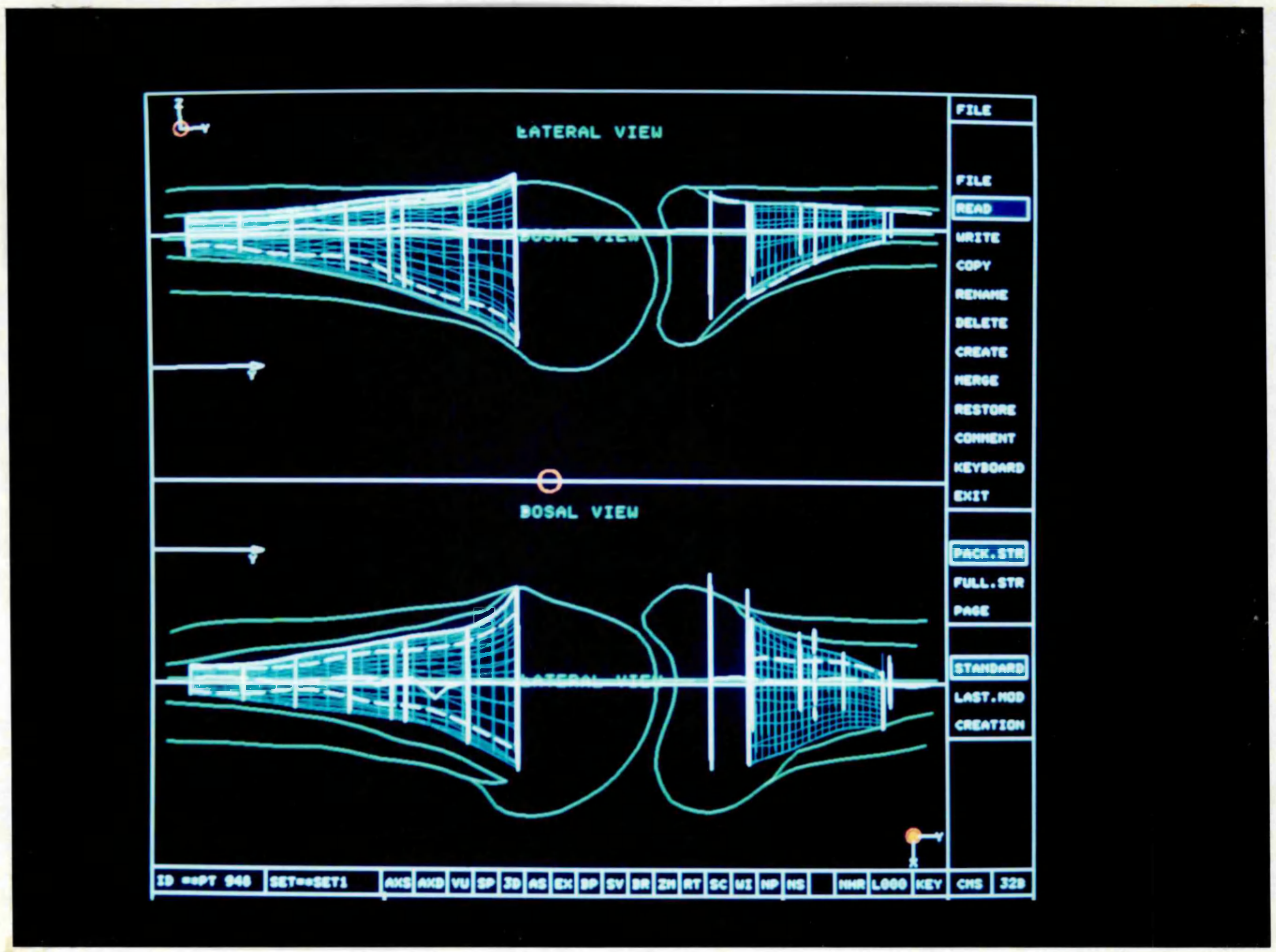


Fig. 6.5.3.1 Model created using photograph data

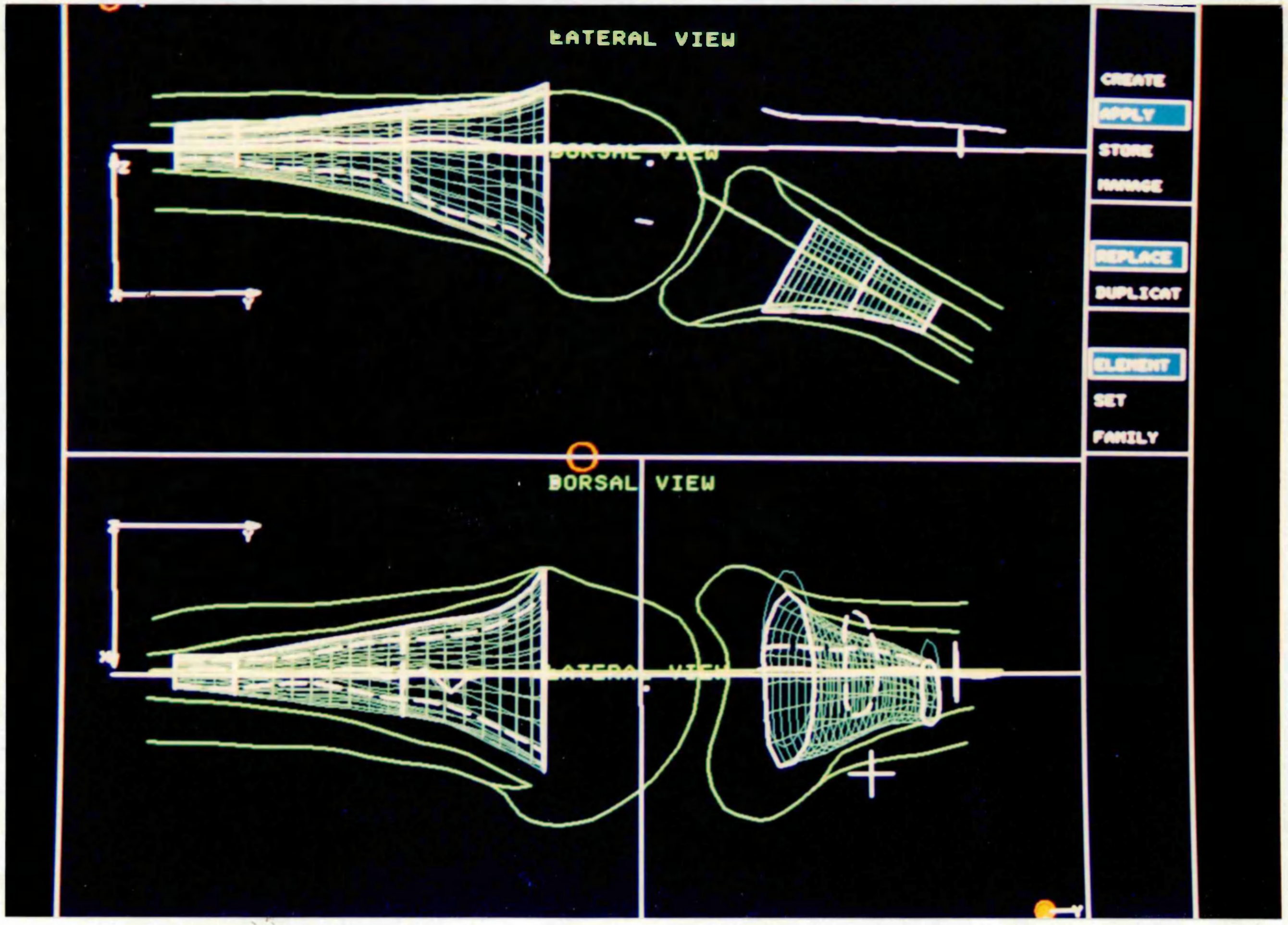


Fig. 6.5.3.2 Simulation of movement of the MCP joint

other tissue attached to the bone and so on.

6.5.3.1 Kinematic simulation of a finger

After the model is created, it can be transfered to the ROBOT mode on CATIA. An assumed point can then be given to be the moving center of the finger. A robotic model can, then, simulate the movement of the MCP joint. This model would be very helpful for the design of an artificial joint prosthesis (6.5.3.2).

6.6 Discussion

In previous sections, present methods of modelling MCP joint, MC and PP bones using different sources of data on GEOMOD and CATIA were presented. From the results, it is clear that different methods created different models. A large number of factors affect the results, these include, 1) methods of data acquisition, including the accuracy of data; 2) procedure to input data, such as alignment, number of points and sections to form the models; 3) Software packages such as GEOMOD and CATIA.

In the following all these factors will be discussed in detail.

6.6.1 Methods used to evaluate the results

In order to evaluate the resulting models, a set of X-rays mentioned in section 6.4.2 together with a set of bone cavity casts were used for comparison of shape and size of the cross-section. However, the bone casts could not be used, due to the technical problems associated with the casting process. The technician who did the casting was not skilled and casts of the cavity was not only incomplete but also seriously deformed when we received them. However, this technique can still be used for comparison with a skilled technician making the casts. Consequently, the casts were only used to make a rough comparison of the general shape. The main elements for comparison, therefore, are the contours of cavities from X-ray, although there is another possibility which will be discussed later.

By means of comparing the casts by eye and putting the models and X-ray contours together, it is found that the models created using CT data with GEOMOD and CATIA are unsatisfactory as is the model created using X-ray data with CATIA. The model created using photograph of each slice with CATIA could be described as satisfactory. The comparison results are shown on Table 6.6.1.

These results are based on a judgemental comparison with X-ray contours and bone casts. So, this method can only roughly reflect the truth.

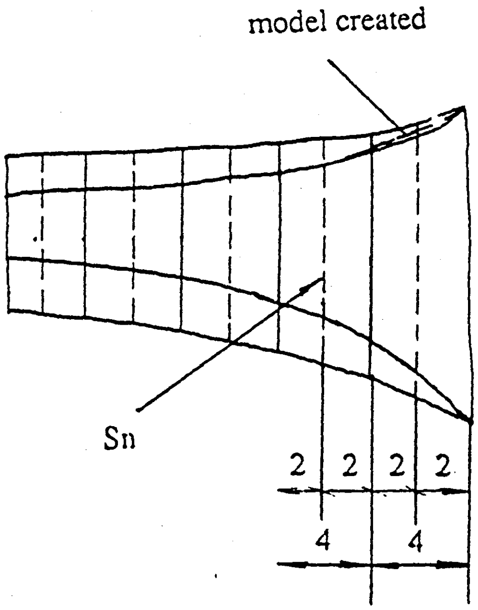
The profiles of the main cross-section used to form the model are obtained from the real bone, the only uncertainty is whether or not the section (Sn in Fig. 6.6.1.1) between the main sections are the same as that of the real finger.

In order to fully support the modelling method, another method should be taken.

Another method of comparing the results is the use of plaster casts. Since plaster becomes hard when set, it can be used to produce a plaster cast of bone cavity. These casts can be sliced to obtain the profiles of any section. Then these profiles can be used to compare with the same one created on the computer.

Table 6.6.1 Comparision of models with the X-ray contours and cavities casts

	Model created by CT data		CATIA	
	GEOMOD	CATIA	Model created using X-ray cadaveric data	Model created using photo cadaveric data
Lateral view	Slightly kinded; the portion of the bone was too thick.	Slightly kinked; the portion of the bone was too thick.	Seriously Kinked	Fit with the X-ray contours well
Dorsal view	Slightly Bent the portion of the bone was too thick.	Slightly buckled; the portion of the bone was too thick.	Serious Bent	A small gap tetween the model and the X-ray contours



- - - - - Sn, sections between the sections used to form model

——— Sections used to form the model

Fig. 6.6.1.1 Diagram showing one portion of MCP bone and sections on it

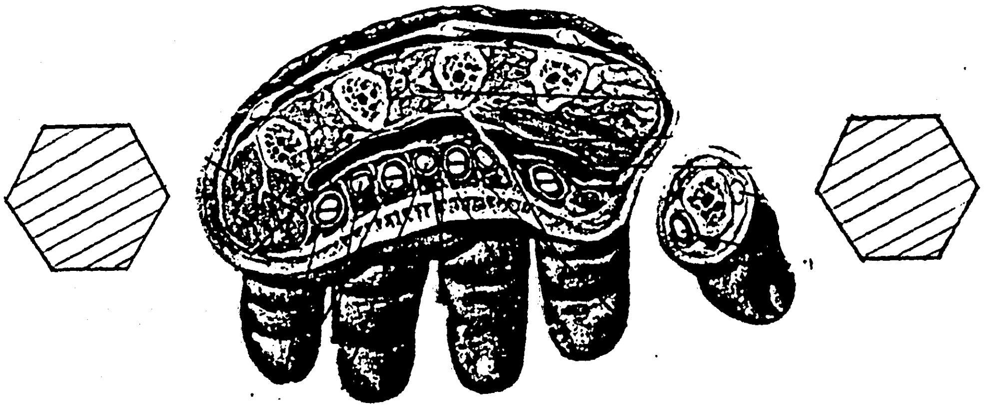


Fig. 6.6.1.2 Two hexagon bars placed aside for reference

The difference in the results have been outlined above. The following discussion will present more reasons for the differences.

6.6.2 *Method using CT data*

In sections 6.2 and 6.3, data was acquired from a two dimensional CT scanner. This kind of data has the following advantages; during the whole scanning process, the cadaveric hand is fixed, therefore, the orientation of the images is ensured. Any error in orientation is caused only by errors occurring when inputting data. The model created at section 6.5.1 (Fig. 6.5.3.1), has a smooth continuous surface, whilst the model in section 6.4 is buckled (kinked). It is obvious that the data used in section 6.4 had problems with orientation between the sections.

With reference to the orientation problem, one may ask, presuming that we are scanning a live hand to obtain the data, how do we ensure that the hand does not move during the scanning. Indeed, the movement of the hand being scanned will affect the production of an image of a section, especially the orientation between each cross-section. However, the development of CT during last 10 years has seen, the scan time of a section reduced from 3 minutes to few seconds. The shortening of the scan time may increase the probability of a good image being taken. Furthermore, other measures such as careful fixing can ensure that the hand is still the hand during the scan.

However, although the data from the CT scanner has good orientation, from sections 6.2 and 6.3, it can be seen that the models created using this data were not satisfactory. From the X-ray images, it is clear that the thickness of the bone is very thin near the joint. Nevertheless, from Fig 6.2.5.1 and Fig. 6.3.4.1, one can see that where the largest cross-section of cavity lies, the bone is still much thicker , more than twice that of the X-ray . In addition, the other part of the model is also thicker than the X-ray. These errors are probably caused by the CT scanner used. The anatomy of the hand shows that within the bone cavity, the edge of the bone is very sharp, and the density of the bone is not the same. In addition, there are some other tissues attached to the bone. Therefore, if the CT scanner does not possess a high resolution or is not operated properly, it will be difficult to distinguish between the edge of the bone and the attached tissue, on the image produced. Consequently, the image produced will not be able to display the correct edges of the bone.

Since CT scanning has the advantage of obtaining data with good orientation and the CT scanning technique has been well developed, it may be a good idea to use a high quality three dimensional CT scanner with high resolution to obtain the whole model then transfer to the CAD system to build the models and database

The accuracy of the data.

Apart from errors in orientation and positioning of the image both on lateral and dorsal views, which occur in inputting the data, affecting the accuracy of the model, other factors also affect the accuracy of the model when the data is in the form of a photograph.

From Fig. 6.2.2.1, one can see that the data for modelling is produced by several stages and errors occurs at each stage.

The first error occurs while using the CT scanner. This error is called an instrumentational error, dependent upon the machine's inherent precision, which is unknown in this case. The PIXEL (picture elements) of a image can reach 1x1 mm or smaller and is dependent upon the particular machine and the area being scanning (see section 5.2.2).

It is impossible to quantify this error here due to the indirect source of data. However, from section 5.2.2, it is roughly known that this error is about 1mm.

The second error is from the photograph. This error is also called an instrumentational error, depending upon the individual photographic enlarged.

When the photograph is enlarged, the whole image many not be enlarged with the same scale in the X and Y direction. Besides taking some measures to ensure the printing paper is parallel to the negative, another measure can also be taken. This can be overcome by placing a hexagonal bar as reference object when scanning (Fig. 6.6.1.2). When the photo is finally produced, measure the dimension of each side of the hexagon to discover whether an error has occurred during printing. This error can not be measured in this research since no measure has been taken.

The third error occurs when picking up points along the edge of the bone, does the designer picks up the correct position of a point? This error is known as a random error, depending upon the individual operator. As already discussed at section 6.2.1, since the photo has been enlarged, this error will be small.

The fourth error is caused by aligning the section of the bone or in another word, it is the orientation problem. From the model created in section 6.4 (Fig. 6.4.3.1), it is obvious that orientation is the most important factor affecting the model. If each section is not correctly orientated, the model created will be twisted and kinked.

Among the four kinds of error, the fourth one dominates the accuracy of the model.

However, the number of points used to form each profile and number of sections used to form the model also affect the accuracy. This will be discussed later, but it will cause little error compared with the problem of orientation. However, one thing must be noted here, when picking up the points along the edge, in most photos, the edges of the cavity are ambiguous. Therefore, it is recommended that the operator should take the points towards the hollow rather than the bone, so that the model will be slightly smaller than the actual cavity, otherwise, when the artificial joint is designed using this model, its stem would be larger than the cavity of the bone and the surgeon would have difficulty implanting the joint.

6.6.3 *Method used in section 6.4*

In section 6.4, the cadaveric data form is used. The bones were sliced , and X-rayed. As we mentioned in Chapter 5, X-rays have a high penetrating ability and the X-ray picture is taken directly through the bone, therefore, the X-ray picture would represent the real contour of the bone. However, the first model created by this method is not only missing one part near the joint, but also bent. Even though the X-ray contour is used to align and modify the position of each section, the modified model still does not fit the X-ray continuous properly. This results from incorrect aligning.

When the bone is sliced , the orientation for each slice is lost, even though tracing paper is used, because the shape of each section is different from the next and has different central points. If no measure is taken, it is impossible to create a satisfactory model using this sort of data. This was discovered when the bone was sliced the first time and no mark was made to align the sections and then an attempt was made to build a model.

Although the cavity of the bone is of interest in this research, the whole image of a slice is still very important for aligning each profile during data input.

In order to obtain good orientation of each section in the computer for modelling, two slots were carved on the bone, according to the principle that 2 points can define a picture on a 2 dimensional plane. These 2 points are determined by drawing (Fig. 6.4.4.8). Since they are determined by drawing, some error of positioning the points occurs. In addition, although X-rays can produce images of the slices with a high resolution, enough of the contours cannot be distinguished for modelling. However, a photograph can improve this shortcoming. Photos can show the contours of the bone clearly. Therefore, it is unnecessary to determine the position of the point by drawing.

6.6.4 *Method used in section 6.5*

In section 6.5, the key point is the creation of a datum. Since the photograph can show a clear image, the drawing geometrical principle is applied. The alignment of each profile when inputting data can then be solved. This ensures the correct orientation between each section. The only thing that needs to be improved is to modify the position of each profile in the lateral and dorsal views according to the X-ray contour. Since the two key points have been solved, the model will be a best one of all the models. Fig. 6.5.3.1 indicates this.

However, from Fig. 6.5.3.1, one can see that in lateral view, the model fits with X-ray contour well. Whilst in dorsal view, only the first section at MC and PP bones fit, whereas the remainder is smaller than the X-ray, so that there is a gap between the model and X-ray contours. However, this does not mean that the model still has some problem. To identify this, we need investigate the X-ray pictures.

From the X-ray picture shown in Fig. 6.4.2.1, one can see that in the lateral view, the bone lies parallel to the project plane. Nevertheless, in dorsal view, both MC and PP bones do not lie parallel to projecting planes. Therefore, according to the geometrical principle, the projecting image would have been deformed. Meanwhile, the model displayed is in a position parallel to both lateral and dorsal view, therefore, its contours on lateral and dorsal views reflect its real shape. Since the gap between model and X-ray contour is small, it can be said that the method is satisfactory.

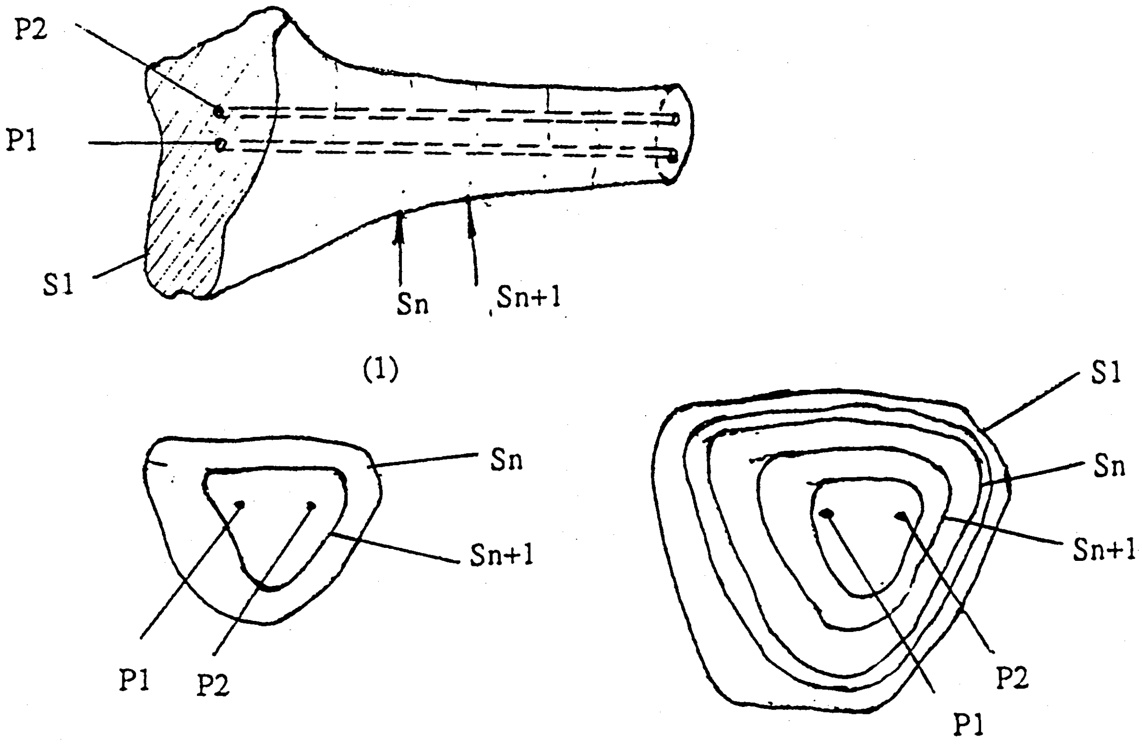
With reference to the method using cadaveric data, from carving bones, slicing, X-raying, photographing, tracing, etc., a lot of effort has been spent in order to obtain good orientation and correct positioning in lateral and dorsal views. Is there any other simple method which is satisfactory for modelling? The following presents a discussion about another method.

It is well known that plaster has been used in medical practice for a long time. In this case, plaster can be used to make cavity casts. Fill the bone cavity with plaster. After the plaster becomes hard, use a tool to cut the bone. Note, the thinner the tool is, the better. It is suggested that a laser beam be used here. Cut the bone at the smallest cross-section and withdraw the cast from the cavity. Use the laser beam to drill two small holes which are parallel to each other and normal to the plane of the large end. Slice the casts using two laser beams. Make sure that each cross-section is parallel to the plane S1 (Fig. 6.6.4.1) Take a photograph of each section. Put the smallest end of a slice towards the camera, then an image with 2 profiles and two small holes (depending upon the diameter of the laser beam) can be obtained. Trace the contours and holes. These two small holes will be very useful as a datum. This will simplify the alignment (see Fig. 6.6.4.1) and improve the accuracy of the model created.

This method can probably produce a model better than all the others. Since every profile has the same datum which is not determined by drawing or rough calculation, and the error will be significantly reduced.

Returning to the use of photography, another method for aligning can probably used by using the fact that one slice can usually produce 3 profiles. See Fig. 6.6.4.2. we can take the photo of the slice from both ends of the slice, one slice can be represented by two photo from A and K directions. From the figure, suppose the cutting tool is very thin, S3 and be regarded equal to S3', and S4 equal to S4'.We can then find that each photo has the relationship which can be used as the datum for aligning. See Fig. 6.6.4.2 (1), we can use photo1 to obtain S1, S2 and S4, since profiles on tracing paper can be seen on both side of the paper, then we can use S1 and S4 as the datum to obtain S3 on photo 2, use S4 to obtain S6 on photo3; use S3 and S6 to obtain S5 on photo 4. According to this logic, we will be able to align all profiles almost correctly to create a better model. The inaccuracy of the model may be caused, because the suppose of S3 = S3' and S4 = S4'. However, this error will be very small.

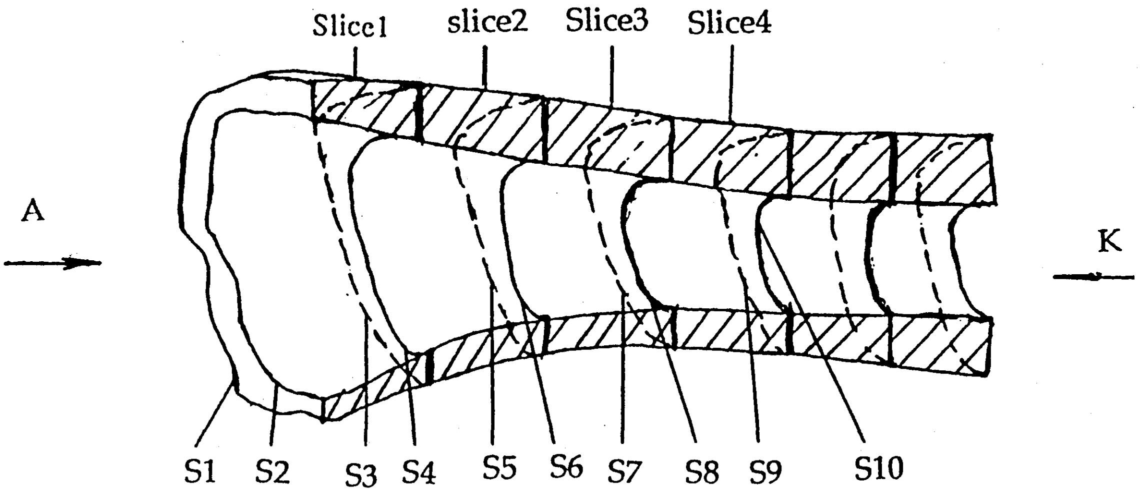
Two problems of accuracy will still occur, one is the geometrical problem which here is the alignment problem, and the other is how many

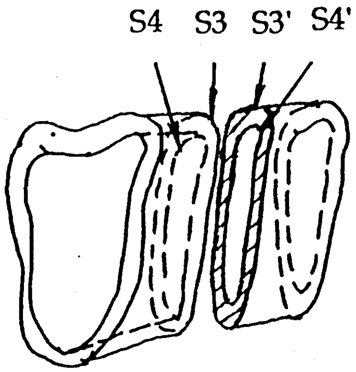


(2)

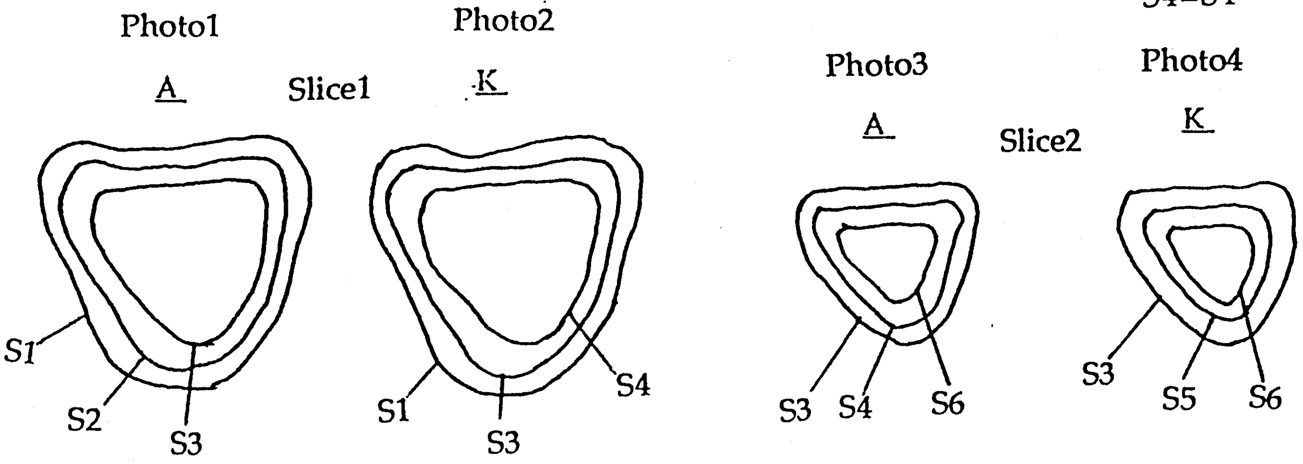
(3) Use P1, P2 to align every section

Fig. 6.6.4.1 Diagram illustrating plaster cast cut using LASER beam





(2) If the cuttuing tool is very thin, it can be regarded that S3=S3' and S4=S4'



(1) Each photograph shows three profiles of a slice

Fig. 6.6.4.2 Diagram shows use of photograph to align each section elements is enough to create a model with reasonable accuracy.

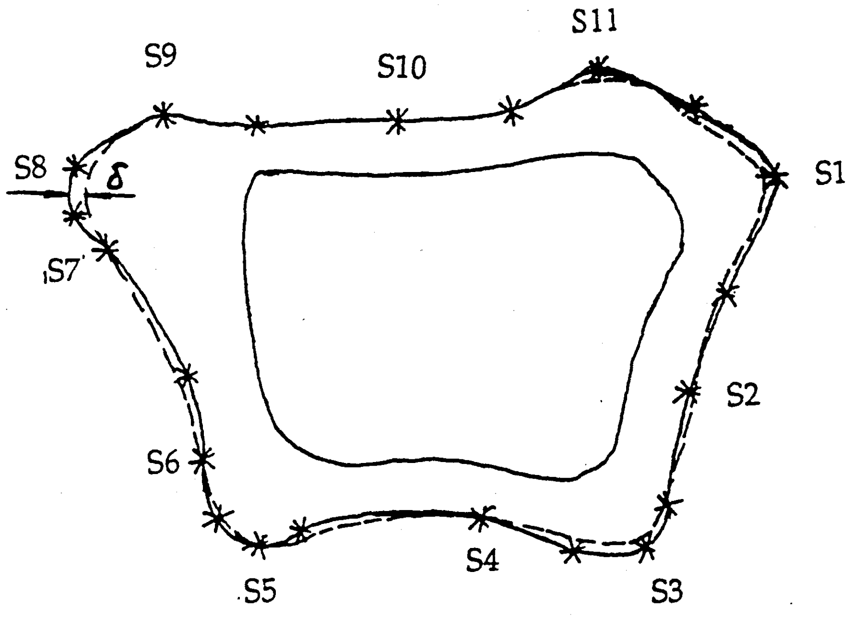
The methods of obtaining and inputting data are a geometrical problem, whilst the accuracy of the models is mathematical problem. After discussing the alignment problem, another factor affecting the accuracy of the model created is the number of points and sections for the model.

Before discussing the accuracy of the model, it is necessary to bear the following basic concepts in mind:

1) A plane in three dimensional space can be defined by not less than 3 points, and a two dimensional rigid image can be defined by 2 points in a two dimensional plane.

2) Two points define a straight line, and 3 points which do not lie on the same straight line defines a curve.

Accuracy problem (involves the computational time problem). How many points are needed for a profile to form the model? The profile of each section is formed by several segments (Fig. 6.6.5.1). According to the mathematical principle, a segment of curve in two dimensional plane can be defined by not less three points. Therefore, before digitizing the points into the computer, the profiles are roughly divided into several segments according to its shape (Fig. 6.6.5.1). Because 3 points are required to define a plane curve, a certain number of points are needed to digitize the picture into computer first. In some segment where the curvature changes sharply, a few more points are needed so that the contour created is a good approximation of the real shape. After the contour is created, in order to save computational time and memory within computer, the proximal function is used. The number of points is reduced step by step. It is found that even though the number of points is reduce to a half, the bigest error of



—— L1, profile created using reasonable number of points, in this case, 21 points.

– – – L2, profile created using proximal function based on L1, the number of points is reduce to 10 points, whilst the bigest deformity (error) caused is only 0.301 mm.

∂ ---- Bigest deformity

Fig. 6.6.5.1 Reducing the number of points and the error caused the resulting profile is very little, about 0.301mm, which can satisfy the accuracy requirement. The example given is the most complex curve amongst all the profiles of cross-sections. Therefore, we can reduce each profile to ten points to define its contour.

With reference to the number of sections required to build the model. At the beginning, since the data obtained from CT scanner has an offset of 2 mm between each profile. this offset was also used for the initial model. In order to shorten computational time and save memory, a offset of 4 mm between each section is used. The model created was almost the same as with the one created by an offset of 2mm in dorsal and lateral view. The only slight difference lies near the end of the joint where the shape of each cross-section changes sharply. See Fig. 6.4.4.3.

6.6.6. Software comparasion

There are two software packages being used in this thesis. Each one has its own characteristics. We shall make some simple comparison between these two software from the convenient use point of view.

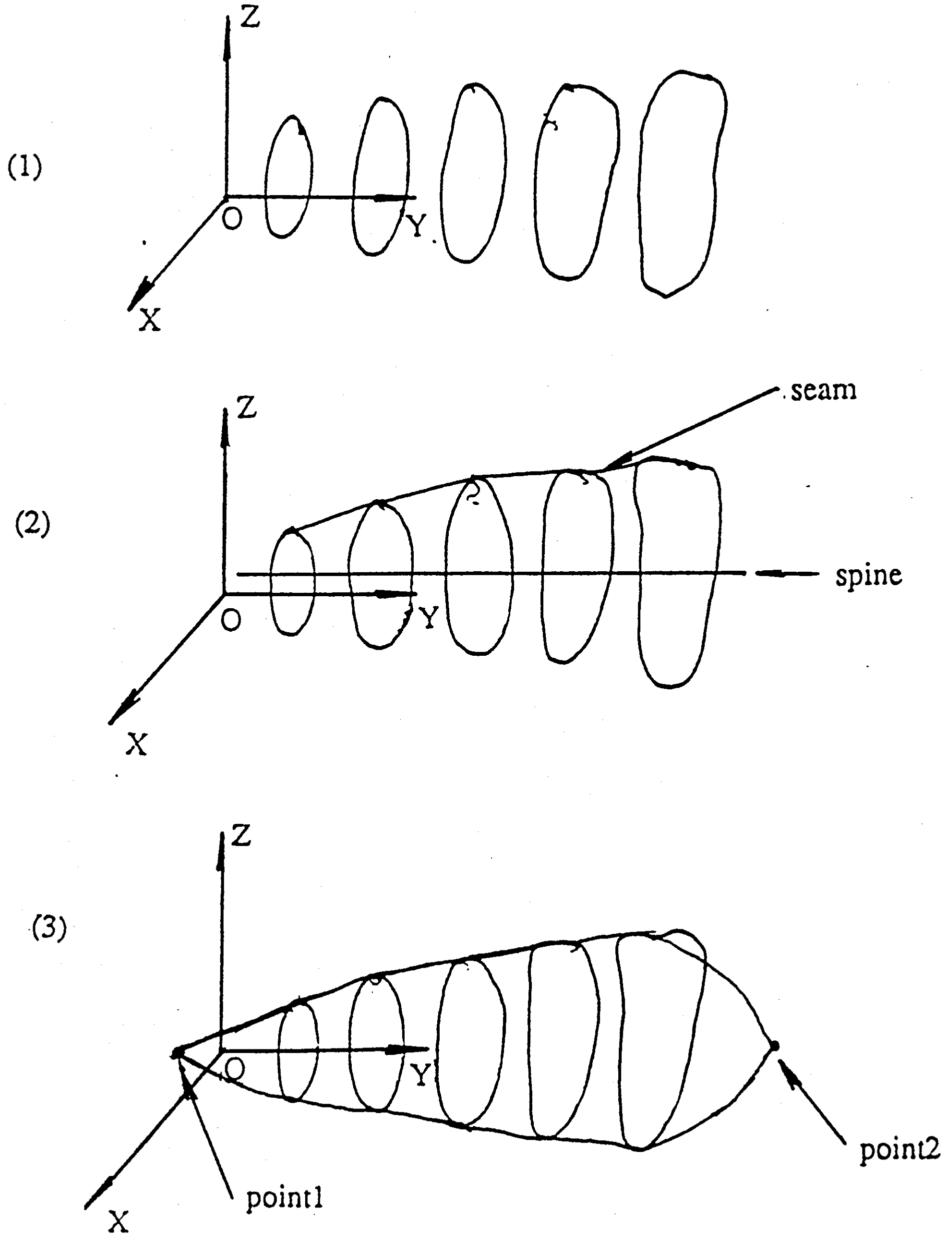
1) CATIA has the more complex philosophy than GEOMOD;

2) To create the required model, it appears more convenient to use GEOMOD:

In GEOMOD, creating a closed profile can be done once; whilst, in CATIA, two open splines with restrict condition must be created first, then join them to obtain a closed profile.

In GEOMOD, one can create a model using multiple sections by the command " Y-DEPTH". This function is very convenient for creating a model if it is has difficult to determine its axis; whilst in CATIA, it is necessary to create the 'spine' and 'seam' for the model. Of course, in CATIA, there is another function for creating solids using multi-sections. It differs from GEOMOD in that, two other points must be added to define the model. See Fig. 6.6.6.1.

However, since CATIA is loaded on IBM 3090 mainframe, it can perform data processing much quicker than GEOMOD and has more memory than GEOMOD at present. Therefore, it might be better to create the models in GEOMOD first, then transfer the data to CATIA for further modelling, such as open more windows on the same screen so as to compare the model with the X-rays on lateral and dorsal views at the same time.



(1) Use Y-DEPTH in GEOMOD;

(2) Use CURVE SURFACE in CATIA;

(3) Use CURVE in CATIA.

Fig. 6.6.6.1 Three functions in GEOMOD and CATIA for creating model

CHAPTER 7. CONCLUSIONS AND RECOMMENDATIONS

7.1 Introduction

Artificial finger joint design is a bioengineering problem. The thesis begins with a discussion of the anatomy of the hand, concentrating on the MCP joint and bones, and then turns to review previous artificial finger joint design. This research is a preliminary investigation for artificial finger joint design. Material selection is also a very important part of the research, so a chapter has been devoted specifically to the choice of materials for artificial implants. The techniques used for modelling are discussed followed by an outline of how the project is to be performed. Finally the modelling and data acquisition are presented along with a discussion of the results. The following presents the conclusions of this work and and recommendations for the further research.

7.2. Conclusions

7.2.1 The hand and its MCP joint

The hand is the important manipulator of the human body. It consists of joints, bones, tendons, ligaments, capsules, sheath and other tissues. Anatomical structure of the hand indicates that the shape of the bone is irregular in any direction. However, the middle of the cavity has the smallest area. The cross-sections increase in size towards each end of the bone. At the joint itself the area of the cavity appears to reduce sharply and then disappear. The metacarpal bone has a cavity which is the largest and near rectangular cross section to the metacarpal phalangeal joint this tapers to a near triangular cross section towards the middle part of the bone and finally at the middle part of the bone becomes near circular. On the PP bone, the largest section near the joint is near semi-circular. Although computerized tomographic data can not yet provide the results required for an accurate model, it can still display the rough cavity of the bones.

Among all the tissues of the hand, the joints, especially the metacarpophalangeal joint, dominate the function of the hand. If the joint is deformed by disease, such as rheumatoid arthritis or by accident, some of the function of the hand needed for daily activities or function needed in social activity is lost. Therefore, it is necessary to replace deformed joints so as to reachieve hand function.

However, it is always advisable to note that there are two ranges of movement of a MCP joint. One is the full range of movement and another is the functional range of movement. The functional range of movement is adequate for use in daily life. Therefore, when an evaluation of the replacement of MCP joint is made, the following two points is should be noted: (i) the reachievement of functional range of movement; (ii) the correction of the deformity.

7.2.2 *Metacarpo-phalangeal joint replacement*

Metacarpo-phalangeal joint replacement was first introduced by Flatt in 1960. Since then, a wide range of MCP joints have been put into medical practice. These joint replacements have more or less released patients from joint deformity and helped patients reachieve hand function needed for daily life. The joint prosthesis which remains in most common use is the

Swanson prosthesis.

However, there are some problems which affect the success of the MCP joint replacement. One of the main problems is the fixation of the implants within the hand bones. This is caused by the geometrical design and the material used for the joint. To attempt to improve this problem, it is required to design the stem of the artificial finger joint according to the geometrical shape of the bone medullary cannal, and to select the proper material for joint manufacture.

7.2.3 Use of material

The artificial finger joint is implanted inside the human body. Therefore, the material requirements are much more stringent than for ordinary mechanisms. When the material is chosen to be used for a prosthesis, both biocompatibility and mechanical functionality must be taken into consideration. Apart from biocompatibility and mechanical properties, another important function of the material used for the implant is its porous characteristic. Porous material can offer a good fixation of the stem with the surrounding tissue within a period after surgery, by allowing bone ingrowth.

The first material used for MCP joint replacement was 316 Stainless steel in 1960. Since then, a large range of materials have been employed in clinical practice. They roughly fall into three categories:

I) Metals, such as, i) Stainless steel, e.g., 316 stainless steel; ii) Cobalt-chromium alloys; iii) Titanium alloys, e.g., Ti-6Al-4V.

II) Polymers, such as, i) Silicone rubber; ii) Polyethylene, e.g., UHMW HD polyethylene; iii) Polypropylene.

III) Ceramic and glasses, such as alumina and bioglass.

However, different materials have different characteristics. The choice of material, therefore, has to be made with reference to the specific orthopaedic application. Generally, these materials are used interchangeablely, but the titanium alloys have marginally superior properties for non-bearing situations, especially when manufactured with a porous stem to obtain good fixation; whilst the wrought cobalt-nickel-chromium-molybdenum alloys are to be preferred for the metallic components of total joint prostheses. With plastics, each has its own area of superiority. UHMW HD polyethylene is used in all metal-plastic articulating prostheses. Silicone rubber is ideal for many non-loaded or lightly loaded situations but the polypropylene is preferred in some cases for its superior mechanical properties.

Ceramic and glasses also have their own advantages, for example, excellent wear resistance and biocompatibility, and bioglasses have good stabilization and reasonable mechanical properties. Nevertheless, they are only reported as being used in hip joint replacement. Further investigation is required for the possibility of applying them in finger joint prostheses.

7.2.4 *Modelling of MCP joint and bones*

With the advance of modern instrumentation, computer equipment and CAD systems, it has become possible to model the MCP joint, MC and PP bones all of which are irregular in shape. This will assist the designing and manufacturing of a better artificial finger joint for the replacement of metacarpo-phalangeal joints.

There are several ways of modelling metacarpo-phalangeal joints:

i) Collect a series of cadaveric hands, and use the method described in section 6.4 and section 6.5 to create a series of models, that is , slice the cadaveric hand and X-ray each slice to obtain the contour of cross-section as the data for modelling. X-raying is a reasonably good technique for obtaining the data needed for modelling because it has a high resolution;

ii) Use two dimensional computerized tomography scanner to collect sets of data for computer modelling. This method appears not to be very suitable for modelling because of the unsatisfactory resulting model.

iii) Use three dimensional, high quality computerized tomography scanner to collect the data, then transfer the data from CT scanner to CAD system to create the model.

Since the MCP joint and bone is irregular in shape, the key point to model them is to obtain the shape (profile) for each section. Then the computer aided modelling system can be used to create the model.

To create the solid model using a CAD system, different magnitudes of offset between each cross-section and different number of points to form each profile can be adopted according to the accuracy required by the model. However, 4 mm between each section and 10 points for forming each profile is enough to ensure the accuracy of the model according to the modelling results.

With reference to the number of point for creating a profile of a cross-section, since the shape is formed by several segments of curve, it is better to create the profile by using about 30 points first, and then use the proximal function found in GEOMOD or CATIA to discover which points are the most significant for forming a new profile with less points, similar to that formed by the original 30 points, and then reduce the number of points to about 10. After this, the profile which is represented by about 10 points can be used to create the solid model of the bones. Since the procedure of modelling is separated and the proximal methods used at the middle stage, on the whole, it can save not only computational time, but also memory within the computer, reducing the size of the database.

Following the creation of models, another model simulating the movement of the joint can be also set up. By modelling the movement of the MCP joint, a series of spaces for different sizes of joint will be obtained. This would go another step towards the design of an better artificial finger joint.

However, even though method i) mentioned above can create satisfactory models, this method is actually very time consuming and takes a large amount of the computer facilities and manpower. Therefore, the third method will probably be the best method for modelling joint and bones if it can be proved that the model created using this method can represent the bone cavity. Since the data will be directly transferred from the three dimensional CT scanner to a CAD system, errors caused by the procedure in section 6.4 and 6.5 will not occur. Therefore, it is easy to control the accuracy of the model.

7.3 Recommendations for the further work

This thesis only presents the selection of material for joint prostheses and the methods of modelling the MCP joint and their results. However, more modelling should be performed to support the idea. The following points should also be taken into account in order to compare with this thesis so as to get the best result:

- Create models using the data obtained by taking photograph from both ends of a slice, which is discussed in section 6.5.

- create models using data from plaster casts, which is also discussed in section 6.5.

- Create solid models using solid modelling function on CATIA. If this can not be proved to be convenient, then create the solid model in GEOMOD and then transfer the models into CATIA for further designing.

- Create models using raw data --- It is suggested that data can be input directly from a high quality three dimensional CT scanner. This may be the best method. It might create the model of the MCP finger joint more efficiently, saving computational time and manpower. If this method can be proved to be suitable, then a very wide range of data, from normal people and patients, can be collected. This will improve the database created, since the use of cadaveric hands is limited.

- create models of diseased hands, then compare with the models of normal hands so as to determine the available space for the joint replacement.

- Try to summarise the models into a series of models with standard sizes and create a database in the CAD/CAM system for further manufacturing of artificial finger joints.

- Design the artificial finger joint using the material selected in Chapter 4., that is, using the titanium as the cover together with other material, such as 316 Stainless Steel, or polymers. Then follow up after a period of time with the clinical cases to observe clinical results.

. Further investigation on the use of ceramic and bioglass on the finger joint prostheses.

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